RULEMAKING ISSUE
AFFIRMATION

December 22, 2006 SECY-06-0244

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: FINAL RULEMAKING—10 CFR PART 26—FITNESS-FOR-DUTY PROGRAMS

PURPOSE:

To obtain Commission approval to publish the final rule for Fitness-for-Duty Programs.

SUMMARY:

The final rule amends the regulations of the U.S. Nuclear Regulatory Commission (NRC) governing the domestic licensing of production and utilization facilities. The final rule does not apply to reactor manufacturing facilities, spent fuel storage facility licensees, or non-power reactor licensees who possess, use, or transport formula quantities of irradiated Strategic Special Nuclear Materials (SSNM). The rule updates the NRC's current requirements under Title 10, Part 26, "Fitness for Duty Programs," of the *Code of Federal Regulations*, for drug and alcohol testing and enhances consistency of Part 26 with advances in relevant Federal rules and guidelines, including the U.S. Department of Health and Human Services' Mandatory Guidelines for Federal Workplace Drug Testing programs (HHS Guidelines) and other Federal drug and alcohol testing programs that impose similar requirements on the private sector. The

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final rule also reorganizes and clarifies Part 26, notably Subparts I and K. Subpart I establishes requirements for managing worker fatigue at operating nuclear power plants. Subpart K clarifies fitness-for-duty (FFD) requirements for new plant construction. Licensees and applicants for light-water reactors and applicants for and holders of combined construction and operating licenses (COLs) or construction permits (CPs) for new reactors must adhere to the requirements of this final rule, as applicable. In addition, the final rule 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 certain FFD program audit frequency requirements. The final rule also partially grants a petition for rulemaking (PRM-26-2) submitted by Barry Quigley on December 28, 1999, by establishing requirements for the management of worker fatigue.

BACKGROUND:

In SECY-05-0074, "Proposed Rule To Amend The Fitness-for-Duty Requirements in 10 CFR Part 26," dated April 28, 2005, the staff presented its proposal to amend the FFD program requirements for licensees authorized to operate or construct a nuclear power reactor, or possess, use, or transport formula quantities of SSNM. Subsequently, the proposed rule was published in the *Federal Register* on August 26, 2005 (70 FR 50442), with a four-month public comment period that ended on December 27, 2005. The NRC also conducted public meetings during the proposed rule comment period at locations near plants to encourage participation from workers who would be affected by changes to the FFD program requirements. Meetings were conducted in Morris, Illinois, and Charlotte, North Carolina (Agencywide Documents Access and Management Systems (ADAMS) Accession No. ML052930058). These meetings provided stakeholders opportunities to ask questions to clarify their understanding of the proposed requirements.

In March 2006, the NRC held a public meeting to discuss the staff's concepts for resolving some of the public comments. The staff presented concepts for alternative fatigue management provisions and certain requirements for FFD programs during new plant construction, and received public input. Subsequently, the staff received comments on the proposed rule and responses to the staff's concepts. Following consideration of public comments, the staff posted for viewing only, the draft final rule text for fatigue management (Subpart I) and FFD programs for new plant construction (Subpart K) in August 2006, and the entire draft final rule text of 10 CFR Part 26 in October 2006, on the NRC's interactive rulemaking Web site http://ruleforum.llnl.gov/cgi-bin/rulemake?source=Part26_risk&st=prule

On November 7, 2006, the NRC held a public meeting with stakeholders to present the technical basis for Subpart K, "FFD Programs for Construction," of the draft final rule and to describe the fitness monitoring option that Subpart K permits in lieu of random testing of certain construction workers. Enclosure 1 of this SECY paper describes that meeting.

DISCUSSION:

Enclosure 3 to this Commission paper is a *Federal Register* notice that would publish the final rule. The staff expects that the final rule will result in substantial enhancement to the public health and safety and the common defense and security. Part 26 will apply to licensees

authorized to operate a nuclear power reactor; licensees authorized to possess, use, or transport formula quantities of SSNM; corporations that obtain certificates of compliance or approved compliance plans under 10 CFR Part 76, “Certification of Gaseous Diffusion Plants,” involving formula quantities of SSNM; and CP or COL applicants or holders with a nuclear power plant under construction. The worker fatigue provisions will apply only to personnel at operating nuclear power plants.

The final rule partially grants 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. However, the final rule denies portions of the petitioner’s request by retaining the current 12-month audit frequency for HHS-certified laboratories and licensee contractor or vendor (C/V) FFD programs in which the C/V personnel “are off site or are not under the direct daily supervision or observation of licensee personnel…,” including but not limited to, contracted medical review officers (MROs), employee assistance programs (EAPs), and specimen collection services.

The final rule also partially grants PRM-26-2, submitted on September 28, 1999, by Barry Quigley. The petition requested that the NRC: (1) add enforceable working hour limits to Part 26, (2) add a criterion to § 55.33(a)(1) to require evaluation of known sleeping disorders, (3) revise the NRC enforcement policy to include examples of work hour violations that warrant various NRC sanctions, and (4) revise NRC Form 396 to include self-disclosure of sleeping disorders by licensed operators. The final rule adds requirements to Part 26 that address item 1 of the petition through requirements that are more flexible and focused on risk than those proposed by the petitioner. The staff is addressing items 2 and 4 concerning sleeping disorders of licensed operators through changes to Regulatory Guide 1.134, Revision 3, “Medical Evaluation of Licensed Personnel at Nuclear Power Plants,” issued March 1998. For item 3 of PRM-26-2, the staff revised and piloted the Physical Protection Significance Determination Process and implemented a new baseline inspection program in February 2003, which includes a procedure for inspecting FFD programs and reflects order EA-03-038, dated April 29, 2003, and will similarly revise the significance determination process and the inspection procedure to be consistent with the final Part 26 rule. In addition, following issuance of the final Part 26 rule and confirmation of licensee implementation of the rule, the staff plans to revoke order EA-03-038.

The final rule includes changes to the proposed rule requirements of Subpart I to address substantive comments regarding certain individual break requirements, the collective work hour limits, and the annual reporting requirements. A summary of the public comments on these matters and how the staff resolved the comments is included in enclosure 1 of this SECY paper. In particular, industry and union representatives opposed the proposed operating work hour controls which would have required a minimum 24-hour break in any 7-day period and a minimum 48-hour break in any 14-day period. The NRC also received comments from the Professional Reactor Operator Society and other public stakeholders supporting these requirements. Following consideration of public comment, the staff replaced the requirements for a 24-hour break in any 7-day period with a requirement for a 34-hour break in any 9-day period to provide additional scheduling flexibility for 8-hour shifts. The staff eliminated the proposed rule requirements for a 48-hour break in any 14-day period and the collective work

hour limits. The staff replaced these requirements with more flexible minimum day off requirements. For periods when a reactor unit is operating, the minimum day off requirements are specific to shift duration (i.e., 8, 10, or 12 hours) and require a minimum number of days off over the duration of the shift cycle.

For periods when a reactor is shutdown for an outage, the final rule requires a minimum of 3 days off in each non-overlapping 15-day period. The staff considered alternatives to this outage requirement as discussed in the statement of considerations (SOC) for the rule. An alternative not discussed in the SOC, but also considered by the staff involved reducing the requirements for obtaining a waiver for work being done only on the non-operating unit. Under this alternative, the requirement that work performed under the waiver be necessary to prevent or mitigate a condition adverse to safety or security would be eliminated. However, the staff would have retained the requirement that, prior to authorizing a waiver of the work hour controls, a supervisor shall assess the individual face-to-face and determine that there is reasonable assurance that the individual will be able to safely and competently perform his or her duties. These alternatives would provide licensees additional flexibility in scheduling and accomplishing work on the non-operating unit. In developing these alternatives, the staff considered that although current licensee scheduling practices exceed the recommended scheduling guidelines for preventing fatigue, few events have been attributed to fatigue. However, for the reasons cited in SECY 01-0113, any estimates of events caused by fatigue should be interpreted with caution. Given these considerations, the staff determined that the technical basis for preventing and mitigating cumulative fatigue is best supported by the minimum day off requirements for outages stated in the draft final rule.

The final rule also establishes a Subpart K, which clarifies the former and proposed rule requirements for FFD programs applicable to the construction of new nuclear power plants. A summary of the public comments on these matters and how staff resolved the comments is included in enclosure 1 of this Commission paper. Enclosure 2 to this Commission paper summarizes the staff views of the impact of various requirements in Subpart K. The Executive Director for Operations (EDO) resolved these different staff positions by: (1) requiring individuals performing construction activities for security- or safety-related structures, systems, and components that occur at a location on licensee- or applicant-owned property where the nuclear power plant will be operated to be subject to an NRC-mandated FFD program; (2) allowing COL and CP holders and applicants to implement either a fitness monitoring program or the combination of a random drug and alcohol testing program and behavioral observation program; (3) allowing COL and CP holders and applicants to appropriately designate individuals who serve as monitors and determine the number of monitors and the frequency with which monitoring will occur, rather than requiring all first-line supervisors to be subject to a “full” FFD program (i.e., the same FFD requirements that apply to operating reactors); (4) removing from the final rule the requirement that the NRC review and approve each applicant’s FFD program plan for construction; and (5) limiting FFD requirements for security personnel to cover only those security officers who are required by the NRC to be on site.

The supporting documents to this Commission paper (e.g., the *Federal Register* notice) do not yet reflect the EDO’s resolutions of the staff positions. The staff will make conforming changes to the final rule text and the supporting documents to reflect the Commission’s directions.

IMPLEMENTATION SCHEDULE:

The staff proposes to have the final rule effective 30 days after the date the rule is issued in the Federal Register and require full implementation of the final rule, except for Subparts I and K, within 365 days of the issuance date. Subpart I would need to be implemented no later than 18 months after the issuance date. No enforcement actions will be considered during these implementation periods. Implementation of Subpart K would be required upon the final rule's effective date. The staff anticipates that licensees and other entities will begin to implement the final rule when it is published in the Federal Register and develop internal guidance documents, revise procedures, and train personnel as necessary to meet these implementation schedules.

IMPLEMENTATION GUIDANCE:

By intent, the detailed nature of the drug and alcohol testing provisions in the final rule obviates the need for a guidance document for those provisions applicable to operating plants. However, the NEI published, and the staff has endorsed, NEI 03-01, Rev. 1 (April 2004), "Nuclear Power Plant Access Authorization Program," to provide guidance for implementing the inter-related access authorization and fitness-for-duty requirements contained in the access authorization orders issued to nuclear power plant licensees on January 7, 2003 (EA–02–261, ''Access Authorization Order,'' (January 13, 2003; 68 FR 1643)). Minor revisions to this document will be necessary when Subpart C, "Granting and Maintaining Authorization," of Part 26 is published in the final rule and the 10 CFR 73.56, "Personnel Access Authorization Requirements for Nuclear Power Plants," rulemaking (71 FR 62664, October 26, 2006) is completed. The staff intends to work with stakeholders to update and endorse this guidance document.

Guidance for implementing Subpart K, "FFD Programs for Construction," of Part 26 is warranted because, by contrast to the prescriptive requirements in Part 26 for FFD programs at operating plants, the requirements for FFD programs for new plant construction provide certain holders of and applicants for combined operating licenses under 10 CFR Part 52 and construction permits under 10 CFR Part 50 with greater flexibility in implementing FFD programs for construction. By letter dated August 4, 2006, the NEI submitted a draft industry guidance document, Revision 0 to NEI 06-06, "Fitness for Duty Program for New Plant Construction Sites," for NRC review and endorsement. The staff has commented on NEI 06-06 by letter dated August 10, 2006, and subsequently conducted a public meeting on August 29, 2006, to clarify staff comments. The staff expects to continue working with stakeholders to publish a Regulatory Guide for Subpart K.

Some of the provisions of Subpart I require guidance prior to final implementation. The NEI has agreed to develop an NEI guidance document, by working with the industry and other stakeholders, and submit it to the NRC for endorsement via a Regulatory Guide. Although the NEI submitted draft guidance, NEI-06-11, "Managing Fatigue at Power Reactor Sites" in October 2006 and subsequently met with the staff in November and December, 2006, to discuss the approach, the guidance cannot be completed until the final rule is available. The NEI intends to have a final industry document available soon after the Commission approves

the final rule. Therefore, the staff has not prepared draft NRC guidance documents to accompany this final rule.

CONTENTS OF THE RULEMAKING PACKAGE:

This rulemaking package includes the *Federal Register* notice for the final rule, which contains the rule language and Statements of Consideration (enclosure 3), Regulatory and Backfit Analyses of the Final Rule to Amend the Fitness-for-Duty Programs (enclosure 4), Summary and Analysis of Public Comments Received on Proposed Revision to 10 CFR Part 26 – Fitness-for-Duty Programs (enclosure 5), and OMB Supporting Statement for 10 CFR Part 26, Fitness-for-Duty Programs (enclosure 6).

REGULATORY AND BACKFIT ANALYSES:

In SRM-01-0134, dated October 3, 2001, the Commission directed the staff to perform an aggregate analysis of the entire rule. Subsequently, by SRM-SECY-04-0045, dated April 21, 2004, the Commission approved revised regulatory analysis guidelines (RA Guidelines) in NUREG/BR-0058, Revision 4, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," dated September 2004. Consistent with the principles underlying the revised guidelines and SRM-01-0134, the staff has prepared the regulatory analysis and backfitting discussion. Sections 4.1.4 and 4.4.2 of enclosure 4 describe the results of the analyses. The results of the regulatory and backfit analyses support issuance of this final rule.

RELATED ACTIVITIES:

In SRM-COMSECY-04-0037, dated September 1, 2004, the Commission determined that FFD enhancements related to the fatigue of security force personnel at independent spent fuel storage installations, decommissioning reactors, Category I fuel cycle facilities, gaseous diffusion plants, and the natural uranium conversion facility should be pursued as a rulemaking activity separate from the FFD final rule with additional stakeholder interactions. The staff anticipates that this rulemaking will begin after publication of Part 26 as a final rule in the Federal Register.

RESOURCES:

The FY 2007 budget includes the following resources for the final rulemaking: 0.7 FTE for NRR, 0.4 FTE for NSIR, 0.3 FTE for OGC, and 0.4 FTE and $100K for RES. These resources are for the development of guidance for fatigue management and FFD programs for construction activities, the review of license amendment submittals associated with work hour controls in Technical Specifications, and the development of guidance for the inspection of licensees' implementation of Part 26.

RECOMMENDATIONS:

That the Commission:

1. Approve the notice of final rulemaking for publication in the *Federal Register* (enclosure 3) with an effective date 30 days after the date of issuance and a phased

implementation of the final rule that includes (1) full implementation of FFD programs applicable to operating nuclear reactor plants within 365 days of the issuance date and (2) full implementation of fatigue management provisions within 18 months of the issuance date, and (3) full implementation of FFD programs applicable to new reactors under construction within 30 days of the issuance date.

2. Certify that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities. The certification is needed to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

3. Note:
   a. The final rule (enclosure 3) will be published in the *Federal Register*.

   b. A final regulatory backfit analysis has been prepared for this rulemaking.

   c. A final environmental assessment has been prepared for this rulemaking.

   d. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the basis for it, as required by the Regulatory Flexibility Act.

   e. The NRC has determined that this action is not a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 and has confirmed this determination with the Office of Management and Budget.

   f. Copies of the final rule will be distributed to all affected Commission licensees. The document will be sent to other interested parties upon request. Copies of the document are also available in ADAMS, in the NRC Public Document Room, and on the NRC rulemaking Web site.

   g. The Office of Public Affairs will issue a press release when the final rule is filed with the Office of the Federal Register.

   h. The appropriate congressional committees will be informed.

   i. The NRC will publish separately the implementation guidance for this rulemaking with regard to fatigue management and FFD programs for applicants and holders of COLs and CPs during construction in the form of regulatory guides.

   j. The information collections contained in the final rule (enclosure 6) will be sent to the Office of Management and Budget (OMB) for review and approval as required by the Paperwork Reduction Act of 1995 (44 U.S.C. § 3501 *et seq.*).

COORDINATION:

The Office of General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections. The ACRS considered this final rule discussion and decided to decline the formal review. The CRGR reviewed the proposed rule and elected to waive a briefing on the final rule.

The ACRS and CRGR have no objection to issuing this final rule. The Office of the Chief Information Officer has reviewed the final rule for information technology and information management implications and concurs in it.

/RA/

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Enclosures:
1. Summary of Discussion of Staff's Resolution (ML062850130)
2. Differences in Staff Positions on FFD Programs for Construction (Subpart K) (ML063540420)
3. Final Rule - Fitness for Duty (ML062550285)
4. Regulatory Analysis (ML062780211)
5. Summary of Analysis of Public Comments (ML062620089)
6. OMB Supporting Statement (ML062850194)

Summary Discussion of Staff's Resolution of Substantive Comments on Fatigue Management and FFD Programs for Construction Provisions in The Proposed Rule

Subpart I, Fatigue Management, Individual Break Requirements, and Collective Work Hour Limits:

Several stakeholders commented that the proposed requirement for individuals to have at least one 24-hour break in any 7-day period would limit their ability to effectively schedule 8-hour shifts. In response to these comments, the staff revised this provision to require a minimum of one 34-hour break in any 9-day rolling period. The final rule requirement provides the flexibility to effectively schedule 8-hour shifts while ensuring that individuals on 8- and 10-hour shifts have periodic days off to prevent and mitigate fatigue.

Industry stakeholders commented that the requirement for a minimum 48-hour break in any rolling 14-day period could adversely affect a licensee's ability to restore inoperable equipment in a timely manner. Other stakeholders were concerned that the 48-hour break requirements would disrupt the sleep patterns of workers on night shifts, thereby increasing the likelihood of fatigue-related errors at work. Stakeholders commenting on the collective work hour limits asserted that they were redundant with other proposed requirements and therefore unnecessary. Other stakeholders were concerned that the collective work hour limits did not address worker fatigue on an individual basis and that the calculation of work hours with regard to these limits could be manipulated. In response to these comments, the staff replaced the 48-hour break and collective work hour limit requirements with provisions that ensure each worker receives a minimum number of days off per week, on average, while the plant is operating and receives a minimum number of days off in each consecutive 15-day period of a unit outage. The final rule also requires security personnel to have a minimum number of days off in each 15-day period during planned security system outages. As a result, the final rule is less complex and more flexible, yet ensures periodic days off and limits average weekly work hours to levels comparable to those that would have been required by the collective work hour limits.

Although the staff believes that these changes have addressed most stakeholder concerns regarding the proposed work hour limits, industry and union stakeholders have asserted that the final rule requirement for minimum days off during unit outages is unnecessarily restrictive and will cause supplemental outage workers to seek employment in other industries where they can work without restriction on the amount of overtime that they work. Although the staff cannot predict with certainty the effect of the work hour limits on the future job seeking behavior of supplemental workers, the staff expects the effect to be limited because (1) the limits reduce the average work week by less than 5 hours while continuing to allow an average of more than 25 hours of overtime per week, and (2) the limits will not apply to all supplemental workers, only those maintaining systems, structures, and components that a risk-informed evaluation process has shown to be significant to public health and safety. As a result, the staff believes that licensees have the flexibility to manage the effect of the work hour limits on supplemental workers. The staff also notes that in establishing the work hour limits the staff considered that the requirements would not only apply to supplemental workers but also licensee employees, many of whom were concerned about impairment from fatigue rather than loss of wages.

Industry stakeholders have also asserted that one 34-hour break in any 7-day period is adequate to provide full recovery from fatigue during unit outages, citing the basis for the Federal Motor Carrier Safety Administration's (FMCSA) requirement for a minimum 34-hour

break for commercial motor vehicle (CMV) operators. The staff reviewed the FMCSA regulations, associated statements of consideration, and the findings of an expert panel commissioned by the FMCSA. The staff concluded that, for a limited range of circumstances, the studies cited by FMCSA support a 34-hour break as a minimum rest period for recovery from cumulative fatigue. However, the staff does not agree that the basis cited by the FMCSA supports a requirement that would routinely allow 72 hours of work before a 34-hour break (i.e., a day off) is required. The staff notes that:

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

(2) The statements of consideration for the FMCSA regulations establish that long work weeks with minimum break periods are the exception for CMV operators. By contrast, application of the industry proposed requirement to the control of work hours during unit outages would allow licensed operators[1] and other plant personnel to work regularly occurring periods of multiple consecutive 72-hour work weeks with minimum break periods.

(3) The FMCSA's expert panel considered the 34-hour break "absolutely minimal" for recovery with a fundamental assumption being that the 34 hours will provide the opportunity for two consecutive nights of sleep between midnight and 6 a.m. Given common outage scheduling practices and day-shift start times, no workers on night-shifts and few workers on day-shifts would meet this assumption. Consequently, full recovery from six consecutive 12-hour shifts would not be likely for the majority of workers .

In summary, given the number of hours worked prior to a break and the outage schedule constraints on the sleep-wake schedule for most workers, the 34-hour break would not be sufficient for full recovery from fatigue. In addition, by allowing multiple consecutive 72-hour work weeks, the staff does not consider the NEI proposal to provide 34-hour breaks on a sufficient frequency to prevent the onset of cumulative fatigue during the course of a multi-week outage. Considering the limitations of the technical basis cited by the industry and its applicability to outage scheduling practices, comments of other stakeholders, and the technical basis cited by the staff with respect to the causes and prevention of cumulative fatigue, the staff concluded that the industry proposal would not effectively prevent cumulative fatigue for multiple consecutive weeks of extended work hours. The staff 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.

Subpart I, Fatigue Management, Reporting Requirements:

Several industry stakeholders objected to the proposed requirement to report waivers from the work hour limits and information concerning fatigue assessments as part of their annual FFD program performance report. They asserted that the NRC should delete the reporting requirements from the rule because the reports would not provide new or unique information,

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

are unnecessary to protect public health and safety, are unnecessary to facilitate NRC oversight of implementation of the revised rule, and are unduly burdensome, and because the NRC has not met its obligation under the Paperwork Reduction Act. The staff revised the reporting requirements in the final rule to ensure that annual reports provide meaningful information for NRC oversight of the rule implementation. However, the staff does not agree with comments suggesting that the NRC delete the annual reporting requirement and maintains that the reports will be important for effective and efficient oversight and consistent implementation of the rule.

The annual reports will provide unique information that is important to NRC oversight of licensee fitness for duty programs and which is not otherwise reported to the NRC. By summarizing licensee use of waivers from the work hour limits the annual reports will indicate how often a licensee relies on individuals who are at increased potential for impairment from fatigue to mitigate or prevent a condition adverse to safety or security, specifically when these functions are associated with risk significant systems, structures, or components, or functions that are essential for effective response to a fire, plant emergency, or implementation of the site security plan. The staff believes that frequent reliance on personnel with a high potential for impairment to resolve these conditions indicates a lack of effective management of worker fatigue and plant risk.

The annual reports will also include information pertaining to licensee fatigue assessments that 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, and (3) individuals are required to remain on duty after declaring that they are not fit for duty because of fatigue. When this information is considered in conjunction with the licensee's use of work hour limit waivers, it will provide an indication of the extent to which these conditions may be the result of the licensee's work scheduling practices.

The annual reporting requirement addresses a lesson learned from the NRC's current policy on worker fatigue. In SECY-01-0113, Fatigue of Workers at Nuclear Power Plants, the NRC documented large differences among licensees in the use of waivers and noted that a number of licensees made extensive use of waivers from their plant technical specification work hour limits. The NRC intended waivers to be used only in "very unusual circumstances." The annual report will enable the NRC to more effectively monitor industry use of waivers to ensure a more consistent implementation of the rule and ensure that licensees use the discretion to authorize waivers in a manner consistent with the objectives of managing worker fatigue, and not as a means to compensate for a lack of adequate staffing.

In addition, the staff expects the annual reports to enable the NRC to: (1) efficiently focus inspection resources on sites, job functions, or specific elements of fatigue management, (2) identify opportunities to amend the rule to improve its effectiveness, and (3) make oversight of the rule more transparent to stakeholders who have asserted that information regarding worker fatigue is often withheld from the public to either protect an alleger's identity, or in the case of security personnel, plant security.

Furthermore, the requirement for annual reporting of information pertaining to management of worker fatigue is consistent with the requirements for reporting information pertaining to drug and alcohol testing, consistent with the Part 26 performance objective for licensees to implement a comprehensive FFD program, and consistent with management of worker fatigue being no less important to worker FFD than the effective detection and deterrence of drug and

alcohol abuse.

FFD Programs for Construction, Clarification of Requirements

In comments on the proposed rule during the public comment period, industry stakeholders noted that the proposed rule did not clearly describe the types of FFD programs the NRC expected during nuclear power plant construction. 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.

In response, the staff developed a new Subpart K, "FFD Programs for Construction," and revised other sections of the rule to clarify the scope of requirements for construction, which were addressed in less detail in § 26.2(c) of the former rule and § 26.3(e) of the proposed rule. The final rule retains the intent of the former and proposed requirements to provide reasonable assurance that individuals involved in the construction of a new nuclear power plant who perform specified duties at the site are fit for duty, trustworthy, and reliable, commensurate with the risk to public health and safety and the common defense and security.

To streamline administration of the FFD program for construction and add flexibility, 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 licensee/permit holder 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 testing at the 50 percent annual rate, behavioral observation training, and a suitable inquiry/employment history check).

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 Subpart I. If an entity elects to implement an FFD program under Subpart K, it has the flexibility either to subject these individuals to random testing for drugs and alcohol or to detect and deter substance abuse by implementing a fitness monitoring program.

If an applicant for or holder of a COL or CP 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 subject to 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 construct safety- and security-related SSCs.

In addition to the flexibility to impose either random testing for drugs and alcohol or a fitness monitoring program to detect and deter substance abuse by workers who construct safety- and security-related SSCs, Subpart K, among other flexibilities, permits applicants for and holders of COLs and CPs 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.

The staff believes that the requirements for FFD programs for construction in 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 risk to public health and safety and the common defense and security, (2) permit applicants for and holders of COLs and CPs the flexibility to implement FFD programs that are appropriate for local circumstances, and (3) ensure that the privacy and other rights (including due process) of individuals who are subject to the requirements will be protected.

Subpart K, FFD Programs for Construction, Need for FFD Programs during Construction:

During the public comment period, some industry commenters indicated that, because there are no immediate radiological risks to public health and safety or the common defense and security during the construction of new plants, the NRC should not require FFD programs for construction that are more rigorous than the industrial safety programs implemented during construction of other large, commercial facilities. During subsequent public meetings between the staff and stakeholders (as described in the "Background" section of this SECY paper), industry stakeholders further asserted that NRC requirements for FFD programs during construction are unnecessary because (1) the NRC-mandated quality assurance processes will detect any errors in construction and are adequate to protect public health and safety and the common defense and security, and (2) the industry will voluntarily implement FFD programs during construction for industrial safety and business reasons.

The staff addressed these comments during the public meeting held on November 7, 2006 to present the technical bases for Subpart K of the draft final rule and to describe the fitness

monitoring option that Subpart K permits in lieu of random testing of certain construction workers. The staff indicated that the NRC is imposing regulatory requirements for FFD programs during construction for four primary reasons: (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 and ITAAC programs 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 to perform their intended functions 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. Therefore, the rule's requirements for construction require a full FFD program for only a limited number of personnel who have critical responsibilities for verifying that safety- and security-related SSCs have been 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 program provides 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.

Stakeholder responses to the staff's presentation varied. Industry stakeholders continued to assert that Part 26 requirements during 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.

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.

In response to the industry's comments, the staff gathered information about FFD programs in other industries. The results of the staff's benchmarking activities have indicated that, in response to the higher incidence of substance problems among construction workers, 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 testing and 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 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 by dedicated observers for the most sensitive construction tasks. The staff 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 that the results of certain construction activities may pose when a plant begins operations, is consistent with the approach implemented by other government agencies.

Based on the staff's assessment of 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, the staff concluded that—

(1) Relying on voluntary FFD programs would not assure that all workers who construct safety- and security-related SSCs or provide oversight of those construction activities are subject to a program;
(2) Relying on voluntary FFD programs that include only pre-employment, for-cause, and post-accident testing would not provide the on-going detection and deterrence of substance abuse that is achieved by either random testing or a fitness monitoring program;
(3) The extensive programs required for operating plants are not warranted for all nuclear power plant construction activities, but consistent implementation of an FFD program that provides on-going detection and deterrence of substance abuse is warranted; and
(4) Public confidence in new plant construction will be enhanced by a program to provide reasonable assurance that individuals who construct safety- and security-related SSCs are fit for duty.

Enclosure 2: Staff Positions on FFD Programs for Construction (Subpart K)

Issue	Rule Text	Position 1	Position 2
Should there be requirements for construction workers?	*Current § 26.2(c):* Certain regulations in this part apply to licensees holding permits to construct a nuclear power plant. Each construction permit holder, with a plant under active construction, shall comply with §§ 26.10, 26.20, 26.23, 26.70, and 26.73 of this part; shall implement a chemical testing program, including random tests; and shall make provisions for employee assistance programs, imposition of sanctions, appeals procedures, the protection of information, and recordkeeping. *Draft final § 26.4(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.	Requirements in the current rule should be retained and clarified by explicitly stating that construction workers fall within the scope of the FFD program for construction. The requirements in the current rule should be retained because: • Construction workers continue to have the highest rate of substance abuse among occupational groups, indicating that FFD requirements in addition to those commonly imposed by industrial/commercial FFD programs are warranted, • Relying on industrial FFD programs does not ensure coverage of all individuals of interest, and • Industrial/commercial FFD programs vary in effectiveness and some may not be effective in meeting the rule's objectives of detecting and deterring substance abuse. To achieve the current rule's objective for requirements that are commensurate with potential risk, limit the program elements required for detecting and deterring substance abuse to: • Pre-assignment, for-cause, and post-accident drug and alcohol testing, and • Either a fitness monitoring program or a random drug and alcohol testing program supplemented by behavioral observation.	Requirements for construction workers are unnecessary because the expected industrial/commercial FFD programs that licensees will undertake to meet their insurance or other demands, in combination with the requirements on first-line supervisors, security officers, QA/QC, and ITAAC personnel, provide a sufficient basis for concluding that the quality of safety and security features of the facility will be reasonably assured.

Issue	Rule Text	Position 1	Position 2
Should the scope include construction activities for security- or safety-related SSCs that occur at any location on licensee- or applicant-owned property where the nuclear power plant will be operated?	*Draft final § 26.5:* *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.	Individuals who are constructing safety- or security-related SSCs on the licensee's or applicant's property where the nuclear power plant will be operated should be subject to the FFD program. If a modular fabrication facility is established on property that is not owned by the licensee or applicant, or it is located on property owned by the licensee or applicant but is not where the nuclear power plant will be operated, the licensee or applicant should not be required to extend the program to include persons involved in construction activities at that facility. Basis: • Applying FFD requirements on the basis of assigned duties and location is consistent with the remainder of the rule, and • These persons' duties will be similar to the duties of others who will be constructing safety- and security-related SSCs where the nuclear power plant will be operated.	Modular fabrication facilities at the location where the nuclear power plant is being constructed and will operate, or in near proximity to the site, will not need to be covered by the proposed rule since the work will be done in a controlled work environment and will be subject to the same QA/QC program as remote fabrication facilities, which are not covered.

Issue	Rule Text	Position 1	Position 2
Should there be a requirement for NRC review and approval of an applicant's FFD program for construction?	*Draft final § 26.401(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.	Review and approval of FFD program plans would enhance the effectiveness and efficiency of the overall program because: • To permit the flexibility needed with a large and transient construction workforce, Subpart K emphasizes performance objectives rather than imposing prescriptive requirements. However, prescriptive requirements have been desired by the industry in the past to avoid unnecessary litigation related to drug and alcohol testing, • Increased inspection resources may be required without prior review and approval, • Enforcement may be more complex without prior approval, and • FFD programs for construction may be implemented for several years before inspections can occur and any weaknesses identified are corrected. The impact of this requirement on staff resources and the new reactor license application review process is expected to be minimal because: • The staff will work with stakeholders to develop a Regulatory Guide and expects licensees and applicants will adopt it, and • Public comment on the Regulatory Guide will provide an opportunity to develop FFD programs that are publicly acceptable.	The FFD program plan review and approval requirement seems to be unnecessary and inconsistent with the goal of streamlining the new reactor license application review process. The draft final part 52 already includes a provision, 52.79(a)(44), that would require a COL application to contain "A description of the fitness-for-duty program required by 10 CFR part 26 and its implementation."

Issue	Rule Text	Position 1	Position 2
Should first-line supervisors be subject to a full FFD program instead of fitness monitors?	*Draft final § 26.4(e):* When construction activities begin, any individual whose duties for the licensees and other entities in § 26.3© 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.	The fitness monitoring program does not require first-line supervisors to be subject to the full program, but instead, permits licensees and applicants to designate the individuals who will monitor those persons who are constructing safety- and security-related SSCs because: • Some first-line supervisors will work at the construction site only for short periods (1-3 weeks). Providing flexibility to designate fitness monitors avoids unnecessary regulatory burden by allowing licensees to invest their resources (i.e., the costs imposed by the full FFD program) in individuals who will work at the site for an extended period, and • Some first-line supervisors will not be directing actual work at the site. Providing flexibility to select fitness monitors ensures that the individuals selected will be on site so that they can observe those who are constructing safety-related and security-related SSCs as the work is being performed. The fitness monitoring option requires monitoring to occur at the work site, but permits licensees and applicants to: • Determine the number of monitors to be present on any given day, based on the number of workers who will be constructing safety- and security-related SSCs on that day (i.e., the ratio of monitors to workers), and • Determine the frequency with which monitoring will occur (e.g., the first-line supervisors for some tasks may be assigned as fitness monitors, while for other tasks, a trained watchman may stop by the job site once or twice a day, or during certain construction stages, monitoring would only occur as individuals enter the construction site at the beginning of a shift and after a lunch break).	First-line supervisors or others designated to oversee safety-related or security-related construction activities should be added to the full FFD program instead of fitness monitors. First-line supervisors should be required to take action when they observe unfit behavior of construction workers working on safety- or security-related structures, systems and components (i.e., a fitness monitoring program).

Issue	Rule Text	Position 1	Position 2
What requirements should apply to security personnel?	*Draft final § 26.4(e):* When construction activities begin, any individual whose duties for the licensees and other entities in § 26.3© 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.	Covering security officers during the construction of safety- and security-related SSCs is appropriate because: • These individuals will have responsibility for detecting and responding to malicious acts involving the safety- and security-related SSCs that are under construction, particularly when no other licensee or applicant personnel are present at the location where the nuclear power plant is being constructed and will operate, and should be able to safely and competently perform their duties, • There should be reasonable assurance that these individuals will be fit for duty (i.e., able to communicate effectively) when interacting with local law enforcement agencies who will respond to any potential or actual malicious acts involving safety- and security-related SSCs under construction, and • These individuals should be trustworthy and reliable, as demonstrated by the avoidance of substance abuse, to provide reasonable assurance that they will not be vulnerable to coercion to actively or passively collude in malicious acts affecting safety- and security-related SSCs under construction. Other considerations: • The NRC is considering access authorization and physical protection requirements for construction, but does not now require security personnel for new plant construction. Therefore, licensees and applicants would not be required to cover security personnel under an FFD program until requirements for security personnel are established. • The draft final rule text does not impose requirements on security officers who will be armed at the behest of the licensee or applicant.	A requirement to cover unarmed security personnel under the full FFD program is unnecessary unless there is fuel on site or the security personnel are armed. The requirement should be limited to only those security personnel who are required under NRC regulations or may be extended to personnel who carry weapons at the behest of a licensee or applicant. However, because the NRC does not have requirements related to security officers for construction, this provision should be removed from the rule.

[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.

FOR FURTHER INFORMATION CONTACT: David Diec, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-2834, Eric Skarpac, Office of Nuclear Security and Incident Response, telephone (301) 415-5631, Dr. David R. Desaulniers, Office of Nuclear Reactor Regulation, telephone (301) 415-1043, or Dr. Valerie Barnes, Office of Nuclear Regulatory Research, telephone (301) 415-5944. All of the above contacts may also be reached by email to FITNESSFORDUTY@NRC.GOV.

SUPPLEMENTARY INFORMATION:

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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) NRC's Policy on Worker Fatigue – NRC guidance documents do not prescribe requirements. Guidance documents establish policy or provide advice on meeting a regulatory requirement. As a result, 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.

[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.

PART 26—FITNESS FOR DUTY PROGRAMS

Subpart A—Administrative Provisions

Subpart B—Program Elements

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.

* * * * *

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)
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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)

Regulatory Analysis of the Final Rulemaking to Amend the Fitness-for-Duty Rule (10 CFR Part 26)

U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation
Office of Nuclear Security and Incident Response

ABSTRACT

The purpose of this document is to present the U.S. Nuclear Regulatory Commission's regulatory analysis of the final revisions to the Fitness-for-Duty (FFD) rule as set forth in Title 10, Part 26, of the Code of Federal Regulations (10 CFR Part 26). It analyzes the final rule's benefits and costs, and it presents a backfit analysis as required by 10 CFR 50.109, 10 CFR 70.76, and 10 CFR 76.76. The analysis is conducted in accordance with the Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG/BR-0058, Revision 4.

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EXECUTIVE SUMMARY

The U.S. Nuclear Regulatory Commission (NRC) is amending the former Fitness-for-Duty (FFD) regulations contained in Title 10, Part 26, of the *Code of Federal Regulations* (10 CFR Part 26). The NRC is amending these regulations to update them and to improve their effectiveness, efficiency, and clarity. With respect to licensee drug and alcohol testing programs, the amendments enhance consistency with the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines) and other Federal drug and alcohol testing programs (e.g., Department of Transportation [DOT] programs) that impose similar requirements. Another goal of the amendments is to further consistency with the NRC's access authorization requirements for nuclear power plants. A third area the rule addresses is fatigue management. While licensees already maintain a variety of work hour controls, the final rule standardizes and strengthens licensee programs in this area. The final rule's drug and alcohol testing and authorization provisions apply to licensees authorized to operate a nuclear power reactor; licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM); corporations that obtain certificates of compliance or approved compliance plans involving formula quantities of SSNM; combined operating license holders; mixed oxide fuel fabrication facilities; and construction permit holders with a plant under active construction. The fatigue management provisions apply to nuclear power reactors. The final rule also applies to contractor/vendors (C/Vs) who implement FFD programs or program elements, to the extent that licensees and other entities rely upon those C/V FFD programs or program elements to meet the requirements of Part 26.

The main analysis presented in this document examines the benefits and costs of the final FFD requirements relative to the baseline of the former FFD requirements, including regulations (including enforcement discretion), and relevant orders. The key findings of the analysis are as follows:

- Total Cost to Industry: The final rule results in a one-time cost to the nuclear industry of approximately $13.7 million, followed by annual costs on the order of $31.7 million. The total present value of these costs is estimated at $444.0 million (using a 7-percent discount rate) and $694.3 million (using a 3-percent discount rate) over the next 49 years.

- Average Cost per Program. The average FFD program, which may include multiple plants and units, incurs a one-time cost of approximately $482,000, followed by annual costs of approximately $1,174,500. The total present value of these costs is estimated at $13,768,000 (using a 7-percent discount rate) and $22,034,000 (using a 3-percent discount rate).

- Relative Costs of Fatigue Management Provisions. The substantial costs of the fatigue management provisions in Subpart I dominate the cost results of the final rule as a whole. For the industry these fatigue management costs are estimated at between $572.9 million (present value using a 7-percent discount rate) and $898.1 million (assuming a 3-percent discount rate). When the other (non-fatigue) provisions are evaluated independently, the results show a savings to industry estimated at

approximately $128.8 million (present value using a 7-percent discount rate) or $203.8 million (assuming a 3-percent discount rate).

- Value of Benefits Not Reflected Above. With the exception of most of the direct monetary savings to industry, the cost figures shown above *do not* reflect the value of the benefits of the final rule. These benefits are evaluated qualitatively in Section 4.1.2 (for drug and alcohol testing and authorization provisions) and in Section 4.1.3 (for fatigue management provisions).[1] This regulatory analysis concluded the costs of the rule are fully justified in view of the qualitative benefits.

- Costs to NRC. The rule results in a one-time cost to NRC of approximately $28,000, followed by annual costs of approximately $47,000. The total present value of these costs is estimated at $665,000 (using a 7-percent discount rate) and $1,025,000 (using a 3-percent discount rate).

- Decision Rationale. Although the NRC did not quantify the benefits of this rule, except as noted above, the staff did qualitatively examine benefits and concluded that the rule provides safety and security-related benefits. The rule accomplishes this by improving the management of worker fatigue at nuclear reactor facilities and by increasing the effectiveness of drug and alcohol testing. It updates and enhances the consistency of 10 CFR Part 26 with advances in other relevant federal rules and guidelines, including the U.S. Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines) and other Federal drug and alcohol testing programs (e.g., those required by the U.S. Department of Transportation [DOT]) that impose similar requirements on the private sector. The rule also enhances regulatory efficiency and effectiveness by improving clarity and, thereby, reducing the need for enforcement discretion, interpretations of rule language and/or exemption requests, and by enhancing consistency between the Part 26 rule and access authorization programs. The NRC also believes that the final rule provides additional assurance to members of the public that their health and safety is protected due to the FFD of personnel at nuclear facilities.

Pre-Order Baseline Sensitivity Analysis. The regulatory analysis contains a sensitivity analysis that is not required by NRC's Regulatory Analysis Guidelines and has not been used for decision-making purposes. It reflects the fact, which has been voiced by stakeholders, that many requirements in the area of fitness-for-duty and access authorization have been imposed or modified as a result of the NRC's "Issuance of Order for Compensatory Measures Related to Access Authorization" (also known as the Access Authorization Order, or AAO), dated January 7, 2003, and "Issuance of Order for Compensatory Measures Related to Fitness-for-Duty Enhancements Applicable to Nuclear Facility Security Force Personnel" (also known as Order EA-03-038), dated April 29, 2003. Therefore, this sensitivity analysis examines the rule relative to a "Pre-Order Baseline."[2] Under this pre-order baseline, the final rule results in a one-time cost to industry of approximately $19.8 million, followed by annual costs on the order of $4.9 million. The total present value of these costs is estimated at $85.1 million (using a 7-

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[1] See Section 3.2 of this document for a discussion of the issues that would be involved in quantifying the benefits of the final rule.

[2] This sensitivity analysis considers only the FFD portions of the requirements in the Access Authorization Order (AAO). Industry savings resulting from these portions of the AAO do not represent the financial impact on the industry of the AAO as a whole.

percent discount rate) and $124.8 million (using a 3-percent discount rate) over the next 49 years. For the average licensee's FFD program, which may include multiple plants and units, this equates to a one-time cost of approximately $618,500, followed by annual costs of approximately $154,600. The total present value of these costs is estimated at $2,581,000 (using a 7-percent discount rate) and $3,582,000 (using a 3-percent discount rate).

ABBREVIATIONS

AAO	Access Authorization Order
ASD	Alcohol Screening Device
BAC	Blood Alcohol Concentration
CFR	*Code of Federal Regulations*
CPL	Conforming Products List
CRGR	Committee to Review Generic Requirements
C/V	Contractor/Vendor
CY	Calendar Year
DOT	U.S. Department of Transportation
EBT	Evidential-grade Breath Alcohol Analysis Device
FFD	Fitness for Duty
FR	*Federal Register*
GL	Generic Letter
HHS	U.S. Department of Health and Human Services
INPO	Institute for Nuclear Power Operations
KA	Knowledge and Ability
MRO	Medical Review Officer
NEI	Nuclear Energy Institute (formerly NUMARC)
NHTSA	U.S. National Highway Transportation Safety Administration
NIDA	National Institute on Drug Abuse (now SAMHSA)
NMSS	Office of Nuclear Material Safety and Safeguards (NRC)
NRC	U.S. Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation (NRC)
NSIR	Office of Nuclear Security and Incident Response (NRC)
NUMARC	Nuclear Management and Resources Council (now NEI)
OMB	Office of Management and Budget
QA	Quality Assurance
SAE	Substance Abuse Expert
SAMHSA	Substance Abuse and Mental Health Services Administration (formerly NIDA)
SRM	Staff Requirements Memorandum
SSNM	Strategic Special Nuclear Material

1. INTRODUCTION

This document presents a regulatory analysis of the revisions to the Fitness-for-Duty (FFD) rule as set forth by the U.S. Nuclear Regulatory Commission (NRC) in Title 10, Part 26, of the Code of Federal Regulations (10 CFR Part 26). This introduction is divided into three sections. Section 1.1 states the problem and the reasons for the rulemaking, Section 1.2 provides background information on the Part 26 rulemaking, and Section 1.3 discusses backfit considerations related to adoption of the revisions to the Part 26 rule.

1.1 Statement of the Problem and Reasons for the Rulemaking

This rulemaking ensures that 10 CFR Part 26 continues to effectively address the related concerns of reliability and trustworthiness of workers at nuclear facilities as demonstrated by the avoidance of substance abuse. Evidence has shown that the use of alcohol or drugs can impair a worker's motor skills and judgment sufficiently that it increases the likelihood of accidents arising from neglect or human error (see Section 4.1.2.1). Licensee or contractor/vendor (C/V) employees who knowingly use illegal drugs, or abuse legal drugs or alcohol, willingly violate the standards set by the licensee as well as society's laws and norms. The Part 26 FFD program requirements are designed to provide reasonable assurance that individuals are trustworthy and reliable in carrying out their duties as demonstrated by the avoidance of substance abuse.

When the NRC published the Part 26 rule in June 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 (SRM dated March 22, 1989). The NRC reviewed information from several sources, including inspections, periodic reports by licensees on FFD program performance, reports of significant FFD events, industry-sponsored meetings and current literature, and initiatives by the Nuclear Management and Resources Council [NUMARC, now the Nuclear Energy Institute (NEI)] and the Substance Abuse and Mental Health Services Administration [SAMHSA, formerly the National Institute on Drug Abuse (NIDA)] and its Drug Testing Advisory Board.

On the basis of that extensive review, the NRC has concluded that the regulatory approach in 10 CFR Part 26 is fundamentally sound and provides a means for both detecting and deterring substance abuse at licensee facilities. However, lessons learned during implementation of the existing rule indicate that NRC should address a number of issues. These issues include:

- *Subversion*. Testing neither detects nor deters substance abuse if testing is easily subverted through the exploitation of vulnerabilities in the testing process.

- *Inefficiencies.* Some Part 26 requirements contribute little to the effectiveness of licensee's FFD programs relative to the resources (time and money) required to meet these requirements.

- *Regulatory efficiency.* NRC licensees are subject to regulation by State and Federal agencies other than the NRC. Additions or changes to the regulatory requirements for drug testing by other agencies, such as Health and Human Services (HHS) and the Department of Transportation (DOT), as well as new legislation since 1989 (e.g., the Americans with Disabilities Act) have created incompatibilities and redundancies with NRC's requirements.

- *Confusion regarding the original intent of the NRC.* Ambiguities in the language of the rule have created some confusion regarding the Commission's original intent in Part 26. Resolving these ambiguities saves NRC staff time, increase consistency in the interpretation of the regulation industry-wide, and thus reduce licensee time in interpreting the regulation.

- *Technical developments.* Recent improvements in drug and alcohol testing practices can increase the effectiveness of licensee's and C/V's FFD programs.

The NRC is issuing this final rule to address these issues through a comprehensive revision of 10 CFR Part 26.

The NRC's continuing analysis of appropriate improvements or changes to the Part 26 rule also has led the NRC to conclude that strengthened fatigue management provisions should be added to 10 CFR Part 26. Research and experience have shown that fatigue can substantially degrade an individual's ability to safely and competently perform a wide range of work-related duties. 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 and make timely and conservative decisions; and communicate and work effectively as a team member. Such degradations in performance, if exhibited by individuals performing risk-significant functions, can adversely affect the safety and security of a nuclear power plant, and can cause levels of worker impairment comparable to those prohibited by Part 26 for alcohol. Although the NRC has established guidelines limiting work hours for personnel performing safety-related functions at nuclear power reactors, conditions that contribute to worker fatigue continue to exist. These conditions include:

- *Extended work shifts*, including the use of 12-hour shifts during normal operations and/or the use of 6 or more consecutive 12-hour shifts during plant outages, have become increasingly common at U.S. nuclear power plants. During outages, some licensees have scheduled personnel for three or more weeks of consecutive 12-hour shifts without intervening days off.

- *Extensive use of overtime.* Extensive use of overtime creates a combined effect of long work hours with reduced break periods.

- *Work schedules affecting normal biological cycles*. Because 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, workers are cyclically affected by a daily biological clock, which runs on about a 24-hour (circadian) cycle. A substantial amount of scientific literature on circadian variations in alertness has demonstrated the significant roles worker fatigue, sleep loss and circadian rhythms play in contributing to errors and accidents.

In addition, the NRC has determined that ambiguities in the existing regulatory framework for matters pertaining to working hours and fatigue should be removed and that the effectiveness of FFD programs should be strengthened by establishing clear and enforceable requirements concerning the management of fatigue of nuclear power plant personnel.

Goals

Specifically, the goals of the rulemaking are as follows:

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

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

3. Improve the effectiveness and efficiency of FFD programs.

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

5. Improve 10 CFR Part 26 by eliminating or modifying unnecessary requirements.

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

7. Protect the privacy rights and other rights (including due process) of individuals who are subject to 10 CFR Part 26.

1.2 Background

1.2.1 Drug and Alcohol Testing Provisions, and General Fitness-for-Duty Provisions

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

When the Part 26 rule was published in 1989, the Commission directed the NRC staff to continue to analyze licensee programs, assess the effectiveness of the rule, and recommend appropriate improvements or changes. The NRC staff reviewed information from several sources including inspections, periodic reports by licensees on FFD program performance, reports of significant FFD events, industry sponsored meetings and current literature, as well as initiatives by industry, the Substance Abuse and Mental Health Services Administration (SAMHSA, formerly the National Institute on Drug Abuse [NIDA]) and SAMHSA's Drug Testing Advisory Board, and recommended improvements and changes.

As a result, the NRC published proposed amendments to the Part 26 rule in the Federal Register on May 9, 1996 (61 FR 21105). The 90-day public comment period for the proposed rulemaking closed on August 7, 1996. The NRC staff reviewed and considered public comments on the proposed rule, and submitted a final rule to the Commission in a Commission paper (SECY-00-0159), dated July 26, 2000. The Commission affirmed the rule in a staff requirements memorandum (SRM) dated December 4, 2000. Subsequently, the affirmed rule was sent to the Office of Management and Budget (OMB) to obtain a clearance under the Paperwork Reduction Act. The request for comments on the clearance was published in the Federal Register on February 2, 2001 (66 FR 8812). OMB and NRC received public comments that objected to some aspects of the rule (responses to those comments are included in the Federal Register notice for the proposed rule). Consequently, in SECY-01-0134, dated July 23, 2001, the NRC staff recommended withdrawing the request for clearance and preparing a new proposed rule. By SRM, dated October 3, 2001, the Commission approved the staff's recommendation to prepare this new proposed rule, rather than incorporating the 1996 proposed amendments into a final rule.

1.2.2 Worker Fatigue Rulemaking

The NRC's "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors" (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. In GL 82-12, the NRC requested that licensees revise the administrative section of their technical specifications to ensure that plant administrative procedures were consistent with the working hours guidelines. Those guidelines are:

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

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

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

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

Further, the guidelines permit deviations from these limits in very unusual circumstances if authorized by the plant manager, his or her deputy, or higher levels of management. The NRC's Policy on Worker Fatigue was incorporated, directly or by reference, and with variations in wording and detail, into the technical specifications of all but three nuclear power plant sites. Those three sites 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, several requirements addressed other causes of impairment, including fatigue. Those requirements included general performance objectives (§§26.10(a) and (b)) that required licensees to provide "...reasonable assurance that nuclear power plant personnel...are not

under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause..." and "...early detection of persons who are not fit to perform activities within the scope of this part..." A requirement was also included in §26.20(a) for licensee policies to "...address other factors that could affect fitness for duty such as mental stress, fatigue and illness."

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

Soon thereafter, the Commission received a petition for rulemaking (PRM-26-2), dated September 28, 1999, from Barry Quigley. The petition 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. (A discussion of the petition, which is addressed by the proposed rulemaking, is included in the Federal Register notice for the proposed rule.)

The Union of Concerned Scientists petitioned the NRC on April 24, 2001, pursuant to 10 CFR 2.206, to issue a Demand for Information (DFI) to specified licensees. The petition asserted that Wackenhut Corporation has the contractual right to fire security guards who refuse to report for mandatory overtime, and that this contractual right conflicts with 10 CFR Part 26.10(a) and (b). The NRC denied the DFI (ADAMS Accession No. ML013230169), but, as described below, addressed the concern highlighted by the petition through the NRC's generic communication process.

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. The Commission decided to initiate a rulemaking to incorporate fatigue management into 10 CFR Part 26 in order to strengthen the effectiveness of FFD programs by establishing clear and enforceable requirements concerning the management of fatigue of nuclear power plant personnel that would reduce the potential for worker fatigue to adversely affect public health and safety and the common defense and security.

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 that a work environment conducive to reporting FFD concerns might be adversely affected if sanctions were to be imposed on workers raising FFD concerns, and the protections afforded workers who make self-declarations by 10 CFR 50.7, "Employee Protection."

During the development of proposed requirements, the NRC observed an increase in concerns (e.g, media and public stakeholder reports, allegations from security personnel) regarding the workload and fatigue of security personnel following the terrorist attacks of September 11, 2001. Following an NRC review of the control of work hours for security force personnel, the NRC issued Order EA-03-038 on April 29, 2003, requiring compensatory measures to reduce fatigue among security personnel at nuclear power plants, including work hour limits.

The compensatory measures imposed by Order EA-03-038 were similar to the guidelines of the NRC's Policy on Worker Fatigue. The compensatory measures differed from the policy guidelines in a few areas in which the NRC believed it was necessary to address previously identified deficiencies in the guidelines, including the need to address cumulative fatigue from prolonged use of extended work hours, matters unique to security personnel, and matters identified through stakeholder input obtained through public meetings concerning the proposed worker fatigue rulemaking and the order. The requirements in the order were imposed to provide the NRC with reasonable assurance that the public health and safety and common defense and security continue to be adequately protected. The NRC plans to withdraw Order EA-03-038 once the fatigue management provisions in Subpart I for security force personnel take effect. Differences between the requirements in Subpart I and the requirements imposed by order, and the rationale for those differences, are discussed in Section VI of the Federal Register notice for this final rule.

1.2.3 Proposed FFD Rulemaking Including Fatigue Requirements

On March 29, 2004, in COMSECY-04-0014, the NRC staff informed the Commission of the status of both rulemakings. The NRC staff also noted that because both rulemakings were being completed in parallel, the proposed fatigue rule draft language was based on the draft language in the overall revision of Part 26, rather than on the current language in Part 26. As a result, meaningful public comment could be confounded by the simultaneous promulgation of two draft rules which are somewhat interdependent and staff action to address a comment on one proposed rule could easily impact the other proposed rule, creating a high potential for the need to repropose one or both rules. In SRM-COMSECY-04-0014, dated May 25, 2004, the Commission directed the staff to combine the rulemaking related to nuclear power plant worker fatigue with the ongoing Part 26 rulemaking activity.

Following the publication of the August 25, 2005, proposed rule (70 Federal Register, 50442), the NRC accepted public comments for a 4-month period. 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). The fatigue provisions of the rule engendered the most comments. As a result, the fatigue provisions in the final rule contain the most revisions relative to the proposed rule.

In addition, the NRC reorganized the overall structure of the proposed rule and renumbered many of the subparts. The regulatory analysis discussion reflects the renumbered sections and new structure of the final rule.

1.3 Backfit Rule Considerations

Section 4.4 of this regulatory analysis presents the NRC's evaluation of changes in the final rule in accordance with the backfit provisions of 10 CFR §50.109, 10 CFR §70.76, and 10 CFR §76.76. Section 4.4.1 examines the aggregation of the final rule requirements that constitute backfits, and explains why many provisions have been appropriately excluded from the backfit analysis. Section 4.4.2 describes a screening analysis conducted in accordance with NRC's Regulatory Analysis Guidelines to ensure that the aggregate analysis does not mask the

inclusion of individual rule provisions that are (1) not cost-beneficial when considered individually and (2) not necessary to meet the goals of the rulemaking.

2. IDENTIFICATION AND PRELIMINARY ANALYSIS OF ALTERNATIVE APPROACHES

This section presents preliminary analysis of the alternatives that the staff considered to meet the regulatory goals identified in the previous section. (Section 4 presents a more detailed analysis of the final rule option.) The staff considered three alternatives for revising Part 26's substance abuse and authorization provisions, and five alternatives addressing fatigue management,[3] as discussed below.

2.1 Alternatives Considered for Part 26 Substance Abuse and Authorization Provisions

The staff considered the following three alternatives relative to the substance abuse and authorization provisons in Part 26:

(1) Take no action.

(2) Revise 10 CFR Part 26 (either in part or in whole).

(3) Address problems through means other than revising 10 CFR Part 26 (e.g., regulatory guides, generic communications, stakeholder meetings).

2.1.1 Option 1: Take No Action

One alternative to rule changes would be to take no action. The no-action alternative would allow current practices to continue, or require the NRC staff to continue to address certain outstanding FFD issues on a case-by-case basis. Taking no action would allow licensees continued flexibility in determining the course of action when they are not constrained by other agencies, legal requirements, or labor negotiations. This would also avoid certain cost increases that the final rule would impose. However, taking no action would disregard the staff and industry recommendations regarding areas for improvement (as described in Section 1.1) and would continue to impose avoidable costs on licensees. Moreover, taking no action at this time would not yield any positive impact on the effectiveness of the rule.

Advantages:

- Licensees would not have to bear the implementation costs of certain rule changes and the NRC would save on rulemaking costs.

- Licensees would have continued flexibility to determine courses of action, thereby avoiding more restrictive regulatory approaches.

[3] Until mid-year 2004, NRC had addressed the possibility of a fatigue management rulemaking separately from the previously-initiated rulemaking to revise the Part 26 substance abuse and authorization regulations.

Disadvantages:

- The identified concerns and lessons learned regarding the current Part 26 rule (described in Section 1.1) would not be resolved.
- Licensee and C/V FFD programs would not realize the potential savings from particular rule changes, including elimination or modification of unnecessary requirements.
- This alternative would not yield permanent solutions to a variety of problems.
- Licensees would have a less comprehensive set of requirements.
- NRC staff and licensees would still be compelled to interpret ambiguous rule language and these interpretations would vary by program. Also, the NRC staff would continue to face difficulties in maintaining consistency among licensees' inspection and enforcement programs.
- This alternative disregards licensees' preference, expressed at meetings with stakeholders, that program implementation details be included in the rule language.
- Depending on whether issues such as the protection of individual rights are addressed as rule requirements or as guidance, this alternative may provide less protection of individual rights.

By definition, the no-action alternative has no incremental benefits or costs, as it does not change the status quo. This option is inconsistent with NRC's goals for the rulemaking.

2.1.2 Option 2: Revise 10 CFR Part 26

This option provides the opportunity to resolve the identified issues and concerns regarding Part 26 (described in Section 1.1). This option includes two alternatives:

(1) Revise the regulation comprehensively to address the identified issues.

(2) Revise portions of the regulation to address only those issues that cannot be resolved through other means (e.g., a regulatory guide, stakeholder meetings).

2.1.2.1 Comprehensive Rule Revision

A comprehensive rulemaking would provide a means of addressing the identified issues and concerns with respect to Part 26. Through a comprehensive revision, the NRC staff could (1) ensure that all licensees would consistently implement measures to prevent subversion; (2) eliminate or modify unnecessary requirements; (3) address adjustments and changes to regulatory positions and requirements of other government agencies; (4) clarify the language of the rule; and (5) incorporate changes to take advantage of technical developments in drug and alcohol testing practices.

Advantages:

- The revised rule would address all requirements for licensee and C/V FFD programs.
- Regulatory change would enhance consistency across programs and provide opportunities for savings (e.g., allowing generic training to be accepted across licensees) that would not be available with more informal approaches.
- The revised rule would provide clear inspection guidance and, therefore, would result in a more efficient inspection process.

Disadvantages:

- Some rule revisions would impose costs on licensees.
- The revised rule would give licensees less flexibility in the implementation of their FFD programs (as a result of the rule's increased clarity).

The NRC has pursued this alternative and estimated the benefits and costs of this option as described in Section 4 of this regulatory analysis.

2.1.2.2 Partial Rule Revision with Other Agency and Licensee Actions

Some problems, such as varying interpretations of the regulation, could be addressed through other means, such as a regulatory guide, generic communications, or stakeholder meetings.

Advantages:

- This alternative would address some problems in some manner.
- This alternative would reduce changes to the regulation (compared to the more comprehensive revision discussed in Section 2.1.2.1) and may have a lower implementation cost to licensees.
- This alternative would allow more informal and potentially more flexible resolutions to some problems, which may be less costly.

Disadvantages:

- This alternative would not yield permanent solutions to a variety of problems.
- This alternative may involve preparation of more documents than comprehensive revision would and could be more time-consuming and costly to the NRC, and less efficient for licensees.
- Licensees would have a less comprehensive set of requirements.
- NRC staff and licensees would still be compelled to interpret ambiguous rule language and these interpretations would vary by program. Also, the NRC staff would continue to

face difficulties in maintaining consistency among licensees' inspection and enforcement programs.

- Because various rule changes are interrelated, it may be inappropriate to have some required in rule text and some suggested in guidance.

- This alternative disregards licensees' preference, expressed at meetings with stakeholders, that program implementation details be included in the rule language.

- Depending on whether issues such as the protection of individual rights are addressed as rule requirements or as guidance, this alternative may provide less protection of individual rights.

The NRC considered this alternative, but determined that the disadvantages are too significant relative to the comprehensive rule revision described in Section 2.1.2.1. Therefore, this regulatory analysis does not evaluate the quantitative benefits and costs of this alternative.

2.1.3 Option 3: Address Issues through Means Other than Revising Part 26

Under this alternative, the NRC staff would not revise 10 CFR Part 26 at all. This alternative differs from the no-action alternative discussed in Section 2.1.1 because this alternative would address FFD concerns through other means, such as new or revised regulatory guides, generic communications, stakeholder meetings, and other agency initiatives.

Advantages:

- This alternative would allow greater flexibility both for NRC staff and licensees.

Disadvantages:

- This alternative would not be able to address all of the identified issues (see Section 1.1), because many issues require direct regulatory changes.

- This alternative would not yield permanent solutions to a variety of issues.

- Preparing multiple documents to address issues could be more time-consuming and costly to the NRC, and less efficient for licensees.

- Inconsistency in program implementation, inspection, and enforcement would be more likely to persist. Some licensees currently have aggressive programs, while other licensee programs address only the licensees' interpretation of the requirements of the rule. Such discrepancies would be likely to continue in areas where changes are not included in the regulation.

- Licensees would not have a single comprehensive source of guidance.

- The process of developing guidance can be as burdensome as rulemaking for both NRC staff and licensees.

- This alternative disregards licensees' preference, expressed at meetings with stakeholders, that the rule language should include program implementation details.

- Depending on whether issues such as the protection of individual rights are addressed as rule requirements or as guidance, there may be less protection of individual rights.

The NRC considered this alternative, but determined that the disadvantages are too significant relative to the alternative described in Section 2.1.2.1. Therefore, this regulatory analysis does not evaluate the quantitative benefits and costs of this alternative.

2.2 Alternatives Considered for Fatigue Management

In PRM-26-2 (December 1, 1999; 64 FR 67202), a petitioner requested that the NRC establish clear and enforceable work hour limits to mitigate the effects of fatigue for nuclear power plant personnel performing safety-related work and presented a detailed proposal for managing fatigue through regulation.[4] The staff evaluated the merits of PRM-26-2 and the comments received in response to the PRM and assessed the policy statement. The staff 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 staff also began considering whether it would be possible to achieve the petitioner's objectives through alternative requirements that are more flexible, more directly focused on risk, and more aligned and integrated with current regulatory requirements.

The staff developed four potential alternatives, plus the no-action alternative, which were presented in the rulemaking plan attached to SECY-01-0113 (June 22, 2001).[5] These four alternatives are as follows:

(1) Implement the proposals in PRM-26-2.

(2) Amend Part 26 to establish thresholds for work hour controls. Provide flexibility and ensure focus on safety through a risk-informed deviation process. Amend Part 26 and RG 1.134, "Medical Evaluation of Licensed Personnel at Nuclear Power Plants," to ensure that fatigue from any cause is addressed through existing licensee programs.

(3) Amend Part 26 to establish thresholds for work hour controls and a defined process for controlling exceptions.

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[4] More specifically, the petition requested that the NRC (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.

[5] NRC prepares a rulemaking plan to establish the goals of a rulemaking, help define potential regulatory alternatives (including whether regulatory action is necessary to resolve the problem), begin specifying the research efforts that should be undertaken, consider schedules and milestones, and undertake preliminary assessments of whether a rule will be cost-effective and feasible to implement.

(4) Amend Part 26 to establish requirements for assessing and managing the risks associated with schedules and conditions that cause fatigue and impaired alertness. Amend Part 26 and RG 1.134 to ensure that fatigue from any cause is addressed through licensee programs.

With respect to the proposal contained in PRM-26-2, the staff determined that implementing the proposals in the petition would (1) ensure that personnel are not impaired and are responsive to plant risk and the likelihood of personnel impairment; (2) establish clear expectations; and (3) increase public confidence.

The rulemaking plan also evaluated each of the other alternatives. The evaluation found that Option 2, in particular, would be equally effective as the petition proposals, while also affording the added benefits of increased scheduling flexibility, stronger focus on risk, and improved alignment and integration with existing programs, including the use of licensee corrective action programs to support a performance based approach. Based on this preliminary analysis, the rulemaking plan recommended Option 2 rather than the other alternatives, including the approach proposed in the petition.

In a Staff Requirements Memorandum (January 10, 2002), the Commission accepted the recommendation presented in SECY-01-0113 and directed the staff to develop a rule using Option 2 as described in the rulemaking plan.

3. EVALUATION OF BENEFITS AND COSTS

This section describes the analysis conducted to identify and evaluate the benefits (values) and costs (impacts) of the final rule. Section 3.1 identifies the attributes that the final rulemaking is expected to affect. Section 3.2 describes the methodology used to analyze the benefits and costs associated with changes to the affected attributes. The results of the analysis are presented in Section 4.

3.1 Identification of Affected Attributes

This section identifies the factors within the public and private sectors that the final rulemaking is expected to affect. These factors are classified as "attributes" using the list of potential attributes provided in Chapter 5 of the NRC's "Regulatory Analysis Technical Evaluation Handbook."[6] Affected attributes from the handbook include the following:

- *Industry Implementation.* The rulemaking requires licensees to modify written policies, procedures, and training materials. In addition, some licensees may be required to modify equipment used to conduct drug and alcohol testing. Some licensees also may be required to modify personnel practices to address fatigue management requirements.

- *Industry Operation.* The rulemaking requires licensees to change their existing practices with respect to authorization (e.g., self-disclosures, suitable inquiries, recordkeeping), behavioral observation and training, drug and alcohol collection and testing practices (e.g., cutoff levels for marijuana and opiates, validity testing, quality assurance procedures, testing of offsite FFD program personnel, reporting), and FFD determinations. Licensees also are required to change their existing practices with respect to work hours and related controls (e.g., days off between work periods, waivers from work hour limitations, and fatigue assessments).

- *Safeguards and Security Considerations.* The final rule clarifies and modifies certain authorization procedures, which should result in improved safeguards and security. The final rule also revises certain drug and alcohol testing provisions to increase assurance that individuals are trustworthy and reliable by enhancing provisions to detect attempts to subvert the testing process. The final rule, which includes security force personnel within the scope of workers covered by fatigue provisions, should result in improved safeguards and security.

- *Public Health (Accident).* The final rule reduces the risk that public health will be affected by accidents that are attributable to the undetected use of drugs or alcohol or to fatigue.

- *Occupational Health (Accident).* The final rule reduces the risk that occupational health will be affected by accidents that are attributable to the undetected use of drugs or alcohol or to fatigue.

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[6] NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook: Final Report," U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, January 1997.

- *Occupational Health (Routine).* The final rule reduces the risk that workers will be subject to unnecessary exposures either as the direct result of cognitive impairments attributable to the influence of drugs or alcohol or to fatigue, or as the result of conducting mitigative and/or cleanup activities following an event caused by cognitive impairment attributable to the influence of drugs or alcohol or to fatigue.

- *Off-Site Property*. The final rule reduces the risk that off-site property will be affected by accidents that are attributable to the undetected use of drugs or alcohol or to fatigue.

- *On-Site Property.* The final rule reduces the risk that on-site property will be affected by accidents that are attributable to the undetected use of drugs or alcohol or to fatigue.

- *Environmental Considerations.* The final rule reduces the risk that the environment will be affected by accidents that are attributable to the undetected use of drugs or alcohol or to fatigue.

- *Regulatory Efficiency.* The final rule reduces uncertainties in the former rule, Orders, and guidance, including guidance on fatigue management, improve consistency of practices among licensee and C/V FFD programs, and improve consistency between the NRC's FFD requirements and guidance and those of other Federal agencies (e.g., HHS, DOT).

- *NRC Implementation.* The rulemaking likely causes NRC to incur one-time costs to train NRC staff reviewers and inspectors on the rule revisions.[7]

- *NRC Operation.* Modified program reporting requirements related to program performance data and reportable FFD events have an impact on NRC staff operations, as does the need to train NRC staff and inspectors on the final rule changes.

- *Other Considerations.* The final rule may improve *public perceptions* regarding the safe operation of nuclear facilities, and may increase *workplace productivity and efficiency* of affected workforces.

The rulemaking is *not* expected to affect the following attributes:

- Public Health (Routine);
- Other Government;
- General Public;
- Improvements in Knowledge; and
- Antitrust Considerations.

3.2 Analytical Methodology

This section describes the methodology used to analyze the benefits and costs associated with the final rule. The benefits of the rule include any desirable changes in affected attributes (e.g.,

[7] Consistent with direction in Section 5.7.9 of the NRC's "Regulatory Analysis Technical Evaluation Handbook", this analysis does not include the predecisional costs of analyzing and promulgating the revised requirements.

improved safety, monetary savings) while the costs include any undesirable changes in affected attributes (e.g., monetary costs).

The analysis evaluates several attributes on a quantitative basis. (These include industry implementation, industry operation, NRC implementation, and NRC operation.) Quantitative analysis requires a baseline characterization of factors such as the number and size of individual FFD programs, the remaining operating life of licensee facilities, hours worked by staff during normal operations and during outages, the use of onsite versus offsite collection and testing facilities, the number of authorization actions conducted annually, the number of drug and alcohol tests conducted annually by type, the number of positive tests, cost information, and a range of other current licensee practices relating to specific program elements. Sections 3.2.1–3.2.4 describe the most significant analytical data, variables, and assumptions used in the quantitative analysis of these attributes.

This analysis relies on a primarily qualitative (rather than quantitative) evaluation of several other affected attributes (safeguards and security considerations, public health, occupational health, offsite property, onsite property, environment considerations, public perception, and workplace productivity/efficiency) due to the difficulty in quantifying the impact of the current rulemaking.[8] These attributes are affected by the regulatory option through the associated reduction in the risks of accidents within the protected area due to worker fatigue or the undetected use of drugs or alcohol, or due to potential inconsistencies between the FFD and the authorization functions. These risks range in severity from workplace safety incidents up to damage to the reactor core. Quantification of any of these attributes would require estimation of factors such as the types, frequencies, and results of damage that now occur (i.e., pre-rule) and would occur post-rule.

Additional details regarding the calculations used in the analysis are presented in two appendices. Appendix 1 provides the specific cost equations used to quantify costs and savings, along with any necessary assumptions not presented elsewhere. Appendix 1 contains 15 sections, one for each of the 15 subparts, A-O, of the revision to 10 CFR Part 26. Appendices 2-3 present data and input calculations referenced in Appendix 1, including data on unit costs, hourly wage rates, FFD programs, costs of eliminating work hour deviations, and other information.

3.2.1 Baselines for Analysis

This regulatory analysis measures the incremental impacts of the final rule relative to a baseline, which reflects anticipated behavior in the event that the final regulation is not imposed. The baseline used in this analysis assumes full licensee compliance with existing NRC requirements, including current regulations and relevant orders.[9] (The current regulations, as

[8] The regulatory efficiency attribute also is evaluated qualitatively, by definition, in accordance with NRC guidelines. See Section 5.5.14 of the NRC's "Regulatory Analysis Technical Evaluation Handbook."

[9] The Commission issued orders to nuclear power plant licensees for Compensatory Measures Related to Access Authorization on January 7, 2003. The Commission issued Order EA-03-038 requiring compensatory measures to reduce fatigue among security personnel at nuclear power plants, including work hour limits, on April 29, 2003.

included in the baseline, take into account the enforcement discretion issued in October 2002.[10]) This is consistent with NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Rev. 4, which states that, "...in evaluating a new requirement for existing plants, the staff should assume that all existing NRC and Agreement State requirements have been implemented." Section 4.1 presents the estimated incremental costs and savings associated with the final rule relative to this baseline. Unless otherwise noted, the estimated costs and savings presented in this document reflect this baseline and are referred to as the "main analysis."

The NRC staff also has prepared two sensitivity analyses as part of this regulatory analysis, in accordance with the agency's regulatory analysis guidelines. The primary sensitivity analysis, like the main analysis, estimates all incremental savings and costs of the final rule, but it assumes an alternative baseline consisting of only the regulations that were in effect before the NRC issued the Access Authorization Order (AAO) on January 7, 2003, and before it issued Order EA-03-038 on April 29, 2003. This analysis is referred to as the "pre-order baseline analysis," and its results appear in Section 4.2.

The purpose of the second sensitivity analysis is to account for the situation that some licensees have interpreted certain provisions of the existing Part 26 rule differently than has NRC. For these provisions, some licensees' practices have only recently changed to comply with the former rule. Therefore, this sensitivity analysis considers a third baseline that reflects industry practices in the recent past, that is, prior to both the AAO and the recent enforcement discretion, and in accordance with licensees' interpretations of existing regulations. For this "industry practices baseline," therefore, the cost of complying with the final rule will exceed the cost estimated using the pre-order baseline. Section 4.3 presents the results of this sensitivity analysis.

3.2.2 FFD Programs and Program Characteristics

This analysis considers 33 individual FFD programs, as follows:

- The analysis models 28 FFD programs that govern 65 facilities with a total of 103 operating power reactors. Each program administered by a nuclear power reactor operator licensee is known to govern a specific number of reactors, which may be located at one or more "facilities." Each facility may include several reactor units that are adjacent to one another. Information on the specific number of reactors and facilities operated by individual licensee FFD programs is taken from NUREG-1350, *NRC Information Digest, 2006-2007 Edition.* The analysis assumes that licensees will seek and obtain a 20-year operating license renewal for each operating reactor and to operate each reactor until the expiration of its renewed license. Thus, for each FFD program, the analysis estimates program-specific costs as a function of (1) the number of facilities operated by the program, (2) the number of reactors operated by the program, (3) the actual remaining operating lives of each reactor, and (4) whether the program uses

[10] The NRC published a revision to NUREG-1600, "General Statement of Policy and Procedure for NRC Enforcement Actions" in the *Federal Register* (67 FR 66311) on October 31, 2002 to include an interim enforcement policy regarding enforcement discretion for certain FFD issues.

onsite or offsite collection and onsite or offsite testing, as discussed below. However, the analysis assumes that all operating power reactors have the same average annual number of personnel covered by the various provisions of Part 26, regardless of operator, facility design or age, or other factors (e.g., periodic need to refuel).

- The analysis models two fuel-cycle facilities, including Nuclear Fuel Services (in Erwin, Tennessee) and BWX Technologies (in Lynchburg, Virginia). Information on these two programs was obtained from NRC documents.

- The analysis models two contractors/vendors (C/Vs) that operate their own FFD programs. The two C/Vs provided information on their own programs.

- The analysis models one additional program to account for a mixed-oxide fuel fabrication facility that would be built under a new license application submitted to the NRC by Duke, Cogema, Stone & Webster. Although this facility does not yet exist, it would be subject to the requirements of Part 26 once it becomes operational.[11] The model for this facility draws upon information available to the NRC.

In addition, the analysis considered the likelihood that the NRC will be receiving applications for new reactors. Programs associated with these facilities would be relevant to Subpart K of the final rule. These facilities are considered only with regard to Subpart K. For further detail, see Appendix 1.

For many provisions of the rule, this analysis estimates that licensee costs will vary, depending on whether a particular licensee operates its collection facilities onsite (using licensee personnel or a contractor), or whether the licensee sends personnel to offsite collection facilities at the time of testing. Where known, the model reflects actual practices (i.e., onsite or offsite collection) for each licensee. For most licensees, however, this information is not readily available, so the analysis calculates costs assuming that these licensees operate "hybrid" collection facilities which reflect a weighted average of 95 percent onsite collection and 5 percent offsite collection.

Similarly, costs may vary depending on whether a particular licensee operates its own drug testing laboratory ("onsite testing") in order to conduct initial tests, or whether the licensee sends all specimens for drug testing to an HHS-certified laboratory ("offsite testing"). Information regarding the specific licensees that operate onsite testing laboratories and those that use only offsite testing facilities was obtained from the nuclear industry and is believed to be current as of May 2003.

3.2.3 Incremental Requirements in the Final Rule

The NRC evaluated every provision contained in the final rule relative to the applicable baselines described in Section 3.2.1. Based on this analysis, the NRC developed equations to estimate costs and savings using available data, augmented by assumptions when necessary. Appendix 1 documents this analysis, including the rationale for why specific provisions do or do not result in incremental impacts and the specific equations used to quantify costs and savings.

[11] The analysis assumes the facility will begin operational testing in 2009. However, operations are expected to start in 2015.

3.2.4 Other Data and Assumptions

The analysis estimates benefits and costs of the final rule for 33 individual licensee and C/V FFD programs based on several program-specific variables, as discussed in Section 3.2.2. The analysis conservatively assumes that the rule will take effect in 2007. The timeframe for which costs are estimated differs by program based on the remaining operating lives of the relevant facilities. For the analysis as a whole, however, costs and savings are estimated over 49 years, with each year's costs or savings discounted back at a 7-percent and 3-percent discount rate, in accordance with NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook." (See Section 4.1 for these results.)

The analysis assumes that licensees and C/Vs incur all costs associated with FFD programs. To the extent that testing laboratories or collection facilities conduct any of the incremental activities required by the rule, the analysis assumes that the costs of those activities are passed on to the licensee. Therefore, the analysis assumes that neither testing laboratories nor collection facilities will incur incremental costs or savings as a result of the final rule.

Qualitative information concerning attributes affected by the rule (e.g., the nature and magnitude of environmental impacts) has been obtained from, or developed primarily in consultation with, staff from the NRC's Office of Nuclear Reactor Regulation (NRR), Office of Nuclear Security and Incident Response (NSIR), and Office of Nuclear Material Safety and Safeguards (NMSS). Other data for the analysis have been derived from information sources including the NRC, licensees (including FFD program managers), experts in drug testing analytical methods and practices, other Federal agencies (including HHS and DOT contacts and information sources), and NEI. For the analysis of the final rule's fatigue management provisions, the NRC used data submitted voluntarily by six nuclear power plants in 2004, as well as survey results for 47 plants submitted by NEI in August, 2000.

Finally, the analysis assumes the only impairments to be prevented or mitigated by the final rule are those relating to substance abuse and worker fatigue. Although other types of impairments may be prevented or mitigated as well (e.g., emotional distress), these other impairments are assumed to be infrequent and they cannot be quantified easily due to a lack of data.

4. RESULTS

This section presents the analytical results, which are organized into six separate sections:

- Section 4.1 presents findings on the overall benefits and costs of the final rule under the main analysis.
- Section 4.2 summarizes the results relative to the pre-order baseline.
- Section 4.3 discusses a sensitivity analysis addressing recent industry practices.
- Section 4.4 considers the findings relative to NRC's backfit rule.
- Section 4.5 addresses the applicability of a safety goal evaluation to the current rulemaking.
- Section 4.6 describes the information required for review by the Committee to Review Generic Requirements (CRGR).

4.1 Benefits and Costs — Main Analysis

This section summarizes the benefits (values) and costs (impacts) estimated for the final rule. Most of the final rule's implementation and operational costs and savings, both to industry and to the NRC, is analyzed quantitatively with the *net* impacts calculated and presented below. However, some benefits could be evaluated only on a qualitative basis (as noted in Section 3.2). Section 4.1.1 provides the detailed results of the quantitative analysis of industry implementation and operation costs and savings for each of the specific provisions in the final rule. Section 4.1.2 presents additional detail on the benefits analyzed qualitatively for the drug and alcohol testing and authorization portions of Part 26. Section 4.1.3, similarly, presents additional detail on the benefits of the fatigue management provisions. Finally, Section 4.1.4 considers the final rule provisions on a disaggregated basis.

Exhibit 4-1 summarizes the results of the benefit-cost analysis. Relative to the no-action alternative, the final rule results in an estimated net quantitative cost to the industry and the NRC of approximately $445 million (total present value), assuming a 7-percent discount rate, or approximately $695 million assuming a 3-percent discount rate. Exhibits 4-2 and 4-3 show how the total net cost to the industry breaks out under the 7-percent and 3-percent discount rate assumptions, respectively, for each subpart (A–O) of 10 CFR Part 26:

- 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 DHHS
- Subpart H: Determining FFD 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, Penalties

Exhibit 4-1
Summary of Benefits and Costs

Net Monetary Savings (+) or Costs (-) (Total Present Value)	Non-Monetary Benefits/Costs
Industry: ($444.0 million) using a 7% discount rate ($694.3 million) using a 3% discount rate **NRC:** ($665,000) using a 7% discount rate ($1.0 million) using a 3% discount rate	***Qualitative Benefits:*** *Safeguards and Security Considerations.* Improved FFD enhances safety and reduces security risks. *Public Health (Accident); Occupational Health (Accident); Occupational Health (Routine); Offsite Property; Onsite Property; Environmental Considerations.* Improved FFD reduces the risk that these attributes will be affected by accidents that are attributable to the undetected use of drugs or alcohol, to fatigue, to potential inconsistencies between the FFD and access authorization functions, or to ambiguities in the existing fatigue management guidelines and programs. *Regulatory Efficiency.* An improved Part 26 rule results in better, less costly compliance because it reduces misinterpretation. It also improves consistency across licensee programs and between the NRC's FFD and access authorization rules. In addition, it enhances the consistency of regulations and policies across Federal agencies (e.g., HHS, DOT). *Public Perception.* The final rule may improve the public's perception of NRC's protection of public health and safety and the common defense and security. *Workplace Productivity and Efficiency.* Improved FFD reduces absenteeism, improves productivity, lowers medical and insurance costs, and reduces plant downtime attributable to human-related errors caused by FFD problems. ***Qualitative Costs:*** *None.*

NRC incurs a net cost under the rule, due to various new reporting provisions and the need to develop implementation materials for NRC staff and inspectors. Most significantly, §26.719(b) will lead to increased processing and review costs associated with an expected increase in the number of reports filed by FFD programs regarding significant policy violations related to validity

testing. This cost is estimated at $49,500 annually. In addition, the one-time development of procedures and training for NRC staff reviewers and inspectors on the rule revisions will result in an initial cost of $28,200. The net effect of all annual costs and savings is an annual cost to the NRC of $47,000, and this contributes to a net present value cost of approximately $664,900, assuming a 7-percent discount rate or $1,025,000, assuming a 3-percent discount rate.

Exhibit 4-2
Industry Savings and Costs by Subpart (7% discount rate)

Sub-part	Average Per FFD Program			Total - All FFD Programs		
	One-Time Saving (Cost)	Annual Saving (Cost)	Net Present Value	One-Time Saving (Cost)	Annual Saving (Cost)	Net Present Value
A	-	$7,600	$103,400	-	$243,000	$3,320,000
B	($44,500)	$285,100	$3,803,500	($1,424,000)	$9,123,000	$122,454,000
C	-	($1,900)	($26,400)	-	($62,000)	($848,000)
D	-	-	-	-	-	-
E	($9,500)	$17,600	$230,400	($304,000)	$564,000	$7,401,000
F	($5,900)	($19,200)	($265,800)	($190,000)	($613,000)	($8,577,000)
G	-	($2,300)	($32,900)	-	($73,000)	($1,037,000)
H	-	$13,300	$181,200	-	$426,000	$5,821,000
I	($421,700)	($1,475,300)	($17,770,000)	($11,808,000)	($41,309,000)	($572,863,000)
J	-	-	-	-	-	-
K	-	-	-	-	-	-
L	-	-	-	-	-	-
M	-	-	-	-	-	-
N	-	$600	$8,700	-	$19,000	$273,000
O	-	-	-	-	-	-
Total	**($481,600)**	**($1,174,500)**	**($13,767,900)**	**($13,726,000)**	**($31,680,000)**	**($444,056,000)**

* Net present value is calculated using a discount rate of 7 percent.
** A licensee's FFD program may include more than one facility. The average annual savings (costs) presented are for the initial years of the analysis and change over time as programs decrease in size with the closure of specific plants. Consequently, the total net present values cannot be derived using only the one-time and annual values shown above.

Exhibit 4-2 is based on an assumed 7-percent discount rate, consistent with NUREG/BR-0184 as well as current OMB "best practices" for regulatory analyses.[12] These NRC and OMB guidelines also indicate that results should be presented using a 3-percent discount rate. Therefore, Exhibit 4-3 below presents the savings (costs) of the rule to the nuclear industry using a discount rate of 3 percent. As shown, industry costs under the 3-percent discount rate increase to approximately $694 million.

[12] Circular A-4, Office of Management and Budget, September 17, 2003.

4.1.1 Costs and Savings Attributable to Industry Implementation and Industry Operation

This analysis quantitatively evaluates the final rule's costs and savings associated with the industry implementation and industry operation attributes. The presentation is organized by subpart of the rule (A–O).

Exhibit 4-3
Industry Savings and Costs by Subpart (3% discount rate)

Subpart	Average Per FFD Program			Total - All FFD Programs		
	One-Time Saving (Cost)	Annual Saving (Cost)	Net Present Value	One-Time Saving (Cost)	Annual Saving (Cost)	Net Present Value
A	-	$7,600	$169,100	-	$243,000	$5,241,000
B	($44,500)	$285,100	$6,202,400	($1,424,000)	$9,123,000	$193,643,000
C	-	($1,900)	($43,200)	-	($62,000)	($1,339,000)
D	-	-	-	-	-	-
E	($9,500)	$17,600	$382,700	($304,000)	$564,000	$11,855,000
F	($5,900)	($19,200)	($427,900)	($190,000)	($613,000)	($13,527,000)
G	-	($2,300)	($57,800)	-	($73,000)	($1,701,000)
H	-	$13,300	$296,500	-	$426,000	$9,187,000
I	($421,700)	($1,475,300)	($28,571,100)	($11,808,000)	($41,309,000)	($898,127,000)
J	-	-	-	-	-	-
K	-	-	-	-	-	-
L	-	-	-	-	-	-
M	-	-	-	-	-	-
N	-	$600	$15,200	-	$19,000	$445,000
O	-	-	-	-	-	-
Total	**($481,600)**	**($1,174,500)**	**($22,034,100)**	**($13,726,000)**	**($31,680,000)**	**($694,324,000)**

* Net present value is calculated using a discount rate of 3 percent.
** A licensee's FFD program may include more than one facility. The average annual savings (costs) presented are for the initial years of the analysis and change over time as programs decrease in size with the closure of specific plants. Consequently, the total net present values cannot be derived using only the one-time and annual values shown above.

4.1.1.1 Savings and Costs of Subpart A Provisions

Subpart A sets forth requirements and standards for establishing and maintaining FFD programs, describes to whom (licensees and other entities) the regulation applies, identifies the individuals subject to the FFD program, defines terms used throughout Part 26, and addresses administrative matters. The only provision that results in an incremental change is §26.4(j), which addresses individuals subject to another acceptable FFD program. As shown in Exhibit 4-4A, annual savings are estimated to total $243,000 (an average of $7,600 per program).

Exhibit 4-4A
Industry Savings and Costs from Revisions to Subpart A:
Administrative Provisions

Section/ Activity	Average per Program		Total -All FFD Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.4(j) Individuals Subject to Another Acceptable Program	-	$7,599	-	$243,179
Total	-	$7,599	-	$243,179

4.1.1.2 Savings and Costs of Subpart B Provisions

Subpart B requires that each licensee subject to Part 26 establish and implement a FFD program, and identifies FFD program performance objectives, training requirements, and drug and alcohol testing requirements. Although industry will incur a one-time cost of $1,424,000 (an average of $44,500 per program) in the first year following implementation of the rule, annual savings are estimated to total $9,123,000 thereafter (an average of $285,000 per program).

The most significant annual savings of this subpart result from provisions under §26.29(c)(2) that allow individuals to take a comprehensive annual examination (i.e., a “challenge exam”) in place of the annual refresher training course required under this paragraph. The shorter length of the challenge examination relative to the refresher course results in significant employee labor burden reductions, estimated at an annual industry-wide savings of $9,347,000 (or an average of $292,100 per program).

Exhibit 4-4B
Industry Savings and Costs from Revisions to Subpart B:
Program Elements

Section/ Activity	Average Per FFD Program		Total - All FFD Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.27(a) Policy and Procedure Revisions - Overall Program	($30,451)	-	($974,444)	-
26.29(a) Revise and Implement Training, Including Behavioral Observation	($1,251)	-	($40,039)	-

Section/ Activity	Average Per FFD Program		Total - All FFD Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.29(b) Comprehensive Examination	($12,793)	($3,127)	($409,362)	($100,049)
26.31(d)(3) Forensic Toxicologist Review of More Stringent Cutoff Levels	($10)	-	($314)	-
26.29(c)(2) Comprehensive Examination in Lieu of Refresher Training	-	$292,105	-	$9,347,351
26.31(b)(1)(i) Background Checks, Psychological Evaluations, Credit History, Criminal History	-	$653	-	$20,880
26.31(b)(2) DOT-Approved Specimen Collection Facilities	-	$140	-	$4,487
26.31(d)(2) Reasonable Effort to Track Randomly Selected Individuals for Testing	-	($3,494)	-	($111,817)
26.33 Behavioral Observation	-	($1,846)	-	($59,066)
26.37(d) Disclosure requirements positive test results	-	($429)	-	($13,725)
26.41(b) Audit Frequency	-	$493	-	$15,779
26.41(c)(2) Elimination of Audit Duplication of HHS-Certified Laboratories	-	$611	-	$19,566
Total	($44,505)	$285,106	($1,424,159)	$9,123,406

Some of these savings will be offset by the annual costs of other provisions including §26.31(d)(2), which specifies requirements for tracking individuals who are randomly selected for testing but are off-site when selected.

Although this subpart yields substantial savings on an annual basis, industry will incur a substantial cost in the first year following the rule's promulgation. The largest of these one-time costs will be incurred to undertake policy and procedure revisions under §26.27(a). The cost of this provision is estimated at $974,000 industry-wide (or an average of $30,500 per program).

4.1.1.3 Savings and Costs of Subpart C Provisions

Subpart C contains FFD requirements for granting and maintaining authorization for unescorted access to protected areas in nuclear facilities and for assignment to perform authorization activities. Industry-wide annual costs are estimated at $62,000 (or an average of $1,900 per program). To a substantial degree, this subpart adopts requirements, contained in NRC's Access Authorization Order (AAO), which have been implemented in advance of this final rule. (See Section 4.2 for estimates of the costs and savings using the alternative pre-AAO baseline.)

Costs under this subpart result from provisions in §§26.55(a)(4), 26.57(a)(4), 26.59(a)(4), and 26.59(c)(3), which require licensees to conduct random drug and alcohol tests on individuals who are seeking authorization for unescorted access. (Currently, only individuals who already have authorization are subject to random testing.)

Exhibit 4-4C
Industry Savings and Costs from Revisions to Subpart C:
Granting and Maintaining Authorization

Section/ Activity	Average Per FFD Program		Total - All FFD Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.55(a)(4) Random Testing Pool for Initial Applicants	-	($527)	-	($16,856)
26.57(a)(4) Random Testing Pool for Update Applicants	-	($78)	-	($2,490)
26.59(a)(4) Random Testing Pool for Reinstatement Applicants with 31-365 Day Interruption	-	($568)	-	($18,176)
26.59(c)(3) Random Testing Pool for Reinstatement Applicants with Less than 31 Day Interruption	-	($768)	-	($24,590)
Total	-	($1,941)	-	($62,113)

4.1.1.4 Savings and Costs of Subpart D Provisions

Subpart D ("Management Actions and Sanctions to be Imposed") specifies sanctions to be imposed when an individual has violated the FFD policy. These requirements do not prohibit the licensee or C/V from taking more stringent action, except for certain limitations on terminating an individual's authorization based solely on a positive, adulterated, substituted, dilute or invalid initial test result. No incremental costs or savings have been estimated for this subpart.

4.1.1.5 Savings and Costs of Subpart E Provisions

Subpart E specifies the requirements for collecting specimens for drug and alcohol testing. This subpart defines the specimens to be collected, collector qualifications and responsibilities, collection sites, acceptable devices for conducting alcohol tests, and procedures for collecting drug and alcohol specimens. Following a one-time industry cost of approximately $304,000, or $9,500 for the average program, the industry is expected to realize an annual industry saving of $564,000 or $17,600 per average program.

Exhibit 4-4E
Industry Savings and Costs from Revisions to Subpart E:
Collecting Specimens for Testing

Section/ Activity	Average Per FFD Program		Total - All FFD Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.83(a) Blood Collection for Confirmatory Alcohol Testing	-	$261	-	$8,365
26.85(a),(b) Urine and Alcohol Collector Training	($3,961)	-	($126,764)	-
26.89(b)(2) Urine Collection: Donors Without Adequate ID	-	$1,987	-	$63,596
26.89(b)(3) Urine Collection: Eliminate Listing Medications on the CCF Form and add description of testing process	-	$7,489	-	$239,654
26.91(b) Purchase of EBT and Calibration Equipment and Related Training	($5,526)	($82)	($176,846)	($2,625)
26.91(c) Required Use of an EBT on the NHTSA CPL for Confirmatory Testing	-	$9	-	$286
26.95(c) One Breath Specimen Collection for Initial Alcohol Test	-	$12,789	-	$409,253
26.99(b) Lowering Initial BAC Requiring Confirmatory Test to BAC 0.02	-	($116)	-	($3,725)
26.103 FFD Manager Determines Confirmed Positive Test for Alcohol (BAC 0.02 < 0.04)	-	($11)	-	($355)
26.105(b) Urine Collection: Inspecting Contents of Donor's Pockets	-	($12,357)	-	($395,429)
26.109(a) Urine Specimen Quantity: Minimum Quantity of 30 mL	-	$9,408	-	$301,065
26.109(b)(2) Urine Specimen: At Least 30 mL, but Less than Predetermined Quantity	-	($240)	-	($7,680)
26.119 Shy Bladder Medical Evaluation	-	($1,500)	-	($47,995)
Total	($9,488)	$17,638	($303,610)	$564,410

The one-time costs result from two provisions. §26.85(a),(b) requires urine and alcohol collector training ($127,000 industry, $4,000 per average program) and §26.91(b) requires the use of an evidential breath testing device meeting the specifications in §26.91(c) ($177,000 industry, $5,500 per average program).

Most of the annual savings from Subpart E provisions will result from §26.95(c), which reduces the number of breath specimens collected during initial alcohol tests from two to one ($409,000

industry, $12,800 per average program); §26.109(a), which reduces the minimum quantity of urine for a specimen collection from 60 mL to 30 mL, thereby decreasing the need for second collections due to fewer “shy bladder” instances ($301,000 industry, $9,400 per program); and §26.89(b)(3), which reduces specimen collection time by eliminating the requirement that donors must list all prescription medications on the custody-and-control form ($240,000 industry, $7,500 per average program). Some of the annual savings will be offset by other annual costs, most notably those from §26.105(b), which requires an inspection of the contents of each donor's pockets before each urine collection ($395,000 industry, $12,400 per program).

4.1.1.6 Savings and Costs of Subpart F Provisions

Subpart F specifies the requirements for licensee testing facilities. This subpart defines the testing facility capabilities, personnel, laboratory procedures, and drug (initial) and validity (screening and initial) testing. The annual industry cost is $613,000 (or approximately $19,200 for the average program). One-time costs, primarily from revisions to licensee testing facility policies and procedures, will result in industry costs of $190,000 (or approximately $5,900 per average program).

The majority of annual costs result from two rule provisions, §26.131(b) and §26.137(e)(6). §26.131(b) requires that licensee testing facilities conduct validity testing on urine specimens. The analysis assumes that all licensee testing facilities will only conduct validity screening tests on urine specimens and send any specimens with an adulterated, substituted, dilute, or invalid initial validity test result to HHS-certified laboratories for further testing. The annual industry cost is estimated at $489,000 or approximately $15,300 per average program. §26.137(e)(6) amends the current quality control provisions to include quality control specimens in each analytical run to licensee testing facilities. The annual industry cost is estimated at approximately $127,800 or $4,000 per average program.

Exhibit 4-4F
Industry Savings and Costs from Revisions to Subpart F:
Licensee Testing Facilities

Section/ Activity	Average Per FFD Program		Total - All FFD Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.127 Licensee Testing Facility Policy and Procedure Revisions	($5,303)	-	($169,696)	-
26.131(b) Initial Validity Tests - Onsite Testing Facilities	($638)	($15,267)	($20,419)	($488,530)
26.133 Change Cutoff Levels for Marijuana and Opiates - Onsite Testing Facilities	-	($368)	-	($11,763)
26.137(e)(6) Quality Control Specimens in Each Analytical Run - Onsite Testing Facilities	-	($3,992)	-	($127,758)

Section/ Activity	Average Per FFD Program		Total - All FFD Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.139(d) Licensee Testing Facility Reporting of Testing Data to FFD program (Monthly to Annually)	-	$459	-	$14,700
Total	($5,941)	($19,167)	($190,115)	($613,351)

4.1.1.7 Savings and Costs of Subpart G Provisions

Subpart G specifies the requirements for HHS-certified laboratories used by licensees and C/Vs to conduct drug and validity testing on urine specimens. This subpart defines HHS-certified laboratory capabilities, personnel, laboratory procedures, and drug (initial and confirmatory) and validity (screening, initial, and confirmatory) testing. The annual industry cost is $73,000, or approximately $2,300 for the average program.

The majority of the annual costs result from the requirement in §26.161(b)(1) for licensees and C/Vs to conduct validity testing on urine specimens ($407,000 industry or $12,700 per average program). Much of the annual costs are offset by annual savings that include §26.168(a)(2), which reduces the number of blind specimens required to be submitted for testing after the first quarter of a new contract with an HHS-certified laboratory ($338,000 industry, $10,600 per average program).

Exhibit 4-4G
Industry Savings and Costs from Revisions to Subpart G:
Laboratories Certified by the DHHS

Section/ Activity	Average Per FFD Program		Total - All FFD Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.153(e) Pre-Award Inspections of HHS-Certified Laboratories	-	($178)	-	($5,692)
26.153(g) Memorandum to HHS-Certified Laboratory for Incorrect CCF Form	-	($28)	-	($887)
26.161(b)(1) All Validity Testing Conducted at HHS-Certified Laboratories	-	($12,711)	-	($406,760)
26.161(g) Unidentified Interfering Substance/Adulterant - Contact MRO and Specimen Retesting	-	($395)	-	($12,643)
26.163(a)(1) Change Cutoff Levels for Marijuana and Opiates - HHS-Certified Laboratories	-	($582)	-	($18,614)

Section/ Activity	Average Per FFD Program		Total - All FFD Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.165(b) Retesting of Single Collection Specimens with Non-Negative Confirmed Drug Test Results	-	($8)	-	($240)
26.168(a)(1) Blind Sample Testing - 1st Quarter of Contract with a HHS-Certified Laboratory	-	$670	-	$21,446
26.168(a)(2) Blind Sample Testing - Contracts with HHS-Certified Laboratories Older Than 90 Days	-	$10,554	-	$337,731
26.169(k) HHS-Certified Laboratory Reporting of Testing Data to FFD program (Monthly to Annually)	-	$403	-	$12,906
Total	-	($2,274)	-	($72,753)

4.1.1.8 Savings and Costs of Subpart H Provisions

Subpart H contains requirements for determining whether a FFD policy violation has occurred and for making a determination of fitness. It establishes requirements for MROs, procedures for verification of FFD policy violations, and requirements for substance abuse experts (SAEs) and determinations of fitness. Industry-wide annual savings are estimated at $426,000 (or an average of $13,300 per program). No incremental one-time costs or savings are expected as a result of this subpart.

Requirements contained in §26.189(b)(3), in conjunction with §26.69(a)(2), is expected to result in annual savings estimated at $571,000 (or an average of $17,900 per program). These savings occur because licensees and C/Vs will not need to conduct determinations of fitness on individuals with potentially disqualifying FFD information, if the information has previously been evaluated by another licensee.

Offsetting some of these savings, §26.189(c) requires determinations of fitness that are conducted for-cause to be conducted through face-to-face interaction between management and the individual under review. The annual industry-wide costs of conducting these face-to-face determinations of fitness are estimated at $145,000 (or an average of $4,500 per program).

Exhibit 4-4H
Industry Savings and Costs from Revisions to Subpart H:
Determining FFD Policy Violations and Determining Fitness

Section/ Activity	Average Per FFD Program		Total - All FFD Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.189(b)(3) Definition of "Potentially Disqualifying Information"	-	$17,858	-	$571,464
26.189(c) Face-to-Face Determinations of Fitness	-	($4,535)	-	($145,117)
Total	-	$13,323	-	$426,348

4.1.1.9 Savings and Costs of Subpart I Provisions

Subpart I contains the rule's provisions governing fatigue management. It applies only to Part 50 licensees, combined license holders under §52.103, and contractor/vendors to nuclear power plant licensees who rely upon contractor/vendor FFD programs or program elements. It does not apply to material licensees.

The annual industry cost is $41,309,000, or approximately $1,475,300 for the average program. One-time industry costs of Subpart I are estimated at $11,808,000, or $421,700 for the average program. The majority of the cost results from two requirements.

Subparagraphs 26.205(d)(4)-(6) establish several mandatory days off for individual workers. Licensees will likely incur some impact during refueling outages and other extended outages given the common industry practice of using "super-crews," which typically work six or seven 12-hour shifts per week during the outage. As implemented in the final rule, the days off in effect require licensees to bring on additional staff to provide the required time off to existing staff. This new staff likely will be temporary workers who must be hired, processed, and paid, thereby generating costs. With respect to the additional need for operators during these periods, the analysis assumes that licensees will maintain a pool of formerly-licensed, semi-retired operators who will be available to provide operations expertise during the outage for duties that do not require a license. The annual cost of this provision is estimated at $605,600 for the average program.

Paragraph 26.207, which places restrictions on the use of waivers as a means of bypassing worker hour limits when necessary, will cost the industry an estimated $588,100 per program annually. This is an average and there is expected to be a large variation between licensees in the cost of implementing this provision between licensees because some licensees currently authorize a much larger number of waivers than others. The analysis of this provision is described in Appendix 1 and Appendix 3.

Licensees also will incur costs related to revising and implementing their fatigue policies and procedures, developing systems to track work hours in the manner specified in the rule, paying a scheduler to plan work schedules, and training staff on the fatigue provisions.

Exhibit 4-4l
Industry Savings and Costs from Revisions to Subpart I:
Managing Fatigue

Section/ Activity	Average Per FFD Program		Total - All FFD Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.203(a)-(b) Policy and Procedures	($32,524)	-	($910,664)	-
26.203(c) Training	($258,887)	($118,152)	($7,248,837)	($3,308,268)
26.203(d) Retaining Fatigue Records	-	($1,749)	-	($48,970)
26.203(e)(1) Summarize Waiver Data	-	($1,233)	-	($34,511)
26.203(e)(2) Summarize Fatigue Assessment Data	-	($1,639)	-	($45,899)
26.203(f) Fatigue Management Audits	-	($3,982)	-	($111,484)
26.205(b) Calculating Work Hours	($116,071)	($34,534)	($3,250,000)	($966,942)
26.205(c) Scheduling Work Hours	($14,240)	($84,599)	($398,734)	($2,368,773)
26.205(d)(4)-(6) Day-off Requirements	-	($605,550)	-	($16,955,400)
26.205(e) Work Hour Control Reviews	-	($2,312)	-	($64,742)
26.207 Waivers from Individual Work Hour Limits	-	($588,111)	-	($16,467,100)
26.209 Self-Declarations of Fatigue	-	($1,617)	-	($45,276)
26.211(a)-(d) Fatigue Assessments	-	($8,943)	-	($250,398)
26.211(e) Post-Fatigue Assessment Controls and Conditions	-	($20,213)	-	($565,956)
26.211(f) Documenting Fatigue Assessments	-	($2,681)	-	($75,075)
Total	($421,723)	($1,475,314)	($11,808,235)	($41,308,794)

4.1.1.10 Savings and Costs of Subpart J Provisions

In the final rule, Subpart J is reserved and therefore contains no regulatory language. As a result, this subpart does not result in any incremental costs or savings.

4.1.1.11 Savings and Costs of Subpart K Provisions

Subpart K ("FFD Programs for Construction") specifies the minimum FFD program elements applicable to: (1) combined license holders (under 10 CFR Part 52) before the Commission has made the finding under Section 52.103(g); (2) combined license applicants who have received the authorization to construct under Section 50.10(e)(3); (3) construction permit holders (under 10 CFR Part 50); and (4) construction permit applicants who have received the authorization to construct under Section 50.10(e)(3). This subpart should generate savings on balance. See Appendix 1 for more detail.

4.1.1.12 Savings and Costs of Subpart L Provisions

In the final rule, Subpart L is reserved and therefore contains no regulatory language. As a result, this subpart does not result in any incremental costs or savings.

4.1.1.13 Savings and Costs of Subpart M Provisions

In the final rule, Subpart M is reserved and therefore contains no regulatory language. As a result, this subpart does not result in any incremental costs or savings.

4.1.1.14 Savings and Costs of Subpart N Provisions

Subpart N describes recordkeeping and reporting requirements for licensees and C/Vs with approved FFD programs. Industry-wide annual savings are estimated at $19,400 (or an average of approximately $600 per average program). No significant one-time costs or savings are expected as a result of this subpart. Savings result from a decrease in the required reporting frequency for licensee performance data reporting and the elimination of duplicative reporting of C/V performance data. (Note that these savings do not reflect new costs resulting from the need to report fatigue management data within the performance data reports. These costs are calculated under Subpart I.) These savings are partly offset by higher costs associated with the increased number of "reportable events" that will result from the rule's new validity testing requirements and modified thresholds for positive test results.

Exhibit 4-4N
Industry Savings and Costs from Revisions to Subpart N:
Recordkeeping and Reporting Requirements

Section/ Activity	Average Per FFD Program		Total - All FFD Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.713(g) Filing of Forensic Toxicologist's Evaluation	($0)	-	($4)	-
26.717(e), (f) FFD Programs: Performance Data Reporting and Review	-	$1,556	-	$49,802
26.717(g) Contractor/Vendor Submission of Performance Data to NRC	-	$28	-	$910
26.719(b) Reporting and Review of Reportable Events Due to New Validity Testing Requirements	-	($980)	-	($31,362)
Total	($0)	$605	($4)	$19,350

4.1.1.15 Savings and Costs of Subpart O Provisions

Subpart O ("Inspections, Violations, Penalties") contains provisions covering the inspection of licensee and C/V programs by NRC representatives, written agreements between licensees and C/Vs, violations, and criminal penalties resulting from violations. No incremental activities are included in this subpart and, therefore, no costs or savings are estimated.

4.1.2 Additional Benefits and Qualitative Cost Savings of Final Part 26 Revisions - Drug and Alcohol Testing and Authorization Provisions

The analysis evaluates nine affected attributes on a qualitative basis, as described in the following three sections. Section 4.1.2.1 collectively examines seven of these attributes (safeguards and security considerations; public health [accident]; occupational health [accident]; occupational health [routine]; offsite property; onsite property; environmental considerations). Section 4.1.2.2 considers regulatory efficiency. Finally, Sections 4.1.2.3 and 4.1.2.4 address the "other considerations" attribute, which in this case involves (1) public perception, and (2) workplace productivity and efficiency.

The regulatory options affect these nine attributes by reducing the risks of accidents and/or security events within the protected area due to the undetected use of drugs or alcohol, or due to potential inconsistencies between the FFD and the access authorization functions. These risks could lead to a variety of workplace safety incidents, including damage to the reactor core. Quantification of any of these attributes would require estimation of such factors as the types, frequencies, and results of damages that now occur (i.e., pre-rule) and would occur (i.e., post-rule) as a result of factors related to the former and final rule.

4.1.2.1 Safeguards and Security Considerations; Public Health (Accident); Occupational Health (Accident); Occupational Health (Routine); Offsite Property; Onsite Property; Environmental Considerations

The NRC estimates that this final rule results in benefits (i.e., safeguards and security considerations, public health, occupational health, occupational health, offsite property, onsite property, environmental considerations) by providing assurance that individuals who are subject to the rule are not under the influence of any legal or illegal substance or mentally or physically impaired from any cause that in any way adversely affects their ability to safely and competently perform their duties. Qualitative benefits primarily accrue from increased safety, which the rule achieves by ensuring that workers are fit for duty,[13] and from the increased effectiveness of the Part 26 rule in addressing performance objectives.

Drug and alcohol use and abuse can impair job performance. This impairment significantly threatens the safety of workers themselves, and may also endanger the health and safety of the public. Drug use or alcohol consumption on the job can adversely affect behavior and diminish both physical and cognitive abilities. The effects of withdrawal, hangover, and long-term chronic abuse resulting from off-duty drug and alcohol use also can affect job performance. Drug and alcohol abuse can have a significant impact on safety-related jobs. Drug use remains prevalent

[13] For discussions of safety-related FFD concerns, see NUREG/CR-5227 (Barnes et al., 1988), NUREG/CR-5227 Supplement 1 (Moore et al., 1989), NUREG/CR-5784 (Durbin et al., 1991), and NUREG/CR 6470 (Durbin & Grant, 1996).

in American society and is an ongoing occupational and safety concern in American industry.[14] More importantly, drug or alcohol abuse by nuclear industry personnel indicates a lack of reliability and trustworthiness and remains a legitimate safety concern for the NRC.[15]

The NRC's backfit analysis, prepared in 1989 in conjunction with promulgation of the Part 26 rule, concluded that drug abuse significantly increases the risk of accidents that are attributable to neglect or human error.[16] Although the NRC did not quantify the reduction in risk associated with the implementation of FFD programs, the 1989 backfit analysis stated that drug and alcohol testing (as part of a comprehensive FFD program) can significantly increase the assurance that employees will be fit for duty. The NRC concluded that FFD program implementation costs would be justified by increasing the assurance of public health and safety.

During 1990, the first calendar year of FFD program implementation, 0.87 percent of tests administered under 10 CFR Part 26 requirements were confirmed as positive for the presence of illegal drugs or the abuse of alcohol. In 1995, the confirmed positive test rate was 0.98 percent. In 2000, the confirmed positive test rate was 1.11 percent. In 2003, 0.86 percent of such tests were confirmed as positive for the presence of illegal drugs or the abuse of alcohol. In 2005, the confirmed positive test rate was 0.72 percent. Exhibit 4-5 shows the breakdown by test

Exhibit 4-5
FFD Test Results for CY 1990, 1995, 2000, 2003, and 2005

Test Category	Positive Test Rate by Year				
	1990 (274,599 tests)	1995 (150,121 tests)	2000 (125,713 tests)	2003 (127,785 tests)	2005 (135,702 tests)
Pre-employment/ Pre-access	1.26%	1.41%	1.41%	1.04%	0.82%
Random	0.37%	0.27%	0.39%	0.27%	0.29%
For-Cause/ Post Accident	29.23%	18.22%	15.63%	11.98%	9.13%
Follow-Up	2.47%	1.07%	1.71%	1.34%	0.76%
Other*	-	-	2.44%	3.08%	3.94%
Total	**0.87%**	**0.98%**	**1.11%**	**0.86%**	**0.72%**

* Includes results from the periodic testing done by some reporting units during annual physicals or similar periodic activities. Although some reporting units specified the nature of the "Other" tests (e.g., return to work), most did not give this information.
Sources: "Fitness For Duty in the Nuclear Power Industry: Annual Summary of Program Performance Reports," NUREG/CR-5758; NRC Information Notice 2003-04, Summary of Fitness-for-Duty Program Performance Reports for Calendar Year 2000, February 6, 2003; and, http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/performance-reports.html.

category. The 1995 confirmed positive test rate should not be compared directly to the rates from previous years because of several changes that occurred during the intervening years.

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[14] NUREG/CR-5784 and NUREG/CR-6470, Ch. 6.

[15] 54 FR 24470, "Fitness-For-Duty Programs; Final Rule and Statement of Policy," June 7, 1989.

[16] SECY-00-0159, July 26, 2000. Attachment F, Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule.

Further, the total number of tests administered decreased between 1990 and 1995 because of changes to testing requirements (58 FR 31467), effective January 1994, which reduced the random testing rate from 100 percent to an annual rate equal to 50 percent of all persons covered by the FFD regulation.

The NRC believes that ensuring that workers are not impaired by drugs or alcohol will decrease the probability of human error and reduce the risk to plant personnel of radiological exposures and exposures to hazardous chemicals produced from licensed material. This reasoning is applicable to the current rulemaking in that changes to improve the effectiveness of the rule should further decrease the risk of accidental exposure attributable to human error caused by an FFD problem. Moreover, the addition of validity testing will increase the likelihood of detection. Although there may be a low probability of a significant accidental radiological release, or a release of hazardous chemicals produced from licensed material, due to drug abuse, such a release could have great consequences. Furthermore, any accident attributed to drug or alcohol use could undermine public perceptions of nuclear industry safety. The relatively low positive test rates reported in the exhibit suggest that drug abuse among nuclear facility personnel may not be as prevalent as in the national work force. Although the positive test rates may not reveal all drug and alcohol abuse and, therefore, may understate drug and alcohol abuse within the industry, the data do indicate a continuous detection of previously undetected drug use through the FFD program. The positive test results presented in this section indicate that there continues to be an occasional nuclear industry worker with a drug or alcohol abuse problem. Therefore, NRC believes efforts to improve the effectiveness of the former Part 26 requirements are warranted.

4.1.2.2 Regulatory Efficiency

An important benefit of this rulemaking is an increase in regulatory efficiency and effectiveness. Increased clarity in the intent of many requirements reduces NRC and licensee costs associated with interpreting this rule. When the specifics of a regulatory requirement are not clear, a licensee could enact programs that are more burdensome than the agency intended or could spend unproductive time trying to understand the requirements. Similarly, lack of clarity could result in licensees inadvertently not complying with the true intent of the regulatory action, which could lead to intervention by the NRC or even enforcement action and litigation. Thus, increasing the clarity of this rule may significantly reduce the costs associated with different interpretations of regulatory requirements. In addition, this rule increases regulatory efficiency and effectiveness by increasing consistency between this rule and access authorization requirements. Furthermore, it also enhances the consistency of regulations and policies across Federal agencies (e.g., HHS, DOT). The NRC believes that these agency and licensee savings could potentially be significant, although they are not easily quantified. The NRC has attempted to analyze many of the savings attributable to this rule, but these estimates do not include all of the savings that the agency anticipates as a result of this increase in regulatory efficiency. In addition, increasing the clarity of this rule (i.e., clarifying intent) may enhance its effectiveness and safety-related benefits.

4.1.2.3 Public Perception

By increasing the effectiveness and clarity of the requirements for FFD programs, this final rule enhances the public's confidence in the NRC's protection of public health and safety and the common defense and security. The changes give the public additional assurance that the NRC is addressing safety concerns raised by the use of drugs and alcohol, and by any other causes of

impairment or questionable reliability or trustworthiness, such as an increase in the probability of safety-significant accidents or other safeguards and security risks.

4.1.2.4 Workplace Productivity and Efficiency

Affected licensees may accrue benefits from the improved effectiveness of the rule, including enhanced workforce productivity, reduced absenteeism, lower medical and insurance costs, and less plant downtime. The effects of human-related errors caused by FFD problems can have direct and indirect effects on overall plant operating costs. For example, a 24-hour outage caused by an FFD-related error may result in a direct revenue loss of several hundred thousand to more than a million dollars. Furthermore, the long-term effects of FFD problems arising from increased absenteeism, lower productivity on the job, and increased use of medical benefits can also result in higher costs to the licensee.[17] These secondary benefits result in additional savings for FFD programs beyond those quantified for industry implementation and operations.

4.1.3 Additional Benefits and Qualitative Cost Savings of Final Part 26 Revisions - Fatigue Management Provisions

This analysis evaluates nine affected attributes, as described in the following five sections. Section 4.1.3.1 collectively examines six of these attributes: public health (accident); occupational health (accident); occupational health (routine); offsite property; onsite property; environmental considerations. Section 4.1.3.2 considers safeguards and security. Section 4.1.3.3 addresses regulatory efficiency. Finally, Sections 4.1.3.4 and 4.1.3.5 address the "other considerations" attribute, which in this case involves (1) public perception, and (2) workplace productivity and efficiency.

The regulatory options affect these attributes by reducing the risks of accidents, fires, property damage, and/or security events due to the effects of worker fatigue. By clarifying the provisions of the regulatory framework relating to fatigue management, the regulatory options indirectly affect these attributes by increasing the likelihood of identifying and addressing worker fatigue.

4.1.3.1 Public Health (Accident); Occupational Health (Accident); Occupational Health (Routine); Offsite Property; Onsite Property; Environmental Considerations

The NRC estimates that the fatigue management provisions of the final rule result in benefits (i.e., the attributes of public health, occupational health, offsite property, onsite property, environmental considerations) by providing assurance that individuals who are subject to the rule are not impaired from acute or cumulative fatigue that will adversely affect their ability to safely and competently perform their duties. The Federal Register notice accompanying the final rule presents a detailed discussion of NRC's considerations related to including fatigue management within the Part 26 rulemaking.

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[17] See, for instance, Crouch, et al. (1989), "A Critical Evaluation of the Utah Power and Light Company's Substance Abuse Management Program: Absenteeism, Accidents and Costs," in: Gust & Walsh (Eds.), Drugs in the Workplace: Research and Evaluation Data, NIDA Research Monograph 91, U.S. Government Printing Office, Washington, DC, pp. 169-193.

In evaluating the anticipated benefits from the fatigue management provisions in Subpart I, the NRC reviewed and assessed the research available on the degradation of worker abilities that are important to safe plant operation. Many studies have shown that fatigue impairs human alertness and performance. 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 former provisions of 10 CFR Part 26. In those studies, individuals who were awake for 17 to 19 hours had cognitive psychomotor performance comparable to individuals with a BAC of 0.05 percent, which is greater than the former breath alcohol cutoff level of 0.04 percent established by 10 CFR Part 26.[18] The NRC considers the insight that fatigue can impair a worker at levels comparable to those prohibited for alcohol to be particularly significant.

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 degraded performance. 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. 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. 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 or days in the schedule when control room operators are less alert, less vigilant, or make more mistakes.

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 individual workers' abilities to sustain attention, analyze problems, make clear decisions and work as a team. Vigilance and attention to detail are fundamental for plant safety, whether an individual is operating or maintaining equipment important to plant safety, conducting surveillance 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. Conservative decision-making also is a cornerstone of safe nuclear power plant operations. Fatigue has been associated with an increased frequency of low effort and more risky decisions and strategies. Fatigue has been found to contribute to poor problem-solving performance, characterized by an individual or group of individuals maintaining a faulty diagnosis or mitigation plan despite contrary information. Sleep-deprived workers fail to appropriately allocate attention, set task priorities, and sample for sources of potentially faulty information. Mental fatigue also contributes to decreased originality and flexibility in problem solving and sub-optimal planning. Fatigue affects skills important to written and oral communication and teamwork. Fatigue degrades speech articulation, verbal fluency, grammatical reasoning and memory. Fatigued individuals also tend to be less communicative and have greater difficulty performing multiple tasks concurrently. As a result, fatigue can not only degrade the fitness of an individual, but also the overall performance of a crew.

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[18] Dawson, D. and Reid, K. (1997). "Fatigue, alcohol and performance impairment." Nature, 388:235; Williamson, A.M. and Feyer, A. (2000). "Moderate sleep deprivation produces impairments in cognitive and motor performance equivalent to legally prescribed levels of alcohol intoxication." Occupational and Environmental Medicine, 57, 649-655.

Conditions that contribute to worker fatigue, resulting 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, are present in the U.S. nuclear power industry. These conditions include the following:

- Extended work shifts with five or more consecutive work days. The use of 12-hour shifts during normal operations has become increasingly common at U.S. nuclear power plants. Furthermore, the use of 6 or more consecutive 12-hour shifts is now standard practice during plant outages. During outages, some licensees have scheduled personnel for three or more weeks of consecutive 12-hour shifts without intervening days off.

- Extensive use of overtime. Recent studies indicated that at approximately one-fourth of the nuclear power plant sites studied, more than 20 percent of the personnel covered by current working hour limits work more than 600 hours of overtime annually. The NRC has found that some licensees authorized hundreds to several thousand deviations from the current 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 research used for this rulemaking (see Appendix 3). Extensive use of overtime creates a combined effect of long work hours with reduced break periods.

- Night work. Because 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, workers are cyclically affected by the daily biological clock, which runs on about a 24-hour (circadian) cycle. A substantial amount of scientific literature on circadian variations in alertness demonstrates the significant roles that worker fatigue, sleep loss, and circadian rhythms play in contributing to errors and accidents. 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), and a nuclear power plant security guard falling asleep while driving a patrol vehicle (2004), despite these individuals recognizing the potential safety and disciplinary consequences, underscore the powerful drive for sleep associated with circadian factors and the fact that shiftwork is a daily influence on the alertness of all shiftworkers at nuclear power plants.

- Site-specific factors. Extended commutes, which are common for some nuclear power plants, contribute to the potential for fatigue associated with early start times.

- Workforce characteristics. In the general U.S. population, sleep disorders, such as sleep apnea, are not uncommon. 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, who constitute a significant proportion of the power plant workforce, than in the general population.

Considering the above factors, the NRC believes that fatigue can have a significant adverse effect on worker abilities, and that the impairment can result in safety significant deteriorations in worker performance. Further, the likelihood of a nuclear power plant worker being impaired from fatigue is likely far greater than the likelihood of impairment from drugs and alcohol, which the NRC currently requires licensees to address through their FFD programs.

Many provisions of Subpart I are expected to lead to benefits that, while difficult or impossible to analyze quantitatively, are quite substantial in magnitude. Three such provisions, in particular, are the requirement that all workers be trained to recognize the factors contributing to worker fatigue and to identify symptoms of worker fatigue, the provision for worker self-declarations of fatigue, and the provision for for-cause fatigue assessments when workers exhibit symptoms of fatigue to managers or co-workers. These provisions will help ensure that individual variations in susceptibility to fatigue, arising from physiology, personal obligations, or life style, will be addressed in ways beyond the individual work hour limits in the final rule. The training, self-declaration, and fatigue assessment provisions will help avoid potential adverse consequences caused by workers who, for whatever reason, are affected by fatigue irrespective of the other provisions of Subpart I. These provisions thus are primary contributors to safety.

The NRC expects that the following provisions will provide substantial benefits:

- The restrictions on waivers of the individual work hour limits;
- The requirement for a 10-hour break between successive work periods;
- The requirement for a 34-hour break in any 9-day period for individual members of the specified job duty groups; and
- The requirements for mandatory days-off.

By limiting the work hours during normal conditions, individuals will be better rested and less susceptible to cumulative fatigue from the long work hours that are common during plant and security system outages. This may increase the potential for shorter outages. Other potential benefits include improved productivity, lower radiological exposures, less re-work, which can increase the availability of important safety systems, and improved environmental protection through the avoidance of inadvertent oil spills or other non-nuclear environmental events or inadvertent radiological releases. The fatigue management provisions provide reasonable assurance that individuals will be better rested prior to an emergency or increased threat condition.

4.1.3.2 Safeguards and Security

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. In order to ensure that these individuals are able to meet their responsibilities for maintaining the common defense and security, it is necessary to ensure that they are not subject to fatigue, which could reduce their alertness and ability to perform the critical job duties of identifying and promptly responding to plant security threats. 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 some individuals had been working up to 60 hours per week for extended periods. Individual concerns regarding their fitness-for-duty, in light of work schedules that did not exceed the specific guidelines of the policy, as well as relevant technical research supporting the basis for cumulative fatigue, caused the NRC to conclude that the work hour guidelines of the policy were inadequate for addressing cumulative fatigue of security personnel. The NRC therefore issued Order EA-03-038 on April 29, 2003. The compensatory measures imposed by Order EA-03-038 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 cumulative fatigue from prolonged use of extended work hours and matters unique to security personnel. The requirements in Order EA-03-038 were imposed to provide the NRC with reasonable assurance that the public health and safety and common defense and security continue to be adequately protected.

The NRC plans to withdraw Order EA-03-038 once the fatigue management provisions in Subpart I for security force personnel take effect. The security force personnel who are subject to work hour controls in the Order are the same individuals who are subject to the work hour controls. Subpart I largely incorporates provisions in the Order, including provisions designed to minimize the use of deviations from the individual work hour limits, and limits that minimize the potential for cumulative fatigue. The requirements established by the Order and incorporated into Subpart I ensure adequate protection of public health and safety and the common defense and security.

Subpart I adds a new requirement not contained in Order EA-03-038 for security personnel to obtain a break of 34 hours every 9 days and receive mandatory days-off. That requirement is also expected to result in improved nuclear power plant security. It will support the individual work hour controls by both preventing and mitigating cumulative sleep debt. The break and days-off requirements ensure opportunities for days off, limits forced overtime, and also may support improved morale and safety culture. The training, self-declaration, and for-cause provisions of Subpart I also are expected to have the same qualitative benefits for security personnel as they do for other categories of nuclear plant personnel.

4.1.3.3 Regulatory Efficiency

Currently, even if licensees have incorporated the NRC's Policy on Worker Fatigue into a license condition, technical specification, or administrative procedure, consistent implementation and/or enforcement of the guidance in the policy is complicated by several 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).
- The technical specifications have inconsistent levels of detail from one nuclear power plant licensee to another.
- Licensees have inconsistently interpreted the scope of personnel who must be subject to the technical specification work hour limits.
- The technical specifications contain varying scopes for other requirements.
- The basic measure–work hours–used to determine whether an individual's situation is within or above the technical specification limits is not implemented consistently from one nuclear power plant to another.

The former Part 26 does not include prescriptive requirements regarding fatigue. Rather, §26.20 uses general, non-mandatory language to state that FFD policy "should" address other factors that can affect a worker's ability to safely and competently perform his or her duties, "such as mental stress, fatigue, and illness." As a result, it is difficult for the NRC to justify a violation of the regulation based on a licensee's failure to limit work hours. In addition, without a numerical limit on work hours, or a provision limiting work hours, a range of work hour practices could be viewed as "reasonable," and therefore in compliance with the regulation. When the specifics of a regulatory requirement are not clear, a licensee could enact programs that are less effective than the agency intended or could spend unproductive time trying to understand the requirements. Similarly, lack of clarity could lead licensees to inadvertently not comply with the true intent of the

regulatory action, which could lead to intervention by the NRC or even enforcement action and litigation. Increasing the clarity of the fatigue management provisions will enhance their effectiveness and safety-related benefits.

4.1.3.4 Public Perception

Many public comments on PRM-26-2 expressed concern that NRC appeared to "look the other way" in matters concerning worker fatigue. More recently, concerns regarding security personnel fatigue and instance of nuclear plant operators and guards falling asleep on the job have been the subject of newspaper articles. By increasing the effectiveness and clarity of the requirements for fatigue management programs, this final rule enhances the public's confidence in the NRC's protection of public health and safety and the common defense and security. The changes give the public additional assurance that the NRC is addressing the safety concern that worker fatigue may increase the probability of safety-significant accidents or may pose safeguards and security risks at power reactors.

4.1.3.5 Workplace Productivity and Efficiency

Affected licensees may accrue cost savings from the improved effectiveness of the rule, including enhanced workforce productivity, reduced absenteeism, lower medical and insurance costs, and less plant downtime. The effects of human-related errors caused by fatigue can have direct and indirect effects on overall plant operating costs. For example, a 24-hour outage caused by a fatigue-related error may result in a direct revenue loss of several hundred thousand to more than a million dollars. Furthermore, the long-term effects of problems arising from increases in illnesses and sick time, increased use of medical benefits, increased industrial accident rates, increased absenteeism, and lower productivity on the job, all of which have been associated with extended work hours and cumulative fatigue, can result in higher costs to the licensee. These secondary benefits result in additional savings for fatigue management programs beyond those discussed above.

4.1.4 Disaggregation

This section addresses the final rule provisions on a disaggregated basis. Section 4.1.4.1 considers the need to examine each requirement on an individual (i.e., fully-disaggregated) basis. Section 4.1.4.2 disaggregates the collection of provisions related to fatigue management from the remainder of the final rule.

4.1.4.1 Screening Review for Disaggregation

In order to comply with the guidance provided in Section 4.3.2 ("Criteria for the Treatment of Individual Requirements") of the Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG/BR-0058, Revision 4, the NRC conducted a screening review to ensure that the aggregate analysis does not mask the inclusion of individual rule provisions that are not cost-beneficial when considered individually and not necessary to meet the goals of the rulemaking. The NRC identified all individual Part 26 rule changes where the total present value cost to industry is expected to reach or exceed approximately $50,000 per program (assuming a 7-percent discount rate), and/or where total initial industry costs are estimated to reach or exceed approximately $1,000,000. Because the NRC determined that all individual changes that

meet the above thresholds are also backfits, the complete discussion of the screening review is included in the Backfit Analysis portion of this document (see Section 4.4.2).

4.1.4.2 Disaggregating Fatigue Management from Other Part 26 Revisions

This section summarizes the division of costs and savings of the final rule between fatigue-related provisions (i.e., the provisions in Subpart I) and all other provisions.[19] The NRC is not required to present this information but is doing so as a courtesy to stakeholders.

As can be seen in Exhibit 4-6, the substantial costs of Subpart I (Fatigue Management) dominate the cost results of the final rule as a whole. When the other (non-fatigue) provisions are evaluated separately, the results show a considerable savings to industry.

For a discussion of the benefits of the fatigue management provisions, refer to Section 4.1.3 of this regulatory analysis. The NRC believes the qualitative benefits of the fatigue management provisions are fully justified relative to the costs.

Exhibit 4-6
Industry Savings and Costs of Fatigue Relative to Other Revisions

	Average Per FFD Program			Total for All FFD Programs		
	One-Time Saving (Cost)	Annual Saving (Cost)	Net Present Value	One-Time Saving (Cost)	Annual Saving (Cost)	Net Present Value
Fatigue (Subpart I)	($421,700)	($1,475,300)	($17,770,000)	($11,808,000)	($41,309,000)	($572,863,000)
Rest of Final Rule	(59,900)	$300,800	$4,002,100	($1,918,000)	$9,628,000	$128,807,000
Total	**($481,600)**	**($1,174,500)**	**($13,767,900)**	**($13,726,000)**	**($31,680,000)**	**($444,056,000)**

* Net present value assumes a discount rate of 7 percent. Using a discount rate of 3 percent, the net present values are estimated as follows: Fatigue provisions result in a cost estimated at $28,571,100 per program, or a cost of $898,127,000 to industry as a whole. The rest of the final rule results in a savings estimated at $6,537,000 per program, or savings of $203,804,000 to industry as a whole. Total net present value for the entire rulemaking is estimated at a cost of $22,034,100 per program, or a cost of $694,324,000 to industry as a whole.
** A licensee's FFD program may include more than one facility.

4.2 Benefits and Costs — Pre-Order Baseline

The NRC has performed a sensitivity analysis using an alternative baseline (called the "pre-order baseline") that considers the incremental impacts of the Part 26 rule relative to only those regulations that were in effect before the NRC issued the AAO on January 7, 2003, and Order EA-03-038 on April 29, 2003. The purpose of this sensitivity analysis is to account for

[19] The "other provisions" consists of all other Part 26 revisions including, in particular, provisions related to drug and alcohol testing and authorization, as well as other FFD matters covered by the rule.

relevant impacts of the orders in addition to those that are incremental to the final rule.[20] These impacts already have been incurred, but they have not previously been quantified.

The results of the sensitivity analysis show lower costs for licensees when compared to the main analysis, both under a 7-percent discount rate and a 3-percent discount rate, as shown in Exhibits 4-7 and 4-8 respectively. Under the pre-order baseline, NRC estimates the present value cost of the final rule at $85,106,000 (or $2,581,200 for the average FFD program) using a 7-percent discount rate and $124,837,000 (or $3,582,400 for the average FFD program) using a 3-percent discount rate. Industry will incur a one-time cost totaling $19,792,000 (or $671,200 for the average program) to implement the rule and will incur subsequent annual costs estimated at $4,946,000 (or $339,100 for the average program).

Exhibit 4-7
Industry Savings and Costs by Subpart under the Pre-Order Baseline (7% discount rate)

Subpart	Average Per FFD Program			Total - All FFD Programs		
	One-Time Saving (Cost)	Annual Saving (Cost)	Net Present Value	One-Time Saving (Cost)	Annual Saving (Cost)	Net Present Value
A	-	$7,600	$103,400	-	$243,000	$3,320,000
B	($234,100)	$250,600	$3,145,900	($7,490,000)	$8,018,000	$101,338,000
C	-	$868,000	$11,817,900	-	$27,777,000	$379,218,000
D	-	-	-	-	-	-
E	($9,500)	$17,600	$230,400	($304,000)	$564,000	$7,401,000
F	($5,900)	($19,200)	($265,800)	($190,000)	($613,000)	($8,577,000)
G	-	($2,300)	($32,900)	-	($73,000)	($1,037,000)
H	-	$13,300	$181,200	-	$426,000	$5,821,000
I	($421,700)	($1,475,300)	($17,770,000)	($11,808,000)	($41,309,000)	($572,863,000)
J	-	-	-	-	-	-
K	-	-	-	-	-	-
L	-	-	-	-	-	-
M	-	-	-	-	-	-
N	-	$600	$8,700	($0,000)	$19,000	$273,000
O	-	-	-	-	-	-
Total	**($671,200)**	**($339,100)**	**($2,581,200)**	**($19,792,000)**	**($4,946,000)**	**($85,106,000)**

* Net present value is calculated using a discount rate of 7 percent.
** A licensee's FFD program may include more than one facility. The average annual savings (costs) presented are for the initial years of the analysis and change over time as programs decrease in size with the closure of specific plants. Consequently, the total net present values cannot be derived using only the one-time and annual values shown above.

[20] The sensitivity analysis considers only those AAO provisions that are relevant to this rulemaking and, therefore, does not quantify the impact of the AAO as a whole.

Exhibit 4-8
Industry Savings and Costs by Subpart under the Pre-Order Baseline (3% discount rate)

Subpart	Average Per FFD Program			Total - All FFD Programs		
	One-Time Saving (Cost)	Annual Saving (Cost)	Net Present Value	One-Time Saving (Cost)	Annual Saving (Cost)	Net Present Value
A	-	$7,600	$169,100	-	$243,000	$5,241,000
B	($234,100)	$250,600	$5,249,800	($7,490,000)	$8,018,000	$163,849,000
C	-	$868,000	$19,361,100	-	$27,777,000	$597,942,000
D	-	-	-	-	-	-
E	($9,500)	$17,600	$382,700	($304,000)	$564,000	$11,855,000
F	($5,900)	($19,200)	($427,900)	($190,000)	($613,000)	($13,527,000)
G	-	($2,300)	($57,800)	-	($73,000)	($1,701,000)
H	-	$13,300	$296,500	-	$426,000	$9,187,000
I	($421,700)	($1,475,300)	($28,571,100)	($11,808,000)	($41,309,000)	($898,127,000)
J	-	-	-	-	-	-
K	-	-	-	-	-	-
L	-	-	-	-	-	-
M	-	-	-	-	-	-
N	-	$600	$15,200	($0,000)	$19,000	$445,000
O	-	-	-	-	-	-
Total	**($671,200)**	**($339,100)**	**($3,582,400)**	**($19,792,000)**	**($4,946,000)**	**($124,837,000)**

* Net present value is calculated using a discount rate of 3 percent.
** A licensee's FFD program may include more than one facility. The average annual savings (costs) presented are for the initial years of the analysis and change over time as programs decrease in size with the closure of specific plants. Consequently, the total net present values cannot be derived using only the one-time and annual values shown above.

Exhibit 4-9 presents only the *additional* costs and savings that accrue under the pre-order baseline relative to the main analysis. As shown, the rule yields additional one-time costs of $6,066,000 ($189,600 for the average program) and additional annual savings of $26,734,000 ($835,000 for the average program), all of which relates to requirements in Subparts B and C.

Exhibit 4-9
Industry Savings and Costs by Subpart: Additional Savings (Costs) under the Pre-Order Baseline Relative to the Main Analysis

Subpart	Average Per FFD Program		Total - All FFD Programs	
	One-Time Saving	Annual Saving	One-Time Saving	Annual Saving
A	-	-	-	-
B	($189,600)	($34,600)	($6,066,000)	($1,105,000)
C	-	$869,900	-	$27,839,000
D	-	-	-	-
E	-	-	-	-
F	-	-	-	-
G	-	-	-	-
H	-	-	-	-
I	-	-	-	-
J	-	-	-	-
K	-	-	-	-
L	-	-	-	-
M				
N	-	-	-	-
O	-	-	-	-
Total	**($189,600)**	**$835,300**	**($6,066,000)**	**$26,734,000**

* A licensee's FFD program may include more than one facility. The average annual savings (costs) presented are for the initial years of the analysis and change over time as programs decrease in size with the closure of specific plants.

Exhibit 4-10 shows the specific provisions within Subparts B and C that contribute added costs and savings under the pre-order baseline. A total of over $27 million in annual savings (over $800,000 per program) results from various revisions to requirements in §§26.55-59 governing the granting of authorization under Subpart C. Some of these provisions eliminate the need to administer pre-access drug and alcohol tests to initial applicants, update applicants, and reinstatement applicants if the applicants have previously had authorization and have been covered by a licensee-approved behavioral observation program and random drug and alcohol testing program throughout the period of interruption. Other provisions allow licensees to forego obtaining self-disclosures from, or undertaking suitable inquiries about, applicants that have previously had authorization and have been covered by a licensee-approved behavioral observation program throughout the period of interruption.

A large one-time cost results from requiring all employees to be trained in behavioral observation and other aspects of the rule under §26.29(a). As a result, licensees will be required to update the training of all existing employees that were previously trained at the non-supervisory-level, resulting in one-time industry-wide costs of $6,066,000 (or an average of $189,600 per program). §26.29(a) also generates lesser annual costs, which are attributable to the need to continue such training in future years.

Exhibit 4-10
Pre-Order Baseline: Industry Savings and Costs from Revisions to Subparts B and C

Section/ Activity	Average Per FFD Program		Total - All FFD Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.29(a) Revise and Implement Training, Including Behavioral Observation	($189,567)	($34,534)	($6,066,139)	($1,105,096)
26.55(a)(1) Self-Disclosure for Initial Applicants	-	$10,372	-	$331,914
26.55(a)(2) Suitable Inquiry for Initial Applicants	-	$20,980	-	$671,352
26.55(a)(3) Pre-Access Testing for Initial Applicants	-	$71,010	-	$2,272,311
26.57(a)(1) Self Disclosure for Update Applicants	-	$829	-	$26,515
26.57(a)(2) Suitable Inquiry for Update Authorization	-	$3,131	-	$100,195
26.57(a)(3) Pre-Access Testing for Update Applicants	-	$10,491	-	$335,716
26.59(a)(1) Self-Disclosure for Reinstatement Applicants with 31-365 Day Interruption	-	$6,047	-	$193,517
26.59(a)(2) Suitable Inquiry for Reinstatement Applicants with 31-365 Day Interruption	-	$22,929	-	$733,729
26.59(a)(3) Pre-Access Testing for Reinstatement Applicants with 31-365 Day Interruption	-	$263,677	-	$8,437,677
26.59(c)(1) Self-Disclosure (and Suitable Inquiry) for Reinstatement Applicants with Less than 31 Day Interruption	-	$49,681	-	$1,589,805
26.59(c)(2) Pre-Access Testing for Reinstatement Applicants with Less than 31 Day Interruption	-	$410,828	-	$13,146,488
Total	($189,567)	$835,441	($6,066,139)	$26,734,124

4.3 Sensitivity Analysis — Industry Practices

This sensitivity analysis considers a baseline that reflects industry practices prior to the AAO and recent enforcement discretion and is in accordance with licensees' interpretation of existing regulations. For a few rule provisions, until recently, some licensees interpreted the existing Part 26 rule inconsistently with the NRC interpretation. For these provisions, some licensees' practices have recently changed (subsequent to enforcement discretion and issuance of the

AAO) to comply with the former rule. Measured relative to the previous practices, therefore, the cost of complying with the relevant provisions in the final rule will exceed that estimated in the pre-order baseline.

Exhibits 4-11 and 4-12 summarize the results of this "Industry Practices" sensitivity analysis, using a 7-percent discount rate and a 3-percent discount rate, respectively. Under this baseline, the present value of net costs to industry is estimated to be $195,604,000, or $6,024,000 for the average program, assuming a 7-percent discount rate. Assuming a 3-percent discount rate, the costs are estimated to be $299,076,000, or $9,222,000 for the average program.

Exhibit 4-11
Industry Savings and Costs by Subpart under the Industry Practices Baseline
(7% discount rate)

Subpart	Average Per FFD Program			Total - All FFD Programs		
	One-Time Saving (Cost)	Annual Saving (Cost)	Net Present Value	One-Time Saving (Cost)	Annual Saving (Cost)	Net Present Value
A	($500)	$7,600	$102,700	($15,000)	$243,000	$3,298,000
B	($234,100)	$250,600	$3,145,900	($7,490,000)	$8,018,000	$101,338,000
C	-	$615,100	$8,375,400	-	$19,685,000	$268,741,000
D	-	-	-	-	-	-
E	($9,500)	$17,600	$230,400	($304,000)	$564,000	$7,401,000
F	($5,900)	($19,200)	($265,800)	($190,000)	($613,000)	($8,577,000)
G	-	($2,300)	($32,900)	-	($73,000)	($1,037,000)
H	-	$13,300	$181,200	-	$426,000	$5,821,000
I	($421,700)	($1,475,300)	($17,770,000)	($11,808,000)	($41,309,000)	($572,863,000)
J	-	-	-	-	-	-
K	-	-	-	-	-	-
L	-	-	-	-	-	-
M	-	-	-	-	-	-
N	-	$600	$8,700	($0,000)	$19,000	$273,000
O	-	-	-	-	-	-
Total	**($672,000)**	**($592,000)**	**($6,024,000)**	**($19,807,000)**	**($13,039,000)**	**($195,604,000)**

* Net present value is calculated using a discount rate of 7 percent.
** A licensee's FFD program may include more than one facility. The average annual savings (costs) presented are for the initial years of the analysis and change over time as programs decrease in size with the closure of specific plants. Consequently, the total net present values cannot be derived using only the one-time and annual values shown above.

Exhibit 4-12
Industry Savings and Costs by Subpart under the Industry Practices Baseline
(3% discount rate)

Subpart	Average Per FFD Program			Total - All FFD Programs		
	One-Time Saving (Cost)	Annual Saving (Cost)	Net Present Value	One-Time Saving (Cost)	Annual Saving (Cost)	Net Present Value
A	($500)	$7,600	$168,300	($15,000)	$243,000	$5,214,000
B	($234,100)	$250,600	$5,249,800	($7,490,000)	$8,018,000	$163,849,000
C	-	$615,100	$13,722,500	-	$19,685,000	$423,729,000
D	-	-	-	-	-	-
E	($9,500)	$17,600	$382,700	($304,000)	$564,000	$11,855,000
F	($5,900)	($19,200)	($427,900)	($190,000)	($613,000)	($13,527,000)
G	-	($2,300)	($57,800)	-	($73,000)	($1,701,000)
H	-	$13,300	$296,500	-	$426,000	$9,187,000
I	($421,700)	($1,475,300)	($28,571,100)	($11,808,000)	($41,309,000)	($898,127,000)
J	-	-	-	-	-	-
K	-	-	-	-	-	-
L	-	-	-	-	-	-
M	-	-	-	-	-	-
N	-	$600	$15,200	($0,000)	$19,000	$445,000
O	-	-	-	-	-	-
Total	**($672,000)**	**($592,000)**	**($9,222,000)**	**($19,807,000)**	**($13,039,000)**	**($299,076,000)**

* Net present value is calculated using a discount rate of 3 percent.
** A licensee's FFD program may include more than one facility. The average annual savings (costs) presented are for the initial years of the analysis and change over time as programs decrease in size with the closure of specific plants. Consequently, the total net present values cannot be derived using only the one-time and annual values shown above.

Exhibit 4-13 details the specific provisions for which costs are higher under the industry practices baseline than under the pre-order baseline.[21] As shown, the NRC estimates that industry would have incurred a total annual cost of about $8,092,000 (or about $252,900 for the average program), as well as a total one-time cost of $15,000 (approximately $500 for the average

[21] Exhibit 4-13 measures the cost of industry coming into compliance with the pre-AAO requirements. Note, however, that the AAO relaxed or eliminated some of the Part 26 requirements with which some licensees had not been complying. Therefore, industry's subsequent compliance actually was achieved partly as a result of a change in its practices and partly as a result of the NRC changing the requirements. For this reason, industry did not "incur" all of the costs shown in Exhibit 4-13. Use of this analytical approach avoids double-counting the results presented in these Exhibits 4-11 and 4-12.

program), to modify recent practices. Most of these costs are associated with licensees' practices for reinstating the authorization of applicants with interruptions of 30 days or less. Appendix 1, which documents the calculation of savings and costs for individual rule requirements (including those cited in Exhibit 4-13), describes the industry practices at issue in this sensitivity analysis.

Exhibit 4-13
Industry Savings and Costs Attributable to Activities
Affected by Recent Changes in Industry Practices

Section/ Activity	Average Per FFD Program		Total - All FFD Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.4(g) FFD Program Personnel Subject to the Rule	($465)	($15)	($14,865)	($480)
26.55(a)(2) Suitable Inquiry for Initial Applicants	-	($4,552)	-	($145,649)
26.57(a)(2) Suitable Inquiry for Update Authorization	-	($672)	-	($21,518)
26.59(a)(2) Suitable Inquiry for Reinstatement Applicants with 31-365 Day Interruption	-	($4,908)	-	($157,052)
26.59(c)(1) Self-Disclosure (and Suitable Inquiry) for Reinstatement Applicants with Less than 31 Day Interruption	-	($35,571)	-	($1,138,288)
26.59(c)(2) Pre-Access Testing for Reinstatement Applicants with Less than 31 Day Interruption	-	($207,184)	-	($6,629,874)
Total	($465)	($252,902)	($14,865)	($8,092,862)

4.4 Backfit Analysis

This section presents the NRC's evaluation of changes in the final rule in accordance with the Backfit Rule, 10 CFR §50.109, 10 CFR §70.76, and 10 CFR §76.76. The backfit provision of 10 CFR §70.76 is applicable to currently licensed Category I fuel fabrication facilities. These facilities have been considered in the aggregate backfit analysis. 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. 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 (see Section 3.2.2) is sufficient for consideration of the impacts to that facility. Although the backfit provision of 10 CFR §76.76 is applicable, 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.

Section 4.4.1 examines the aggregation of the individual Part 26 rule requirements that constitute backfits, which excludes (1) matters that are not subject to the Backfit Rule, and (2) matters that do not fall within the definition of "backfitting" as defined in the Backfit Rule and discussed below. Section 4.4.2 describes a screening analysis conducted in accordance with NRC's Regulatory Analysis Guidelines to ensure that the aggregate analysis does not mask the inclusion of individual rule provisions that are (1) not cost-beneficial when considered individually and (2) not necessary to meet the goals of the rulemaking. Both analyses examine the impacts of the rule relative to the baseline used in the main analysis, which consists of existing requirements including the recently issued orders and enforcement discretion.

4.4.1 Aggregated Backfit Analysis

The backfit analysis examines the aggregation of the subset of the final Part 26 regulatory requirements that constitute backfits as defined in 10 CFR §50.109(a)(1), 10 CFR §70.76(a)(1), and 10 CFR §76.76(a)(1). These provisions are identified in two exhibits. Exhibit 4-14 presents the requirements that both constitute backfits and result in incremental savings or costs. Exhibit 4-15 specifies requirements that constitute backfits that either do not result in incremental costs or savings or that result in incremental costs or savings only in conjunction with other requirements. The analysis excludes individual requirements that are not subject to the Backfit Rule or that are not backfits by definition, which include requirements that fall into one or more of the following categories.

- *Administrative matters*. Revisions that make minor administrative changes, such as correction of typographic errors, correction of inconsistencies, relocating requirements from one section to another, and combining existing requirements into a single section.

- *Information collection and reporting requirements*. Revisions that either amend existing information collection and reporting requirements or impose new information and collection and reporting requirements, which are not considered to be backfits, as set forth in the Committee to Review Generic Requirements (CRGR) charter.

- *Clarifications*. Revisions that clarify current requirements to assure consistent understanding and implementation of the NRC's original intent for these requirements. Without changing the underlying requirements stated in these sections, these revisions remove the ambiguities that produced regulatory uncertainty.

- *Permissive relaxations/Voluntary alternatives*. Revisions that permit, but not require, relaxations or alternatives to current requirements (i.e., licensees are free to either comply with current requirements or adopt the relaxed requirements/voluntary alternative as a binding requirement).

- *Provisions required under the NRC's AAO or Order EA-03-038.* Provisions that have been addressed in a recent FFD AAO and/or Order EA-03-038 and/or

enforcement discretion are excluded from the backfit analysis under the exclusion in 10 CFR §50.109(a)(4), 10 CFR §70.76(a)(4), and 10 CFR §76.76(a)(4).

The analysis also excludes the requirements in Subpart K because the provisions in Subpart K do not apply to existing licensees and other entities.

(Exhibit 4-16 presents the rationale for excluding particular requirements from the backfit analysis. This exhibit does not address numerous requirements that were excluded because they merely restate, clarify, or move requirements in the former rule.)

The NRC then evaluated the aggregated set of requirements constituting backfits in accordance with 10 CFR §50.109, 10 CFR §70.76, and 10 CFR §76.76 to determine if the costs of implementing the rule would be justified by a substantial increase in public health and safety or common defense and security. In performing this analysis, the NRC considered the quantitative and qualitative costs and benefits of the rule, as discussed below.

Exhibit 4-14
FFD Regulatory Requirements that Constitute Backfits and Result in Incremental Costs or Savings

Section/ Activity	Average per Program		Total - All Licensee/CV Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.27(a) Policy and Procedure Revisions - Overall Program	($30,451)	-	($974,444)	-
26.29(a) Revise and Implement Training, Including Behavioral Observation	($1,251)	-	($40,039)	-
26.29(b) Comprehensive Examination	($12,793)	-	($409,362)	-
26.31(d)(3) Forensic Toxicologist Review of More Stringent Cutoff Levels	($10)	-	($314)	-
26.85(a),(b) Urine and Alcohol Collector Training	($3,961)	-	($126,764)	-
26.91(b) Purchase of EBT and Calibration Equipment and Related Training	($5,526)	-	($176,846)	-
26.127 Licensee Testing Facility Policy and Procedure Revisions	($5,303)	-	($169,696)	-
26.131(b) Initial Validity Testing - Onsite Licensee Testing Facilities	($638)	-	($20,419)	-
26.203(a)-(b) Policy and Procedures	($32,524)	-	($910,664)	-
26.203(c) Training	($258,887)	-	($7,248,837)	-
26.205(b) Calculating Work Hours	($116,071)	-	($3,250,000)	-
26.205(c) Scheduling Work Hours	($14,240)	-	($398,734)	-
26.29(b) Comprehensive Examination	-	($3,127)	-	($100,049)
26.31(b)(1)(i) Background Checks, Psychological Evaluations, Credit History, Criminal History	-	$653	-	$20,880

Section/ Activity	Average per Program		Total - All Licensee/CV Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.31(b)(2) DOT-Approved Specimen Collection Facilities	-	$140	-	$4,487
26.31(d)(2) Reasonable Effort to Track Randomly Selected Individuals for Testing	-	($3,494)	-	($111,817)
26.33 Behavioral Observation	-	($1,846)	-	($59,066)
26.41(b) Audit Frequency	-	$493	-	$15,779
26.55(a)(4) Random Testing Pool for Initial Applicants	-	($527)	-	($16,856)
26.57(a)(4) Random Testing Pool for Update Applicants	-	($78)	-	($2,490)
26.59(a)(4) Random Testing Pool for Reinstatement Applicants with 31-365 Day Interruption	-	($568)	-	($18,176)
26.59(c)(3) Random Testing Pool for Reinstatement Applicants with Less than 31 Day Interruption	-	($768)	-	($24,590)
26.83(a) Blood Collection for Confirmatory Alcohol Testing	-	$261	-	$8,365
26.89(b)(2) Urine Collection: Donors Without Adequate ID	-	$1,987	-	$63,596
26.89(b)(3) Urine Collection: Eliminate Listing Medications on the CCF Form and add description of testing process	-	$7,489	-	$239,654
26.91(b) Purchase of EBT and Calibration Equipment and Related Training	-	($82)	-	($2,625)
26.91(c) Required Use of an EBT on the NHTSA CPL for Confirmatory Testing	-	$9	-	$286
26.95(c) One Breath Specimen Collection for Initial Alcohol Test	-	$12,789	-	$409,253
26.99(b) Lowering Initial BAC Requiring Confirmatory Test to BAC 0.02	-	($116)	-	($3,725)
26.103 FFD Manager Determines Confirmed Positive Test for Alcohol (BAC 0.02 < 0.04)	-	($11)	-	($355)
26.105(b) Urine Collection: Inspecting Contents of Donor's Pockets	-	($12,357)	-	($395,429)
26.109(a) Urine Specimen Quantity: Minimum Quantity of 30 mL	-	$9,408	-	$301,065
26.109(b)(2) Urine Specimen: At Least 30 mL, but Less than Predetermined Quantity	-	($240)	-	($7,680)
26.119 Shy Bladder Medical Evaluation	-	($1,500)	-	($47,995)
26.131(b) Initial Validity Testing - Onsite Licensee Testing Facilities	-	($15,267)	-	($488,530)

Section/ Activity	Average per Program		Total - All Licensee/CV Programs	
	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
26.133 Change Cutoff Levels for Marijuana and Opiates - Onsite Testing Facilities	-	($368)	-	($11,763)
26.137(e)(6) Quality Control Specimens in Each Analytical Run - Onsite Testing Facilities	-	($3,992)	-	($127,758)
26.161(b)(1) All Validity Testing Conducted at HHS-Certified Laboratories	-	($12,711)	-	($406,760)
26.161(g) Unidentified Interfering Substance/Adulterant - Contact MRO and Specimen Retesting	-	($395)	-	($12,643)
26.163(a)(1) Change Cutoff Levels for Marijuana and Opiates - HHS-Certified Laboratories	-	($582)	-	($18,614)
26.165(b) Retesting of Single Collection Specimens with Confirmed Positive Drug and/or Validity Test Results	-	($8)	-	($240)
26.168(a)(1) Blind Sample Testing - 1st Quarter of Contract with a HHS-Certified Laboratory	-	$670	-	$21,446
26.168(a)(2) Blind Sample Testing - Contracts with HHS-Certified Laboratories Older Than 90 Days	-	$10,554	-	$337,731
26.189(c) Face-to-Face Determinations of Fitness	-	($4,535)	-	($145,117)
26.203(c) Training	-	($118,152)	-	($3,308,268)
26.203(f) Fatigue Management Audits	-	($3,982)	-	($111,484)
26.205(b) Calculating Work Hours	-	($34,534)	-	($966,942)
26.205(c) Scheduling Work Hours	-	($84,599)	-	($2,368,773)
26.205(d)(4)-(6) Day-off Requirements	-	($605,550)	-	($16,955,400)
26.205(e) Work Hour Control Reviews	-	($2,312)	-	($64,742)
26.207 Waivers from Individual Work Hour Limits	-	($588,111)	-	($16,467,100)
26.209 Self-Declarations of Fatigue	-	($1,617)	-	($45,276)
26.211(a)-(d) Fatigue Assessments	-	($8,943)	-	($250,398)
26.211(e) Post-Fatigue Assessment Controls and Conditions	-	($20,213)	-	($565,956)
Total	($481,657)	($1,486,129)	($13,726,119)	($41,684,076)

The exhibit presents the requirements that both constitute backfits and result in incremental savings or costs. Backfits that do not result in incremental savings or costs, or that result in incremental savings or costs only in conjunction with other requirements, are identified in Exhibit 4-15. Other requirements do not qualify as backfits for reasons explained in Exhibit 4-16, except that Exhibit 4-16 does not address requirements that do not constitute backfits because they represent administrative changes, restatements, or clarifications of requirements in the former rule.

Exhibit 4-15
Backfits Resulting in No Direct Incremental Costs or Savings

Subpart A	
§26.4(g)	
Subpart B	
§§26.23(a)–(d)	§§26.31(b)(1)(ii)– (iv)
§26.23(e)	§26.31(c)(3)
§26.27(b)	§26.31(d)(1)
§§26.27(b)(1)–26.27(b)(10)	§26.31(d)(1)(i)
§26.27(b)(11)	§26.31(d)(1)(ii)
§§26.27(c)(2)(iii)–(v)	§26.31(d)(4)
§26.27(c)(4)	§26.39(a)
§26.31(b)(1)	§26.41(d)(2)
Subpart C	
§26.53(b)	§26.69(b)
§26.55(a)(1)	§26.69(c)
§26.55(a)(2)	§26.69(d)
§26.55(a)(3)	§26.71(b)
Subpart D	
§26.75(b)	§26.75(f)
§26.75(c)	§26.75(g)
§26.75(d)	§26.77(b)
§26.75(e)	
Subpart E	
§26.85(c)	§26.105(e)
§26.85(d)	§26.107(a)
§26.87(b)	§26.107(b)
§26.87(c)	§26.107(c)
§26.87(e)(1)	§26.109(b)(1)
§26.87(e)(3)	§26.109(b)(3)

§26.87(f)(4)	§26.109(b)(4)
§26.89(a)	§26.111(a)
§26.89(c)	§26.111(c)
§26.91(c)	§26.111(d)
§26.91(e)	§26.111(e)
§26.93(a)(1)	§§26.113(a)-(c)
§§26.93(a)(2)-(3)	§26.115(b)
§26.93(a)(4)	§26.115(c)
§26.93(a)(5)	§26.115(f)
§26.93(b)	§26.115(g)
§26.99(a)	§26.115(h)
§26.101(a)	§26.117(j)
§26.101(b)	§26.117(k)
§26.101(c)	
Subpart F	
§26.123	§26.137(b)
§§26.125(a)-(c)	§26.137(c)
§26.127(c)	§26.137(d)
§26.127(e)	§26.137(e)(1)
§26.129(b)	§26.137(e)(2)
§26.129(c)	§26.137(e)(5)
§26.129(e)	§26.137(e)(7)
§26.129(f)	§26.137(f)
§26.129(h)	§26.139(a)
§26.131(a)	§26.139(f)
Subpart G	
§26.153(a)	§26.165(d)
§26.153(b)	§26.165(e)
§26.153(f)	§26.165(f)
§26.155(b)	§26.167(a)

§26.157(a)	§26.167(b)
§26.157(b)	§26.165(a)
§26.159(b)	§26.165(c)
§26.159(c)	§26.167(c)
§26.159(f)	§26.167(d)
§26.159(g)	§26.167(e)
§26.159(i)	§26.167(f)
§26.159(j)	§26.167(h)
§26.161(a)	§§26.168(b)-(f)
§§26.161(c)-(f)	§26.169(a)
§26.161(h)	§26.169(c)
§26.163(a)(2)	§26.169(e)
§26.163(b)	§26.169(g)
Subpart H	
§26.183(a)	§§26.185(h)(2)–(3)
§26.183(b)	§26.185(i)
§26.183(c)	§26.185(j)(1)
§26.183(d)	§26.185(j)(4)
§26.185(a)	§26.185(j)(5)
§26.185(b)	§26.185(j)(6)
§26.185(d)	§26.185(n)
§26.185(e)	§26.185(o)
§26.185(f)(1)	§26.187
§26.185(f)(2)	§26.189(a)(1)
§26.185(f)(3)	§§26.189(a)(2)–(5)
§26.185(g)(1)	§26.189(b)(4)
§26.185(g)(2)	§26.189(c)(1)
§26.185(g)(3)	§26.189(c)(2)
§26.185(h)(1)	§26.189(d)

Subpart I	
§26.205(a)	§26.205(d)(7)
Subpart N	
§26.719(d)	
Subpart O	
None.	

The exhibit presents the requirements that constitute backfits but either do not result in incremental savings or costs or result in incremental savings or costs only in conjunction with other requirements. For requirements that both constitute backfits and result in incremental savings or costs, refer to Exhibit 4-14. Other requirements do not qualify as backfits for reasons explained in Exhibit 4-16, except that Exhibit 4-16 does not address requirements that do not constitute backfits because they represent administrative changes, restatements, or clarifications of requirements in the former rule.

Exhibit 4-16
Rationale for Excluding Particular Requirements from the Backfit Analysis

Requirement	Reason
Subpart A	
§26.4(i)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.4(j)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.11	This revision does not constitute a backfit because it is an information collection and reporting requirement.
Subpart B	
§26.29(c)(2)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.29(c)(3)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.29(d)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.31(b)(1)(i)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.31(b)(2)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.31(c)(1)	This revision does not constitute a backfit because the actions addressed in this provision are already required under the NRC's AAO.

Requirement	Reason
§26.31(d)(5)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.37(c)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.37(d)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.41(c)(2)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
Subpart C	
§26.53(a)	This revision does not constitute a backfit because the actions addressed in this provision are already required under the NRC's AAO.
§26.53(d)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.55(a)	This revision does not constitute a backfit because the actions addressed in this provision are already required under the NRC's AAO.
§26.57(a)	This revision does not constitute a backfit because the actions addressed in this provision are already required under the NRC's AAO.
§26.57(a)(1)	This revision does not constitute a backfit because it restates existing requirements and because the actions addressed in this provision are already required under the NRC's AAO.
§26.57(a)(2)	This revision does not constitute a backfit because it restates existing requirements and because the actions addressed in this provision are already required under the NRC's AAO.
§26.57(a)(3)	This revision does not constitute a backfit because it restates existing requirements and because the actions addressed in this provision are already required under the NRC's AAO.
§26.59(a)	This revision does not constitute a backfit because the actions addressed in this provision are already required under the NRC's AAO.
§26.59(a)(1)	This revision does not constitute a backfit because it restates existing requirements and because the actions addressed in this provision are already required under the NRC's AAO.
§26.59(a)(2)	This revision does not constitute a backfit because the actions addressed in this provision are already required under the NRC's AAO.
§26.59(a)(3)	This revision does not constitute a backfit because the actions addressed in this provision are already required under the NRC's AAO.

Requirement	Reason
§26.59(b)	This revision does not constitute a backfit because the actions addressed in this provision are already required under the NRC's AAO.
§26.59(c)	This revision does not constitute a backfit because the actions addressed in this provision are already required under the NRC's AAO.
§26.59(c)(1)	This revision does not constitute a backfit because it restates existing requirements and because the actions addressed in this provision are already required under the NRC's AAO.
§26.59(c)(2)	This revision does not constitute a backfit because it restates existing requirements and because the actions addressed in this provision are already required under the NRC's AAO.
§26.61(a)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§§26.61(a)(1)–(2)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§§26.61(b)(1)–(3)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.61(c)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.63(a)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.63(b)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.63(c)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.63(d)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.63(f)(1)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.63(f)(2)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.

Requirement	Reason
§26.63(f)(3)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.65(b)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.65(c)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.65(d)(1)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.65(d)(2)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.65(e)(1)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§§26.65(e)(2)(i) and (iii)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.65(e)(2)(ii)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.65(e)(3)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.65(f)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.65(g)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.67(a)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.67(a)(2)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
§26.67(b)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.

Requirement	Reason
§26.67(c)	These provisions are not independent requirements, and their applicability depends upon the provisions in §§26.55 through 26.59. Therefore, any backfitting implications are addressed in the backfit discussion of those sections.
Subpart D	
None.	
Subpart E	
§§26.97(a)-(e)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.101(d)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.111(c)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.115(d)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
Subpart F	
§26.135(b)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.137(e)(3)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.137(h)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.139(b)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.139(d)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.139(e)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
Subpart G	
§26.153(e)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.153(g)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.155(d)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.155(f)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.157(c)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.159(a)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.

Requirement	Reason
§26.169(b)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.169(c)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.169(f)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.169(h)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
Subpart H	
§26.185(c)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.185(g)(4)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.189(b)(3)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
Subpart I	
§26.203(d)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.203(e)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.203(e)(1)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.203(e)(2)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.205(d)(1)	This provision does not constitute a backfit, except for three reactors, because licensees are free to comply with the existing Technical Specification requirement or to adopt the permissive relaxation. The three reactors that do not have this requirement within their Technical Specifications have implemented it as part of their administrative procedures. For these three reactors, this provision constitutes a backfit. The cost of this backfit would be very small, however, and is not significant to the analysis. (The cost would include some administrative costs related to authorizing work hour deviations under certain high workload situations. Any other costs related to the new requirement are addressed under appropriate provisions.)
§26.211(f)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
Subpart J	
None.	

Requirement	Reason
Subpart K	
None.	
Subpart L	
None.	
Subpart M	
None.	
Subpart N	
§26.711(b)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§§26.713(a)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§§26.713(b)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§§26.713(c)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§§26.713(d)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§§26.713(e)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§§26.713(f)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§§26.713(g)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§§26.715(a) and 26.715(b)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.717(b)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.717(c)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§§26.717(e) and 26.717(f)	This revision does not constitute a backfit because licensees are free to continue to comply with the existing requirement or to adopt the final provision.
§26.717(g)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
§26.719(b)	This revision does not constitute a backfit because it is an information collection and reporting requirement.

Requirement	Reason
§26.719(c)(3)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
Subpart O	
None.	

The exhibit presents the requirements that do not constitute backfits, along with the reasons the requirements do not constitute backfits, but excludes requirements that do not constitute backfits because they represent administrative changes, restatements, or clarifications of requirements in the former rule. For requirements that both constitute backfits and result in incremental savings or costs, refer to Exhibit 4-14. Exhibit 4-15 identifies requirements that constitute backfits that either do not result in incremental savings or costs or that result in incremental savings or costs only in conjunction with other requirements.

Collectively, the individual requirements in the final rule that qualify as backfits result in an estimated net cost of approximately $580 million to industry over the next 49 years (present value), assuming a 7-percent discount rate, or approximately $908.4 million assuming a 3-percent discount rate.[22] The present value of these costs to the average program is calculated to be approximately $21,161,400 assuming a 7-percent discount rate, and approximately $34,607,300 using a 3-percent discount rate.

For the average licensee FFD program, these backfits mean an initial one-time cost of approximately $481,700, followed by annual costs of about $1,486,100 per year. For industry as a whole, NRC estimates that the backfits result in approximately $13.7 million in one-time costs, and about $41.7 million in annual costs.

With regard to safety benefits afforded by the Part 26 rule's provisions, as documented in both this regulatory analysis and the statement of considerations of the final Part 26 rule, the NRC considered them in qualitative terms. (See Section 3.2 of this document for a discussion of the issues that would be involved in quantifying the benefits of the final rule.) NRC also qualitatively determined whether the costs of the rule are justified in light of the safety benefits. By contrast, the NRC evaluated costs and cost reductions in quantitative terms, as documented in the regulatory analysis and in the statement of considerations of the final rule.

In performing this analysis, the NRC considered the nine factors in 10 CFR §50.109, 10 CFR §70.76, and 10 CFR §76.76, as follows:

(i) *Statement of the specific objectives that the backfit is designed to achieve.*

The rulemaking constitutes an integrated regulatory initiative directed at the singular regulatory matter of FFD requirements at nuclear facilities. The goals of the final rule are as follows:

1. Update and enhance the consistency of 10 CFR Part 26 with advances in other relevant Federal rules and guidelines, including the U.S. Department of Health and Human Services Mandatory Guidelines for Federal

[22] For more information regarding the derivation of these cost estimates and assumptions employed, see Section 3.2 and Appendix 1.

Workplace Drug Testing Programs (HHS Guidelines) and other Federal drug and alcohol testing programs (e.g., those required by the U.S. Department of Transportation [DOT]) that impose similar requirements on the private sector.

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

3. Improve the effectiveness and efficiency of FFD programs.

4. Improve consistency between Part 26 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.

7. Protect the privacy and due process rights of individuals who are subject to 10 CFR Part 26.

(ii) *General description of the activity that is required by the licensee or applicant in order to complete the backfit.*

In general terms, the Part 26 rule: requires licensees to modify their procedures for training, scheduling and monitoring work hours, granting authorization, and conducting onsite testing; requires offsite laboratories used by licensees and C/Vs to comply with HHS guidelines, perform additional testing in specific circumstances, and comply with certain procedures intended to protect the rights of tested individuals; and ensures that persons who are impaired and/or are using illegal drugs do not perform safety or security functions at a nuclear facility. Detailed discussions of what activities and procedural changes are required by the Part 26 rule are set forth in this analysis and the statement of considerations of the final Part 26 rule.

(iii) *Potential change in the risk to the public from the accidental offsite release of radioactive material or hazardous chemicals produced from licensed material.*

The rulemaking is intended to provide added assurance that the risk of offsite releases, of either radioactive material or hazardous chemicals produced from licensed materials, as a result of cognitive impairment from fatigue or the use of legal and illegal drugs is acceptably low and consistent with the NRC's Safety Goals. However, the reduction in risk to the public from offsite releases of radioactive materials and hazardous chemicals has not been fully quantified because there is insufficient information and modeling to support such quantification (see Section 3.2).

(iv) *Potential impact on facility employees from radiological exposure or exposure to hazardous chemicals produced from licensed material.*

The rulemaking provides added assurance that nuclear industry workers are not subjected to unnecessary radiological or hazardous chemical exposures either directly as the result of cognitive impairment (*e.g*., where a worker receives an exposure which is greater than expected because of impairment while performing a work function), or because cognitive impairment causes an accident leading to a release of radiation or hazardous chemicals produced from licensed material, which workers then are exposed to as the result of mitigative and/or clean-up activities.

(v) *Installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay*.

Part 26 is primarily programmatic in nature and does not involve changes to the licensed facility itself; hence there are no installation or direct downtime costs associated with implementing this rule. The regulatory analysis for the Part 26 rule sets forth the NRC's estimate of the initial costs for implementing the major elements of the final Part 26 rule, and the ongoing costs and savings to the licensees. The estimated one-time industry net cost of this rule is approximately $13.7 million (or $0.5 million for the average program), and the annually recurring cost is slightly more than $31.7 million (or $1.2 million for the average program). Combining these initial and annual costs, this analysis estimates that the final Part 26 rule will cost industry approximately $444 million (present value, assuming a 7-percent discount rate) to $694 million (present value, assuming a 3-percent discount rate).

(vi) *The potential safety impact of changes in plant or operational complexity, including the relationship to final and former regulatory requirements.*

The final Part 26 rule makes no change with respect to the design of a nuclear power plant or other facility. Therefore, this rule is not expected to have any effect on facility complexity.

The final rule also does not affect the direct procedures for operating the plant. For example, the duties of operators are not affected by the rule, although the number of hours that any given operator works each week may be affected. Rather, the changes to Part 26 in the final rule are directed at ancillary procedures and supporting administrative organization associated with operating the plant. The final rule requires modified work schedules, additional testing (*e.g.*, employees who are offsite when selected for testing), and changes to Part 26 program procedures to ensure greater integrity of tests and to reduce tampering of specimens and subversion of tests. These "costs" in terms of increased complexity in FFD procedures are discussed in this Part 26 regulatory analysis, which indicates that the added FFD program complexity is not significant and will not substantially impact licensees' operational practices or result in substantial indirect costs.

(vii) *The estimated resource burden on the NRC associated with the backfit and the availability of such resources.*

The rulemaking does not result in a substantial increase in expenditures of agency resources, as the NRC is already inspecting licensees' implementation of FFD programs required by Part 26, and the final Part 26 rule does not substantially expand the FFD activities formerly required under Part 26 for which NRC oversight is needed. The regulatory analysis estimates an annual cost to NRC of $47,000.

(viii) *The potential impact of differences in facility type, design or age on the relevancy and practicality of the backfit.*

The final requirements for FFD in Part 26 do not relate to, and are independent of, the facility type, design or age. Therefore, the benefits and costs attributable to the final Part 26 rule do not vary based upon the facility type, design or age.

(ix) *Whether the backfit is interim or final and, if interim, the justification for imposing the backfit on an interim basis.*

The backfit, when implemented at the final rule stage, is final.

The NRC finds that the backfits contained in the Part 26 rule, when considered in the aggregate, constitute a substantial increase in protection to public health and safety and security, by addressing the following seven key areas that have been identified by the Staff as posing recurring and, in some cases, significant problems with respect to the effectiveness, integrity, and efficiency of FFD programs at nuclear facilities.

(i) High potential for worker fatigue

Although all power reactor licensees have implemented work hour controls, these controls vary considerably across licensees due in part to differing interpretations of NRC guidance. NRC has found that some licensees authorized hundreds to several thousand deviations from current work hour limits, resulting in substantial overtime hours for workers. The use of 12-hour shifts, including 6 or more consecutive 12-hour shifts per week during outages, is very common. (The average refueling outage lasts 39 days.) These and other factors, discussed in Section 4.1.3 of the regulatory analysis, contribute to a high potential for worker fatigue and degradation of worker fitness for duty at power reactors. For example, there have been instances of operators falling asleep in the control rooms at a nuclear power station and at a test and research reactor, as well as a security officer falling asleep at a nuclear power plant while driving a patrol vehicle, despite these individuals recognizing the potential safety and disciplinary consequences. Since September 11, 2001, the NRC has received reports of nuclear security officers found asleep while on duty. In addition, the NRC received numerous allegations from nuclear security officers that certain licensees have required them to work excessive amounts of overtime over long periods due to the post-September 11 threat environment. The NRC believes that the final rule's work hour controls will reduce the potential for worker fatigue, and that other provisions will increase the likelihood that workers experiencing fatigue (from any

cause) are removed from duty. Considering the importance of reliable human performance to the safe operation of nuclear power plants, the NRC concludes that these protections constitute a substantial increase in protection to public health and safety, and contribute to Goal 2 for the rulemaking. (Subpart I does not apply to the materials licensees who are otherwise subject to Part 26 because there is no evidence of excessive overtime use by these materials licensees.)

(ii) Subversion of the detection/testing process

The NRC's intent when it first adopted Part 26 was that FFD programs have a high degree of effectiveness such that nuclear facilities would be essentially "drug-free" (54 FR 24468; June 7, 1989). To that end, the former Part 26 rule contains several provisions aimed at preventing subversion. However, subversion techniques have evolved and grown more sophisticated since the adoption of the anti-subversion provisions of the 1989 rule. The NRC believes that the adoption of the anti-subversion provisions in the final Part 26 rule serve to keep pace with the evolution of subversion techniques, thereby maintaining the level of effectiveness that the Commission originally intended when it adopted the 1989 Part 26 rule. Accordingly, the NRC concludes that provisions in the final Part 26 rule aimed at preventing subversion constitute a substantial increase in protection to public health and safety, and contribute to Goals 1 and 3 for the rulemaking.

(iii) Regulatory efficiency

The 1989 Part 26 rule requirements were based upon, and keyed to, the drug testing provisions in the HHS Guidelines. HHS, as the lead Federal agency for the development of FFD programs and drug testing requirements, has periodically revised its guidelines based upon its review and experience with both Federal and private-sector FFD and drug testing programs. The NRC believes that there is substantial benefit to conforming its regulations to the most recent HHS Guidelines, taking into account the unique characteristics of the nuclear industry which may warrant departures from specific aspects of the HHS Guidelines. As the Commission stated in its June 30, 1993, SRM, conformance with national standards may be a basis for finding substantial increase in protection. In view of the nature of the HHS Guidelines, the NRC believes that the FFD changes to conform Part 26 to the HHS Guidelines do represent such an instance, and contribute to Goal 1 for the rulemaking.

(iv) Ineffective/unnecessary Part 26 requirements

A significant number of the final Part 26 rule's changes remove requirements from Part 26 which implementation experience shows are either unnecessary or ineffective in achieving the intended objective of the requirement. Removing such requirements simplifies the FFD program and permits licensees to focus their attention on Part 26 requirements that have a more direct impact on FFD program effectiveness. Accordingly, the NRC regards these provisions as providing a substantial increase in protection to public health and safety, and contributing to Goals 3 and 5 for the rulemaking.

(v) Ambiguous or imprecise regulatory language in Part 26

A substantial number of provisions in the final Part 26 rule are intended to clarify former Part 26 requirements and other NRC guidance that use ambiguous or imprecise language. These changes are based upon the NRC Staff's experience with the implementation of Part 26 and fatigue management, which has included situations where the licensee's interpretation resulted in increased work hour deviations, increased opportunities for subversion, decreased assurance of FFD test integrity, and ineffective corrective action in response to confirmed positive results. Utilizing more precise regulatory language should result in a higher level of performance by licensees or other entities and provide a clear regulatory basis for enforcement action against licensees or other entities who fail to meet the clarified regulatory requirements. Accordingly, the NRC concludes that these provisions, which are intended to correct the deficiencies attributable to ambiguous or imprecise regulatory language, provide a substantial increase in protection, and contribute to Goal 6 for the rulemaking.

(vi) Technical developments resulting in higher levels of effectiveness

A number of the final Part 26 rule provisions are intended to reflect the technological improvements in testing methodologies, which improve the capability to identify specific drug metabolites and isomers indicative of illegal drugs and which have increased sensitivity permitting detection at lower levels. Such improvements can reduce false positives, thereby reducing the adverse effects to individuals, and they can reduce licensee resources currently expended on validating false positives. The improvements also have the capability to reduce false negatives, thus providing greater assurance that persons who have reduced cognitive functions due to illegal drug use are detected and prevented from performing safety-related work. There also is greater assurance that those who are less trustworthy and reliable, on average (as evidenced by drug and alcohol abuse) do not have access to the protected area and, therefore, do not pose a safeguards or security risk. The NRC concludes that these provisions constitute a substantial increase in protection to public health and safety, and contribute to Goals 1, 3, and 4 for the rulemaking.

(vii) Part 26 program integrity and protection of individual rights

Several of the final Part 26 rule provisions are intended to ensure that the FFD program requirements are implemented fairly by the licensee, and that individuals with significant responsibilities are not inappropriately influenced when performing their duties. Other provisions are intended to protect the rights of tested workers by providing a fair opportunity to address any findings of illegal drug use. The NRC concludes that these changes, when considered collectively, provide a substantial increase in protection to public health and safety, and contribute to Goal 7 for the rulemaking. A successful FFD program, and more generally a positive regulatory environment, depends in part upon the perception of workers at nuclear facilities that the NRC's regulatory requirements and their implementation by licensees are fair and appropriate. Workers who do not believe that NRC requirements are fair may be less likely to regard other NRC

requirements, or licensee procedures which implement NRC requirements, as justified and may be more likely to disregard them.

These key areas, and the manner in which specific Part 26 rule provisions address these areas and issues, are discussed in detail in the Statement of Considerations of the final Part 26 rule.

In light of the findings above, the NRC submits that the qualitative safety benefits of the final Part 26 rule provisions that qualify as backfits, considered in the aggregate, constitute a substantial increase in protection to public health and safety and the common defense and security, and that the costs of this rule are justified in view of the increase in protection to safety and security provided by the backfits embodied in the final rule.

4.4.2 Screening Review for Disaggregation

This section presents a screening analysis conducted to ensure that the aggregate analysis does not mask the inclusion of individual rule provisions that are not cost-beneficial when considered individually and not necessary to meet the goals of the rulemaking. This analysis has been conducted in accordance with direction provided in the Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG/BR-0058, Revision 4.

The NRC conducted a two-step screening review to determine whether any final rule provisions should be evaluated on a disaggregated basis before including it in the overall rule.

In the first step of the screening review, the NRC identified all individual Part 26 rule changes that qualify as backfits where the total present value cost to industry is expected to reach or exceed approximately $50,000 per program (assuming a 7-percent discount rate), and/or where total initial industry costs are estimated to reach or exceed approximately $1,000,000. This step is necessary due to the large number of changes contained in this particular rulemaking. The threshold levels have been selected to be relatively inclusive (i.e., conservatively low) in recognition of the differing opinions expressed on various provisions during extensive stakeholder involvement. The $50,000 threshold also corresponds roughly to the cost of paying one worker for one year. The Staff believes the $1,000,000 threshold is a reasonable figure to consider significant for one-time costs to industry as a whole. Exhibit 4-17 presents the rule provisions identified in this initial step.

Exhibit 4-17
Identification of Requirements to Analyze Individually

Individual Requirement	Per Program Total Cost > $50,000 (Present Value)	Initial Cost to Industry > $1,000,000
26.27(a) Policy and Procedure Revisions - Overall Program	No	$974,444
26.29(b) Comprehensive Examination	$55,325	No
26.105(b) Inspecting Contents of Donor's Pockets	$168,105	No
26.131(b) Onsite Lab Initial Validity Tests	$207,706	No

Individual Requirement	Per Program Total Cost > $50,000 (Present Value)	Initial Cost to Industry > $1,000,000
26.137(e)(6) Quality Control Specimens in Each Analytical Run - Onsite Testing Facilities	$54,052	No
26.161(b)(1) HHS Lab Validity Testing	$173,356	No
26.189(c) Face-to-Face Determinations of Fitness	$61,692	No
26.203(a)-(b) Fatigue Policy and Procedures	No	$910,664
26.203(c) Training and Examinations for Fatigue	$1,886,662	$7,248,837
26.203(f) Fatigue Management Audits	$55,455	No
26.205(b) Calculating Work Hours	$597,050	$3,250,000
26.205(c) Work Hour Scheduling	$1,192,520	No
26.205(d)(4)-(6) Day-off Requirements	$8,437,945	No
26.207 Waivers from Individual Work Hour Limits	$8,191,100	No
26.211(a)-(d) Fatigue Assessments	$124,554	No
26.211(e) Post- Assessment Controls and Conditions	$281,519	No

In the second step of the screening review, the NRC determined whether each of the provisions identified in Exhibit 4-17 is necessary to meet one or more of the stated goals of the rule, as listed below (and discussed in additional detail in the Federal Register notice accompanying the final rule):

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

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

3. Improve the effectiveness and efficiency of FFD programs.

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

5. Improve 10 CFR Part 26 by eliminating or modifying unnecessary requirements.

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

7. Protect the privacy rights and other rights (including due process) of individuals who are subject to 10 CFR Part 26.

The results of the second step of the screening review, which are discussed in the remainder of this section and summarized in Exhibit 4-18, show that all of the individual requirements identified in the first step of the review are necessary to meet one or more goals of the rulemaking. Consequently, it is not necessary to evaluate any of the requirements independently to determine whether they are cost-justified on a stand-alone basis.

[The NRC is aware of some stakeholder comments arguing that provisions related to the second goal of the rulemaking, which relates to fatigue management, should be as a separate rulemaking. Inclusion of fatigue management within the current rulemaking, however, is consistent with the NRC's former rule, which in §26.20(a) explicitly identifies fatigue as a factor that could affect fitness for duty and that should be addressed by FFD programs. It also is consistent with the NRC's long-held policy, stated in 1982 in Generic Letter 82-12, that seeks to "prevent situations where fatigue could reduce the ability of operating personnel to keep the reactor in a safe condition." Nevertheless, in response to these stakeholder comments, the NRC has evaluated the costs and savings of the final rule's fatigue management provisions considered as a discrete set of requirements. This evaluation is presented in Section 4.1.4 of this regulatory analysis.]

Exhibit 4-18
Relationship of Individual "Step 1" Requirements to the Goals of the Rulemaking

Individual Requirement	Necessary to Rulemaking?
26.27(a) Policy and Procedure Revisions - Overall Program	Yes, necessary for goal 3
26.29(b) Comprehensive Examination	Yes, necessary for goals 3 and 5
26.105(b) Inspecting Contents of Donor's Pockets	Yes, necessary for goals 1 and 3
26.131(b) Onsite Lab Initial Validity Tests	Yes, necessary for goals 1 and 3
26.137(e)(6) Quality Control Specimens in Each Analytical Run - Onsite Testing Facilities	Yes, necessary for goal 3
26.161(b)(1) HHS Lab Validity Testing	Yes, necessary for goals 1 and 3
26.189(c) Face-to-Face Determinations of Fitness	Yes, necessary for goal 3
26.203(a)-(b) Fatigue Policy and Procedures	Yes, necessary for goals 2 and 3
26.203(c) Training and Examinations for Fatigue	Yes, necessary for goals 2 and 3
26.203(f) Fatigue Management Audits	Yes, necessary for goal 2
26.205(b) Calculating Work Hours	Yes, necessary for goals 2 and 3
26.205(c) Work Hour Scheduling	Yes, necessary for goal 2
26.205(d)(4)-(6) Day-off Requirements	Yes, necessary for goal 2

Individual Requirement	Necessary to Rulemaking?
26.207 Waivers from Individual Work Hour Limits	Yes, necessary for goal 2
26.211(a)-(d) Fatigue Assessments	Yes, necessary for goal 2
26.211(e) Post- Assessment Controls and Conditions	Yes, necessary for goal 2 and 7

§26.27(a), Policy and Procedure Revisions - Overall Program, is necessary for improving the effectiveness and efficiency of FFD programs (Goal 3). Clearly written FFD policy and procedures will make the programs more effective by ensuring that individuals subject to the rule know what is expected of them and what consequences may result from a lack of adherence to the policy and procedures. Development of the policy and procedures by management, and implementation of procedural controls within the facilities, are necessary to ensure that licensees' FFD management programs are properly and consistently implemented, and to avoid potential impacts on public health and safety and security if individuals are not fit to perform work safely. In addition, written policies and procedures will help to make adherence to the policy and procedures easier and more efficient for individuals who move from program to program.

§26.29(b), Comprehensive Examination, is necessary for ensuring the effectiveness and efficiency of FFD programs (Goal 3). By establishing a method to ensure that individuals understand the requirements with which they must comply (including remedial training for individuals that fail the comprehensive examination), the rule will make the programs more effective by ensuring that the FFD training has been effective. §26.29(b) 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 that relates to improving the efficiency of FFD programs. The permission also meets Goal 5 to improve Part 26 by eliminating or modifying unnecessary requirements, by providing flexibility in the methods that licensees and other entities may use to administer the required examination.

§26.105(b), Inspecting Contents of Donor's Pockets, is necessary for updating and enhancing the consistency of 10 CFR Part 26 with advances in other relevant federal rules and guidelines, including the U.S. Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines) and other Federal drug and alcohol testing programs (e.g., those required by the U.S. Department of Transportation [DOT]) that impose similar requirements on the private sector (Goal 1). Similar to this section of the final rule, DOT drug testing regulations require that a donor is asked to empty his or her pockets and display the items in them so the collector can identify items that the donor could use to adulterate or substitute his or her urine. This section is necessary to enhance the consistency of urine collection procedures in 10 CFR Part 26 with other relevant federal rules.

§26.105(b) also is necessary for improving the effectiveness and efficiency of FFD programs (Goal 3). Because collectors are required to ask the donor to empty his or her pockets, this section is necessary to provide assurance that the donor is not able to subvert the drug testing process. As a result, this section is necessary to improve the effectiveness and efficiency of FFD programs.

§26.131(b), Onsite Lab Initial Validity Tests, is necessary for updating and enhancing 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 DOT) that impose similar requirements on the private sector (Goal 1). Current HHS Guidelines contain requirements regarding initial validity tests and criteria for determining whether a specimen must be forwarded to the HHS-certified laboratory for further validity testing. This section adds similar requirements relative to testing each urine specimen for its creatinine concentration, pH, and the presence of one or more oxidizing adulterants, such as nitrite or bleach. This section is necessary because it harmonizes a licensee's initial validity testing procedures with HHS Guidelines. As a result, this section is necessary to enhance the consistency of 10 CFR Part 26 with other relevant federal rules.

§26.131(b) also is necessary for improving the effectiveness and efficiency of FFD programs (Goal 3). Because FFD programs are not permitted to establish more stringent cutoff levels for validity screening and initial validity testing, this section is necessary to decrease the risk of obtaining false positive test results and ensures that donors are not subject to sanctions on the basis of inaccurate test results. As a result, this section is necessary to improve the effectiveness and efficiency of FFD programs.

§26.137(e)(6) Quality Control Specimens in Each Analytical Run - Onsite Testing Facilities, is necessary for improving the effectiveness of FFD programs (Goal 3). The final rule applies requirements for quality controls to licensee testing facilities to provide greater assurance that the results of initial drug tests performed by these facilities are accurate. The increased performance testing is 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.

§26.161(b)(1), HHS Lab Validity Testing, is necessary for updating and enhancing 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 DOT) that impose similar requirements on the private sector (Goal 1). Current HHS Guidelines contain requirements regarding methods for conducting specimen validity testing at HHS-certified laboratories. This section adds similar requirements relative to HHS-certified laboratory testing requirements for validity tests. As a result, this section is necessary to enhance the consistency of 10 CFR Part 26 with other relevant federal rules.

§26.161(b)(1) also is necessary for improving the effectiveness and efficiency of FFD programs (Goal 3). Because HHS-certified laboratories are required to conduct initial validity tests, this section is necessary to decrease the risk of obtaining false positive test results and ensures that donors are not subject to sanctions on the basis of inaccurate test results. As a result, this section is necessary to improve the effectiveness and efficiency of FFD programs.

§26.189(c), Face-to-Face Determinations of Fitness, is necessary for improving the effectiveness and efficiency of FFD programs (Goal 3). Establishing requirements for face-to-face determinations of fitness will ensure that the professional who is performing the determination has available all of the sensory information that may be required for the assessment, such as the smell of alcohol or the individual's physical appearance. As a result, the effectiveness and efficiency of these determinations of fitness will be enhanced.

§§26.203(a)-(b), Fatigue Policy and Procedures, are necessary for strengthening the effectiveness of FFD programs by establishing clear and enforceable requirements concerning the management of fatigue (Goal 2). Requiring each licensee to develop a written policy statement that describes management's expectations and methods for managing fatigue, and requiring licensees to incorporate their fatigue management policy statement into written FFD policies and procedures will help to ensure that fatigue does not adversely affect individuals' abilities to safely and competently perform their duties. 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, indicates that there is a need for individuals to clearly understand their fatigue management responsibilities and those of the licensee. These requirements will ensure that there is a written record of how each FFD program subject to Subpart I meets the objectives and requirements of Part 26, Subpart I, and also a record of any allowable variations in the program. Clearly written fatigue policy and procedures will make the programs more effective by ensuring that individuals subject to the rule know what is expected of them and what consequences may result from a lack of adherence to the policy and procedures. In addition, because some licensees may choose to impose sanctions on individuals for failing to comply with the fatigue management policy or procedures, communication of the policy and its sanctions is necessary in order to protect individuals' rights to due process under the rule. Development of the policy and procedures by management and implementation of procedural controls within the plant are both necessary to ensure that licensees' fatigue management programs are properly and consistently implemented to avoid potential impacts on public health and safety and national security if individuals are too fatigued to perform work safely.

§§26.203(a)-(b) also are necessary for improving the effectiveness and efficiency of FFD programs generally (Goal 3). Written policies and procedures will help to make adherence to the policy and procedures easier and more efficient for individuals who move from program to program.

§26.203(c), Training and Examinations for Fatigue, is necessary for strengthening the effectiveness of FFD programs by establishing clear and enforceable requirements concerning the management of fatigue (Goal 2). Training will provide nuclear plant workers with knowledge of specific, fatigue-related topics that will 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 (knowledge and abilities) without training. Training and examinations are the most effective and efficient means of ensuring that all individuals assigned to duties within the scope of Part 26, Subpart I, have the KAs necessary to detect conditions that arise from fatigue, know the personal and public health and safety hazards associated with fatigue, know the proper actions to be initiated to respond to those hazards, and understand their roles and responsibilities in the implementation of the FFD program as it addresses fatigue. Training will ensure that individuals are able to: (1) self-manage fatigue that is due to causes 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. This knowledge will also allow workers to make use of the provision for worker self-declarations of fatigue and the provision for for-cause fatigue assessments when workers exhibit symptoms of fatigue to managers or co-workers. The training, self-declaration, and fatigue assessment provisions will help ensure that individual variations in susceptibility to fatigue, arising from physiology, personal obligations, or life style, will be addressed outside and in addition to the individual work hour limits in the final rule. The

training provision will help avoid potential adverse consequences being caused by workers who, for whatever reason, are affected by fatigue irrespective of the other provisions of Subpart I.

§26.203(c) also is necessary for improving the effectiveness and efficiency of FFD programs generally (Goal 3). Training in specified KAs will help to make FFD programs more consistent from licensee to licensee, thereby making adherence to the policy and procedures easier and more efficient for individuals who move from program to program.

§26.203(f) Fatigue Management Audits, is necessary to strengthen the effectiveness of FFD programs by establishing clear and enforceable requirements for the management worker fatigue (Goal 2). Including the requirement for fatigue management audits is necessary to establish a method to ensure that a licensee or other entity's overall fatigue management program complies with the requirements in Part 26. The fatigue management audits will evaluate the effectiveness of a licensee or other entity's fatigue management program. The audits will identify program deficiencies that licensees and other entities must strengthen. Without such audits, FFD programs may not be as effective as possible due to weak fatigue management program elements. Therefore, §26.203(f) is necessary to strengthen the effectiveness of FFD programs through enforceable worker fatigue requirements.

§26.205(b), Calculating Work Hours, is necessary for strengthening the effectiveness of FFD programs by establishing clear and enforceable requirements concerning the management of fatigue (Goal 2). A consistent method of calculating work hours is a key component of any fatigue-management program, necessary to ensure that other program components are implemented effectively. Because under the NRC's Policy on Worker Fatigue, the concept of "work hours" was not defined and criteria for calculating work hours were not established, licensees have been inconsistent in defining and calculating work hours when implementing the Policy through their technical specifications and administrative procedures. Proper implementation of individual hour requirements established in §26.205(b), (c), and (d), is not possible in the absence of accurate calculation of work hours. This provision therefore is necessary to ensure that the safety benefits and other benefits of the work hours requirements are achieved. The final rule defines work hours and requirements for calculating them to ensure consistent and accurate implementation of the work hour controls.

§26.205(b) also is necessary for improving the effectiveness and efficiency of FFD programs generally (Goal 3). The provision will help to make FFD programs more consistent from licensee to licensee, thereby enabling the NRC to focus its inspection resources more efficiently.

§26.205(c), Work Hour Scheduling, is necessary for strengthening the effectiveness of FFD programs by establishing clear and enforceable requirements concerning the management of fatigue (Goal 2). This provision complements other fatigue-management provisions, including limits on individual waivers of work hour controls and requirements for breaks and days off at specified frequencies. Because human alertness and the propensity to sleep vary markedly through the course of a 24-hour period, as a consequence of circadian physiological rhythms that are outside the control of the individual, work scheduling (i.e., the sequencing of day, evening, and night shifts and the use of break periods between these shifts) can either optimize the ability of personnel to obtain adequate sleep and effectively transition from one shift to another, or challenge the individual's ability to get adequate rest. The duration of shifts, the number of consecutive shifts, the duration of breaks between blocks of shifts, and the direction of shift rotation, particularly for personnel who work rotating shifts, are critical elements of fatigue management. This section requires licensees to schedule the work hours of individuals in a

manner that is consistent with the objective of preventing impairment from fatigue and consequent safety-related risks due to the duration, frequency, or sequencing of successive shifts. This requirement provides a benefit separate from the maximum work hour and minimum break and days-off requirements that are specified in§26.205(d), which are intended for infrequent, temporary circumstances, and not as guidelines or limits for routine work scheduling. In addition, §26.205(d) does not address several elements of routine schedules that can significantly affect worker fatigue, such as shift length. Although §26.205(c) requires licensees to schedule personnel consistent with preventing impairment from fatigue from these scheduling factors, the NRC 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.

§26.205(d)(4)-(6), Individual Days-Off, is necessary for strengthening the effectiveness of FFD programs by establishing clear and enforceable requirements concerning the management of fatigue (Goal 2). The day-off provisions for outage periods are key components of fatigue management, because they require licensees to provide adequate days off for individuals who are performing the duties listed in §26.205(a). The day-off requirements help both to prevent and mitigate cumulative sleep debt, by providing opportunities for mitigative sleep and also provide time that individuals need to meet the many daily living obligations that they cannot otherwise readily meet (although due to individual variations in susceptibility to cumulative fatigue, arising from physiology, personal obligations, or life style, the other individual work hour controls and work scheduling provisions contained in Subpart I also are necessary). Without such 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, which will result in impairment on the job. These provisions therefore are necessary components of the FFD fatigue management program.

§26.207, Waiver of Individual Work Hour Controls, is necessary for strengthening the effectiveness of FFD programs by establishing clear and enforceable requirements concerning the management of fatigue (Goal 2). The section provides for limited use of waivers allowing individuals to exceed the individual work hour limits. The waiver must be justified by circumstances in which compliance with the work hour controls could have immediate adverse consequences for the protection of public health and safety or the common defense and security. The provision specifies that an operations shift manager must determine that the waiver is necessary to mitigate or prevent a condition adverse to safety, or a security shift manager must determine that the waiver is necessary to maintain the security of the facility, or a site senior-level manager with requisite signature authority must make either determination. This provision will ensure that waivers of individual work hour controls are not used inappropriately. NRC's reviews of industry work scheduling practices during outages and of records of deviations from technical specification work hour controls indicated that previously the most common deviation was to permit individuals to work more than 72 hours in 7 days, frequently by working more than six consecutive 12-hour days, and that this practice was used extensively at a number of sites.[23] Some licensees were scheduling outages with several weeks of 12-hour shifts with no scheduled days off. The NRC's Policy on Worker Fatigue recognized that "very unusual circumstances may arise requiring deviation from the [work hour] guidelines." However, in SECY-01-0113, the NRC noted that the frequency of guideline deviations at a substantial proportion of sites appeared to

[23] As part of the NRC's rulemaking development efforts, the NRC reviewed information submitted voluntarily by six nuclear power plants in 2004.

be inconsistent with the intent of the policy. The criteria for granting waivers from the individual work hour controls in §26.205(d) are expected to significantly reduce the granting of waivers for work schedules that exceed the individual work hour limits. Such waivers are justified only for limited circumstances in which compliance with the work hour controls could have immediate adverse consequences for the protection of public health and safety or the common defense and security. The provision is intended to ensure that licensees grant waivers only to address circumstances that the licensee could not have reasonably controlled. This provision therefore is consistent with the objective of preventing impairment from fatigue and consequent safety-related risks due to the duration, frequency, or sequencing of work. This requirement supports the maximum work hour and minimum break and day-off requirements that are specified in §26.205(d) by limiting the circumstances in which the work hour provisions may be waived to conditions in which granting a waiver is consistent with maintaining safety.

§§26.211, Fatigue Assessments, is necessary for strengthening the effectiveness of FFD programs by establishing clear and enforceable requirements concerning the management of fatigue (Goal 2). By providing that fatigue assessments should be performed for cause, after a self-declaration, after an event that requires post-event drug and alcohol testing, as a followup to returning an individual to work after a self-declaration, and as a followup to a plant event that requires drug or alcohol testing, the provision will help to ensure that 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 are evaluated to determine whether they can, in fact, safely and competently perform their duties Fatigue assessments provide a necessary complement to work hour controls. Appropriately assessing fatigue is important because workers who are experiencing either acute or cumulative fatigue may not be able to perform their duties safely and competently. 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). In addition, there are substantial individual differences in the ability of individuals to work for extended periods without performance degradation from fatigue. Therefore, the work hours controls of §26.205 provide only partial assurance that individuals are not fatigued. The objective of the fatigue assessments is for licensees to appropriately identify and address instances of worker fatigue, including those that are not prevented by the work hour controls, regardless of the number of hours the individual has worked or rested. §26.211(b) and (c) specify who may perform the assessment, and the factors that must be addressed. Ensuring that the assessments are conducted by appropriate persons and cover appropriate topics is essential because, following a finding of fatigue, licensees are required by §26.211(e) to determine and implement the controls and conditions that are necessary if the individual who was the subject of the assessment is to resume performing duties for the licensee. Fatigue assessments are important for effective fatigue management because they provide the basis for fatigue management actions that may be necessary to address individual or programmatic issues contributing to recurring instances of fatigue.

§26.211(e), Post-Assessment Controls and Conditions, is necessary for strengthening the effectiveness of FFD programs by establishing clear and enforceable requirements concerning the management of fatigue (Goal 2). The fatigue assessments provide the basis for licensees to appropriately address instances of worker fatigue, including those that are not prevented by the work hour controls, regardless of the number of hours that the subject individual has worked or rested. Licensee actions for fatigue management could include either short-term corrective actions necessary to ensure that individuals are able to safely and competently perform their duties or long-term corrective actions that may be necessary to address issues contributing to recurring instances of fatigue.

§26.211(e) also is necessary for the protection of the privacy rights and other rights (including due process) of individuals who are subject to 10 CFR Part 26 (Goal 7). Because the corrective actions following a fatigue assessment could include relieving an individual of duties, this section is necessary to provide assurance that fatigue assessments include sufficient and appropriate information to support a valid assessment of the individual relative to fatigue and therefore an appropriate basis for management decisions and actions and protection of the privacy rights and other rights (including due process) of individuals who are subject to 10 CFR Part 26.

4.5 Safety Goal Evaluation

Safety goal evaluations are applicable only to regulatory initiatives considered to be generic safety enhancement backfits subject to the substantial additional protection standard at 10 CFR 50.109(a)(3).[24] The current rulemaking provides added assurance that individuals working at nuclear facilities are fit for duty and, consequently, the rule reduces safety and security risks ranging from workplace safety incidents up to radiological damage to the reactor core. The requirements may qualify, therefore, as generic safety enhancements because they may affect the likelihood of core damage, which generally is the focus of a quantitative safety goal evaluation. However, the magnitude of this change is not readily quantifiable due to uncertainties discussed in Section 3.2 of this analysis. A more dominant effect of the rule is to reduce the probability of other types of accidents and damages associated with a wide array of acts related to drug and alcohol abuse and fatigue, although this effect is equally difficult to quantify. Because the change in safety associated with the rulemaking cannot be quantified, the regulatory changes cannot be compared to the NRC's safety goals.

Certain aspects of the current rulemaking qualify as relaxations of requirements because they result in incrementally fewer activities needed to achieve the same goals. However, relaxations of requirements affecting nuclear power plants are not subject to safety goal evaluation. Therefore, no safety goal evaluation is needed for these requirements.

4.6 CRGR Results

This section addresses regulatory analysis information requirements for rulemaking actions or staff positions subject to review by the Committee to Review Generic Requirements (CRGR). All information called for by the CRGR is presented in this regulatory analysis, or in the Federal Register Notice for the final Part 26 rule. As a reference aid, Exhibit 4-19 provides a cross-reference between the relevant information and its location in this document or the Federal Register Notice.

[24] A safety goal evaluation is not needed, therefore, for new requirements falling within the backfit exceptions of 10 CFR 50.109(a)(4)(i)-(iii).

Exhibit 4-19
Specific CRGR Regulatory Analysis Information Requirements

CRGR Charter Citation	Information Item to be Included in a Regulatory Analysis Prepared for CRGR Review	Where Item is Discussed
IV.B(1)	Proposed generic requirement or staff position as it is proposed to be sent out to licensees. When the objective or intended result of a proposed generic requirement or staff position can be achieved by setting a readily quantifiable standard that has an unambiguous relationship to a readily measurable quantity and is enforceable, the proposed requirements should specify the objective or result to be attained rather than prescribing how the objective or result is to be attained.	Final rule text in Section XVII of the Federal Register Notice.
IV.B(iii)	The sponsoring office's position on whether the proposed action would increase requirements or staff positions, implement existing requirements or staff positions, or relax or reduce existing requirements or staff positions.	Regulatory Analysis, Section 4.1.
IV.B(iv)	The proposed method of implementation.	Regulatory Analysis, Section 6.
IV.B(vi)	Identification of the category of power reactors or nuclear materials facilities/activities to which the generic requirement or staff position will apply.	Regulatory Analysis, Section 3.2.2.
IV.B(vii) IV.B(viii)	If the proposed action involves a power reactor backfit and the exceptions at 10 CFR 50.109(a)(4) are not applicable, the items required at 10 CFR 50.109(c) and the required rationale at 10 CFR 50.109(a)(3) are to be included.	Regulatory Analysis, Section 4.4.
IV.B(x)	For proposed relaxations or decreases in current requirements or staff positions, a rationale is to be included for the determination that (a) the public health and safety and the common defense and security would be adequately protected if the proposed reduction in requirements or positions were implemented, and (b) the cost savings attributed to the action would be substantial enough to justify taking the action.	Section VI, "Section-by-Section Analysis of Substantive Changes," in the Federal Register Notice for the final rule.
IV.B(xii)	Preparation of an assessment of how the proposed action relates to the Commission's Safety Goal Policy Statement.	Regulatory Analysis, Section 4.5.

Exhibit has been adapted from NUREG/BR-0184, Table 2.3.

5. DECISION RATIONALE

5.1 Regulatory Analysis

Relative to the “no-action” alternative, the final rule results in a net cost estimated as approximately $444.7 million (total present value over a 49-year period), assuming a 7-percent discount rate, or approximately $695.3 million assuming a 3-percent discount rate. All of this cost accrues to industry, except for approximately $665,000 (7 percent) or $1,025,000 (3 percent) that accrues to the NRC. The rule results in one-time industry costs of approximately $13.7 million ($481,600 for the average program), and then generates annual costs of about $31.7 million ($1.2 million per program).

Offsetting this net cost, the NRC believes that the rule results in substantial non-quantified benefits related to safety and security, as well as enhanced regulatory efficiency and effectiveness, public perceptions, and improved workplace productivity and efficiency. These benefits are discussed in Sections 4.1.2 and 4.1.3 of this document. Based on the NRC's assessment of the costs and benefits of the final rule on licensee facilities, the agency has concluded that the final rule provisions is justified.

5.2 Backfit Analysis

The NRC conducted a backfit analysis of the final Part 26 rule relative to the backfit requirements in 10 CFR §50.109, 10 CFR §70.76, and 10 CFR §76.76. The analysis evaluates the aggregation of provisions that constitute backfits under the backfit rules. This analysis estimates that these provisions result in a net cost to industry of $580 million (present value) assuming a 7-percent discount rate, or $908.4 million assuming a 3-percent discount rate. The provisions cost industry about $13.7 million in initial costs and generate about $41.7 million in annual costs. For the average program, this equates to about $481,700 in one-time costs, and about $1.5 million in annual costs. Nevertheless, the NRC concludes that these impacts are justified by the substantial increase in the protection of public health and safety provided by this rule.

The NRC also conducted a screening analysis in accordance with NRC’s Regulatory Analysis Guidelines to ensure that the aggregate analysis does not mask the inclusion of individual rule provisions that are (1) not cost-beneficial when considered individually and (2) not necessary to meet the goals of the rulemaking. As discussed in Section 4.4.2, this review concludes that each of the individual backfit requirements are necessary to meet the goals of the rulemaking.

6. IMPLEMENTATION

This section identifies how and when the final action will be implemented, the required NRC actions to ensure implementation, and the impact on NRC resources.

6.1 Schedule

The action will be enacted through a final rule, with promulgation of the final rule within 30 days from the date of publication. However, licensees and other applicable entities may defer implementation of this rule, except for Subparts I and K, by one year from the date of publication. Subpart I must be implemented by licensees and other applicable entities no later than 18 months from the date of publication. Further, licensees and other applicable entities shall comply with the requirements of Subpart K within 30 days from the date of publication. The staff has not identified any impediments to implementing the recommended alternatives.

6.2 Impact on Other Requirements

As discussed in Section 4.1, affected licensee and C/V FFD programs will experience the principal impact of the revisions to 10 CFR Part 26. The NRC further expects that the revisions will have relatively small impacts on NRC resources, as also discussed in Section 4.1. Since 1982, the NRC has used existing personnel for regulatory activities concerning FFD programs, and the NRC does not anticipate the need to add staff or administrative personnel because current personnel will absorb the administration of the revised rule. Moreover, it is expected that the rule will reduce NRC's annual expenditures associated with implementation of the FFD program.

7. OTHER PROCEDURAL REQUIREMENTS

This final rule affects only licensees who are authorized to operate nuclear power reactors or to possess, use, or transport formula quantities of strategic special nuclear material (SSNM); corporations that obtain certificates of compliance or approved compliance plans involving formula quantities of SSNM; combined operating license holders; mixed oxide fuel fabrication facilities; and construction permit holders who have a plant under active construction. The companies that own these facilities do not fall within the definition of “small entities” set forth in the Regulatory Flexibility Act or the size standards adopted by the NRC on April 11, 1995 (60 FR 1834; 10 CFR 2.810). Therefore, this rule will not have a significant economic impact on a substantial number of small entities, as applicable under the Regulatory Flexibility Act of 1980 [(5 U.S.C. 605(b))].

APPENDIX 1: INCREMENTAL ACTIVITIES AND COST EQUATIONS FOR INDIVIDUAL PROVISIONS OF THE FINAL RULE

This appendix presents a detailed analysis of the incremental activities (including activities that qualify as backfits) required by each individual provision in the final rule. It also specifies the equations that the NRC staff used to estimate any costs or savings resulting from the individual rule provisions.

The appendix contains 15 "subparts" that directly correspond to the 15 subparts of the final Part 26 rulemaking:

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 DHHS

Subpart H: Determining FFD 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

Subpart A: Administrative Provisions

26.1 Purpose

This section of the final rule imposes no cost and affords no saving because it merely simplifies and amends §26.1 of the former rule by removing certain references and provisions that are addressed elsewhere in the rule.

26.3 Scope

Paragraph 26.3 reorganizes and amends §26.2 of the former rule, as discussed below.

Paragraphs 26.3(a) - (c)

These paragraphs of the final rule impose no incremental cost and afford no saving because they merely clarify those licensees who are subject to the rule as already stated in paragraph 26.2(a) of the former rule.

Paragraph 26.3(d)

This paragraph of the final rule imposes no cost and affords no saving because it states that the regulations in this part also apply to contractor vendors (C/Vs) who implement FFD programs or program elements to the extent that the licensees and other entities specified in paragraphs 26.3(a) - (c) rely on those C/V FFD programs or program elements to meet the requirements of this part. C/Vs are already subject to the requirements of the former rule as stated in §26.23 of the former rule.

Paragraph 26.3(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates requirements contained in paragraph 26.2(b) of the former rule that stipulated that the regulations of this part do not apply to those licensees who possess, use, or transport formula quantities of irradiated SSNM.

26.4 FFD Program Applicability to Categories of Individuals

Paragraph 26.4(a)

This paragraph specifies those individuals who are subject to an FFD program that meets all of the requirements of 10 CFR Part 26, except Subpart K. This paragraph of the final rule imposes no incremental cost and affords no saving because it merely restates part of paragraph 26.2(a) of the former rule.

Paragraphs 26.4(b) - (c)

This paragraph specifies those individuals who are subject to an FFD program that meets all of the requirements of 10 CFR Part 26, except § 26.205 and Subpart K. This paragraph of the final rule imposes no incremental cost and affords no saving because it merely restates part of paragraph 26.2(a) of the former rule.

Paragraph 26.4(d)

This paragraph specifies those individuals who are subject to an FFD program that meets all of the requirements of 10 CFR Part 26, except Subparts I and K. This paragraph of the final rule imposes no incremental cost and affords no saving because it merely restates part of paragraph 26.2(a) of the former rule.

Paragraph 26.4(e)

Paragraph 26.4(e) of the final rule clarifies the FFD requirements for any individual whose duties for the licensees and other entities in § 26.3(c) require him or her to perform the following activities when construction activities begin at the location where the nuclear power plant will be constructed and operated: (1) serve as a security officer under NRC requirements; (2) perform quality assurance activities, as specified in Appendix B to part 50; (3) monitor the fitness of individuals specified in paragraph 26.4(f), as designated under section 26.406; or (4) determine that inspections, tests, and analyses, or parts thereof, required under part 52 have been successfully completed. Specifically, these individuals must be subject to an FFD program that meets all of the requirements of 10 CFR Part 26, except Subparts I and K. This paragraph imposes additional requirements relative to paragraph 26.2(c) of the former rule. This analysis, however, assumes that new reactor construction will be co-located with existing reactor sites. The licensees operating the reactors will be the same as those undertaking the construction activities at the co-located site. The analysis assumes that licensees and other entities will include the individuals identified above as part of the FFD program at the co-located operating reactor site. The NRC believes that any additional cost to include these individuals within the scope of the FFD program already being conducted is insignificant relative to the overall costs of the FFD program. Therefore, this analysis does not calculate incremental costs for this requirement of the final rule.

Paragraph 26.4(f)

Paragraph 26.4(f) of the final rule clarifies the FFD requirements for any individual who is constructing safety- or security-related structures, systems, and components (SSCs). Specifically, these individuals must be subject to an FFD program that meets the requirements of Subpart K, 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. This final paragraph imposes no incremental cost and affords no saving because it clarifies paragraph 26.2(c) of the former rule.

Paragraph 26.4(g)

Paragraph 26.4(g) clarifies that FFD program personnel shall be subject to the provisions and policies of the FFD program. Although the language of the former rule did not explicitly state that FFD program personnel were subject to the former rule, this was the Commission's intent. Further, FFD program personnel were required to meet the highest standards for honesty and integrity to ensure that the program yields valid results that are not being subverted (as addressed by Appendix A Section 2.3 of the former rule). Consequently, the revised subparagraph imposes no incremental cost and affords no saving.

Sensitivity Analysis - Industry Practices

Most licensees already subject FFD program personnel to drug and alcohol testing, as well as behavioral observation programs in order to meet the requirements of the former rule. Until recently, however, some licensee practices were inconsistent with the NRC staff's interpretation of the requirements and did not subject their medical review officers (MROs) to the provisions and policies of the FFD program. These licensees will incur additional one-time and annual costs to cover their MROs under their FFD programs in compliance with final regulation. The *one-time cost per program* results from the sum of the following costs:[1]

- One-time costs per program to subject their MROs to pre-access drug and alcohol testing to comply with the final regulation are calculated as follows:

  $NUM_{MROs} \times COST_{Test} \times PER_{Compliance}$

- One-time costs per program to pay for MRO travel to a licensee collection facility to comply with the final regulation are calculated as follows:

  $NUM_{MROs} \times HOURS_{Travel} \times WAGE_{MRO} \times PER_{Compliance}$

[1] The analysis assumes that licensees already test and appropriately train in-house FFD program personnel as required under Appendix A Section 2.3 of the former rule. The analysis also assumes that 25 percent of licensees will each need to address two contracted MROs under their testing and training programs in order to comply with this paragraph.

- One-time costs per program to conduct FFD training and to administer the comprehensive examination on their MROs to comply with final regulation are calculated as follows:

  $NUM_{MROs} \times HOURS_{Training} \times WAGE_{MRO} \times PER_{Compliance}$

Parameter	Description
$COST_{Test}$	Drug and alcohol testing cost per test (as described in Appendix 2, Exhibit A2-13)
$HOURS_{Training}$	Length of FFD program training for MROs (as described in assumptions below)
$HOURS_{Travel}$	Hours of MRO travel, waiting, and specimen collection time (as described in assumptions below)
NUM_{MROs}	Number of MROs per program (as described in assumptions below)
$PER_{Compliance}$	Percentage multiplier to spread compliance costs across all programs (as described in assumptions below)
$WAGE_{MRO}$	MRO wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Number of MROs per program: 2.

- Length of FFD program training for MROs: 2 hours.

- Hours of MRO travel, waiting, and specimen collection time, on average, under the former rule: 6 hours.

- Given their small number, the MROs will be added to existing training sessions and will not require incremental costs of providing additional training sessions.

- The per-unit cost of a pre-access drug and alcohol test for an MRO working for a licensee with *onsite testing facilities* includes the following factors:
  (1) collection of drug and alcohol specimens (labor of the collector only and collection materials)
  (2) onsite licensee testing costs per urine specimen for drugs and validity
  (3) labor of FFD manager to process paperwork for negative test results.

- The per-unit cost of a pre-access drug and alcohol test for an MRO working for a licensee with *offsite testing facilities* includes the following factors:
  (1) collection of drug and alcohol specimens (labor of the collector only and collection materials);
  (2) HHS-certified laboratory costs per urine specimen for drugs and validity
  (3) labor of FFD manager to process paperwork for negative test results.

- No positive drug or alcohol test results are anticipated for the MRO.

- Licensees have estimated that 25 percent of licensees may not interpret the former regulation to require inclusion of the MRO under the FFD program. Because the analysis cannot identify which facilities were interpreting the former rule correctly and which were not, the analysis assumes that each program will incur the incremental cost of 25 percent of the activity ($PER_{Compliance}$).

Annual costs will arise from adding MROs to the random drug and alcohol testing program. The *annual costs per program* result from the sum of the following costs:

- Annual cost per program to administer a random drug and alcohol testing program for FFD program personnel to comply with the final regulation are calculated as follows:

  $$NUM_{MROs} \times PER_{Random} \times COST_{Test} \times PER_{Compliance}$$

- Annual cost per program to pay for MROs selected for random drug and alcohol testing to travel to the specimen collection facility and provide a specimen to comply with the final regulation are calculated as follows:

  $$NUM_{MROs} \times PER_{Random} \times HOURS_{Travel} \times WAGE_{MRO} \times PER_{Compliance}$$

Parameter	**Description**
$COST_{Test}$	Drug and alcohol testing cost per test (as described in Appendix 2, Exhibit A2-13)
$HOURS_{Travel}$	Hours of MRO travel, waiting, and specimen collection time (as described in assumptions below)
NUM_{MROs}	Number of MROs per program (as described in assumptions below)
$PER_{Compliance}$	Percentage multiplier to spread compliance costs across all programs (as described in assumptions below)
PER_{Random}	Percentage tested by a random drug and alcohol testing program per year (as described in assumptions below)
$WAGE_{MRO}$	MRO wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Number of MROs per program: 2.

- Percentage tested by a random drug and alcohol testing program: 50%.

- Hours of MRO travel, waiting, and specimen collection time, on average, under the former rule: 6 hours.

- The per-unit cost of a random drug and alcohol test for an MRO working for a licensee with onsite testing facilities includes the following factors:
  (1) collection of drug and alcohol specimens (labor of the collector only and collection materials)
  (2) onsite licensee testing costs per urine specimen for drugs and validity
  (3) labor of FFD manager to process paperwork for negative test results.

- The per-unit cost of a random drug and alcohol test for an MRO working for a licensee with offsite testing facilities includes the following factors:
  (1) collection of drug and alcohol specimens (labor of the collector only and collection materials)
  (2) HHS-certified laboratory costs per urine specimen for drugs and validity
  (3) labor of FFD manager to process paperwork for negative test results.

- No positive drug or alcohol test results are anticipated for the MRO.

- Licensees have estimated that 25 percent of licensees did not interpret the former regulation to require inclusion of the MRO under the FFD program. Because the analysis cannot identify which facilities were interpreting the former rule correctly and which were not, the analysis assumes that each program will incur the incremental cost of 25 percent of the activity.

Paragraph 26.4(h)

This paragraph of the final rule adds a provision specifying that individuals who have applied for authorization to have the types of access or perform the activities described in paragraphs 26.4(a)-(g) must be subject to the applicable requirements of this part and provided with the applicable protections of this part. The incremental costs and savings from this final paragraph are calculated in their respective sections.

Paragraph 26.4(i)

This paragraph [including subparagraphs (i)(1)-(i)(4)] specifies the individuals who are not subject to an FFD program.

Subparagraph 26.4(i)(1)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely states that persons who are not employed by, nor routinely provide services for, a licensee or other entity, but who may be called on to provide an FFD program service are not covered under the final rule. Some licensees have indicated that their auditors have insisted that local hospitals, treatment facilities, or other facilities providing infrequent FFD program services must be audited annually. Nevertheless, this analysis calculates no savings because the prevalence of such auditing practices is unknown.

Subparagraph 26.4(i)(2)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely restates requirements contained in paragraph 26.2(b) of the former rule, which stated that NRC employees, law enforcement personnel, and offsite emergency fire and medical response personnel responding onsite are not subject to the final rule.

Subparagraph 26.4(i)(3)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely restates requirements contained in paragraph 26.2(b) of the former rule. The final subparagraph states that strategic special nuclear material (SSNM) transporter personnel who are subject to U.S. Department of Transportation drug and alcohol fitness programs that require random testing for drugs and alcohol are not subject to the FFD program.

Subparagraph 26.4(i)(4)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely states that 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 are not subject to the FFD 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. This analysis calculates no saving because the prevalence of such personnel is unknown.

Paragraph 26.4(j)

This paragraph is a new requirement that allows licensee's FFD programs to exclude individuals who are covered by another program that is regulated by a Federal or State agency, provided that the program meets the general performance objectives of the FFD rule, as well as the requirements under subparagraphs 26.4(j)(1)–(5). Licensees need only subject these individuals to those elements of the FFD program that are not included in the other program. 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. This revision will yield annual savings by eliminating the duplication of pre-access testing, training (non-supervisory level training under

the former rule), and comprehensive examinations (including retesting and remedial training for those who fail the comprehensive examinations) for applicants for initial authorization. Savings from being able to forego the suitable inquiry are not calculated because licensees would still be required to verify that the other program provides adequate coverage and complies with the requirements in this part. The provision also will yield an annual savings by eliminating duplicate random drug and alcohol testing coverage for existing employees. Under the final rule, cutoff levels for drugs and drug metabolites are harmonized with other Federal drug testing programs (per §§26.131 and 26.163), which also increases the likelihood that other programs will be acceptable.

The annual savings per program result from the sum of the following savings:

- The *annual savings per program* from bypassing pre-access drug and alcohol testing for the percentage of applicants covered by an acceptable program are calculated as follows:[2]

  - Pre-access drug and alcohol tests need not be performed at *facilities with onsite testing laboratories* for the percentage of applicants who are covered by an acceptable program. The associated savings are estimated as follows:

    $$NUM_{Applicants} \times PER_{Covered} \times COST_{Onsite} \times NUM_{Units}$$

  - Pre-access drug and alcohol tests need not be performed at *facilities with offsite testing laboratories* for the percentage of applicants who are covered by an acceptable program. The associated savings are estimated as follows:

    $$NUM_{Applicants} \times PER_{Covered} \times COST_{Offsite} \times NUM_{Units}$$

- The *annual savings per program* from bypassing the training and examination requirements for the percentage of applicants covered by an acceptable program are calculated as follows:

  $$NUM_{Applicants} \times PER_{Covered} \times (HOURS_{Non\text{-}Supervisory} + HOURS_{Exam}) \times WAGE_{Worker} \times NUM_{Units}$$

- The *annual savings per program* from requiring fewer contracted trainer hours to conduct trainings and examinations on the percentage of applicants who are covered by acceptable program are calculated as follows:

[2] These incremental savings will vary for programs depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified testing laboratory.

$NUM_{Sessions} \times (HOURS_{Non\text{-}Supervisory} + HOURS_{Exam} + HOURS_{Preparation}) \times WAGE_{Trainer} \times NUM_{Units}$

- The *annual savings per program* from not conducting remedial training and reexamining the percentage of applicants who are covered by an acceptable program and fail the comprehensive examination are calculated as follows:

  $PER_{Failing} \times [(NUM_{Applicants} \times PER_{Covered}) \times (HOURS_{Remedial\ Training} + HOURS_{Exam}) \times WAGE_{Worker}] \times NUM_{Units}$

- The *annual savings per program* from requiring fewer contracted trainer hours to conduct remedial training and reexamining those applicants covered by an acceptable program that fail the comprehensive examination are calculated as follows:

  $[NUM_{Sessions} \times (HOURS_{Remedial} + HOURS_{Exam}) \times WAGE_{Trainer}] \times PER_{Failing} \times NUM_{Units}$

- The *annual savings per program* from not subjecting existing employees who are covered by another acceptable program to a duplicative random drug and alcohol testing program are calculated as follows.

  $(NUM_{Employees} \times PER_{Covered}) \times (COST_{Test} \times PER_{Random}) \times NUM_{Units}$

Parameter	**Description**
$COST_{Offsite}$	Drug and alcohol testing cost at facilities with offsite testing laboratories per test (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{Onsite}$	Drug and alcohol testing cost at facilities with onsite testing laboratories per test (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$HOURS_{Exam}$	Length of comprehensive examination (as described in assumptions below)
$HOURS_{Non\text{-}Supervisory}$	Length of non-supervisory-level training (as described in assumptions below)
$HOURS_{Preparation}$	Hours of preparation and examination grading per session (as described in assumptions below)
$HOURS_{Remedial}$	Length of remedial non-supervisory-level training (as described in Appendix 2, Exhibit A2-3)
$NUM_{Applicants}$	Annual number of applicants for initial authorization per unit who are covered by any other Federal or State program (as described in assumptions below)
$NUM_{Employees}$	Number of existing employees covered by any other Federal or State program (described in assumption below)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)

Parameter	Description
$NUM_{Sessions}$	Annual number of training and examination sessions (as described in assumptions below)
$PER_{Covered}$	Percentage of Federal or State programs qualifying under subparagraph 26.25(c)(1) per year (as described in assumptions below)
$PER_{Failing}$	Percentage failing comprehensive examination (as described in assumptions below)
PER_{Random}	Percentage tested by a random drug and alcohol testing program per year (as described in assumptions below)
$WAGE_{Trainer}$	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Annual number of applicants for initial authorization per unit covered by any other Federal or State Program: 10.
- Percentage of Federal or State Programs qualifying under subparagraph 26.4(j)(1): 50%.
- Length of non-supervisory-level training: 2 hours.
- Length of comprehensive examination: 0.5 hours.
- Percentage failing comprehensive examination: 10%.
- Percentage tested by random drug and alcohol testing program per year: 50%.
- Number of training sessions assumes 20 workers per session.
- Hours of preparation and examination grading: 2 hours.
- Number of existing employees covered by any other Federal or State program: 40.
- All affected personnel take non-supervisory-level training under the former rule.[3]

[3] This assumption has been made to simplify the above calculation for MROs. Elsewhere the analysis assumes that 85 percent of personnel are being trained at the non-supervisory-level under the former rule, and that the remaining 15 percent are being trained at the supervisory-level.

- The per-unit cost of an onsite pre-access and random drug and alcohol test includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) onsite licensee testing costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

- The per-unit cost of an offsite pre-access and random drug and alcohol test includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) HHS-certified laboratory costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results.

- Individuals whose pre-access drug and alcohol tests yield positive results will be eliminated from the hiring process.

26.5 Definitions

This section of the final rule re-states, clarifies, and adds definitions that are used throughout the entire final FFD rule. A number of these added and revised definitions will require licensees and C/Vs to modify or update their interpretation of current FFD policy, thereby resulting in incremental costs or savings. These costs and savings, however, are discussed in relevant sections of this analysis. The section adds a number of definitions, including those listed below, which are addressed later in this analysis within the context of the requirements that reference them.

- acute fatigue
- alertness
- best effort
- circadian variation in alertness and performance
- cumulative fatigue
- directing
- fatigue
- formula quantity
- increase in threat condition
- other entity
- validity screening test

26.7 Interpretations

This section of the final rule imposes no incremental cost and affords no saving because it merely restates §26.4 of the former rule and provides that interpretation of the meaning of the regulations requires a written interpretation by the General Counsel in order to be recognized as binding upon the Commission.

26.8 Information Collection Requirements: OMB Approval

This section of the final rule [including paragraphs 26.8(a) and (b)] imposes no incremental cost and affords no saving because it merely renumbers and amends §26.8 of the former rule to reference the revised recordkeeping requirements of the final rule. The information collection requirements and their associated costs are discussed in subsequent sections.

26.9 Specific Exemptions

This section of the final rule imposes no incremental cost and affords no saving because it merely restates §26.6 of the former rule and provides that the NRC may (in instances authorized by law and deemed not to endanger life, property, or the public interest) grant exemptions from the requirements of Part 26.

26.11 Communications

This section provides consistency with other 10 CFR parts and states that all communications, applications, and reports concerning the regulations in this part must be sent to a specified NRC address. The section will, however, add a requirement that copies of all communications to the NRC be sent to the appropriate regional office and resident inspector. No incremental costs arise from this requirement, however, as the additional cost to send the additional copies electronically is negligible.

Subpart B: Program Elements

26.21 Fitness-for-Duty Program

This section of the final rule imposes no incremental cost and affords no saving because it merely states that licensees and other entities specified in paragraph 26.3(a) through (c) must implement FFD programs that comply with this part, as required by paragraph 26.3(b) of the former rule.

26.23 Performance Objectives

Paragraphs 26.23(a)–(d)

Paragraphs 26.23(a)-(c) of the final rule merely clarify the program performance objectives contained in paragraphs 26.10(a)-(b) of the former rule. Paragraph 26.23(d) of the final rule amends and clarifies former paragraph 26.10(c) regarding the objective that FFD programs provide reasonable assurance that workplaces specified in § 26.3(a), (b), and, if applicable, (c) are free from the presence and effects of illegal drugs and alcohol. The analysis assumes that any incremental costs and savings related to this objective are imposed by subsequent provisions that implement this objective.

Paragraph 26.23(e)

This paragraph of the final rule amends the performance objectives for FFD programs to include reasonable assurance that the effects of fatigue and degraded alertness are managed commensurate with maintaining public health and safety. Incremental costs associated with this performance objective are analyzed under the relevant sections that implement the objective, particularly the provisions in Subpart I.

26.25 Reserved

26.27 Written Policy and Procedures

Paragraph 26.27(a)

This paragraph amends requirements, in §26.20 of the former rule, regarding the establishment, implementation, and maintenance of written policies and procedures designed to meet the general performance objectives and requirements of this part. Licensees and other entities must revise their existing policies, procedures, and contracts with labs or other C/Vs according to paragraphs 26.27(b) and (c), resulting in incremental costs. The costs of the revisions will include policy and procedure development and revision, legal support, and clerical support. Costs associated with revisions to the FFD training program are calculated separately in connection with paragraph 26.29(a).

The *one-time cost per program* results from the sum of the following costs:

- One-time costs per program to account for FFD manager and clerical personnel time and to contract a legal consultant are calculated as follows:

  $(HOURS_{Manager} \times WAGE_{Manager}) + (HOURS_{Legal} \times WAGE_{Legal}) + (HOURS_{Clerical} \times WAGE_{Clerical})$

- One-time costs per program to account for facility supervisor time to implement the corporate policies at the facility level are calculated as follows:

  $HOURS_{Facility\ Supervisor} \times WAGE_{Facility\ Supervisor} \times NUM_{Facilities}$

Parameter	**Description**
$HOURS_{Clerical}$	Hours of clerical personnel to support revision of policies, procedures, and contracts per program (as described in assumptions below)
$HOURS_{Facility\ Supervisor}$	Hours of facility supervisor time to implement revised corporate policies and procedures per facility (as described in assumptions below)
$HOURS_{Legal}$	Hours of legal assistance to review and revise policies, procedures, and contracts per program (as described in assumptions below)
$HOURS_{Manager}$	Hours of FFD program manager labor to develop and revise policies, procedures, and contracts per program (as described in assumptions below)
$NUM_{Facilities}$	Number of facilities (as described in Appendix 2, Exhibit A2-14)
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Facility\ Supervisor}$	Facility supervisor wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Legal}$	Legal consultant wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Manager}$	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of FFD program manager labor to develop and revise policies, procedures, and contracts per program: 370 hours.

- Hours of legal assistance to review and revise policies, procedures, and contracts per program: 95 hours.

- Hours of clerical personnel to support revision of policies, procedures, and contracts per program: 95 hours.

- Hours of facility supervisor time to implement revised corporate policies and procedures: 40 hours.

- Policy and procedure revisions are developed once per operating firm, regardless of the number of sites or facilities the firm operates.

Paragraph 26.27(b)

This paragraph of the final rule establishes regulatory requirements regarding the content of policy statements. The final paragraph requires that written policies and procedures be clear, concise and readily available to all individuals subject to the policy such that they may understand what is expected of them and what consequences may result from lack of adherence to the policy. These requirements amend the requirements contained in §26.20 of the former rule. The analysis calculates the cost of this revision as part of the related revisions required under paragraph 26.27(a) except as discussed below.

Subparagraphs 26.27(b)(1)–26.27(b)(10)

These subparagraphs of the final rule establish regulatory requirements regarding the content of policy statements. These subparagraphs of the final rule highlight the minimum content of the written policies and procedures available to individuals subject to the policy. These subparagraphs provide more detail on what to include in the written policies and procedures than is contained in paragraph 26.20(a) of the former rule. The analysis calculates the cost of this revision as part of the related revisions required under paragraph 26.27(a).

Subparagraph 26.27(b)(11)

This paragraph requires licensees' written policies and procedures to describe the responsibility of individuals subject to the FFD program (i.e., other than the supervisors, managers, and escorts who are addressed in 26.27(b)(10)) to report FFD concerns (e.g., concerns identified as a result of behavioral observation). The cost of revising the policies and procedures to include this description is included in the calculation under 26.27(a). The new policy will be communicated to employees through the training program required under 26.29 (the costs of which are calculated under 26.29). As a result of the new policy, there will be an increase in the number of for-cause referrals, the number of drug and alcohol tests performed, and the number of positive test results that must undergo confirmatory testing. The analysis calculates the cost of these activities under paragraph 26.33.

Paragraph 26.27(c)

Subparagraph 26.27(c)(1)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it only describes the written procedures that must be prepared, implemented, and maintained by

licensees and other entities related to testing for drugs and alcohol. The requirement to address these procedures is already contained in paragraph 26.20(c) of the former rule.

Subparagraph 26.27(c)(2)(i) and (ii)

These subparagraphs of the final rule impose no incremental cost and afford no saving because they merely state that licensee and other entity written policies and procedures must describe the immediate and follow-up actions to be taken and procedures to be followed when an individual has been involved in the use, sale, or possession of illegal drugs and when an individual has consumed any alcohol during the abstinence period, while on duty, or to excess before reporting to duty. These requirements are already contained in paragraph 26.20(d) of the former rule.

Subparagraph 26.27(c)(2)(iii)–(v)

These subparagraphs of the final rule impose no incremental cost and afford no saving because they merely state that licensee and other entity written policies and procedures must describe the follow-up actions to be taken and procedures to be followed when an individual has attempted to subvert the testing process, refused to provide a specimen for analysis, and had legal action taken on a drug or alcohol related charge. The costs associated with revising licensee and other entity written policy and procedures to address these violations of FFD policy are addressed in paragraph 26.27(a).

Subparagraph 26.27(c)(3)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it only requires that licensee and other entity written policies and procedures must describe (1) the process to ensure that persons called in to perform an unscheduled working tour are fit for duty, and (2) the requirements for licensee and other entity personnel who are scheduled by licensee emergency plans and procedures to physically report to a licensee's Technical Support Center or Emergency Operations Facility. The former rule already required these descriptions to be contained in licensee written policies and procedures under former subparagraph 26.20(e).

Subparagraph 26.27(c)(4)

This subparagraph of the final rule requires that licensee and other entity written policies and procedures must describe the process to be followed if an individual's behavior indicates a potential FFD concern. Although licensees have indicated that the written procedure for managers, supervisors, and escorts to report FFD concerns is well established, the final rule, in conjunction with 26.27(b)(11), adds provisions that all employees are required to report FFD concerns. As a result, the procedures may need to be revised. The incremental cost of these revisions are included in the complete written policy revision calculated under 26.27(a) of this analysis, and the cost of implementing the policy and process is calculated under 26.33.

Paragraph 26.27(d)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely retains requirements contained in paragraph 26.20(f) of the former rule stating that the NRC may review licensee or other entity written policies and procedures at any time to assure that the performance objectives of this part are met.

26.29 Training

Paragraph 26.29(a)

This paragraph requires licensees to revise their training programs and training materials to account for the new FFD provisions in the final rule and to include behavioral observation training for all individuals subject to this Subpart. (Currently, behavioral observation is included only in supervisory-level training.) Licensees will incur costs to revise their training programs and materials to reflect the new regulatory provisions. However, the provision to include behavioral observation training for all individuals subject to the rule is already in effect due to the AAO. Therefore, there will be no incremental costs associated with the behavioral observation training provision, except under the alternative Pre-Order Baseline.

The *one-time cost per program* associated with revising the training program and training materials to account for new FFD provisions in the final rule are calculated as follows:

$$(HOURS_{Trainer} \times WAGE_{Trainer}) + (HOURS_{Training\_Manager} \times WAGE_{Training\_Manager}) + (HOURS_{Manager} \times WAGE_{Manager}) + (HOURS_{Clerical} \times WAGE_{Clerical})$$

Parameter	Description
$HOURS_{Manager}$	One-time hours of FFD program manager time per program to review the revised training program and revised training materials to account for new FFD provisions in the final rule (described in assumptions below)
$HOURS_{Trainer}$	One-time hours of trainer time per program to revise the training program and training materials to account for new FFD provisions in the final rule (described in assumptions below)
$HOURS_{Training\_Manager}$	One-time hours of training manager time per program to review the revised training program and revised training materials to account for new FFD provisions in the final rule (described in assumptions below)
$HOURS_{Clerical}$	One-time hours of clerical personnel per program to support the revision of the training program and training materials to account for new FFD provisions in the final rule (described in assumptions below)
$WAGE_{Trainer}$	Trainer wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Training\_Manager}$	Training manager wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Manager}$	FFD program manager wage rate (described in Appendix 2, Exhibit A2-11)

Parameter	Description
$WAGE_{Clerical}$	Clerical personnel wage rate (described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of trainer time per program to revise the training program and training materials to address new FFD provisions in the final rule: 20 hours.

- Hours of training manager time per program to review the revised training program and revised training materials to address new FFD provisions in the final rule: 2 hours.

- Hours of FFD program manager time per program to review the revised training program and revised training materials to address new FFD provisions in the final rule: 2 hours.

- Hours of clerical personnel to support the revision of the training program and training materials addressing new FFD provisions in the final rule: 4 hours.

Sensitivity Analysis Note - Pre-Order Baseline

Relative to the regulations in effect prior to NRC's issuance of the Access Authorization Order, this final paragraph results in additional incremental costs. The additional costs arise from the requirement to include behavioral observation training for all individuals subject to the rule. (Currently, behavioral observation is included only in supervisory-level training.)

The revisions to the training program and processes related to behavioral observation training will cause licensees to incur incremental costs for the following activities:

- Training course revisions
- Upgrade to supervisory-level training addressing behavioral observation
  - One-time
  - Annual
- Refresher training

Training Course Revisions. The incremental changes presented in subparagraph 26.29(a)(9) (as well as the AAO) will require licensees to revise their training programs to incorporate behavioral observation training for all individuals subject to the rule. *The one-time cost per program* associated with revising the training program result from the following:

$$(HOURS_{Trainer} \times WAGE_{Trainer}) + (HOURS_{Training\_Manager} \times WAGE_{Training\_Manager}) + (HOURS_{Manager} \times WAGE_{Manager}) + (HOURS_{Clerical} \times WAGE_{Clerical})$$

Parameter	Description
$HOURS_{Trainer}$	Hours of trainer time per program to make revisions to the training program (as described in assumptions below)
$HOURS_{Training\_Manager}$	Hours of training manager time per program to review the revised training program (as described in assumptions below)
$HOURS_{Clerical}$	Hours of clerical personnel per program to support the training program revisions process (as described in assumptions below)
$HOURS_{Manager}$	Hours of FFD program manager time per program to review the revised training program (as described in assumptions below)
$WAGE_{Trainer}$	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Training\_Manager}$	Training manager wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Manager}$	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of trainer time per program to make revisions to the training program addressing behavioral observation for all individuals subject to the rule: 12 hours.

- Hours of training manager time per program to review revisions to the training program addressing behavioral observation for all individuals subject to the rule: 2 hours.

- Hours of FFD program manager time per program to review revisions to the training program addressing behavioral observation for all individuals subject to the rule: 2 hours.

- Hours of clerical personnel per program to support the training program revisions process: 4 hours.

Initial Behavioral Observation Training for All Individuals Who Are Subject to the Rule. Paragraph 26.29(a) also requires training in behavioral observation for all individuals who are subject to the rule, rather than only for supervisors and escorts as required in §26.22 of the former rule. In other words, all individuals must receive what currently is supervisory-level training. As a result of this new training requirement, licensees will incur a one-time cost to retrain all existing employees who have not previously received training in behavioral observation, an annual cost to train newly hired employees in behavioral observation and an annual cost to provide behavioral observation refresher training as required under subparagraph 26.29(c)(2).

Licensees will incur a *one-time incremental cost* in order to provide updated training to all individuals who are already covered by the FFD program, but who have not already had full supervisory-level training. The *one-time cost per program* results from the sum of the following costs:[1]

- One-time costs per program for employees not previously trained at the supervisory level to take updated behavioral observation training and a comprehensive examination are calculated as follows:

  $$[NUM_{Employees} \times PER_{Non\text{-}Supervisory} \times (HOURS_{Training} + HOURS_{Examination}) \times WAGE_{Worker} \times NUM_{Units}] \times PER_{Cost}$$

- One-time costs per program for trainers to administer behavioral observation training to those employees not previously trained at the supervisory level are calculated as follows:[2]

  $$[NUM_{Sessions} \times (HOURS_{Training} + HOURS_{Examination} + HOURS_{Preparation}) \times WAGE_{Trainer} \times NUM_{Units}] \times PER_{Cost}$$

Parameter	**Description**
$HOURS_{Examination}$	Length of comprehensive examination (as described in assumptions below)
$HOURS_{Preparation}$	Hours of preparation and examination grading per session (as described in assumptions below)
$HOURS_{Training}$	Length of updated supervisory-level training (as described in assumptions below)
$NUM_{Employees}$	Number of employees per unit (as described in Appendix 2, Exhibit A2-14)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$NUM_{Sessions}$	Number of training sessions per unit (as described in assumptions below)
PER_{Cost}	Percentage of cost applied to a given unit (as described in assumptions below)
$PER_{Non\text{-}Supervisory}$	Percentage of employees trained at the non-supervisory level under the former rule (as described in assumptions below)
$WAGE_{Trainer}$	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

[1] This calculation includes costs associated with administering a comprehensive examination because the entire activity of requiring existing employees to update their training and pass an examination represents an incremental requirement.

[2] Although many licensees may be conducting computer-based trainings, the analysis utilizes a class-based format, which may result in an overestimate of the cost of incremental training activities.

Assumptions:

- Percentage of employees trained at the non-supervisory level under the former rule: 85%.
- Length of updated training, including behavioral observation: 4 hours.
- Length of comprehensive examination: 0.5 hours.
- Number of training sessions assumes 50 workers per session.
- Hours of preparation and examination grading per session: 2 hours.
- Licensees have indicated that 75 percent of facilities already train all employees at this higher supervisory level and, therefore, would not incur any incremental cost under this requirement. Because the analysis cannot identify which facilities are already training at the higher level and which are not, the analysis assumes that each unit will incur the incremental cost of 25 percent of the activity.

Annual Initial Training. An incremental cost for annual training for individuals, such as new workers not yet covered under FFD programs or workers updating their authorization, will also lead to increased costs. This is attributable to the longer length of supervisory-level training in relation to training previously conducted under the former rule. The *annual cost per program* results from the sum of the following costs:[3]

- Annual costs per program for incoming employees to take the longer training course addressing behavioral observation are calculated as follows:

  $$[NUM_{Applicants} \times PER_{Non\text{-}Supervisory} \times (HOURS_{Supervisory} - HOURS_{Non\text{-}Supervisory}) \times WAGE_{Worker} \times NUM_{Units}] \times PER_{Cost}$$

- Annual costs per program for trainers to administer the longer behavioral observation training to incoming employees are calculated as follows:[4]

  $$[NUM_{Sessions} \times (HOURS_{Supervisory} - HOURS_{Non\text{-}Supervisory}) \times WAGE_{Trainer} \times NUM_{Units}] \times PER_{Cost}$$

[3] This calculation does not include the costs associated with administering the comprehensive examination required under paragraph 26.29(b) because new hires are already required to take a comprehensive examination. Therefore, the examination does not represent an incremental requirement.

[4] Although many licensees may be conducting computer-based trainings, the analysis utilizes a class-based format, which may result in an overestimate of the cost of incremental training activities.

Parameter	Description
$HOURS_{Non\text{-}Supervisory}$	Length of non-supervisory-level training course per applicant (as described in assumptions below)
$HOURS_{Supervisory}$	Length of supervisory-level training course per applicant (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for initial and update authorization per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$NUM_{Sessions}$	Annual number of supervisory-level training sessions per unit (as described in assumptions below)
PER_{Cost}	Percentage of cost applied to a given facility (as described in assumptions below)
$PER_{Non\text{-}Supervisory}$	Percentage of applicants for initial and update authorization trained at the non-supervisory-level under the former rule (as described in assumptions below)
$WAGE_{Trainer}$	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of applicants for initial and update authorization trained at the non-supervisory level under the former rule: 85%.
- Length of supervisory-level training course per applicant: 4 hours.
- Length of non-supervisory-level training course per applicant: 2 hours.
- Annual number of supervisory-level training sessions per unit assumes 20 workers per session.
- Licensees have indicated that 75 percent of facilities already train all employees at this higher supervisory level and, therefore, would not incur any incremental cost under this requirement. Because the analysis cannot identify which facilities are already training at the higher level and which are not, the analysis assumes that each unit will incur the incremental cost of 25 percent of the activity.

Annual Refresher Training. Licensees will have to conduct refresher training. As a result, licensees will incur an incremental cost for some employees (i.e., those who are currently taking non-supervisory-level refresher training) because of the increased time required to conduct behavioral observation refresher training instead of non-supervisory-level training as required by the former rule. Although providing only one level of training (as opposed to two) may represent a potential savings, the savings are difficult to quantify and may be negligible when considering

administrative costs associated with providing an optional comprehensive examination in lieu of refresher training under subparagraph 26.29(c)(2). Despite the provision of this optional comprehensive "challenge" examination, the savings of which are presented separately, some workers will continue to take refresher training. The *annual costs per program* result from the sum of the following costs:

- Annual costs per program for employees to take the longer behavioral observation refresher training are calculated as follows:

  $$[NUM_{Employees} \times PER_{Non\text{-}Supervisory} \times PER_{Refresher} \times (HOURS_{Supervisory} - HOURS_{Non\text{-}Supervisory}) \times WAGE_{Worker} \times NUM_{Units}] \times PER_{Cost}$$

- Annual costs per program for trainers to administer the longer behavioral observation refresher training are calculated as follows:[5]

  $$[NUM_{Sessions} \times (HOURS_{Supervisory} - HOURS_{Non\text{-}Supervisory}) \times WAGE_{Trainer} \times NUM_{Units}] \times PER_{Cost}$$

Parameter	**Description**
$HOURS_{Non\text{-}Supervisory}$	Length of non-supervisory-level refresher training course (described in assumptions below)
$HOURS_{Supervisory}$	Length of new refresher training course including behavioral observation (described in assumptions below)
$NUM_{Employees}$	Annual number of employees per unit covered by FFD program (as described in Appendix 2, Exhibit A2-14)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$NUM_{Sessions}$	Annual number of refresher training sessions per unit (as described in assumptions below)
PER_{Cost}	Percentage of cost applied to a given facility (as described in assumptions below)
$PER_{Non\text{-}Supervisory}$	Percentage of employees trained at the non-supervisory level under the former rule (as described in assumptions below)
$PER_{Refresher}$	Percentage of employees taking refresher training instead of the comprehensive "challenge" examination (described in assumptions below)
$WAGE_{Trainer}$	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

[5] Although many licensees may be conducting computer-based trainings, the analysis utilizes a class-based format, which may result in an overestimate of the cost of incremental training activities.

Assumptions:

- Percentage of employees trained at the non-supervisory level under the former rule: 85%.
- Percentage of employees taking refresher instead of the comprehensive "challenge" examination: 20%.
- Length of new training course including behavioral observation: 4 hours.
- Length of non-supervisory-level training course per applicant: 2 hours.
- Annual number of supervisory-level refresher training sessions assumes 20 workers per session.
- Licensees have indicated that 75 percent of facilities already train all employees at this higher supervisory level and, therefore, would not incur any incremental cost under this requirement. Because the analysis cannot identify which facilities are already training at the higher level and which are not, the analysis assumes that each unit will incur the incremental cost of 25 percent of the activity.

Paragraph 26.29(b)

This final paragraph adds an explicit requirement to administer a comprehensive examination following FFD training. Although the former rule did not explicitly require comprehensive examinations, it did require licensees to ensure that training is achieving the desired results, and licensees normally accomplished this goal through examinations. Licensees have indicated that they already administer comprehensive examinations in order to ensure employee understanding. Thus, the clarified requirement to administer a comprehensive examination imposes no incremental cost and affords no saving. Note that even though there is no incremental cost to administer examinations, the content of the examination must now reflect new material, as discussed above in connection with paragraph 26.29(a). The cost of updating the training course itself also is addressed in connection with paragraph 26.29(a).

This final paragraph also requires that individuals who fail the comprehensive examination must take remedial training and retake the examination. The remedial training requires workers to review specific areas of the examination in which they performed poorly. Although licensees have indicated that they already retest non-supervisory individuals who fail the comprehensive examination, they may not be retraining them. Therefore, this analysis assumes that the new rule will result in incremental costs to retrain existing non-supervisory employees who fail the comprehensive examination following the updated training as well as those applicants for initial and update authorization who fail the examination after initial training.

Licensees will incur a *one-time cost* to require licensees to retrain individuals who fail the comprehensive examination after first taking the updated training addressing behavioral observation. The costs associated with the initial training update are calculated separately above. The *one-time cost per program* results from the following costs:

- One-time costs per program for employees to take remedial training after failing the initial comprehensive examination when updating their training are calculated as follows:

  $$[NUM_{Employees} \times PER_{Non\text{-}Supervisory} \times PER_{Failing} \times HOURS_{Remedial} \times WAGE_{Worker}] \times NUM_{Units}$$

- One-time costs per program for trainers to administer remedial training on those employees who fail the initial comprehensive examination when updating training are calculated as follows:[6]

  $$NUM_{Sessions} \times HOURS_{Remedial} \times WAGE_{Trainer} \times NUM_{Units}$$

Parameter	**Description**
$HOURS_{Remedial}$	Length of remedial supervisory-level training (as described in assumptions below)
$NUM_{Employees}$	Number of employees per unit (as described in Appendix 2, Exhibit A2-14)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$NUM_{Sessions}$	Number of supervisory-level update training sessions per facility (as described in assumptions below)
$PER_{Failing}$	Percentage of employees failing the comprehensive examination (as described in assumptions below)
$PER_{Non\text{-}Supervisory}$	Percentage of employees trained at the non-supervisory level under the former rule (as described in assumptions below)
$WAGE_{Trainer}$	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

[6] Although many licensees may be conducting computer-based trainings, the analysis utilizes a class-based format, which may result in an overestimate of the cost of incremental training activities.

Assumptions:

- Length of remedial supervisory-level training: 0.75 hours.
- Percentage of employees trained at the non-supervisory level under the former rule: 85%.
- Percentage of employees failing comprehensive examination: 10%.
- Number of supervisory-level update retraining sessions per facility assumes 20 workers per session.

In addition to the one-time costs, licensees will incur an annual cost as a result of the new requirement to retrain all subsequent applicants who fail the comprehensive examination for initial and updated authorization. The *annual costs per program* result from the sum of the following costs:

- Annual costs per program for applicants to take remedial training after failing the initial comprehensive examination are calculated as follows:

  $NUM_{Applicants} \times PER_{Failing} \times HOURS_{Remedial} \times WAGE_{Worker} \times NUM_{Units}$

- Annual costs per program for trainers to administer remedial training on applicants who fail the initial comprehensive examination are calculated as follows:[7]

  $NUM_{Sessions} \times HOURS_{Remedial} \times WAGE_{Trainer} \times NUM_{Units}$

Parameter	**Description**
$HOURS_{Remedial}$	Length of remedial supervisory-level training (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants per unit who take the examination for initial and updated authorization (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$NUM_{Sessions}$	Annual number of supervisory-level training sessions per unit (as described in assumptions below)
$PER_{Failing}$	Percentage of applicants failing the comprehensive examination per year (as described in assumptions below)
$WAGE_{Trainer}$	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)

[7] Although many licensees may be conducting computer-based trainings, the analysis utilizes a class-based format, which may result in an overestimate of the cost of incremental training activities.

Parameter	Description
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Length of remedial supervisory-level training: 0.75 hours.
- Percentage of applicants failing the comprehensive examination per year: 10%.
- Number of supervisory-level training sessions per facility assumes 20 workers per session.

Paragraph 26.29(c)

Subparagraph 26.29(c)(1)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely requires licensee employees to complete their training before being assigned activities under Part 26, as required under paragraph 26.21(b) of the former rule. Additionally, this final subparagraph eliminated a former provision to allow 3 months to upgrade training for newly assigned supervisors. The elimination of this provision will impose no additional cost because all employees will be required to train at the same supervisory level under paragraph 26.29(a).

Subparagraph 26.29(c)(2)

This subparagraph requires refresher training on a 12-month frequency, as required under paragraphs 26.21(b) and 26.22(c) of the former rule. Thus, no incremental cost or saving will result specifically from this requirement. However, the final subparagraph also adds a provision to allow workers to take a comprehensive annual examination in lieu of refresher training (i.e., a "challenge" exam). This provision represents potential incremental savings, as the examination requires less time to complete than the refresher training. The amount of the savings per employee depends on whether the employee who chooses to take the comprehensive examination is currently taking supervisory-level or non-supervisory-level refresher training. Although incremental savings are associated with workers taking less training, the savings will be partially offset because the cost of examination grading must be considered and subtracted. Licensees will also incur a one-time cost to develop procedures for administering the challenge examination, the cost of which is included in the calculations described in 26.29(a).

The *annual savings per program* result from the sum of the following savings:

- Annual savings per program for those employees choosing to take the shorter comprehensive examination in lieu of (the current non-supervisory-level) refresher training are calculated as follows:

  $NUM_{Employees} \times PER_{Non\text{-}Supervisory} \times PER_{Examination} \times (HOURS_{Non\text{-}Supervisory} - HOURS_{Exam}) \times WAGE_{Worker} \times NUM_{Units}$

- Annual savings per program for those employees choosing to take the shorter comprehensive examination in lieu of (the current supervisory-level) refresher training are calculated as follows.

  $NUM_{Employees} \times PER_{Supervisory} \times PER_{Examination} \times (HOURS_{Refresher} - HOURS_{Exam}) \times WAGE_{Worker} \times NUM_{Units}$

- Annual savings per program from reduced training costs due to employees choosing to take the shorter comprehensive examination in lieu of (the current non-supervisory-level) refresher training are calculated as follows:[8]

  $[NUM_{Sessions\ Non\text{-}Supervisory} \times (HOURS_{Non\text{-}Supervisory} + HOURS_{Preparation} - HOURS_{Exam} - HOURS_{Grading}) \times WAGE_{Trainer}] \times NUM_{Units}$

- Annual savings per program from reduced training costs due to employees choosing to take the shorter comprehensive examination in lieu of (the current supervisory-level) refresher training are calculated as follows:

  $[NUM_{Sessions\ Supervisory} \times (HOURS_{Refresher} + HOURS_{Preparation} - HOURS_{Exam} - HOURS_{Grading}) \times WAGE_{Trainer}] \times NUM_{Units}$

Parameter	**Description**
$HOURS_{Exam}$	Length of comprehensive examination per exam (as described in assumptions below)
$HOURS_{Grading}$	Hours of examination grading per session (as described in assumptions below)
$HOURS_{Non\text{-}Supervisory}$	Length of non-supervisory-level refresher training course per session (as described in assumptions below)
$HOURS_{Preparation}$	Hours of trainer time to prepare for training course per session (as described in assumptions below)

[8] Although many licensees may be conducting computer-based trainings, the analysis utilizes a class-based format, which may result in an overestimate of the cost of incremental training activities.

Parameter	Description
$HOURS_{Refresher}$	Length of new refresher course per session (as described in assumptions below)
$NUM_{Employees}$	Number of employees per unit (as described in Appendix 2, Exhibit A2-14)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$NUM_{Sessions\ Supervisory}$	Annual number of comprehensive examination sessions per unit replacing supervisory-level refresher training (as described in assumptions below)
$NUM_{Sessions\ Non\text{-}Supervisory}$	Annual number of comprehensive examination sessions per unit replacing non-supervisory-level refresher training (as described in Appendix 2, Exhibit A2-3)
$PER_{Examination}$	Percentage of employees choosing to take comprehensive examination in lieu of refresher training (as described in assumptions below)
$PER_{Non\text{-}Supervisory}$	Percentage of employees trained at the non-supervisory level under the former rule (as described in assumptions below)
$PER_{Supervisory}$	Percentage of employees trained at the supervisory level under the former rule (as described in assumptions below)
$WAGE_{Trainer}$	Trainer wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of employees trained at the non-supervisory level under the former rule: 85%.
- Percentage of employees choosing to take the comprehensive examination in lieu of refresher training: 80%.
- Percentage of employees trained at the supervisory level under the former rule: 15%.
- Length of non-supervisory-level refresher training course per session: 2 hours.
- Length of comprehensive examination per exam: 0.5 hours.
- Length of new refresher course per session: 4 hours.
- Number of comprehensive examination sessions replacing refresher course assumes 20 workers per training session.

- Hours of trainer time to prepare for training course per session: 1 hour.
- Hours of examination grading per session: 0.5 hours.

Subparagraph 26.29(c)(3)

This subparagraph of the final rule imposes no incremental cost and affords no saving because the added provision only authorizes licensees to conduct training via a variety of mediums. Alternative training mediums might allow licensees to take advantage of more effective and more efficient techniques. The final subparagraph clarifies the requirements in paragraph 26.21 of the former rule. Any savings that result from this provision are considered to be insignificant.

Subparagraph 26.29(d)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely allows licensees to forego training and testing of individuals who have taken Part 26 training within the prior 12 months. The NRC and licensees have indicated that this provision is already practiced under the former rule, in accordance with guidance in NUREG-1385.

26.31 Drug and Alcohol Testing

Paragraph 26.31(a)

This paragraph of the final rule imposes no incremental cost or saving because it merely retains the requirements in paragraph 26.24(a) of the former rule which related to the implementation of drug and alcohol testing programs for persons who are subject to this Subpart of the final rule.

Paragraph 26.31(b)

Subparagraph 26.31(b)(1)

This subparagraph amends Appendix A, Section 2.3 of the former rule to include FFD program personnel in the drug and alcohol testing program requirements. Incremental costs associated with adding FFD program personnel to the testing program are calculated in the discussion of subparagraph 26.4(g).

Subparagraph 26.31(b)(1)(i)

This final subparagraph revises the requirements in Appendix A, Section 2.3(2), of the former rule. The final rule 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 and other affected facilities are acceptable means for meeting this requirement addressing the honesty and integrity of FFD program personnel. The analysis assumes that a criminal history and credit check are included in the

background check already required in order to grant unescorted access authorization under a licensee's access authorization program and, therefore, assumes no incremental cost. The final rule also relaxes a former provision that required licensees to update the background investigation every three years, thereby realizing an incremental saving. Although licensees must continue to update the psychological assessment and criminal history and credit checks, the final rule reduces the frequency of such updates from every 3 years to every 5 years, resulting in additional incremental savings.

The *annual savings per program* result from the *sum* of the following factors:

- The *base annual savings per program* (i.e., regardless of whether the program uses onsite or offsite collection facilities and testing laboratories) from eliminating the requirement to update background checks every 3 years are estimated as follows:

  $NUM_{Personnel\text{-}Base} \times COST_{Background\ Investigation\ Update} \times PER_{Annualized\text{-}1} \times NUM_{Units}$

- Additional savings per program from eliminating the requirement to update background checks every 3 years *per program with onsite testing* are estimated as follows:

  $NUM_{Personnel\text{-}Onsite\ Testing} \times COST_{Background\ Investigation\ Update} \times PER_{Annualized\text{-}1} \times NUM_{Facilities}$

- Additional savings per program from eliminating the requirement to update background checks every 3 years *per program with onsite collection* are estimated as follows:

  $NUM_{Personnel\text{-}Onsite\ Collection} \times COST_{Background\ Investigation\ Update} \times NUM_{Facilities} \times PER_{Collection} \times PER_{Annualized\text{-}1}$

- *Base annual savings per program* (i.e., regardless of whether the program uses onsite or offsite collection and testing facilities) from reducing the frequency with which licensees must update the psychological evaluations and the criminal history and credit checks are estimated as follows:

  $NUM_{Personnel\text{-}Base} \times [COST_{Criminal/Credit\ Update} + COST_{Psychological\ Evaluation\ Update}] \times NUM_{Units} \times PER_{Annualized\text{-}2}$

- Additional savings per program from reducing the frequency with which licensees must update the psychological evaluations and the criminal history and credit check *per program with onsite testing laboratories* are estimated as follows:

  $NUM_{Personnel\text{-}Onsite\text{-}Testing} \times [COST_{Criminal/Credit\ Update} + COST_{Psychological\ Evaluation\ Update}] \times PER_{Annualized\text{-}2} \times NUM_{Facilities}$

- Additional savings per program from reducing the frequency with which licensees must update psychological evaluations and the criminal history and credit check update *per program with onsite collection facilities* are estimated as follows:

  $NUM_{Personnel\text{-}Onsite\text{-}Collection} \times [COST_{Criminal/Credit\ Update} + COST_{Psychological\ Evaluations}] \times PER_{Collection} \times PER_{Annualized\text{-}2} \times NUM_{Facilities}$

Parameter	**Description**
$COST_{Background\ Investigation\ Update}$	Cost of updating an individual's background investigations, excluding the credit check and criminal history check (as described in assumptions below)
$COST_{Criminal/Credit\ Update}$	Cost of updating an individual's criminal and credit history (as described in assumptions below)
$COST_{Psychological\ Evaluation\ Update}$	Cost of updating an individual's psychological evaluation (as described in assumptions below)
$NUM_{Facilities}$	Number of facilities per program (as described in Appendix 2, Exhibit A2-14)
$NUM_{Personnel\text{-}Base}$	Base number of FFD program personnel per unit for each program (as described in the assumptions below)
$NUM_{Personnel\text{-}Onsite\text{-}Testing}$	Additional number of FFD program personnel per facility for programs with onsite testing laboratories (as described in assumptions below)
$NUM_{Personnel\text{-}Onsite\text{-}Collection}$	Additional number of FFD program personnel per facility for programs with onsite collection facilities (described in assumption below)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Annualized\text{-}1}$	Factor to adjust the periodic savings (every 3 years) to an annual savings (as described in assumptions below)
$PER_{Annualized\text{-}2}$	Factor to adjust to the periodic savings (two updates eliminated every 15 years) to an annual savings (as described in assumptions below)
$PER_{Collection}$	Percentage of facilities with onsite collection per program (as described in Appendix 2, Exhibit A2-1)

Assumptions:

- Base number of FFD program personnel (i.e., regardless of whether the program uses onsite or offsite collection facilities or testing laboratories) per unit: 1.5.

- Additional number of FFD program personnel per facility with onsite testing laboratories: 1.

- Additional number of FFD program personnel per facility for programs with onsite collection facilities: 0.5.

- Each facility in a program with onsite testing will have a separate testing laboratory with its own testing staff.

- Each facility in a program with onsite collection will have a separate collection site with its own collection staff.

- Cost of updating an individual's background investigations (excluding the credit and criminal history check): $150.

- Cost of updating an individual's psychological evaluation: $300.

- Cost of updating an individual's criminal and credit history: $50.

- Factor to annualize the 3-year periodic saving equals 1/3, or 33.3 percent (i.e., the final rule eliminates one background check update and one psychological evaluation, the savings of which are spread over 3 years).

- Factor to annualize the periodic saving from reducing a 3-year review frequency to a 5-year review frequency equals 2/15, or 13.3 percent (i.e., the final rule eliminates two criminal and credit history updates are eliminated, the savings of which are spread over 15 years).

Subparagraph 26.31(b)(1)(ii)– (iv)

These subparagraphs of the final rule impose no incremental cost and afford no saving because they merely amend the requirements in Appendix A, Section 2.3(1) of the former rule to prohibit assessment or evaluation by a person having a personal relationship with the donor or by an FFD program supervisor or co-workers within the same work group of the individual being tested. The final subparagraphs add a requirement prohibiting determinations of fitness (discussed with respect to §26.189) by FFD program personnel if the FFD program staff member has a personal relationship with the individual being tested. Specimen collection that does not require direct observation can be conducted by an individual who has a personal relationship with the donor so

long as the collection process is monitored by a second individual who is trained to monitor specimen collections and the preparation of specimens for transfer or shipping and who does not have a personal relationship with the donor. When directly observed specimen collection is required, however, the collector may have no personal relationship with the donor.

Subparagraph 26.31(b)(1)(v)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely restates the requirements in Appendix A, Section 2.3(3) of the former rule, which require licensees to subject all persons "responsible for administering the testing program" (including the MRO when on site) to a behavioral observation program.

Subparagraph 26.31(b)(2)

This subparagraph relaxes former requirements by authorizing FFD program personnel who are undergoing drug and alcohol testing to use collection services at a local hospital or other organization, provided that the facility conforms to DOT drug and alcohol testing requirements. This provision results in incremental cost and saving by allowing offsite FFD personnel (i.e., MROs) to utilize local collection services rather than traveling to the licensee's facility. Specifically, licensees may incur higher testing costs at local collection facilities, as opposed to licensee testing facilities. This analysis assumes that the costs associated with periodic collections at non-licensee collection facilities will be greater than the collection cost at licensee facilities. Offsetting some of these costs, MROs and other offsite contracted personnel will experience reduced travel, waiting, and specimen collection time, on average.

The *annual costs per program* from allowing MROs and other offsite contracted personnel to utilize other facilities conforming to DOT requirements are calculated as follows:

$$[(NUM_{MROs} \times PER_{Random} \times PER_{Distance} \times (COST_{Local\ facility} - COST_{Licensee\ facility})] \times NUM_{Facilities}$$

Parameter	**Description**
$COST_{Local\ facility}$	Cost to conduct specimen collection at a local DOT-approved facility (as described in Appendix 2, Exhibit A2-13)
$COST_{Licensee\ facility}$	Cost to conduct specimen collection at the licensee facility (as described in Appendix 2, Exhibit A2-13)
$NUM_{Facilities}$	Number of facilities per program (as described in Appendix 2, Exhibit A2-14)
NUM_{MROs}	Number of offsite contracted MROs per facility (as described in assumptions below)

Parameter	Description
$PER_{Distance}$	Percentage of contracted FFD personnel who live closer to a DOT-approved collection facility than to a licensee's standard collection facility (as described in assumptions below)
PER_{Random}	Percentage tested by a random drug and alcohol testing program per year (as described in assumptions below)

Assumptions:

- Number of offsite contracted MROs per facility: 2.
- Percentage tested by a random drug and alcohol testing program per year: 50%.
- Percentage of contracted FFD personnel who live closer to a DOT-approved collection facility than to a licensee's standard collection facility: 33.3%.

The *annual savings per program* from allowing MROs and other offsite contracted personnel to utilize other facilities conforming to DOT requirements are calculated as follows:

$$[(NUM_{MROs} \times PER_{Random} \times PER_{Distance} \times (HOURS_{Travel} \times WAGE_{MRO}))] \times NUM_{Facilities}$$

Parameter	Description
$HOURS_{Travel}$	Hours of travel, waiting, and specimen collection time (on average) saved by utilizing DOT-approved facility (as described in assumptions below)
$NUM_{Facilities}$	Number of facilities per program (as described in Appendix 2, Exhibit A2-14)
NUM_{MROs}	Number of offsite contracted MROs per facility (as described in assumptions below)
$PER_{Distance}$	Percentage of contracted FFD personnel who live closer to a DOT-approved collection facility than to a licensee's standard collection facility (as described in assumptions below)
PER_{Random}	Percentage tested by a random drug and alcohol testing program per year (as described in assumptions below)
$WAGE_{MRO}$	MRO wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Number of offsite contracted MROs per facility: 2.
- Percentage tested by a random drug and alcohol testing program per year: 50%.
- Percentage of contracted FFD personnel who live closer to a DOT-approved collection facility than to a licensee's standard collection facility: 33.3%.
- Hours of MRO travel time saved by utilizing DOT-approved facility in lieu of the licensee's collection site: 2 hours.

Paragraph 26.31(c)

Subparagraph 26.31(c)(1)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies that licensees and other entities with licensee-approved FFD programs must administer pre-access drug and alcohol testing in order to grant initial, updated, and reinstated authorization as specified in §26.65. Although pre-access testing is already required under 26.24(a)(1) of the former rule, the final rule adopts provisions from the AAO that create different requirements for individuals with different lengths of interruptions between periods of authorization. As a result, this subparagraph of the final rule imposes no incremental costs and affords no savings because it is based on non-safeguards information requirements imposed by the NRC's AAO dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis-Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the final subparagraph does not directly result in incremental costs or savings. The specific pre-access drug and alcohol testing requirements for the three authorization types are contained in §26.65, and the incremental costs and savings of these requirements are calculated there.

Subparagraph 26.31(c)(2)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely describes the situations that warrant for-cause drug and alcohol testing, retaining provisions that are already included in subparagraph 26.24(a)(3) of the former rule.

Subparagraph 26.31(c)(3)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely describes situations that warrant post-event drug and alcohol testing, renumbering and

clarifying provisions that are already included in subparagraph 26.24(a)(3) of the former rule. The final subparagraph does provide a new requirement establishing a threshold for the types of workplace personal injuries and illnesses for which post-event testing is required. Further, the final subparagraph changes a former requirement such that post-event testing is required regardless of whether there was "reasonable suspicion" that the individual was abusing drugs or alcohol for the consequences listed in the final paragraph.

Subparagraph 26.31(c)(4)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely prescribes that licensees must conduct followup drug and alcohol testing on individuals who have violated FFD policy in the past to ensure continued abstinence, as required under subparagraph 26.24(a)(4) of the former rule.

Subparagraph 26.31(c)(5)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely rephrases requirements in subparagraph 26.24(a)(2) of the former rule and requires licensees to conduct random drug and alcohol testing on a statistically random and unannounced basis.

Paragraph 26.31(d)

Subparagraph 26.31(d)(1)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely reorganizes paragraph 26.24(c) and Appendix A, Section 2.1(a)–(c), of the former rule. This revised subparagraph clarifies the six types of drugs for which each urine specimen must be analyzed and permits licensees and other entities to conduct testing for drugs or other substances that are not explicitly specified by the rule. The final subparagraph adds a requirement such that licensees and other entities must test for adulterants when conducting drug and alcohol testing.

Subparagraph 26.31(d)(1)(i)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely retains the permission provided in paragraph 26.24(c) of the former rule for licensees to consult with local law enforcement or other sources to identify additional drugs that are likely to be used in the particular geographic locale of the FFD program. This final subparagraph also extends this permission to other entities with licensee-approved FFD programs and provides procedures for testing additional substances that are identified. The final subparagraph adds requirements that an independent and qualified forensic toxicologist must certify that testing results for other substances not explicitly identified by subparagraph 26.31(d)(1) are scientifically sound and legally defensible. The qualifications of the forensic toxicologist are also defined in this final paragraph. Although these additional testing requirements may result in

additional costs, the identification of additional substances to test for is rare and the costs are, therefore, assumed to be negligible.

Subparagraph 26.31(d)(1)(ii)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies that licensees and other entities are allowed to test for any suspected drugs, drug metabolites, or any other substances and adulterants that the licensee or other entity suspects that an individual may have abused when conducting post-event, followup, and for-cause testing. These requirements are already contained in Appendix A, Sections 2.1(b) and (e) of the former rule. The new provision, however, adds a requirement that testing at the confirmatory assay's LOD may only be performed if the initial test result suggests the presence of a drug or metabolite within 35% of the established cutoff concentration for drugs that the licensee or other entity suspects an individual may have abused. In addition, the final subparagraph specifies that test results that fall below the established cutoff levels may not be considered when determining appropriate management actions and sanctions (per Subpart D), except if the specimen is dilute and the licensee or other entity has requested the HHS-certified laboratory to evaluate the specimen under final §§ 26.163(a)(2) or 26.185(g)(3).
This limitation has been added to assure the privacy rights of individuals whose urine specimens may be tested under this provision. As licensees and other entities are already abiding by these protections, no incremental cost is anticipated.

Subparagraph 26.31(d)(1)(iii)

This subparagraph of the final rule requires licensee and other entities to 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. The incremental cost associated with this requirement is calculated within paragraph 26.27(a) of the final rule.

Subparagraph 26.31(d)(2)

This paragraph revises subparagraph 26.24(a)(2) of the former rule to clarify that licensees are required to ensure that all persons in the population subject to testing have an equal probability of being randomly selected and tested. Under the final subparagraph, in the event that a selected individual cannot be tested immediately, (i.e., on leave, out sick, etc.), the licensee must make reasonable efforts to test the individual at the earliest reasonable and practical opportunity when both the donor and collectors are available. Thus, licensees will incur an incremental cost to satisfy the "reasonable effort" requirement by tracking the randomly selected individuals who are unavailable during the selected testing date and testing them at the next (earliest) reasonable and practical opportunity. This final subparagraph also further clarifies that licensees must conduct testing on an unpredictable schedule, including weekends, backshifts, and holidays." This provision imposes no additional costs because former subparagraph 26.24(a)(2) included these time periods, as described in Section 4.6 of NUREG-1385.

The *annual costs per program* from requiring greater effort to track individuals selected for random drug and alcohol testing result from the following:[9]

$$NUM_{Employees} \times PER_{Random} \times PER_{Unavailable} \times HOURS_{Manager} \times WAGE_{Manager} \times NUM_{Units}$$

Parameter	Description
$HOURS_{Manager}$	Hours of FFD manager tracking time per randomly selected employee who is unavailable for the scheduled test (as described in assumptions below)
$NUM_{Employees}$	Number of employees per unit (as described in Appendix 2, Exhibit A2-14)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
PER_{Random}	Percentage of employees per year who are randomly selected for drug and alcohol testing (as described in assumptions below)
$PER_{Unavailable}$	Percentage of randomly selected employees per year who are unavailable for the scheduled test (as described in assumptions below)
$WAGE_{Manager}$	FFD manager wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of employees per year who are randomly selected for drug and alcohol testing: 50%.
- Percentage of randomly selected employees per year who are unavailable for the scheduled test: 25%.
- Hours of FFD manager tracking time per randomly selected employee who is unavailable for the scheduled test: 0.25 hours.

Subparagraph 26.31(d)(3)

This subparagraph specifies general requirements for drug testing and combines paragraph 26.24(f) and Appendix A Sections 1.1(3), 2.8(e)(1), 4.1(a) and (b) of the former rule. An amendment adds validity testing, the costs of which are described under §26.131 in Subpart F and subparagraph 26.161(b)(1) in Subpart G. This final subparagraph also establishes requirements for FFD programs that use more stringent cutoff levels for initial drug testing. (Each licensee and other entity must apply consistent cutoffs to all tests performed.) This final

[9] This analysis assumes that all licensees will be affected by the added provision. However, because some licensees may already be tracking and testing individuals unavailable at the time of random selection, the results may overestimate the true incremental cost.

paragraph also requires documentation of the more stringent cutoff levels in the FFD program policy and procedures. The final subparagraph adds a new requirement such that, before implementing the more stringent cutoffs, an independent forensic toxicologist must evaluate and certify them as technically sound and legally defensible, with two exceptions. An evaluation by an independent forensic toxicologist is not required if the U.S. Department of Health and Human Services revises the cutoff levels in the HHS Guidelines and the FFD program adopts the lower HHS cutoffs. Certification by a forensic toxicologist also is not required if the licensee received written approval from NRC to test for lower cutoff levels before the implementation date of the final rule, in accordance with Appendix A, Section 1.1(2) of the former rule.

The one-time costs per FFD program to employ more stringent cutoff level(s) for drugs result from the following:

$$[(HOURS_{tox.review} + HOURS_{tox.report}) \times WAGE_{toxicologist}] \times PER_{more\ stingent\ cutoffs} \times PER_{non\text{-}report} + (HOURS_{Manager} \times WAGE_{Manager} \times PER_{more\ stingent\ cutoffs} \times PER_{non\text{-}report})$$

Parameter	**Description**
$HOURS_{Manager}$	Hours of FFD program manager labor to review the results of the forensic toxicologist's evaluation of the FFD program's more stringent cutoff levels per program (as described in assumptions below)
$HOURS_{tox.report}$	Hours of time spent by a forensic toxicologist to write an evaluation of the cutoff levels per FFD program (as described in assumptions below)
$HOURS_{tox.review}$	Hours of review by a forensic toxicologist per FFD program using more stringent cutoff level(s) for drug testing (as described in assumptions below)
$PER_{more\ stringent}$	Percentage likelihood that the FFD program uses more stringent cutoff levels for drug testing (as described in assumptions below)
$PER_{non\text{-}report}$	Percentage likelihood that the FFD program, if it uses more stringent cutoff levels for drug testing, has not received NRC written approval (as described in assumptions below)
$WAGE_{Manager}$	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{toxicologist}$	Toxicologist wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of review by a forensic toxicologist per FFD program using more stringent cutoff level(s) for drug testing: 3.5 hours.

- Hours of time spent by a forensic toxicologist to write an evaluation of the cutoff levels per FFD program: 0.5 hours.

- Hours of time spent by FFD program manager to review the results of the forensic toxicologist's evaluation per FFD program: 0.5 hours.

- Percentage likelihood that the FFD program will use more stringent cutoff levels for drug testing after the final rule is enacted: 10 percent.

- Percentage likelihood that the FFD program, if it will use more stringent cutoff levels for drug testing after the final rule is enacted, did not previously use these more stringent cutoff levels (and, therefore, has not received Commission approval): 25 percent.

Subparagraph 26.31(d)(4)

This subparagraph revises requirements in 26.24(g) of the former rule, which pertained to alcohol testing. Specifically, this revised subparagraph modifies the applicable threshold requirement by reducing the threshold level of breath alcohol concentration from 0.04 to 0.02 for an initial breath test requiring confirmatory testing. Incremental costs associated with this revision are calculated and discussed in connection with §26.97. Another revision permits the use of oral fluids for initial breath testing and is discussed in §26.95 of this analysis.

Subparagraph 26.31(d)(5)

This subparagraph permits the MRO to authorize alternative specimen collection and evaluation procedures in instances in which an individual has a medical condition that makes it difficult or hazardous to collect breath, oral fluids, or urine specimens. Although this clarification offers licensees more flexibility in collecting specimens, the analysis assumes that these situations are extremely rare, making any potential savings speculative and negligible.

Subparagraph 26.31(d)(6)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it restates that specimens collected can only be used for Part 26 testing, and clarifies that specimens may only be collected and tested within a licensee or licensee-approved other entity FFD program that meets the requirements of this part, as required by Section 2.1(d) of Appendix A of the former rule.

26.33 Behavioral Observation

This section of the final rule represents a new requirement, which requires that individuals with authorization (i.e., other than supervisors, managers, and escorts as required under subparagraph 26.27(b)(10)) are required to report fitness concerns to persons designated by the licensee. Costs associated with behavioral observation training are calculated in connection with §26.29. In addition, the new behavioral observation requirements and the additional requirement for individuals with authorization to report FFD concerns about other individuals who are present at

the licensee's or other entity's site or facility may result in additional for-cause referrals. As a result, there will be an increase in both the number of drug and alcohol tests performed, and the number of positive test results that must undergo confirmatory testing. The analysis calculates the cost of these activities below. The observation and reporting provisions of this final paragraph impose no incremental cost and afford no saving.

The *annual costs per program* result from the sum of the following costs:

- Annual costs per program to review additional for-cause referrals are calculated as follows:

  $NUM_{For\text{-}Cause} \times PERI_{For\text{-}Cause} \times [(HOURS_{Worker} \times WAGE_{Worker}) + (HOURS_{Manager} \times WAGE_{Manager})] \times NUM_{Units}$

- Annual cost per program to conduct additional drug and alcohol tests due to increased for-cause referrals are calculated as follows:[10]

  - Annual costs per program to conduct additional drug and alcohol tests due to increased for-cause referrals at programs with onsite testing laboratories (yielding negative results) result from the following:

    $NUM_{For\text{-}Cause} \times PERI_{For\text{-}Cause} \times PER_{Negative} \times COST_{Onsite\text{-}Negative} \times NUM_{Units}$

  - Annual costs per program to conduct additional drug and alcohol tests due to increased for-cause referrals at programs with offsite testing laboratories (yielding negative results) result from the following:

    $NUM_{For\text{-}Cause} \times PERI_{For\text{-}Cause} \times PER_{Negative} \times COST_{Offsite\text{-}Negative} \times NUM_{Units}$

  - Annual costs per program to conduct additional drug and alcohol tests due to increased for-cause referrals at programs with onsite testing laboratories (yielding non-negative results) result from the following:

    $NUM_{For\text{-}Cause} \times PERI_{For\text{-}Cause} \times (1\text{-}PER_{Negative}) \times COST_{Onsite\text{-}Non\text{-}Negative} \times NUM_{Units}$

  - Annual costs per program to conduct additional drug and alcohol tests due to increased for-cause referrals at programs with offsite testing laboratories (yielding negative results) result from the following:

    $NUM_{For\text{-}Cause} \times PERI_{For\text{-}Cause} \times (1\text{-}PER_{Negative}) \times COST_{Offsite\text{-}Non\text{-}Negative} \times NUM_{Units}$

[10] The increased costs will vary for programs depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified testing laboratory.

- Annual costs per program to retest confirmed positive drug test results at a second HHS-certified laboratory at the request of the donor are calculated as follows:

  $NUM_{For\text{-}Cause} \times PERI_{For\text{-}Cause} \times (1\text{-}PER_{Negatives}) \times PER_{Retest} \times COST_{Retest} \times NUM_{Units}$

- Annual costs per program for the percentage of workers with confirmed positive test results who initiate an appeals process are calculated as follows:

  $NUM_{For\text{-}Cause} \times PERI_{For\text{-}Cause} \times (1\text{-}PER_{Negatives}) \times PER_{Appeals} \times COST_{Appeals} \times NUM_{Units}$

Parameter	**Description**
$COST_{Appeals}$	Cost of appeals process per appeal (as described in Appendix 2, Exhibit A2-11, Exhibit A2-13)
$COST_{Offsite\text{-}Negative}$	For-cause testing cost for a negative result per test at programs with offsite testing laboratories (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{Offsite\text{-}Non\text{-}Negative}$	For-cause testing cost for a non-negative result per test at programs with offsite testing laboratories (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{Onsite\text{-}Negative}$	For-cause testing cost for a negative result per test at programs with onsite testing laboratories (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{Onsite\text{-}Non\text{-}Negative}$	For-cause testing cost for a non-negative result per test at programs with onsite testing laboratories (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{Retest}$	Cost of drug retest per test (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$HOURS_{Manager}$	Hours of FFD program manager review per for-cause referral (as described in assumptions below)
$HOURS_{Worker}$	Hours of facility worker hours under review per for-cause referral (as described in assumptions below)
$NUM_{For\text{-}Cause}$	Pre-rule annual number of for-cause tests/referrals per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Appeals}$	Percentage of workers who have positive test results and initiate an appeals process (as described in assumptions below and in Appendix 2, Exhibit A2-6)
$PERI_{For\text{-}Cause}$	Percentage increase in for-cause tests/referrals as a result of the final rule (as described in assumptions below)
$PER_{Negative}$	Percentage of for-cause tests that yield negative test results (as described in Appendix 2, Exhibit A2-12)

Parameter	Description
PER_{Retest}	Percentage of workers who have positive test results and request retesting (as described in assumptions below)
$WAGE_{Manager}$	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage increase in for-cause tests/referrals beginning with new rule: 10%.
- Hours of facility worker hours under review per for-cause referral: 4 hours per review.
- Hours of FFD program manager review per for-cause referral: 4 hours per review.
- Percentage of workers who have positive test results and request retesting: 5%.
- Percentage of workers who have positive test results and initiate an appeals process: 1%.
- The per-unit cost of an *onsite for-cause drug and alcohol test yielding negative results* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) onsite licensee testing costs per urine specimen for drugs and validity
  (4) labor of FFD manager to process paperwork for negative test results.
- The per-unit cost of an *offsite for-cause drug and alcohol test yielding negative results* includes including the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) HHS-certified laboratory costs per urine specimen for drugs and validity;
  (4) labor of FFD manager to process paperwork for negative test results
- The per-unit cost of *an onsite for-cause drug and alcohol test yielding positive results* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)

(3) onsite licensee testing costs per urine specimen for drugs
(4) HHS-certified laboratory cost per specimen for drugs and validity
(5) cost of subsequent actions resulting from a confirmatory positive drug/validity test result

- The per-unit cost of *an offsite for-cause drug and alcohol test yielding positive results* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) HHS-certified laboratory costs per urine specimen for drugs and validity
  (4) cost of subsequent actions resulting from a confirmatory positive drug/validity test result

26.35 Employee Assistance Programs

Paragraph 26.35(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely restates and clarifies the language in §26.25 of the former rule, which requires licensees and other entities to have employee assistance programs (EAPs).

Paragraph 26.35(b)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies language in §26.25 of the former rule, which requires that licensees and other entities are not required to provide EAP services to C/V employees nor to individuals who have applied for, but have not yet been granted, authorization.

Paragraph 26.35(c)

This paragraph of the final rule [including subparagraphs 26.35(c)(1)–(3)] imposes no incremental cost and affords no saving because it merely restates and clarifies the language in §26.25 of the former rule regarding the role of EAP staff in protecting the identity and privacy of any individual's seeking assistance. The new paragraph does allow the EAP to bypass the privacy requirement in the event that the individual waives the right to privacy in writing or if a determination of fitness deems an individual's condition or actions pose or have posed an immediate hazard to himself or herself or others. In such cases, EAP personnel shall inform FFD management. The final paragraph also adds specificity to the former rule, providing examples of individual conditions or actions that require EAP personnel to report the individual to management. This final paragraph parallels elements covered in §26.25 of the former rule.

26.37 Protection of Information

Paragraph 26.37(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely combines and clarifies wording from paragraph 26.29(a) and Appendix A, Section 3.1, of the former rule.

Paragraph 26.37(b)

This paragraph of the final rule [including subparagraphs 26.37(b)(1)–(8)] imposes no incremental cost and affords no saving because it restates and separates elements of paragraph 26.29(b) of the former rule.

Paragraph 26.37(c)

This paragraph of the final rule requires licensees and other entities to disclose personal information collected under this part to other licensees or other entities, including C/Vs, legitimately seeking the information for authorization decisions. As indicated by NRC guidance in NUREG-1600, "Revision to the NRC Enforcement Policy" (per 67 FR 66311, October 31, 2002) licensees are already sharing this information. The analysis also assumes that C/Vs are already sharing such information with other C/Vs. Whether licensees are sharing information with C/Vs is unknown, but such instances are assumed to be rare. Therefore, the final paragraph imposes no incremental cost and affords no saving.

Paragraph 26.37(d)

This paragraph combines elements of paragraph 26.29(b) of the former rule to clarify information disclosure requirements for individuals. Although the former rule required similar disclosure processes, some licensees interpreted the former provisions in a manner that complicates the process through which employees can have access to their records. In an effort to clarify the NRC's original intent, the revised paragraph requires the FFD program (including, but not limited to, the collection site, HHS-certified laboratory, substance abuse expert, or MRO) to give requesting individuals copies of all of their own FFD records, including but not limited to records pertaining to a violation of FFD policy. The copying, packaging, and shipping of these records will result in an incremental cost to licensees.

The *annual costs per program* to provide individuals with easier access to personal documents result from the following:[11]

$$NUM_{Positives} \times PER_{Requesting} \times [(HOURS_{Clerical} \times WAGE_{Clerical}) + COST_{Mailing}] \times NUM_{Units}$$

Parameter	Description
$COST_{Mailing}$	Cost of mailing (express mail) per information disclosure request (as described in Appendix 2, Exhibit A2-6)
$HOURS_{Clerical}$	Additional clerical personnel hours to copy, package, and ship records per disclosure request (as described in assumptions below)
$NUM_{Positives}$	Annual number of drug tests yielding positive results per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Unit}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Requesting}$	Percentage of employees who have positive test results and request records (as described in assumptions below)
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- For the purposes of this analysis, it is assumed that individuals request their own FFD records only when they are found in violation of FFD policy.
- Percentage of employees who have positive test results and request records: 50%.
- Additional clerical personnel hours to copy, package, and mail records per disclosure request: 1 hour.

Paragraph 26.37(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it retains a portion of Section 3.1 of Appendix A to the former rule.

Paragraph 26.37(f)

This paragraph of the final rule imposes no incremental cost and affords no saving because it retains a portion of paragraph 26.29(b) of the former rule.

[11] The analysis assumes that all licensees will incur costs as a result of this provision. However, because some licensees may already be providing adequate access to records, the results may overestimate the true incremental cost.

26.39 Review Process for Fitness-for-Duty Policy Violations

Paragraph 26.39(a)

This paragraph of the final rule, which states that an objective and impartial review process for FFD policy violations must be established, imposes no incremental cost and affords no saving because any incremental costs associated with revising or rewriting procedures are calculated in connection with §26.27. The final paragraph, however, adds requirements to the language in paragraph 26.28 of the former rule by requiring an objective and impartial review of the facts.

Paragraph 26.39(b)

This paragraph of the final rule imposes no incremental cost and affords no saving because it requires that an individual under review must be allowed to offer additional relevant information, as provided under §26.28 of the former rule.

Paragraph 26.39(c)

This paragraph requires that a review of potential FFD policy violations be conducted by an individual who is not associated with FFD program administration. Under the subparagraph 26.27(b)(3) of the former rule, licensees were required to establish satisfactory management and medical assurance of an individual's fitness for duty before granting unescorted access following a previous violation of policy. According to NRC guidance contained in NUREG-1385, "Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions," licensees were free to interpret how best to meet the "satisfactory assurance" requirement, which at a minimum involves a review by a single individual. This paragraph of the final rule imposes no incremental cost and affords no saving because it retains the intent of subparagraph 26.27(b)(3) of the former rule.

Paragraph 26.39(d)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely requires licensees to update their records in the event that review finds in favor of the individual. Further, the final paragraph clarifies paragraph 26.28 of the former rule, which implicitly required corrections of records after a successful appeal.

Paragraph 26.39(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies provisions in paragraph 26.28 of the former rule. Specifically, this final paragraph states that 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 must ensure that the review procedure required in this section is provided to the individual. In addition, this final paragraph states that licensees who rely on a

C/Vs FFD program are *not* required to give C/V employees a review procedure for violations identified through a C/V's drug and alcohol testing program.

26.41 Audits and Corrective Action

Paragraph 26.41(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies the licensee's responsibility for ensuring the continued effectiveness of all elements of the FFD program, including programs and program elements implemented by C/Vs, as well as programs implemented by HHS-certified laboratories. These requirements are addressed in connection with paragraph 26.80 of the former rule.

Paragraph 26.41(b)

This paragraph reduces the audit frequency for licensees and other entities (with onsite collection services) from every 12 months under paragraph 26.80(a) of the former rule to "as needed, but no less frequently than every 24 months," resulting in a potential incremental savings. Total annual savings will depend on whether a given licensee has onsite or offsite collection and testing facilities (i.e., because the final rule [in paragraph 26.41(c)(1)] does not reduce the frequency of licensee audits of HHS-certified laboratories or offsite collection facilities that do not maintain their own FFD program). The reduced audit frequency will also yield savings from reduced auditor travel costs, which are calculated separately below.

The *annual savings per program*, excluding travel savings (which are calculated separately later in the discussion), are calculated as the *sum* of the following factors:

- The *annual base saving per program* (regardless of whether the program uses onsite or offsite testing and collection facilities) from the reduced audit frequency are estimated as follows:

  $$[(HOURS_{Auditor\text{-}Base} \times WAGE_{Auditor}) + (HOURS_{Manager\text{-}Base} \times WAGE_{Manager}) + (HOURS_{Clerical\text{-}Base} \times WAGE_{Clerical})] \times PER_{Annualized} \times NUM_{Facilities}$$

- The additional *annual savings per program* from the audit frequency reduction that accrue to programs with *onsite testing* are estimated as follows:

  $$[(HOURS_{Auditor\text{-}Onsite\ Testing} \times WAGE_{Auditor}) + (HOURS_{Manager\text{-}Onsite\ Testing} \times WAGE_{Manager}) + (HOURS_{Clerical\text{-}Onsite\ Testing} \times WAGE_{Clerical}) + (HOURS_{Lab\ Manager} \times WAGE_{Lab\ Manager}) + (HOURS_{Lab\ Staff} \times WAGE_{Lab\ Staff})] \times PER_{Annualized} \times NUM_{Facilities}$$

- The additional *annual savings per program* from the audit frequency reduction that accrue *to programs with onsite collection* are estimated as follows:

$$[(HOURS_{Auditor\text{-}Onsite\ Collection} \times WAGE_{Auditor}) + (HOURS_{Manager\text{-}Onsite\ Collection} \times WAGE_{Manager}) + (HOURS_{Clerical\text{-}Onsite\ Collection} \times WAGE_{Clerical}) + [NUM_{Facilities} \times ((HOURS_{Collection\ Manager} \times WAGE_{Collection\ Manager}) + (HOURS_{Collection\ Staff} \times WAGE_{Collection\ Staff}))]] \times PER_{Collection} \times PER_{Anualized} \times NUM_{Facilities}$$

Parameter	**Description**
$HOURS_{Auditor\text{-}Base}$	Base hours of contracted auditor time that each facility saves per full program audit (as described in assumptions below)
$HOURS_{Auditor\text{-}Onsite\ Collection}$	Additional hours (i.e., above the base described previously) of contracted auditor time saved per full program audit of a facility with onsite collection facilities (as described in assumptions below)
$HOURS_{Auditor\text{-}Onsite\ Testing}$	Additional hours (i.e., above the base described previously) of contracted auditor time saved per full program audit of a facility with onsite testing laboratories (as described in assumptions below)
$HOURS_{Clerical\text{-}Base}$	Base hours of clerical personnel time that each facility saves per full program audit (as described in assumptions below)
$HOURS_{Clerical\text{-}Onsite\ Collection}$	Additional hours (i.e., above the base described previously) of clerical personnel time saved per full program audit of a facility with onsite collection facilities (as described in assumptions below)
$HOURS_{Clerical\text{-}Onsite\ Testing}$	Additional hours (i.e., above the base described previously) of clerical personnel time saved per full program audit of a facility with onsite testing laboratories (as described in assumptions below)
$HOURS_{Collection\ Staff}$	Hours of collection site staff time saved per full program audit of a facility with onsite collection facilities (as described in assumptions below)
$HOURS_{Collection\ Manager}$	Hours of collection site manager time saved per year per facility with onsite collection facilities (as described in assumptions below)
$HOURS_{Lab\ Manager}$	Hours of testing laboratory manager time saved per full program audit of a facility with onsite testing laboratories (as described in assumptions below)
$HOURS_{Lab\ Staff}$	Hours of testing laboratory staff time saved per full program audit of a facility with onsite testing laboratories (as described in assumptions below)
$HOURS_{Manager\text{-}Base}$	Base hours of FFD program manager time that each facility saves per full program audit (as described in assumptions below)
$HOURS_{Manager\text{-}Onsite\ Testing}$	Additional hours (i.e., above the base described previously) of FFD program manager time saved per full program audit of a facility with onsite testing laboratories (as described in assumptions below)

Parameter	Description
$HOURS_{Manager\text{-}Onsite\ Collection}$	Additional hours (i.e., above the base described previously) of FFD program manager time saved per full program audit of a facility with onsite collection facilities (as described in assumptions below)
$NUM_{Facilties}$	Number of facilities per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Annualized}$	Percentage multiplier to yield annualized savings (as described in assumptions below)
$PER_{Collection}$	Percentage of facilities with onsite collection per program (as described in Appendix 2, Exhibit A2-4)
$WAGE_{Auditor}$	Contract auditor wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Collection\ Manager}$	Collection site manager wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Collection\ Staff}$	Collection site staff wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Lab\ Staff}$	Laboratory staff wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Lab\ Manager}$	Laboratory manager wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Manager}$	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage multiplier to yield annualized savings is 50% because the frequency reduction allows facilities to eliminate 1 audit over a 2-year period.
- Base hours of contracted auditor time that each facility saves per full program audit: 25 hours.
- Base hours of FFD program manager time that each facility saves per full program audit: 13 hours.
- Base hours of clerical personnel time that each facility saves per full program audit: 5 hours.
- Additional hours (i.e., above the base described above) of contracted auditor time saved per full program audit of a facility with onsite testing laboratories: 12 hours.

- Additional hours (i.e., above the base described above) of FFD program manager time saved per full program audit of a facility with onsite testing laboratories: 7 hours.

- Additional hours (i.e., above the base described above) of clerical personnel time saved per full program audit of a facility with onsite testing laboratories: 0 hours.

- Each program with onsite testing maintains a separate onsite testing laboratory.

- Additional hours (i.e., above the base described above) of contracted auditor time saved per full program audit of a facility with onsite collection facilities: 5 hours.

- Additional hours (i.e., above the base described above) of FFD program manager time saved per full program audit of a facility with onsite collection facilities: 0 hours.

- Additional hours (i.e., above the base described above) of clerical personnel time saved per full program audit of a facility with onsite collection facilities: 0 hours.

- Hours of testing laboratory manager time saved per full program audit of a facility with onsite testing laboratories: 2 hours.

- Hours of testing laboratory staff time saved per full program audit of a facility with onsite testing laboratories: 1 hours.

- Hours of collection site manager time saved per full program audit of a facility with onsite collection facilities: 2 hours.

- Hours of collection site staff time saved per full program audit of a facility with onsite collection facilities: 1 hour.

- Each facility in a program with onsite collection maintains a separate onsite collection site.

The audit frequency reduction will also result in reduced travel costs. The *annual savings per program* result from the sum of the following savings:

- The reduced audit frequency will result in reduced travel costs for auditors. The associated *annual base savings per program* from the reduced travel at each facility (i.e., regardless of whether a program uses onsite or offsite collection facilities and testing laboratories) are calculated as follows:

  $[NUM_{Auditors\text{-}Base} \times (COST_{Travel} + (COST_{Lodging} \times NUM_{Nights–Base}) + (HOURS_{Travel} \times WAGE_{Auditor}))] \times PER_{Annualized}$

- Additional annual savings per program that accrue due to reduced auditor travel to facilities with *onsite testing laboratories* are estimated as follows:

  $NUM_{Auditors\text{-}Onsite\ Testing} \times COST_{Lodging} \times NUM_{Nights\text{-}Onsite\ Testing} \times PER_{Annualized}$

- Additional annual savings per program that accrue due to reduced auditor travel to facilities with *onsite collection facilities* are estimated as follows:

  $NUM_{Auditors\text{-}Onsite\ Collection} \times COST_{Lodging} \times NUM_{Nights\text{-}Onsite\ Collection} \times PER_{Collection} \times PER_{Annualized}$

Parameter	**Description**
$COST_{Lodging}$	Cost of lodging and per diem per night (as described in assumptions below)
$COST_{Travel}$	Cost of round trip travel per auditor per audit (as described in assumptions below)
$HOURS_{Travel}$	Hours of round trip travel auditor per audit (as described in assumptions below)
$NUM_{Auditors\text{-}Base}$	Base number of auditors per program audit (as described in assumptions below)
$NUM_{Auditors\text{-}Onsite\ Testing}$	Additional number of auditors per program with onsite testing laboratories (as described in assumptions below)
$NUM_{Auditors\text{-}Onsite\ Collection}$	Additional number of auditors per program with onsite collection facilities (as described in assumptions below)
$NUM_{Nights\text{-}Base}$	Base number of nights of lodging that each program saves per full program audit (as described in assumptions below)
$NUM_{Nights\text{-}Onsite\ Testing}$	Additional number of nights of lodging each program saves per full program audit of a program with onsite collection and offsite testing (as described in assumptions below)
$NUM_{Nights\text{-}Onsite\ Collection}$	Additional number of nights of lodging each program saves per full program audit of a program with offsite collection and offsite testing (as described in assumptions below)

Parameter	Description
$PER_{Annualized}$	Percentage multiplier to yield annual savings (as described in assumptions below)
$PER_{Collection}$	Percentage of facilities with onsite collection per program (as described in Appendix 2, Exhibit A2-4)
$WAGE_{Auditor}$	Auditor wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Base number of auditors per program audit (regardless of whether the program uses onsite or offsite collection sites and testing laboratories): 1.
- Additional number of auditors per program with onsite testing laboratories: 1.
- Additional number of auditors per program with onsite collection facilities: 0.[12]
- Cost of round trip travel per auditor per audit: $300.
- Cost of lodging and per diem per night: $150.
- Hours of round trip travel per auditor per audit: 4 hours.
- Base number of nights of lodging each program saves per full program audit: 3 nights.
- Additional number of nights of lodging each program saves per full program audit of a program with onsite testing laboratories: 1 night.
- Additional number of nights of lodging each program saves per full program audit of a program with onsite collection facilities: 0 nights.
- Percentage multiplier to yield annualized savings is 50% because the frequency reduction allows facilities to eliminate 1 audit over a 2-year period.
- Each facility in a program with onsite collection maintains a separate onsite collection site.

[12] Programs with onsite testing laboratories are also believed to operate onsite collection facilities. In this case, the additional auditor calculated for the onsite collection facility is also assumed to audit the onsite testing facility.

Although licensees and other entities with approved FFD programs are allowed to audit less frequently, they are expected to conduct additional auditing activities when performance indicators suggest a potential area of weakness in the FFD program. The cost of these additional, focused audits, which targets specific FFD program activities and requires a shorter amount of time to complete than a full program audit, partially offsets the savings resulting from the reduced frequency of full program audits. The *annual costs per program* to conduct focused audits addressing problem areas of the FFD program result from the following:

$$[(HOURS_{Focused\ Auditor} \times WAGE_{Auditor}) + (HOURS_{Focused\ Manager} \times WAGE_{Manager}) + (HOURS_{Focused\ Clerical} \times WAGE_{Clerical})] \times NUM_{Facilities} + [NUM_{Auditors} \times (COST_{Travel} + (COST_{Lodging} \times NUM_{Nights\text{-}Focused}) + (HOURS_{Travel} \times WAGE_{Auditor}))]$$

Parameter	**Description**
$COST_{Lodging}$	Cost of lodging and per diem per night (as described in assumptions below)
$COST_{Travel}$	Cost of round trip travel per focused audit (as described in assumptions below)
$HOURS_{Focused\ Clerical}$	Hours of clerical personnel time per focused audit per facility (as described in assumptions below)
$HOURS_{Focused\ Manager}$	Hours of FFD program manager time per focused audit per facility (as described in assumptions below)
$HOURS_{Focused\ Auditor}$	Hours of contracted auditor time per focused audit per facility (as described in assumptions below)
$HOURS_{Travel}$	Hours of round trip auditor travel per focused audit (as described in assumptions below)
$NUM_{Auditors}$	Number of auditors per focused audit (as described in assumptions below)
$NUM_{Facilities}$	Number of Facilities per program (as described in Appendix 2, Exhibit A2-14)
$NUM_{Nights\text{-}Focused}$	Number of nights of lodging required by the auditor to complete a focused audit (as described in assumptions below)
$WAGE_{Auditor}$	Contract auditor wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Manager}$	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of contracted auditor time conducting a focused audit per facility: 4 hours.
- Hours of FFD program manager time per a focused audit per facility: 3 hours.
- Hours of clerical personnel time conducting a focused audit per facility: 1 hours.
- Number of auditors per focused audit: 2.
- Cost of round trip travel per focused audit: $300.
- Cost of lodging and per diem per night: $150.
- Hours of round trip auditor travel per focused audit: 4 hours.
- Number of nights of lodging required by the auditor to complete a focused audit: 1 night.

Paragraph 26.41(c)

Subparagraph 26.41(c)(1)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies that C/Vs located offsite or not under the direct supervision or observation of licensee personnel must be audited at a 12-month frequency, as specified in paragraph 26.80(a) of the former rule. The C/V services subject to this requirement include contracted MRO services, EAP or specimen collection services, and the services provided by HHS-certified laboratories. As described and calculated in 26.41(b), those C/V services that are provided onsite under the direct daily supervision of licensee personnel will be audited at a frequency of at least once every 24 months.

Subparagraph 26.41(c)(2)

This subparagraph adds a provision that allows licensees and other entities to rely upon the HHS certification reports and audits of HHS-certified laboratories, thereby eliminating audit duplication. Services provided to the licensee or other entity not addressed in the certification review must continue to be audited. Further duplication is eliminated by exempting organizations that do not routinely provide FFD services to a licensee or other entity, such as local hospitals or substance abuse treatment facilities. The elimination of audit duplication under this final subparagraph will result in incremental savings.

The *annual savings per program* from eliminating audit duplication result from the following:

$(HOURS_{Auditor} \times WAGE_{Auditor}) + (HOURS_{Manager} \times WAGE_{Manager}) + (HOURS_{Clerical} \times WAGE_{Clerical})$

Parameter	Description
$HOURS_{Auditor}$	Hours of contracted auditor time saved annually per program in elimination of audit duplication (as described in assumptions below)
$HOURS_{Clerical}$	Hours of clerical personnel time saved annually per program in elimination of audit duplication (as described in assumptions below)
$HOURS_{Manager}$	Hours of FFD program manager time saved annually per program in elimination of audit duplication (as described in assumptions below)
$WAGE_{Auditor}$	Contracted auditor wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Manager}$	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of contracted auditor time saved annually per program in elimination of audit duplication: 7 hours.
- Hours of FFD program manager time saved annually per program in elimination of audit duplication: 4 hours.
- Hours of clerical personnel time saved annually per program in elimination of audit duplication: 1 hour.

Paragraph 26.41(d)

Subparagraph 26.41(d)(1)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely restates the provision in Appendix A, Section 2.7(m) of the former rule regarding the reservation of the right to audit C/Vs, the C/V's subcontractors providing FFD services, and the HHS-certified laboratories at any time.

Subparagraph 26.41(d)(2)

This subparagraph of the final rule adds a new requirement stating that licensees' and other entities' contracts with C/Vs or HHS-certified laboratories must permit the licensee or other entity to obtain copies of any documents to assure that the C/V or the laboratory are performing their functions properly and that staff and procedures meet applicable requirements. The C/V or HHS-certified laboratory, however, does have the ability to reasonably limit the use and dissemination of any documents to ensure the protection of proprietary information and donors' privacy. Although not explicitly required in the former rule, the analysis assumes that current industry practices provide for the sharing of such information. As a result, no incremental costs or savings result from this final subparagraph.

Subparagraph 26.41(d)(3)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely restates requirements in Appendix A, Section 2.7(m) of the former rule. The final subparagraph requires licensees to conduct pre-award inspections and audits of the procedural aspects of HHS laboratory operations, except as provided in 26.41(g)(5), discussed below.

Paragraph 26.41(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely states that audits must focus on the effectiveness of FFD programs and auditors must remain independent of FFD program management and other personnel responsible for implementing the FFD program, as required by paragraph 26.80(b) of the former rule.

Paragraph 26.41(f)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely states licensees must document audit results and report them to senior corporate and site management, who must take and document appropriate corrective actions, including possible re-auditing of deficient areas (as discussed in paragraph 26.41(b)). These provisions are contained in paragraph 26.80(c) of the former rule.

Paragraph 26.41(g)

This paragraph of the final rule [including subparagraphs 26.41(g)(1)–(5)] imposes no incremental cost and affords no saving because it clarifies and/or explicitly sets forth implementation requirements under paragraph 26.80(a) of the former rule, and permitted practices regarding the sharing of audits. Subparagraph 26.41(g)(5) allows licensees and other entities to immediately use another HHS-certified laboratory in the event that their contracted HHS-laboratory loses its certification (the effect of which is discussed in paragraph 26.153(e) of this analysis).

Subpart C: Granting and Maintaining Authorization

26.51 Applicability

This section of the final rule imposes no incremental cost and affords no saving because it merely states that Subpart C applies to: (1) 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, the individuals in § 26.4(g) and, if necessary, § 26.4(j); (2) the licensees and other entities specified in § 26.3(c) for the categories of individuals in § 26.4(e) and, at the licensee's or entity's discretion, the categories of individuals identified in § 26.4(f), and; (3) the entities in § 26.4(d) to the extent that a licensee or other entity relies on the C/V to meet the requirements of this Subpart. This section also states that certain requirements in Subpart C apply to the individuals in § 26.4(h).

26.53 General Provisions

Paragraph 26.53(a)

This paragraph establishes categories of individuals applying for authorization and states that licensees must ensure that the requirements applicable for the individual's category have been met before granting authorization to initial authorizations, authorization updates, authorization reinstatements, and authorization with potentially disqualifying FFD information. This paragraph of the final rule is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order (AAO) dated January 7, 2003, and published in the Federal Register on January 13, 2003. As a result, the final paragraph imposes no incremental costs and affords no savings.

Sensitivity Analysis - Pre-Order Baseline

Relative to regulations that were in effect before the NRC issued the AAO, the paragraph indirectly results in incremental costs and savings for the different categories of applicants (as described in §§26.55, 26.57, 26.59, and 26.69 of the final rule). The incremental costs and savings that result from these differences are calculated in subsequent relevant sections of this analysis.

Paragraph 26.53(b)

This paragraph of the final rule defines new requirements for the beginning and ending dates of an individual's period of interruption of authorized status. The period of interruption begins on the day after authorization was previously terminated and ends with the day the licensee or other entity actually grants or denies authorization. Costs and savings associated with each category of authorization are presented below in the analysis of §§26.55, 26.57, and 26.59.

Paragraph 26.53(c)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely states that FFD training requirements must be met by an applicant for authorization before licensees can grant authorization, which parallels the requirements in paragraph 26.21(b) of the former rule.

Paragraph 26.53(d)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies that licensees and other entities seeking to grant authorization to an individual who is maintaining authorization under another FFD program may rely on that other program to satisfy the applicable requirements of this part. The receiving FFD program must ensure that the program elements to which the individual is subject under the transferring FFD program remain current. This practice is already allowed under §26.23 and subparagraph 26.24(a)(1) of the former rule, as well as guidance contained in NUREG-1385, "Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions."

Paragraph 26.53(e)

This paragraph of the final rule allows licensees and other entities to 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. This provision is a permissive relaxation of the former rule requirements providing licensees and other entities with flexibility to rely on a C/V's FFD program.

Subparagraph 26.53(e)(1)

This subparagraph of the final rule is a new requirement that allows a C/V's FFD program to grant and maintain an individual's authorization under the C/V's FFD program. The final subparagraph also states that 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). Costs and savings associated with each category of authorization are presented below in the analysis of §§26.55, 26.57, and 26.59.

Subparagraph 26.53(e)(2)

This subparagraph of the final rule requires C/Vs to inform affected licensees and other entities of the denial or unfavorable termination of an individual's authorization if the individual is performing any duties for the licensee or other entity. This final subparagraph also requires the licensee and other entity to either 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 set forth in § 26.69 in order to maintain the individual's authorization to perform those duties. This final paragraph imposes no incremental cost and affords no saving because this analysis assumes that C/Vs already share information regarding access authorization denials and unfavorable terminations with licensees and other entities.

Subparagraph 26.53(e)(3)

This subparagraph of the final rule is a new requirement that allows a licensee or other entity to grant authorization to an individual or maintain an individual's authorization if the individual is maintaining authorization under a C/V's FFD program. The individual must continue 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 must ensure that the program elements to which the individual is subject under the C/V's FFD program remain current. This provision is a permissive relaxation of the former rule requirements providing licensees and other entities with flexibility to rely on a C/V's FFD program.

Paragraph 26.53(f)

This paragraph of the final rule establishes that 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 access authorization requirements of Subpart C, except if the program or program elements of the FFD program for construction satisfy the applicable requirements of Part 26. Costs and savings associated with each category of authorization are presented below in the analysis of §§26.55, 26.57, and 26.59.

Paragraph 26.53(g)

This paragraph of the final rule requires licensees and C/Vs to identify an individual's violations of FFD requirements to licensees who have relied on or intend to rely on the FFD program elements of which the individual is in violation. This paragraph of the final rule is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order (AAO) dated January 7, 2003, and published in the Federal Register on January 13, 2003. As a result, the final paragraph imposes no incremental costs and affords no savings.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph does not result in any incremental costs. Although the final paragraph adopts provisions from the AAO that require licensees and C/Vs to identify an individual's violations of FFD requirements to licensees who have relied on or intend to rely on the FFD program elements of which the individual is in violation, this analysis assumes that licensees and C/Vs already share

information regarding FFD violations. Therefore, the analysis anticipates that this new requirement will not result in any additional costs.

Paragraph 26.53(h)

This paragraph of the final rule prohibits 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. This paragraph of the final rule is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order (AAO) dated January 7, 2003, and published in the Federal Register on January 13, 2003. As a result, the final paragraph imposes no incremental costs and affords no savings.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph does not result in any incremental costs. Although the final paragraph adopts provisions from the AAO that require licensees and other entities to gain an individual's consent before gathering information about the individual's authorization history, this analysis assumes that this is a standard business practice for licensees and other entities. Therefore, the analysis anticipates that this new requirement will not result in any additional costs.

Paragraph 26.53(i)

This paragraph of the final rule requires licensees to inform, in writing, individuals who are applying for authorization that the following actions 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; (3) refusal to provide written consent for the sharing of personal information with other licensees or C/Vs; (4) failure to report any legal actions. This paragraph of the final rule contains access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003. Therefore, this paragraph of the final rule does not impose any incremental costs on licensees.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph results in incremental costs. The final paragraph adopts provisions from the AAO that require licensees and other entities to inform, in writing, individuals applying for authorization of actions that are sufficient cause for denial or unfavorable termination of authorization. This analysis calculates the one-time cost associated with developing a written notification document as part of the one-time costs calculated in §26.27(a), Written Policy and Procedures.

26.55 Initial Authorization

Paragraph 26.55(a)

This paragraph of the final rule establishes that an initial applicant is any individual who either has never held authorization or whose authorization was terminated favorably and has been interrupted for a period of 3 or more years. No incremental costs or savings result from this provision because it is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order (AAO) dated January 7, 2003, and published in the Federal Register on January 13, 2003.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations in effect before the NRC issued the AAO, the paragraph indirectly results in incremental costs and savings because it imposes different requirements for the different categories of applicants than does the former rule. The incremental costs and savings associated with these changes are presented and calculated in the subparagraphs below.

Subparagraph 26.55(a)(1)

This subparagraph of the final rule requires licensees to ensure that self-disclosures have been obtained and reviewed, as described by §26.61, from applicants for initial authorization before granting authorization. This final paragraph imposes no incremental cost and affords no saving because, under provisions of the AAO, applicants for unescorted access are subject to similar self-disclosure requirements.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the subparagraph, in conjunction with subparagraph 26.61(a)(1), does result in incremental savings. The savings result from provisions that state that applicants for initial authorization whose last authorization was terminated favorably and who have been covered by a behavioral observation and arrest-reporting program throughout the period of interruption do not need to submit self-disclosures to licensees and other entities. The *annual savings per program* result from the *sum* of the following savings:

- The annual savings per program from reduced facility worker labor burden for those initial applicants who qualify for the self-disclosure relaxation are estimated as follows:

  $$NUM_{Applicants} \times PER_{Qualify} \times HOURS_{Worker} \times WAGE_{Worker} \times NUM_{Units}$$

- The annual savings per program resulting from a reduced clerical personnel labor burden (because fewer self-disclosures submitted by initial applicants will need to be processed) are calculated as follows:

$$NUM_{Applicants} \times PER_{Qualify} \times HOURS_{Clerical} \times WAGE_{Clerical} \times NUM_{Units}$$

Parameter	Description
$HOURS_{Clerical}$	Clerical personnel hours saved in a self-disclosure (as described in assumptions below)
$HOURS_{Worker}$	Facility worker hours saved in a self-disclosure (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for initial authorization per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Qualify}$	Percentage of $NUM_{Applicants}$ who qualify for the relaxation (as described in assumptions below)
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage $NUM_{Applicants}$ who qualify for the relaxation: 50%.
- Facility worker hours saved in a self-disclosure: 0.25 hours per update.
- Clerical personnel hours saved in a self-disclosure: 0.25 hours per update.

Subparagraph 26.55(a)(2)

This subparagraph of the final rule requires licensees to ensure that a suitable inquiry has been completed, as described by §26.63, on applicants for initial authorization before granting authorization. This final subparagraph imposes no incremental cost and affords no saving because, under provisions in the AAO, applicants for unescorted access are subject to similar suitable inquiry requirements.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the subparagraph, in conjunction with subparagraph 26.63(a), does result in incremental savings. The savings result from provisions that state that licensees and other entities do not need to conduct suitable inquiries on applicants for initial authorization whose last authorization was terminated

favorably and who have been covered by a behavioral observation and arrest-reporting program throughout the period of interruption. The *annual savings per program* from not conducting the suitable inquiry on initial applicants qualifying for the relaxation result from the following:

$$NUM_{Applicants} \times PER_{Qualify} \times HOURS_{HR} \times WAGE_{HR} \times NUM_{Units}$$

Parameter	Description
$HOURS_{HR}$	HR personnel hours saved per applicant due to the relaxation of a suitable inquiry under former rule, but prior to the AAO (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for initial authorization per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Qualify}$	Percentage of $NUM_{Applicants}$ who qualify for the behavioral observation relaxation (as described in assumptions below)
$WAGE_{HR}$	HR personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of $NUM_{Applicants}$ who qualify for the behavioral observation relaxation: 50%.

- HR personnel hours saved in the relaxation of a suitable inquiry under the former rule, but prior to the AAO: 1 hour per inquiry.

In addition, the final subparagraph, in conjunction with subparagraph 26.63(f)(1), results in additional incremental savings relative to the regulations in effect before the NRC issued the AAO. The savings result from provisions that reduce the licensees' labor burden to conduct suitable inquiries on applicants that have not identified any potentially disqualifying FFD information on their self-disclosures. This labor burden is reduced in three ways by (1) reducing the time period that the suitable inquiry must cover from 5 years under the former rule to 3 years, if no potentially disqualifying information is identified, (2) requiring licensees to contact only those employers whom the applicant identified as having worked for the longest in a given calender month during the first and second years of the 3 year period,[1] and (3) by allowing licensees to take credit for a portion of the suitable inquiry that has been conducted by other licensees. The *annual savings per program* due to the reduced suitable inquiry coverage period and scope for those initial applicants qualifying for the relaxation result from the following:

$$NUM_{Applicants} \times PER_{Not\ Qualifying} \times PER_{Non\text{-}PDFFDI} \times HOURS_{HR} \times WAGE_{HR} \times NUM_{Units}$$

[1] Licensees must contact all employers for the year immediately preceding the request for authorization, as required by subparagraph 26.63(f)(1).

Parameter	Description
$HOURS_{HR}$	HR personnel hours saved per applicant as a result of the reduced suitable inquiry coverage period and the reduced number of employers who must be contacted (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for initial authorization per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Not\ Qualifying}$	Percentage of applicants for initial authorization per year who do not qualify for the behavioral observation relaxation under subparagraph 23.63(a) (as described in assumptions below)
$PER_{Non\text{-}PDFFDI}$	Percentage of $NUM_{Applicants}$ who have no potentially disqualifying FFD information to disclose on their self-disclosures (as described in assumptions below)
$WAGE_{HR}$	HR personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of applicants for initial authorization per year who do not qualify for the behavioral observation relaxation: 50%

- Percentage of $NUM_{Applicants}$ who have no potentially disqualifying FFD information to disclose on their self-disclosures: 95%

- Hours of HR personnel time saved per applicant as a result of the reduced suitable inquiry coverage period and the reduced number of employers who must be contacted: 0.5 hours.

Sensitivity Analysis - Industry Practices

The former rule stipulated that a suitable inquiry must address all employers for whom the applicant worked over the past 5 years. Nonetheless, until recently, industry practices were inconsistent with NRC's interpretation of the requirements such that licensees conducting suitable inquiries did not call those employers for whom an applicant worked for less than 30 days. As a result, licensees will incur an incremental cost to comply with requirements in the former rule regarding applicants for initial authorization. The *annual costs per program* to conduct a more thorough suitable inquiry on applicants for initial authorization to comply with the former regulation result from the following:

$$NUM_{Applicants} \times HOURS_{HR} \times WAGE_{HR} \times NUM_{Units}$$

Parameter	Description
$HOURS_{HR}$	Additional HR personnel hours required to conduct a suitable inquiry consistent with former regulations (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for initial authorization per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units at a given program (as described in Appendix 2, Exhibit A2-14)
$WAGE_{HR}$	HR personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Additional HR personnel hours required to conduct a suitable inquiry consistent with former regulations: 10 minutes (a 20-percent increase over the current estimate of 50 minutes per applicant).

Subparagraph 26.55(a)(3)

This subparagraph of the final rule requires licensees to administer a pre-access drug and alcohol test, as described in §26.65, on applicants for initial authorization before granting authorization. This final subparagraph imposes no incremental cost and affords no saving because, under provisions of the AAO, applicants for unescorted access are subject to similar drug and alcohol testing requirements.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph, in conjunction with paragraph 26.65(c), does result in incremental savings. The savings result from provisions that allow licensees and other entities to grant authorization without administering a pre-access drug and alcohol test to applicants whose previous authorization was terminated favorably and who have been covered by both a licensee-approved random drug and alcohol testing program and a behavioral observation and arrest reporting program throughout the period of interruption.[2] The *annual savings per program* result from the sum of the following savings:

- The annual savings per program from not administering a pre-access drug and alcohol test on initial applicants covered by both a random drug and alcohol

[2] In conjunction with §26.65, licensees and other entities are also allowed to grant authorization without administering a pre-access drug and alcohol test to applicants relying upon negative results from drug and alcohol tests conducted before the individual applied for authorization if the individual has been subject to a behavioral observation and arrest reporting program and a random drug and alcohol testing program since the testing was conducted. This provision, however, will not generate any savings that are not already captured by the calculation of savings for §26.65(b).

testing program and a behavioral observation and arrest-reporting program throughout the period of interruption are calculated as follows:[3]

- Pre-access drug and alcohol tests need not be performed at facilities with onsite testing laboratories for the percentage of applicants who are covered by both a random drug and alcohol testing program and a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption. The associated savings are estimated as follows:

  $$NUM_{Applicants} \times PER_{Qualify} \times COST_{Onsite} \times NUM_{Units}$$

- Pre-access drug and alcohol tests need not be performed at facilities with offsite testing laboratories for the percentage of applicants who are covered by both a random drug and alcohol testing program and a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption. The associated savings are calculated as follows:

  $$NUM_{Applicants} \times PER_{Qualify} \times COST_{Offsite} \times NUM_{Units}$$

- The annual savings per program from bypassing required worker labor in the administration of a pre-access drug and alcohol tests for initial applicants covered by both a random drug and alcohol testing program and a behavioral observation and arrest-reporting are calculated as follows:

  - The final paragraph reduces the number of hours of lost worker productivity awaiting negative test result verification from *onsite testing laboratories*. The associated savings are calculated as follows:

    $$NUM_{Applicants} \times PER_{Qualify} \times HOURS_{Onsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$$

  - The final paragraph reduces the number of hours of lost worker productivity awaiting negative test result verification from *offsite testing laboratories*. The associated savings are calculated as follows:

    $$NUM_{Applicants} \times PER_{Qualify} \times HOURS_{Offsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$$

[3] The incremental savings from this provision will vary per individual program depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified testing laboratory.

Parameter	Description
$COST_{Offsite}$	Pre-access drug and alcohol testing cost at a facility with offsite testing laboratories (described in the assumption below and in Appendix 2, Exhibit A2-13)
$COST_{Onsite}$	Pre-access drug and alcohol testing cost at a facility with onsite testing laboratories (described in the assumptions below and in Appendix 2, Exhibit A2-13)
$HOURS_{Offsite\ Worker}$	Hours of facility worker time at a unit with offsite testing laboratories awaiting a negative test verification and not working under the former rule (as described in assumptions below)
$HOURS_{Onsite\ Worker}$	Hours of facility worker time at a unit with onsite testing laboratories awaiting a negative test verification and not working under the former rule (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for initial authorization per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Qualify}$	Percentage of $NUM_{Applicants}$ who qualify for the pre-access drug and alcohol test relaxation per year (as described in assumptions below)

Assumptions:

- Percentage of $NUM_{Applicants}$ who qualify for the pre-access drug and alcohol test relaxation per year: 25%.

- Hours of facility worker time at a unit with onsite testing laboratories awaiting negative test verification and not working under the former rule: 4 hours per reinstatement.[4]

- Hours of facility worker time at a unit with offsite testing laboratories awaiting negative test verification and not working under the former rule: 8 hours per reinstatement.

- The per-unit cost of an *onsite pre-access drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) onsite licensee testing costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

[4] Verification usually requires 1 to 3 business days, depending on whether the given licensee engages in onsite or offsite testing. Although some of the time awaiting verification may be used by applicants for other work-related activities, the analysis assumes that applicants are paid, but unproductive, for a portion of this waiting period.

- The per-unit cost of an *offsite pre-access drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) HHS-certified laboratories costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

- Applicants who qualify for the relaxation are not expected to yield positive drug and alcohol test results under the former regulations.

Subparagraph 26.55(a)(4)

This subparagraph of the final rule adds provisions that require licensees and other entities to include applicants for initial authorization in a random drug and alcohol testing pool, in accordance with §26.67. Licensees and other entities are expected to use the same random testing pool for this purpose as specified under subparagraph 26.31(d)(2). Licensees and other entities must administer a drug and alcohol test on those applicants randomly selected, although authorization can be granted before results have been verified provided that all other applicable requirements for authorization have been met. The former rule did not contain these provisions.

The *annual costs per program* from the implementation of a random drug and alcohol testing program on initial applicants in applicant status are calculated as follows:[5]

- The final paragraph increases the number of random drug and alcohol tests performed at facilities with *onsite testing laboratories*. The associated costs are estimated as follows:

  $$NUM_{Applicants} \times PER_{Random} \times COST_{Onsite} \times NUM_{Units}$$

- The final paragraph increases the number of random drug and alcohol tests performed at facilities with *offsite testing laboratories*. The associated costs are calculated as follows:

  $$NUM_{Applicants} \times PER_{Random} \times COST_{Offsite} \times NUM_{Units}$$

[5] The costs from this provision will vary by individual program depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified testing laboratory.

Parameter	Description
$COST_{Offsite}$	Offsite random drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{Onsite}$	Onsite random drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$NUM_{Applicants}$	Annual number of applicants for initial authorization per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
PER_{Random}	Percentage of $NUM_{Applicants}$ selected for random drug and alcohol testing (as described in assumptions below)

Assumptions:

- Percentage of $NUM_{Applicants}$ selected for random drug and alcohol testing: 1.0%.[6]

- The per-unit cost of an *onsite random drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) onsite licensee testing costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

- The per-unit cost of an *offsite random drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) HHS-certified laboratory costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

Paragraph 26.55(b)

This paragraph of the final rule requires licensees and other entities to take the management action specified in §26.69 when potentially disqualifying FFD information is disclosed or discovered for an applicant for initial authorization. This final paragraph imposes no incremental cost and affords no saving because, under §26.27 of the former rule, applicants for

[6] This figure is calculated by assuming that on any given day an individual in applicant status has a chance of being selected equivalent to the following: (1 day / 365 days) x required annual testing rate of 50% x number of days in applicant status. Initial applicants are assumed to be in applicant status for an average period of 7 days.

unescorted access were subject to similar requirements. These management actions are further discussed in relevant sections of the analysis.

26.57 Authorization Update

Paragraph 26.57(a)

This paragraph of the final rule establishes that an update applicant is any 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. No incremental costs or savings result from this provision, however, because it is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order (AAO) dated January 7, 2003, and published in the Federal Register on January 13, 2003.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations in effect before the NRC issued the AAO, the paragraph indirectly results in incremental costs and savings because it imposes different requirements for the different categories of applicants than does the former rule. The incremental costs and savings associated with these changes are presented and calculated in the subparagraphs below.

Subparagraph 26.57(a)(1)

This subparagraph of the final rule requires licensees to ensure that self-disclosures have been obtained and reviewed, as described by §26.61, from applicants updating authorization before granting authorization. This final paragraph imposes no incremental cost and affords no saving because, under §26.27(a)(1) of the former rule and provisions of the AAO, applicants for unescorted access were subject to similar self-disclosure requirements.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the subparagraph, in conjunction with subparagraph 26.61(a)(1), does result in incremental savings. The savings result from provisions that state that update authorization applicants whose last authorization was terminated favorably and who have been covered by a behavioral observation and arrest-reporting program throughout the period of interruption do not need to submit self-disclosures to licensees and other entities. The *annual savings per program* result from the *sum* of the following savings:

- The annual savings per program from reduced facility worker labor burden for those applicants for updated authorization who qualify for the self-disclosure relaxation are calculated as follows:

  $$NUM_{Applicants} \times PER_{Qualify} \times HOURS_{Worker} \times WAGE_{Worker} \times NUM_{Units}$$

- The annual savings per program resulting from reduced clerical personnel labor burden (because fewer self-disclosures submitted by applicants for updated authorization will need to be processed) are calculated as follows:

$$NUM_{Applicants} \times PER_{Qualify} \times HOURS_{Clerical} \times WAGE_{Clerical} \times NUM_{Units}$$

Parameter	Description
$HOURS_{Clerical}$	Clerical personnel hours saved in a self-disclosure (as described in assumptions below)
$HOURS_{Worker}$	Facility worker hours saved in a self-disclosure (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization updates per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Qualify}$	Percentage of applicants for authorization updates who qualify for the relaxation (as described in assumptions below)
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of applicants for authorization updates who qualify for the relaxation: 50%.

- Facility worker hours saved in a self-disclosure: 0.25 hours per update.

- Clerical personnel hours saved in a self-disclosure: 0.25 hours per update.

Subparagraph 26.57(a)(2)

This subparagraph of the final rule requires licensees to ensure that a suitable inquiry has been completed, as described by §26.63, on applicants updating authorization. This final subparagraph imposes no incremental cost and affords no saving because, under §26.27 of the former rule and provisions in the AAO, applicants for unescorted access were subject to similar suitable inquiry requirements.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the subparagraph, in conjunction with subparagraph 26.63(a), does result in incremental savings. The savings result from provisions that state that licensees and other entities do not need to conduct suitable

inquiries on update applicants whose last authorization was terminated favorably and who have been covered by a behavioral observation and arrest-reporting program throughout the period of interruption. The *annual savings per program* from not conducting the suitable inquiry on applicants for updated authorization qualifying for the relaxation result from the following:

$$NUM_{Applicants} \times PER_{Qualify} \times HOURS_{HR} \times WAGE_{HR} \times NUM_{Units}$$

Parameter	Description
$HOURS_{HR}$	HR personnel hours saved per applicant due to the relaxation of a suitable inquiry under former rule, but prior to the AAO (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization updates per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Qualify}$	Percentage of applicants for authorization updates who qualify for the behavioral observation relaxation (as described in assumptions below)
$WAGE_{HR}$	HR personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of applicants for authorizations updates who qualify for the behavioral observation relaxation: 50%.

- HR personnel hours saved in the relaxation of a suitable inquiry under the former rule, but prior to the AAO: 1 hour per inquiry.

In addition to the relaxation discussed above, additional incremental savings result from this final subparagraph, in conjunction with paragraph 26.63(b) and subparagraph 26.63(f)(2) relative to the regulations that were in effect before the NRC issued the AAO. These savings result from provisions that reduce the licensee labor burden to conduct a suitable inquiry on individuals who have no potentially disqualifying FFD information to disclose and who do not qualify for the relaxation discussed above. The scope of the suitable inquiry is reduced in three ways: (1) by reducing the time period required to be covered by the suitable inquiry from 5 years under the former rule to the period since authorization was last terminated favorably, (2) by requiring licensees to contact only those employers whom the applicant identified as having worked for the longest in a given calendar month after the first year of interruption (for which licensees must contact all employers, regardless of the duration of employment) until authorization was terminated, and (3) by allowing licensees to take credit for a portion of the suitable inquiry that has been conducted by other licensees. The *annual savings per program* due to the reduced suitable inquiry coverage period and scope for applicants for updated authorization qualifying for the relaxation result from the following:

$$NUM_{Applicants} \times PER_{Not\ Qualifying} \times PER_{Non\text{-}PDFFDI} \times HOURS_{HR} \times WAGE_{HR} \times NUM_{Units}$$

Parameter	Description
$HOURS_{HR}$	Hours of HR personnel time saved per suitable inquiry as a result of the reduced coverage period and number of employees who must be contacted (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for updated authorization per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Unit}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Non\text{-}PDFFDI}$	Percentage of $NUM_{Applicants}$ who have no potentially disqualifying FFD information to disclose on their self-disclosures (as described in assumptions below)
$PER_{Not\ Qualifying}$	Percentage of applicants for updated authorization per year who do not qualify for the relaxation under subparagraph 26.63(a) (as described in assumptions below)
$WAGE_{HR}$	HR personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of $NUM_{Applicants}$ who have no potentially disqualifying FFD information to disclose on their self-disclosures: 98%.
- Percentage of applicants for updated authorization per year who do not qualify for the relaxation under subparagraphs 26.63(a): 50%.
- Hours of HR personnel time saved per suitable inquiry as a result of the reduced scope of coverage: 0.5 hours.

Sensitivity Analysis - Industry Practices

The former regulation stipulated that a suitable inquiry must address all employers for whom applicants for authorization updates worked over the past 5 years. Nonetheless, until recently, industry practices were inconsistent with the NRC's interpretation of the requirements such that licensees conducting suitable inquiries did not call those employers for whom an applicant worked for less than 30 days. As a result, licensees will incur an incremental cost to comply with former requirements for suitable inquiries. The *annual costs per program* to conduct a more thorough suitable inquiry on applicants for updated authorization to comply with the former regulation result from the following:

$$NUM_{Applicants} \times HOURS_{HR} \times WAGE_{HR} \times NUM_{Units}$$

Parameter	Description
$HOURS_{HR}$	Additional HR personnel hours required to conduct suitable inquiries consistent with former regulations (as described in assumptions below)

Parameter	Description
$NUM_{Applicants}$	Annual number of applicants for authorization updates per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$WAGE_{HR}$	HR personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Additional HR personnel hours required to conduct suitable inquiries consistent with former regulations: 10 minutes (i.e., a 20-percent increase over the current estimate of 50 minutes per applicant).

Subparagraph 26.57(a)(3)

This subparagraph of the final rule requires licensees to administer a pre-access drug and alcohol test, as described in §26.65, on applicants updating authorization before granting authorization. This final subparagraph imposes no incremental cost and affords no saving because, under §26.24(a) of the former rule and provisions of the AAO, applicants for unescorted access were subject to similar drug and alcohol testing requirements.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph, in conjunction with paragraph 26.65(c), does result in incremental savings. The savings result from provisions that allow licensees and other entities to grant authorization without administering a pre-access drug and alcohol test to applicants whose previous authorization was terminated favorably and who have been covered by both a licensee-approved random drug and alcohol testing program and a behavioral observation and arrest reporting program throughout the period of interruption.[7] The *annual savings per program* result from the sum of the following savings:

- The annual savings per program from not administering a pre-access drug and alcohol test on update applicants covered by both a random drug and alcohol

[7] In conjunction with §26.65, licensees and other entities are also allowed to grant authorization without administering a pre-access drug and alcohol test to applicants relying upon negative results from drug and alcohol tests conducted before the individual applied for authorization if the individual has been subject to a behavioral observation and arrest reporting program and a random drug and alcohol testing program since the testing was conducted. This provision, however, will not generate any savings that are not already captured by the calculation of savings for §26.65(b).

testing program and a behavioral observation and arrest-reporting program throughout the period of interruption are calculated as follows:[8]

- Pre-access drug and alcohol tests need not be performed at facilities with onsite testing laboratories for the percentage of applicants who are covered by both a random drug and alcohol testing program and a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption. The associated savings are estimated as follows:

  $$NUM_{Applicants} \times PER_{Qualify} \times COST_{Onsite} \times NUM_{Units}$$

- Pre-access drug and alcohol tests need not be performed at facilities with offsite testing laboratories for the percentage of applicants who are covered by both a random drug and alcohol testing program and a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption. The associated savings are calculated as follows:

  $$NUM_{Applicants} \times PER_{Qualify} \times COST_{Offsite} \times NUM_{Units}$$

- The annual savings per program from bypassing required worker labor in the administration of a pre-access drug and alcohol tests for update applicants covered by both a random drug and alcohol testing program and a behavioral observation and arrest-reporting are calculated as follows:

  - The final paragraph reduces the number of hours of lost worker productivity awaiting negative test result verification from *onsite testing laboratories*. The associated savings are calculated as follows:

    $$NUM_{Applicants} \times PER_{Qualify} \times HOURS_{Onsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$$

  - The final paragraph reduces the number of hours of lost worker productivity awaiting negative test result verification from *offsite testing laboratories*. The associated savings are calculated as follows:

    $$NUM_{Applicants} \times PER_{Qualify} \times HOURS_{Offsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$$

[8] The incremental savings from this provision will vary per individual program depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified testing laboratory.

Parameter	Description
$COST_{Offsite}$	Pre-access drug and alcohol testing cost at a facility with offsite testing laboratories (described in the assumption below and in Appendix 2, Exhibit A2-13)
$COST_{Onsite}$	Pre-access drug and alcohol testing cost at a facility with onsite testing laboratories (described in the assumptions below and in Appendix 2, Exhibit A2-13)
$HOURS_{Offsite\ Worker}$	Hours of facility worker time at a unit with offsite testing laboratories awaiting a negative test verification and not working under the former rule (as described in assumptions below)
$HOURS_{Onsite\ Worker}$	Hours of facility worker time at a unit with onsite testing laboratories awaiting a negative test verification and not working under the former rule (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization updates per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Qualify}$	Percentage of $NUM_{Applicants}$ who qualify for the pre-access drug and alcohol test relaxation per year (as described in assumptions below)

Assumptions:

- Percentage of $NUM_{Applicants}$ who qualify for the pre-access drug and alcohol test relaxation per year: 25%.

- Hours of facility worker time at a unit with onsite testing laboratories awaiting negative test verification and not working under the former rule: 4 hours per reinstatement.[9]

- Hours of facility worker time at a unit with offsite testing laboratories awaiting negative test verification and not working under the former rule: 8 hours per reinstatement.

- The per-unit cost of an *onsite pre-access drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) onsite licensee testing costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

[9] Verification usually requires 1 to 3 business days, depending on whether the given licensee engages in onsite or offsite testing. Although some of the time awaiting verification may be used by applicants for other work-related activities, the analysis assumes that applicants are paid, but unproductive, for a portion of this waiting period.

- The per-unit cost of an *offsite pre-access drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) HHS-certified laboratories costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

- Applicants who qualify for the relaxation are not expected to yield positive drug and alcohol test results under the former regulations.

Subparagraph 26.57(a)(4)

This subparagraph of the final rule adds provisions that require licensees and other entities to include applicants for updated authorization in a random drug and alcohol testing pool, under §26.67. Licensees and other entities are expected to use the same random testing pool for this purpose as is specified under subparagraph 26.31(d)(2) of the final rule. Licensees and other entities must administer a drug and alcohol test on those applicants randomly selected, although applicants can be granted authorization before results have been verified, provided that all other applicable requirements for authorization have been met.

The *annual costs per program* due to the increase in the number of random drug and alcohol tests performed on applicants for updated authorization are calculated as follows:[10]

- The final paragraph increases the number of random drug and alcohol tests performed at facilities with *onsite testing laboratories*. The associated costs are estimated as follows:

  $$NUM_{Applicants} \times PER_{Random} \times COST_{Onsite} \times NUM_{Units}$$

- The final paragraph increases the number of random drug and alcohol tests performed at facilities with *offsite testing laboratories*. The associated costs are calculated as follows:

  $$NUM_{Applicants} \times PER_{Random} \times COST_{Offsite} \times NUM_{Units}$$

Parameter	**Description**
$COST_{Offsite}$	Offsite random drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)

[10] The costs from this provision will vary by individual program depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified testing laboratory.

Parameter	Description
$COST_{Onsite}$	Onsite random drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$NUM_{Applicants}$	Annual number of applicants for updated authorization per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
PER_{Random}	Percentage of $NUM_{Applicants}$ selected for random drug and alcohol testing (as described in assumptions below)

Assumptions:

- Percentage of $NUM_{Applicants}$ selected for random drug and alcohol testing: 1.0%.[11]

- The per-unit cost of an *onsite random drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) onsite licensee testing costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

- The per-unit cost of an *offsite random drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) HHS-certified laboratory costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

Paragraph 26.57(b)

This paragraph of the final rule requires licensees and other entities to take the management action specified in §26.69 when potentially disqualifying FFD information is disclosed or discovered for an applicant for updated authorization. This final paragraph imposes no incremental cost and affords no saving because, under §26.27 of the former rule, applicants for unescorted access were subject to similar requirements. These management actions are further discussed in relevant sections of the analysis.

[11] This figure is calculated by assuming that on any given day, an individual in applicant status has a chance of being selected equivalent to the following: (1 day / 365 days) x required annual testing rate of 50% x number of days in applicant status. Initial applicants are assumed to be in applicant status for an average period of 7 days.

26.59 Authorization Reinstatement

Paragraph 26.59(a)

This paragraph of the final rule [including subparagraphs 26.59(a)(1) – (3)] addresses reinstatement applicants with an interruption of more than 30 days but not more than 365 days and whose last period of authorization was terminated favorably. No incremental costs or savings result from this provision, however, because it is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order (AAO) dated January 7, 2003, and published in the Federal Register on January 13, 2003.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations in effect before the NRC issued the AAO, the paragraph indirectly results in incremental costs and savings because it imposes different requirements for the different categories of applicants relative to the requirements of the former rule. These incremental costs and savings are presented and calculated in the subparagraphs below.

Subparagraph 26.59(a)(1)

This subparagraph of the final rule requires licensees to ensure that self-disclosures have been obtained and reviewed, as described by §26.61, from applicants for reinstatement authorization with an interruption of more than 30 days but not more than 365 days, before granting authorization. This final subparagraph imposes no incremental cost and affords no saving because, under §26.27 of the former rule and provisions of the AAO, applicants for unescorted access were subject to similar self-disclosure requirements.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the subparagraph, in conjunction with subparagraph 26.61(a)(1), does result in incremental savings. The savings result from provisions that state that previously authorized applicants whose last authorizations were terminated favorably and who have been covered by a behavioral observation and arrest-reporting program throughout the period of interruption do not need to submit self-disclosures to licensees and other entities. The *annual savings per program* result from the *sum* of the following savings:

- The annual savings per program from reduced facility worker labor burden for those applicants for authorization reinstatement who qualify for the self-disclosure relaxation are calculated as follows:

  $$NUM_{Applicants} \times PER_{Qualify} \times HOURS_{Worker} \times WAGE_{Worker} \times NUM_{Units}$$

- The annual savings per program from reduced clerical personnel labor burden (because fewer self-disclosures submitted by applicants for authorization reinstatement will need to be processed) are calculated as follows:

$$NUM_{Applicants} \times PER_{Qualify} \times HOURS_{Clerical} \times WAGE_{Clerical} \times NUM_{Units}$$

Parameter	Description
$HOURS_{Clerical}$	Clerical personnel hours saved in a self-disclosure (as described in assumptions below)
$HOURS_{Worker}$	Facility worker hours saved in a self-disclosure (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization reinstatement with an interruption of more than 30 days but not more than 365 days per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Qualify}$	Percentage of applicants for authorization reinstatement who qualify for the relaxation (as described in assumptions below)
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of applicants for authorization reinstatements who qualify for the relaxation: 50%.

- Facility worker hours saved in a self-disclosure: 0.25 hours per update.

- Clerical personnel hours saved in a self-disclosure: 0.25 hours per update.

Subparagraph 26.59(a)(2)

This subparagraph of the final rule requires licensees to ensure that a suitable inquiry has been completed, as described by §26.63, on applicants for reinstatement authorization with an interruption of more than 30 days but not more than 365 days, before granting authorization. This final subparagraph imposes no incremental cost and affords no saving because, under §26.27 of the former rule, applicants for unescorted access were subject to similar suitable inquiry requirements. The final subparagraph also adopts provisions from the NRC's AAO that (1) eliminate the suitable inquiry requirement for the subset of applicants whose previous authorization was terminated favorably and who have been covered by a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption [in conjunction with 26.63(a)], (2) reduce the labor burden associated with conducting a suitable inquiry, and (3) allow licensees to grant authorization prior to the completion of a suitable

inquiry, provided that it is completed within 10 business days. There is no incremental savings from these provisions, except under the alternative Pre-Order Baseline as discussed below, because they are based on non-safeguards information requirements imposed by the NRC's AAO dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations in effect before the NRC issued the AAO, the subparagraph does result in incremental savings by not requiring suitable inquiries for reinstatement applicants with interruptions of 31–365 days if their last authorization was terminated favorably and they were covered by a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption. The *annual savings per program* from not conducting the suitable inquiry on applicants for authorization reinstatement qualifying for the relaxation result from the following:

$$NUM_{Applicants} \times PER_{Qualify} \times HOURS_{HR} \times WAGE_{HR} \times NUM_{Units}$$

Parameter	Description
$HOURS_{HR}$	HR personnel hours saved per applicant by not conducting a suitable inquiry due to the relaxation (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants per unit for authorization reinstatement with interruption of more than 30 days but not more than 365 days per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Qualify}$	Percentage of $NUM_{Applicants}$ covered by a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption (as described in assumptions below)
$WAGE_{HR}$	HR personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of authorization reinstatement applicants who qualify for the behavioral observation relaxation: 50%.

- HR personnel hours saved per applicant by not conducting a suitable inquiry due to the relaxation: 1 hour per suitable inquiry.

In addition to the relaxation discussed above, this subparagraph of the final rule, in conjunction with paragraph 26.63(b) and 26.63(f)(3), adopts provisions from the NRC's AAO that result in incremental savings by reducing the scope (and associated labor burden) of the suitable inquiry for reinstatement applicants with interruptions of 31–365 days who have no potentially

disqualifying FFD information to disclose and who do not qualify for the relaxations discussed above. The scope is reduced in three ways: (1) by reducing the time period required to be covered by the suitable inquiry from 5 years under the former rule to the period since authorization was last terminated favorably, (2) by requiring licensees to contact only those employers whom the applicant identified as having worked for the longest in a given calender month (as opposed to all employers under the former rule), and (3) by allowing licensees to take credit for a portion of the suitable inquiry that has been conducted by other licensees. The *annual savings per program* due to the reduced suitable inquiry coverage period and scope for applicants for authorization reinstatement qualifying for the relaxation result from the following:

$$NUM_{Applicants} \times PER_{Not\ Qualifying} \times PER_{Non\text{-}PDFFDI} \times HOURS_{HR} \times WAGE_{HR} \times NUM_{Units}$$

Parameter	Description
$HOURS_{HR}$	Hours of HR personnel time saved per suitable inquiry due to reduced suitable inquiry coverage period and a reduction in the number of employees that must be contacted (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants per unit for authorization reinstatement with interruption of more than 30 days but not more than 365 days per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Non\text{-}PDFFDI}$	Percentage of $NUM_{Applicants}$ who have no potentially disqualifying FFD information to disclose on their self-disclosures (as described in assumptions below)
$PER_{Not\ Qualifying}$	Percentage of $NUM_{Applicants}$ not covered by a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption (as described in assumptions below)
$WAGE_{HR}$	HR personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of $NUM_{Applicants}$ not covered by a licensee-approved behavioral observation and arrest-reporting program throughout the period of interruption: 50%.

- Percentage of $NUM_{Applicants}$ who have no potentially disqualifying FFD information to disclose on their self-disclosures: 99%.

- Hours of HR personnel time saved per suitable inquiry as a result of the reduced scope of coverage: 0.5 hours.

In addition to the relaxation discussed above, this final subparagraph adopts provisions from the AAO that allow for applicants for authorization reinstatement with an interruption of 31–365

days to be granted authorization *prior to* the completion of a suitable inquiry, provided that the inquiry is completed within 10 business days of granting reinstated authorization. If after 10 business days the suitable inquiry has not been completed, authorization must be administratively withdrawn until it is completed. This provision does not change the activities that must be conducted. It could lead to savings, however, by reducing the amount of lost worker productivity while awaiting completion of the inquiry. The analysis assumes, however, that workers are engaged in other work-related activities (such as training, testing, and other non-FFD-related activities) that do not require authorization while the suitable inquiry is being conducted.

Sensitivity Analysis - Industry Practices

The former regulation stipulated that a suitable inquiry must address all employers for whom applicants for authorization worked over the past 5 years. Nonetheless, until recently, industry practices were inconsistent with NRC's interpretation of the requirements such that industry practice has been that licensees conducting suitable inquiries did not call employers for whom an applicant worked for 30 days or less. As a result, licensees should have incurred an incremental cost to comply with former requirements for suitable inquiries on applicants with an interruption of 31–365 days. The *annual cost per program* to conduct a more thorough suitable inquiry on applicants for authorization reinstatement to comply with the former regulation result from the following:

$$NUM_{Applicants} \times HOURS_{HR} \times WAGE_{HR} \times NUM_{Units}$$

Parameter	Description
$HOURS_{HR}$	Additional HR personnel hours required to conduct a suitable inquiry consistent with the former regulations (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization reinstatement with an interruption of more than 30 days but not more than 365 days (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$WAGE_{HR}$	HR personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Additional HR personnel hours required to conduct suitable inquiries consistent with the former regulations: 10 minutes (i.e., a 20-percent increase over the current estimate of 50 minutes per applicant).

Subparagraph 26.59(a)(3)

This subparagraph of the final rule requires licensees to administer a pre-access drug and alcohol test, as described in §26.65, on applicants for reinstatement authorization with an interruption of more than 30 days but not more than 365 days, before granting authorization. The final subparagraph imposes no incremental cost and affords no saving because, under the former rule, applicants for unescorted access were subject to similar drug and alcohol testing requirements under 26.24(a). The final subparagraph does, however, adopt provisions from the NRC's AAO that eliminate the pre-access drug and alcohol testing requirement for those applicants whose previous authorization was terminated favorably and who have been covered both by behavioral observation and arrest program and by a licensee-approved random drug and alcohol testing program throughout the period of interruption. Other provisions adapted from the AAO allow licensees to grant authorization reinstatement to applicants prior to receiving verification of negative drug test results as long as verification occurs within 5 business days. If verification does not occur during this time frame, authorization must be administratively withdrawn until completed. There is no incremental savings from these provisions, except under the alternative *Pre-Order Baseline* as discussed below, because they are based on non-safeguards information requirements imposed by the NRC's AAO dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations in effect before the NRC issued the AAO, the subparagraph, in conjunction with §26.65(d), does result in incremental saving. According to §26.24 of the former rule as well as guidance provided by the NRC in NUREG-1385, "Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions," licensees could not grant authorization without administering a drug and alcohol test and verifying negative test results. Provisions in this final rule, however, allow applicants for authorization reinstatement with an interruption of 31–365 days to forego pre-access drug and alcohol testing if covered by a licensee-approved random drug and alcohol testing program and a behavioral observation and arrest reporting program throughout the period of interruption.[12] As a result, savings arise from the reduction in the number of pre-access tests administered and the reduction in the loss of worker productivity awaiting negative test results.

The *annual savings per program* result from the *sum* of the following savings:

[12] In conjunction with §26.65, licensees and other entities are also allowed to grant authorization without administering a pre-access drug and alcohol test to applicants relying upon negative results from drug and alcohol tests conducted before the individual applied for authorization if the individual has been subject to a behavioral observation and arrest reporting program and a random drug and alcohol testing program since the testing was conducted. This provision, however, will not generate any savings that are not already captured by the calculation of savings for §26.65(b).

- Annual savings per program from allowing reinstatement applicants covered by a random drug and alcohol testing program and a behavioral observation and arrest reporting program throughout the period of interruption to forego pre-access drug and alcohol testing are calculated as follows:[13]

  - The final paragraph reduces the number of pre-access drug and alcohol tests performed at facilities with *onsite testing laboratories*. The associated savings are calculated as follows:

    $NUM_{Applicants} \times PER_{Qualify} \times COST_{Onsite} \times NUM_{Units}$

  - The final paragraph reduces the number of pre-access drug and alcohol tests performed at facilities with *offsite testing laboratories*. The associated savings are calculated as follows:

    $NUM_{Applicants} \times PER_{Qualify} \times COST_{Offsite} \times NUM_{Units}$

- Annual savings per program from reducing the number of hours of lost worker productivity for reinstatement applicants covered by both a random drug and alcohol testing program and a behavioral observation and arrest reporting program are calculated as follows:[14]

  - The final paragraph reduces the number of hours of lost worker productivity awaiting negative test result verification from *onsite testing laboratories*. The associated savings are calculated as follows:

    $NUM_{Applicants} \times PER_{Qualify} \times HOURS_{Onsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$

  - The final paragraph reduces the number of hours of lost worker productivity awaiting negative test result verification from *offsite testing laboratories*. The associated savings are calculated as follows:

    $NUM_{Applicants} \times PER_{Qualify} \times HOURS_{Offsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$

[13] The incremental savings from this provision will vary by individual program depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified testing laboratory.

[14] The incremental savings from this provision will vary by individual program depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified testing laboratory.

Parameter	Description
$COST_{Offsite}$	Offsite pre-access drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{Onsite}$	Onsite pre-access drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$HOURS_{Offsite\ Worker}$	Hours of facility worker time at a unit with offsite testing laboratories awaiting a negative test verification and not working under the former rule (as described in assumptions below)
$HOURS_{Onsite\ Worker}$	Hours of facility worker time at a unit with onsite testing laboratories awaiting a negative test verification and not working under the former rule (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization with an interruption of more than 30 days but not more than 365 days per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Qualify}$	Percentage of $NUM_{Applicants}$ covered by a licensee approved random drug and alcohol testing program and a behavioral observation and arrest reporting program (as described in assumptions below)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of $NUM_{Applicants}$ covered by a licensee approved random drug and alcohol testing program and behavioral observation and arrest reporting program: 25%.

- Hours of facility worker time at a unit with onsite testing laboratories awaiting negative test verification and not working under the former rule: 4 hours per reinstatement.[15]

- Hours of facility worker time at a unit with offsite testing laboratories awaiting negative test verification and not working under the former rule: 8 hours per reinstatement.

[15] Verification usually requires 1 to 3 business days, depending on whether the given licensee engages in onsite or offsite testing. Although some of the time awaiting verification may be used by applicants for other work-related activities, the analysis assumes that applicants are paid, but unproductive, for a portion of this waiting period.

- The per-unit cost of an *onsite pre-access drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) onsite licensee testing costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

- The per-unit cost of an *offsite pre-access drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) HHS-certified laboratory costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

In addition, this final subparagraph adopts provisions from the AAO that allow licensees to grant authorization reinstatement to applicants with interruptions of 31–365 days prior to receiving verification of negative drug test results as long as verification occurs within 5 business days of specimen collection. (This applies only to those applicants that must take a pre-access test, thereby excluding those covered by the preceding relaxation). Verification usually requires 1 to 3 business days, depending on whether the given licensee engages in onsite or offsite testing. Although some of the time awaiting verification may be used by applicants for other work-related activities, the analysis assumes that applicants are paid, but unproductive, for a portion of this waiting period. *The annual savings per program* resulting from this group of applicants not having to await verification of negative results before granting authorization are calculated as follows:[16]

- The final paragraph decreases the number of hours of lost worker productivity awaiting negative test result verification from *onsite testing laboratories*. The associated savings are calculated as follows:

  $$NUM_{Applicants} \times PER_{Not\ Qualifying} \times HOURS_{Onsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$$

- The final paragraph decreases the number of hours of lost worker productivity awaiting negative test result verification from *offsite testing laboratories*. The associated savings are calculated as follows:

  $$NUM_{Applicants} \times PER_{Not\ Qualifying} \times HOURS_{Offsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$$

[16] The incremental savings from this provision will vary by individual program depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified testing laboratory.

Parameter	Description
$HOURS_{Offsite\ Worker}$	Hours of facility worker time at a unit with offsite testing laboratories awaiting a negative test verification and not working under the former rule (as described in assumptions below)
$HOURS_{Onsite\ Worker}$	Hours of facility worker time at a unit with onsite testing laboratories awaiting a negative test verification and not working under the former rule (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization reinstatement with an interruption of more than 30 days but not more than 365 days per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Not\ Qualifying}$	Percentage of $NUM_{Applicants}$ not covered by a licensee-approved random drug and alcohol testing program and a behavioral observation and arrest reporting program throughout the period of interruption (as described in assumptions below)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of $NUM_{Applicants}$ not covered by a licensee-approved random drug and alcohol testing program and a behavioral observation and arrest reporting program throughout the period of interruption: 75%.

- Hours of facility worker time at a unit with onsite testing laboratories awaiting negative test verification and not working under the former rule: 4 hours per reinstatement.[17]

- Hours of facility worker time at a unit with offsite testing laboratories awaiting negative test verification and not working under the former rule: 8 hours per reinstatement.

Subparagraph 26.59(a)(4)

This subparagraph of the final rule adds provisions that require licensees and other entities to include applicants for reinstatement authorization with an interruption of more than 30 days but not more than 365 days in a random drug and alcohol testing pool, under §26.67. Licensees and other entities are expected to use the same random testing pool for this purpose as specified under subparagraph 26.31(d)(2) of the final rule. Licensees and other entities must administer a drug and alcohol test on those applicants randomly selected. Authorization may be granted

[17] Verification usually requires 1 to 3 business days, depending on whether the given licensee engages in onsite or offsite testing. Although some of the time awaiting verification may be used by applicants for other work-related activities, the analysis assumes that applicants are paid, but unproductive, for a portion of this waiting period.

before results have been verified provided that all other applicable requirements for authorization have been met.

The *annual costs per program* to conduct random drug and alcohol tests on applicants randomly selected while awaiting the granting of authorization are calculated as follows:[18]

- The final paragraph increases the number of drug and alcohol tests performed at facilities with *onsite testing laboratories*. The associated costs are calculated as follows:

  $NUM_{Applicants} \times PER_{Random} \times COST_{Onsite} \times NUM_{Units}$

- The final paragraph increases the number of pre-access drug and alcohol tests performed at facilities with *offsite testing laboratories*. The associated costs are calculated as follows:

  $NUM_{Applicants} \times PER_{Random} \times COST_{Offsite} \times NUM_{Units}$

Parameter	**Description**
$COST_{Offsite}$	Offsite random drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{Onsite}$	Onsite random drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$NUM_{Applicants}$	Annual number of applicants for authorization reinstatement with an interruption of more than 30 days but not more than 365 days per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
PER_{Random}	Percentage of $NUM_{Applicants}$ selected for random drug and alcohol testing (as described in assumptions below)

[18] The incremental savings from this provision will vary by individual program depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified testing laboratory.

Assumptions:

- Percentage of $NUM_{Applicants}$ selected for random drug and alcohol testing: 1.0%.[19]

- The per-unit cost of an *onsite random drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) onsite licensee testing costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

- The per-unit cost of an *offsite random drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) HHS-certified laboratory costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

Paragraph 26.59(b)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it is added to ensure that the administrative withdrawal of an individual's authorization is not recorded as an unfavorable termination. No incremental costs or savings result from this provision, however, because it is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order (AAO) dated January 7, 2003, and published in the Federal Register on January 13, 2003.

Paragraph 26.59(c)

This paragraph of the final rule [including subparagraphs 26.59(c)(1) – (3)] addresses reinstatement applicants with an interruption of no more than 30 days and whose last period of authorization was terminated favorably. No incremental costs or savings result from this provision, however, because it is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order (AAO) dated January 7, 2003, and published in the Federal Register on January 13, 2003.

[19] This figure is calculated by assuming that on any given day, an individual in applicant status has a chance of being selected equivalent to the following: (1 day / 365 days) x required annual testing rate of 50% x number of days in applicant status. The analysis assumed an average applicant status of 7 days. Applicants for reinstatement authorization, however, are likely to have a much shorter review period. Consequently, the analysis likely overstates these costs.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations in effect before the NRC issued the AAO, the paragraph indirectly results in incremental costs and savings because it imposes different requirements for the different categories of applicants relative to the requirements of the former rule. The incremental costs and savings associated with these changes are presented and calculated in the subparagraphs below.

Subparagraph 26.59(c)(1)

This paragraph of the final rule requires licensees to ensure that self-disclosures have been obtained and reviewed, as described by §26.61, from applicants for reinstatement authorization with an interruption of no more than 30 days. This final subparagraph imposes no incremental cost and affords no saving because, under the former rule, applicants for unescorted access were subject to similar self-disclosure requirements under §26.27. In addition, the final paragraph does not require licensees and other entities to conduct suitable inquiries on these applicants, as required by the former rule under §26.27. There are no incremental savings from this provision, except under the alternative *Pre-Order Baseline* as discussed below, because it is based on non-safeguards information requirements imposed by the NRC's AAO dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the subparagraph, in conjunction with subparagraph 26.61(a)(1), does result in incremental savings. The savings result from provisions that state that previously authorized applicants whose last authorizations were terminated favorably and who have been covered by a behavioral observation and arrest-reporting program throughout the period of interruption do not need to submit self-disclosures to licensees and other entities. The *annual savings per program* result from the *sum* of the following savings:

- The annual savings per program from reduced facility worker labor burden for those applicants for authorization reinstatement who qualify for the self-disclosure relaxation are calculated as follows:

  $NUM_{Applicants} \times PER_{Qualify} \times HOURS_{Worker} \times WAGE_{Worker} \times NUM_{Units}$

- The annual savings per program from reduced clerical personnel labor burden (because fewer self-disclosures submitted by applicants for authorization reinstatement will need to be processed) are calculated as follows:

  $NUM_{Applicants} \times PER_{Qualify} \times HOURS_{Clerical} \times WAGE_{Clerical} \times NUM_{Units}$

Parameter	Description
$HOURS_{Clerical}$	Clerical personnel hours saved in a self-disclosure (as described in assumptions below)
$HOURS_{Worker}$	Facility worker hours saved in a self-disclosure (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization reinstatement with an interruption of not more than 30 days per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Qualify}$	Percentage of applicants for authorization updates who qualify for the relaxation (as described in assumptions below)
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of $NUM_{Applicants}$ who qualify for the relaxation: 50%.
- Facility worker hours saved in a self-disclosure: 0.25 hours per update.
- Clerical personnel hours saved in a self-disclosure: 0.25 hours per update.

In addition to the relaxation discussed above, the final subparagraph, like the AAO, but in contrast to the former rule, allows licensees and other entities to grant authorization reinstatement to applicants with interruptions of not more than 30 days without conducting a suitable inquiry. Under subparagraph 26.27(a)(2) of the former rule, licensees had to conduct a suitable inquiry on all applicants before granting authorization. The *annual savings per program* from not conducting the suitable inquiry on applicants for authorization reinstatement with an interruption of not more than 30 days result from the following:

$$NUM_{Applicants} \times HOURS_{HR} \times WAGE_{HR} \times NUM_{Units}$$

Parameter	Description
$HOURS_{HR}$	HR personnel hours saved in suitable inquiries under former regulations (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization reinstatement with an interruption of not more than 30 days per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$WAGE_{HR}$	HR personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- HR personnel hours saved in suitable inquiries under former regulations: 1 hour per inquiry.

- Percentage of individuals who have potentially disqualifying FFD information is assumed to be negligible.

Sensitivity Analysis - Industry Practices

As previously noted, former subparagraph 26.27(a)(1) required licensees to obtain self-disclosures from applicants before granting authorization reinstatement. Nonetheless, until recently, industry practices were inconsistent with NRC's interpretation of the requirements such that licensees did not consider it a requirement to obtain self-disclosures from applicants for reinstatement who have experienced an interruption of authorization of not more than 30 days. This fraction of licensees (assumed to be 50 percent) should have incurred additional costs to meet former requirements. The *annual costs per program* result from the sum of the following costs:[20]

- The annual costs per program for applicants for authorization reinstatement with interruptions of not more than 30 days to submit self-disclosures to comply with self-disclosure requirements are estimated as follows:

  $$NUM_{Applicants} \times PER_{Non\text{-}Compliance} \times HOURS_{Worker} \times WAGE_{Worker} \times NUM_{Unit}$$

- The annual costs per program for clerical personnel to process additional self-disclosures for applicants for authorization reinstatement with interruptions of not more than 30 days to comply with self-disclosure requirements are estimated as follows:

  $$NUM_{Applicants} \times PER_{Non\text{-}Compliance} \times HOURS_{Clerical} \times WAGE_{Clerical} \times NUM_{Unit}$$

[20] Based on current industry practices, this cost is expected to accrue to the 50 percent of facilities that have not previously interpreted the former rule as requiring a self-disclosure for applicants with an interruption of authorization of not more than 30 days. NRC believes that the remaining 50 percent of facilities interpreted the former FFD rule correctly, so costs for them should not be calculated. However, as the identity of licensees falling within the two groups is not known, this analysis assumes that 100 percent of facilities will incur costs of 50 percent of the calculated amount.

Parameter	Description
$HOURS_{Clerical}$	Clerical personnel hours required to process a self-disclosure (as described in assumptions below)
$HOURS_{Worker}$	Facility worker hours required to complete a self-disclosure (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization reinstatement with an interruption of not more than 30 days per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Unit}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Non\text{-}Compliance}$	Percentage of cost applied to a given program (as described in assumptions below)
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Facility worker hours required to complete a self-disclosure: 0.25 hours per self-disclosure.

- Clerical personnel hours required to process self-disclosure: 0.25 hours per self-disclosure.

- Licensees have indicated that 50 percent of licensees did not interpret the former regulation as requiring a self-disclosure for applicants with interruptions of not more than 30 days. Because the analysis cannot identify which facilities are or are not appropriately interpreting the requirement, the analysis assumes that each unit will incur the incremental cost of 50 percent of the activity.

In addition to the incremental activities discussed above, some licensees should have conducted additional suitable inquiries. As previously noted, paragraph 26.27(a) of the former rule required licensees to conduct suitable inquiries on all reinstatement applicants before granting authorization. Nonetheless, until recently, many licensees did not consider it a requirement to conduct suitable inquiries on reinstatement applicants with interruptions of not more than 30 days. This fraction of licensees (assumed to be 50 percent) should have incurred additional costs to conduct suitable inquires in a manner that meets former requirements. The *annual cost per*

program to conduct suitable inquiries on applicants for authorization reinstatement with an interruption of not more than 30 days to comply with the former regulations result from the *sum* of the following costs:[21]

$$NUM_{Applicants} \times PER_{Non\text{-}Compliance} \times HOURS_{HR} \times WAGE_{HR} \times NUM_{Units}$$

Parameter	Description
$HOURS_{HR}$	HR personnel hours saved in suitable inquiries under former regulations (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization reinstatement with an interruption of not more than 30 days per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Non\text{-}Compliance}$	Percentage cost applied to a given program (as described in assumptions below)
$WAGE_{HR}$	HR personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- HR personnel hours required to conduct a suitable inquiry under former regulations: 1 hour per inquiry.

- Licensees have indicated that 50 percent of licensees did not interpret the former regulations as requiring a suitable inquiry to be conducted on applicants with interruptions of not more than 30 days. Because the analysis cannot identify which facilities are or are not appropriately interpreting the requirement, the analysis assumes that each facility will incur 50 percent of the incremental cost of the activity.

In addition to the incremental activities discussed above, some licensees also should have conducted more thorough suitable inquiries. As previously noted, the former regulation stipulated that a suitable inquiry must address all employers for whom applicants for authorization reinstatements worked over the past 5 years. Nonetheless, until recently, industry practice was that licensees conducting background investigations did not call those employers for whom an applicant worked for less than 30 days. As a result, the portion of licensees that are interpreting the former rules incorrectly should have incurred an incremental cost to comply with

[21] Based on current industry practices, this cost is expected to accrue to the 50 percent of facilities that have not previously interpreted the former rule as requiring a suitable inquiry to be conducted for reinstatement applicants with an interruption of not more than 30 days. The remaining 50 percent of facilities interpreted the former FFD rule correctly, costs for them should not be calculated. However, because data are not available regarding which specific facilities will incur costs, this analysis assumes that 100 percent of facilities will incur costs of 50 percent of the calculated amount.

former requirements for suitable inquiries. The *annual cost per program* to conduct a more thorough suitable inquiry on applicants for authorization reinstatement with an interruption of 5 days or less to comply with the former regulation result from the following:

$$NUM_{Applicants} \times HOURS_{HR} \times WAGE_{HR} \times NUM_{Units}$$

Parameter	Description
$HOURS_{HR}$	Additional HR personnel hours required to conduct suitable inquiries consistent with the former regulation (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization reinstatement with an interruption of not more than 30 days per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$WAGE_{HR}$	HR personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumption:

- Additional HR personnel hours required to conduct suitable inquires consistent with the former regulation: 10 minutes (i.e., a 20-percent increase over the current estimate of 50 minutes per applicant).

Subparagraph 26.59(c)(2)

This subparagraph of the final rule requires licensees and other entities to administer pre-access drug and alcohol testing on all applicants with an interruption of more than 5 days but not more than 30 days under §26.65. This final paragraph imposes no incremental cost and affords no saving because, under the former rule, applicants for unescorted access were subject to similar drug and alcohol testing requirements under paragraph 26.24(a). The final paragraph does, however, allow licensees and other entities to forego the pre-access testing requirement for those applicants with an interruption of 5 days or less. There are no incremental savings from this provision, except under the alternative Pre-Order Baseline as discussed below, because it is based on non-safeguards information requirements imposed by the NRC's AAO dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the subparagraph, does result in incremental savings. The final subparagraph, like the AAO, but in contrast to the former rule, allows licensees to grant authorization reinstatement to applicants with interruptions of 5 days or less without administering a pre-access drug and alcohol test. According to §26.24 of the former rule as well as guidance provided by the NRC in NUREG-1385, "Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions," licensees could not grant authorization without administering a drug and alcohol test and verifying negative test

results. The *annual savings per program* associated with the administration of fewer pre-access drug and alcohol tests results from the *sum* of the following savings:[22]

- The annual savings per program from not administering a pre-access drug and alcohol test on applicants for authorization reinstatement with an interruption of 5 days or less are calculated as follows:
    - Pre-access drug and alcohol tests need not be performed at facilities with onsite testing laboratories. The associated savings are estimated as follows:

      $NUM_{Applicants} \times COST_{Onsite} \times NUM_{Units}$

    - Pre-access drug and alcohol tests need not be performed at facilities with offsite testing laboratories. The associated savings are calculated as follows:

      $NUM_{Applicants} \times COST_{Offsite} \times NUM_{Units}$

- The annual savings per program from bypassing required worker labor in the administration of a pre-access drug and alcohol tests for applicants for authorization reinstatement with an interruption of 5 days or less are calculated as follows:
    - The final paragraph reduces the number of hours of lost worker productivity awaiting negative test result verification from *onsite testing laboratories*. The associated savings are calculated as follows:

      $NUM_{Applicants} \times HOURS_{Onsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$

    - The final paragraph reduces the number of hours of lost worker productivity awaiting negative test result verification from *offsite testing laboratories*. The associated savings are calculated as follows:

      $NUM_{Applicants} \times HOURS_{Offsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$

Parameter	**Description**
$COST_{Offsite}$	Offsite pre-access drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)

[22] The incremental savings from this provision will vary per individual program depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified testing laboratory.

Parameter	Description
$COST_{Onsite}$	Onsite pre-access drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$HOURS_{Offsite\ Worker}$	Hours of facility worker time at a unit with offsite testing laboratories awaiting a negative test verification and not working under the former rule (as described in assumptions below)
$HOURS_{Onsite\ Worker}$	Hours of facility worker time at a unit with onsite testing laboratories awaiting a negative test verification and not working under the former rule (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization reinstatement with an interruption of 5 days or less per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of facility worker time at a unit with onsite testing laboratories awaiting negative test verification and not working under the former rule: 4 hours per reinstatement.[23]

- Hours of facility worker time at a unit with offsite testing laboratories awaiting negative test verification and not working under the former rule: 8 hours per reinstatement.

- The per-unit cost of an *onsite pre-access drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) onsite licensee testing costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

- The per-unit cost of an *offsite pre-access drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) HHS-certified laboratory costs per urine specimen for drugs

[23] Verification usually requires 1 to 3 business days, depending on whether the given licensee engages in onsite or offsite testing. Although some of the time awaiting verification may be used by applicants for other work-related activities, the analysis assumes that applicants are paid, but unproductive, for a portion of this waiting period.

(4) labor of FFD manager to process paperwork for negative test results

- Applicants who qualify for the relaxation are not expected to yield positive drug and alcohol test results under the former regulations.

In addition to the incremental changes discussed above, the final subparagraph results in additional pre-order baseline incremental savings. According to §26.24 of the former rule as well as guidance provided by the NRC in NUREG-1385, "Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions," licensees could not grant authorization to any applicant without administering a drug and alcohol test and verifying negative test results. Provisions in the final subparagraph, however, allow licensees and other entities to forego pre-access drug and alcohol testing on applicants that are either covered by a licensee-approved random drug and alcohol testing program and behavioral observation and arrest-reporting program, or are not randomly selected for a pre-access drug and alcohol test under the requirements of subparagraph 26.59(c)(3) discussed below. As a result, savings accrue from the reduction in the number of pre-access tests administered and the reduction in the loss of worker productivity awaiting negative test results.[24] The *annual savings per program* result from the *sum* of the following savings:[25]

- The annual savings per program from allowing reinstatement applicants who have been covered by a random drug and alcohol testing program and by a behavioral observation and arrest-reporting program throughout the period of interruption to forego the pre-access drug and alcohol test are calculated as follows:

  - The final paragraph reduces the number of pre-access drug and alcohol tests performed at facilities with *onsite testing laboratories*. The associated savings are calculated as follows:

    $$NUM_{Applicants} \times PER_{Covered} \times COST_{Onsite} \times NUM_{Units}$$

  - The final paragraph reduces the number of pre-access drug and alcohol tests performed at facilities with *offsite testing laboratories*. The associated savings are calculated as follows:

    $$NUM_{Applicants} \times PER_{Covered} \times COST_{Offsite} \times NUM_{Units}$$

- Annual savings per program from bypassing required worker labor in the administration of a pre-access drug and alcohol tests for reinstatement applicants

[24] These savings are calculated in replacement of the costs calculated in the main analysis under paragraph 26.59(c)(2).

[25] The incremental savings from this provision will vary by individual program depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified testing laboratory.

who have been covered by a random drug and alcohol testing program and by a behavioral observation and arrest-reporting program throughout the period of interruption are calculated as follows:

- The final paragraph reduces the number of hours of lost worker productivity at facilities with *onsite testing laboratories*. The associated savings are calculated as follows:

  $NUM_{Applicants} \times PER_{Covered} \times HOURS_{Onsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$

- The final paragraph reduces the number of hours of lost worker productivity at facilities with *offsite testing laboratories*. The associated savings are estimated as follows:

  $NUM_{Applicants} \times PER_{Covered} \times HOURS_{Offsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$

- Annual savings per program from allowing reinstatement applicants who have not been covered by a random drug and alcohol testing program and by a behavioral observation and arrest-reporting program throughout the period of interruption, but who have not been randomly selected for pre-access testing, to forego the pre-access drug and alcohol test are calculated as follows:

  - The final paragraph reduces the number of pre-access drug and alcohol testing at facilities with *onsite testing laboratories*. The associated savings are calculated as follows:

    $NUM_{Applicants} \times (1\text{-}PER_{Covered}) \times PER_{Not\ Selected} \times COST_{Onsite} \times NUM_{Units}$

  - The final paragraph reduces the number of pre-access drug and alcohol tests at facilities with *offsite testing laboratories*. The associated savings are calculated as follows:

    $NUM_{Applicants} \times (1\text{-}PER_{Covered}) \times PER_{Not\ Selected} \times COST_{Offsite} \times NUM_{Units}$

- Annual savings per program from reducing the number of hours of lost worker productivity for reinstatement applicants who are not covered and are not selected for random pre-access drug and alcohol testing are calculated as follows:

  - The final paragraph reduces the number of hours of lost worker productivity at facilities with *onsite testing laboratories*. The associated savings are calculated as follows:

    $NUM_{Applicants} \times (1\text{-}PER_{Covered}) \times PER_{Not\ Selected} \times HOURS_{Onsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$

- The final paragraph reduces the number of hours of lost worker productivity at facilities with *offsite testing laboratories*. The associated savings are calculated as follows:

  $NUM_{Applicants} \times (1\text{-}PER_{Covered}) \times PER_{Not\ Selected} \times HOURS_{Offsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$

Parameter	Description
$COST_{Offsite}$	Offsite pre-access drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{Onsite}$	Onsite pre-access drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$HOURS_{Offsite\ Worker}$	Hours of facility worker time at a unit with offsite testing laboratories awaiting a negative test verification and not working under the former rule (as described in assumptions below)
$HOURS_{Onsite\ Worker}$	Hours of facility worker time at a unit with onsite testing laboratories awaiting a negative test verification and not working under the former rule (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for reinstatement authorization with an interruption of more than 5 days but not more than 30 days per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Covered}$	Percentage of $NUM_{Applicants}$ covered by a licensee-approved random drug and alcohol testing program and a behavioral observation and arrest-reporting program (as described in assumptions below)
$PER_{Not\ Selected}$	Percentage of qualifying applicants not randomly selected for pre-access drug and alcohol testing (as described in assumptions below)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of $NUM_{Applicants}$ covered by a licensee-approved random drug and alcohol testing program and a behavioral observation and arrest-reporting program: 50%.

- Percentage of qualifying applicants not randomly selected for pre-access drug and alcohol testing: 97.95%.

- Hours of facility worker time at a unit with onsite testing laboratories awaiting negative test verification and not working under the former rule: 4 hours per reinstatement.[26]

- Hours of facility worker time at a unit with offsite testing laboratories awaiting negative test verification and not working under the former rule: 8 hours per reinstatement.

- The per-unit cost of an *onsite pre-access drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) onsite licensee testing costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

- The per-unit cost of an *offsite pre-access drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) HHS-certified laboratory costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

Sensitivity Analysis - Industry Practices

In addition to incremental activities discussed above, some licensees should have administered additional pre-access tests. As previously noted, §26.24 of the former rule required licensees to administer pre-access drug and alcohol tests on all reinstatement applicants before granting authorization. Nonetheless, until recently, many licensees did not consider it a requirement to administer pre-access drug and alcohol tests on reinstatement applicants with interruptions of 30 days or less. This fraction of licensees (assumed to be 50 percent) should have incurred additional costs to administer pre-access drug and alcohol tests in a manner that meets former requirements. The *annual costs per program* to comply with pre-access drug and

[26] Verification usually requires 1 to 3 business days, depending on whether the given licensee engages in onsite or offsite testing. Although some of the time awaiting verification may be used by applicants for other work-related activities, the analysis assumes that applicants are paid, but unproductive, for a portion of this waiting period.

alcohol testing requirements for applicants with interruptions of not more than 30 days result from the *sum* of the following costs:[27]

- The annual costs per program to administer additional pre-access drug and alcohol tests are calculated as follows:[28]
  - Additional pre-access drug and alcohol tests need to be performed at facilities with onsite testing laboratories. The associated costs are calculated as follows:

    $$NUM_{Applicants} \times PER_{Compliance} \times COST_{Onsite} \times NUM_{Units}$$

  - Additional pre-access drug and alcohol tests need to be performed at facilities with offsite testing laboratories. The associated costs are calculated as follows:

    $$NUM_{Applicants} \times PER_{Compliance} \times COST_{Offsite} \times NUM_{Units}$$

- The annual costs per program from increased lost worker productivity awaiting verification of negative test results are calculated as follows:
  - Additional hours of lost worker productivity awaiting negative test result verification from *onsite testing laboratories* will be expended. The associated savings are calculated as follows:

    $$NUM_{Applicants} \times PER_{Compliance} \times HOURS_{Onsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$$

  - Additional hours of lost worker productivity awaiting negative test result verification from *offsite testing laboratories* will be expended. The associated savings are calculated as follows:

    $$NUM_{Applicants} \times PER_{Compliance} \times HOURS_{Offsite\ Worker} \times WAGE_{Worker} \times NUM_{Units}$$

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[27] Based on current industry practices, this cost is expected to accrue to the 50 percent of facilities that have not previously interpreted the former rule as requiring a pre-access drug and alcohol test to be administered for reinstatement applicants with an interruption of not more than 30 days. The remaining 50 percent of facilities interpreted the former FFD rule correctly, so costs for them should not be calculated. However, because data are not available regarding which specific facilities will incur costs, this analysis assumes that 100 percent of facilities will incur costs of 50 percent of the calculated amount.

[28] The incremental savings from this provision will vary per individual program depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified testing laboratory.

Parameter	Description
$COST_{Offsite}$	Offsite pre-access drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{Onsite}$	Onsite pre-access drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$HOURS_{Offsite\ Worker}$	Hours of facility worker time at a unit with offsite testing laboratories awaiting a negative test verification and not working under the former rule (as described in assumptions below)
$HOURS_{Onsite\ Worker}$	Hours of facility worker time at a unit with onsite testing laboratories awaiting a negative test verification and not working under the former rule (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization reinstatement with an interruption of not more than 30 days per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{Compliance}$	Percentage cost applied to a given program (as described in assumptions below)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of facility worker time at a unit with onsite testing laboratories awaiting negative test verification and not working under the former rule: 4 hours per reinstatement.[29]

- Hours of facility worker time at a unit with offsite testing laboratories awaiting negative test verification and not working under the former rule: 8 hours per reinstatement.[30]

[29] Verification usually requires 1 to 3 business days, depending on whether the given licensee engages in onsite or offsite testing. Although some of the time awaiting verification may be used by applicants for other work-related activities, the analysis assumes that applicants are paid, but unproductive, for a portion of this waiting period.

[30] Verification usually requires 1 to 3 business days, depending on whether the given licensee engages in onsite or offsite testing. Although some of the time awaiting verification may be used by applicants for other work-related activities, the analysis assumes that applicants are paid, but unproductive, for a portion of this waiting period.

- The per-unit cost of an *onsite pre-access drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) onsite licensee testing costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

- The per-unit cost of an *offsite pre-access drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) HHS-certified laboratory costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

- Licensees have indicated that 50 percent of licensees did not interpret the former regulations as requiring a pre-access drug and alcohol test to be administered on applicants with interruptions of 30 days or less. Because the analysis cannot identify which facilities are or are not appropriately interpreting the requirement, the analysis assumes that each unit will incur 50 percent of the incremental cost of the activity.

Subparagraph 26.59(c)(3)

This subparagraph of the final rule adds provisions that require licensees and other entities to include applicants for reinstatement authorization with an interruption of not more than 30 days in a random drug and alcohol testing pool, under §26.67. Licensees are expected to use the same random testing pool for this purpose as is specified under subparagraph 26.31(d)(2) of the final rule. Licensees and other entities must administer a drug and alcohol test on those applicants randomly selected although verification of results does not delay the granting of authorization.

The *annual costs per program* to conduct additional random drug and alcohol tests on reinstatement applicants selected for random testing are calculated as follows:[31]

[31] The incremental costs of this provision will vary by individual program depending on whether the program has onsite testing capabilities or utilizes an offsite HHS-certified laboratory.

- The final paragraph increases the number of random drug and alcohol tests performed at facilities with *onsite testing laboratories*. The associated costs are estimated as follows:

  $NUM_{Applicants} \times PER_{Random} \times COST_{Onsite} \times NUM_{Units}$

- The final paragraph increases the number of random drug and alcohol tests performed at facilities with *offsite testing laboratories*. The associated costs are estimated as follows:

  $NUM_{Applicants} \times PER_{Random} \times COST_{Offsite} \times NUM_{Units}$

Parameter	**Description**
$COST_{Offsite}$	Offsite random drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{Onsite}$	Onsite random drug and alcohol testing cost (as described in assumptions below and in Appendix 2, Exhibit A2-13)
$NUM_{Applicants}$	Annual number of applicants for authorization reinstatement with an interruption of not more than 30 days per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
PER_{Random}	Percentage of $NUM_{Applicants}$ selected for random drug and alcohol testing (as described in assumptions below)

Assumptions:

- Percentage of $NUM_{Applicants}$ selected for random drug and alcohol testing: 1.0%.[32]

- The per-unit cost of an *onsite random drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) onsite licensee testing costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

[32] This figure is calculated by assuming that on any given day, an individual in applicant status has a chance of being selected equivalent to the following: (1 day / 365 days) x required annual testing rate of 50% x number of days in applicant status. The analysis assumes an average applicant status of 7 days. Applicants for reinstatement authorization, however, are likely to have a much shorter review period. Consequently, the analysis likely overstates these costs.

- The per-unit cost of an *offsite random drug and alcohol test* includes the following factors:
  (1) travel time of the worker
  (2) collection of drug and alcohol specimens (labor of the collector and the worker, as well as collection materials)
  (3) HHS-certified laboratory costs per urine specimen for drugs
  (4) labor of FFD manager to process paperwork for negative test results

Paragraph 26.59(d)

This paragraph of the final rule requires licensees and other entities to take the management action specified in §26.69 when potentially disqualifying FFD information is disclosed or discovered for an applicant for reinstatement authorization. This final paragraph imposes no incremental cost and affords no saving because, under §26.27 of the former rule, applicants for unescorted access were subject to similar requirements. These management actions are further discussed in relevant sections of the analysis.

26.61 Self-Disclosure and Employment History

Paragraph 26.61(a)

This paragraph of the final rule requires that licensees to ensure that a self-disclosure and employment history has been obtained from all applicants for authorization before authorization may be granted. Under the former rule, licensees were required to obtain an equivalent "written statement" from these applicants under subparagraph 26.27(a)(1).

Subparagraphs 26.61(a)(1)–(2)

These paragraphs of the final rule add provisions that allow licensees to forego the self-disclosure requirement for those applicants who have previously held authorization, had their previous termination terminated favorably, and have been covered by a licensee-approved behavioral observation program that includes arrest reporting throughout the period of interruption. Additionally, those applicants who have had their authorizations terminated favorably within the last 30 days, regardless of whether they were covered by a behavioral observation and arrest-reporting program, need not submit an employment history. For applicants for updated or reinstated authorization, there is no incremental cost or saving due to this provision because this paragraph is based on non-safeguards information requirements imposed by the NRC's AAO dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643). For applicants for initial authorization, however, this represents a relaxation over the former rule. Savings associated with this provision are calculated under subparagraph 26.55(a)(1).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph does result in incremental savings relative to the former rule. Savings associated with this provision are calculated and discussed in the *Sensitivity Analysis - Pre-Order Baseline* under §§26.57 and 26.59.

Paragraph 26.61(b)

Subparagraphs 26.61(b)(1)–(3)

These subparagraphs of the final rule describe the types of events and the time period that must be addressed in the self-disclosure. The disclosure of most of this information was required under subparagraphs 26.27(a)(1) and (2) of the former rule. Although the final subparagraphs include additional information disclosure requirements and allow individuals to address only events that have occurred within the past 5 years, rather than all relevant events that have ever occurred, there is no incremental cost or saving due to these added provisions (discussed below) because this revised paragraph is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis Note - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, these paragraphs do result in incremental changes. The reduction in the time period within which events must be disclosed on the self-disclosure may reduce the amount of applicant time required to complete one. Simultaneously, however, the additional events that must be reported (i.e., any legal or employment action taken for alcohol or drug use) may increase the amount of time required to complete a self-disclosure. The analysis assumes that the two incremental changes offset each other, thereby resulting in no discernable net incremental costs or savings.

Paragraph 26.61(c)

This paragraph of the final rule requires applicants for authorization to submit an employment history report for verification during the suitable inquiry. This final paragraph imposes no incremental cost and affords no saving because, under the former rule and guidance contained in NUMARC 89-01: Industry Guidelines for Nuclear Power Plant Access Authorization Programs, applicants had to submit an employment history. The final paragraph does reduce the scope of the employment history from the past 5-years under former regulations to the shortest of (1) the past 3 years; (2) since the individual's eighteenth birthday; or (3) since authorization was last terminated, if authorization was terminated favorably. This provision, however, is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis Note - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph does not result in incremental costs or savings. These paragraphs adopt provisions that reduce the period of time that an individual must address in an employment history. This reduction, however, is not anticipated to result in any significant reductions in the amount of labor required to fill out an employment history and, therefore, no savings result.

26.63 Suitable Inquiry

Paragraph 26.63(a)

This subparagraph of the final rule [including subparagraphs 26.63(a)(1)–(3)] imposes no incremental cost and affords no saving because it merely requires licensees and other entities to ensure that a suitable inquiry has been conducted on the self-disclosures submitted by applicants for authorization in order to verify the information contained therein and to determine whether any potentially disqualifying FFD information exists. Under the former rule, applicants for unescorted access were subject to similar suitable inquiry requirements under §26.27. The provision also adds a provision that allows licensees and other entities to forego the suitable inquiry requirement on those applicants who have previously held authorization, had that authorization terminated favorably, and who have been covered by a licensee-approved behavioral observation program that includes arrest reporting throughout the period of interruption. This provision, however, is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis Note - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph does result in incremental savings relative to the former rule. Savings associated with this provision are calculated and discussed as appropriate in the *Sensitivity Analysis - Pre-Order Baseline* under §§26.57 and 26.59.

Paragraph 26.63(b)

This paragraph of the final rule allows licensees to rely on information gathered by other licensees and other entities for previous periods of authorization for the purpose of completing suitable inquiries and determinations of fitness. Although this represents a relaxation of the former regulations, there is no incremental savings because this final paragraph is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph does not result in incremental costs or savings because licensees have indicated that they were already sharing information extensively and relying on such information to complete suitable inquiries, as noted in NRC guidance in NUREG-1600, "Revision to the NRC Enforcement Policy" (per 67 FR 66311, October 31, 2002).

Paragraph 26.63(c)

This paragraph of the final rule [including subparagraphs 26.63(c)(1)–(3)] imposes no incremental cost and affords no saving because it merely clarifies the manner in which licensees must ensure that a suitable inquiry has been conducted for periods of claimed employment, military service, and education (in lieu of employment). Provisions under subparagraph 26.27(a)(2) of the former rule required a suitable inquiry, but do not explicitly describe how licensees should conduct the suitable inquiry. The analysis assumes that licensees are already conducting suitable inquiries in a manner similar to that described in the final rule, although the final rule more explicitly describes the required process.

Paragraph 26.63(d)

This paragraph mandates that licensees and other entities must share information regarding a denial of authorization or unfavorable termination with other licensees and other entities who are legitimately seeking the information and have obtained a signed release from the subject individual for the purpose of conducting a suitable inquiry. This final paragraph imposes no incremental cost and affords no saving because licensees have indicated that they already share information, as noted in the NRC guidance in NUREG-1600, "Revision to the NRC Enforcement Policy" (per 67 FR 66311, October 31, 2002).

Paragraph 26.63(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies the media (i.e., telephone, email, facsimile) that licensees may use to conduct a suitable inquiry. The final paragraph also requires licensees to make a written record of any suitable inquiry conducted over the telephone. Licensees must maintain such records (along with other documents and electronic files) in accordance with the recordkeeping requirements of the final rule. No costs are calculated for this provision because paragraph 26.71(a) of the former rule already required licensees to retain records of suitable inquiries.

Paragraph 26.63(f)

Subparagraph 26.63(f)(1)

This paragraph of the final rule defines the scope of suitable inquiries conducted on applicants for initial authorization 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 suitable inquiry must address the past 3-year period or since the applicants eighteenth birthday, whichever is shorter. The suitable inquiry must address every employer the applicant identified as having worked for during the 1-year period immediately preceding the application for authorization. For the remaining 2-year period, the suitable inquiry must address the employer for whom the applicant identified as having worked for the longest in each calendar month, if applicable. There is no incremental cost or saving due to this provision because this final paragraph is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph does result in incremental savings relative to the former rule. Savings associated with this provision are calculated and discussed in the *Sensitivity Analysis - Pre-Order Baseline* for subparagraph 26.55(a)(2).

Subparagraph 26.63(f)(2)

This paragraph of the final rule defines the scope of suitable inquiries conducted on applicants for updated authorization 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 suitable inquiry must address the period since authorization was last terminated. The suitable inquiry must address every employer the applicant identified as having worked for during the 1-year period immediately preceding the application for authorization. For each remaining calendar month in the period since authorization was terminated, the suitable inquiry must address the employer for whom the applicant identified as having worked for the longest, if applicable. There is no incremental cost or saving due to this provision because this final paragraph is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph does result in incremental savings relative to the former rule. Savings associated with this provision are calculated and discussed in the *Sensitivity Analysis - Pre-Order Baseline* for subparagraph 26.57(a)(2).

Subparagraph 26.63(f)(3)

This paragraph of the final rule defines the scope of suitable inquiries conducted on applicants for authorization reinstatement after an interruption of more than 30 days 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 suitable inquiry must address the period since authorization was last terminated. The suitable inquiry must address the applicant's current employer. In addition, for each calendar month since authorization was terminated, the suitable inquiry must address the employer whom the applicant identified as having worked the longest for, if applicable. There is no incremental cost or saving due to this provision because this final paragraph is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph does result in incremental savings relative to the former rule. Savings associated with this provision are calculated and discussed in the *Sensitivity Analysis - Pre-Order Baseline* for subparagraph 26.59(c)(2).

26.65 Pre-Access Drug and Alcohol Testing

Paragraph 26.65(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it describes the purpose of this section as containing the pre-access testing requirements for granting authorization. The former rule already required pre-access testing under subparagraph 26.24(a)(1).

Paragraph 26.65(b)

This paragraph of the final rule allows licensees and other entities to forego the pre-access drug and alcohol testing requirement for those applicants who have had negative test results from a drug and alcohol test performed under the requirements of this part within the 30-day period ending the day authorization is granted or denied. Although this provision is based on

subparagraph 26.24(a)(1) of the former rule, the revised subparagraph reduces the period within which a previous drug and alcohol test will be accepted from 60 to 30 days. There is no incremental cost or saving due to this provision because this revised paragraph is based on non-safeguards information requirements imposed by the NRC's AAO dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraphs do not result in any incremental costs. Although the final paragraphs adopt provisions from the AAO that reduce the time period within which pre-access drug and alcohol testing must be completed from 60 days under the former rule to 30 days, licensees and other entities are expected to adjust their pre-access testing schedules to accommodate the smaller time frame. The analysis anticipates that this adjustment will not result in any additional costs.

Paragraph 26.65(c)

This paragraph of the final rule [including subparagraphs 26.65(c)(1) and (2)] requires licensees to administer a pre-access drug and alcohol test and verify negative results before granting authorization to any applicant for initial authorization (i.e., an applicant who has never been authorized or who has not been authorized within the past 3 years) or for updated authorization (i.e., an applicant with an interruption of more than 365 days, but not more than 3 years). Under the former rule, applicants for unescorted access were subject to similar drug and alcohol testing requirements under 26.24(a). The final subparagraphs do, however, adopt provisions from NRC's AAO that allow licensees and C/Vs to forego the pre-access drug and alcohol test requirement for certain applicants. Licensees and C/Vs may forego the pre-access drug and alcohol test requirement for individuals whose previous authorization had been terminated favorably and who have been covered by licensee-approved behavioral observation program that includes behavioral observation and a random drug and alcohol testing programs throughout the period of interruption, or who have had a negative result from a licensee-approved drug and alcohol test conducted anytime in the past and are covered by licensee-approved behavioral observation program that includes behavioral observation and a random drug and alcohol testing program beginning on the date of the drug and alcohol test through the date the individual is granted authorization. For applicants for updated authorization, the provision affords no savings except under the alternative Pre-Order Baseline, because it is based on non-safeguards information requirements imposed by the NRC's AAO dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643). For applicants for initial authorization, however, this represents a relaxation relative to the former rule. Savings associated with this provision are calculated under subparagraph 26.55(a)(3).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the subparagraph does result in incremental savings relative to the former rule. Savings associated with this

provision are calculated and discussed in the *Sensitivity Analysis - Pre-Order Baseline* for paragraph 26.57(a)(3).

Paragraph 26.65(d)

Subparagraph 26.65(d)(1)

This subparagraph of the final rule requires licensees to verify results of the pre-access alcohol test and collect a specimen for pre-access drug testing before granting authorization to any reinstatement applicant with an interruption of more than 30 days but no more than 365 days. Verification of negative drug test results must be completed within 5 business days of specimen collection. If verification has not occurred within this time frame, authorization must be administratively withdrawn until negative results have been received. Under the former rule, applicants for unescorted access were subject to similar drug and alcohol testing requirements under 26.24(a), except that licensees must verify negative results of both the drug and alcohol tests before authorization may be granted. The provision affords no savings, however, except under the alternative Pre-Order Baseline, because it is based on non-safeguards information requirements imposed by the NRC's AAO dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the subparagraph does result in incremental savings relative to the former rule. Savings associated with this provision are calculated and discussed in the *Sensitivity Analysis - Pre-Order Baseline* for paragraph 26.59(c)(2).

Subparagraph 26.65(d)(2)

This subparagraph of the final rule allows licensees to forego the pre-access drug and alcohol testing requirements on certain applicants for authorization reinstatement with interruptions of more than 30 days but not more than 365 days. Licensees and C/Vs may forego the pre-access drug and alcohol test requirement for individuals whose previous authorization had been terminated favorably and who have been covered by licensee-approved behavioral observation program that includes arrest reporting and a random drug and alcohol testing program throughout the period of interruption, or who have had a negative result from a licensee-approved drug and alcohol test conducted anytime in the past and are covered by licensee-approved behavioral observation program that includes behavioral observation and a random drug and alcohol testing program beginning on the date of the drug and alcohol test through the date the individual is granted authorization. For these reinstatement applicants, the provision affords no savings except under the alternative Pre-Order Baseline, because it is based on non-safeguards information requirements imposed by the NRC's AAO dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the subparagraph does result in incremental savings relative to the former rule. Savings associated with this provision are calculated and discussed in the *Sensitivity Analysis - Pre-Order Baseline* for paragraph 26.59(a)(3).

Paragraph 26.65(e)

Subparagraph 26.65(e)(1)

This subparagraph of the final rule allows licensees to forego the pre-access drug and alcohol tests for applicants for reinstatement authorization with an interruption of 5 days or less. Under paragraph 26.24(a) of the former rule, all applicants for unescorted access were required to be subjected to a pre-access drug and alcohol test before authorization can be granted. The provision affords no savings, however, except under the alternative Pre-Order Baseline, because it is based on non-safeguards information requirements imposed by the NRC's AAO dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

This paragraph of the final rule also adds a provision that allows licensees and other entities to forego the pre-access drug and alcohol testing requirement for those applicants for authorization with an interruption of fewer than 30 days whose previous authorization was terminated favorably and who have been covered by a licensee-approved drug and alcohol testing program that included random testing and a licensee-approved behavioral observation program that includes arrest reporting throughout the period of interruption. Under paragraph 26.24(a) of the former rule, all applicants for unescorted access were required to be subjected to a pre-access drug and alcohol test before authorization can be granted. There is no incremental cost or saving due to this provision, however, because this revised paragraph is based on non-safeguards information requirements imposed by the NRC's AAO dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph does result in incremental savings. Savings associated with these provisions are calculated and discussed in the *Sensitivity Analysis - Pre-Order Baseline* for subparagraph 26.59(c) and (c)(2).

Subparagraph 26.65(e)(2)

Subparagraph 26.65(e)(2)(i) and (iii)

This subparagraph of the final rule adds provisions that require licensees and other entities to subject applicants for authorization reinstatement with an interruption of more than 5 days but not more than 30 days to random selection for a pre-access drug and alcohol test at a one-time

probability that is equal to or greater than the normal random testing rate specified in subparagraph 26.31(d)(2) calculated for a 30-day period. For applicants randomly selected for pre-access drug and alcohol testing, licensees and other entities must verify negative results of the alcohol test and collect a drug test specimen before granting authorization. Drug test results must be verified within 5 business days of the granting of authorization or authorization must be administratively terminated. Costs associated with this provision are calculated and discussed under 26.59(c)(2).

Subparagraph 26.65(e)(2)(ii)

This subparagraph of the final rule adds provisions that allow licensees and other entities to forego the pre-access drug and alcohol testing requirement for those reinstatement applicants with interruptions of more than 5 days but not more than 30 days if not randomly selected. Under paragraph 26.24(a) of the former rule, all applicants for unescorted access were required to be subjected to a pre-access drug and alcohol test before authorization can be granted. The provision affords no savings, however, except under the alternative Pre-Order Baseline, because it is based on non-safeguards information requirements imposed by the NRC's AAO dated January 7, 2003, and published in the Federal Register on January 13, 2003 (68 FR 1643).

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraphs do result in incremental savings. Savings associated with this provision are calculated and discussed in the *Sensitivity Analysis - Pre-Order Baseline* for subparagraph 26.59(c)(2).

Paragraph 26.65(f)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it is added to ensure that the administrative withdrawal of an individual's authorization is not recorded as an unfavorable termination.

Paragraph 26.65(g)

This paragraph of the final rule [including subparagraphs 26.65(h)(1)–(3)] describes the minimum management actions and sanctions that must be met in the event of a positive, adulterated, or substituted random drug, validity, or alcohol test after selection during the applicant period. Licensees and other entities are required to either deny authorization [as required by paragraphs 26.75(b), (d), (e)(2), or (g)], terminate authorization if it has been granted [under paragraphs 26.75(e)(1) or (f)], or grant authorization under §26.69. No incremental costs are anticipated to result from this final paragraph because the management actions are similar to those already required under the former rule.

26.67 Random Drug and Alcohol Testing of Individuals who have Applied for Authorization

Paragraph 26.67(a)

This paragraph of the final rule [including subparagraphs 26.67(a)(1) and (2)] adds a requirement for licensees and other entities to subject applicants for authorization to random drug and alcohol testing under subparagraph 26.31(d)(2) once the licensee collects specimens from an individual for any pre-access testing that may be required under §§26.65 or 26.69. This added provision will result in incremental costs. These costs, however, are presented separately for each applicant type under §§26.55, 26.57, and 26.59.

Subparagraph 26.67(a)(1)

This subparagraph states that licensees and other entities can forego the random drug and alcohol testing requirement presented in paragraph 26.67(a) if authorization is not granted. This requirement imposes no incremental activity relative to the former rule and, therefore, results in no incremental cost or saving.

Subparagraph 26.67(a)(2)

This subparagraph states that if the licensee or other entity, to meet the applicable requirements for pre-access testing, relies upon drug and alcohol testing conducted before the individual applied for authorization from the licensee, the licensee or other entity shall subject the individual to random testing beginning upon arrival at the facility for in-processing. Because this requirement ultimately will not change the time period within which random testing must be conducted, this requirement imposes no incremental cost or saving.

Paragraph 26.67(b)

This paragraph of the final rule states that if an individual is selected for random drug and alcohol testing after the requirement for pre-access testing has been meet, the licensee or other entity may grant authorization before test results are verified, provided that they are available within the time period specified in §26.65 (10 business days). No incremental costs or savings result because licensees already allow access to be granted following the completion of pre-access drug and alcohol testing.

Paragraph 26.67(c)

This paragraph of the final rule [including subparagraphs 26.67(c)(1)–(3)] describes the minimum management actions and sanctions that must be met in the event of a positive, adulterated, or substituted random drug, validity, or alcohol test after selection during the applicant period. Licensees and other entities are required to either deny authorization [as required by paragraphs 26.75(b), (d), (e)(2), or (g)], terminate authorization if it has been granted

[as required by paragraphs 26.75(e)(1) or (f)], or grant authorization under §26.69. No incremental costs are anticipated to result from this final paragraph because the management actions are similar to those of current industry practice.

26.69 Authorization with Potentially Disqualifying Fitness-for-Duty Information

Paragraph 26.69(a)

This paragraph of the final rule states that the purpose of §26.69 is to define the management actions for granting authorization when potentially disqualifying information has been discovered. Such management actions were defined in subparagraph 26.27(a)(3) of the former rule. In addition, the final paragraph allows licensees and other entities to rely on past reviews and determinations of potentially disqualifying FFD information conducted by previous licensees. This provision may result in incremental savings as the number of applicants that require a determination of fitness is likely to decrease. These incremental savings are calculated and presented under subparagraph 26.189(b)(3).

Paragraph 26.69(b)

This paragraph of the final rule describes the procedures for licensees and other entities to follow in granting and maintaining authorization for an individual whose authorization was denied for 5 years under §26.75(c), (d), (e)(2), or (f) or terminated unfavorably for a first confirmed positive drug or alcohol test result by a licensee or other entity. This procedure includes a more thorough suitable inquiry than required under paragraph 26.61,[33] a determination of fitness (as required by 26.27(a)(3) of the former rule), verification of negative results of a pre-access drug and alcohol test with collection under direct observation, and completion of or compliance with any follow-up testing program. Although this final paragraph includes some new provisions that may require additional labor burden, the analysis assumes that licensees and other entities will rarely hire or grant authorization to individuals with confirmed first positive drug and alcohol test results. Consequently, the requirements impose no added cost or savings.

Paragraph 26.69(c)

This paragraph of the final rule describes the procedures for licensees and other entities to follow in granting authorization to an applicant for whom potentially disqualifying FFD information, other than a first confirmed drug or alcohol test result, has been discovered or disclosed. This procedure includes a more thorough suitable inquiry than required under paragraph 26.61, a determination of fitness (as required by 26.27(a)(3) of the former rule) if necessary, verification of negative results of a pre-access drug and alcohol test, and completion of or compliance with any follow-up testing program. Although this final paragraph includes some new provisions that may require an additional labor burden, the analysis assumes that licensees and other entities will

[33] This more thorough suitable inquiry is equivalent to what was called for under the former rule.

rarely hire or grant authorization to individuals who have been denied authorization for a period of 5 years. Consequently, the requirements impose no added cost or savings.

Paragraph 26.69(d)

This paragraph of the final rule describes the procedures for licensees and other entities to follow in order to maintain authorization of an individual when potentially disqualifying FFD information is discovered or disclosed after authorization has been granted. The procedure requires that the licensee's or other entity's designated reviewing official complete a review of the circumstances associated with the information. Upon the direction of the reviewing official, the appropriate professional (e.g., SAE) must conduct a determination of fitness and verify that the individual is fit to safely and competently perform his or her duties. Authorization may be maintained with the approval of the reviewing official and following the implementation of any recommendations for treatment and followup drug and alcohol testing as well as assurance of compliance with any such recommendations and treatments. The provisions impose no incremental cost and afford no saving because paragraph 26.27(b) of the former rule already required licensees and other entities to determine whether an individual who is suspected of potential impairment or questionable fitness is fit to safely and competently perform activities required under this part.

Paragraph 26.69(e)

This paragraph [including subparagraphs 26.69(e)(1) and (2)] addresses the transfer of an individual who is in a treatment and/or follow-up testing plan to a different FFD program. The final paragraph requires the licensee or other entity who imposed the treatment and/or followup testing plan to ensure that information documenting the treatment and/or followup plan is identified to any subsequent licensee or other entity who seeks to grant authorization to the individual. The paragraph also requires that the receiving licensee ensure that the treatment and follow-up testing requirements are met. No incremental costs or savings are expected to result from this requirement because the former rule already required (in subparagraph 26.27(a)(3)) that follow-up testing requirements apply to an individual wherever he or she goes, and as such, this final paragraph represents a clarification of former requirements. The language clarifies that the receiving licensee may take credit for the portion of a follow-up drug and alcohol testing program that was completed under a previous licensee, and that individuals will not need to start over with follow-up testing when transferring to a new licensee. Although these provisions may result in incremental savings for those licensees who have been hiring such individuals and restarting the follow-up testing program, the analysis does not quantify them given the rarity of situations in which a licensee will chose to hire such individuals.

Paragraph 26.69(f)

This paragraph of the rule describes the sanctions that licensees and other entities must implement in the event that an applicant applying for authorization with potentially disqualifying FFD information receives confirmed positive, adulterated, or substituted drug, validity, or

alcohol test results. In such situations, licensees and other entities are required to either deny authorization or terminate an individual's authorization (if they already have been authorized). These procedures were already contained in paragraph 26.27(b)(2) of the former rule. As a result, the final paragraph imposes no incremental costs and affords no savings.

26.71 Maintaining Authorization

Paragraph 26.71(a)

Subparagraph 26.71(a)(1)

This paragraph of the final rule states that individual's must comply with licensee and other entity FFD policies and procedures in order to maintain authorization. This final subparagraph imposes no incremental cost and affords no saving because the former rule already required individuals to conform to this provision based on the actions that would warrant revocation of the individual's authorization in paragraph 26.27(b) of the former rule.

Subparagraph 26.71(a)(2)

This paragraph of the final rule states that individuals must remain subject to an approved drug and alcohol testing program in order to maintain authorization. It imposes no incremental costs and affords no saving because this already is required under §26.24 of the former rule.

Subparagraph 26.71(a)(3)

This paragraph states that individuals must be subject to a behavioral observation program in order to maintain authorization, as required by subparagraph 26.22(a)(4) of the former rule. Incremental costs indirectly related to this provision are addressed in connection with §26.29.

Subparagraph 26.71(a)(4)

This paragraph of the final rule imposes no incremental cost and affords no saving because FFD policy training already is required under §26.21 of the former rule. Costs or savings associated with changes to training requirements are calculated and discussed in connection with §26.29.

Paragraph 26.71(b)

This paragraph of the final rule adds provisions that require the licensee or other entity to terminate authorization of any authorized individual who for a period of 30 days has not been subject to a licensee-approved FFD program that meets the requirements of this part. The analysis assumes that current industry practice already allows a limited period of time during which authorized individuals may be away from the FFD program to account for vacations and other approved short-term leaves of absence. Therefore, the analysis assumes the final paragraph imposes no incremental costs and affords no savings.

Subpart D: Management Actions and Sanctions to be Imposed

26.73 Applicability

This section of the final rule imposes no incremental cost and affords no saving because it merely states that the requirements in Subpart D apply to the: (1) licensees and other entities identified in § 26.3(a) and (b) for the categories of individuals specified in § 26.4(a) through (d); (2) licensees and other entities specified in § 26.3(c) for the categories of individuals in § 26.4(e), and, at the licensee's or entity's discretion, for the categories of individuals identified in § 26.4(f); (3) 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, and; (4) individuals specified in § 26.4(h) and (j), as appropriate.

26.75 Sanctions

Paragraph 26.75(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely introduces the subsequent provisions regarding minimum sanctions required in the event of violations of the drug and alcohol provisions of an FFD policy, which are similar to those required by paragraph 26.27(b) of the former rule.

Paragraph 26.75(b)

Licensees may realize incremental savings as a result of this paragraph, which requires licensees to deny authorization permanently to individuals who refuse to be tested or have engaged, or attempted to engage, in subversion of the testing process. This is a new requirement that was not addressed in the former rule. Requiring permanent denial of authorization may prevent, currently and in the future, disputes which require lengthy discussion or questioning of the grounds for denial in such instances. This analysis does not quantify any associated savings, however, because neither refusals nor subversion attempts are common, and data are not available to support a meaningful estimate.

Paragraph 26.75(c)

This paragraph of the final rule revises paragraph 26.27(b)(3) of the former rule to require licensees and other entities to deny authorization for a period of at least 5-years if an employee 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 activities that require the individual to be subject to this part. Although the addition of the consumption of alcohol to this requirement represents a new requirement, no incremental cost or savings is anticipated to result because it is assumed that licensees already impose similar sanctions under their current policies.

Paragraph 26.75(d)

This paragraph of the final rule revises the requirements located in paragraph 26.27(c) of the former rule to require licensees and other entities to deny authorization for a period of at least 5 years if an employee resigns or withdraws his application for authorization in anticipation of having their authorization terminated unfavorably as a result of a violation of the drug and alcohol provisions of the FFD policy. Although this is a new requirement, no incremental saving is estimated, even though future authorizing licensees or other entities may realize some savings by avoiding initial processing of these individuals.

Paragraph 26.75(e)

This paragraph revises the requirement located in subparagraph 26.27(b)(2) of the former rule by requiring the presumption that alcohol consumption (in addition to drug use) occurred off-site unless evidence suggests otherwise. Although the addition of the consumption of alcohol to this requirement represents a new requirement, no incremental cost or savings is anticipated to result because it is assumed that licensees already impose similar sanctions under their current policies.

Paragraph 26.75(f)

This paragraph of the final rule revises requirements contained in subparagraph 26.27(b)(5) of the former rule. The former rule stated that current licensee sanctions for confirmed misuse of alcohol, valid prescription drugs, and over-the-counter drugs must be sufficient to deter such abuse, and therefore it does not apply certain management actions to such misuse specified in this section. The final rule removes confirmed alcohol use from this category and specifically applies the management actions in 26.75(e) to such abuse. Although this is a new requirement, the final paragraph imposes no incremental cost and affords no saving, however, because it is not a significant change to licensee and other entity policy and because there is no incremental cost or saving associated with 26.75(e).

Paragraph 26.75(g)

This paragraph of the final rule requires licensees and other entities to permanently deny authorization to any individual who violates the drug and alcohol provisions of FFD policy after already having a denial of authorization of at least 5 years under paragraphs 26.75(c)–(f). Under the former rule, only a second positive test result, or sale, use, or possession of drugs while on duty could result in a permanent denial of authorization. Although this new requirement may result in additional permanent denials of authorization that will require additional record-keeping activities in conjunction with paragraph 26.713(c), no incremental costs are expected to result because licensees already store records of such violations under §26.71 of the former rule and the incremental activities associated with recording the violation as a permanent denial is anticipated to be negligible. Additionally, the longer 40-year retention period [specified in §26.713(c)], as compared to the 5-year period under the former rule, is not expected to result in

incremental costs because the most substantial costs associated with retaining the records (filing, removal) do not change as a result of this final paragraph.

Paragraph 26.75(h)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely renumbers and revises paragraph 26.24(d)(2) of the former rule. The revisions add terminology to be consistent with the rest of the rule, as well as references to validity testing.

Paragraph 26.75(i)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely renumbers and revises paragraph 26.24(d)(2) of the former rule. The revisions add terminology to be consistent with the rest of the rule, as well as references to validity testing.

26.77 Management Actions Regarding Possible Impairment

Paragraph 26.77(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely states the purpose of the section, which is to describe management actions that licensees and other entities must take when an individual who is subject to this part shows indications of not being fit to safely and competently perform activities within the scope of this part.

Paragraph 26.77(b)

This paragraph of the final rule imposes no incremental costs and affords no savings because it merely requires licensees and other entities to take immediate action with drug and alcohol testing if an employee exhibits an indication of possible impairment while performing activities within the scope of this part, as already required under paragraph 26.27(b)(1) of the former rule. The revised paragraph does, however, add provisions allowing licensees and other entities the option of conducting only an alcohol test (but not a drug test) when the evidence of possible impairment is the smell of alcohol. The analysis has not quantified any incremental savings from this provision. Additionally, the provision requires that observed behaviors or physical conditions suggesting impairment solely from fatigue shall result in a fatigue assessment in accordance with §26.211 rather than a determination of fitness. Additional costs associated with the fatigue assessment are calculated under §26.211 of this analysis.

Paragraph 26.77(c)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely renumbers paragraph 26.27(d) of the former rule, which stated that licensees must provide escorted access to NRC employees or contractors when there are indications of questionable fitness to perform activities within the scope of this part.

Subpart E: Collecting Specimens for Testing

26.81 Purpose and applicability

This section of the final rule imposes no incremental cost and affords no saving because it merely explains that Subpart E presents the requirements associated with collecting specimens for drug and alcohol testing by or on behalf of the licensees and other entities in §26.3. This section also states that 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, "Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs," as permitted under §§ 26.4(j), 26.31(b)(2), and Subpart K.

26.83 Specimens to be collected

Paragraph 26.83(a)

This paragraph of the final rule revises the requirements in former §26.24(g), which specified the types of specimens permitted to be analyzed for alcohol testing. Requirements in former §26.24(g) of the former rule permitted the use of breath specimens for initial and confirmatory alcohol tests and blood specimens for additional confirmatory alcohol testing. The final rule eliminates the use of blood specimens for confirmatory alcohol testing which was permitted in former Section 2.2(d)(4) in Appendix A to Part 26. The final rule adds a new provision permitting the collection of oral fluids (in addition to breath) for initial alcohol tests. The use of oral fluids is a permissive relaxation of the former rule requirements providing licensees with flexibility in using an alternative specimen testing (saliva) method to conduct initial alcohol testing (see the discussion of §26.91(a) of this analysis). Elimination of blood samples for confirmatory alcohol testing will result in minor licensee savings by eliminating the costs associated with collecting blood specimens from donors, analyzing blood specimens, lost worker productivity, and MRO time to review and communicate blood test results to the worker and FFD management.

The *annual savings per FFD program* are estimated as follows:

$$NUM_{blood} \times [(COST_{blood\ draw} + COST_{blood\ testing}) + (HOURS_{worker} \times WAGE_{worker}) + (HOURS_{MRO} \times WAGE_{MRO})]$$

Parameter	Description
NUM_{blood}	Number of blood tests per FFD program per year under the former rule (as discussed in the assumptions below)
$COST_{blood\ draw}$	Cost per blood test for a phlebotomist/RN to arrive at the onsite collection site and conduct a blood draw (as discussed in Appendix 2, Exhibit A2-13).
$COST_{blood\ testing}$	Cost per blood test for a laboratory to analyze a blood specimen for alcohol (as discussed in Appendix 2, Exhibit A2-13)

Parameter	Description
$HOURS_{worker}$	Hours of lost worker productivity resulting from receiving a blood test (as discussed in the assumptions below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-13)
$HOURS_{MRO}$	Hours of MRO time to review blood test results and communicate the results to the worker and FFD management (as discussed in the assumptions below)
$WAGE_{MRO}$	MRO wage rate (as discussed in Appendix 2, Exhibit A2-13)

Assumptions:

- Number of blood tests per FFD program per year under the former rule: 1.

- Hours of lost worker productivity per test resulting from receiving a blood test includes waiting time for phlebotomist/RN to arrive at the onsite collection site, conduct a blood draw, and complete paperwork: 45 minutes.

- Hours of MRO time to review blood test results and communicate the results to worker and FFD management: 45 minutes.

- Blood specimen is collected at the same collection site where the confirmatory evidential breath testing device (EBT) testing is conducted.

Paragraph 26.83(b)

This paragraph of the final rule imposes no incremental cost and affords no saving because it clarifies requirements in former §26.24(f) which specified "urine drug testing" on all specimens at licensee testing facilities and/or HHS-certified laboratories. Since no other type of specimen is described in the former rule language as acceptable alternative for drug testing, this final paragraph simply clarifies the former rule requirements.

26.85 Collector qualifications and responsibilities

Paragraphs 26.85(a) and (b)

Paragraph 26.85(a) addresses urine collector qualifications and training requirements and paragraph 26.85(b) addresses alcohol collector qualifications and training. These final paragraphs revise requirements in former Section 2.2(d) in Appendix A to Part 26, which addressed training of collection site personnel. The former requirements specified collector training in maintaining the integrity of the specimen collection and transfer process, donor privacy issues, and appropriate collector conduct. The final rule adds requirements that collectors must be knowledgeable about Part 26, as well as the FFD policy and procedures of

licensees and other entities, and must keep up to date with urine and alcohol collection procedures. It also requires all collectors to receive qualification training on problem collections and the correction of problems associated with collections.[1] FFD programs will incur incremental costs associated with conducting one-time collector training classes and the labor costs for all collectors to attend a training class.[2]

The *one-time costs per FFD program* are estimated as follows:

$$NUM_{collectors} \times [(HOURS_{collector\ training} \times WAGE_{collector}) + COST_{training\ course})] \times NUM_{facilities}$$

Parameter	**Description**
$NUM_{collectors}$	Number of collectors per licensee facility (as discussed in the assumptions below)
$HOURS_{collector\ training}$	Length of training course (as discussed in the assumptions below)
$WAGE_{collector}$	Collection site personnel wage rate (as discussed in Appendix 2, Exhibit A2-11)
$COST_{training\ course}$	Cost of a commercial vendor to conduct an onsite collector training course per facility (as discussed in the assumptions below)
$NUM_{facilities}$	Number of facilities in a given FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Each facility uses a unique collection site.
- Each collector is trained to conduct urine and breath collections.
- Number of collectors per licensee facility: 4.
- Length of training course (includes urine and breath collections): 8 hours.
- Cost of collector training course for a commercial vendor to conduct onsite at a collection site: $1,000.

[1] All urine and breath collectors used by a licensee or other entity's collection site will receive re-training to meet the requirements in §26.85(a) and (b) as well as to receive training on all new collection procedures resulting from the rule revision. Some of the urine collectors at a licensee collection site may be medical professionals, technologists, or technicians who are no longer exempted from the former rule requirement in Section 2.2(d)(2) in Appendix A due to the provision in §26.85(c), and thus, may be receiving training for the first time.

[2] The analysis estimates no incremental cost for future training (e.g., due to normal employee turnover) because it is believed that new collectors already receive on-the-job training as part of their normal training activities given that the topics for qualification training are necessary for fulfilling job responsibilities (e.g., completing the custody-and-control form, shy bladder procedures, specimen integrity procedures, donor privacy protections).

Paragraph 26.85(c)

This paragraph of the final rule revises the requirements in former Section 2.2(d)(2) in Appendix A to Part 26, which permitted medical professionals, technologists, and technicians to collect urine specimens without receiving training or demonstrating proficiency in specimen collections, as long as these collectors received the instructions in former Section 2.2(3) in Appendix A to Part 26 and perform collections in accordance with those instructions. The final paragraph adds a requirement that limits the persons excused from the training and demonstration of proficiency requirements for specimen collections to medical professionals, technologists, or technicians who are not employed by the licensee's or other entity's FFD program and whose workplace is not at the licensee's or other entity's facility. This revision will increase the incremental cost per FFD program associated with the training costs for medical professionals, technologists, and technicians who serve as collectors, but who are no longer excused from training. The incremental cost resulting from additional training required under the new provision is discussed in connection with §§26.85(a) and (b).

Paragraph 26.85(d)

This paragraph of the final rule revises the former requirements in Section 2.7(o)(5) in Appendix A to Part 26, which required licensee testing facility and HHS-certified laboratory personnel to be 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 reported by the licensee's testing facility or the HHS-certified laboratory. This final paragraph extends this requirement to qualified collection site personnel. The analysis estimates no incremental cost or saving will result from this final rule provision because the requirement is consistent with existing licensee and collection site actions with respect to personnel appearing for administrative or disciplinary proceedings related to a specimen collection.

Paragraph 26.85(e)

This paragraph of the final rule adds a new requirement that specifies the records that must be retained for collection site personnel. The paragraph requires that collection site personnel files include each individual's resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluations and advancement; incident reports, if any; results of tests that establish employee competency for the position he or she holds; and appropriate data to support determinations of honesty and integrity conducted in accordance with this part. This final paragraph extends to collection site personnel the records retention requirements in former Sections 2.5(f) and 2.6(c) in Appendix A to Part 26 for laboratory personnel and licensees' testing facility personnel, respectively. The analysis estimates no incremental cost will result from this final rule provision because it is assumed that these files are already kept for collection site personnel.

26.87 Collection sites

Paragraph 26.87(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies former requirements in Section 2.4(a) in Appendix A to Part 26, which related to designated collection sites.

Paragraph 26.87(b)

This paragraph of the final rule adds a new requirement that each collection site must provide visual privacy while a donor and collector view the results of a breath alcohol test. The former requirements in Sections 2.4(g)(8) and 2.4(f) in Appendix A to Part 26 required only that a donor must be permitted to provide a urine specimen in the privacy of a stall or otherwise partitioned area. The requirement is estimated to result in no incremental cost or saving because collection sites that need to modify collection procedures to meet this new requirement can do so using readily available office supplies. For example, a piece of cardboard may be affixed over the EBT readout to prevent anyone other than the collector and donor from viewing test results.

Paragraph 26.87(c)

This paragraph of the final rule extends the requirement in former Section 2.7(m) in Appendix A to Part 26, which mandated that licensees must include in contracts for collection site services a provision that both NRC and licensees have the authority to conduct unannounced inspections and audits. The final paragraph extends the provisions in former Section 2.7(m) in Appendix A to other entities and their contracts for collection site services. The incremental costs associated with modifying other entity contracts with collection sites is discuss in connection with §26.27(a).

Paragraph 26.87(d)

This paragraph of the final rule clarifies requirements in former Section 2.4(c) in Appendix A to Part 26 regarding collection site security procedures. Final §26.87(d)(2) provides examples of methods that may be used to assure the security of a collection site such as locking doors, using alarms, or visually monitoring the collection site, and clarifies that designated collection sites must be secure at all times. Former Section 2.4(c) instructed that "security procedures shall provide for the designated collection site to be secure" while the former requirement in Section 2.4(c)(1) required that for specimen collections in a public rest rooms, the rest rooms be posted against access during the collection process. This paragraph of the final rule imposes no incremental cost and affords no saving because it clarifies former requirements by providing examples of methods to secure a collection site, but does not prescribe how the facility is to be secured.

Paragraph 26.87(e)

This section of the final rule discusses collection procedures that urine collectors must follow prior to and after a specimen collection to deter and detect instances where a donor attempts to adulterate, dilute, or substitute their urine specimen.

Subparagraph 26.87(e)(1)

This subparagraph amends the former requirement in Section 2.4(g)(1) in Appendix A to Part 26, which mandated the addition of toilet bluing agents to the water in the toilet tank in the enclosure where a urine specimen collection is conducted. By contrast, the final rule provides added flexibility for collection sites to use coloring agents other than blue (excluding yellow). This paragraph of the final rule imposes no incremental cost and affords no saving because many similarly priced coloring agents existing on the market today that can meet the provision.

Subparagraph 26.87(e)(2)

This subparagraph imposes no incremental cost and affords no saving because it restates a former requirement in Section 2.4(g)(1) in Appendix A to Part 26, which required that sources of water present in an enclosure used for a specimen collection must be secured or monitored to detect and prevent specimen dilution.

Subparagraph 26.87(e)(3)

This subparagraph establishes a new provision under which a urine collector, before each collection, must inspect and secure or remove from the privacy enclosure all chemicals and products that could be used by a donor to adulterate their urine specimen. This subparagraph imposes no incremental cost or saving because it is consistent with existing collection site security procedures.

Paragraph 26.87(f)

This paragraph restates and clarifies former requirements in Section 2.4(c)(1)–(2) in Appendix A to Part 26 regarding procedures for collecting urine specimens at locations other than designated collection sites (e.g., public restroom, on-site restroom, hospital examining room). In addition, as described in the subparagraph discussions below, several of the revised subparagraphs include new provisions. However, no incremental costs or savings will result from the provisions in this final paragraph because urine specimen collections at non-designated collection sites are rare events (i.e., they apply to only some post-event tests and some for-cause tests).

Subparagraph 26.87(f)(1)

This subparagraph of the final rule adds a new provision to permit an individual to be assigned to prevent unauthorized access to a public restroom being used during a urine collection. The final

rule also includes a requirement from former Section 2.4(c)(1) in Appendix A to Part 26 that a sign may be posted to prevent unauthorized access. No incremental cost or saving will result from this revised subparagraph because the new provision is a relaxation, permitting an alternative method to prevent unauthorized access to a public restroom.

Subparagraph 26.87(f)(2)

This subparagraph of the final rule revises the requirement in Section 2.4(g)(10) in Appendix A to Part 26 of the former rule that the collector add a toilet bluing agent in the bowl and any accessible toilet tank for a specimen collection conducted at a location other than a dedicated collection site. The revised subparagraph provides added flexibility by permitting collection sites to use coloring agents in addition to blue (excluding yellow) as described in final §26.87(e)(1) and clarifies that the urine collector must add a water coloring agent to any accessible source of standing water within the enclosure where a donor is to provide a specimen. No incremental cost or saving is estimated to result from these provisions which provide flexibility in the use additional types of coloring agents, and clarify existing collection practices to add coloring agents to accessible water sources within the privacy enclosure.

Subparagraph 26.87(f)(3)

This subparagraph of the final rule amends a former requirement in Section 2.4(g)(10) of Appendix A to Part 26 regarding the use of a same gender urine collector to accompany a donor into the area used for a specimen collection, if a multi-stalled bathroom is used. If a collector of the same gender is unavailable, the revised subparagraph provides additional flexibility by adding a provision that permits another person of the same gender who has been instructed in the requirements of Subpart E to assist in the collection. This revised subparagraph also adds a new requirement that the name of the same gender person must be documented on the custody-and-control form in situations where a same-gender collector is not available. No incremental cost or saving will result from this final subparagraph because the new provisions provide an alternative method to existing collection practices at non-dedicated collection sites.

Subparagraph 26.87(f)(4)

This subparagraph of the final rule imposes an additional inspection requirement to former Section 2.4(g) of Appendix to Part 26. The new requirement pertains to specimen collections at non-designated collection sites. Upon receiving a urine specimen from a donor, the collector must inspect the privacy enclosure where the specimen was provided to ensure that there is no evidence of a donor subversion attempt. This subpargraph also adds a requirement that the collector and not the donor flush the toilet at the completion of a specimen donation. A requirement in former Section 2.4(g)(10) permitted the donor to flush the toilet under certain circumstances. No incremental cost or saving is estimated to result from this revised subparagraph due to the rarity of collections at non-dedicated collection sites.

Subparagraph 26.87(f)(5)

This subparagraph of the final rule revises former requirements in Section 2.4(c)(2) in Appendix A to Part 26 which pertain to urine specimen collections conducted at non-dedicated collection facilities and which directed urine collectors to maintain physical control of donor urine specimens. The final provision relaxes the former requirement by permitting the collector to designate another individual to maintain custody of the specimen until it is shipped (i.e., in the case of an opposite gender collector who instructs a same gender individual to assist in a urine collection). This revised subparagraph also requires that, in the case where the collector uses an individual to assist in the collection process, the individual's name must be documented on the custody-and-control form. No incremental cost or saving is estimated to result from this final subparagraph due to the rarity of collections at non-dedicated collection sites.

26.89 Preparing to collect specimens for testing

Paragraph 26.89(a)

This paragraph of the final rule revises former requirements in Section 2.4(g)(3) in Appendix A to Part 26 regarding the actions to take if a donor does not arrive at the collection site for drug and/or alcohol testing. The former requirement instructed the collection site staff to contact "the appropriate authority to obtain guidance on the action to be taken." The final paragraph adds a new requirement that mandates that FFD program management investigate and determine whether the absence or tardiness of a donor is an attempt to subvert the testing process and to take appropriate action when necessary. This revision is believed to be consistent with long-term licensee practice and, therefore, will not result in incremental costs or savings.

Paragraph 26.89(b)

Subparagraphs 26.89(b)(1)–(2)

The subparagraphs revise former requirements in Section 2.4(g)(2) in Appendix A to Part 26, which describe the process for identifying a donor before collecting a specimen. Subparagraph 26.89(b)(1) clarifies former requirements pertaining to acceptable donor identification. Subparagraph 26.89(b)(2) now requires (rather than prohibits) a collection to proceed in cases where the donor does not produce acceptable identification, except for pre-access testing. The collector will now proceed with the specimen collection even without positively identifying the donor and will inform FFD program management that the employee could not be positively identified. FFD program management must then contact the individual's supervisor to verify in person the individual's identity, or if unavailable, take other steps to establish the individual's identity, and investigate the circumstances to determine whether the employee's behavior was an attempt to subvert the testing process. As a result, FFD programs may realize savings related to reduced worker productivity losses because workers will no longer have to leave the collection site, obtain appropriate identification, and return to the collection site for a test. Management

time is not expected to change based on whether the manager's investigation occurs prior to or subsequent to the collection, in accordance with the former and final rules, respectively.

Subparagraph 26.89(b)(2) also adds a provision prohibiting a specimen collection in these cases if the test is a pre-access test. The analysis estimates no incremental cost or saving will result from this provision due to the rarity of these situations.

The *annual savings per FFD program* resulting from §26.89(b)(2) are estimated as follows:

$$NUM_{selected\ individuals} \times PER_{no\text{-}ID} \times (HOURS_{worker} \times WAGE_{worker}) \times NUM_{reactors}$$

Parameter	**Description**
$NUM_{selected\ individuals}$	Number of individuals selected for drug and alcohol testing per reactor per year (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12)
$PER_{no\text{-}ID}$	Percentage of individuals without identification (as discussed in the assumptions below)
$HOURS_{worker}$	Time a donor without identification would spend to leave the collection site, obtain appropriate identification, and return to the collection site for drug and alcohol testing (as discussed in the assumptions below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of individuals selected for drug and alcohol testing per reactor per year is equivalent to the number of drug tests conducted per reactor per year (a drug and alcohol test is conducted each time an individual is tested). This assumes that each individual selected for testing is actually tested.

- Percentage of individuals without identification: 1 percent.
  The analysis assumes only 1 percent because employees subject to FFD program requirements must have identification with them at all times while at a licensed facility and, therefore, cases where an employee does not have adequate identification are rare.

- Time a donor without identification would spend to leave the collection site, obtain appropriate identification, and return to the collection site for drug and alcohol testing: 45 minutes.

- FFD management will incur no incremental costs or savings related to the final rule revisions. The analysis assumes that, under the former rule, the collection site notified FFD management after an employee arrived for a specimen

collection without adequate identification, and FFD management investigated the situation with the employee. The final rule requires the collection site to contact FFD management after completing a test, but the activities and time required of the FFD management would be similar.

Subparagraph 26.89(b)(3)

This subparagraph restates the former requirements in Sections 2.4(g)(4) and (g)(23)(ii) in Appendix A to Part 26 with the exception of the requirement for the collector to direct the donor to list on the chain-of-custody form the prescription medications and over-the-counter (OTC) preparations taken within 30 days prior to their urine specimen collection. This revised subparagraph now prohibits the donor from listing prescription medications and OTC preparations recently used. This revised subparagraph also adds a new requirement for the collector to explain the testing procedure to each donor. Each FFD program will recognize incremental savings per urine collection resulting from the reduced time of the collection process due to the elimination of the donor listing medications and OTC preparations on the custody-and-control form. Theses savings are offset to a small extent by the increase in time related to the collector describing the testing process to each donor. Overall, a reduction in lost worker productivity and reduced collector wages will be realized by FFD programs.[3]

The *annual savings per FFD program* are estimated as follows:

$$NUM_{collections} \times [(HOURS_{saved} - HOURS_{added}) \times (WAGE_{worker} + WAGE_{collector})] \times NUM_{reactors}$$

Parameter	Description
$NUM_{collections}$	Number of urine collections per reactor per year (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12)
$HOURS_{saved}$	Time saved per average collection because the donor does not list medications on the chain-of-custody form (as discussed in the assumptions below)
$HOURS_{added}$	Time added per average collection for the collector to explain the testing process to the donor (as discussed in the assumption below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$WAGE_{collector}$	Collection site personnel wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

[3] In order to capture total costs and savings, the analysis assumes that savings incurred by any offsite collection sites are passed back to licensees (i.e., through lower costs per collection). This assumption depends on the degree to which the offsite collection site industry is price competitive. To the extent that it is not price competitive, savings will accrue as estimated, but will benefit the offsite collection site rather than licensees (i.e., offsite collection sites will recognize savings in labor costs because of the reduced collection time, but will not reduce the cost per collection charged to the licensee).

Assumptions:

- Number of urine collections per reactor per year is equal to the number of drug tests per reactor per year.

- Time saved per average collection because the donor does not list medications on the CCF: 2 minutes.

- Time added per average collection for the collector to explain the testing process to the donor: 45 seconds.

Paragraph 26.89(c)

This paragraph of the final rule adds a new requirement directing the collector to 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 or diluted 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) will be considered as a refusal to test. No incremental cost or saving is estimated to result from this final paragraph because providing the directions to the donor will only take seconds per collection, and the number of instances in which a donor will leave the collection site before testing or will refuse to cooperate with the collection process will be very low due to the severity of the consequences.

Paragraph 26.89(d)

This paragraph restates former requirements in Section 2.4(e) in Appendix A to Part 26 which require that a collector only conduct one urine specimen collection at a time and defines when a collection process is complete, that is, when the donor has left the collection site.

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

Paragraph 26.91(a)

This paragraph of the final rule expands the acceptable breath alcohol testing devices beyond the former requirements in §26.24(g). The final paragraph permits FFD programs to conduct initial tests for alcohol using NHTSA-certified alcohol screening devices (ASDs), including devices that test specimens of oral fluids or breath, that are on the NHTSA Conforming Products List (CPL). This provision affords licensees added flexibility in conducting initial tests for alcohol. However, because an EBT compliant with §26.91(c) is required for confirmatory tests, the ability to use ASDs does not eliminate the need for an evidential breath testing device (EBT). The analysis assumes that licensees, in order to simplify their testing and training procedures,

will conduct alcohol testing using only EBTs under normal circumstances, and that licensees will use ASDs only when a screening test must be conducted at a non-standard location (e.g., in the case of some post-event tests or possibly some for-cause tests). Because the need to conduct tests at non-standard locations is infrequent, the analysis assumes that any costs associated with the use of ASDs are insignificant to the analysis.

Paragraph 26.91(b)

This paragraph of the final rule adds a new requirement that all EBTs used to conduct confirmatory alcohol testing must meet the specific functionalities (e.g., provide a printed result for each breath test, test an air blank) as stated in §26.91(c). This final paragraph also revises former requirements in §26.24(g) and Section 2.4(g)(18) in Appendix A to Part 26 which mandated the use of two different EBTs for initial versus confirmatory alcohol testing. This final paragraph permits licensees to use a single EBT for both initial and confirmatory breath alcohol testing if the EBT meets the specifications in §26.91(c). This final paragraph will result in an incremental one time cost for some FFD programs to purchase EBTs (along with necessary calibration equipment) meeting the specifications in §26.91(c) for confirmatory breath alcohol testing, along with the one time cost to train breath alcohol collectors in the use of the new EBTs. Incremental annual costs incurred by FFD programs that purchase EBTs to comply with §26.91(c) will consist of the cost to purchase calibration equipment to conduct quality control checks on the new EBTs.

One time costs per FFD program are estimated as the *sum* of the following*:*

- Purchase EBTs meeting the specifications in §26.91(c):

  $COST_{EBT} \times NUM_{new\ EBTs} \times PER_{purchase\ EBT} \times NUM_{facilities}$

- Purchase a regulator used in calibrating new EBT equipment[4]:

  $COST_{regulator} \times PER_{purchase\ EBT} \times NUM_{facilities}$

- Breath alcohol collector training on use of new EBTs:

  $[COST_{training\ course} + (NUM_{collectors} \times (HOURS_{collector\ training} \times WAGE_{collector}))] \times NUM_{facilities} \times PER_{purchase\ EBT}$

Annual costs per FFD program are estimated as follows:

- Purchase calibration device for new EBTs:

[4] A regulator is a piece of equipment used to attach a calibration canister to an EBT in order to conduct quality control checks. One regulator can calibrate multiple EBTs.

$COST_{calibration\ device}\ x\ PER_{purchase\ EBT}\ x\ NUM_{facilities}$

Parameter	Description
$COST_{EBT}$	Cost of an EBT compliant with §26.91(c) (as discussed in Appendix 2, Exhibit A2-8)
$NUM_{new\ EBTs}$	Number of new EBTs compliant with §26.91(c) purchased per facility (as discussed below and in Appendix 2, Exhibit A2-8)
$PER_{purchase\ EBT}$	Percentage of collection sites that will purchase an EBT meeting the specifications in §26.91(c) (as discussed in the assumptions below)
$COST_{regulator}$	Cost of purchasing a regulator which attaches the calibration canister to the EBT (as discussed in the assumptions below and in Appendix 2, Exhibit A2-13)
$COST_{training\ course}$	Cost of EBT manufacturer to conduct an onsite training course per collection site (as discussed in the assumptions below)
$NUM_{collectors}$	Number of breath alcohol collectors per collection site (as discussed in Appendix 2, Exhibit A2-8)
$HOURS_{collector\ training}$	Length of training course (as discussed in the assumptions below)
$WAGE_{collector}$	Collection site personnel wage rate (as discussed in Appendix 2, Exhibit A2-11)
$COST_{calibration\ canister}$	Cost of purchasing a calibration canister for quality control checks on new EBTs compliant with §26.91(c) (as discussed in the assumptions below and in Appendix 2, Exhibit A2-13)
$NUM_{facilities}$	Number of facilities per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Each facility uses one collection site.
- Percentage of collection sites that will purchase an EBT meeting the specifications in §26.91(c): 50 percent.[5]
- Each collection site that purchases an EBT meeting the specifications in this §26.91(c) will purchase one EBT.

[5] The 50 percent estimate is based on an NEI industry survey (May 2004) in which 21 FFD programs that represent 32 facilities reported on the number of EBTs that would be purchased to meet the requirements in 26.91(c). Of the 32 facilities, 24 facilities had EBTs compliant with §26.91(c) and would not purchase any new equipment. The remaining 8 facilities in the survey reported that 16 new EBTs would be purchased. As an industry, 16 new EBTs would be purchased for the 32 facilities surveyed, or an average of 0.5 EBTs per facility. Therefore, 50 percent of collection sites will purchase one EBT.

- The EBTs purchased by any given collection site will be of the same manufacturer make and model and therefore, only one breath collector training class and only one regulator will be needed.

- Each calibration canister provides enough product to calibrate one EBT for two year of use. The annual cost of the calibration canister is the price of the canister divided by 2 years.

Paragraph 26.91(c)

This paragraph of the final rule establishes the required functionalities that an EBT must have to be used to conduct confirmatory alcohol testing. The incremental costs associated with some licensees purchasing EBTs meeting the functionalities in this final paragraph are described in §26.91(b). This final paragraph also revises the former requirements in §26.24(g) and Section 2.4(g)(18) in Appendix A to Part 26 which required the use of different EBTs for initial and confirmatory alcohol tests. This provision provides flexibility for licensees using an EBT meeting the criteria specified in this final paragraph by permitting the use of the same EBT for both initial and confirmatory tests. Incremental savings for FFD programs with collection sites that use EBTs meeting the specifications in this final paragraph will consist of a reduction in the time between conducting initial and confirmatory breath alcohol tests.

Annual savings per FFD program are estimated as follows:

$$NUM_{confirmatory\ alcohol\ tests} \times PER_{new\ EBT} \times [HOURS_{saved} \times (WAGE_{worker} + WAGE_{collector})] \times NUM_{reactors}$$

Parameter	Description
$NUM_{confirmatory\ alcohol\ tests}$	Number of confirmatory alcohol tests per reactor per year (as discussed in Appendix 2, Exhibit A2-12)
$PER_{new\ EBT}$	Percentage of collection sites that will use an EBT meeting the specifications in paragraph 26.91(c) for both initial and confirmatory alcohol tests (as discussed in the assumptions below)
$HOURS_{saved}$	Time per test to set-up a second EBT (locate the EBT, turn on the equipment) to conduct confirmatory testing as required under the former requirements in §26.24(g) and §2.4(g)(18) (as discussed in the assumptions below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$WAGE_{collector}$	Collection site personnel wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of confirmatory alcohol tests conducted per reactor per year is equivalent to the number of confirmatory positive alcohol test results per reactor per year.

- Time per test to set-up a second EBT to conduct confirmatory testing: 2 minutes. If a second EBT is needed, the collector must prepare the second EBT to be used for the confirmatory test.

- Percentage of collection sites that will use an EBT meeting the specifications in paragraph 26.91(c) for both initial and confirmatory alcohol test: 50 percent.

Paragraph 26.91(d)

This paragraph establishes the quality assurance and quality control requirements for ASDs. The final paragraph requires that licensees using ASDs must implement the quality assurance plan (QAP) submitted by the manufacturer to NHTSA. No incremental cost or saving is estimated to result from this provision because the use of ASDs provides an alternative to former requirements for conducting initial alcohol testing.

Paragraph 26.91(e)

This paragraph establishes a new requirement that licensees and other entities implement the quality assurance and quality control requirements for EBTs as described in the most recent quality assurance plan (QAP) submitted by each EBT manufacturer to NHTSA. Adherence to the QAP for an EBT is consistent with existing collection site practices given that the specifications in the QAP are necessary for normal equipment operation and for accurate and defensible results. This paragraph adds an optional provision for collection sites to conduct an external calibration check immediately after a positive test result. This provision is optional and will not result in any incremental cost or saving given that the number of positive tests is infrequent.

26.93 Preparing for alcohol testing

Paragraph 26.93(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it clarifies former requirements in Section 2.4(g)(18) in Appendix A to Part 26 regarding testing procedures for conducting initial breath alcohol tests, including a mandatory 15 minute waiting period if the donor has consumed any potential sources of mouth alcohol (e.g., breath fresheners) or has ingested or expelled any other substances (e.g., via eating, smoking, regurgitation of stomach contents from vomiting or burping). This paragraph of the final rule also adds several requirements as described in the subparagraph discussions below.

Subparagraph 26.93(a)(1)

This subparagraph of the final rule clarifies a former requirement in Section 2.4(g)(18) in Appendix A to Part 26. This final subparagraph also adds a new requirement for a collector to instruct the donors to avoid eating, drinking, belching, or putting anything in their mouth during the collection process. No incremental cost or saving will result from this final subparagraph because this activity will only take seconds to complete.

Subparagraphs 26.93 (a)(2)–(3)

These subparagraphs of the final rule clarify former breath collection requirements in Section 2.4(g)(18) in Appendix A to Part 26 which directed the collector to proceed with a collection if a donor has not consumed any substance prior to the test. Subparagraph 26.93(a)(3) adds a requirement for the breath collector to inform the donor that a mandatory 15-minute waiting period is necessary to prevent an accumulation of mouth alcohol from leading to an artificially high breath alcohol reading if the donor has consumed a substance (e.g., ate, smoked) or belched prior to a test. No significant incremental cost or saving will result from §26.93(a)(2) as it restates former requirements, nor from §26.93(a)(3), which require an activity that will only take seconds to complete.

Subparagraph 26.93(a)(4)

This subparagraph of the final rule adds a new requirement to the former breath collection procedures in Section 2.4(g)(18) in Appendix A to Part 26. This final subparagraph requires that breath alcohol collectors explain to each donor, when needed, that during the mandatory 15-minute waiting period it is to the donor's benefit to avoid the activities described by the collector in §26.93(a)(1). No significant incremental cost or saving will result from this final subparagraph because this activity is conducted during the mandatory waiting period.

Subparagraph 26.93(a)(5)

This subparagraph of the final rule adds a new requirement to the former breath collection procedures in Section 2.4(g)(18) in Appendix A to Part 26. The new provision adds a requirement for breath alcohol collectors to inform each donor who indicated that they have demonstrated behaviors described in §26.93(a)(1) within 15-minutes before an initial alcohol test, that an initial test (and confirmatory test, when necessary) will be performed at the end of the 15-minute waiting period, even if the donor did not follow the instructions given by the collector during the waiting period. No significant incremental cost or saving will result from this final subparagraph because this activity is conducted during the mandatory waiting period.

Subparagraph 26.93(a)(6)

This subparagraph of the final rule adds a new requirement to the former breath collection procedures in Section 2.4(g)(18) in Appendix A to Part 26. The new provision requires that breath collectors document that directions regarding the breath alcohol collection process were communicated to each donor. This activity will result in no significant incremental cost or saving because the activity will take only seconds to complete (i.e., the collector notes on the testing form the phrase "instructions given to donor").

Paragraph 26.93(b)

This paragraph adds a new requirement to the former drug and alcohol testing procedures in §26.24(a)(3). The new provision directs licensees to minimize delays in administering for-cause drug and alcohol tests. This final paragraph also adds a requirement that specifies the sequence of specimen testing in for-cause testing situations (i.e., requires alcohol testing be conducted before drug testing). The former rule did not specify the order that drug and alcohol testing was to be conducted in for-cause testing situations. No incremental cost or saving will result from the final paragraph because for-cause drug and/or alcohol testing is already required by the former requirement in §26.24(a)(3). The final paragraph only specifies that delays in testing should be minimized and specifies the sequence for conducting for-cause alcohol and drug testing.

26.95 Conducting an initial test for alcohol using a breath specimen

This section, including paragraphs (a)–(c), revises former requirements in Section 2.4(g)(18) in Appendix A to Part 26, which mandated the collection of two breath specimens for each screening alcohol test using an EBT. The tests must be conducted no less than 2 minutes and no more than 10 minutes apart. Paragraph 26.95(c) reduces the number of breath specimens collected from two to one unless problems arise. FFD programs will realize a reduction in alcohol testing costs due to a decrease in the duration of the testing process, reducing equipment costs (using fewer exhalent tubes), decreasing worker productivity losses, and reducing collector labor costs.[6]

The *annual savings per FFD program* resulting from §26.95(c) are estimated as follows:

$$NUM_{alcohol\ tests} \times [HOURS_{saved} \times (WAGE_{worker} + WAGE_{collector}) + COST_{exhalent\ tube}] \times NUM_{reactors}$$

[6] In order to capture the total costs and savings, the analysis assumes that savings incurred by offsite collection sites are passed back to licensees (i.e., lower costs per collection). This assumption depends on the degree to which the offsite collection site industry is price-competitive. To the extent that it is not price competitive, savings will accrue as estimated, but will benefit the offsite collection site rather than licensees (i.e., offsite collection sites will realize savings in labor costs because of the reduced collection time, but will not reduce the cost per collection charged to licensees).

Parameter	Description
$NUM_{alcohol\ tests}$	Number of alcohol tests per reactor per year (as discussed in Appendix 2, Exhibit A2-12)
$HOURS_{saved}$	Reduction in collection time from one fewer breath collection per initial screening test (as discussed in the assumptions below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$WAGE_{collector}$	Collection site personnel wage rate (as discussed in Appendix 2, Exhibit A2-11)
$COST_{exhalent\ tube}$	Cost per exhalent tube (as discussed in Appendix 2, Exhibit A2-13)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Reduction in collection time resulting from one fewer breath collection per initial screening test: 2 minutes/60 minutes = 0.033 hours.

- Each breath specimen collection requires a new exhalent tube (i.e., for a screening test under the former regulations, two exhalent tubes would be used).

26.97 Conducting an initial test for alcohol using a specimen of oral fluids

This section, including paragraphs (a)–(e), establishes collection procedures for conducting initial alcohol tests using ASDs. The former requirements in §26.24(g) only permit the collection of breath specimens (for initial and confirmatory alcohol tests) and blood specimens (for confirmatory alcohol testing). The use of ASDs provides licensees with flexibility in conducting alcohol testing by permitting the testing of an alternative specimen type (i.e., saliva) to breath for initial alcohol testing as discussed in §26.91(a).

26.99 Determining the need for a confirmatory test for alcohol

Paragraph 26.99(a)

This paragraph of the final rule establishes that a breath alcohol concentration (BAC) of less than 0.02 percent constitutes a negative alcohol test result. This revision modifies former requirements in §26.24(g) and Section 2.7(e)(1) in Appendix A to Part 26 which specified that a breath alcohol testing result of less than 0.04 is a negative test result. Incremental costs associated with the final paragraph are described in the discussion of §26.99(b).

Paragraph 26.99(b)

This paragraph of the final rule revises former requirements in §26.24(g) and Section 2.7(e)(1) in Appendix A to Part 26 by reducing the BAC of an initial alcohol test that requires a confirmatory

test from 0.04 percent to 0.02 percent. FFD programs will incur incremental costs because of an increase in the number of initial alcohol tests requiring confirmatory testing and the costs of FFD administrative actions resulting from additional confirmed positive alcohol test results. This final paragraph also adds a new provision that directs the collector to document the time of the initial breath alcohol test result (if 0.02 percent or greater) and inform the donor that a confirmatory test is required. The requirements to document the time of the test result and notify the employee that a confirmatory test must be performed are consistent with existing collection practices and will result in no incremental cost or saving.

The *annual costs per FFD program* are estimated as follows:

$$(NUM_{IPAT} \times PERI_{IPAT}) \times [(HOURS_{CAT} \times (WAGE_{worker} + WAGE_{collector}) + COST_{exhalent\ tube} + (HOURS_{FFD\ manager} \times WAGE_{FFD\ manager})] \times NUM_{reactors}$$

Parameter	**Description**
NUM_{IPAT}	Number of initial positive breath alcohol test (IPAT) results per reactor per year under the former requirements (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12)
$PERI_{IPAT}$	Percentage increase in the number of initial positive alcohol test (IPAT) results under the lower screening level BAC that remain positive after confirmatory testing (as discussed in the assumptions below)
$HOURS_{CAT}$	Time to conduct a confirmatory alcohol test under the final rule (as discussed in the assumptions below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$WAGE_{collector}$	Collection site personnel wage rate (as discussed in Appendix 2, Exhibit A2-11)
$COST_{exhalent\ tube}$	Cost of an exhalent tube for a confirmatory alcohol test (as discussed in Appendix 2, Exhibit A2-13)
$HOURS_{FFD\ manager}$	Hours of FFD manager time associated with personnel activities and administrative actions resulting from a confirmed positive alcohol test result (as discussed in the assumptions below)
$WAGE_{FFD\ manager}$	FFD management wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of initial positive breath alcohol test (IPAT) results per reactor per year under the former requirements in Part 26 is assumed to be equal to the number of confirmed positive alcohol tests under the former rule per reactor per year.

- Percentage increase in the number of initial positive breath alcohol test results under the lower screening level BAC that will remain positive after confirmatory testing: 20 percent.

- Time to conduct a confirmatory alcohol test under the final rule: 3 minutes.

- Hours of FFD manager time associated with personnel activities and administrative actions resulting from a confirmed positive alcohol test result (i.e., worker notification interview, paperwork, and administrative proceedings: 2.5 hours.

- All initial positive alcohol test results are confirmed positive.

26.101 Conducting a confirmatory test for alcohol

Paragraph 26.101(a)

This paragraph of the final rule revises former requirements in Section 2.4(g)(18) in Appendix A to Part 26, which relate to confirmatory alcohol testing. The final rule requires that a confirmatory alcohol test be conducted as soon as possible following an initial alcohol test result of 0.02 BAC or greater and no later than 30-minutes after the initial test result. This paragraph of the final rule is estimated to impose no incremental cost and afford no saving because (even though the former rule did not specify a 30-minute time frame for testing), licensees will still incur testing costs, and the instances when a confirmatory test could not be conducted as soon as possible after an initial breath test are very low (delays in testing would most likely only result from equipment malfunctions which are rare).

Paragraph 26.101(b)

This paragraph establishes collection procedures for conducting a confirmatory alcohol test using an EBT as required in final rule provisions in §§26.91(b) and (c). This provision will result in one time training costs of breath alcohol collectors which is discussed in this analysis in connection with §§26.85(a) and (b).

Paragraph 26.101(c)

This paragraph revises former requirements in Section 2.4(g)(18) in Appendix A to Part 26, which required when necessary, two additional breath specimens be collected from an individual for confirmatory testing. This final paragraph reduces the number of breath specimens collected from two to one unless problems encountered while administering the confirmatory breath test require an additional collection. This final paragraph also prohibits an activity permitted under the former requirements in Section 2.4(g)(18) in Appendix A to Part 26. Specifically, the final paragraph prohibits licensees from calculating an average or otherwise combine results from two or more breath specimens to determine the confirmatory breath alcohol test result. FFD

programs will realize minor savings in confirmatory alcohol testing costs resulting from decreasing the duration of the testing process, reducing equipment costs (using fewer exhalent tubes), decreasing worker productivity losses, and reducing collector labor costs.[7] However, the analysis does not calculate any savings because of the infrequency of confirmatory alcohol testing events (less than 2 per reactor per year),[8] and the minor savings (2 minutes and the cost of one exhalent tube per confirmatory - see assumptions in §26.95).

Paragraph 26.101(d)

This paragraph of the final rule establishes that 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. The former requirements in §26.24(g) required that initial and confirmatory alcohol testing be conducted using different EBTs. Incremental savings associated with this provision are accounted for in the discussion on §26.91(c).

26.103 Determining a confirmed positive test result for alcohol

This section, including paragraphs (a)–(b), revises former requirements in §26.24(g) and Section 2.7(f)(2) in Appendix A to Part 26 pertaining to the screening alcohol test result that constitutes a positive test result for a confirmatory alcohol test. The final rule establishes BACs that are more stringent than the former rule's BAC level of 0.04, depending on the length of time an employee has been in work status. Thus, a confirmatory test may yield a positive result with a BAC that is equal to or greater than 0.02 BAC. Each FFD program will incur incremental costs for FFD manager labor to determine the work status for an individual with a confirmatory BAC test result that is equal to or greater than 0.02 and less than 0.04.[9]

The *annual costs per FFD program* are estimated as follows:

$$(NUM_{CPAT} \times PERI_{CPAT}) \times (HOURS_{FFD\ manager} \times WAGE_{FFD\ manager}) \times NUM_{reactors}$$

[7] In order to capture the total costs and savings, the analysis assumes that all savings incurred by offsite collection sites are passed back to licensees (i.e., through lower costs per collection). This assumption depends on the degree to which the offsite collection site industry is price-competitive. To the extent that it is not price competitive, savings will accrue as estimated, but will benefit the offsite collection site rather than licensees (i.e., offsite collection sites will realize savings in labor costs because of the reduced collection time, but will not reduce the cost per collection charged to licensees).

[8] The NRC Information Notice 2003-04 "Summary of Fitness-for-Duty Program Performance Reports for Calendar Year 2000" reported 211 confirmed positive alcohol test results for all licensees.

[9] The incremental costs of other activities resulting from additional confirmed positive alcohol test results attributable to the BAC thresholds are estimated and discussed in connection with paragraph 26.99(b).

Parameter	Description
NUM_{CPAT}	Number of confirmed positive breath alcohol test (CPAT) results per reactor per year under former requirements (as discussed in Appendix 2, Exhibit A2-12)
$PERI_{CPAT}$	Percentage increase in the number of confirmed positive alcohol test (CPAT) results under the BACs (as discussed in the assumptions below)
$HOURS_{FFD\ manager}$	Time (per test) for the FFD manager to determine the length of time the employee has been in work status for BACs equal to or greater than 0.02 and less than 0.04 (as discussed in the assumptions below)
$WAGE_{FFD\ manager}$	FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Percentage increase in the number of confirmed positive breath alcohol test (CPAT) results under the BACs: 20 percent.

- Time (per test) for the FFD manager to determine the length of time the employee has been in work status for BACs equal to or greater than 0.02 and less than 0.04: 15 minutes.

26.105 Preparing for urine collection

This section restates former requirements in Section 2.4(g)(5)–(7) in Appendix A to Part 26, which required the collector to instruct donors to remove any unnecessary outer garments, wash their hands, and remain in the presence of the collector until proceeding to the privacy enclosure to provide a urine specimen. This section also adds a new requirement in §26.105(b) for the collector to evaluate the contents of each donor's pockets of each donor before a specimen donation can commence.

Paragraph 26.105(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.4(g)(5) in Appendix A to Part 26.

Paragraph 26.105(b)

This paragraph of the final rule adds a new requirement for donors to empty their pockets and display the items to the collector. If the donor refuses to show the collector the contents of their pockets, this action is considered a refusal to test. If the collector identifies an item in a donor's pockets that appears to be a potential adulterant or substitute specimen, the collector must contact the FFD program manager or the MRO for direction as to whether a directly observed collection is warranted. If an item is identified in a donor's pocket which the collector

determines to be inadvertently brought to the collection site, the collector is to secure the item and continue with a normal collection process. The number of instances in which a donor may attempt to conceal a potential adulterant or substitute specimen in their pocket is deemed low (due to the donor's knowledge of the inspection process) as is the likelihood of a donor refusing to display the contents of his/her pockets (given the consequences of their action). Incremental costs will result from additional time per collection to empty and inspect the contents of a donor's pockets. Each FFD program will incur a per specimen collection cost of additional lost worker productivity and additional collector labor.

The *annual costs per FFD program* are estimated as follows:

$$NUM_{collections} \times HOURS_{inspection} \times (WAGE_{worker} + WAGE_{collector}) \times NUM_{reactors}$$

Parameter	Description
$NUM_{collections}$	Number of urine collections per reactor per year (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12)
$HOURS_{inspection}$	Time per collection to empty and inspect contents of a donor's pockets (as discussed in the assumptions below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$WAGE_{collector}$	Collection site personnel wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of urine collections per reactor per year is assumed to be equal to the number of drug tests per reactor per year.

- Time per specimen collection for a donor to empty and the collector to evaluate the contents of a donor's pockets: 2 minutes.

Paragraphs 26.105(c) - (d)

These paragraphs of the final rule impose no incremental cost and afford no saving because they restate former requirements in Section 2.4(g)(6) - (7) in Appendix A to Part 26.

Paragraph 26.105(e)

This paragraph of the final rule establishes collection site procedures for the collector/donor to select and unwrap collection kit materials. This final paragraph imposes no incremental cost and affords no saving because this collection procedure will not increase the time of a specimen collection. The same activity of selecting and unwrapping the collection materials will still occur, but the donor rather than the collector may conduct the activity.

26.107 Collecting a urine specimen

This section restates and clarifies former requirements in Section 2.4 in Appendix A to Part 26, which addressed collector responsibilities during the urine collection process. This section also adds several new requirements, as indicated in the paragraph discussions below.

Paragraph 26.107(a)

This paragraph of the final rule restates a former requirement in Section 2.4(g)(8) in Appendix A to Part 26. This final paragraph also adds a provision which provides the urine collector with discretion as to setting "a reasonable time limit for voiding" by the donor. No significant incremental cost or saving will result from the revision because on average, it is uncommon for donors to take long periods of time to provide specimens.

Paragraph 26.107(b)

This paragraph of the final rule clarifies the former requirements in Sections 2.4(g)(9) and (g)(25) in Appendix A to Part 26 which required the collector to consult with a "higher level supervisor in the drug testing program to review and concur that a collection under direct observation should proceed." This final paragraph clarifies that the collector must contact "FFD program management" to receive direction as to whether an observed collection is warranted in cases where a donor attempts to subvert the collection process (e.g., bringing in a substituted urine specimen or adulterant). No incremental cost or saving will result from this provision as it only clarifies who the collector is to contact regarding a direct observation. In addition, this final paragraph directs the collector to document on the custody and control form a description of the donor's actions that the collector believed demonstrated an attempt by the donor to subvert the testing process. This collector requirement to document the reason for believing a donor has attempted to subvert the testing process offers an employee protection from unwarranted observed collections as the collector must justify the reason that an observed collection is needed. Because the collector's action of documenting a description of the donor's actions on the custody and control form will be very rare, no significant cost or saving will be incurred.

Paragraph 26.107(c)

This paragraph of the final rule restates a former requirement in Section 2.4(g)(12) in Appendix A to Part 26. This final paragraph also adds a new requirement for the collector to inspect the toilet bowl and privacy area used by a donor for a specimen collection for evidence of a subversion attempt. No significant incremental cost or saving will result from the provision because this action is both consistent with current collection site practices, and because inspecting a privacy enclosure takes only a matter of seconds per collection.

26.109 Urine specimen quantity

Paragraph 26.109(a)

This paragraph of the final rule revises the former requirement in Section 2.4(g)(11) in Appendix A to Part 26, under which the minimum quantity of urine to be collected for a drug test was 60 mL. The final rule introduces the term, "predetermined quantity" of urine to describe that a donor must provide a specific quantity of urine based on the licensee's or other entity's testing program. The new provision reduces the minimum quantity of urine to be collected from a donor from 60 mL to 30 mL. That is, at a minimum, the donor must provide 30 mL of urine to permit an HHS-certified laboratory to conduct initial (and confirmatory, when necessary) validity and drug tests as required by 10 CFR Part 26. An additional 15 mL of urine is permitted to be collected for split specimen collections. The final rule also permits licensee and other entity testing programs to collect additional quantities of urine as part of the predetermined quantity based on their own additional specific testing and collection procedures. No incremental change is estimated for the added flexibility in permitting licensees to conduct additional testing beyond the rule requirements in 10 CFR Part 26, as that is allowed as an accommodation to licensees. The reduction in the minimum quantity of urine required (from 60 mL to 30 mL) will reduce the number of instances in which a donor cannot provide the minimum specimen quantity on a first attempt. Therefore, FFD programs will recognize incremental savings attributable to a reduction in lost worker productivity and reduced collector labor resulting from fewer shy bladder instances.[10]

The *annual savings per FFD program* are estimated as follows:

$$(NUM_{collections} \times PER_{low\ quantity} \times PERD_{low\ quantity}) \times (HOURS_{saved} \times (WAGE_{worker} + WAGE_{collector})) \times NUM_{reactors}$$

Parameter	Description
$NUM_{collections}$	Number of urine collections per reactor per year (as discussed in Appendix 2, Exhibit A2-12)
$PER_{low\ quantity}$	Percentage of collections that are of inadequate quantity after the initial attempt to provide a specimen under the former requirements (as discussed in the assumptions below)
$PERD_{low\ quantity}$	Percentage decrease in the number of shy bladder tests per year that produce inadequate specimens resulting from the reduction in the minimum specimen quantity (from 60 mL to 30 mL) (as discussed in the assumptions below)

[10] In order to capture the total costs and savings, this analysis assumes that savings incurred by offsite collection sites are passed back to licensees (i.e., lower costs per specimen collection). The validity of this assumption depends on the degree to which the offsite collection site industry is price-competitive. To the extent that it is not price-competitive, savings will accrue as estimated, but will benefit the offsite collection site rather than licensees (i.e., offsite collection sites will realize savings in labor costs because of the reduced collection time, but will not reduce the cost per collection charged to licensees).

Parameter	Description
$HOURS_{saved}$	Average time per test saved because a donor can provide a sufficient specimen under the final rule (as discussed in the assumptions below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$WAGE_{collector}$	Collection site personnel wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of urine collections per reactor per year is assumed to be equal to the number of drug tests per reactor per year.

- Percentage of collections (per year) that are of inadequate quantity after the initial attempt to provide a specimen under the former requirements : 6.7 percent.[11]

- Percentage decrease in the number of shy bladder tests per year that produce inadequate specimens: 25 percent.

- Average time per test saved because a donor can provide a sufficient specimen under the final rule: 1.5 hours.

Paragraph 26.109(b)

This paragraph of the final rule [including subparagraphs (b)(1)–(4)] revises former requirements in Section 2.4(g)(11) in Appendix A to Part 26, which described the collection procedures in the event that a donor provides less than the minimum quantity of urine needed to complete a specimen collection during his or her initial attempt. The incremental costs and savings for this final paragraph are discussed in connection with subparagraphs (b)(1)–(4).

Subparagraph 26.109(b)(1)

This subparagraph revises a former requirement in Section 2.4(g)(11) in Appendix A to Part 26, which permitted a donor to be provided with "a reasonable amount of liquid to drink for this purpose (e.g., a glass of water)" if they cannot provide a urine specimen that meets the minimum quantity requirement during their initial attempt. The revision directs the collector to encourage the donor to drink up to a specific amount of fluid (i.e., 40 ounces) over a three-hour time period. The former rule contained no such maximum restriction on fluid consumption. This analysis

[11] Landers, Peter. April 22, 2003. "Looking for Relief, Shy bladder syndrome is widespread. But in many cases it can be treated successfully." Special Report: Personal Health Quarterly 2003-2, The Wall Street Journal. The article cites a 1994 study indicating that 6.7 percent of Americans suffer from shy-bladder syndrome, or what is called paruresis.

assumes that no incremental cost or saving will result from this revised subparagraph because the activity (of providing fluids to the donor) is common to both the former and final rules.

Subparagraph 26.109(b)(2)

This subparagraph adds three new requirements. First, this subparagraph prohibits a licensee or other entity from requiring a donor to provide additional urine specimens to try to meet the licensee's or other entity's predetermined quantity if the donor's initial specimen is at least 30 mL, but less than the predetermined quantity (greater than 30 mL). That is, a donor cannot be compelled to make additional attempts to provide a specimen that meets the licensees's or other entity's predetermined quantity, after the donor has successfully provided an initial specimen of at least 30 mL. Second, this subparagraph prohibits any sanctions from being imposed on a donor who provides a specimen of at least 30 mL but less than the predetermined quantity. Third, this subparagraph requires that a specimen of 30 mL but less than the predetermined quantity be forwarded directly to the an HHS-certified laboratory for testing. The three new requirements in this subparagraph will not result in any incremental costs or savings for FFD programs that send all urine specimens to HHS-certified laboratories. However, the provisions will result in incremental costs for FFD programs with onsite licensee testing facilities because specimens meeting the minimum 30 mL quantity (but less than the predetermined quantity) cannot be tested at the licensee testing facility and must be forwarded directly to an HHS-certified laboratory for testing.

The *annual incremental costs per FFD program with onsite testing facilities* are estimated as follows:

$$(NUM_{drug\ tests} \times PER_{not\ predetermined\ quantity}) \times (COST_{test\ at\ HHS\ lab} - COST_{test\ at\ licensee\ lab}) \times NUM_{reactors}$$

Parameter	**Description**
$NUM_{drug\ tests}$	Number of drug tests per reactor per year (as discussed in Appendix 2, Exhibit A2-12)
$PER_{not\ predetermined\ quantity}$	Percentage of urine specimens at least 30 mL in volume, but less than the licensee's or other entity's predetermined quantity of urine (as discussed in the assumptions below)
$COST_{test\ at\ HHS\ lab}$	Cost to conduct initial drug testing and initial validity testing on a urine specimen at an HHS-certified laboratory for FFD programs that primarily use onsite testing facilities (as discussed in Appendix 2, Exhibit A2-13)
$COST_{test\ at\ licensee\ lab}$	Cost to conduct initial drug testing and initial validity testing on a urine specimen at an onsite licensee testing facility (as discussed in the assumptions below and in Appendix 2, Exhibit A2-13)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- FFD programs that conduct initial drug testing at onsite testing facilities send fewer specimens to HHS-certified laboratories than do FFD programs that do not operate onsite testing facilities, and so must pay a higher per specimen cost for drug and validity testing (both initial and confirmatory, when necessary).

- Percentage of urine specimens of at least 30 mL in volume, but less than the licensee or other entity's predetermined quantity: 1 percent.

Subparagraph 26.109(b)(3)

The paragraph revises former requirements in Section 2.4(g)(11) in Appendix A to Part 26. In situations where a donor has not provided a urine specimen of adequate volume (at least 30 mL) within 3 hours of the initial unsuccessful attempt, this revised subparagraph instructs the collector to terminate the testing process and notify the FFD manager or MRO to initiate the shy bladder procedures in §26.119. The former rule only required that the collector contact the appropriate authority to obtain guidance on the action to be taken. The final paragraph provides a specific requirement for the collector to notify the FFD manager or MRO to initial shy bladder procedures. This final subparagraph will not result in any incremental costs or savings because the collector must still contact an individual to initiate additional actions related to the shy bladder situation.

Subparagraph 26.109(b)(4)

This subparagraph revises the former requirement in Section 2.4(g)(11) in Appendix A to Part 26, to prohibit, rather than require, the pooling of successive urine specimens. Donors must now provide a minimum of 30 mL of urine in a single specimen collection attempt. The final rule also requires that urine collectors must discard specimens of less than 30 mL. If the collector has a reason to believe that a donor has diluted, adulterated, substituted, or tampered with their specimen of 15 mL or more but less than 30 mL, the specimen must be sent to an HHS-certified laboratory for testing. Although FFD programs may realize an additional cost to send specimens to an HHS-certified laboratory that are 15 mL or more but less than 30 mL and collected from a donor who is suspected of diluting, adulterating, substituting, or tampering with their specimen, the analysis assumes that no incremental costs or savings will result because of the infrequency of these situations.

26.111 Checking the acceptability of the urine specimen

Paragraph 26.111(a)

This paragraph of the final rule revises former requirements in Section 2.4(g)(13) in Appendix A to Part 26, which required collectors to measure the temperature of a urine specimen within 4 minutes of receiving the specimen from the donor. This paragraph of the final rule revises the

former rule's urine specimen temperature requirements in Section 2.4(g)(14) in Appendix A to Part 26. Specifically, the final rule expands the acceptable urine specimen temperature range from (90.5°F – 99.8°F) to (90°F – 100°F). Any specimen outside the (90°F – 100°F) temperature range indicates that a donor may have attempted to subvert the testing process. The analysis does not estimate any saving from this revision because the change in the temperature range is minor.

Paragraph 26.111(b)

This paragraph of the final rule revises former requirements in Section 2.4(g)(15) in Appendix A to Part 26, which specified that "immediately after a urine specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted in the permanent record book." This final paragraph requires that immediately after a urine specimen is collected, "the collector shall also inspect the specimen to determine its color and clarity and look for any signs of contaminants or adulteration. Any unusual findings must be noted on the custody-and-control form." This final paragraph changes the required location that the information is to be recorded from a permanent recordbook to the custody-and-control form. This final paragraph imposes no incremental cost and affords no saving because the collector must still inspect each specimen and document any unusual findings (even if in a different place).

Paragraph 26.111(c)

This paragraph of the final rule revises former requirements in Sections 2.4(g)(17) and 2.4(g)(25) in Appendix A to Part 26, which instructed the urine collector, after receiving approval from a "higher level supervisor in the drug testing program," to perform a second collection as soon as possible under direct observation "whenever there is a reason to believe that a particular individual may alter or substitute the urine specimen." The final paragraph specifies that the collector should contact the designated FFD program manager if there is reason to believe the individual may have diluted, substituted, or adulterated the specimen based upon temperature or other observations. It also permits the FFD manager to consult with the MRO to determine whether a subversion attempt has occurred. There are no incremental costs or savings attributable to these clarifications because this analysis assumes that these requirements are consistent with existing practices.

Paragraph 26.111(d)

This paragraph of the final rule revises former Section 2.4(g)(16) in Appendix A to Part 26, which required all urine specimens suspected of being adulterated or diluted to be "forwarded to the laboratory for testing." This revised paragraph specifies that a specimen of sufficient quantity (at least 15 mL) that is suspected of having been diluted, substituted, or adulterated and any specimen of 15 mL or more that has been collected under direct observation in accordance with paragraph (c) of this section, must be "sent directly to the HHS-certified laboratory for testing." The only minor incremental costs or savings that may result from the requirement pertain to FFD programs with onsite licensee testing facilities, because FFD programs that send

all specimens offsite for testing at an HHS-certified laboratory already comply with this requirement. The analysis assumes, however, that even FFD programs with onsite testing facilities already send any suspect urine specimens directly to an HHS-certified laboratory because HHS-certified laboratories have more sophisticated equipment to identify potential specimen validity concerns.

Paragraph 26.111(e)

This paragraph of the final rule revises former Section 2.4(g)(16) in Appendix A to Part 26, which required all urine specimens suspected of being adulterated or diluted to be forwarded to an HHS-certified laboratory. This final paragraph specifies that the collector must also preserve a suspect urine specimen for possible testing. This paragraph of the final rule imposes no incremental cost and affords no saving because it is consistent with existing collection site practices.

Paragraph 26.111(f)

This paragraph of the final rule defines the specific criteria to be used by a collector to determine whether a urine specimen is acceptable (i.e., is free of apparent contaminants, meets the required quantity of at least 30 mL, and is within acceptable temperature range). This analysis assumes no incremental costs or savings are attributable to this final paragraph because collectors currently use these criteria to determine whether a urine specimen is acceptable, although the minimum quantity of urine has been reduced from 60 mL to 30 mL, as discussed in connection with §26.109.

26.113 Splitting the urine specimen

This section of the final rule [including paragraphs (a)–(c)] imposes no incremental costs and affords no savings because it clarifies the former requirements in Sections 2.4(g)(20) and 2.7(j) in Appendix A to Part 26, which detailed the procedures for collecting split specimens. Paragraph 26.113(b) revises the former requirement in Section 2.7(j) which instructed the urine collector to pour one half of the urine specimen into each specimen bottle. Paragraph 26.113(b) instructs the collector, to pour 30 mL of urine into Bottle A and a minimum of 15 mL into Bottle B. The final paragraph also requires that if there is less than 15 mL of urine available for Bottle B, then the collector must 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. The quantities apportioned to each split specimen bottle have been revised, but no cost or saving will result from this modified procedure.

26.115 Collecting a urine specimen under direct observation

Paragraph 26.115(a)

This paragraph of the final rule restates without substantive change former requirements in Section 2.4(f)(1)-(3) in Appendix A to Part 26 which specified the criteria indicating exclusive grounds that a donor has attempted to alter or substitute their urine specimen.

Paragraph 26.115(b)

This paragraph establishes a new requirement that in instances where an observed collection is deemed warranted by the collector, the collector must obtain agreement of the FFD manager or MRO to obtain a specimen under direct observation. No incremental cost or savings will result from this final paragraph because situations where an observed collection is warranted are rare.

Paragraphs 26.115(c)

The paragraph of the final rule adds a requirement that the collector 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. No costs or savings will result from this final paragraph because situations where an observed collection is warranted are rare.

Paragraph 26.115(d)

The paragraph of the final rule establishes new recordkeeping requirements related to the directly observed collection. The final paragraph requires the collector to record on the specimen's custody-and-control form that the specimen was collected under direct observation and the reason for the directly observed collection. The requirement is necessary to ensure that the HHS-certified laboratory and the MRO have this information available when the specimen is tested and the MRO conducts his or her review of the test results, as is required under §26.185. No costs or savings will result from this final paragraph because situations where an observed collection is warranted are rare.

Paragraph 26.115(e)

This paragraph of the final rule 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, which 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).

Paragraph 26.115(f)

This paragraph of the final rule adds new requirements for conducting directly observed collections. 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 changes have been made to increase the likelihood of detecting such attempts to subvert the testing process and, thereby, increase the effectiveness of directly observed collections in assuring that a valid specimen is obtained from the donor. No costs or savings will result from this final paragraph because situations where an observed collection is warranted are rare.

Paragraph 26.115(g)

This paragraph of the final rule has been added to clarify that a donor's refusal to participate in the directly observed collection constitutes 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 fails to cooperate with the specimen collection process, including, but not limited, to a refusal to provide a complete specimen, complete paperwork, or initial the specimen bottles. The 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. No costs or savings will result from this final paragraph because situations where an observed collection is warranted are rare.

Paragraph 26.115(h)

This paragraph of the final rule adds new collection requirements for collectors to follow if a directly observed collection was required, but was not performed. The collector would inform the FFD program manager or designee of the omission, who would ensure that a directly observed collection is immediately performed. No costs or savings will result from this final paragraph because situations where an observed collection is warranted are rare.

26.117 Preparing urine specimens for storage and shipping

Paragraph 26.117(a)

This paragraph of the final rule restates without substantive change former requirements in Section 2.4(g)(20) in Appendix A to Part 26, which pertained to the collector keeping the urine specimen in view of the donor at all times before sealing and labeling the specimen. This paragraph of the final rule imposes no incremental cost and affords no saving because it is consistent with existing licensee collection practices.

Paragraph 26.117(b)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.4(g)(21) in Appendix A to Part 26.

Paragraph 26.117(c)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.4(g)(22) in Appendix A to Part 26.

Paragraph 26.117(d)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.4(g)(23) in Appendix A to Part 26.

Paragraph 26.117(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive changes the former requirements in Section 2.4(g)(26) in Appendix A to Part 26.

Paragraph 26.117(f)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.4(g)(27) in Appendix A to Part 26.

Paragraph 26.117(g)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.4(g)(28) in Appendix A to Part 26.

Paragraph 26.117(h)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.4(c)(2) in Appendix A to Part 26.

Paragraph 26.117(i)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive changes former requirements in Section 2.4(i) in Appendix A to Part 26 which pertain to specimen packaging procedures.

Paragraph 26.117(j)

This paragraph of the final rule clarifies and revises former requirements (primarily in Section 2.7(c) in Appendix A to Part 26) regarding refrigerating specimens to protect them from degradation. This final paragraph restates portions of the former rule and adds a performance standard regarding "appropriate and prudent actions" to minimize specimen degradation. Licensees would likely achieve the performance standard by implementing the more specific criteria from the former rule, which are also restated in the final rule. The final paragraph also relaxes refrigeration criteria for most specimens, but tightens them for specimens that are suspected of having been substituted, adulterated, or tampered with. Finally, the final paragraph adds a requirement that the collection site must send specimens to a licensee testing facility or HHS-certified laboratory as soon as reasonably practical, with a time limit of 2 business days from the shipping of a specimen to the receipt of the specimen at the appropriate laboratory, except under unusual circumstances. It is believed that the new provisions in this final paragraph are consistent with current industry practices. To the extent (if any) that the new refrigeration standards (some relaxed, some tightened) might require licensees to change their operating practices, the net effect is likely to be small. As a result of these uncertainties (including a lack of data) and the likelihood that any impact would be small, this analysis does not quantify costs or savings resulting from the final paragraph.

Paragraph 26.117(k)

This paragraph of the final rule clarifies former requirements in Section 2.4(h) in Appendix A to Part 26, stating that the date and purpose be documented on the chain-of-custody form for a specimen each time the specimen is handled or transferred, and every individual in the chain of custody shall be identified. This final paragraph clarifies that because couriers, express carriers, and postal service personnel do not have access to the custody-and-control forms, these individuals are not required to document chain of custody during transit of a urine specimen. However, this final paragraph adds a new requirement that the custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service. This paragraph of the final rule imposes no incremental cost and affords no saving because it describes existing courier, express carrier, and postal service shipment tracking practices.

26.119 Determining "shy" bladder

This section of the final rule replaces former requirements in Section 2.4(g)(11) in Appendix A to Part 26, which required that the collection site must contact the appropriate authority to obtain guidance on the action to be taken when a donor cannot provide an adequate volume of urine. This final paragraph adopts "shy bladder procedures" consistent with U.S. DOT regulations (49 CFR 40.193). All costs are considered incremental because this is a new requirement. Specific incremental costs include labor (or productivity losses) associated with the donor, the FFD manager, the MRO, and a licensed physician, and are described in the paragraph discussions below.

The equation presented at the end of this section calculates the incremental costs combined for all seven paragraphs within §26.119, as follows:

- Paragraph 26.119(a) establishes a new requirement for the FFD program personnel to direct the donor to obtain a medical evaluation from a licensed physician within 5 business days of a donor's inability to provide an adequate urine specimen of at least 30 mL. The MRO must approve the physician to conduct the evaluation (an MRO can perform the evaluation if he or she possesses appropriate expertise). Incremental costs per FFD program consist of lost worker productivity while obtaining the medical evaluation, MRO labor to evaluate and agree with the selection of physician, and the cost of the medical evaluation.

- Paragraphs 26.119(b), (c), and (d) establish new requirements necessitating that the MRO provide the physician selected to perform a medical evaluation with the physical and psychological conditions that constitute a medical condition that could preclude a donor from providing an adequate quantity of urine. The MRO must also instruct the physician to provide a written statement of the conclusions of the evaluation to the MRO. The incremental costs include MRO labor to communicate the specific evaluation requirements to the examining physician.

- Paragraphs 26.119(e) and (f) require the physician evaluating the donor to provide a written statement to the MRO regarding the findings and conclusions from his or her evaluation. The report must state whether a medical condition exists that precludes the donor from providing sufficient specimens in future collections. The incremental cost consists of the cost of obtaining the physician's written statement.

- Paragraph 26.119(g) describes the required MRO findings, which are to be based on results of the physician's evaluation of the donor. Incremental costs consist of MRO labor to review the physician evaluation, make a determination on the donor's condition, and communicate the results.

The annual costs per FFD program associated with section 26.119 are estimated as follows:

$$NUM_{shy\ bladder} \times [COST_{medical\ evaluation} + ((HOURS_{medical\ evaluation} \times WAGE_{worker}) + (HOURS_{FFD\ manager} \times WAGE_{FFD\ manager}) + (HOURS_{MRO} \times WAGE_{MRO}))] \times NUM_{facilities}$$

Parameter	**Description**
$NUM_{shy\ bladder}$	Number of urine collections unable to be completed because of inadequate specimen volume after 3 hours, per facility per year (as discussed in the assumptions below)
$COST_{medical\ evalutaion}$	Cost of a medical evaluation and written report from a licensed physician per incident where an employee is unable to provide the minimum quantity of urine after 3 hours (as discussed in the assumptions below)

Parameter	Description
$HOURS_{medical\ evaluation}$	Time per medical evaluation (including travel to and from the physician's office) (as discussed in the assumptions below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$HOURS_{FFD\ manager}$	Time for an FFD manager per incident where an employee is unable to provide the minimum quantity of urine after 3 hours (as discussed in the assumptions below)
$WAGE_{FFD\ manager}$	FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11)
$HOURS_{MRO}$	MRO time per incident where a donor is unable to provide the minimum quantity of urine after 3 hours to select a physician, instruct the physician on the medical evaluation that must be conducted, and review and communicate the medical evaluation results to the FFD manager and worker (as discussed in the assumptions below)
$WAGE_{MRO}$	MRO wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{facilities}$	Number of facilities per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of urine collections unable to be completed because of inadequate specimen volume after 3 hours, per facility per year: 1.

- Cost of a medical evaluation and written report from a physician per incident where a donor is unable to provide the minimum quantity of urine after 3 hours: $300.00.

- Time per medical evaluation (including travel to and from the physician's office): 1.5 hours.

- Time for an FFD program manager per incident where an employee is unable to provide the minimum quantity of urine after 3 hours to direct an employee to proceed to a physician for a medical evaluation, to consult with the MRO regarding an appropriate physician to conduct a shy bladder examination, and to perform administrative activities associated with the MRO's results: 2 hours.

- MRO time per incident where an employee is unable to provide the minimum quantity of urine after 3 hours to select a physician, instruct the physician on the medical evaluation that must be conducted, and communicate the medical evaluation results to the FFD manager and worker: 2 hours.

Subpart F: Licensee Testing Facilities

26.121 Purpose

This section of the final rule imposes no incremental cost and affords no saving because it merely states that Subpart F contains requirements for laboratories operated by licensees to perform initial drug testing and validity testing on urine specimens.

26.123 Testing facility capabilities

This section of the final rule revises former requirements in Section 2.7(l)(2) in Appendix A to Part 26, which required that licensee testing facilities must have the capability to perform initial drug tests on urine specimens for each of the five drugs and drug metabolites as required in §2.7(e)(1). The final rule adds a requirement that each licensee testing facility must have the capability to perform validity screening or initial validity tests on urine specimens. This analysis captures any incremental costs associated with this section in §26.131 of the final rule.

26.125 Licensee testing facility personnel

This section of the final rule [including paragraphs (a)–(c)] imposes no incremental cost and affords no saving because it restates and clarifies former requirements in Section 2.6(a)–(c) in Appendix A to Part 26, which pertained to the requirements for licensee testing facility personnel responsible for the day-to-day management of operations and supervision of testing technicians, other technicians, non-technical staff, and licensee testing facility personnel files. Paragraph 26.125(b) of the final rule revises former requirement in Section 2.6(c), which described collector proficiency requirements, by adding a new requirement that technicians who perform urine specimen testing have documented proficiency in operating the testing instruments and devices used at the testing facility. This new provision will result in no incremental cost or saving because it is consistent with existing licensee testing facility training practices and documentation procedures.

26.127 Procedures

This section of the final rule clarifies former requirements in Sections 2.2 and 2.7 in Appendix A to Part 26 as discussed in paragraphs (a)–(f) below. No incremental costs or savings will result directly from the clarifications in this final section. However, FFD programs with onsite licensee testing facilities will incur incremental costs to comply with the requirements in this section and therefore must revise current laboratory policies and procedures to incorporate necessary changes related to other sections of Subpart F (e.g., validity testing, modified cutoff levels for marijuana and opiates, blind performance specimen testing, quality assurance procedures). The analysis evaluates the incremental costs of all licensee testing facility policy revisions required because of the final rule revisions in this section of the analysis.

The one-time cost per FFD program with onsite licensee testing facilities is estimated as follows:

$(HOURS_{FFD\ manager} \times WAGE_{FFD\ manager}) + (HOURS_{Lab\ supervisor} \times WAGE_{Lab\ supervisor}) + (HOURS_{Clerical} \times WAGE_{Clerical}) + (HOURS_{Legal} \times WAGE_{Legal})$

Parameter	Description
$HOURS_{FFD\ manager}$	Hours of FFD manager's time to revise the laboratory procedures manual (as discussed in the assumptions below)
$WAGE_{FFD\ manager}$	FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11)
$HOURS_{Lab\ supervisor}$	Hours of laboratory supervisor's time to revise the laboratory procedures manual (as discussed in the assumptions below)
$WAGE_{Lab\ supervisor}$	Laboratory supervisor wage rate (as discussed in Appendix 2, Exhibit A2-11)
$HOURS_{Clerical}$	Hours of clerical personnel time to revise the laboratory procedures manual (as discussed in the assumptions below)
$WAGE_{Clerical}$	Clerical personnel wage rate (as discussed in Appendix 2, Exhibit A2-11)
$HOURS_{Legal}$	Hours of legal time to review the laboratory procedures manual (as discussed in the assumptions below)
$WAGE_{Legal}$	Legal wage rate (as discussed in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours for procedure revisions per FFD program with onsite licensee testing facilities by labor category (total of 360 hours):
  - FFD manager: 120 hours.
  - Laboratory supervisor: 160 hours.
  - Clerical: 40 hours.
  - Legal: 40 hours.

- Each FFD program with onsite licensee testing facilities uses a single procedures manual for all testing facilities.

Paragraph 26.127(a)

The paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements within Section 2.2 in Appendix A to Part 26, which related to the maintenance and documentation of procedures for the collection, shipment, and accession of urine specimens.

Paragraph 26.127(b)

The paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change the former requirements in Section 2.7(a)(2) in Appendix A

to Part 26, which pertained to the content and implementation of specimen chain-of-custody procedures for licensee testing facilities.

Paragraph 26.127(c)

The paragraph of the final rule revises without substantive change former requirements within Section 2.7(o)(1) in Appendix A to Part 26 which specified that licensee testing facilities must maintain a procedures manual detailing the numerous components of the drug testing process. The final paragraph extends the former requirement to include a provision requiring documentation of standard operating procedures for each specimen validity testing assay performed. In addition, this final paragraph requires that the licensee testing facility maintain written procedures, but no longer specifies that these procedures must be maintained in a "procedure manual." Incremental costs associated with revisions to the licensee testing facility policy and procedures are discussed in connect with §26.127.

Paragraph 26.127(d)

The paragraph of the final rule imposes no incremental cost and affords no saving because it restates a former requirement in Section 2.7(o)(3)(iii) in Appendix A to Part 26.

Paragraph 26.127(e)

The paragraph of the final rule imposes no incremental cost and affords no saving because it restates and clarifies former requirements in Section 2.7(o)(4) in Appendix A to Part 26, which maintained that a licensee testing facility must develop, implement, and maintain procedures for remedial actions if systems are out of acceptable limits or errors are detected. This paragraph adds a new requirement for licensee testing facilities that use validity screening testing tests to maintain procedures for instrumented and non-instrumented testing. As discussed in §26.131(a) of the analysis, the analysis assumes that no licensee testing facilities will conduct validity screening tests. Therefore, this revised provision will result in no incremental cost or saving because license testing facilities will not have to maintain procedures for instrumented and non-instrumented validity screening tests.

26.129 Assuring specimen security, chain of custody, and preservation

Paragraph 26.129(a)

There are no incremental costs or savings from this paragraph because it clarifies former requirements in Section 2.7(a)(1) in Appendix A to Part 26.

Paragraph 26.129(b)

This paragraph of the final rule revises former requirements in Section 2.7(b)(1) in Appendix A to Part 26, which required that licensee testing facility personnel must inspect each package

containing urine specimens to identify any evidence of possible tampering and must notify licensee officials of any tampering as soon as possible, but within 8 hours of identifying a potential tampering incident. By contrast, the provisions in this paragraph will require each licensee testing facility to conduct an investigation into possible tampering and take corrective actions when necessary. This paragraph of the final rule adds a provision to require the licensee testing facility to obtain a memorandum for the record from the specimen collector to document correction of the discrepancy, which must accompany the specimen(s) and custody-and-control forms to the HHS-certified laboratory, if the specimen(s) must be transferred. This paragraph also adds specific instances that would require testing of a specimen to be cancelled. If the licensee testing facility personnel identify any reason to believe that the integrity and/or identity of a specimen is in question, the specimen is not to be tested and the licensee or other entity must ensure that another collection occurs as soon as reasonably practicable. This analysis estimates that no incremental costs or savings will result from this final paragraph because the requirements are believed to be consistent with existing licensee practices used to address issues associated with discrepancies of information, specimen bottles, and/or the specimen custody-and-control form. The new requirement that a memorandum for the record be obtained from the specimen collector only ensures that the error correction is made to the custody-and-control form, but the level of effort to resolve the error is unchanged.

Paragraph 26.129(c)

This paragraph of the final rule clarifies and revises former requirements in Section 2.7(b)(2) in Appendix A to Part 26, which pertained to the handling of urine specimens at licensee testing facilities and the use of chain-of-custody forms. Specifically, this paragraph clarifies that licensee testing facilities must use laboratory chain-of-custody forms or other appropriate methods of tracking aliquot custody and control while conducting validity testing (screening and/or initial) and initial drug testing on urine specimens. This final paragraph also establishes that both the original specimen and the original specimen custody-and-control form must remain in secure storage. Finally, this paragraph clarifies that licensee testing facilities may discard specimens as soon as practical after receiving negative results for validity screening and/or initial validity and initial drug tests. No incremental costs or savings will result from this final paragraph because it is considered to be consistent with existing licensee testing facility practices for urine specimen handling, storage, and disposal. The analysis does not quantify the costs for any licensee testing facilities to use alternative custody and control tracking methods to accommodate validity testing, as these costs, if any, are deemed to be insignificant.

Paragraph 26.129(d)

This final paragraph imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 2.7(a)(2) in Appendix A to Part 26, which pertained to chain-of-custody procedures and information required to be included on custody-and-control forms used to track urine specimens at licensee testing.

Paragraph 26.129(e)

This paragraph of the final rule clarifies and revises former requirements in Section 2.7(d) in Appendix A to Part 26, which pertained to the shipment of "presumptive positive" urine specimens to an HHS-certified laboratory for confirmatory testing. The former requirements did not designate a time by which the licensee testing facility must send a specimen identified as positive or of questionable validity to an HHS-certified laboratory. The final paragraph replaces the term "presumptive positive" with "positive or of questionable validity" to account for drug positive specimens and specimens with validity test results that require additional testing and directs licensee testing facilities to send these specimens to an HHS-certified laboratory as soon as reasonably practical. No incremental costs or savings are estimated because the revised provision is consistent with current specimen shipping practices used by licensee testing facilities.

Paragraph 26.129(f)

This paragraph of the final rule clarifies and revises former requirements (which primarily appear in Section 2.7(c) in Appendix A to Part 26), as they relate to refrigerating specimens to protect them from degradation. This final paragraph restates portions of the former rule and adds a performance standard regarding "appropriate and prudent actions" to minimize specimen degradation. (Licensees would likely meet the performance standard by implementing the more specific criteria from the former rule, which are also restated in the final rule.) The revised paragraph also relaxes the refrigeration criteria for most specimens, but tightens them for specimens identified as positive or of questionable validity that will undergo validity screening, initial validity, or initial drug testing. The analysis assumes that the provisions are consistent with current industry practice. To the extent (if any) that the refrigeration standards (some relaxed, some tightened) might require licensees to change their operating practices, the net effect is likely to be negligible. As a result of these uncertainties (including a lack of data) and the likelihood that any impact would be negligible, this analysis does not quantify costs or savings resulting from this final paragraph.

Paragraph 26.129(g)

This paragraph of the final rule clarifies former requirements in Section 2.4(i) in Appendix A to Part 26, which specified packaging and shipping requirements for urine specimens that are sent from a licensee testing facility to an HHS-certified laboratory. No incremental costs or savings will result from this final paragraph because it is consistent with former requirements.

Paragraph 26.129(h)

This paragraph of the final rule clarifies that because couriers, express carriers, and postal service personnel do not have access to the custody-and-control forms or the specimen bottles, they are not required to document chain-of-custody of a urine specimen in transit. However, this paragraph adds a new requirement that the custody accountability of the shipping containers

during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service. No incremental costs or savings will result from the final paragraph because it describes former courier, express carrier, and postal service shipment tracking practices.

26.131 Cutoff levels for validity screening and initial validity tests

Paragraph 26.131(a)

This paragraph of the final rule establishes that licensee testing facilities must conduct validity screening and/or initial validity testing on all urine specimens collected under the requirements in 10 CFR Part 26. Specimens with a validity screening and/or initial validity test result of questionable validity must be sent to an HHS-certified laboratory for further validity testing. The analysis assumes that all licensee testing facilities will choose to conduct initial validity testing (rather than validity screening testing) on all urine specimens. As discussed in the Statement of Considerations, NRC is allowing the use of validity screening tests for the potential future benefit of licensees and other entities even though no such devices currently meet the quality assurance and quality control requirements in §26.137(b) of the final rule. All validity testing costs are considered incremental because this is a new regulatory requirement.[1] The analysis estimates all specimen validity testing costs in the discussion of §26.131(b) of the final rule.

Paragraph 26.131(b)

This paragraph of the final rule establishes specimen validity testing requirements for licensee testing facilities and requires that each urine specimen be analyzed for creatinine, pH, and one or more oxidizing adulterants and specifies the cutoff levels for each validity test (screening and initial validity). The provisions in this paragraph prohibit licensees and other entities from using more stringent cutoff levels for validity tests than those specified in 10 CFR Part 26.

The regulatory analysis calculates under this paragraph not only the costs related to conducting initial validity testing at licensee testing facilities, but also the subsequent costs for some specimens to receive initial and confirmatory validity and drug testing at an HHS-certified laboratory, and the associated costs resulting from confirmed adulterated or substituted validity and/or positive drug test results (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen). Even though many of these costs are directly related to other provisions in the final rule, as referenced below, this approach consolidates the

[1] By assuming that no licensees currently conduct validity testing, the analysis overstates the incremental costs to be incurred by FFD programs as a result of the validity testing provisions. This assumption is necessary, however, because of the lack of available data regarding the types of validity testing being conducted throughout the industry.

series of actions that are initiated under §26.131, allowing for a unified (hence clearer) presentation of related actions and a simpler analysis.

One-time costs captured below consist of training laboratory technicians at licensee testing facilities in the methods and procedures to conduct initial validity testing, and the annual costs associated with conducting initial validity testing at licensee testing facilities on all urine specimens (including calibrating validity testing equipment), conducting initial and confirmatory validity testing at an HHS-certified laboratory for specimens with test results of questionable validity[2] from the licensee testing facility, the labor costs of MRO and FFD personnel for administrative activities for confirmed positive drug test results and/or confirmed adulterated or substituted validity test results, the costs of retesting some specimens with confirmed drug positive, adulterated, substituted, or invalid test results at the donor's request (MRO's request for invalid specimens), and the costs of the appeals process for some drug positive, adulterated, or substituted test results that donors choose to contest. In addition, because HHS certified laboratory testing procedures and required licensee actions vary based on the type of confirmatory validity test result (e.g., dilute, invalid), the analysis discusses the costs for each validity test result type separately (designated below as "Results A, B, and C").

- "Result A": adulterated and substituted specimens
- "Result B": dilute specimens
- "Result C": invalid specimens

Annual costs per FFD program with an onsite licensee testing facility are estimated as the *sum* of the following:

- Cost to conduct initial validity testing at onsite licensee testing facilities for all urine specimens

  $NUM_{validity} \times [(COST_{validity\ test\ reagents} + (HOURS_{lab\ tech} \times WAGE_{lab\ tech})] \times NUM_{reactors}$

- Cost to conduct daily calibration of validity testing equipment

  $NUM_{days} \times [COST_{calibration\ reagents} + (HOURS_{lab\ tech\text{-}calibrate} \times WAGE_{lab\ tech})] \times NUM_{facilities}$

[2] The final rule in § 26.5 created a definition for licensee testing facility validity test results. Any specimen that indicates the specimen may be adulterated, substituted, dilute, or invalid is referred to as having a validity test result of "questionable validity." The use of the term "questionable validity" is necessary because licensee testing facilities cannot conduct specific gravity testing to determine if a specimen is dilute or adulterated and therefore, NRC has decided to improve the clarity of the final rule by creating a single term to cover all specimens with a validity test result requiring further testing at an HHS-certified laboratory.

- Annualized cost of purchasing validity testing equipment (i.e., pH meter)[3]

  $NUM_{pH\ meter} \times COST_{pH\ meter} \times NUM_{facilities}$

- Cost of sending and testing all urine specimens with initial validity test result of questionable validity to an HHS-certified laboratory for initial and confirmatory validity testing (and drug testing under specific instances), as described by the following validity test result cases (Results A, B, and C).

  - Result A: HHS-certified laboratory validity testing costs for specimens with test results of adulterated or substituted consist of the following:

    $NUM_{validity} \times (PER_{adulterated} + PER_{substituted}) \times COST_{HHS\ validity\ testing} \times NUM_{reactors}$

  - Result B: HHS-certified laboratory validity testing costs for specimens with test results of dilute. Additional costs include confirmatory drug testing to the limit of detection (LOD) for some specimens.[4] The costs include the following:

    $NUM_{validity} \times PER_{dilute} \times (COST_{HHS\ validity\ testing} + COST_{HHS\ LOD\ testing}) \times NUM_{reactors}$

  - Result C: HHS-certified laboratory validity testing costs for specimens with a test results of invalid. Additional costs include collecting a second urine specimen under direct observation, as specified in §26.185(f)(3) of the final rule, and then validity and drug testing the second specimen at an HHS-certified laboratory. The costs include the following:

    $NUM_{validity} \times PER_{invalid} \times [COST_{HHS\ validity\ testing} + (COST_{2nd\ collection} + COST_{HHS\ validity\ \&\ drug\ testing})] \times NUM_{reactors}$

- Cost of subsequent actions for all adulterated, substituted, dilute, or invalid validity test results and positive drug test results identified because of the validity testing requirements in §26.131(b) and §26.185(f)(3) (sum of adulterated, substituted, dilute, and invalid validity test results and positive drug tests from Results A, B, and C). FFD programs with onsite licensee testing facilities may also incur costs associated with some donors requesting the retesting of an aliquot of a single specimen or the testing of their

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[3] The analysis assumes that each licensee testing facility will only need to purchase one pH meter to comply with the validity testing requirements because all licensee testing facilities already either lease or have purchased desktop sized drug testing instrument using enzyme immunoassay (EIA) technology to comply with the former requirements in 10 CFR Part 26. Reagents are commercially available for testing of creatinine and some adulterants using EIA based testing equipment. Creatinine and adulterant testing is performed on urine specimens using the same basic testing procedures as employed in conducting testing for each of the five drugs.

[4] Paragraph 26.163(a)(2) of the final rule permits FFD programs to require confirmatory LOD drug testing for any drug with an initial drug test result equal to or greater than 50 percent of the cutoff calibrator.

split specimen and/or some donors appealing confirmed adulterated or substituted validity and/or positive drug test results (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen)

- Cost for actions subsequent to confirmed adulterated or substituted validity, and/or positive drug (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen) test results

  $NUM_{validity} \times [(PER_{adulterated} + PER_{substituted} + (PER_{dilute} \times PER_{positive\text{-}dilute}) + (PER_{invalid} \times PER_{drug\ positive\ 2nd\ collection}))] \times COST_{subsequent\ actions} \times NUM_{reactors}$

- When requested by some donors, the cost of retesting specimens with confirmed adulterated or substituted validity, and/or positive drug (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen) test results at a second HHS-certified laboratory

  $NUM_{validity} \times [(PER_{adulterated} + PER_{substituted} + (PER_{dilute} \times PER_{positive\ at\ LOD}) + (PER_{invalid} \times PER_{drug\ positive\ 2nd\ collection}))] \times PER_{retest} \times COST_{retest} \times NUM_{reactors}$

- When requested by some donors, the cost of the appeals process for confirmed adulterated or substituted validity and/or positive drug test results (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen)

  $NUM_{validity} \times [(PER_{adulterated} + PER_{substituted} + (PER_{dilute} \times PER_{positive\ at\ LOD}) + (PER_{invalid} \times PER_{drug\ positive\ 2nd\ collection}))] \times PER_{appeal} \times [(HOURS_{FFD\ manager} \times WAGE_{FFD\ manger}) + (HOURS_{Worker} \times WAGE_{Worker})] \times NUM_{reactors}$

One time costs per FFD program with onsite licensee testing facilities are estimated as the following:

- One time costs to train laboratory technicians in the procedures and methods to conduct initial validity tests.[5]

  $[(NUM_{technicians} \times HOURS_{tech\ training} \times NUM_{training\ courses}) + COST_{training\ course}] \times NUM_{facilities}$

[5] Additional laboratory technician training will be necessary because of normal employee turnover at onsite licensee testing facilities. However, this analysis estimates no incremental cost because it is assumed that laboratory technicians will receive on-the-job training as part of their normal training activities.

Parameter	Description
$NUM_{validity}$	Number of validity tests per reactor per year (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12)
$COST_{validity\ test\ reagents}$	Cost of reagents used to perform initial validity testing (pH, creatinine, and one adulterant) per urine specimen at an onsite licensee testing facility (as discussed in Appendix 2, Exhibit A2-13)
$HOURS_{lab\ tech}$	Hours of time for a laboratory technician to conduct initial validity testing (pH, creatinine, and one adulterant) per urine specimen at an onsite licensee testing facility (as discussed in Appendix 2, Exhibit A2-13)
$WAGE_{lab\ tech}$	Laboratory technician wage rate (as discussed in Appendix 2, Exhibit A2-11)
NUM_{days}	Number of days that a licensee testing facility conducts drug and validity testing per year (as discussed in assumptions below)
$COST_{calibration\ reagents}$	Cost of reagents used to perform daily calibration of validity testing equipment at a licensee testing facility (as discussed in Appendix 2, Exhibit A2-13)
$HOURS_{lab\ tech\ calibrate}$	Hours of time per day for a laboratory technician at a licensee testing facility to conduct daily calibration of validity testing equipment (as discussed in Appendix 2, Exhibit A2-13)
$NUM_{pH\ meter}$	Number of pH meters purchased per licensee testing facility per year. (as discussed in the assumptions below)
$COST_{pH\ meter}$	Annualized cost per pH meter, which includes the cost of replacement probes (as discussed in the assumptions below and in Appendix 2, Exhibit A2-13)
$PER_{adulterated}$	Percentage of urine specimens with validity test results of adulterated (as discussed in Appendix 2, Exhibit A2-12)
$PER_{substituted}$	Percentage of urine specimens with validity test results of substituted (less than 2 mg/dL of creatinine) (as discussed in Appendix 2, Exhibit A2-12)
$COST_{HHS\ validity\ testing}$	Cost of conducting initial and confirmatory validity testing at an HHS-certified laboratory per urine specimen with an initial validity test result of questionable validity determined at an onsite licensee testing facility. Costs included preparation of urine specimen and shipping costs to the HHS-certified laboratory (as discussed in the assumptions below)
PER_{dilute}	Percentage of urine specimens with validity test results of dilute (as discussed in Appendix 2, Exhibit A2-12)
$COST_{HHS\ LOD\ testing}$	Cost per specimen to conduct initial drug testing and confirmatory drug testing to the level of detection (LOD) for drug(s) identified during initial testing, as permitted by § 26.163(a)(2) of the final rule (as discussed in Appendix 2, Exhibit A2-13)
$PER_{invalid}$	Percentage of urine specimens with validity test results of invalid (as discussed in Appendix 2, Exhibit A2-12)

Parameter	Description
$COST_{2nd\ collection}$	Cost of collecting a second urine specimen under direct observation from a donor with a confirmatory validity test result of invalid for the initial urine specimen collected. The cost of the second collection includes the labor for the donor's travel time to and from the collection site, donor's time spent at the collection site, as well as the labor of the collector (as discussed in Appendix 2, Exhibit A2-13)
$COST_{HHS\ validity\ \&\ drug\ testing}$	Cost of validity and drug testing a urine specimen that is sent by an onsite licensee testing facility to an HHS-certified laboratory for testing. Costs include confirmatory drug and/or validity testing when necessary (as discussed in Appendix 2, Exhibit A2-13)
$PER_{positive\ at\ LOD}$	Percentage of dilute specimens that test positive for drug(s) during initial testing (equal to or greater than 50 percent of the cutoff calibrator) and at confirmatory LOD testing (as discussed in the assumptions below)
$PER_{drug\ positive\ 2nd\ collection}$	Percentage of specimens collected under direct observation as a result of an initial specimen with an invalid test result that is positive for drugs (as discussed in the assumptions below)
$COST_{subsequent\ actions}$	Labor costs associated with MRO and FFD program personnel activities and administrative actions resulting from a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result (as discussed in Appendix 2, Exhibit A2-13)
PER_{retest}	Percentage of urine specimens with confirmed positive drug, and/or adulterated, or substituted validity test results retested at the request of the donor at a second HHS-certified laboratory (as discussed in the assumptions below)
$COST_{retest}$	Cost of specimen retesting at a second HHS-certified laboratory including specimen preparation and shipping costs (as discussed in Appendix 2, Exhibit A2-13)
PER_{appeal}	Percentage of confirmed positive drug test results (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen) and/or adulterated or substituted validity test results appealed by some donors (as discussed in the assumptions below)
$HOURS_{FFD\ manager}$	Average amount of FFD manager time per appeal for a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result appealed by some donors (as discussed in the assumptions below)
$WAGE_{FFD\ manger}$	FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11)

Parameter	Description
$HOURS_{Worker}$	Average amount of worker time per appeal process for a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result (as discussed in the assumptions below)
$WAGE_{Worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{technicians}$	Number of laboratory technicians per licensee testing facility (as discussed in the assumptions below)
$HOURS_{tech\ training}$	Length of laboratory technician training course (as discussed in assumptions below)
$NUM_{training\ courses}$	Number of laboratory technician training courses per licensee testing facility (as discussed in the assumptions below)
$COST_{training\ course}$	Cost per laboratory technician training course conducted by a commercial vendor at the licensee testing facility (as discussed in the assumptions below)
$NUM_{facilities}$	Number of licensee testing facilities per FFD program (as discussed in Appendix 2, Exhibit A2-14)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of validity tests per reactor per year is equivalent to the number of drug tests conducted per year per reactor.

- Each licensee facility that conducts onsite testing has one testing facility.

- Each licensee testing facility purchases one pH meter, which is replaced every six years. Each pH meter requires a replacement probe every two years.

- Number of days a licensee testing facility operates per year: 365 days.

- Cost per specimen to conduct initial and confirmatory validity testing at an HHS-certified laboratory for a urine specimen with an adulterated, substituted, dilute, or invalid initial validity test result at an onsite licensee testing facility: $1.50 + (cost of drug test at HHS-certified laboratory, as discussed in Appendix 2, Exhibit A2-13). FFD programs contract with HHS-certified laboratories at a fixed price per urine specimen analysis which includes drug testing (initial and confirmatory when necessary) and will also include specimen validity testing (initial and confirmatory when necessary) under the final rule. The analysis assumes that the testing cost per urine specimen will increase by $1.50 to account for validity testing in addition to drug testing costs. This testing event did not occur under the

former rule because no validity testing was required (i.e., no specimen would be sent to an HHS laboratory for further testing based on validity problems).

- All urine specimens with initial validity test result of questionable validity at an onsite licensee testing facility will receive test results of adulterated, substituted, dilute, or invalid after initial and confirmatory validity testing at an HHS-certified laboratory.

- All FFD programs choose to test dilute specimens according to the optional provisions in § 26.163(a)(2). That is, any specimen with an initial drug test result equal to or greater than 50 percent of the cutoff calibrator will receive confirmatory LOD drug testing.

- Percentage of dilute specimens that test positive for drug(s) during initial testing and at confirmatory LOD testing: 33 percent.

- For all urine specimens with validity test results of invalid, the analysis assumes that a second specimen is collected under direct observation.

- Percentage of specimens collected under direct observation as a result of an initial specimen with an invalid test result that test positive for drugs (as discussed in the assumptions below):[6] 33 percent.

- Percentage of urine specimens with confirmed positive drug, and/or adulterated or substituted validity test result retested at the request of the donor at a second HHS-certified laboratory: 5 percent.

- Average amount of FFD manager time per appeal process for a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result: 12.5 hours.

- Average amount of worker time per appeal process for a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result appealed by some donors: 2.0 hours.

[6] A second specimen is collected under direct observation for donors that have an initial specimen with an invalid test result to reduce the probability that their second specimen will be altered (e.g., use of adulterants) and therefore, the drug use that was attempted to be masked during the initial specimen donation will more likely be detected in the second specimen collected.

- Percentage of confirmed positive drug test results (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test results appealed by some donors: 1 percent.

- Number of laboratory technicians per licensee testing facility: 4.

- Length of laboratory technician training course: 4 hours.

- Number of laboratory technician training courses per licensee testing facility: 1.

- Cost per laboratory technician training course conducted by a commercial vendor at a licensee testing facility: $500.00.

26.133 Cutoff levels for drugs and drug metabolites

This section revises former requirements in Section 2.7(e)(1) in Appendix A to Part 26, which pertained to the initial cutoff levels for drugs (marijuana, cocaine, opiate, phencyclidine, amphetamines). The final rule will lower the initial cutoff level for marijuana metabolites from 100 ng/mL to 50 ng/mL. FFD programs using onsite testing facilities will incur annual incremental costs as a result of the more stringent testing cutoff level, which will increase the number of positive drug tests for marijuana.[7] The additional costs will consist of the costs of initial and confirmatory drug testing at an HHS-certified laboratory, labor costs for the MRO and FFD personnel activities resulting from confirmed positive drug test results, the costs of retesting specimens at a second HHS-certified laboratory at the request of some donors, and the costs of the appeals process for some positive test results that donors choose to contest. The final rule will also raise the initial cutoff level for opiate metabolites from 300 ng/mL to 2,000 ng/mL. FFD programs using onsite licensee testing facilities will realize annual incremental savings as a result of the less stringent testing cutoff level, which will substantially reduce the number of positive opiate drug tests that MROs ultimately verify as negative. Savings are associated with eliminating specimen testing costs at an HHS-certified laboratory, labor costs of the MRO and FFD personnel activities resulting from positive drug tests results, the costs of retesting specimens at a second HHS-certified laboratory at the request of some donors, and the cost of the appeals process for some positive test results that donors choose to contest.

Annual costs per FFD program with an onsite licensee testing facility for additional confirmed positive marijuana drug tests are estimated as the sum of the following:

- Cost for initial and confirmatory drug tests at HHS-certified laboratories

[7] The analysis over-estimates the costs of additional confirmed positive marijuana test results due to the lower initial cut-off level (50 ng/mL) because some licensees may already be testing to the cut-off level.

$(NUM_{marijuana} \times PERI_{marijuana} \times COST_{HHS\ validity\ \&\ drug\ testing}) \times NUM_{reactors}$

- Cost for actions subsequent to positive confirmatory marijuana drug test results from the HHS-certified laboratory

  $(NUM_{marijuana} \times PERI_{marijuana} \times COST_{subsequent\ actions}) \times NUM_{reactors}$

- Cost for retesting specimens with confirmed positive marijuana drug test results at a second HHS-certified laboratory at the request of some donors

  $(NUM_{marijuana} \times PERI_{marijuana} \times PER_{retest} \times COST_{retest}) \times NUM_{reactors}$

- Cost of appeals process for confirmed positive marijuana test results that some donors choose to contest

  $(NUM_{marijuana} \times PERI_{marijuana} \times PER_{appeal}) \times [(HOURS_{FFD\ manager} \times WAGE_{FFD\ manger}) + HOURS_{Worker} \times WAGE_{Worker})] \times NUM_{reactors}$

Annual savings per FFD program with an onsite licensee testing facility for fewer confirmed positive opiate drug test results are estimated as the sum of the following:

- Saving from fewer specimens with positive opiate drug tests requiring testing at HHS-certified laboratories

  $(NUM_{opiate} \times PERD_{opiate} \times COST_{HHS\ validity\ \&\ drug\ testing}) \times NUM_{reactors}$

- Saving from fewer specimens with confirmed positive opiate drug test results associated subsequent actions

  $(NUM_{opiate} \times PERD_{opiate} \times COST_{subsequent\ actions}) \times NUM_{reactors}$

- Saving from fewer confirmed positive opiate drug test specimens retested at another HHS-certified laboratory at the request of donors

  $(NUM_{opiate} \times PERD_{opiate} \times PER_{retest} \times COST_{retest}) \times NUM_{reactors}$

- Saving from fewer appeals for some confirmed positive opiate drug test results

  $(NUM_{opiate} \times PERD_{opiate} \times PER_{appeal}) \times [(HOURS_{FFD\ manager} \times WAGE_{FFD\ manger}) + HOURS_{Worker} \times WAGE_{Worker})] \times NUM_{reactors}$

Parameter	Description
$NUM_{marijuana}$	Number of confirmed positive marijuana drug test results per reactor per year under the former rule (as discussed in Appendix 2, Exhibit A2-12)
$PERI_{marijuana}$	Percentage increase in positive marijuana drug tests results due to the more stringent cutoff level in the final rule (as discussed in the assumptions below)
$COST_{HHS\ validity\ \&\ drug\ testing}$	Cost of preparing and shipping a urine specimen with an initial positive drug test result to an HHS-certified laboratory and the cost of validity and drug testing at the HHS-certified laboratory (as discussed in Appendix 2, Exhibit A2-13)
$COST_{subsequent\ actions}$	Labor costs associated with MRO and FFD program personnel activities and administrative actions resulting from a confirmed positive drug test result (as discussed in Appendix 2, Exhibit A2-13)
PER_{retest}	Percentage of urine specimens with confirmed positive drug test results retested at the request of the donor at a second HHS-certified laboratory (as discussed in the assumptions below)
$COST_{retest}$	Cost of specimen retesting at second HHS-certified laboratory including specimen preparation and shipping costs (as discussed in Appendix 2, Exhibit A2-13)
NUM_{opiate}	Number of confirmed positive opiate drug test results per reactor per year under former rule (as discussed in Appendix 2, Exhibit A2-12)
$PERD_{opiate}$	Percentage decrease in confirmed positive opiate drug test results due to the higher cutoff level in the final rule (as discussed in the assumptions below)
PER_{appeal}	Percentage of confirmed positive drug test results appealed by some donors (as discussed in the assumptions below)
$HOURS_{FFD\ manager}$	Average amount of FFD manager time per appeal process for a confirmed positive drug test result (as discussed in the assumptions below)
$WAGE_{FFD\ manager}$	FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11)
$HOURS_{Worker}$	Average amount of worker time per appeal process for a confirmed positive drug test result (as discussed in the assumptions below)
$WAGE_{Worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Changing the cutoff thresholds for marijuana and opiates will not result in a change in assay costs, nor will the changes require the upgrading of testing facility equipment. Testing facilities will have to purchase new standards and controls specific for the changes in the cutoff thresholds; however, the purchasing of standards and controls is a normal operations cost and will not result in an incremental change.

- FFD programs pay HHS-certified laboratories a per specimen cost, which includes both initial and confirmatory drug testing.

- Percentage increase in positive marijuana drug tests results due to the more stringent cutoff level in the final rule: 40 percent.[8]

- Percentage decrease in confirmed positive opiate drug test results due to the higher cutoff level in the final rule: 75 percent.[9]

- Percentage of urine specimens with confirmed positive drug test results retested at the request of the donor at a second HHS-certified laboratory: 5 percent.

- Average amount of FFD manger time per appeal process for a confirmed positive drug test result: 12.5 hours.

- Average amount of worker time per appeal process for a confirmed positive drug test result: 2.0 hours.

- Percentage of confirmed positive drug test results appealed by some donors: 1 percent.

26.135 Split specimens

Paragraph 26.135(a)

No incremental costs or savings will result from this final paragraph, which restates without substantive change the former requirements in Section 2.7(j) in Appendix A to Part 26, which pertained to split-specimen handling, testing, and storage procedures. The revisions conform the former requirements with the terminology used in other parts of the final rule, but they do not change the meaning of the former requirements.

[8] The experience of HHS-certified laboratories when U.S. DOT changed the marijuana metabolite cutoff level from 100 ng/mL to 50 ng/mL increased the number of positive marijuana test results from 25-40 percent. Several licensees currently test for marijuana metabolites at the 50 ng/mL cutoff level. One licensee reported 49 additional positive test results over a two and one-half year period, (an increase of 57 percent over the 100 ng/ml cutoff level).

[9] Raising the initial cutoff level for opiate metabolites will almost eliminate poppy seed false positive results, and unless an individual consumes large prescribed doses of codeine based cough syrup or other cold prescriptions, the threshold will significantly reduce positive screening results for opiates due to legitimate use of prescribed cold and cough prescriptions.

Paragraph 26.135(b)

This paragraph of the final rule restates and revises former requirements in Section 2.7(j) in Appendix A to Part 26, which specified the specimen shipping procedures for licensee testing facilities when notified that a donor has requested that a split specimen be tested by a second HHS-certified laboratory. The former requirement maintained that the licensee testing facility could forward the split specimen to a second HHS-certified laboratory on the same day that the laboratory receives notice that a donor has requested testing of their split specimen. The final paragraph relaxes the former requirement by providing one business day following the day of the donor's request for the specimen to be forwarded to a second HHS-certified laboratory (per §26.165(b) of the final rule). No incremental costs or savings will result from this final paragraph as it provides licensees with additional time to respond to a donor's request for specimen retesting, but does not change the required activity.

Paragraph 26.135(c)

There is no incremental cost or saving from this final paragraph as it clarifies former requirements in Section 2.7(h) in Appendix A to Part 26, which pertained to long-term frozen storage of positive, adulterated, substituted, and invalid urine specimens.

26.137 Quality assurance and quality control

Paragraph 26.137(a)

This paragraph of the final rule restates without substantive change the former requirements in Section 2.8(a) in Appendix A to Part 26, which describe the elements of a licensee testing facility quality assurance program.

Paragraph 26.137(b)

This paragraph of the final rule establishes performance testing and quality control requirements for validity screening tests conducted at licensee testing facilities. As discussed in §26.131(a) of the analysis, the analysis assumes that no licensee testing facilities will conduct validity screening tests. However, given that the final rule in §26.131(a) now requires validity testing of each urine specimen (either validity screening and/or initial validity testing) by licensee testing facility, compliance with this final paragraph or that of §§26.137(c) or (d) is a new requirement. No incremental costs or savings will result from this final paragraph because the analysis assumes that licensees will conduct initial validity tests. The costs for all licensee testing facility validity tests costs are included in §26.137(d).

Paragraph 26.137(c)

This paragraph establishes that if a licensee testing facility conducts validity screening tests on urine specimens, for specimens with results of questionable validity, the licensee testing facility

must either then perform initial validity testing or must send the specimens to an HHS-certified laboratory for additional validity testing. As discussed in §26.131(a), the analysis assumes that no licensee testing facilities will conduct validity screening tests. Therefore, no incremental costs or savings will result from this final paragraph. However, given that the final rule in §26.131(a) now requires validity testing of each urine specimen (either validity screening and/or initial validity testing) by each licensee testing facility, compliance with this final paragraph or that of §§26.137(b) or (d) is a new requirement.

Paragraph 26.137(d)

This paragraph of the final rule establishes the quality control requirements that analytical equipment must meet in order to be used to perform initial validity tests and specifies the quality control samples that must be included in each analytical run. The incremental costs of initial validity testing (including quality control measures) are included in the per test cost to conduct initial validity testing, as discussed in connection with §26.131.

Paragraph 26.137(e)

This paragraph of the final rule revises quality control requirements for initial drug tests that are performed at licensee testing facilities, as discussed in §§26.137(e)(1)–(8).

Subparagraph 26.137(e)(1)

There are no incremental costs or savings from this final subparagraph as it clarifies former requirements in Section 2.7(e)(1) in Appendix A to Part 26, which required licensee testing facilities to conduct initial drug tests using an immunoassay meeting the requirements of the Food and Drug Administration (FDA) for commercial distribution. This subparagraph also adds a new provision that prohibits non-instrumented immunoassay testing devices that are pending HHS/Substance Abuse and Mental Health Services Administration (SAMHSA) review and approval from being used for initial drug testing under this part. The subparagraph also adds a provision that licensees and other entities may not take management action against an individual based on any drug test results obtained from non-instrumented devices that may be used for validity screening tests. The new requirements in this subparagraph will result in no incremental costs or savings for licensee testing facilities because the provisions simply prohibit the use of specific analytical equipment and prevent management action based on non-instrumented devices.

Subparagraph 26.137(e)(2)

This subparagraph of the final rule establishes that negative urine specimens must be discarded or pooled for use in the licensee testing facility's internal quality control program, as long as the specimens are certified as drug-negative and valid by an HHS-certified laboratory. The analysis assumes that licensee testing facilities will choose the most cost-effective method of obtaining negative urine specimens to be used as their quality control testing specimens, and that licensee

testing facilities already (1) purchase negative urine specimens directly from a vendor selling HHS-certified drug negative urine or from an HHS-certified laboratory, (2) pool the negative urine specimens analyzed at their testing facility and submit them to an HHS-certified laboratory for testing to certify that they are drug-negative. The final rule will not change these practices, so no incremental costs or savings will result.

Subparagraph 26.137(e)(3)

No incremental cost or saving will result from this final subparagraph as it affords licensee testing facilities the flexibility to conduct multiple initial drug tests for the same drug or drug class, provided that all tests meet the cutoffs and quality control requirements in this part.

Subparagraph 26.137(e)(4)

No incremental cost or saving will result from this final subparagraph, which restates former requirements in Section 2.8(b) in Appendix A to Part 26.

Subparagraph 26.137(e)(5)

This subparagraph of the final rule revises a former requirement in Section 2.8(b) in Appendix A to Part 26, which mandated that each licensee testing facility submit a "sampling" of urine specimens screening negative for drugs from each test run to an HHS-certified laboratory for additional drug testing to ensure that the drug testing process of the licensee testing facility is accurate, with no false negative tests results. This subparagraph revises the former requirement by clarifying that the term "sampling" means a minimum of 5 percent (or at least 1) of the drug test specimens screening negative for drugs from every analytical run. Some FFD programs using onsite licensee testing facilities may realize annual incremental savings resulting from this final rule revision. Licensee testing facilities that submit a sample of negative drug test specimens from each analytical run below the 5 percent maximum level will not be affected by this final subparagraph because current practice already meets the final rule requirement. Even though some onsite licensee testing facilities may be submitting more than 5 percent of negative drug test specimens per analytical run to an HHS-certified laboratory, an accurate estimate on savings is not possible due to a lack of data on current onsite licensee testing facility practices.

Subparagraph 26.137(e)(6)

This subparagraph of the final rule extends to licensee testing facilities the former requirements in Section 2.8(c) in Appendix A to Part 26, which mandated that HHS-certified laboratories must include a minimum of 10 percent of the total number of urine specimens in each analytical run as quality control samples. This subparagraph of the final rule also extends to licensee testing facilities the former requirements in Section 2.8(c) in Appendix A to Part 26, which pertained to the quality control samples that must be included in each analytical run of initial drug tests performed by HHS-certified laboratories. The quality control samples must consist of: (1) specimen(s) certified to contain no drug (i.e., negative urine samples), (2) at least one positive

control with drug(s) or drug metabolite(s) targeted at 25 percent above the cutoff, (3) at least one positive control with drug(s) or drug metabolite(s) targeted at 25 percent below the cutoff, (4) a sufficient number of calibrators to ensure and document the linearity of the assay method over time in the concentration area of the cutoff, and (5) sample(s) that appear to be a donor specimen to the laboratory analysts. With regard to the quality control samples that must be included in each analytical run, this subparagraph imposes no incremental cost because licensee testing facilities are assumed to use appropriate control specimens in each analytical run, as specified by the manufacturer's operating manuals for drug testing equipment. However, the change in the composition of the blind performance testing samples results in an incremental cost per urine specimen analyzed to comply with this final paragraph.

The *annual cost per FFD program with onsite licensee testing facilities* are estimated as follows:

$$(NUM_{specimens} \times COST_{specimen} \times PERI_{cost}) \times NUM_{reactors}$$

Parameter	Description
$NUM_{specimens}$	Number of urine specimens analyzed per reactor per year for FFD programs with onsite licensee testing facilities (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12)
$COST_{specimen}$	Cost per urine specimen to conduct drug testing as specified in the former requirements (as discussed in Appendix 2, Exhibit A2-11)
$PERI_{cost}$	Percentage increase in the average urine specimen analysis cost based on the change in costs to comply with the quality control specimen testing requirements (as discussed in the assumptions below)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of urine specimens analyzed per reactor per year for FFD programs with onsite licensee testing facilities is equivalent to the number of drug tests performed per reactor per year for FFD programs with onsite licensee testing facilities.

- Percentage increase in the average urine specimen analysis cost based on the change in costs to comply with the quality control specimen testing requirements [this includes the increase in costs per blind performance test specimen to comply with the inclusion of adulterated, substituted, dilute and invalid specimens as a part of the percentage of specimens as discussed in §26.167(f) of Subpart G]: 10 percent.

Subparagraph 26.137(e)(7)

This subparagraph of the final rule extends to licensee testing facilities the former requirements in Section 2.8(c) in Appendix A to Part 26, which mandated that (HHS-certified) laboratories must implement procedures to ensure that carryover does not contaminate the testing of a donor's specimen. This subparagraph imposes no incremental cost and affords no savings because it is consistent with existing specimen handling procedures used by licensee testing facilities.

Paragraph 26.137(f)

This paragraph of the final rule clarifies that it is the licensees' responsibility to investigate errors in the testing of quality control samples, the testing of actual specimens, or the processing of management reviews and/or MRO reviews, as well as any other errors or matters that could reflect adversely on the licensees' testing process. The licensees' mandated responsibility also includes taking action to correct errors that are within the licensees' control. This analysis assumes that no incremental costs or savings will result from the final paragraph because licensees were formerly responsible [under a performance standard in Section 2.8(a) in Appendix A to Part 26] for having "a quality assurance program which encompasses all aspects of the testing process."

Paragraph 26.137(g)

There is no incremental cost or saving from this final paragraph as it restates a former rule requirement in Section 2.7(o)(3)(i) in Appendix A to Part 26.

Paragraph 26.137(h)

This paragraph of the final rule clarifies and revises former requirements in Section 2.7(o)(2) in Appendix A to Part 26, which required licensee testing facilities to use "HHS-certified laboratory standards." The final rule relaxes the former requirements by permitting licensee testing facilities to use "stock standard solutions obtained from other laboratories, or standard solutions obtained from commercial manufacturers." This analysis assumes that any incremental saving from this final paragraph will be insignificant.

26.139 Reporting initial validity and drug test results

Paragraph 26.139(a)

No incremental cost or saving is estimated for this final paragraph, which restates without substantive change requirements in §2.7(g)(2) in Appendix A to Part 26, as they relate to drug testing. Paragraph 26.131(a) of the final rule requires validity screening and/or initial validity test results. The new provisions in this paragraph add reporting requirements for negative and questionable validity test results for validity screening and initial validity tests. Except as

permitted under paragraph 26.75(h), licensee testing facilities are prohibited from reporting positive test results from initial drug tests and results from validity screening or initial validity testing to licensee or other entity management. The new provisions in this final paragraph will result in no incremental costs or savings because the provisions prohibit communication of specific types of test results rather than require any specific activity. In addition, because licensee testing facilities already have established communication methods to transmit drug test results to licensee and FFD management, the inclusion of validity test results will result in an no incremental cost or saving.

Paragraph 26.139(b)

This paragraph of the final rule restates without substantive change a former requirement in §26.24(d)(1), which limited access to initial drug test results to licensee testing staff, the MRO, the FFD manager, and EAP personnel (when appropriate). The final rule also permits the SAE to access initial drug test results. No incremental cost or savings will result from the final paragraph because it clarifies who is permitted access to test results.

Paragraph 26.139(c)

No incremental costs or savings will result from this final paragraph which restates the former requirements in Section 2.7(o)(5) in Appendix A to Part 26, which mandated that a licensee testing facility must have qualified personnel available to testify at proceedings against an individual based on urinalysis results.

Paragraph 26.139(d)

This paragraph of the final rule revises the former requirements in Section 2.7(g)(6) in Appendix A to Part 26, which specified that licensee testing facilities must provide a monthly statistical summary of urinalysis data to a licensee official responsible for coordinating the FFD program. The final paragraph only requires that licensee testing facilities must prepare the information required for the annual report that each FFD program must provide to NRC on an annual basis, as discussed in §26.717 of the final rule. Therefore, licensee testing facilities will now prepare the statistical summary of urinalysis data only on an annual basis. Incremental savings will be realized by each FFD program due to the reduction in labor costs associated with the elimination of monthly statistical summary reports. Some of the savings will be offset by the labor costs associated with annual report preparation.

- *Annual savings per FFD program with onsite testing facilities* are estimated as follows:

$$(HOURS_{monthly\ report} \times WAGE_{laboratory\ supervisor} \times NUM_{monthly\ reports} \times NUM_{facilities}) - (HOURS_{annual\ report} \times WAGE_{laboratory\ supervisor} \times NUM_{facilities})$$

Parameter	Description
$HOURS_{monthly\ report}$	Time for a laboratory supervisor per licensee testing facility to prepare a monthly statistical summary report of urinalysis testing data (as discussed in the assumptions below)
$WAGE_{laboratory\ supervisor}$	FFD manager wage rate (as discussed in Appendix 2)
$NUM_{monthly\ reports}$	Number of monthly reports per FFD program per year
$HOURS_{annual\ report}$	Time for a laboratory supervisor per licensee testing facility to prepare an annual statistical summary report of urinalysis testing data (as discussed in the assumptions below)
$NUM_{facilities}$	Number of licensee testing facilities per FFD program (as discussed in Appendix 2)

Assumptions:

- Time for a laboratory supervisor per licensee testing facility to prepare a monthly statistical summary report of urinalysis testing data: 1.5 hours.

- Time per report for a laboratory supervisor to prepare an annual statistical summary report of drug testing data: 4 hours.

Paragraph 26.139(e)

This paragraph of the final rule revises the former requirements in Section 2.7(g)(7) in Appendix A to Part 26, which pertained to the reporting of drug testing results to NRC. Under the former rule, if a licensee conducted drug testing using more stringent cutoff levels than required in 10 CFR Part 26, the licensee had to report the drug test results for the cutoff levels mandated by Part 26, as well as more stringent levels. The final rule relaxes the reporting requirements and only requires licensees to report in the annual report to NRC the drug testing information for either the cutoff levels specified in §26.31(d)(1) or for any more stringent cutoff levels used by the FFD program. In addition, if the licensee tests for additional drugs beyond those specified in §26.31(d)(1), this final paragraph adds a requirement that the annual report also include the number of positive test results and the cutoff levels used for those additional drugs and drug metabolites. No incremental costs or savings are estimated for the final paragraph because licensee testing facilities conducting drug testing using more stringent cutoff levels and/or testing for additional drugs beyond Part 26 requirements already tabulate the necessary testing data under the former rule.

Paragraph 26.139(f)

This paragraph of the final rule adds a new requirement that the designated FFD program official 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. No incremental costs or savings are estimated because this requirement is consistent with current oversight practices of existing FFD programs.

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

26.151 Purpose

This section of the final rule imposes no incremental cost and affords no saving because it merely states that the purpose of this Subpart is to present requirements pertaining to HHS-certified laboratories used by licensees and C/Vs for specimen validity and drug testing.

26.153 Using certified laboratories for testing urine specimens

Paragraph 26.153(a)

This paragraph of the final rule revises former requirements in § 26.24(f) and Sections 1.1(3), 2.7(l)(1), and 4.1(a) in Appendix A to Part 26, which authorized licensees to use only HHS-certified laboratories to perform urine drug testing, except for initial drug tests conducted at a licensee's testing facility as permitted by § 26.24(d)(2). This final paragraph only authorizes the use of HHS-certified laboratories that have the capability at the same location to perform drug testing and specimen validity testing except for initial drug and validity testing that may be performed at a licensee's testing facilities, as allowed by § 26.31(d)(3)(ii). These requirements impose no incremental cost and afford no saving because HHS-certified laboratories are already qualified to conduct validity testing (the incremental costs associated with validity testing are discussed in § 26.161(b)(1)-(5)).

Paragraph 26.153(b)

This paragraph of the final rule revises former requirements in Section 2.7(l)(2) in Appendix A to Part 26, which directed licensees to use only HHS-certified laboratories that had the capability at the same location to conduct both initial and confirmatory testing for the drugs required in Part 26. The final paragraph requires that HHS-certified laboratories must also have the capability to perform initial and confirmatory tests for specimen validity. These requirements impose no incremental cost and afford no saving because HHS-certified laboratories already have this capability and have been conducting validity testing for U.S. DOT-regulated entities.

Paragraph 26.153(c)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 2.7(k) in Appendix A to Part 26, which prohibited HHS-certified laboratories from subcontracting work unless authorized by the licensee. This paragraph clarifies that this restriction also applies to HHS-certified laboratories used by other entities who have licensee approved FFD programs.

Paragraph 26.153(d)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 4.1(b) in Appendix A to Part 26, which pertained to the use of HHS-certified laboratories when conducting drug testing beyond Part 26 requirements.

Paragraph 26.153(e)

This paragraph of the final rule clarifies and amends former requirements in Section 2.7(m) in Appendix A to Part 26, which required licensees to conduct a pre-award inspection and evaluation of the procedural aspects of a laboratory's drug testing operation before awarding a contract to the laboratory. The final paragraph clarifies that pre-award inspections and evaluations must be conducted by qualified personnel. Also, the final paragraph adds a provision allowing licensees to immediately begin using the services of a second HHS-certified laboratory without first conducting a pre-award inspection if the licensee's first laboratory loses its certification and the second laboratory is already conducting drug and validity testing for another licensee or other entity subject to 10 CFR Part 26. Incremental savings will result from the elimination of pre-award inspection and evaluation costs for FFD programs that need to replace a decertified laboratory with a new HHS-certified laboratory that is already in use by another FFD program.

The *annual savings per FFD program* are estimated as follows:

$$HOURS_{inspection} \times WAGE_{FFD\ manager} \times PER_{decertification} \times PER_{known\ HHS\ lab}$$

Parameter	Description
$HOURS_{inspection}$	Hours per pre-award inspection of an HHS-certified laboratory conducted by licensee personnel or a designee (as discussed in the assumptions below)
$WAGE_{FFD\ manager}$	FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11)
$PER_{decertification}$	Percentage of FFD programs that must change to a new HHS-certified laboratory per year because their current HHS-certified laboratory loses its certification (as discussed in the assumptions below)
$PER_{known\ HHS\ lab}$	Percentage of instances in which a replacement HHS-certified laboratory is being used by another FFD program (also identified in this analysis as a "known" HHS lab) (as discussed in the assumptions below)

Assumptions:

- Hours per pre-award inspection: 100 hours, assumed to be the FFD manager.
- Each FFD program only contracts with one HHS-certified laboratory for testing services.

- Percentage of FFD programs that must change to a new HHS-certified laboratory per year because their current HHS-certified laboratory loses its HHS-certification or withdraws from the certification program: 10 percent.

- Percentage of instances in which a replacement HHS-certified laboratory is already in use by another FFD program (also identified in this analysis as "known" HHS-certified laboratory): 50 percent.

Paragraph 26.153(f)

This paragraph of the final rule restates former requirements in Section 2.7(m) in Appendix A to Part 26, which mandated that licensees require their HHS-certified laboratories to implement and comply with all applicable requirements in Part 26.[1] The final subparagraphs specify the minimum contractual terms between a licensee or C/V and their HHS-certified laboratory as discussed below:

- Subparagraph 26.153(f)(1) restates former requirements in Section 2.7(l)(1) in Appendix A to Part 26.

- Subparagraph 26.153(f)(2) clarifies former requirements in Section 2.7(o)(5) in Appendix A to Part 26.

- Subparagraph 26.153(f)(3) clarifies former requirements in Section 3.1 in Appendix A to Part 26.

- Subparagraph 26.153(f)(4) clarifies former requirements in Section 3.2 in Appendix A to Part 26.

- Subparagraph 26.153(f)(6) clarifies former requirements in Section 2.7(m) in Appendix A to Part 26.

Paragraph 26.153(f) of the final rule also adds one new contract term as discussed below:

- Subparagraph 26.153(f)(5) prohibits HHS-certified laboratories from entering into any relationships with a licensee's or other entity's MRO when such relationships may be construed as potential conflicts of interest. Although this is a new requirement, it is consistent with ethical business practices and Section 2.4(g)(6) in the HHS Guidelines (April 13, 2004). Consequently, although programs may incur an incremental cost to

[1] HHS-certified laboratories will pass on the costs associated with specific rule revisions to licensees through increased specimen testing costs. The analysis accounts for these incremental costs associated with implementation of validity testing requirements in § 26.131(a) and § 26.161(b), the most significant testing change in the final rule.

revise certain contracts to incorporate the new provision, such costs would fall only on programs with contracts that (a) do not already contain such a provision, and (b) will not update themselves automatically by incorporating the NRC provisions "by reference." The analysis assumes that any costs resulting from this provision are reflected within the legal and managerial costs calculated for § 26.27(a).

Paragraph 26.153(g)

This paragraph of the final rule adds a requirement that licensees and other entities must provide their HHS-certified laboratory with an explanatory memorandum for the record in situations where a non-Federal custody-and-control form is used for a specimen collection. The memorandum must describe why the form is being used and must state that the form contains all information required in the Federal custody-and-control form. Incremental costs per FFD program result from the labor costs of collection site personnel to write each memorandum.

The *annual costs per FFD program* are estimated as follows:

$$[NUM_{memoranda} \times (HOURS_{collector} \times WAGE_{collector})] \times NUM_{facilities}$$

Parameter	Description
$NUM_{memoranda}$	Number of memoranda per year a collection site used by a facility will write because it uses a non-Federal custody-and-control form for a specimen collection (as discussed in the assumptions below)
$HOURS_{collector}$	Time for collection staff to draft a memorandum(as discussed in the assumptions below)
$WAGE_{collector}$	Wage of collection site personnel (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{facilities}$	Number of facilities per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of memoranda per year a collection site used by a facility will write because it uses a non-Federal custody-and-control form for a specimen collection: 2.

- Time for collection staff to draft a memorandum: 15 minutes.

26.155 Laboratory personnel

Paragraph 26.155(a)

The final paragraph restates without substantive change a former requirement in Section 2.5(a)(1) in Appendix A to Part 26. The final rule replaces the term "qualified individual" used in the former rule with the term "responsible person." Subparagraphs (a)(1)–(6)

in the final rule restate the former requirements in Sections 2.5(a)(2)–(7) in Appendix A to Part 26 that defined the qualifications and responsibilities of the individual responsible for the HHS-certified laboratory's testing facility. Therefore, this final paragraph imposes no incremental costs and affords no savings.

Paragraph 26.155(b)

This paragraph of the final rule revises a former requirement in Section 2.5(b) in Appendix A to Part 26, which described the "qualified individual who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports." The final paragraph introduces the term "certifying scientist" to clarify the term "qualified individual" used in the former rule. The final rule also establishes the qualifications for a certifying scientist. No incremental costs or savings are expected to result from this final paragraph because the qualifications for a certifying scientist are consistent with existing HHS-laboratory personnel qualification requirements.

Paragraph 26.155(c)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 2.5(c) in Appendix A to Part 26.

Paragraph 26.155(d)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 2.5(d) in Appendix A to Part 26.

Paragraph 26.155(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 2.5(e) in Appendix A to 10 CFR Part 26.

Paragraph 26.155(f)

This paragraph of the final rule simplifies former requirements in Section 2.5(f) in Appendix A to Part 26, which mandated that laboratory personnel files must include: "resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds . . ." Under the final paragraph, personnel files will no longer need to include: references, referrals, and incident reports, but must still 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." Even though the

final paragraph represents a relaxation of the former recordkeeping requirements applicable to HHS-certified laboratories, the analysis assumes that laboratories will not alter their file maintenance practices (and will not incur savings) because businesses commonly maintain the aforementioned documents that are no longer required.

26.157 Procedures

Paragraph 26.157(a)

This paragraph of the final rule revises former requirements in Section 2.2 in Appendix A to Part 26, which pertained to the maintenance and documentation of procedures for collecting, shipping, and accessing urine specimens. The final rule clarifies that the HHS-certified laboratory must also maintain procedures for receiving and testing specimens. The final paragraph imposes no incremental cost and affords no saving because it is consistent with the procedures and practices of existing HHS-laboratories.

Paragraph 26.157(b)

This paragraph of the final rule revises former requirements in Section 2.7(a)(2) in Appendix A to Part 26, which pertained to the content and implementation of specimen chain-of-custody procedures for HHS-certified laboratories. The final rule adds a provision that the HHS-certified laboratory must have written chain-of-custody procedures for shipping specimens to another HHS-certified laboratory. The final paragraph imposes no incremental cost and affords no saving because the new requirement is consistent with the existing specimen chain-of custody procedures used by HHS-certified laboratories.

Paragraph 26.157(c)

The final paragraph revises former requirements in Section 2.7(o)(1) in Appendix A to Part 26, which required that each HHS-certified laboratory maintain a "procedure manual." The final paragraph clarifies that HHS-certified laboratories must develop, implement, and maintain a "written standard operating procedures manual." The revision imposes no incremental costs or savings because it restates without substantive change former requirements.

Paragraph 26.157(d)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change a former requirement in Section 2.7(o)(3)(iii) in Appendix A to Part 26.

Paragraph 26.157(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 2.7(o)(4) in Appendix A to Part 26, which mandated that licensee testing facilities develop, implement, and maintain procedures for remedial actions if systems do not meet acceptable limits or errors are detected.

26.159 Assuring specimen security, chain of custody, and preservation

Paragraph 26.159(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements in §2.7(a)(1) in Appendix A to Part 26, which pertained to laboratory security. This final paragraph provides added flexibility to security requirements by enumerating individuals who are permitted to be unescorted in an HHS-certified laboratory (e.g., personnel conducting inspections and audits on behalf of licensees, other entities, the NRC, the Secretary of the DHHS, and emergency personnel).

Paragraph 26.159(b)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.7(b)(1) in Appendix A to Part 26. The final rule also requires each licensee to investigate possible specimen tampering and take corrective actions when necessary. If there is a reason to believe that the integrity or identity of a specimen is in question, the specimen is not to be tested and the licensee or C/V must ensure that another collection occurs as soon as reasonably practicable. The final rule adds a provision that another collection is not required if either bottle from a split specimen collection remains intact and contains at least 15 mL of urine. In this case, the split specimen must be sent to the HHS-certified laboratory for testing. The final rule also specifies exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen. The analysis estimates that these final provisions will impose no incremental costs and afford no savings because the requirements are consistent with existing licensee practices, and because of the infrequent occurrence of specimen tampering events.

Paragraph 26.159(c)

This paragraph of the final rule revises former requirements in Section 2.7(b)(2) in Appendix A to Part 26, which pertained to the handling of urine specimens at HHS-certified laboratories and the use of internal custody and control forms. The final rule clarifies that laboratory chain-of-custody forms must be used while conducting initial and confirmatory testing of aliquots of an original urine specimen. The final rule also establishes that the original specimen and original specimen custody-and-control form must remain in secure storage. This final paragraph will impose no incremental cost and affords no saving because it is consistent with the existing urine specimen handling and storage practices of HHS-certified laboratories.

Paragraph 26.159(d)

This paragraph of the final rule revises former requirements in Section 2.7(a)(2) in Appendix A to Part 26, which pertained to the use of internal custody and control forms by HHS-certified laboratories. The final rule expands the required information contained on the laboratory custody-and-control form to now include the identity of the donor. Adding this information to the custody-and-control form will not result in any incremental costs.

Paragraph 26.159(e)

This paragraph of the final rule restates without substantive change former requirements in Section 2.7(a)(2) in Appendix A to Part 26, which pertained to completing the custody-and-control form each time a specimen is handled or transferred within the laboratory. The final paragraph imposes no incremental cost and affords no saving because the requirements are believed to be consistent with existing specimen chain-of-custody procedures used by HHS-certified laboratories.

Paragraph 26.159(f)

The final paragraph revises former requirements in Section 2.4(d) in Appendix A to Part 26, which pertained to specimen chain of custody procedures. This final paragraph also extends to HHS-certified laboratories the specimen packaging and shipping requirements in former Section 2.4(i) in Appendix A to Part 26, which only applied to collection sites. The final paragraph imposes no incremental cost and affords no saving because it is consistent with current HHS-certified laboratory practices.

Paragraph 26.159(g)

This paragraph of the final rule clarifies that couriers, express carriers, and postal service personnel do not have access to the custody-and-control forms or to the specimen bottles and, therefore, are not required to document chain-of-custody on the custody and control form of a urine specimen in transit. However, this paragraph adds a new requirement that the custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service. The final paragraph imposes no incremental cost and affords no saving because it describes existing courier, express carrier, and postal service specimen shipping practices.

Paragraph 26.159(h)

The final paragraph imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 2.7(c) in Appendix A to Part 26, which pertained to short-term refrigeration storage procedures of urine specimens.

Paragraph 26.159(i)

This paragraph of the final rule revises former requirements in Section 2.7(h) in Appendix A to Part 26, which specified long-term storage requirements for positive urine specimens so that they can be made available for any necessary retesting. The final paragraph adds specimens with adulterated, substituted, and invalid test results to those that already must be stored for possible further testing. The analysis assumes that the storage costs for any additional urine specimens that must be retained by the HHS-laboratory as a result of validity test results will be accounted for in the per test cost that an HHS-certified laboratory charges each licensee. Therefore, any incremental cost resulting from the final paragraph are captured in the new validity test costs estimated in connection with §§ 26.131 and 26.161(b)(1)-(5) of the final rule.

Paragraph 26.159(j)

This paragraph of the final rule establishes a new requirement that specimens testing negative on initial or confirmatory drug testing be discarded or may be pooled for use in the HHS-certified laboratory's internal quality control program, unless validity testing indicates that the specimen is invalid. The paragraph also adds a new provision that the laboratory may not retain any information linking donors to specimens pooled for use in the internal quality control program. The final paragraph imposes no incremental cost and affords no saving because it is consistent with current practices of HHS-certified laboratories.

26.161 Cutoff levels for validity testing

Paragraph 26.161(a)

This paragraph of the final rule establishes that each initial validity test must be performed on one aliquot of a donor's urine specimen. 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 specified by the licensee's or other entity's testing program. To report an adulterated, substituted, dilute, or invalid test result, a confirmatory validity test must be performed on a second aliquot of the donor's urine specimen. All costs associated with validity testing are considered to be incremental[2] because validity testing is a new regulatory provision. Incremental costs associated with validity testing are discussed in connection with § 26.161(b)(1)-(5).

[2] By assuming that no licensees currently conduct validity testing, the analysis overstates the incremental costs to be incurred by FFD programs as a result of the validity testing provisions. This assumption is necessary, however, because of the lack of available data regarding the types of validity testing being conducted throughout the industry.

Paragraph 26.161(b)

Subparagraphs 26.161(b)(1)-(5)

These subparagraphs of the final rule establish initial validity testing requirements, including the types of initial tests to be performed (creatinine, pH, adulterants) and the specific criteria to determine whether a specimen may be adulterated, substituted, dilute, or invalid, and thus, require confirmatory validity testing. The analysis accounts for validity testing costs under this requirement based on a per specimen testing cost at HHS-certified laboratories (i.e., initial validity testing or initial and confirmatory validity testing have the same cost).

The regulatory analysis calculates under these subparagraphs not only the costs related to conducting initial and confirmatory validity testing, but also the subsequent costs for some specimens to receive initial and confirmatory drug testing, and the associated costs resulting from confirmed adulterated or substituted validity and/or positive drug test results (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen). Even though many of these costs are directly related to other provisions, as referenced below, this approach consolidates the series of actions that are initiated under § 26.161(b)(1)-(5), allowing for a unified (hence clearer) presentation of related actions and a simpler analysis.

FFD programs using HHS-certified laboratories for all drug testing will incur a per specimen incremental cost to conduct validity testing, as well as the labor costs of MRO and FFD personnel for administrative activities for confirmed positive drug test results and/or confirmed adulterated or substituted validity test results, the costs of retesting some specimens with confirmed drug positive, adulterated, substituted, or invalid test results at the donor's request (MRO's request for invalid specimens), and the costs of the appeals process for some drug positive, adulterated, or substituted test results that donors choose to contest. In addition, because HHS certified laboratory testing procedures and required licensee actions vary based on the type of confirmatory validity test result (e.g., dilute, invalid), the analysis discusses the costs for each validity test result type separately (designated below as "Results A, B, and C")

- "Result A": adulterated and substituted specimens
- "Result B": dilute specimens
- "Result C": invalid specimens

Annual costs per FFD program that conducts all drug testing (and validity testing) at an HHS-certified laboratory are estimated as follows:[3]

- Cost to conduct validity testing (initial and confirmatory when necessary) at an HHS-certified laboratory:

  $NUM_{validity} \times COST_{HHS\ validity\ testing} \times NUM_{reactors}$

- Additional testing may be required based on specific confirmatory validity test results, as described by the following result cases (Results A, B, and C).

  - Result A: Specimens with HHS-certified laboratory confirmatory validity test results of adulterated or substituted (creatinine concentration less than 2 mg/dL). No additional testing procedures.

  - Result B: Specimens with HHS-certified laboratory confirmatory validity test results of dilute. Additional costs include confirmatory drug testing to the limit of detection (LOD) for some specimens.[4] The costs include the following:

    $NUM_{validity} \times PER_{dilute} \times COST_{HHS\ LOD\ testing} \times NUM_{reactors}$

  - Result C: Specimens with HHS-certified laboratory confirmatory validity test results of invalid. Additional costs include collecting a second urine specimen under direct observation, as specified in § 26.185(f)(3) of the final rule, and then validity and drug testing the second specimen at an HHS-certified laboratory. The costs include the following:

    $NUM_{validity} \times PER_{invalid} \times [(COST_{2nd\ collection} + COST_{HHS\ validity\ \&\ drug\ testing})] \times NUM_{reactors}$

- Cost of subsequent actions for all adulterated, substituted, dilute, or invalid validity test results and positive drug test results identified because of the validity testing requirements in §26.161(b) and §26.185(f)(3) (sum of adulterated, substituted, dilute, and invalid validity test results and positive drug tests from Results A, B, and C). FFD programs may also incur costs associated with some donors requesting testing of their split specimen and/or some donors appealing their positive, adulterated, or substituted validity and/or drug test results.

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[3] Incremental costs associated with validity testing for FFD programs using onsite licensee testing facilities are discussed in connection with § 26.131.

[4] Paragraph 26.163(a)(2) of the final rule permits FFD programs to require confirmatory LOD drug testing for any drug with an initial drug test result equal to or greater than 50 percent of the cutoff calibrator.

- Cost for actions subsequent to confirmed adulterated or substituted validity, and/or positive drug (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen) test results

  $(NUM_{validity} \times [(PER_{adulterated} + PER_{substituted}) + (PER_{dilute} \times PER_{positive\ at\ LOD}) + (PER_{invalid} \times PER_{drug\ positive\ 2^{nd}\ collection})] \times COST_{subsequent\ actions}) \times NUM_{reactors}$

- When requested by some donors, the cost of retesting specimens with confirmed adulterated or substituted validity, and/or positive drug (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen) test results at a second HHS-certified laboratory

  $(NUM_{validity} \times [(PER_{adulterated} + PER_{substituted}) + (PER_{dilute} \times PER_{positive\ at\ LOD}) + (PER_{invalid} \times PER_{drug\ positive\ 2^{nd}\ collection})] \times PER_{retest} \times COST_{retest}) \times NUM_{reactors}$

- When requested by some donors, the cost of the appeals process for confirmed adulterated or substituted validity and/or positive drug test results (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen)

  $NUM_{validity} \times [(PER_{adulterated} + PER_{substituted}) + (PER_{dilute} \times PER_{positive\ at\ LOD}) + (PER_{invalid} \times PER_{drug\ positive\ 2^{nd}\ collection})] \times PER_{appeal} \times [(HOURS_{FFD\ manager} \times WAGE_{FFD\ manager}) + HOURS_{Worker} \times WAGE_{Worker})] \times NUM_{reactors}$

Parameter	**Description**
$NUM_{validity}$	Number of validity tests per reactor per year (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12)
$COST_{HHS\ validity\ testing}$	Incremental cost per urine specimen to conduct validity testing (initial validity test and confirmatory validity test when necessary) at an HHS-certified laboratory (as discussed in the assumptions below)
PER_{dilute}	Percentage of urine specimens with validity test results of dilute (as discussed in Appendix 2, Exhibit A2-12)
$COST_{HHS\ LOD\ testing}$	Cost per specimen to conduct initial drug testing and confirmatory drug testing to the level of detection (LOD) for drug(s) identified during initial testing, as permitted by § 26.163(a)(2) of the final rule (as discussed in Appendix 2, Exhibit A2-13)
$PER_{invalid}$	Percentage of urine specimens with validity test results of invalid (as discussed in Appendix 2, Exhibit A2-12)

Parameter	Description
$COST_{2nd\ collection}$	Cost of collecting a second urine specimen under direct observation from a donor with a confirmatory validity test result of invalid for the initial urine specimen collected. The cost of the second collection includes the labor for the donor's travel time to and from the collection site, donor's time spent at the collection site, as well as the labor of the collector (as discussed in Appendix 2, Exhibit A2-13)
$COST_{HHS\ validity\ \&\ drug\ testing}$	Cost per specimen to conduct initial drug and initial validity testing at an HHS-certified laboratory, as well as confirmatory drug and/or validity testing when necessary (as discussed in Appendix 2, Exhibit A2-13)
$PER_{adulterated}$	Percentage of urine specimens with validity test results of adulterated (as discussed in Appendix 2, Exhibit A2-12)
$PER_{substituted}$	Percentage of urine specimens with validity test results of substituted (less than 2 mg/dL creatinine) (as discussed in Appendix 2, Exhibit A2-12)
$PER_{positive\ LOD}$	Percentage of dilute specimens that test positive for drug(s) at LOD testing (as discussed in the assumptions below)
$PER_{drug\ positive\ 2nd\ collection}$	Percentage of specimens collected under direct observation as a result of an initial specimen with a confirmatory validity test result of invalid that test positive for drugs (as discussed in the assumptions below)
$COST_{subsequent\ actions}$	Labor costs associated with MRO and FFD program personnel activities and administrative actions resulting from a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result (as discussed in Appendix 2, Exhibit A2-13)
PER_{retest}	Percentage of urine specimens with confirmed positive, adulterated, substituted, dilute, or invalid validity and/or drug test results retested at the request of the donor at a second HHS-certified laboratory (as discussed in the assumptions below)
$COST_{retest}$	Cost of specimen retesting at a second HHS-certified laboratory, including specimen preparation and shipping costs (as discussed in Appendix 2, Exhibit A2-13)
PER_{appeal}	Percentage of confirmed adulterated and substituted validity test results and positive drug test results appealed by some donors (as discussed in the assumptions below)
$HOURS_{FFD\ manager}$	Average amount of FFD manager time per appeal for a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result appealed by some donors (as discussed in the assumptions below)
$WAGE_{FFD\ manger}$	FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11)

Parameter	Description
$HOURS_{Worker}$	Average amount of worker time per appeal of a confirmed adulterated or substituted validity test result and/or positive drug test result (as discussed in the assumptions below)
$WAGE_{Worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of validity tests per reactor per year is equivalent to the number of drug tests conducted by each reactor per year.

- Each FFD program contracting with an HHS-certified laboratory to conduct all drug and validity testing of urine specimens will pay a fixed cost per specimen, which will account for initial drug and validity testing and confirmatory drug and validity testing when necessary.[5]

- All FFD programs choose to test dilute specimens according to the optional provisions in § 26.163(a)(2). That is, any specimen with an initial drug test result equal to or greater than 50 percent of the cutoff calibrator will receive confirmatory LOD drug testing.

- Percentage of dilute specimens that test positive for drug(s) at LOD testing: 33 percent.

- All urine specimens that test as adulterated, substituted (< 2 mg/dL creatinine), or invalid on initial validity testing, remain adulterated, substituted, and invalid after confirmatory validity testing.

- For all urine specimens with validity test results of invalid, the analysis assumes that a second specimen is collected under direct observation.

[5] Some HHS-certified laboratories may not charge licensees to conduct initial and confirmatory validity testing, given the other tests that are being performed. However, to be conservative, the analysis assumes that a validity test at an HHS-certified laboratory will cost $1.50.

- Percentage of specimens collected under direct observation as a result of an initial specimen with a confirmatory validity test result of invalid that test positive for drugs: 33 percent.[6]

- Percentage of urine specimens with confirmed positive drug, and/or adulterated or substituted validity test result retested at the request of the donor at a second HHS-certified laboratory: 5 percent.

- Percentage of confirmed positive, adulterated, and substituted validity and drug test results appealed by some donors: 1 percent.

- Average amount of FFD manager time per appeal process for a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result: 12.5 hours.

- Average amount of worker time per appeal process for a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result appealed by some donors: 2.0 hours.

Paragraphs 26.161(c), (d), (e), and (f)

The final paragraphs establish the analytical test result thresholds, which indicate that a urine specimen is adulterated, substituted, dilute, or invalid. The incremental costs associated with validity testing are discussed in connection with §§ 26.131 and 26.161(b)(1)-(5).

Paragraph 26.161(g)

This paragraph of the final rule adds a new requirement that if a urine specimen is suspected of containing an unidentified interfering substance or adulterant that could make a validity test invalid, the HHS-certified laboratory must consult with the licensee's or other entity's MRO to obtain instruction as to whether to send the specimen to a second HHS-certified laboratory that has the capability to identify the suspected substance or adulterant.

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[6] A second specimen is collected under direct observation for donors that have an initial specimen with an invalid test result to reduce the probability that their second specimen will be altered (e.g., use of adulterants) and therefore, the drug use that was attempted to be masked during the initial specimen donation will more likely be detected in the second specimen collected. (Note: the analysis assumes that if the MRO chooses to retest the initial invalid specimen at a second HHS-certified laboratory, the second laboratory will be unable to identify what is causing the specimen result to be invalid and a second specimen collection under direct observation would commence.)

The *annual costs per FFD program* are estimated as follows:

$$NUM_{new\ adulterant} \times [COST_{retest} + (HOURS_{MRO} \times WAGE_{MRO})] \times NUM_{facilities}$$

Parameter	Description
$NUM_{new\ adulterant}$	Number of urine specimens per facility per year that are suspected of having a new adulterant or interfering agent that could make a test result invalid and the MRO decides to send to a second HHS-certified laboratory for additional validity testing (as discussed in the assumptions below)
$COST_{retest}$	Cost per specimen to conduct validity retesting at a second HHS-certified laboratory, including specimen preparation and shipping costs (as discussed in Appendix 2, Exhibit A2-13)
$HOURS_{MRO}$	Time per specimen for an MRO to speak with the HHS-certified laboratory and determine whether a specimen is to be retested at a second HHS-certified laboratory, and the time to review the results of validity testing at the second HHS-certified laboratory (as discussed in the assumptions below)
$WAGE_{MRO}$	MRO wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{facilities}$	Number of facilities per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of urine specimens per facility per year that are suspected of having a new adulterant or interfering agent that could make a test result invalid and the MRO decides to send to a second HHS-certified laboratory for additional validity testing: 1.

- Time per specimen for an MRO to speak with the HHS-certified laboratory and determine whether a specimen is to be retested at a second HHS-certified laboratory, and the time to review the results of validity testing at the second HHS-certified laboratory: 30 minutes.

- MRO chooses to retest all specimens that are suspected of containing adulterants or interfering agents that could make a test result invalid.

Paragraph 26.161(h)

The final paragraph imposes no incremental cost and affords no saving because it prohibits licensees and C/Vs from using validity testing cutoff levels that are more stringent than those specified in Part 26. The costs associated with validity testing are discussed in connection with §§ 26.131 and 26.161(b)(1)-(5) of the final rule.

26.163 Cutoff levels for drugs and drug metabolites

Subparagraph 26.163(a)(1)

This subparagraph revises former requirements in Section 2.7(e)(1) in Appendix A to Part 26, which pertained to the initial cutoff levels for drugs and drug metabolites (marijuana, cocaine, opiates, phencyclidine, amphetamines). The final rule will lower the initial cutoff level for marijuana metabolites from 100 ng/mL to 50 ng/mL. FFD programs conducting initial drug testing at HHS-certified laboratories will incur annual incremental costs attributable to the more stringent cutoff testing level, which will increase the number of positive drug tests for marijuana. The additional costs will consist of labor costs for the MRO and FFD personnel activities resulting from confirmed positive drug test results, the costs of retesting specimens at a second HHS-certified laboratory at the request of some donors, and the costs of the appeals process for some positive test results that donors choose to contest. The final rule will also raise the initial cutoff level for opiate metabolites from 300 ng/mL to 2,000 ng/mL. FFD programs conducting initial drug testing at HHS-certified laboratories will realize annual incremental savings resulting from the less stringent cutoff level, which will significantly reduce the number of positive opiate drug tests that MROs will ultimately verify as negative. Incremental savings will result from eliminating labor costs associated with the MRO and FFD personnel activities as a result of fewer confirmed positive drug test results, savings associated with fewer donors requesting retesting of their specimen at a second HHS-certified laboratory, and the savings from fewer appeals for some positive drug test results that donors choose to contest.

Annual costs per FFD program using HHS-certified laboratories for initial drug testing for additional confirmed positive marijuana drug test results are estimated as the sum of the following:

- Cost for actions subsequent to additional positive confirmatory marijuana drug test results:

  $(NUM_{marijuana} \times PERI_{marijuana} \times COST_{subsequent\ actions}) \times NUM_{reactors}$

- Cost for retesting specimens with confirmed positive marijuana drug test specimens at a second HHS-certified laboratory at the request of some donors:

  $(NUM_{marijuana} \times PERI_{marijuana} \times PER_{retest} \times COST_{retest}) \times NUM_{reactors}$

- Cost of appeals process for confirmed positive marijuana test results that some donors choose to contest:

  $(NUM_{marijuana} \times PERI_{marijuana} \times PER_{appeal}) \times [(HOURS_{FFD\ manager} \times WAGE_{FFD\ manager}) + HOURS_{worker} \times WAGE_{worker})] \times NUM_{reactors}$

Annual savings per FFD program using HHS-certified laboratories for initial drug testing for fewer confirmed positive opiate drug tests are estimated as the sum of the following:

- Saving from fewer specimens with positive confirmatory opiate drug test results:

  $(NUM_{opiate} \times PERD_{opiate} \times COST_{subsequent\ actions}) \times NUM_{reactors}$

- Saving from fewer positive opiate drug test specimens retested at another HHS-certified laboratory at the request of some donors:

  $(NUM_{opiate} \times PERD_{opiate} \times PER_{retest} \times COST_{retest}) \times NUM_{reactors}$

- Saving from fewer appeals for confirmed positive opiate drug test results that some donors choose to contest:

  $(NUM_{opiate} \times PERD_{opiate} \times PER_{appeal}) \times [(HOURS_{FFD\ manager} \times WAGE_{FFD\ manager}) + HOURS_{worker} \times WAGE_{worker})] \times NUM_{reactors}$

Parameter	**Description**
$NUM_{marijuana}$	Number of confirmed marijuana positive drug test results under the former rule per reactor per year (as discussed in Appendix 2, Exhibit A2-12)
$PERI_{marijuana}$	Percentage increase in positive marijuana drug test results due to the more stringent cutoff level in the final rule (as discussed in the assumptions below)
$COST_{subsequent\ actions}$	Labor costs associated with MRO and FFD program personnel activities and administrative actions resulting from a confirmatory positive drug test result (as discussed in Appendix 2, Exhibit A2-13)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)
PER_{retest}	Percentage of urine specimens with confirmed positive drug test results which the donors request specimen retesting at a second HHS-certified laboratory (as discussed in the assumptions below)
$COST_{retest}$	Cost of specimen retesting at a second HHS-certified laboratory, including specimen preparation and shipping costs, per specimen (as discussed in Appendix 2, Exhibit A2-13)
PER_{appeal}	Percentage of confirmed positive drug test results appealed by some donors (as discussed in the assumptions below)
$HOURS_{FFD\ manager}$	Average amount of FFD manager time per appeal of a confirmed positive validity test result (as discussed in the assumptions below)
$WAGE_{FFD\ manager}$	FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11)
$HOURS_{worker}$	Average amount of worker time per appeal of a confirmed positive drug test result (as discussed in the assumptions below)

Parameter	Description
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
NUM_{opiate}	Number of confirmed positive opiate drug test results under the former rule per reactor per year (as discussed in Appendix 2, Exhibit A2-12)
$PERD_{opiate}$	Percentage decrease in positive opiate drug test results due to the higher cutoff level in the final rule (as discussed in the assumptions below)

Assumptions:

- Percentage increase in positive marijuana drug test results due to the more stringent cutoff level in the final rule: 40 percent.[7]

- Percentage of urine specimens with confirmed positive drug test results which the donors request specimen retesting at a second HHS-certified laboratory (as discussed in the assumptions below): 5 percent.

- Percentage decrease in positive opiate drug test results due to the higher cutoff level in the final rule: 75 percent.[8]

- Changing the cutoff thresholds for marijuana and opiates will not result in a change in assay costs and will not require upgrading testing facility equipment because HHS-certified laboratories currently conduct testing to the cut-off levels for DOT regulated entities covered by 49 CFR Part 40.

- Percentage of confirmed positive drug test results appealed by some donors: 1 percent.

- Average amount of FFD manager time per appeal of a confirmed positive drug test result: 12.5 hours.

- Average amount of worker time per appeal of a confirmed positive drug test result: 2.0 hours.

[7] When U.S. DOT changed the marijuana metabolite cutoff level from 100 ng/mL to 50 ng/mL, HHS-certified laboratories experienced an increase in the number of positive marijuana test results from 25 to 40 percent. Several licensees currently test for marijuana metabolites at the 50 ng/mL cutoff level, as required in the final rule. One licensee reported 49 additional positive test results over a 2½-year period (an increase of 57 percent over the 100 ng/ml cutoff level).

[8] Relaxing the initial cutoff level for opiate metabolites will almost entirely eliminate the false positive issue associated with consuming poppy seeds and, unless an individual consumes large prescribed doses of codeine-based cough syrup or other cold prescriptions, the threshold will significantly reduce the number of tests that screen positive for opiates as a result of legitimate use of prescribed cold and cough prescriptions.

Subparagraph 26.163(a)(2)

This subparagraph establishes that a licensee or other entity may require the HHS-certified laboratory to conduct special analyses on dilute specimens. The subparagraph states that if the initial validity test result of a urine specimen is dilute, the licensee or other entity has the option to require the laboratory to compare the quantitative test results for each drug tested to the cutoff calibrator in each drug class. If the initial test result for any drug is equal to or greater than 50 percent of the cutoff, the laboratory must conduct confirmatory testing to the LOD for the drug(s) and/or drug metabolites. These incremental costs are estimated and discussed in connection with §§ 26.131 and 26.161(b)(1)-(5).

Paragraph 26.163(b)

This paragraph revises former requirements in Section 2.7(f)(2) in Appendix A to Part 26, which pertained to the cutoff levels for confirmatory drug testing. The final rule will increase the cutoff levels used in confirmatory tests for morphine and codeine from 300 ng/mL to 2,000 ng/mL. The final paragraph will also establish a cutoff level of 10 ng/mL for 6-acetylmorphine, which is to be evaluated for specimens in which morphine is detected at or above the 2,000 ng/mL cutoff level. The incremental costs of the final rule changes are estimated and discussed in connection with §§ 26.133 and 26.163(a)(1) and include additional confirmed positive marijuana drug test results and fewer positive opiate drug test results.

26.165 Testing split specimens and retesting single specimens

Paragraph 26.165(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely restates without substantive change former requirements in Section 2.7(j) in Appendix A to Part 26, which pertain to the split specimen testing procedures for Bottles A and B of a urine specimen, based on whether the licensee testing facility or HHS-certified laboratory analyzed the specimen in Bottle A.

Paragraph 26.165(b)

This paragraph of the final rule establishes a new provisions that permits a donor from an FFD program that does not follow split specimen collection procedures to request (through the MRO) a retest of an aliquot of a single specimen with a confirmed positive, adulterated, or substituted test result (provided the specimen quantity is 30 mL or more and the specimen is not invalid). This paragraph also restates former requirements in Section 2.7(j) in Appendix A to Part 26, which permitted testing of a split specimen with a confirmed positive drug test result for the initial specimen tested. The final rule adds a provision to permit split specimen testing for confirmed adulterated and substituted validity test results. The incremental costs associated with

retesting split specimens with confirmed positive, adulterated, or substituted test results are estimated in connection with §§ 26.131 and 26.161(b)(1)-(5).

Incremental costs associated with a retest of an aliquot of a single specimen with a confirmed positive, adulterated, or substituted test result includes an increased number of retests for FFD programs that currently use single specimen collections, given that donors do not currently have the option to request a retest. The incremental costs estimated in this section account only for the retesting of an aliquot of a single specimen that returns a confirmed positive drug test result. The incremental costs calculated here do not include those associated with retesting an aliquot of a single specimen with confirmed adulterated or substituted validity test result, which are estimated separately in connection with §§ 26.131 and § 26.161(b)(1)-(5). Similarly, changes in cutoff levels for marijuana and opiates are estimated in connection with §§ 26.133, and 26.163(a)(1).

The *annual incremental costs per FFD program* are estimated as follows:

$$(NUM_{confirmed} \times PER_{retest} \times PERI_{retest} \times COST_{retest}) \times NUM_{reactors}$$

Parameter	Description
$NUM_{confirmed}$	Number of positive drug test results per reactor per year (as discussed in Appendix 2, Exhibit A2-12)
PER_{retest}	Percentage of urine specimens with positive drug test results retested at the request of the donor at a second HHS-certified laboratory (as discussed in the assumptions below)
$PERI_{retest}$	Percentage increase in retesting of positive urine specimens based on the final rule provision to allow retesting of single specimens (as discussed in the assumptions below)
$COST_{retest}$	Cost of specimen retesting at a second HHS-certified laboratory including, specimen preparation and shipping costs (as discussed in Appendix 2, Exhibit A2-13)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Percentage of urine specimens with positive drug test results retested at the request of the donor at a second HHS-certified laboratory (as discussed in the assumptions below): 5 percent.

- Percent increase in retesting of positive drug test specimens based on the final rule provision to allow retesting of single specimens: 10 percent.

Paragraph 26.165(c)

This paragraph of the final rule revises former requirements in Section 2.7(i) and (j) in Appendix A to Part 26, which pertained to the procedures for testing split specimens for drugs at a second

HHS-certified laboratory. The final rule adds procedures for retesting single specimens. The retesting of a urine specimen must be confirmatory testing for drugs and drug metabolites only for the drugs(s) that the specimen tested positive at the first HHS-certified laboratory. If the second HHS-certified laboratory fails to reconfirm the presence of the drug(s) detected at the initial HHS-certified laboratory, the second HHS-certified laboratory shall conduct specimen validity testing. The incremental costs for retesting single specimens is calculated and discussed in connection with § 26.165(b).

Paragraph 26.165(d)

This paragraph of the final rule establishes procedures for retesting urine specimens with confirmatory validity test results of adulterated at a second HHS-certified laboratory. Retesting of adulterated urine specimens is limited to conducting confirmatory testing only for the adulterant(s) identified by the first HHS-certified laboratory. The incremental costs associated with retesting urine specimens for adulterants are estimated and discussed in connection with §§ 26.131 and 26.161(b)(1)-(5).

Paragraph 26.165(e)

This paragraph of the final rule establishes procedures for retesting urine specimens with confirmatory validity test results of substituted at a second HHS-certified laboratory. Retesting of substituted urine specimens is limited to conducting confirmatory testing only for creatinine and specific gravity. The incremental costs associated with retesting urine specimens for substitution are estimated and discussed in connection with §§ 26.131 and 26.161(b)(1)-(5).

Paragraph 26.165(f)

This paragraph of the final rule establishes FFD management actions and sanctions pertaining to situations where a donor has a confirmed positive, adulterated, or substituted drug and/or validity test result and requests the retesting of their specimen at a second HHS-certified laboratory. If the results of the retest do not confirm the initial result, that is, the second test indicates a negative drug and/or validity test result, this paragraph specifies procedures that the licensee and other entities must follow. The procedures and actions include not imposing any sanctions on the individual; eliminating any records from the individual's personnel files pertaining to the temporary administrative actions; prohibiting the disclosure of temporary administrative action in response to a suitable inquiry, a background investigation, or any other inquiry or investigation; and providing a written statement to the individual 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. The analysis does not estimate the costs of the administrative actions (FFD program management labor to discard records and draft a written statement) associated with this final paragraph due to the infrequency of instances where the retesting of a positive, adulterated, or substituted validity and/or drug test specimen at a second HHS-certified laboratory fails to confirm the initial HHS-certified laboratory positive, adulterated, or substituted test result.

26.167 Quality assurance and quality control

Paragraph 26.167(a)

This paragraph of the final rule clarifies former requirements in Section 2.8(a) and (d) in Appendix A to Part 26, which specified that HHS-certified laboratories must implement a quality assurance program that encompasses all aspects of the testing process. The final rule adds a new requirement for the quality assurance program to encompass the certification of calibrators and controls to ensure that calibrators and controls are accurate. This paragraph in the final rule imposes no incremental costs and afford no savings because the requirements are consistent with the existing quality assurance programs implemented by HHS-certified laboratories.

Paragraph 26.167(b)

This paragraph of the final rule revises former requirements in Sections 2.8(c) and (d) in Appendix A to Part 26, which required HHS-certified laboratories to include appropriate calibrators and controls in each analytical run of initial and confirmatory drug test specimens. The final paragraph adds the requirement that appropriate calibrators and controls must be included in each analytical run for initial and confirmatory validity test specimens. The incremental costs resulting from validity testing are discussed in connection with § 26.161. This paragraph in the final rule imposes no incremental costs and afford no savings for drug testing because the requirements are consistent with the existing quality assurance programs implemented by HHS-certified laboratories

Paragraph 26.167(c)

This paragraph establishes quality control requirements for conducting initial and confirmatory validity tests at HHS-certified laboratories. This final paragraph will impose incremental costs per FFD program on a per specimen test basis. That is, the per test cost to conduct validity testing includes the costs to comply with the quality control requirements in this paragraph. The incremental cost for FFD programs to conduct validity testing is calculated in §§ 26.131 and 26.161(b)(1)-(5).

Paragraph 26.167(d)

This paragraph of the final rule revises former requirements in Section 2.7(e)(1) in Appendix A to Part 26, which mandated that initial drug tests must be performed using an immunoassay that meets the FDA requirements for commercial distribution. The final rule prohibits the use of non-instrumented immunoassay testing devices pending HHS/SAMHSA review and approval from being used for initial drug testing under this part. The final rule also revises former requirements in Section 2.8(c) in Appendix A to Part 26, which pertained to the quality control requirements for performing initial drug tests at HHS-certified laboratories. This final paragraph imposes no incremental costs and affords no savings because the provisions are consistent with the existing practices of HHS-certified laboratories.

Paragraph 26.167(e)

This paragraph of the final rule revises former requirements in Sections 2.7(f)(2) and 2.8(d) in Appendix A to Part 26, which pertained to quality control requirements for performing confirmatory drug tests at HHS-certified laboratories. This final paragraph imposes no incremental costs and affords no savings because the provisions are consistent with existing practices of HHS-certified laboratories.

Paragraph 26.167(f)

This paragraph of the final rule clarifies former requirements in Sections 2.8(e)(4)–(6) in Appendix A to Part 26, which pertained to errors in HHS-certified laboratory testing of blind performance test specimens and actual specimens, as well as errors identified through processing reviews and any matters that may adversely affect the testing process. The final paragraph requires licensees and C/Vs to ensure that the HHS-certified laboratory conducts investigations into any testing errors and takes corrective action when necessary. The final paragraph will impose no incremental costs and affords no savings because the requirement is consistent with current quality assurance procedures used by HHS-certified laboratories.

Paragraph 26.167(g)

This paragraph of the final rule imposes no cost and affords no savings because it restates former requirements in Section 2.7(o)(3)(i) in Appendix A to Part 26.

Paragraph 26.167(h)

This paragraph of the final rule revises without substantive change the former requirements in Section 2.7(o)(2) in Appendix A to Part 26 which described the preparation and handling procedures for standards and controls. This paragraph clarifies that HHS-certified laboratories may prepare calibrators and controls from stock solutions obtained from other laboratories or commercial manufacturers. This final paragraph also adds a provision that prohibits HHS-certified laboratories from using calibrators and controls prepared from the same stock solution. No incremental cost or saving will result from the provisions in this paragraph because they are consistent with existing laboratory practices pertaining to calibrator and control preparation.

26.168 Blind Performance Testing

Paragraph 26.168(a)

This paragraph of the final rule revises former requirements in Section 2.8(e)(2)–(3) in Appendix A to Part 26, which pertained to blind performance test samples. This revision will result in incremental savings for each FFD program, as discussed in connection with § 26.168(a)(1)–(2).

Subparagraph 26.168(a)(1)

This subparagraph in the final rule revises former requirements in Section 2.8(e)(2) in Appendix A to Part 26, which pertained to the number of blind performance test samples that licensees and other entities were required to submit to an HHS-certified laboratory during the initial 90 days of any contract (not including rewritten or renewed contracts). Under the former requirements, during the initial 90 days of a contract, 50 percent of the total number of specimens submitted were required to be blind performance test samples (up to a maximum of 500 samples). The final rule reduces the number of blind performance test samples that must be submitted by a licensee or other entity in the initial 90 days of a contract to 20 percent (up to a maximum of 100 blind samples) or 30 blind samples, whichever is greater. The final rule will result in incremental savings for some FFD programs and costs for other FFD programs, as follows:

- FFD programs that conduct all testing at HHS-certified laboratories ("offsite laboratories") will recognize savings related to the reduced number of blind performance test samples purchased from commercial vendors and analyzed at HHS-certified laboratories.

- In contrast, FFD programs that conduct initial validity and drug testing of specimens at onsite licensee testing facilities send HHS-certified laboratories many fewer urine specimens for testing under the former rule requirements.[9] Unlike the former rule, the final rule requires an FFD program to submit a minimum number of blind performance test samples to their HHS-certified laboratory. Therefore, this provision increases the number of blind samples that FFD programs with onsite licensee testing facilities must submit to HHS-certified laboratories. For this reason, FFD programs using onsite licensee testing facilities will incur incremental costs for an increased number of blind samples purchased from commercial vendors and analyzed at HHS-certified laboratories.

Annual savings per FFD program that uses an HHS-certified laboratory for all validity and drug testing of urine specimens are calculated as the difference between the costs under the former rule and costs under the final rule, as follows:

$$[(NUM_{\text{drug tests per quarter}} \times PER_{\text{blind samples, initial 90 days, former rule}} \times COST_{\text{blind sample and testing, former rule}} \times NUM_{\text{reactors}}) - (NUM_{\text{drug tests per quarter}} \times PER_{\text{blind samples, initial 90 days, final rule}} \times COST_{\text{blind sample and testing, final rule}} \times NUM_{\text{reactors}})] \times PER_{\text{change HHS lab}}$$

[9] Specifically, FFD programs with onsite licensee testing facilities submit to HHS-certified laboratories only positive initial drug test specimens, and a "sampling" of negative urine specimens (assumed to be 1 percent) analyzed at the licensee testing facility.

Annual costs per FFD program that conducts initial validity and drug testing of specimens at an onsite licensee testing facility are calculated as the difference between the costs under the former rule and costs under the final rule, as follows:

$$[(NUM_{\text{specimens to HHS lab per quarter from LTF}} \times PER_{\text{blind samples, initial 90 days, former rule}} \times COST_{\text{blind sample and testing, former rule}} \times NUM_{\text{reactors}}) - (NUM_{\text{specimens to HHS per quarter from LTF}} \times PER_{\text{blind samples, initial 90 days, final rule}} \times COST_{\text{blind sample and testing, final rule}} \times NUM_{\text{reactors}})] \times PER_{\text{change HHS lab}}$$

Parameter	Description
$NUM_{\text{drug tests per quarter}}$	Number of drug tests per reactor per quarter (as discussed in the assumptions below and in Appendix 2, Exhibit A2-14)
$PER_{\text{blind samples, initial 90 days, former rule}}$	Percentage of drug test specimens under the former rule that must be blind performance test samples submitted in the first 90 days of a contract with an HHS-certified laboratory (as discussed in the assumptions below)
$COST_{\text{blind sample and testing, former rule}}$	Cost per blind specimen under the former rule for an FFD program to purchase a blind performance test sample from a commercial vendor, prepare the sample (fill out custody-and-control form, submit the sample for testing to an HHS-certified laboratory, drug test the specimen, and labor to verify that the test results are accurate (as discussed in Appendix 2, Exhibit A2-13)
$PER_{\text{blind samples, initial 90 days, final rule}}$	Percentage of drug test specimens under the final rule that must be blind performance test samples submitted in the first 90 days of a contract with an HHS-certified laboratory (as discussed in the assumptions below)
$COST_{\text{blind sample and testing, final rule}}$	Cost under the final rule provisions for an FFD program to purchase a blind performance test sample from a commercial vendor, prepare the sample (fill out custody-and-control form), submit the sample for testing to an HHS-certified laboratory, drug and validity test the specimen, and labor to verify that the test results are accurate (as discussed in Appendix 2, Exhibit A2-13)
$PER_{\text{change HHS lab}}$	Percentage of years that an FFD program enters a contract with a different HHS-certified laboratory (as discussed in the assumptions below)
$NUM_{\text{specimens to HHS lab per quarter from LTF}}$	Number of urine specimens per reactor per quarter submitted to an HHS-certified laboratory by FFD programs that conduct initial specimen testing at an onsite licensee testing facility (LTF) (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12)
NUM_{reactors}	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- The number of drug tests conducted per reactor per quarter is equivalent to the number of drug tests per conducted per reactor per year (see Appendix 2, Exhibit A2-14) divided by 4 quarters in the year.

- Percentage of years that a FFD program enters a contract with a different HHS-certified laboratory: 10 percent. That is, on average, a FFD program will choose to use a different HHS-certified laboratory every 10 years.

- Percentage price increase per blind performance test sample purchased from a commercial vendor under the final rule due to the inclusion of adulterated, substituted, and dilute validity test specimens as well as samples submitted as a false negative challenge §§ 26.168(a)(3)–(a)(6): 75 percent.

- The number of urine specimens per reactor per quarter submitted to an HHS-certified laboratory by FFD programs that conduct initial specimen testing at an onsite licensee testing facility (LTF) is equal to the total per quarter of the following:

    - positive initial drug test specimens, and

    - a "sampling" of negative urine specimens [assumed to be 1 one percent] as a check on false negative rate

Subparagraph 26.168(a)(2)

This subparagraph of the final rule revises former requirements in Section 2.8(e)(2) in Appendix A to Part 26, which pertained to the number of blind performance test specimens that licensees and C/Vs must submit to their HHS-certified laboratory during each quarter after the initial 90 days of the contract with the laboratory. Under the former regulations, 10 percent of the total number of samples submitted per quarter (up to a maximum of 250 samples) had to be blind performance test specimens. Th final rule reduces that number to a minimum of 1 percent of the total number of samples submitted per quarter (up to a maximum of 100 samples) or 10 blind specimens, whichever is greater. This subparagraph in the final rule will result in incremental savings for some FFD programs and costs for other FFD programs, as follows:

- FFD programs that send all urine specimens to HHS-certified laboratories ("offsite laboratories") will recognize incremental savings related to the reduced number of blind performance test specimens purchased from commercial vendors and validity and drug tested at HHS-certified laboratories.

- In contrast, FFD programs that conduct testing at onsite licensee testing facilities send HHS-certified laboratories many fewer specimens for testing under the former rule.[10] Unlike the former rule, the final rule requires licensees testing facilities to submit a minimum number of blind performance test samples to their HHS-certified laboratories.

[10] Specifically, FFD programs with onsite licensee testing facilities submitted to HHS-certified laboratories only positive initial drug test specimens, and a "sampling" of negative urine specimens [assumed one percent].

Therefore, the final rule increases the number of blind specimens that onsite licensee testing facilities must submit to HHS-certified laboratories. For this reason, FFD programs that conduct testing of urine specimens at onsite licensee testing facilities will incur incremental costs for an increased number of blind performance test samples purchased from commercial vendors and submitted to HHS-certified laboratories for drug and validity testing.

Annual savings per FFD program that uses an HHS-certified laboratory to conduct all urine specimen testing. The savings per FFD program with a contract with an HHS-certified laboratory that has been in place for more than 90 days are calculated as the difference between the costs under the former rule and the costs after implementation of the final rule, as follows:

$$(NUM_{\text{drug tests per quarter}} \times PER_{\text{blind specimens, former rule}} \times COST_{\text{blind specimen testing, former rule}} \times NUM_{\text{reactors}} \times NUM_{\text{quarters in year}}) - (NUM_{\text{drug tests per quarter}} \times PER_{\text{blind specimens, final rule}} \times COST_{\text{blind specimen testing, final rule}} \times NUM_{\text{reactors}} \times NUM_{\text{quarters in year}})$$

Annual costs per FFD program that conducts testing of urine specimens at a licensee testing facility (LTF) are calculated as the difference between the costs under the former rule and costs after implementation of the final rule, as follows:

$$(NUM_{\text{drug tests to HHS lab per quarter, LTF}} \times PER_{\text{blind specimens, former rule}} \times COST_{\text{blind specimen testing, former rule}} \times NUM_{\text{reactors}} \times NUM_{\text{quarters in year}}) - (NUM_{\text{drug tests to HHS lab per quarter, LTF}} \times PER_{\text{blind specimens, final rule}} \times COST_{\text{blind specimen testing, final rule}} \times NUM_{\text{reactors}} \times NUM_{\text{quarters in year}})$$

Parameter	**Description**
$NUM_{\text{drug tests per quarter}}$	Number of drug tests per reactor per quarter (as discussed in the assumptions below)
$PER_{\text{blind specimens, former rule}}$	Percentage of drug tests under the former rule that must be blind performance test specimens submitted during each quarter for a contract with an HHS-certified laboratory that has been in place for more than 90 days (as discussed in the assumptions below)
$COST_{\text{blind specimen testing, former rule}}$	Cost per blind specimen under the former rule for an FFD program to purchase a blind performance test specimen from a commercial vendor, prepare the specimen for testing (fill out custody-and-control form), submit the specimen for testing at the HHS-certified laboratory, and verify that the test results are accurate (as discussed in Appendix 2, Exhibit A2-13)
$PER_{\text{blind specimens, final rule}}$	Percentage of drug tests under the final rule that must be blind performance test specimens submitted during each quarter for a contract with an HHS-certified laboratory that has been in place for more than 90 days (as discussed in the assumptions below)

Parameter	Description
$COST_{\text{blind specimen testing, final rule}}$	Cost per blind specimen under the former rule for an FFD program to purchase a blind performance test specimen from a commercial vendor, prepare the specimen for testing (fill out custody-and-control form), submit the specimen for testing at the HHS-certified laboratory, and verify that the test results are accurate (as discussed in Appendix 2, Exhibit A2-13)
$NUM_{\text{drug tests to HHS lab per quarter, LTF}}$	Number of drug tests submitted to an HHS-certified laboratory per reactor per quarter for licensees that conduct testing of urine specimens at onsite licensee testing facilities (LTF) (as discussed in the assumptions below)
$NUM_{\text{quarters in year}}$	Number of quarters in a year (as discussed in the assumptions below)
NUM_{reactors}	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- The number of drug tests per reactor per quarter is equivalent to the number of drug tests per reactor per year (see Appendix 2, Exhibit A2-14) divided by the number of quarters in a year.

- The number of quarters in a year:[11] 4.

- The number of specimens per reactor per quarter submitted to an HHS-certified laboratory from FFD programs with onsite licensee testing facilities (LTF) is equal to the total per quarter of:

    - positive initial drug test specimens, and

    - a "sampling" of negative urine specimens [assumed to be 1 one percent] as a check on the false negative rate

- Percentage price increase per blind performance test sample purchased from a commercial vendors under the final rule due to the inclusion of adulterated,

[11] The § 26.168(a)(2) equations for FFD programs that have onsite licensee testing facilities and those that send all specimens to an HHS-certified laboratory for testing both account for four quarters of blind specimen testing costs. For the ten percent of FFD programs accounted for in § 26.168(a)(1) that switch to new HHS-certified laboratories, this means that there is one quarter of over counting of costs/savings under § 26.168(a)(2). Consequently, the equations in § 26.168(a)(2) somewhat overstate the savings/costs for those FFD programs accounted for in § 26.168(a)(1). The net overstatement is small, however, and does not merit the complication that would be needed to provide a more precise estimate.

substituted, dilute samples, as well as "false negative challenge" samples as required by §§ 26.168(d) and (e): 75 percent.

Paragraph 26.168(b)

This paragraph in the final rule revises the former requirements in Section 2.8(e)(3) in Appendix A to Part 26, which specified the percentage of positive blind specimens that licensees and other entities had to submit to their HHS-certified laboratories. Under the former regulations, 20 percent of the total number of blind performance test specimens submitted per quarter had to be positive for one or more drugs. The final rule increases the percentage of blind performance test samples positive for one or more drugs or drug metabolites that must be submitted to HHS-certified laboratories to 60 percent. The provision changes the "mix" or composition of blind performance test samples that FFD programs must submit for testing and will result in an incremental cost per program associated with the composition change in the blind performance test samples is accounted for in connection with §§ 26.168(a)(1)–(a)(2).

Paragraph 26.168(c)

This paragraph in the final rule establishes a requirement that licensee and other entities may only submit blind performance test samples positive for only the drugs that the FFD program tests the presence for in each specimen. No incremental cost or saving will result from the final provision because the requirement simple ensures that the licensee and other entity is measuring the ability of the HHS-certified laboratory to detect drugs that the FFD program is testing for in each specimen.

Paragraph 26.168(d)

This paragraph of the final rule establishes a new requirement that licensees and other entities 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). This provision will result in incremental costs associated with purchasing false negative challenge samples and submitting the samples for testing. These incremental costs are accounted for in connection with § 26.168(a)(1) and (2).

Paragraph 26.168(e)

This paragraph of the final rule establishes a new requirement that licensees and other entities must submit approximately 20 percent of all blind samples as adulterated, diluted, or substituted specimens. This paragraph will result in incremental costs associated with purchasing adulterated, substituted, and dilute samples meeting the requirements in § 26.168(g)(4) - (g)(6) and submitting the samples for testing. These incremental costs are accounted for in connection with § 26.168(a)(1) and (2).

Paragraph 26.168(f)

This paragraph in the final rule revises the former requirements in Section 2.8(e)(3) in Appendix A to Part 26, which specified the percentage of negative blind specimens that licensees and other entities had to submit to their HHS-certified laboratories. Under the former regulations, 80 percent of the total number of blind specimens submitted per quarter had to be "blank." Licensees will realize an incremental increase in costs associated with the increased number of more costly adulterated, diluted, substituted and false negative challenge blind performance test samples required in § 26.168(d) and (e) of the final rule. These incremental costs are accounted for in connection with §§ 26.168(a)(1)–(2).

Paragraph 26.168(g)

This paragraph specifies the criteria that each type of blind performance test specimens must meet. This paragraph specifies that blind performance test samples must be certified by the supplier to be negative (i.e., certified by immunoassay and confirmatory testing as containing no drug), drug positive (i.e., certified by immunoassay and confirmatory testing as containing one or more drug(s)/and/or metabolite(s)), adulterated (i.e., certified using one or more appropriate analytical procedure(s)) as being adulterated with a specific adulterant), substituted (i.e., certified as having a creatinine concentration and a specific gravity that satisfy the criteria for a substituted specimen) or a false negative challenge. The provisions in this paragraph will result in incremental costs for FFD programs to purchase blind performance test samples that meet the specifications of the final rule, as discussed in connection with § 26.168(a)(1) and (a)(2).

Paragraph 26.168(h)

Paragraph 26.168(h) establishes requirements for blind performance test samples that licensees and other entities must submit to the HHS-certified laboratories to ensure to the consistency and effectiveness of the blind performance testing process. The paragraph requires the supplier of the blind samples to: (1) certify that all blind specimen lots are confirmed by an HHS-certified laboratory prior to being put into service, (2) provide an expiration date for each sample, and (3) to monitor each open lot on a bi-monthly (i.e., every two month) basis to ensure that samples remaining in the lot do not fall below the criteria in this section. Although these provisions may be normal industry practice for some manufacturers, the analysis accounts for an incremental cost that may result for some manufacturers that would pass the additional cost to the licensee or other entity in terms of higher blind sample costs. The costs associated with these provisions are accounted for in the increased cost to purchase a blind performance test sample under the final provisions in § 26.168(a)(1) and (2).

Paragraph 26.168(i)

This paragraph of the final rule establishes the procedures that a licensees and other entities must follow to ensure that each blind performance test sample that is sent to an HHS-certified laboratory for testing is indistinguishable from a donor specimen sent to a laboratory. The

paragraph requires that the blind performance test samples be sent from the same channels that donor specimens are sent to the laboratory (e.g., from the collection site, licensee testing facility). The paragraph also requires that if split specimen collection is performed, the tamper-evident bottle seals must be initialed and the collector must inform the MRO on the MRO copy of the custody and control form that the sample is a blind performance test sample. Finally, the paragraph requires that if a licensee or other entity uses split specimen collections for donors, the blind performance test sample must also be a split specimen sample. No incremental cost or saving will result from the provisions in this paragraph because they are consistent with existing blind performance test sample preparation.

26.169 Reporting results

Paragraph 26.169(a)

This paragraph of the final rule revises former requirements in Section 2.7(g)(1) in Appendix A to Part 26, which pertained to HHS-certified laboratories reporting drug test results to MROs. The final rule will add a requirement that the laboratory's reports must include validity testing results and any indications of tampering, adulteration, or substitution. The final paragraph will impose no incremental costs and affords no savings because HHS-certified laboratories already conduct validity testing for some U.S. DOT-regulated entities and, therefore, have the capability to report validity testing results, using existing automated systems.

Paragraph 26.169(b)

This paragraph of the final rule revises former requirements in Section 2.7(g)(7) in Appendix A to Part 26, which pertained to HHS-certified laboratories reporting test results for licensees who use cutoff levels that are more stringent than those required in Part 26. Currently, HHS-certified laboratories must report drug test results for both the Part 26 cutoff levels, and the licensee's more stringent cutoff levels. By contrast, under the final rule HHS-certified laboratories are only required to report the results for the more stringent cutoff levels. Given that HHS-certified laboratories use automated systems to tabulate testing data, printing fewer data items for the test results is unlikely to result in any incremental costs or savings to either FFD programs or HHS-certified laboratories.

Paragraph 26.169(c)

This paragraph of the final rule clarifies and amends former requirements in Section 2.7(g)(2) in Appendix A to Part 26, which pertained to HHS-certified laboratories reporting negative and positive, adulterated, substituted, dilute, and invalid test results. The final rule also establishes that HHS certified laboratories must report negative, positive, adulterated, substituted, dilute, and invalid test results. The final paragraph will impose no incremental costs and affords no

savings because HHS-certified laboratories already conduct validity testing for U.S. DOT-regulated entities and, therefore, have the capability to report validity testing results, using existing automated systems.

Paragraph 26.169(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements within Section 2.7(g)(4) in Appendix A to Part 26 pertaining to the acceptable transmission methods to send test results from the HHS-certified laboratory to the MRO. This final paragraph also revises a former requirement in Section 2.7(g)(4) in Appendix A to Part 26 which required the HHS-certified laboratory to ensure that security of data transmission, data access, storage, and retrieval systems. This final paragraph clarifies that the licensee or other entity, directly or through the HHS-certified laboratory, must ensure the security of data transmission, data storage, and data retrieval systems. Under the former rule the licensee or other entity is still ultimately responsible for the compliance of the HHS-certified laboratory (given licensee and other entity oversight requirements) even though the text in Section 2.7(g)(4) did not clearly specify this responsibility. This revision will result in no increment cost or savings because it is consistent with existing licensee and other entity data security evaluation procedures.

Paragraph 26.169(f)

This paragraph of the final rule revises former requirements in Section 2.7(g)(5) in Appendix A to Part 26, which pertained to acceptable methods for HHS-certified laboratories to use in transmitting the custody-and-control form to the MRO. Currently, HHS-certified laboratories are required to transmit a certified copy of the original custody-and-control form with a copy of the test report. The final paragraph expands the acceptable methods of transmitting the custody-and-control form to include fax, courier, mail, and electronic transmission. Although this final paragraph provides flexibility in the transmission mechanism, it will result in insignificant incremental costs or savings.

Paragraph 26.169(g)

This paragraph of the final rule clarifies that the HHS-certified laboratory must retain the original custody-and-control form for any specimen with a positive, adulterated, substituted, dilute, or invalid result and transmit to the MRO a copy of the original custody-and-control form signed by the certifying scientist. No incremental costs or savings will result from the final paragraph as it is consistent with existing HHS-certified laboratory recordkeeping practices.

Paragraph 26.169(h)

This paragraph of the final rule revises and amends former requirements in Sections 2.7(g)(6) and (g)(7) in Appendix A to Part 26, which required HHS-certified laboratories to prepare statistical summary reports of each licensee's drug test results, and submit those reports to the

licensee official on a monthly basis. By contrast, the final paragraph will reduce the reporting frequency from monthly to annually thereby providing more flexibility in the reporting of this data. However, the final rule includes a new reporting requirement in the summary reports to include validity testing results (i.e., information on specimens with adulterated, substituted, diluted, or invalid test results). No incremental costs are expected to result from the requirement to include validity test summary data, because HHS-certified laboratories already have the data management systems to provide summary test result information. However, this final paragraph will yield incremental savings by reducing the required frequency of statistical summary reports (i.e., reduced labor and postage costs).

The *annual savings per FFD program* are estimated as follows:[12]

$$[(HOURS_{lab\ tech} \times WAGE_{lab\ tech}) + COST_{postage}] \times NUM_{reports} \times NUM_{facility}$$

Parameter	Description
$HOURS_{lab\ tech}$	Time for the laboratory technician to generate and send an annual or monthly statistical summary report per facility (as discussed in the assumptions below)
$WAGE_{lab\ tech}$	Laboratory technician wage rate (as discussed in Appendix 2, Exhibit A2-11)
$COST_{postage}$	Cost to send an annual or monthly statistical summary report via the U.S. Postal Service (as discussed in the assumptions below)
$NUM_{reports}$	Number of reports that will no longer be sent to a facility per year (as discussed in the assumptions below)
$NUM_{facilities}$	Number of facilities per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Time for the laboratory technician to generate an send annual or monthly statistical summary report per facility: 30 minutes.
- Cost to send an annual or monthly statistical summary report via the U.S. Postal Service: $2.00.
- Number of reports that will no longer be sent to a facility per year: 11.
- An annual summary report requires the same amount of labor and postage as a monthly summary report.

[12] In order to capture total costs and savings, the analysis assumes that savings recognized by HHS-certified laboratories will be passed back to licensees (i.e., lower specimen testing costs).

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

26.181 Purpose

This section of the final rule imposes no incremental cost and affords no saving because it merely describes the purpose of Subpart H.

26.183 Medical Review Officer

Paragraph 26.183(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies the qualifications of the medical review officer (MRO), as currently defined under §26.3 and Appendix A, paragraph 2.9(b), of the former rule. In addition, subparagraph 26.25(a)(4) added MROs to the list of FFD program personnel subject to this part. The final paragraph also adds a requirement that within 2 years of the implementation of this rule, all MROs must pass an examination administered by a nationally recognized MRO certification board. However, licensees have indicated that most MROs currently meet the clarified MRO qualifications and that the 2-year phase-in period, in conjunction with revised hiring practices, will ensure that costs will be insignificant.

Paragraph 26.183(b)

This paragraph of the final rule establishes requirements regarding the relationships between the MRO and HHS-certified laboratories. The requirements add more explicit conflict-of-interest requirements to prohibit MROs from having a relationship or vested financial interest in a laboratory or contracted operator of a licensee testing facility for which the MRO reviews drug testing results for the licensee or other entity. Although this is a newly required provision, it is consistent with standard ethical business practices. Consequently, this analysis assumes that the only incremental costs that might result from this provision involves the revision of employee labor contracts to incorporate these prohibited relationships. However, the analysis also assumes that existing contracts incorporate "by reference" the applicable provisions of 10 CFR Part 26. Consequently, the provision is believed to take effect automatically when the rule is promulgated and, therefore, it will not result in any incremental cost or saving.

Paragraph 26.183(c)

This paragraph of the final rule [including subparagraphs 26.183(c)(1)–(2)] imposes no incremental cost and affords no saving because it renumbers and retains the requirements contained in paragraph 2.9(b) of Appendix A to the former rule, as they relate to overall MRO responsibilities. The final paragraph does add a provision that requires the MRO to advise and assist licensee and other entity management in planning and overseeing the overall FFD program. The analysis anticipates no incremental cost from this added provision, however, because the MRO already meets these obligations given current industry practice.

Paragraph 26.183(d)

This paragraph of the final rule [including subparagraphs 26.183(d)(1)–(2)] imposes no incremental cost and affords no saving because it merely clarifies and explicitly states the MRO staff responsibilities that are already effective under the former rule. The final paragraph also adds requirements to ensure that MRO staff are properly supervised by the MRO and are independent from the licensee or other entity management while performing MRO staff functions. This provision does not result in an incremental cost because it incorporates existing practices into written regulation and makes the procedures consistent with HHS-recommended practices.

26.185 Determining a Fitness-for-Duty Policy Violation

Paragraph 26.185(a)

This paragraph amends former requirements in Appendix A, paragraph 2.9(a), that describe the MRO's responsibility to review drug and alcohol test results. The final paragraph amends language to include validity testing in the reviewing process. The final paragraph also references other entities as subject to this requirement. In addition, the final paragraph eliminates the blood testing option for the alcohol test, resulting in savings that are calculated under paragraph 26.83(b) of the analysis.

Paragraph 26.185(b)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely retains requirements in the last sentence of Appendix A, paragraph 2.9(a) of the former rule. The final paragraph also adds a new provision that prohibits the MRO and MRO staff from communicating positive, adulterated, substituted, or invalid initial test results to management, except as specified under paragraph 26.75(h), but that provision does not result in any incremental costs.

Paragraph 26.185(c)

This paragraph of the final rule renumbers and amends former requirements in Appendix A, paragraph 2.9(c), of the former rule. Specifically, the final paragraph retains requirements for the MRO to discuss a positive, adulterated, substituted, or invalid drug test result or other occurrence with the donor before determining whether a violation of FFD policy has occurred. The MRO is required to discuss positive, adulterated, substituted, or invalid validity test results with the donor as part of the verification process. Contacting the EAP is no longer required and is at the discretion of the MRO. Potential savings are assumed to be insignificant because the MRO must still contact management.

Paragraph 26.185(d)

This paragraph of the final rule [including subparagraphs 26.185(d)(1)–(3)] specifies three circumstances in which the MRO may determine that a positive, adulterated, substituted, or invalid test result or other occurrence is an FFD policy violation without having discussed the result or occurrence directly with the donor: (1) the donor expressly declining the opportunity to discuss the test result or other occurrence with the MRO; (2) the donor failing to contact the MRO after a representative of the licensee has successfully made contact and instructed them to contact the MRO directly or (3) a failure on the part of the MRO to contact the donor after making reasonable efforts to contact the donor over a 24-hour period. For all circumstances, the MRO or the licensee's representative must clearly document the attempted contacts, the successful contact, and any declination of opportunities to discuss the possible violation with the MRO. Although the requirement to document such interactions represents a new provision, the analysis assumes that MROs already document such attempts in a manner that meets the requirements of this final paragraph.

Paragraph 26.185(e)

This paragraph of the final rule imposes no cost and affords no saving because it merely provides more detailed guidance than contained in Appendix A, paragraph 2.9, of the former rule. The provision allows donors, in circumstances in which the MRO has not discussed a positive, adulterated, substituted, or invalid test result or other occurrence directly with the donor, to present information documenting the circumstances that prevented the donor from contacting or being contacted by the MRO in a timely manner. Although this provision may require additional MRO time when these events occur, NRC believes this will happen very infrequently. Therefore, the analysis estimates no incremental costs for this provision.

Paragraph 26.185(f)

This paragraph of the final rule describes the actions that an MRO must take when a urine specimen has an invalid test result.

Subparagraph 26.185(f)(1)

This subparagraph of the final rule establishes a provision directing the MRO, in instances where an HHS-certified laboratory reports an invalid result, to consult with the laboratory to determine whether additional testing could help in determining whether the specimen is positive or adulterated. This final subparagraph also permits the MRO to send a specimen to a second HHS-certified laboratory for additional testing when appropriate. The incremental costs per FFD program associated with this final subparagraph are discussed in connection with §26.161(g).

Subparagraph 26.185(f)(2)

This subparagraph of the final rule establishes a new requirement that requires the MRO, in instances where a urine specimen has an invalid test result with no technical explanation for the result, to contact the donor to determine if an acceptable medical explanation can explain the invalid test result. If an acceptable medical explanation exists, the MRO must report to the licensee or other entity that a negative test result was not obtained. If the medical reason for the invalid result is a temporary condition, the licensee or other entity must collect a second urine specimen (unobserved collection) from the donor and rely upon the MRO's review of the test results from the second specimen. 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. The analysis estimates that the incremental cost per FFD program associated with the requirements in this final subparagraph are insignificant due to the infrequency of such invalid test results.

Subparagraph 26.185(f)(3)

This subparagraph of the final rule establishes a new requirement that requires the licensee, in instances where a urine specimen has an invalid test result with no technical or medical explanation, to obtain a second collection under direct observation. The analysis estimates that the incremental cost associated with the requirements in this final subparagraph are insignificant due to the infrequency of such invalid test results.

Paragraph 26.185(g)

This paragraph of the final rule describes the actions that an MRO must take when a urine specimen has a dilute test result.

Subparagraph 26.185(g)(1)

This subparagraph of the final rule adds a requirement to §2.7(f)(2) of Appendix A to 10 CFR Part 26 of the former rule, which specifies the confirmatory cut-off levels for drug metabolites, indicating a laboratory positive drug test result. This subparagraph of the final rule provides that the MRO must declare a violation of FFD policy if the HHS-certified laboratory reports a specimen as dilute with drug(s) or drug metabolites at or above the cutoff levels, there is no legitimate medical explanation for the result, and a clinical examination, if required under paragraph (g)(4) of this section, has been conducted. This analysis assumes that no incremental cost or saving will result from this new provision.

Subparagraph 26.185(g)(2)

This subparagraph of the final rule establishes procedures for the MRO to follow in the event that an attempt at subversion through dilution of the collected specimen is suspected. If evidence of potential subversion [of the sort defined in subparagraphs 26.185(g)(2)(i)–(iii)] is

present, the MRO may require the laboratory to conduct the special analysis of dilute specimens permitted in § 26.163(a)(2). NRC believes that this provision will apply in very few instances and, therefore, the analysis estimates no incremental cost for this provision.

Subparagraph 26.185(g)(3)

This subparagraph of the final rule allows the MRO to conduct confirmatory testing of a dilute specimen at the levels of detection if it was collected under direct observation. No incremental cost or saving will result from this final subparagraph as discussed in connection with final §26.69.

Subparagraph 26.185(g)(4)

This subparagraph of the final rule revises former requirements in §2.9(d) of Appendix A to 10 CFR Part 26 under which the MRO must evaluate donors with opiate positives through clinical examination and a review of prescription medication use before determining that the donor has violated the FFD policy. The subparagraph permits the MRO to select a designee (who must be a licensed physician) to conduct a clinical evaluation in situations where drugs detected in a dilute specimen are opium, opiate, or opium derivative or over-the-counter medications. No incremental costs or savings will result from the requirements in this final subparagraph.

Subparagraph 26.185(g)(5)

This subparagraph of the final rule revises former requirements in §2.7(f)(2) of Appendix A to 10 CFR Part 26 of the former rule. The provision states that an MRO review is not required for specimens that the HHS-certified laboratory reports as negative and dilute. Under these circumstances, the licensee or other entity may not take any administrative actions or impose any sanctions on a donor who submits negative and dilute specimens. NRC believes that this provision will apply in very few instances and, therefore, the analysis calculates no incremental saving for this provision.

Paragraph 26.185(h)

This paragraph of the final rule describes the actions that an MRO must take when a urine specimen has a substituted test result.

Subparagraph 26.185(h)(1)

This subparagraph of the final rule adds new provisions that require the MRO to allow the donor to provide an acceptable medical explanation for the substituted result when 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 donor must then present creditable evidence within 5

business days of the specimen collection. This analysis estimates the costs associated with urine specimens having creatinine concentrations below 2 mg/dL in connection with §§26.131 and 26.161(b)(1).

Subparagraph 26.185(h)(2)–(3)

These subparagraphs of the final rule establish procedures for the MRO to follow when a medical explanation is provided by the donor of a urine specimen with a substituted test result. If an acceptable medical explanation is not identified, the MRO must declare the specimen to be substituted and a violation of FFD policy. If an acceptable medical explanation is provided by the donor, the MRO is required to report to the licensee or other entity that no FFD violation has occurred. The incremental cost associated with the requirements in this final subparagraph are discussed in connection with final §§26.131 and 26.161(b)(1).

Paragraph 26.185(i)

This paragraph describes the procedure to be followed in the event that the laboratory reports a specimen as adulterated. The final paragraph requires the MRO to allow the donor an opportunity to provide a medical explanation for the adulterated specimen. Depending on the donor's evidence, the MRO will determine whether an FFD policy violation has occurred. This procedure differs from that established in the former rule under Appendix A, paragraph 2.4. The incremental cost of the revised procedures are described in connection with §§26.131(f) and 26.161(b).

Paragraph 26.185(j)

Subparagraph 26.185(j)(1)

This subparagraph of the final rule revises and expands upon the former requirements in 2.9(d) in Appendix A to 10 CFR Part 26 pertaining to determining whether a legitimate medical explanation for positive confirmatory test results for opiates and prescription medication use. The former rule requires the MRO to confirm a positive drug test result for unauthorized use of opium, opiate, or opium derivative (e.g., morphine/codeine) through clinical evidence. This final subparagraph permits a designee of the MRO, who must be a licensed physician, to conduct the clinical examination. In addition, this final subparagraph includes a provision that limits the circumstances where an MRO may find a medically acceptable reason for opiate consumption. Food products may not be considered as a legitimate medical explanation for morphine or codeine concentrations at or above 15,000 ng/mL. No significant incremental costs or savings will result from the revisions given the low number of opiate positive drug test results under the former cut-off levels, as well as the increase in the initial cut-off level for opiate metabolites as discussed in §§26.133 and 26.163(a)(1).

Subparagraph 26.185(j)(2)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it restates requirements contained under Appendix A, paragraph 2.9(d), of the former rule. The provision requires that if the MRO determines that no legitimate medical explanation for positive confirmatory test results exists, the MRO must determine whether there is clinical evidence of unauthorized use of certain prescription drugs or over-the-counter preparations.

Subparagraph 26.185(j)(3)

This subparagraph imposes no incremental cost and affords no saving because it merely clarifies procedures [contained in Appendix A, paragraph 2.9(d) of the former rule] for the MRO to follow when a positive, adulterated, substituted, or invalid test result is due to unauthorized use of another individual's prescription medication. In such situations, the MRO must determine whether there exists clinical evidence of abuse. If no clinical evidence of abuse is detected, the MRO would report to the appropriate licensee or other entity management that the donor has misused a prescription medication. If clinical evidence of abuse is detected, the MRO must report to the licensee that the donor has violated the FFD policy.

Subparagraph 26.185(j)(4)

This subparagraph has been added to provide guidance to help define the procedure for determining whether the use of a prescription medication from a foreign country qualifies as a legitimate medical explanation for a positive confirmatory test result. Although this provision is not explicitly contained in the former rule, it likely is the case that when an individual with a positive, adulterated, substituted, or invalid drug test result acknowledges use of a valid prescription obtained in a foreign country, the MRO takes the information into consideration when making the decision to verify positive, adulterated, substituted, or invalid test results as positive.

Subparagraph 26.185(j)(5)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely states that the consumption of food products, supplements, or other preparations that contain substances which may trigger a positive confirmatory drug test result may not be considered a legitimate medical explanation when the presence of drugs or drug metabolites in the urine specimen exceeds the cutoff levels specified in section 26.163. This final subparagraph explicitly limits the discretion of the MRO, as provided under Appendix A, paragraph 2.9(f) of the former rule.

Subparagraph 26.185(j)(6)

This subparagraph of the final rule revises former requirements in paragraph 1.2 in Appendix A to 10 CFR Part 26, which defines illegal drugs as "Those drugs included in Schedules I through

V of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law." The subparagraph establishes that the MRO cannot consider the use of any drug contained in Schedule I of section 202 of the Controlled Substances Act [21 U.S.C. 012] 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. No incremental cost or saving will result from this revision because licensees must currently have written policies governing the prescription drug use of covered employees, as specified in §26.20(a). This analysis assumes that FFD programs effectively train and inform covered employees regarding the use of prescription drugs and, therefore, that no situations arise where an individual has a laboratory positive test result due to the consumption of a prescription drug.

Paragraph 26.185(k)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies Appendix A, paragraph 2.9(f), of the former rule requiring the MRO to assess the likely public health and safety risk of an individual's legitimate drug use. If the MRO determines a potential risk, a determination of fitness would be required.

Paragraph 26.185(l)

This paragraph of the final rule restates without change former requirements in §2.9(e) of Appendix A to 10 CFR Part 26, which permit the MRO to request a retest of a donor's specimen at a second HHS-certified laboratory at the request of the donor. No incremental cost or saving will result from the clarification.

Paragraph 26.185(m)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely renumbers former requirements contained in Appendix A, paragraph 2.9(g), of the former rule.

Paragraph 26.185(n)

This paragraph of the final rule imposes no incremental cost and affords no saving because it provides the procedure and policy to be followed for MRO verification decisions based on retests by a second laboratory. Although the final paragraph contains new requirements, the analysis assumes that licensees already follow these procedures to comply with elements of the former rule, including Appendix A, paragraph 2.9(e).

Paragraph 26.185(o)

This paragraph of the final rule imposes no incremental cost and affords no saving because it provides the procedure and policy to be followed by the MRO when evaluating drug test results from individuals seeking re-authorization following a first violation of the FFD policy based on a confirmed positive drug test result. Although the final paragraph contains new requirements, the analysis assumes that this circumstance is infrequent. Therefore, no incremental cost or saving will result from the revisions.

Paragraph 26.185(p)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely limits to 10 business days the time within which the MRO must review test results and notify licensee and other entity management. These provisions were formerly required under paragraph 26.24(e) of the former rule.

26.187 Substance Abuse Expert

This section of the final rule creates a new position of a substance abuse expert (SAE), with paragraphs 26.187(a)–(g) describing requirements for credentials, basic knowledge, qualifications training, continuing education, responsibilities and prohibitions, and documentation to demonstrate that the SAE meets the required qualifications under this section. In conjunction with subparagraph 26.189(a)(1), the final paragraph requires that when substance abuse is involved an SAE must conduct all determinations of fitness instead of the MRO as required by the former rule. Licensees whose MROs do not qualify as SAEs need to contract additional labor to have an SAE perform the necessary determinations of fitness. (The analysis estimates that the SAE wage rate is approximately equivalent to that of the MRO.) This provision, however, imposes no incremental costs and affords no savings because most MROs will also qualify as an SAE.

26.189 Determination of Fitness

Paragraph 26.189(a)

Subparagraph 26.189(a)(1)

This subparagraph of the final rule establishes requirements that allow determinations of fitness associated with suspected or confirmed substance abuse to be conducted by an individual qualifying as an SAE, as defined in §26.187. The SAE is required to make determinations of fitness following an unfavorable termination or denial of authorization under this part. The incremental impacts of this requirement area discussed in more depth under §26.187.

Subparagraphs 26.189(a)(2)–(5)

These subparagraphs of the final rule establish requirements that allow determinations of fitness associated with use of psychoactive medications, illness, injury, fatigue, or use of legal medications to be conducted by relevant professionals, such as clinical psychologists, psychiatrists, or physicians, provided that a substance abuse problem is not involved. Although in some instance, using such individuals may result in incremental savings due to a lower wage rate, the analysis assumes that there will be no savings on average, as quantified under §26.187.

Paragraph 26.189(b)

Subparagraphs 26.189(b)(1) and 26.189(b)(2)

These subparagraphs of the final rule impose no incremental cost and afford no saving because they merely renumber and clarify elements that are already covered in Appendix A, paragraph 2.9(f) and §26.27(b)(1) and §26.27(b)(4) the former rule.

Subparagraph 26.189(b)(3)

This subparagraph, in conjunction with §§26.69 and 26.65, requires licensees to conduct determinations of fitness in cases where potentially disqualifying FFD information is identified, as is already required under the former rule. The subparagraph adds a provision [in conjunction with §26.69(a)(2)], however, that eliminates the requirement to conduct the determination of fitness in cases where the potentially disqualifying FFD information has previously been evaluated by another licensee. As a result, fewer determinations of fitness will be conducted under the final rule. NRC anticipates that this decrease will more than offset the slight increase in the number of determinations of fitness that otherwise result from this provision due to the effects of revisions to the definition of "potentially disqualifying FFD information" (discussed in §26.5) and the additional information that will have to be reported by individuals on their self-disclosures [as required by §26.61(b)]. Therefore, the net result of these changes will be a savings for licensees and other entities, as quantified below.

The *annual savings per program* result from the sum of the following savings:

- Annual savings per program from the reduction in the number of determinations of fitness requiring SAE review are calculated as follows:

  $[(NUM_{Applicants} \times PER_{PDFFDI\text{-}Former}) - (NUM_{Applicants} \times PER_{PDFFDI\text{-}Final})] \times HOURS_{SAE} \times WAGE_{SAE} \times NUM_{Units}$

- Annual savings per program from the reduction in the number of determinations of fitness requiring FFD program manager review are calculated as follows:

$[(NUM_{Applicants} \times PER_{PDFFDI\text{-}Former}) - (NUM_{Applicants} \times PER_{PDFFDI\text{-}Final})] \times HOURS_{Manager} \times WAGE_{Manager} \times NUM_{Units}$

- Annual savings per program from the reduction in the number of determinations of fitness requiring clerical personnel support are calculated as follows:

  $[(NUM_{Applicants} \times PER_{PDFFDI\text{-}Former}) - (NUM_{Applicants} \times PER_{PDFFDI\text{-}Final})] \times HOURS_{Clerical} \times WAGE_{Clerical} \times NUM_{Units}$

Parameter	**Description**
$HOURS_{Clerical}$	Clerical personnel hours of support per determination of fitness (as described in assumptions below)
$HOURS_{Manager}$	FFD program manager hours of review per determination of fitness (as described in assumptions below)
$HOURS_{SAE}$	SAE hours of review per determination of fitness (as described in assumptions below)
$NUM_{Applicants}$	Annual number of applicants for authorization per unit (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$PER_{PDFFDI\text{-}Former}$	Percentage of applicants for authorization requiring a determination of fitness based on potentially disqualifying FFD information under the former rule (as described in assumptions below)
$PER_{PDFFDI\text{-}Final}$	Percentage of applicants for authorization requiring a determination of fitness based on potentially disqualifying FFD information under the final rule (as described in assumptions below)
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Manager}$	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{SAE}$	SAE wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of applicants for authorization requiring a determination of fitness under the former rule: 10%.

- Percentage of applicants for authorization requiring a determination of fitness under the final rule: 5%.

- SAE hours of review per determination of fitness: 2 hours.

- FFD program manager hours of review per determination of fitness: 2 hours.

- Clerical personnel hours of support per determination of fitness: 2 hours.

Subparagraph 26.189(b)(4)

This subparagraph imposes no incremental cost and affords no saving because it simply clarifies elements covered in §26.69 of the final rule. The provision requires determinations of fitness when potentially disqualifying FFD information is identified and the licensee's or other entity's reviewing official determines that a determination of fitness is warranted under §26.69.

Paragraph 26.189(c)

This paragraph adds a new requirement that all determinations of fitness that are conducted for-cause be conducted through face-to-face interaction with the individual under review to ensure that the professional who is performing the determination has available all of the sensory information that may be required for the assessment. Determinations of fitness for other purposes, however, can continue to be conducted in the absence of the individual under review or over the phone. This added requirement will result in lost labor productivity for the individual under review.

The *annual costs per program* from requiring that a for-cause determination of fitness be conducted face-to-face with the individual under review results from lost worker productivity for the individuals under review, calculated as follows:

$$NUM_{For\text{-}Cause} \times HOURS_{Worker} \times WAGE_{Worker} \times NUM_{Units}$$

Parameter	Description
$HOURS_{Worker}$	Hours of worker time required per face-to-face determination of fitness (as described in assumptions below)
$NUM_{For\text{-}Cause}$	Number of for-cause referrals per unit per year (as described in Appendix 2, Exhibit A2-12)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
$WAGE_{Worker}$	Facility worker wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of worker time required per face-to-face determination of fitness: 2 hours.

Subparagraph 26.189(c)(1)

This subparagraph imposes no incremental cost and affords no saving because it merely requires that when a for-cause determination of fitness is conducted, as required by paragraph 26.189(b), individuals shall be determined to be fit for duty when no conclusive evidence and no significant basis for concern exists. The subparagraph does, however, provide a more specific procedure that must be followed when making a determination of fitness.

Subparagraph 26.189(c)(2)

This subparagraph imposes no incremental cost and affords no saving because it merely requires that individuals being reviewed in a for-cause determination of fitness must be determined to be unfit for duty when there is a significant basis for concern, even when there is no conclusive evidence of an FFD policy violation. This provision does, however, provide a more specific procedure that must be followed when making a determination of fitness.

Paragraph 26.189(d)

This subparagraph imposes no incremental cost and affords no saving because it merely requires that the professional who performed the initial determination of fitness be responsible for any changes or modifications made to the determination, and prohibits individuals, licensees, and other entities from seeking a second determination of fitness if one has already been performed.

Subpart I: Managing Fatigue

Note: For analytical purposes, the regulatory analysis calculates an average cost per program for each provision in Subpart I. The NRC notes, however, that actual programs vary considerably in terms of (1) the number of sites and units per program, and (2) the staffing levels per site. Consequently, some programs will have much lower costs or savings than estimated, and others will have much higher costs or savings than estimated.

26.201 Applicability

This section of the final rule indicates that Subpart I applies to Part 50 licensees, combined license holders under 52.103, and contractor/vendors to nuclear power plant licensees who rely upon contractor/vendor FFD programs or program elements. Subpart I does not apply to material licensees. This section also states that the requirements in §§ 26.203 and 26.207 through 26.211 apply to the individuals identified in § 26.4(a) through (c). The final language also specifies that the requirements in § 26.205 apply to the individuals identified in § 26.4(a). Incremental costs associated with the new provisions of this Subpart are addressed in the relevant paragraphs.

26.203 General Provisions

Paragraph 26.203(a)-(b)

These paragraphs of the final rule require licensees to establish a policy and develop, implement, and maintain procedures for the management of fatigue in accordance with the final rule. Procedures must address self-declarations, work hour controls, fatigue assessments, and sanctions. Licensees and C/Vs will incur incremental costs to revise their existing policies and procedures to include the fatigue provisions.

The *one-time cost per program* to address fatigue policies and procedures, including self-declarations, work hour controls, fatigue assessments, and sanctions, includes the sum of the following factors:

- One-time costs per program to account for FFD staff, manager, and clerical labor and to contract a legal consultant to incorporate fatigue provisions into the written policies and procedures are calculated as follows:

  $$(HOURS_{FFD\_Staff} \times WAGE_{FFD\_Staff}) + (HOURS_{Manager} \times WAGE_{Manager}) + (HOURS_{Legal} \times WAGE_{Legal}) + (HOURS_{Clerical} \times WAGE_{Clerical})$$

- One-time costs per program for facility supervisors to implement the corporate policies on the management of fatigue at the facility level (e.g., for development of any site-specific implementing procedures, delineation and delegation of roles and responsibilities under revised policies and procedures, and for other miscellaneous administrative implementation costs not accounted for under other provisions) are calculated as follows:

  $HOURS_{Supervisor} \times WAGE_{Supervisor} \times NUM_{Facilities}$

Parameter	Description
$HOURS_{Clerical}$	One-time hours of clerical personnel to support revision of policies and procedures per program (described in assumptions below)
$HOURS_{Manager}$	One-time hours of labor of various managers to review and approve policies and procedures for fatigue per program (described in assumptions below)
$HOURS_{FFD\_Staff}$	One-time hours of FFD program staff labor to develop and revise policies and procedures for fatigue provisions per program (described in assumptions below)
$HOURS_{Legal}$	One-time hours of legal assistance to review and revise policies and procedures for provisions per program (described in assumptions below)
$HOURS_{Supervisor}$	One-time hours of facility supervisor time to implement revised corporate policies and procedures for fatigue per facility (e.g., for development of any site-specific implementing procedures, delineation and delegation of roles and responsibilities under revised policies and procedures, and for other miscellaneous administrative implementation costs not accounted for under other provisions) (described in assumptions below)
$NUM_{Facilities}$	Number of facilities (described in Appendix 2, Exhibit A2-14)
$WAGE_{Manager}$	FFD program manager wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{FFD\_Staff}$	FFD staff wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Legal}$	Legal consultant wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Clerical}$	Clerical personnel wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Supervisor}$	Facility supervisor wage rate (described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of FFD program staff labor to develop and revise policies and procedures for fatigue provisions per program: 80 hours.

- Hours of labor of various managers to review and approve policies and procedures for fatigue provisions per program: 40 hours.

- Hours of legal assistance to review and revise policies and procedures for fatigue provisions per program: 20 hours.

- Hours of clerical personnel to support revision of policies and procedures for fatigue provisions per program: 40 hours.

- Hours of facility supervisor time to implement revised corporate fatigue policies and procedures (e.g., for development of any site-specific implementing procedures, delineation and delegation of roles and responsibilities under revised policies and procedures, and for other miscellaneous administrative implementation costs not accounted for under other provisions): 160 hours.

- Policy and procedure revisions are developed once per operating firm, regardless of the number of sites or facilities the firm operates.

Paragraph 26.203(c)

This paragraph of the final rule requires licensees and C/Vs to incorporate the fatigue-related knowledge and abilities (KAs) into the training that is required in final paragraph 26.29(a) and the comprehensive examination required in final paragraph 26.29(b). Licensees and C/Vs will incur incremental costs for the following activities:

- Training course revisions
- Employee training addressing new fatigue KAs
  - one-time initial training of covered employees
  - annual initial training of new employees
- Annual refresher training for all covered employees

Training Course Revisions. The final provision will require licensees to revise their training programs to address the fatigue-related KAs presented in final subparagraphs 26.197(c)(1) and (2).

The *one-time cost per program* associated with revising the training program to include fatigue KAs results from the following:

$$(HOURS_{Consultant} \times WAGE_{Consultant}) + (HOURS_{Trainer} \times WAGE_{Trainer}) + (HOURS_{Training\_Manager} \times WAGE_{Training\_Manager}) + (HOURS_{Manager} \times WAGE_{Manager}) + (HOURS_{Clerical} \times WAGE_{Clerical})$$

Parameter	Description
$HOURS_{Consultant}$	Hours of industry consultant time per program to develop generic training materials for use by the entire industry (described in assumptions below)
$HOURS_{Manager}$	One-time hours of FFD program manager time per program to revise the training materials to address fatigue KAs (described in assumptions below)
$HOURS_{Clerical}$	One-time hours of clerical personnel to support the revision of the training materials to include fatigue KAs (described in assumptions below)
$HOURS_{Trainer}$	One-time hours of trainer time per program to revise the training materials to address fatigue KAs (described in assumptions below)
$HOURS_{Training\_Manager}$	One-time hours of training manager time per program to revise the training materials to address fatigue KAs (described in assumptions below)
$WAGE_{Manager}$	FFD program manager wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Clerical}$	Clerical personnel wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Consultant}$	Consultant wage rate (described in Appendix 2, Exhibit A2-15)
$WAGE_{Trainer}$	Trainer wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Training\_Manager}$	Training manager wage rate (described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of industry consultant time per program to develop generic training materials for use by the entire industry: 2.6 hours (i.e., 80 hours divided by 31 programs).

- Hours of trainer time per program to revise the training materials to address fatigue KAs: 8 hours.

- Hours of training manager time per program to review the training materials addressing fatigue KAs: 2 hours.

- Hours of FFD program manager time per program to review the training materials addressing fatigue KAs: 2 hours.

- Hours of clerical personnel to support the revision of the training materials addressing fatigue KAs: 4 hours.

Initial Fatigue KA Training for All Individuals Subject to the Rule. Licensees and C/Vs will be required to incur a one-time cost to retrain affected employees to be familiar with the fatigue-related KAs, an annual cost to train newly hired employees in the additional KAs, and an annual cost to provide refresher training that includes the fatigue KAs.

Licensees and C/Vs will incur a one-time incremental cost to train affected individuals who are already covered by the FFD program, but who must now be retrained in the additional fatigue-related KAs. The costs calculated below assume that the fatigue training will be presented as an incremental unit of the training already conducted under §26.29. The *one-time cost per program* results from the sum of the following costs:

- One-time costs per program to retrain existing employees on the fatigue-related KAs are calculated as follows:

  $NUM_{Employees} \times (HOURS_{Training\text{-}Fatigue} + HOURS_{Examination\text{-}Fatigue}) \times WAGE_{Worker} \times NUM_{Units}$

- One-time costs per program for trainers to administer the training on the fatigue-related KAs are calculated as follows:[1]

  $NUM_{Sessions} \times (HOURS_{Training\text{-}Fatigue} + HOURS_{Examination\text{-}Fatigue} + HOURS_{Preparation\text{-}Fatigue}) \times WAGE_{Trainer} \times NUM_{Units}$

Parameter	**Description**
$HOURS_{Training\text{-}Fatigue}$	Length of training increment addressing the fatigue-related KAs (described in assumptions below)
$HOURS_{Examination\text{-}Fatigue}$	Length of comprehensive examination increment addressing the fatigue-related KAs (described in assumptions below)
$HOURS_{Preparation\text{-}Fatigue}$	Hours of incremental preparation and examination grading per session addressing the fatigue-related KAs (described in assumptions below)
$NUM_{Employees}$	Number of employees per unit covered by FFD program requirements (described in Appendix 2, Exhibit A2-14)
NUM_{Units}	Number of units per program (described in Appendix 2, Exhibit A2-14)
$NUM_{Sessions}$	Number of training sessions per facility (described in assumptions below)
$WAGE_{Worker}$	Utility worker wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Trainer}$	Trainer wage rate (described in Appendix 2, Exhibit A2-11)

Assumptions:

- Length of training addressing the fatigue-related KAs per session: 1 hour.

[1] Although many licensees may be conducting computer-based trainings, the analysis assumes a class-based format and may overestimate the cost of incremental training activities.

- Length of comprehensive examination increment addressing the fatigue-related KAs per session: 10 minutes.

- Number of training sessions assumes 50 workers per session.

- Hours of preparation and examination grading per session addressing the fatigue-related KAs: 0.5 hours.

Annual Initial Training for other affected individuals, such as new workers not yet covered under FFD programs will also lead to increased costs due to the additional fatigue-related KAs. The costs calculated below assume that the fatigue training will be presented as an incremental unit of the training already conducted under §26.29. The *annual cost per program* results from the sum of the following factors:

- Incoming employees must take the training course increment for fatigue-related KAs:

  $NUM_{Applicants} \times HOURS_{Training\text{-}Fatigue} \times WAGE_{Worker} \times NUM_{Units}$

- Annual costs per program for trainers to administer the training course increment for fatigue-related KAs are calculated as follows:[2]

  $NUM_{Sessions} \times HOURS_{Training\text{-}Fatigue} \times WAGE_{Trainer} \times NUM_{Units}$

Parameter	**Description**
$HOURS_{Training\text{-}Fatigue}$	Length of fatigue-related KA training increment (described in assumptions below)
$NUM_{Applicants}$	Number of applicants (e.g., new hires including outage workers) covered by FFD program requirements per year (described in Appendix 2, Exhibit A2-14 and in assumptions below)
$NUM_{Sessions}$	Number of training sessions per unit (described in assumptions below)
NUM_{Units}	Number of units per program (described in Appendix 2, Exhibit A2-14)
$WAGE_{Worker}$	Utility worker wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Trainer}$	Trainer wage rate (described in Appendix 2, Exhibit A2-11)

Assumptions:

- Length of training increment addressing the fatigue-related KAs: 1 hour.

[2] Although many licensees may be conducting computer-based trainings, the analysis assumes a class-based format and may overestimate the cost of incremental training activities.

- Hours of incremental preparation and examination grading per session addressing the fatigue-related KAs: 0.5 hours.

- Number of training sessions assumes 20 workers per session.

- Number of applicants (e.g., new hires including outage workers) covered by FFD program requirements per facility per year represents new employees due to staff turnover. The analysis assumes a turnover rate of 25%.

Annual Refresher Training. Licensees and C/Vs also will be required to reflect the fatigue-related KAs in the required annual refresher training. As a result, licensees and C/Vs will incur an incremental cost. The costs calculated below assume that the fatigue training will be presented as an incremental unit of the training already conducted under §26.29. The *annual costs per program* result from the sum of the following costs:

- Annual costs per program for employees to take the refresher training increment addressing fatigue-related KAs are calculated as follows:

  $NUM_{Employees} \times PER_{Refresher} \times HOURS_{Fatigue\ Training} \times WAGE_{Worker} \times NUM_{Units}$

- Annual costs per program for trainers to administer the refresher training increment addressing fatigue-related KAs are calculated as follows:[3]

  $NUM_{Sessions} \times (HOURS_{Fatigue\ Training} + HOURS_{Preparation\text{-}Fatigue}) \times WAGE_{Trainer} \times NUM_{Units}$

Parameter	**Description**
$HOURS_{Preparation\text{-}Fatigue}$	Hours of training preparation and examination grading for fatigue-related training (described in assumptions below)
$HOURS_{Fatigue\ Training}$	Length of fatigue-related refresher training course (described in assumptions below)
$NUM_{Employees}$	Number of employees per program covered by FFD program requirements (described in Appendix 2, Exhibit A2-14)
$NUM_{Sessions}$	Annual number of additional refresher training sessions per facility (described in assumptions below)
NUM_{Units}	Number of units per program (described in Appendix 2, Exhibit A2-14)

[3] Although many licensees may be conducting computer-based trainings, the analysis assumes a classroom-based format and may overestimate the cost of incremental training activities.

Parameter	Description
$PER_{Refresher}$	Percentage of employees taking refresher training (described in assumptions below)
$WAGE_{Worker}$	Utility worker wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Trainer}$	Trainer wage rate (described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of employees taking refresher training rather than the comprehensive "challenge" exam described under §26.29(c)(2): 20%.
- Hours of training preparation and examination grading addressing the fatigue-related KAs: 0.5 hours.
- Length of fatigue-related refresher training increment: 1 hour.
- Annual number of refresher training sessions assumes 20 workers per session.

Paragraph 26.203(d)

This paragraph of the final rule [including subparagraphs 26.203(d)(1)–(5)] requires each licensee to retain records associated with certain fatigue requirements for a period of at least three years or until completion of all related legal proceedings, whichever is later. These records include (1) records of work hours for individuals subject to the work hour controls as specified in final paragraph 26.205, (2) documentation of shift schedules and shift cycles of individuals who are subject to the work hour controls in final paragraph 26.205, (3) documentation of waivers required under final subparagraph 26.205(a)(4), (4) documentation of work hour reviews conducted in accordance with final subparagraphs 26.205(e)(3) and (e)(4), and (5) documentation of any fatigue assessments conducted in accordance with final paragraph 26.211(f). The burden of preparing the documents covered by this recordkeeping requirement (e.g., preparing records of fatigue assessments) is calculated under the respective sections of the rule (e.g., 26.211(f) for fatigue assessments). However, licensees will incur annual costs for recordkeeping under subparagraphs (1) - (5) of this paragraph, as discussed below.

Licensees will incur incremental annual costs to physically place the documentation required under 26.203(d)(1), (2),(4), and (5) into storage.

The *annual cost per program* is estimated as follows:

$$[(HOURS_{Work\_Hours} + HOURS_{Reviews} + HOURS_{Assessments}) \times WAGE_{Clerical}] \times NUM_{Facilities}$$

Parameter	Description
$HOURS_{Work\_Hours}$	Annual number of hours per facility to store individuals' work hours under final rule (described in assumptions below)
$HOURS_{Reviews}$	Annual number of hours per facility to store work hour reviews under final rule (described in assumptions below)
$HOURS_{Assessments}$	Annual number of hours per facility to store fatigue assessment documentation under final rule (described in assumptions below)
$WAGE_{Clerical}$	Utility clerical wage rate (described in Appendix 2, Exhibit A2-11)
$NUM_{Facilities}$	Number of facilities per program (described in Appendix 2, Exhibit A2-14)

Assumptions:

- Annual number of hours per facility to store individuals' work hours under final rule: 40 hours.

- Annual number of hours per facility to store work hour reviews under final rule: 4 hours.

- Annual number of hours per facility to store fatigue assessment documentation under final rule: 10 hours.

Subparagraph 26.203(d)(3) of the final rule requires licensees to document waivers as required in final subparagraph 26.203(d)(5)(v). This subparagraph modifies recordkeeping activities that licensees currently undertake under their plant technical specifications. These currently require licensees to keep on file each authorized deviation from the extended work hour limits contained in their specifications. The provision will result in annual savings because fewer waivers will be issued after the final rule takes effect.

The *annual savings per program* are estimated as the difference between the new costs and the current costs as follows:

$$(HOURS_{WaiverNew} - HOURS_{WaiverTS}) \times WAGE_{Clerical} \times NUM_{Facilities}$$

Parameter	Description
$HOURS_{WaiverTS}$	Annual number of hours per facility to file deviation authorizations under existing licensee technical specifications (described in assumptions below)
$HOURS_{WaiverNew}$	Annual number of hours per facility to file waivers under final rule (described in assumptions below)
$NUM_{Facilities}$	Number of facilities per program (described in Appendix 2, Exhibit A2-14)
$WAGE_{Clerical}$	Utility clerical wage rate (described in Appendix 2, Exhibit A2-11)

Assumptions:

- Annual number of hours per facility to file deviation authorizations under existing licensee technical specifications: 12 hours.

- Annual number of hours per facility to file waivers under final rule: 1 hour.

Paragraph 26.203(e)

This paragraph of the final rule specifies the fatigue-related information that licensees must include in the annual FFD program performance report required under Section 26.717. Incremental costs and savings to licensees are addressed below under the relevant subparagraph.

In addition, NRC will experience annual costs under this provision in conjunction with the requirements of §26.717. Under the former rule, FFD program performance reports do not address fatigue requirements. NRC, therefore, will incur incremental costs related to the increased effort needed to review the annual FFD program performance reports. On an annual basis, a member of the NRC staff reads, reviews, and summarizes the performance reports in an annual agency report. The *annual cost to the NRC* from reviewing and summarizing the additional information on fatigue is calculated as follows:

$$(HOURS_{Clerical} \times WAGE_{Clerical}) + (HOURS_{NRC\_Staff} \times WAGE_{NRC\_Staff})$$

Parameter	Description
$HOURS_{NRC\_Staff}$	NRC staff hours per year to review and summarize the additional information addressing fatigue (described in assumptions below)
$WAGE_{NRC\_Staff}$	NRC staff wage rate (described in Appendix 2, Exhibit A2-11)
$HOURS_{Clerical}$	NRC clerical hours per year to assist in reviewing and summarizing the additional information addressing fatigue (described in assumptions below)
$WAGE_{Clerical}$	NRC clerical wage rate (described in Appendix 2, Exhibit A2-11)

Assumptions:

- NRC staff hours per year to review and summarize the additional information addressing fatigue: 24 hours.

- NRC clerical hours per year to assist in reviewing and summarizing the additional information addressing fatigue: 24 hours.

Subparagraph 26.203(e)(1)

This subparagraph of the final rule requires licensees to include, within the annual FFD program performance report required under §26.717, 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). Licensees must report the number of instances each work hour control was waived during operating and outage periods. In addition, the licensee must report a summary that shows the distribution of waiver use among the individuals in each category identified in paragraph 26.4(a).

This analysis assumes that licensees will incur an annual cost to review their waiver documentation, categorize the instances of waivers as required, and report the data and frequency distribution in the FFD program performance report.

The *annual cost per program* is calculated as follows:

$$[(HOURS_{Clerical} \times WAGE_{Clerical}) + (HOURS_{Manager} \times WAGE_{Manager})] \times NUM_{Facilities}$$

Parameter	**Description**
$HOURS_{Clerical}$	Annual hours of clerical worker labor per facility to tally the annual number of waivers of each type, separate operating waivers from outage waivers, produce a summary of the distribution, and report these data in the FFD program report (described in assumptions below)
$HOURS_{Manager}$	Annual hours of managerial labor per facility to review the waivers data included in the FFD program report (described in assumptions below)
$WAGE_{Manager}$	Utility managerial wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Clerical}$	Utility clerical wage rate (described in Appendix 2, Exhibit A2-11)
$NUM_{Facilities}$	Number of facilities per program (described in Appendix 2, Exhibit A2-14)

Assumptions:

- Hours of clerical worker labor per facility to tally the annual number of waivers of each type, separate operating waivers from outage waivers, produce a summary of the distribution, and report these data in the FFD program report: 10 hours.

- Hours of managerial labor to review the waivers data included in the FFD program report: 10 hour.

Subparagraph 26.203(e)(2)

This subparagraph of the final rule requires licensees to report a summary for each nuclear power plant site of the instances of fatigue assessments conducted during the previous calendar year, including: the conditions under which each fatigue assessment was conducted (i.e., self-declaration, for cause, post-event, follow-up); a statement of whether the individual was working on outage activities at the time of the fatigue assessment; the category of duties the individual was performing if the individual was performing one of the duties described in the 26.4(a)(1) through (a)(5) of the final rule; and the management actions, if any, resulting from each fatigue assessment. This information should be readily available based on documentation prepared under 26.211(f). This analysis assumes that licensees will incur an annual cost to review and summarize the relevant fatigue assessment documentation.

The *annual cost per program* is calculated as follows:

$$[(HOURS_{Clerical} \times WAGE_{Clerical}) + (HOURS_{Manager} \times WAGE_{Manager})] \times NUM_{Facilities}$$

Parameter	**Description**
$HOURS_{Clerical}$	Annual hours of clerical labor per facility to summarize instances of fatigue assessments conducted during the previous calendar year to be included in the FFD program report (described in assumptions below)
$HOURS_{Manager}$	Annual hours of manager labor per facility to review the summary information to be sent to NRC (described in assumptions below)
$NUM_{Facilities}$	Number of facilities per program (described in Appendix 2, Exhibit A2-14)
$WAGE_{Clerical}$	Utility clerical wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Manager}$	Utility manager wage rate (described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of clerical labor per facility to summarize instances of fatigue assessments conducted during the previous calendar year to be included in the FFD program report: 20 hours.

- Hours for manager per facility to review the summary information to be sent to NRC : 10 hours.

Paragraph 26.203(f)

This paragraph of the final rule requires licensees to audit the management of worker fatigue. The audits must be conducted as part of the overall FFD program audit required by paragraph 26.41 of the final rule. Under the former rule, FFD program audits do not address the fatigue requirements. Licensees, therefore, will incur an ongoing implementation cost to audit worker fatigue management.

The *annual cost per program* is calculated as follows:

$$[(HOURS_{Auditor} \times WAGE_{Auditor}) + (HOURS_{Manager} \times WAGE_{Manager}) + (HOURS_{Clerical} \times WAGE_{Clerical})] \times NUM_{Facilities} \times PER_{Annualized}$$

Parameter	Description
$HOURS_{Auditor}$	Annual hours of auditor labor per facility to audit the management of worker fatigue (described in assumptions below)
$HOURS_{Clerical}$	Annual hours of clerical labor per facility to assist with the audit of fatigue management program (described in assumptions below)
$HOURS_{Manager}$	Annual hours of manager labor per facility to assist with the audit of fatigue management program (described in assumptions below)
$NUM_{Facilities}$	Number of facilities per program (described in Appendix 2, Exhibit A2-14)
$PER_{Annualized}$	Percentage multiplier to yield annualized savings (as described in assumptions below)
$WAGE_{Auditor}$	Contract auditor wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Clerical}$	Utility clerical wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Manager}$	Utility manager wage rate (described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of auditor labor per facility to audit the management of worker fatigue: 40 hours.
- Hours of clerical labor per facility to assist with the audit of fatigue management program: 16 hours.
- Hours for manager per facility to review the summary information to be sent to NRC : 16 hours.
- Percentage multiplier to yield annualized savings is 50% because the audits occur every 2 years.

26.205 Work Hours

Paragraph 26.205(a)

This paragraph of the final rule describes the individuals subject to the work hour controls of §26.205. NRC's Generic Letter 82-12 and existing plant work hour technical specifications require that licensees establish administrative procedures to limit the working hours of "plant staff who perform safety-related functions (e.g., licensed SROs, licensed ROs, health physicists, auxiliary operators, and key maintenance personnel)." The final paragraph requires that individuals be subject to the work hour controls if they perform duties within one of the following five job duty groups: (1) operating or on-site directing of the operation of systems and components that a risk-informed evaluation process has shown to be significant to public health and safety; (2) performing maintenance or on-site directing of the maintenance of structures, systems, and components that a risk-informed evaluation process has shown to be significant to public health and safety; (3) performing Health Physics or Chemistry duties required as a member of the on-site emergency response organization minimum shift complement; (4) performing the duties of a Fire Brigade member who is responsible for understanding the effects of fire and fire suppressants on safe shutdown capability; or (5) performing security duties as an armed security force officer, alarm station operator, response team leader, or watchperson, hereinafter referred to as security personnel. Incremental costs related to this provision are addressed in the analysis of paragraphs 26.205(b)-(e) of the final rule. In addition, substantial savings are expected to accrue to numerous licensees that will likely apply fatigue management rules to fewer workers than they do currently.[4] NRC believes these savings might be as high as one-third of all fatigue management costs incurred under the former requirements. These savings have not been quantified, however, because of a lack of data.

[4] Relative to Generic Letter 82-12 and existing plant work hour technical specifications, the final rule more precisely identifies workers subject to fatigue management provisions. This could lead licensees not to cover workers that had been covered unnecessarily due to ambiguity in the rules or for administrative ease.

Paragraph 26.205(b)

This final paragraph, including subparagraphs (1) - (5), specifies the work hours to be included when calculating individual work hours. The analysis assumes that licensees will incur costs to modify their existing timekeeping systems and to monitor, manage, and document the actual hours worked by individuals covered under 26.205.[5]

Licensees will incur a one-time cost to modify their existing timekeeping systems in order to record, track, and document the actual hours worked and rest breaks and days off received by individuals covered under the individual work hour controls of paragraph 26.205(d) of the final rule. The *one-time costs per program* result from the following:

$$COST_{System} \times NUM_{Facilities}$$

Licensees will incur an annual cost associated with monitoring and managing the hours actually worked by individuals, including filing or backing up work hour records. The *annual costs per program* result from the following:

$$[(HOURS_{Supervisor} \times WAGE_{Supervisor}) + (HOURS_{Clerical} \times WAGE_{Clerical})] \times NUM_{Facilities}$$

Parameter	Description
$COST_{System}$	One-time cost per facility to modify a facility's existing timekeeping systems, or develop new systems, to record and track work hour data (described in Appendix 2, Exhibit A2-16)
$HOURS_{Supervisor}$	Annual hours of supervisory labor to monitor and manage the hours actually worked by individuals at one facility, including filing or backing up work hour records (described in assumptions below)
$HOURS_{Clerical}$	Annual hours for clerical labor to monitor and manage the hours actually worked by individuals at one facility, including filing or backing up work hour records (described in assumptions below)
$NUM_{Facilities}$	Number of facilities per program (described in Appendix 2, Exhibit A2-14)
$WAGE_{Supervisor}$	Utility managerial wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Clerical}$	Utility clerical wage rate (described in Appendix 2, Exhibit A2-11)

[5] Based on available information, NRC believes that licensees will use timekeeping systems (e.g., electronic timesheets) or access control systems (e.g., electronic card-key badge readers) to record employee work hour data.

Assumptions:

- One-time cost to modify a facility's existing systems, or develop a new system, to record, track, and document workers' actual hours worked is inclusive of all labor, management, contractor, and software.

- Annual hours of supervisory labor to monitor and manage the hours actually worked by individuals, including filing or backing up copies of work hour records: 200 hours.

- Annual hours for clerical labor to monitor and manage the hours actually worked by individuals, including filing or backing up copies of work hour records: 50 hours.

Sensitivity Analysis - Pre-Order Baseline

The preceding analysis addresses the cost of modifying timekeeping systems and tracking hours of all workers covered by §26.205, including security personnel, operators, maintenance, health physics/chemistry emergency response, and fire brigade. For one subset of these workers – security personnel – licensees already have undertaken activities similar to those described above due to the requirements of Order EA-03-038. In particular, licensees already have developed modified timekeeping systems to track hours of security personnel as necessary to implement certain individual work hour limits. These timekeeping systems are inadequate, however, with respect to conducting the tracking necessary to implement the rest break and day-off provisions required under §26.205(d)(2)-(3). This analysis assumes, therefore, that licensees will replace the systems developed in response to Order EA-03-038 in favor of new systems, as costed above.

Paragraph 26.205(c)

This final paragraph requires licensees to schedule the work hours of individuals who are subject to §26.205 consistent with the objective of preventing impairment from fatigue due to the duration, frequency, or sequencing of successive shifts.

Licensees may incur one-time costs to renegotiate collective bargaining agreements, or discuss changes with employee committees (for non-union facilities), in order to address issues related to the assignment of overtime. *One-time costs per program* are calculated as follows:

$$[(HOURS_{Management} \times WAGE_{Management}) + (HOURS_{Legal} \times WAGE_{Legal})] \times PER_{Negotiation} \times NUM_{Facilities}$$

Licensees will incur annual costs to prepare modified work schedules on an ongoing basis for all employees covered by the rule as required by this paragraph, as well as by other provisions of the final rule. *Annual costs per program* are calculated as follows:

$$HOURS_{Scheduler} \times WAGE_{Scheduler} \times NUM_{Facilities}$$

Parameter	Description
$HOURS_{Scheduler}$	Annual hours needed for workers to support supervisors in reviewing, analyzing, and modifying schedules (described in the assumptions below)
$HOURS_{Management}$	One-time hours needed for licensee management to work with union representatives in collective bargaining (described in the assumptions below)
$HOURS_{Legal}$	One-time hours needed for licensee legal staff to work with union representatives in collective bargaining (described in the assumptions below)
$NUM_{Facilities}$	Number of facilities per program (described in Appendix 2, Exhibit A2-14)
$PER_{Negotiation}$	Percentage of licensees whose schedule modifications lead to revisions to collective bargaining agreements or to discussions with employee committees (for non-union facilities) (described in the assumptions below)
$WAGE_{Scheduler}$	Utility worker wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Management}$	Licensee management wage rate (described in Appendix 2, Exhibit A2-11)
$WAGE_{Legal}$	Licensee legal wage rate (described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours needed for licensee management to prepare for and bargain with union representatives or discuss changes with employee committees: 60 hours.

- Hours needed for licensee legal staff to prepare for and bargain with union representatives or discuss changes with employee committees: 40 hours.

- Percentage of facilities whose schedule modifications lead to revisions to collective bargaining agreements or to discussions with employee committees (for non-union facilities): 100 percent.

- An additional level of effort averaging ½ FTE per site will be needed to prepare and maintain all worker schedules in a manner that complies with

new fatigue requirements, including the break and day-off requirements in the final rule. This level of effort includes any necessary work associated with special scheduling during a unit outage, security system outage, or increased threat condition. This analysis assumes that the additional work is not occurring on a routine basis, and instead covers instances, for example, where individuals are call in for work on weekends.

Sensitivity Analysis - Pre-Order Baseline

The preceding analysis addresses the cost of preparing modified work schedules on an ongoing basis for all employees covered by the final rule (including security personnel, operators, maintenance, health physics/chemistry emergency response, and fire brigade) consistent with the objective of preventing impairment from fatigue due to the duration, frequency, or sequencing of successive shifts. For one subset of these workers – security personnel – licensees already have undertaken activities similar to those described above due to the requirements of Order EA-03-038. In particular, licensees already have developed modified work schedules for security personnel as necessary to implement certain individual work hour limits. These schedules may not be adequate, however, with respect to implementing the break and day-off provisions required under §26.205(d)(2)-(3). This analysis assumes, therefore, that licensees will replace the schedules developed in response to Order EA-03-038 in favor of new scheduling practices, as costed above.

Paragraph 26.205(d)

Subparagraph 26.205(d)(1)

This subparagraph of the final rule establishes work hour limits for individuals subject to §26.205. Except as allowed by the waiver provisions of paragraph 26.207 of the final rule, licensees must ensure that employee work hours do not exceed the following individual work hour limits:

- 16 work hours in any 24-hour period;
- 26 work hours in any 48-hour period; and
- 72 work hours in any 7-day period.

This paragraph imposes no incremental cost and affords no savings because licensees' existing technical specifications, based on Generic Letter 82-12, contain almost identical requirements. The only change is that under the final rule employee work hours must not exceed 26 hours (instead of 24 hours) in any 48-hour period. This slight relaxation in the work hour limit relieves licensees from the requirement of granting a waiver in those cases where it would have permitted the employee to work up to two additional hours. The associated savings are accounted for in the analysis of subparagraph 26.207 of the final rule. Order EA-03-038 imposed the requirements in §26.205(d)(1) of the final rule on security personnel. Therefore, the provision results in no incremental costs for security personnel.

Although licensees' existing plant technical specifications contain almost identical requirements, some licensees are applying them more broadly to encompass some plant workers who would not be subject to individual work hour controls under §26.205(d)(1) of the final rule. For those workers, the final rule results in savings because licensees are no longer required to complete paperwork when necessary to waive the individual work hour limits. These savings also are accounted for under §26.207.

Sensitivity Analysis - Pre-Order Baseline

Relative to the requirements that were in effect before the NRC issued Order EA-03-038, which established certain fatigue management provisions for security personnel, the final subparagraph represents an entirely new requirement as applied to security personnel. NRC, however, believes that even prior to Order EA-03-038, security personnel rarely exceeded the individual work hour limits in the final rule. A 72-hour work week consisting of six 12-hour days, for example, would meet the limits in the final rule, and NRC believes that security personnel worked substantially fewer hours. Therefore, the analysis assumes that any incremental costs resulting from this subparagraph are insignificant to the analysis.

Subparagraph 26.205(d)(2)

This subparagraph of the final rule revises and amends requirements related to mandatory rest breaks. Licensee work hour technical specifications based on Generic Letter 82-12 currently require that individuals performing safety-related functions must receive a minimum break of at least 8 hours, including shift turnover time, between work periods. There currently is no other required break. The final rule extends the minimum break between shifts to 10 hours (or a minimum 8-hour break when a break of less than 10 hours is necessary to accommodate a crew's scheduled transition between work schedules or shifts). The final rule also introduces a 34-hour break in any 9-day period.

NRC expects that licensees will be able to meet the break provisions in the final rule at no incremental cost other than the scheduling cost described under paragraph 26.205(c) of the final rule, except under unusual circumstances, as addressed under paragraph 26.207 of the final rule. This includes any costs during power operation to ensure staff coverage over weekends as well as the availability of personnel during and after unscheduled call-ins. NRC came to this conclusion based on analysis of sample shift schedules provided by industry and on related industry comments.

Sensitivity Analysis Note - Pre-Order Baseline

Relative to the requirements that were in effect before the NRC issued Order EA-03-038, the final subparagraph also establishes mandatory breaks for security personnel. NRC expects that licensees will be able to meet the break provisions of the final rule at no incremental cost other than the scheduling cost described under paragraph 26.205(c) of the final rule and the calculation

and monitoring cost described under paragraph 26.205(b) of the final rule, except under unusual circumstances, as addressed under paragraph 26.207 of the final rule.

Subparagraph 26.205(d)(3)

Under the final subparagraph, licensees must ensure that individuals have, at a minimum, the number of days off specified in this subparagraph. The final language defines a day off as a day during which an individual does not start a work shift. The final language introduces the following mandatory days off for affected workers:

- For individuals working 8-hour shift schedules, at least 1 day off per week, averaged over a shift cycle
- For individuals working 10-hour shift schedules, at least 2 days off per week, averaged over a shift cycle
- For non-security personnel working 12-hour shift schedules, at least 2 ½ days off per week, averaged over a shift cycle
- For security personnel working 12-hour shift schedules, at least 3 days off per week, averaged over a shift cycle

The final rule also specifies that a shift cycle may not exceed six weeks.

NRC expects that licensees will be able to meet the day-off provisions at no incremental cost other than the scheduling cost described under paragraph 26.205(c) of the final rule, except under unusual circumstances, as addressed under paragraph 26.207 of the final rule. This includes any costs during power operation to ensure staff coverage over weekends as well as the availability of personnel during and after unscheduled call-ins. NRC came to this conclusion based on analysis of sample shift schedules provided by industry and on related industry comments.

Subparagraphs 26.205(d)(4)-(6)

Subparagraphs 26.205(d)(4)-(6) provide exceptions to the day-off requirements in paragraph 26.205(d)(3) of the final rule.

For non-security personnel, licensees do not need to meet the day-off requirements in §26.205(d)(3) during the first 60 days of a unit outage. In addition, for security personnel, licensees do not need to meet the day-off requirements in §26.205(d)(3) during the first 60 days of a unit outage, security system outage, or increased threat condition. Instead, during these periods, licensees must ensure that:

- Non-security personnel receive at least three days off in each successive (i.e., non-rolling) 15-day period during the first 60 days of a plant outage; and

- Security personnel receive at least four days off in each successive (i.e., non-rolling) 15-day period during the first 60 days of a unit outage or planned security system outage.
- Security personnel need not meet the requirements of paragraphs 26.205(d)(3) and 26.205(d)(5)(i) during unplanned security system outages or increased threat conditions.

Subparagraph 26.205(d)(6) of the final rule allows licensees to extend these day-off provisions beyond the first 60 days of a unit or security system outage or increased threat condition. Licensees may extend these provisions for an individual for seven days for each independent seven-day period in which the individual has worked less than 48 hours during the plant or security system outage or increased threat condition.

NRC expects that licensees will incur incremental costs to be able to meet the day-off provisions of the final rule during unit outages. NRC came to this conclusion based on analysis of sample shift schedules provided by industry and on related industry comments. These incremental costs are described below, as well as under paragraph 26.205(c) of the final rule, and as addressed under paragraph 26.207 of the final rule.

NRC expects that licensees using "Super Crew" 12-hour shifts during outages will incur incremental costs associated with drawing upon additional workers in order to continue obtaining the same level of effort during outage periods. These staff may be permanent part-time staff or temporary contract staff hired to work during the outage, depending on the relevant job duty group, as follows:

- Operators - the analysis assumes that licensees will meet the additional need for operators by (1) maintaining a pool of semi-retired, formerly-licensed, operators that work only during outages and (2) obtaining some additional contract operator staff (i.e., fuel handlers). (Licensees are assumed to obtain contracted operator staff, such as refueling floor operators, only to the extent that current contract operator staffing levels cease to be adequate.) The analysis assumes there is no "slack" in available operator staff, and may, therefore, overstate costs. This may be particularly true if operators work fewer than 72 hours during some portions of an outage. Licensees will incur annual costs to coordinate, maintain, and pay a small pool of semi-retired, formerly-licensed operators to work during outages. These costs, however, are more than offset by savings associated with reduced overtime wages paid to current operators. These savings have not been calculated because they will vary depending on (1) whether the semi-retired operators are any less efficient than the current operators, and (2) the size of the pool of semi-retired operators (e.g., if the pool is large enough, then none of the semi-retired operators will be paid for overtime, thereby maximizing savings to licensees).

- Maintenance - the analysis assumes that licensees will obtain additional contract maintenance staff during the period of the outage.

- Health Physics/Chemistry Emergency Response - the analysis assumes that additional health physics/chemistry emergency response staff are not needed during outage periods.[6]

- Fire Brigade - the analysis assumes that additional fire brigade staff also are operators and are costed only as part of that group in order to avoid double counting.

- Security Personnel - the analysis assumes that additional security personnel will not be needed to comply with the requirement for four days off in any successive 15-day period during an plant outage, security system outage, or increased threat condition. Under Order EA-03-038, these staff already must average no more than 60 hours per week during planned outages and are not limited during unplanned outages. Licensees do not need to modify a typical 60-hour schedule of five 12-hour days, and other possible schedules (e.g., six 10-hour days) could be adjusted (e.g., to five 12-hour days) without changing staffing levels.

Based on a sample Super Crew 12-hour shift schedule provided by industry (see Table A below), seven crews are scheduled to work six straight days of 12-hour shifts. Assuming the schedule is used for operators and maintenance staff, two crews (D7 and N7) receive 3 days off during successive 15-day periods, but the remaining 5 crews receive only two days off during successive 15-day periods.

Table A. Super Crew Outage Scheduling

Days	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M
D1	D	D	D	D	D	D	X	D	D	D	D	D	D	X	D
D2	D	D	D	D	D	X	D	D	D	D	D	D	X	D	D
D3	D	D	D	D	X	D	D	D	D	D	D	X	D	D	D
D4	D	D	D	X	D	D	D	D	D	D	X	D	D	D	D
D5	D	D	X	D	D	D	D	D	D	X	D	D	D	D	D
D6	D	X	D	D	D	D	D	D	X	D	D	D	D	D	D
D7	X	D	D	D	D	D	D	X	D	D	D	D	D	D	X

[6] Although HP/Chemistry staff typically work large number of hours during an outage, the only HP/Chemistry staff covered by the final rule are the small number actually assigned emergency response duties (a number that does not change depending on whether or not the plant is in outage). Therefore, even if any licensees respond to the final rule by shifting hours from the HP/Chemistry emergency response team to other HP/Chemistry personnel, this will not result in incremental costs beyond the scheduling costs calculated under paragraph 26.205(c).

Days	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M
Night															
N1	N	N	N	N	N	N	X	N	N	N	N	N	N	X	N
N2	N	N	N	N	N	X	N	N	N	N	N	N	X	N	N
N3	N	N	N	N	X	N	N	N	N	N	N	X	N	N	N
N4	N	N	N	X	N	N	N	N	N	N	X	N	N	N	N
N5	N	N	X	N	N	N	N	N	N	X	N	N	N	N	N
N6	N	X	N	N	N	N	N	N	X	N	N	N	N	N	N
N7	X	N	N	N	N	N	N	X	N	N	N	N	N	N	X

D: 12-hour day shift
N: 12-hour night shift
X: Day off

To comply with the requirements of the final rule, this analysis assumes that licensees will provide operators and maintenance staff with an additional day off by adding another crew to the rotation. As a result, licensees may continue to work six crews during each shift. Table B shows the new scheduling for the eight crews.

Table B. Super Crew Outage Scheduling For Non-Security Personnel

Days	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M
D1	D	D	D	D	D	D	X	X	D	D	D	D	D	X	D
D2	D	D	D	D	D	X	X	D	D	D	D	D	X	D	D
D3	D	D	D	D	X	X	D	D	D	D	D	X	D	D	D
D4	D	D	D	X	X	D	D	D	D	D	X	D	D	D	D
D5	D	D	X	X	D	D	D	D	D	X	D	D	D	D	D
D6	D	X	X	D	D	D	D	D	X	D	D	D	D	D	D
D7	X	X	D	D	D	D	D	X	D	D	D	D	D	D	X
D8	X	D	D	D	D	D	X	D	D	D	D	D	D	X	D
Night															
N1	N	N	N	N	N	N	X	X	N	N	N	N	N	X	N
N2	N	N	N	N	N	X	X	N	N	N	N	N	X	N	N

Days	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
N3	N	N	N	N	X	X	N	N	N	N	N	X	N	N	N
N4	N	N	N	X	X	N	N	N	N	N	X	N	N	N	N
N5	N	N	X	X	N	N	N	N	N	X	N	N	N	N	N
N6	N	X	X	N	N	N	N	N	X	N	N	N	N	N	N
N7	X	X	N	N	N	N	N	X	N	N	N	N	N	N	X
N8	X	N	N	N	N	N	X	N	N	N	N	N	N	X	N

D: 12-hour day shift
N: 12-hour night shift
X: Day off

The *annual costs per program* result from the following:

- As a result of the additional hires, licensees will incur annual costs to pay for in-processing two additional contract operator crews at the time of an outage:

  $(COST_{Process\_Contract\_Ops} \times NUM_{Crews} \times FACTOR_{Outage} \times NUM_{Facilities}) \times PER_{SuperCrew}$

- Licensees will incur annual costs to pay for additional contract operator staff during an outage:

  $(WEEKS_{Outage} \times WCOST_{Contract\_Ops} \times NUM_{Crews} \times FACTOR_{Outage} \times NUM_{Facilities}) \times PER_{SuperCrew}$

- Licensees will incur annual costs to pay for in-processing of additional contract maintenance staff at the time of an outage:

  $(COST_{Process\_Maint} \times NUM_{Crews} \times FACTOR_{Outage} \times NUM_{Facilities}) \times PER_{SuperCrew}$

- Licensees will incur annual costs to pay for additional contract maintenance staff during an outage:

  $(WEEKS_{Outage} \times WCOST_{Contract\_Maint} \times NUM_{Crews} \times FACTOR_{Outage} \times NUM_{Facilities}) \times PER_{SuperCrew}$

Parameter	**Description**
$COST_{Process\_Contract\_Ops}$	The average cost to conduct in-processing of an additional contract operator crew (described in Appendix 2, Exhibit A2-15)

Parameter	Description
$COST_{Process\_Maint}$	The average cost to conduct in-processing of an additional contract maintenance crew (described in Appendix 2, Exhibit A2-16)
$FACTOR_{Outage}$	Adjustment factor to annualize modeled outages that do not occur annually (described in the assumptions below)
NUM_{Crews}	Number of crews added (described in Appendix 2, Exhibit A2-16)
$NUM_{Facilities}$	Number of facilities per program (described in Appendix 2, Exhibit A2-14)
$PER_{SuperCrew}$	Percent of facilities that use Super Crew scheduling for operators and maintenance workers during outages (described in the assumptions below)
$WCOST_{Contract\_Ops}$	The weekly cost of an additional contract operator crew (described in Appendix 2, Exhibit A2-16)
$WCOST_{Contract\_Maint}$	The weekly cost of an additional contract maintenance crew (described in Appendix 2, Exhibit A2-16)
$WEEKS_{Outage}$	Number of weeks in modeled refueling outage (described in Appendix 2, Exhibit A2-15)

Assumptions:

- Percent of facilities that use Super Crew scheduling for operators and maintenance workers during outages: 100 percent.

- Significant outages (refueling outages) are assumed to occur only once every 18 months at some reactors and once every 24 months at other reactors. The analysis assumes that each facility (which, on average, has 1.6 units) experiences one significant outage per year. Therefore, the equation applies an "outage factor" ($FACTOR_{Outage}$) of 1 as a means of annualizing the above cost.

Sensitivity Analysis Note - Pre-Order Baseline

Relative to the requirements that were in effect before the NRC issued Order EA-03-038, the proposed subparagraph also establishes mandatory days-off for security personnel. NRC expects that licensees will be able to meet the day-off provisions in the final rule at no incremental cost other than the scheduling cost described under Paragraph 26.205(c) and the calculation and monitoring cost described under Paragraph 26.205(b), except under unusual circumstances, as addressed under Paragraph 26.207.

Subparagraph 26.205(d)(7)

This final subparagraph specifies that if two or more plant outages occur at a licensee's site and the interval(s) between the successive outages is (are) less than 2 weeks, then the day-off requirements of 26.205(d)(4)-(6) must be applied based upon the beginning of the first plant outage. In effect, this provision requires licensees to treat certain instances of two or more outages as a single outage for purposes of controlling work hours. The analysis addresses outage-related costs under the final rule provisions that give rise to the costs [e.g., under §26.207]. NRC believes, however, that instances of successive outages at a site are uncommon and that, in the vast majority of instances, the latter outage(s) and the "combined" outage period is not long enough to materially affect the costs calculated under the other final rule provisions.

Paragraph 26.205(e)

This paragraph of the final rule requires licensees to review at least twice per year the control of work hours for individuals who are subject to this section. The reviews do not need to cover periods of equal duration, but must collectively cover the entire calendar year. If any outages or increased threat conditions occurred since the licensee completed the most recent review, the licensee must include in the review an assessment of the control of work hours during the outages or increased threat conditions.

The *annual costs per program* to conduct work hour control reviews include the following:

$$[(NUM_{Reviews} \times HOURS_{Review} \times NUM_{Managers}) \times WAGE_{Manager}) - (HOURS_{Current\_Review} \times WAGE_{Manager})] \times NUM_{Facilities}$$

Parameter	Description
$HOURS_{Review}$	Time per participating supervisor to review overtime hours under final rule, per review (described in the assumptions below)
$HOURS_{Current\_Review}$	Annual time for manager to review overtime hours under existing technical specifications (described in assumptions below)
$NUM_{Facilities}$	Number of affected facilities (described in Appendix 2, Exhibit A2-14)
$NUM_{Manager}$	Number of manager participating in the review (described in assumptions below)
$NUM_{Reviews}$	Annual number of times a facility will review the control of work hours for individuals who are subject to this Subpart (described in the assumptions below)
$WAGE_{Manager}$	Utility manager wage rate (described in Appendix 2, Exhibit A2-11)

Assumptions:

- Annual number of times a facility will review the control of work hours for individuals who are subject to this Subpart: 2.
- Annual hours for participating managers to review work hours under final rule: 4 hours.
- Number of managers participating in the review: 4 supervisors.
- Annual time for managers to review overtime hours under existing technical specifications: 4 hours.

26.207 Waivers and Exceptions

Paragraph 26.207(a)

Under NRC's Generic Letter No. 82-12 and licensees' existing technical specifications, a deviation from extended work hour limits may be authorized in advance by the plant manager or his deputy or higher levels of management but must be documented and available for NRC review.

Under the final subparagraph, licensees may grant a waiver of the individual work hour controls contained in paragraphs (d)(1)-(5)(i) only if an operations shift manager determines that the waiver is necessary to mitigate or prevent conditions 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. In addition, a qualified supervisor must assess the individual and determine that there is reasonable assurance that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver will be granted. To the extent practicable, licensees must only rely upon the granting of waivers to address circumstances that could not have been reasonably controlled. Licensees also must document the basis for individual waivers.

As a result of the final subparagraph, licensees will be unable to issue waivers to address most of the situations that they currently handle using deviations. Incremental costs result from licensees addressing the situation through means other than a waiver. This may entail using replacement staff who are fully qualified, but less efficient or less familiar with the job. This analysis assumes that this is the case for all instances and estimates the related costs on a weekly basis, both for outage and non-outage periods. Appendix 3 describes the derivation of these weekly costs. In addition, for those waivers that can be granted under the final rule, incremental costs arise from the need to conduct and document a fatigue assessment. This cost is calculated under §26.205 and §26.211.

The *annual cost per program* is calculated as follows:

$$[(WEEKS_{Outage} \times WEEKLYCOSTS_{Outage}) + (WEEKS_{Power} \times WEEKLYCOSTS_{Power})] \times NUM_{Facilities}$$

Parameter	Description
$NUM_{Facilities}$	Number of facilities per program (described in Appendix 2, Exhibit 2-14)
$WEEKS_{Outage}$	Number of weeks per year during which facilities experience outage conditions (described in assumptions below)
$WEEKS_{Power}$	Number of weeks per year during which facilities experience full power conditions (described in assumptions below)
$WEEKLYCOSTS_{Outage}$	The costs per week under outage conditions incurred by facilities as a result of their restricted ability to grant waivers (described in Appendix 3)
$WEEKLYCOSTS_{Power}$	The costs per week under at-power conditions incurred by facilities as a result of their restricted ability to grant waivers (described in Appendix 3)

Assumptions:

- Number of weeks per year during which an average facility experiences outage conditions: 8 weeks.

- Number of weeks per year during which facilities experience full power conditions: 44 weeks.

Paragraph 26.207(b)

Under this final paragraph, when calculating an individual's number of days off, licensees may exclude shifts worked by security personnel during the actual conduct of NRC-evaluated force-on-force tactical exercises. This provision will result in savings to licensees. This analysis does not quantify these savings, however, because the amount would be a relatively small value compared to others in this analysis.

Paragraph 26.207(c)

This paragraph states that when informed in writing by the NRC that the requirements of section 26.205 are waived for security personnel to ensure the common defense and security, licensees need not meet the specified requirements of section 26.205 for the duration of the period defined by the NRC. This provision could result in savings to licensees under unusual security

conditions. These savings will occur very infrequently, however, and are not calculated in the analysis.

Paragraph 26.207(d)

This paragraph states that licensees need not meet the requirements of paragraphs 26.205(c) and (d) during declared emergencies, as defined in the licensee's emergency plan. This provision could result in savings to licensees under unusual conditions. These savings will occur very infrequently, however, and are not calculated in the analysis.

26.209 Self-Declarations

This final paragraph requires licensees to stop any individual from performing any duties listed in paragraph 26.4(a) if the individual is performing, or being assessed for, work under a waiver of the requirements contained in 26.205(d)(1)-(5)(i) and declares that he or she is unable to safely and competently perform his or her duties due to fatigue. If the individual is required to continue performing those duties by certain other requirements, then the licensee must immediately take action to relieve the individual. The licensee must permit or require the individual to take a rest break of at least 10 hours or, alternatively, the licensee may reassign the individual to other duties if a fatigue assessment indicates that the individual is fit to safely and competently perform those other duties.

The analysis calculates costs for this provision by assuming that, in the event of a self-declaration, licensees (1) send the fatigued worker home to take a rest break of at least 10 hours, and (2) call in a replacement worker. Note that the assumed licensee actions may overstate the costs of the final provision, which also allows licensees to perform a fatigue assessment and then reassign fatigued individuals to other duties. To the extent that licensees are able to reassign fatigued staff, there is an offset to the costs calculated below.

Licensees will incur management and labor costs related to replacing fatigued workers. The *annual cost per program* is calculated as follows:

- Licensees will incur incremental management costs to call in replacement workers to substitute for any workers who are sent home to rest following a self-declaration:

  $$NUM_{Waivers} \times PER_{Self\text{-}Declare} \times (HOURS_{Supervisor} \times WAGE_{Supervisor}) \times NUM_{Facilities}$$

- Licensees also will incur incremental labor costs due to the extra time for the worker to "turn over" his/her duties to the replacement worker and other lost labor productivity:

  $$NUM_{Waivers} \times PER_{Self\text{-}Declare} \times (HOURS_{Turnover} \times WAGE_{Worker}) \times NUM_{Facilities}$$

- Licensees also will incur incremental labor costs associated with the replacement worker:[7]

$$NUM_{Waivers} \times PER_{Self\text{-}Declare} \times (HOURS_{Substitute} \times WAGE_{Worker}) \times NUM_{Facilities}$$

Parameter	Description
$HOURS_{Supervisor}$	Supervisor hour expended to identify and call in a replacement worker (described in the assumptions below)
$HOURS_{Turnover}$	Labor hours resulting from an additional turnover due to the replacement of a fatigued worker with a substitute worker (described in the assumptions below)
$HOURS_{Substituted}$	Average number of hours worked by the replacement worker per incident (described in the assumptions below)
$NUM_{Facilities}$	Number of facilities per program (described in Appendix 2, Exhibit A2-14)
$NUM_{Waivers}$	Total annual number of persons, per site, granted waivers from the requirements contained in 26.205(d)(1) and (2) (described in Appendix 3)
$PER_{Self\text{-}Declare}$	Percentage of $NUM_{Waivers}$ that self-declare to a condition of fatigue (described in the assumptions below)
$WAGE_{Worker}$	Utility worker wage rate (described in Appendix 2, Exhibit A2-11)

Assumptions:

- Total annual number of persons, per site, granted waivers from the requirements contained in 26.205(d)(1) - (5)(i) of the final rule: 15.

- Percentage of $NUM_{Waivers}$ that self-declare to a condition of fatigue: 10 percent.

- Supervisor hours expended to identify and call in a replacement worker: 1/2 hour.

- Labor hours resulting from an additional turnover due to the replacement of a fatigued worker with a substitute worker: 1 hour (i.e., 30 minutes for each of two workers).

[7] The analysis assumes that replacement workers are drawn from staff who are present at the site but have flexibility to change assignments for the remainder of the day. Therefore, this cost represents an opportunity cost. The analysis assumes that wages paid to the replacement worker are offset by wages not paid to the fatigued worker.

- Average number of hours worked by the replacement worker per incident: 6 hours.

26.211 Fatigue Assessments

Paragraph 26.211(a)–(d)

These paragraphs introduce a requirement that fatigue assessments must be conducted under four conditions: (1) for-cause; (2) self-declarations; (3) post-event; and (4) follow-up. Only supervisors and FFD program personnel, trained in accordance with the requirements of §§26.29 and 26.203(c), may conduct the fatigue assessment. The fatigue assessment must be face to face with the individual whose alertness may be impaired. The fatigue assessment must address acute fatigue, cumulative fatigue, and circadian variations in alertness and performance, and must provide the information necessary for management decisions and actions in response to the circumstance that initiated the assessment. Individuals subject to the fatigue assessment must provide complete and accurate information needed by the licensee to conduct the assessment. If an individual disagrees with the results of a fatigue assessment, the licensee must follow the procedures developed under §26.203(b)(1)(iii). Incremental costs associated with these fatigue assessments are addressed below.

The *annual costs per program* result from the following factors:

- Licensees must conduct a fatigue assessment for cause, for self-declarations, post-event, and follow-up.[8]

  $$[NUM_{Assessments} \times HOURS_{Assessment} \times (WAGE_{Worker} + WAGE_{Supervisor})] \times NUM_{Facilities}$$

- Licensees will incur costs to resolve challenges that may be brought by workers who, after self-declaring to a state of fatigue, object to negative results from their fatigue assessment:

  $$(NUM_{Self\text{-}Declarations} \times PER_{Not\_Fatigued} \times PER_{Object}) \times [(HOURS_{Worker} \times WAGE_{Worker}) + (HOURS_{ECM} \times WAGE_{ECM}) + (HOURS_{Supervisor} \times WAGE_{Supervisor})] \times NUM_{Facilities}$$

[8] If a fatigue assessment is conducted for-cause or in response to a self-declaration, and the licensee returns the individual to duty following a rest break of less than 10 hours in duration, the licensee must reassess the individual for fatigue as well as the need to implement controls and conditions before permitting the individual to resume performing any job duties. Incremental costs associated with these paragraphs are reflected in the analysis of paragraph 26.201(e) of the final rule.

Parameter	Description
$HOURS_{Worker}$	Amount of worker time to raise and resolve one incident (described in assumptions below)
$HOURS_{ECM}$	Number of hours of Employee Concerns Manager time to raise and resolve one incident (described in assumptions below)
$HOURS_{Supervisor}$	Number of hours of supervisor time to raise and resolve one incident (described in assumptions below)
$HOURS_{Assessment}$	Hours needed to complete one fatigue assessment (described in the assumptions below)
$NUM_{Facilities}$	Number of facilities per program (described in Appendix 2, Exhibit A2-14)
$NUM_{Assessments}$	Total annual number of fatigue assessments per unit, including those conducted for-cause, self-declared, post-event, and follow-up (described in assumptions below)
$NUM_{Self\text{-}Declarations}$	Annual number of self-declarations of fatigue per facility (described in assumptions below)
$PER_{Not\_Fatigued}$	Percent of $NUM_{Self\_Declarations}$ where the results of the fatigue assessment are negative (described in assumptions below)
PER_{Object}	Percent of negative fatigue assessment results that are challenged by workers (described in assumptions below)
$WAGE_{Worker}$	Average hourly wage of worker (described in Appendix 2, Exhibit A2-11)
$WAGE_{ECM}$	Average hourly wage of Employee Concerns Manager (described in Appendix 2, Exhibit A2-11)
$WAGE_{Supervisor}$	Average hourly wage of supervisor (described in Appendix 2, Exhibit A2-11)
$WAGE_{Worker}$	Utility worker wage rate (described in Appendix A2-11)
$WAGE_{Supervisor}$	Utility supervisory wage rate (described in Appendix A2-11)

Assumptions:

- Annual number of self-declarations of fatigue per facility: 20.

- Total annual number of fatigue assessments per facility, including those conducted for-cause, self declarations, post-event, and follow-up: 50 [including approximately 5 for cause, 20 for self declarations, 5 post-event, 5 follow-up, and 15 related to the waiver provisions of §26.207.]

- Time needed to conduct a fatigue assessment (including supervisor transit to the worker): 0.5 hours.

- Percent of $NUM_{Self\_Declarations}$ where the results of the fatigue assessment are negative: 50%.

- Percent of negative fatigue assessment results that are challenged by workers: 30%.

- Amount of worker time to raise and resolve one incident: ½ hour (i.e., two 15-minute meetings).

- Number of hours of Employee Concerns Manager time to address and resolve one incident: 2.5 hours.

- Number of hours of supervisor time to address and resolve one incident: 1 hour.

Paragraph 26.211(e)

This paragraph requires licensees, following a fatigue assessment [the cost of which is calculated under subparagraph 26.211(a) - (d)], to determine and implement the controls and conditions, if any, that are necessary to allow the individual to resume performing duties for the licensee, including the need for a rest break.

The analysis calculates costs for this provision by assuming that licensees take the following actions depending on the result of the fatigue assessment.

Results of Fatigue Assessment	*Modeled Licensee Actions*
Finding of no fatigue	Licensee allows the worker to return to duty with no further controls and no further cost to the licensee (except if the assessment was performed under §26.207, which is costed under that provision).
Finding of acute fatigue, either from work-related or non-work-related causes, or circadian variations in alertness and performance	Licensee sends the worker home for a 24 hour rest break and calls in a replacement worker
Finding of cumulative fatigue, either from work-related or non-work-related causes	Licensee sends the worker home for a 48-hour rest break and calls in a replacement worker

Note that the modeled licensee actions may be more than anticipated by the final rule, which allows licensees to return workers to duty under suitable controls and conditions following a fatigue assessment, and allows licensees not to conduct fatigue assessments in most cases if the licensee permits or requires the individual to take a rest break of at least 10 hours before returning to duty. Consequently, by calculating the cost of the actions shown above, the analysis likely overstates the cost of the provision. However, it follows that if licensees take the assumed actions (i.e., send workers home for rest breaks in the event of any finding of fatigue), then licensees will not incur the lesser costs of developing and implementing controls or conditions related to sending fatigued workers back to duty. In addition, the analysis overstates costs further because it does not give licensees any credit for the actions they currently take with respect to workers who they find to be fatigued.

Licensees will incur management and labor costs related to replacing fatigued workers. The *annual cost per program* results from the sum of the following factors:

- Licensees will incur incremental management costs to call in replacement workers to substitute for any workers who are sent home to rest following a fatigue assessment:

  $$NUM_{Assessments} \times PER_{Fatigue} \times (HOURS_{Supervisor} \times WAGE_{Supervisor}) \times NUM_{Facilities}$$

- Licensees also will incur incremental labor costs due to the extra "turnover" of duties to the replacement worker and other lost labor productivity:

  $$NUM_{Assessments} \times PER_{Fatigue} \times (HOURS_{Turnover} \times WAGE_{Worker}) \times NUM_{Facilities}$$

- Licensees also will incur incremental labor costs associated with the replacement worker:[9]

$$NUM_{Assessments} \times PER_{Fatigue} \times (HOURS_{Substituted} \times WAGE_{Worker}) \times NUM_{Facilities}$$

Parameter	Description
$HOURS_{Supervisor}$	Supervisory hour expended to identify and call in a replacement worker (described in assumptions below)
$HOURS_{Turnover}$	Labor hours resulting from an additional turnover due to the replacement of a fatigued worker with a substitute worker (described in assumptions below)
$HOURS_{Substituted}$	Average number of hours worked by the replacement worker per incident (described in assumptions below)
$NUM_{Assessments}$	Total annual number of fatigue assessments per unit, including those conducted for-cause, self-declared, post-event, and follow-up (described in assumptions below)
$NUM_{Facilities}$	Number of facilities per program (described in Appendix 2, Exhibit A2-14)
$PER_{Fatigue}$	Percentage of fatigue assessments that result in a finding of fatigue (described in assumptions below)
$WAGE_{Worker}$	Utility worker wage rate (described in Appendix A2-11)
$WAGE_{Supervisor}$	Utility supervisory wage rate (described in Appendix A2-11)

Assumptions:

- The analysis assumes that worker breaks are accounted for as annual leave or are otherwise uncompensated.

- Total annual number of fatigue assessments per facility, including those conducted for-cause, self declarations, post-event, and follow-up: 50 [including approximately 5 for cause, 20 for self declarations, 5 post-event, 5 follow-up, and 15 related to the waiver provisions of §26.207.]

[9] The analysis assumes that replacement workers are drawn from staff who are present at the site but have flexibility to change assignments for the remainder of the day. Therefore, this cost represents an opportunity cost. The analysis assumes that wages paid to the replacement worker are offset by wages not paid to the fatigued worker. The analysis assumes that worker breaks are accounted for as annual leave or are otherwise uncompensated.

- Percentage of fatigue assessments that result in a finding of fatigue: 37.5%[10].
- Manager hours expended to identify and call in a replacement worker: 0.5 hours.
- Labor hours resulting from an additional "turnover" due to the replacement of a fatigued worker with a substitute worker: 1 hour (i.e., 0.5 hours for each of two workers).
- Average number of hours worked by the replacement worker per incident: 6 hours.

Paragraph 26.211(f)

This paragraph requires licensees to document the results of any fatigue assessments conducted, the circumstances that necessitated the fatigue assessment, and any controls and conditions that were implemented.

Annual costs per program result from the following:

$$NUM_{Assessments} \times HOURS_{Document} \times WAGE_{Supervisor} \times NUM_{Facilities}$$

Parameter	Description
$HOURS_{Document}$	Time needed to document a fatigue assessment (described in the assumptions below)
$NUM_{Assessments}$	Total annual number of fatigue assessments per unit (described in assumptions)
$NUM_{Facilities}$	Number of facilities per program (described in Appendix 2, Exhibit A2-14)
$WAGE_{Supervisor}$	Utility supervisory wage rate (described in Appendix A2-11)

Assumption:

- Time needed to document a fatigue assessment: 20 minutes.
- Total annual number of fatigue assessments per facility, including those conducted for-cause, self declarations, post-event, and follow-up: 50 [including approximately 5 for cause, 20 for self declarations, 5 post-event, 5 follow-up, and 15 related to the waiver provisions of §26.207.]

[10] This represents a weighted average based on the following results depending on the reason for the assessment: for cause - 90%; self-declarations - 50%; post-event - 5%; follow-up - 50%; waivers under §26.207 - 25%.

Subpart J: [Reserved]

In the final rule, Subpart J is reserved and therefore contains no regulatory language. As a result, this subpart does not result in any incremental costs or savings.

Subpart K: FFD Program for Construction

26.401 General

Paragraph 26.401(a)

This paragraph of the final rule states that a combined license holder (under 10 CFR Part 52) before the Commission has made the finding under Section 52.103(g), combined license applicant who has received the authorization to construct under Section 50.10(e)(3), construction permit holder (under 10 CFR Part 50), and construction permit applicant who has received the authorization to construct under Section 50.10(e)(3) may establish, implement and maintain an FFD program that meets the requirements of Subpart K to apply to any individual constructing safety- or security-related SSCs at the location where the nuclear power plant will be constructed and operated.

This paragraph also states that if the licensees and other entities identified above do not elect to implement an FFD program that meets the requirements of Subpart K, then they must subject the individuals referenced above to an FFD program that meets the requirements of Subparts A through H, N and O. This section of the final rule imposes no incremental cost and affords no saving because it provides licensees with the flexibility to implement a more comprehensive FFD program. This enhanced flexibility is a voluntary provision. Although an FFD program that includes the requirements of Subparts A through H, N and O is generally considered more burdensome relative to the requirements of Subpart K, this may not be true for all licensees and other entities. For example, it is possible that the more comprehensive program could be less burdensome for some licensees where construction is co-located with an operating reactor. This analysis assumes that new reactor construction will be co-located with existing reactor sites and that the licensees operating the reactors will be the same as those undertaking the construction activities at the co-located site.

Paragraph 26.401(b)

This paragraph of the final rule requires licensees and other entities who intend to implement an FFD program under Subpart K to submit an FFD program plan to NRC for review and approval. This is a new requirement that imposes incremental costs on licensees and other entities. The NRC anticipates that the FFD program plan will be very closely related to the written policy and procedures that the licensee and other entity must develop (as required by the former and final rule). This analysis does not quantify the incremental costs because they are assumed to be insignificant.

Paragraph 26.401(c)

This paragraph of the final rule states that a combined license holder (under 10 CFR Part 52) before the Commission has made the finding under Section 52.103(g), combined license applicant who has received the authorization to construct under Section 50.10(e)(3), construction

permit holder (under 10 CFR Part 50), and construction permit applicant who has received the authorization to construct under Section 50.10(e)(3) may subject individuals that perform construction activities at the location where the nuclear power plant will be constructed and operated to an FFD program that meets all of the requirements of Part 26, or to FFD program elements that meet all of the applicable requirements of Part 26.

This section of the final rule imposes no incremental cost and affords no saving because it provides licensees with the flexibility to implement a more comprehensive FFD program. This enhanced flexibility is a voluntary provision. Although an FFD program that includes all of the requirements of Part 26 is generally considered more burdensome relative to the requirements of Subpart K, this may not be true for all licensees and other entities. For example, it is possible that the more comprehensive program could be less burdensome for some licensees where construction is co-located with an operating reactor. This analysis assumes that any anticipated new reactor construction will be co-located with existing reactor sites and that the licensees operating the reactors will be the same as those undertaking the construction activities at the co-located site.

26.403 Written Policy and Procedures

This section of the final rule requires licensees and other entities who implement an FFD program under Subpart K to develop, implement, and maintain written procedures that address FFD program elements. The section also requires licensees and other entities to provide a clear, concise, written FFD policy statement to individuals who are subject to the program. These requirements are required under § 26.20 of the former rule, with a few minor exceptions. Specifically, licensees and other entities must include additional information in their written procedures, such as the immediate and followup actions that will be taken in cases where individuals attempt to subvert the testing process by adulterating or diluting specimens, substituting specimens, or by any other means; refuse to provide a specimen for analysis; and have legal action taken relating to drug or alcohol use. In addition, the written procedures must include the process to be followed if an individual's behavior raises a concern regarding (1) the possible use, sale, or possession of illegal drugs on or off site, (2) the possible use or possession of alcohol while constructing safety- or security-related SSCs, or (3) impairment from any cause which in any way could adversely affect the individual's ability to safely and competently perform his or her duties. This analysis does not calculate this cost because the NRC believes that the incremental burden of including these provisions within the set of procedures that already must be developed under the former rule is not significant.

26.405 Drug and Alcohol Testing

This section of the final rule establishes the drug and alcohol testing procedures that licensees and other entities who implement an FFD program under Subpart K must follow. Paragraph 26.2(c) of the former rule required licensees and other entities to "implement a chemical testing program, including random tests." The final rule differs from the former rule in two ways. First, the final rule provides licensees and other entities with the option to implement a fitness

monitoring program (as described under paragraph 26.406 of the final rule) in place of a random testing program for individuals who perform construction activities. This analysis assumes that any anticipated new reactor construction will be co-located with existing reactor sites and that the licensees operating the reactors will be the same as those undertaking the construction activities at the co-located site. Therefore, if these licensees and other entities implement an FFD program under Subpart K and choose to randomly test individuals for drugs and alcohol under this paragraph, then it is likely the testing will be conducted in close conjunction with the random testing already being conducted for the FFD program at the co-located operating reactor site. For this reason, the NRC believes that any additional cost to test the individuals at the construction site simultaneously with the testing already being conducted is insignificant relative to the overall costs of the current random testing program. Consequently, the analysis does not calculate incremental costs for this requirement of the final rule.

Second, the final rule also includes more detail regarding the types of testing, other than random testing, that licensees and other entities must conduct, the types of drugs that FFD programs must test for, testing procedures to protect donor's privacy, urine testing that must be conducted by HHS-certified laboratories, and required MRO reviews. The NRC believes that the added detail merely clarifies the testing requirements in the former rule because licensees would have implemented these details even in the absence of the rule revisions. Therefore, this section of the final rule does not impose any incremental costs on licensees or other entities.

26.406 Fitness Monitoring

This section of the final rule allows licensees and other entities, at their option, to subject individuals specified in paragraph 26.4(f) to a fitness monitoring program, rather than a random testing program for drugs and alcohol (as required under paragraph 26.405 of the final rule). This section requires licensees and other entities choosing to use this option to establish procedures for fitness monitors to follow, train the monitors to implement the program, and ensure that the fitness of individuals is monitored effectively while the individuals are constructing safety- and security-related SSCs. To achieve this objective, licensees and other entities must consider the number and placement of monitors required, the necessary ratio of monitors to individuals, and the frequency with which the individuals must be monitored while constructing each safety- or security-related SSC. The final rule also requires licensees and other entities to establish procedures that monitors must follow in response to the indications of possible use, sale, or possession of illegal drugs, use or possession of alcohol on site or while on duty, impairment from any cause that if left unattended may result in a risk to public health and safety or the common defense and security, and any actions or other indications that call into question an individual's trustworthiness and reliability.

The requirements in this section provide flexibility to licensees and other entities relative to the requirements in section 26.2(c) of the former rule, which required licensees and other entities to "implement a chemical testing program, including random tests." This analysis assumes that licensees and other entities will implement a fitness monitoring program only if it is less

expensive to do so than to implement a random testing program. Therefore, the analysis does not calculate incremental costs for this requirement.

26.407 Behavioral Observation

This paragraph of the final rule requires licensees and other entities to ensure that individuals specified in §26.4(f) are subject to behavioral observation if they are not subject to fitness monitoring. Licensees and other entities must subject these individuals to behavioral observation while these individuals are constructing safety- or security-related SSCs. Under the former rule, licensees were required during construction to comply with Section 26.10(b) to "provide reasonable measures for the early detection of persons who are not fit to perform" their duties. The NRC believes that licensees would have complied with this former rule requirement by implementing a behavioral observation program that is very similar to the one now required under Section 26.407. Therefore, this requirement does not impose any incremental cost on licensees or other entities.

26.409 Sanctions

This section of the final rule requires licensees and other entities who implement an FFD program under Subpart K to establish sanctions for FFD policy violations. In Section 26.2(c) of the former rule, FFD programs were required to include the "imposition of sanctions." The final rule includes additional detail regarding minimum sanctions; individuals who violate FFD policy at least must be prohibited 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. The NRC believes that the added detail merely clarifies the sanction requirements in the former rule because licensees would have implemented these details even in the absence of the rule revisions. Therefore, this section of the final rule does not impose any incremental costs on licensees or other entities.

26.411 Protection of Information

This section of the final rule requires licensees and other entities who implement an FFD program under Subpart K to establish and maintain files and procedures to protect personal information. The section also requires licensees and other entities to obtain a signed consent that authorizes the disclosure of the personal information before licensees or other entities disclose the information. Section 26.2(c) of the former rule required FFD programs to make provisions for "the protection of information." The NRC believes that the added detail merely clarifies protection of information requirements in the former rule because licensees would have implemented these details even in the absence of the rule revisions. Therefore, this section of the final rule does not impose any incremental costs on licensees or other entities.

26.413 Review Process

This section of the final rule requires licensees and other entities who implement an FFD program under Subpart K to establish and implement review procedures (including an objective and impartial review of the facts) in cases where individuals have violated FFD policy. Section 26.2(c) of the former rule required FFD programs to make provisions for "appeals procedures." The NRC believes that the added detail merely clarifies the review process requirements in the former rule because licensees would have implemented these details even in the absence of the rule revisions. Therefore, this section of the final rule does not impose any incremental costs on licensees or other entities.

26.415 Audits

This section of the final rule requires licensees and other entities who implement an FFD program under Subpart K to conduct audits to ensure the continuing effectiveness of their FFD programs, including FFD program elements provided by C/Vs and the FFD programs of C/Vs that are accepted by the licensee and other entity. The final rule specifies that the audits occur at a frequency that assures the continuing effectiveness of the program and that corrective actions are taken to resolve any problems identified. The final rule language allows joint audits, and licensees and other entities may accept audits of C/Vs that are conducted by others. Under the final rule, licensees and other entities do not need to audit HHS-certified laboratories.

This analysis assumes that new reactor construction will be co-located with existing reactor sites. The licensees operating the reactors will be the same as those undertaking the construction activities at the co-located site. The analysis assumes that the audits for construction sites will be conducted as part of the audits already being conducted for the FFD program at the co-located operating reactor site. The NRC believes that any additional cost to include the construction site's FFD program within the scope of the audits already being conducted is insignificant relative to the overall costs of the program audit. Therefore, this analysis does not calculate incremental costs for this section of the final rule.

26.417 Recordkeeping and Reporting

Paragraph 26.417(a)

This paragraph of the final rule requires licensees and other entities who implement an FFD program under Subpart K to 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. Section 26.2(c) of the former rule required that licensees and other entities make provisions for "recordkeeping." The NRC believes that the added detail in the final rule merely clarifies the recordkeeping requirements in the former rule because licensees would have implemented these details even in the absence of the rule revisions. Therefore, this section of the final rule does not impose any incremental costs on licensees or other entities.

Paragraph 26.417(b)

This paragraph of the final rule identifies specific reporting requirements.

Subparagraph 26.417(b)(1)

This subparagraph of the final rule requires licensees and other entities who implement an FFD program under Subpart K to report to the NRC Operations Center within 24 hours any discoveries of intentional acts that cast doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program. Section 26.73(a) of the former rule required licensees and other entities to "inform the Commission of significant fitness-for-duty events," including the following:

- The sale, use, or possession of illegal drugs within the protected area; and,
- Any instances where a person licensed under 10 CFR part 55 to operate a power reactor or a supervisor –
  - (1) sells, uses, or possesses a controlled substance,
  - (2) receives a confirmed positive test result,
  - (3) uses alcohol within the protected area, or
  - (4) receives a determination of unfitness for scheduled work due to the consumption of alcohol.

The NRC believes that the detail in the final rule restates the reporting requirements in the former rule. Therefore, this section of the final rule does not impose any incremental costs on licensees or other entities.

Subparagraph 26.417(b)(2)

This subparagraph of the final rule requires licensees and other entities who implement an FFD program under Subpart K to submit annual program performance reports to the NRC. This analysis assumes that new reactor construction will be co-located with existing reactor sites. The licensees operating the reactors will be the same as those undertaking the construction activities at the co-located site. The analysis assumes that the annual program performance reports for construction sites will be compiled as part of the annual program performance report already being compiled for the FFD program at the co-located operating reactor site. The NRC believes that any additional cost to include the construction site's FFD program within the scope of the annual program performance report already being compiled is insignificant relative to the overall costs of the annual program performance report. Therefore, this analysis does not calculate incremental costs for this subparagraph of the final rule.

26.419 Suitability and Fitness Evaluations

This section of the final rule requires licensees and other entities who implement an FFD program under Subpart K to develop, implement, and maintain procedures for evaluating whether to assign individuals to construct safety- and security-related SSCs. The 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." This final rule language restates and clarifies the former rule language. Specifically, former Section 26.2(c) required licensees to conform with former paragraph 26.10(a), which stated that the FFD program "provide reasonable assurance that [personnel] will perform their tasks in a reliable and trustworthy manner and are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties." Therefore, this section of the final rule imposes no incremental cost on licensees or other entities.

Subpart L: [Reserved]

In the final rule, Subpart L is reserved and therefore contains no regulatory language. As a result, this subpart does not result in any incremental costs or savings.

Subpart M: [Reserved]

In the final rule, Subpart M is reserved and therefore contains no regulatory language. As a result, this subpart does not result in any incremental costs or savings.

Subpart N: Recordkeeping and Reporting Requirements

26.709 Applicability

This section of the final rule imposes no incremental cost and affords no saving because it merely states that the requirements of Subpart N apply to the FFD programs of licensees and other entities specified in final § 26.3, except for FFD programs that are implemented under Subpart K.

26.711 General Provisions

Paragraph 26.711(a)

This paragraph of the final rule restates former requirements, presented in §§26.71 and 26.73 of the former rule, which stated that licensees and other entities that have approved FFD programs must maintain records and submit reports to the NRC. The final paragraph adds a provision specifying that required records must be retained until license termination if the rule does not specify another retention period. Although this may extend the period of retention of certain records (depending on current licensee practices), the most substantial costs associated with retaining the records (filing, removal, etc.) do not change as a result of this final paragraph. The incremental burden of maintaining the necessary storage space for those particular records until the time of license termination is insignificant to this analysis.

Paragraph 26.711(b)

This paragraph of the final rule adds provisions to allow licensees to use electronic recordkeeping. Although this provision may result in savings for some licensees, such savings are likely to be small and are not calculated for purposes of this analysis.

Paragraph 26.711(c)

This paragraph of the final rule 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. This paragraph of the final rule is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order (AAO) dated January 7, 2003, and published in the Federal Register on January 13, 2003. As a result, the final paragraph imposes no incremental costs and affords no savings.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph does not result in any incremental costs. Although the final paragraph adopts provisions from the AAO that require licensees and other entities to inform individuals of their right to review FFD information about the individual, this analysis assumes that this is a standard business practice for licensees and other entities. Therefore, the analysis anticipates that this new requirement will not result in any additional costs.

Paragraph 26.711(d)

This paragraph of the final rule requires licensees and other entities to ensure that only correct and complete information about individuals is retained and shared with other licensees and other entities. In addition, this paragraph requires that licensees and other entities must correct or augment the shared information used to determine an individual's eligibility for authorization if the information changes or new information is developed. This paragraph of the final rule is based on non-safeguards information requirements imposed by the NRC's Access Authorization Order (AAO) dated January 7, 2003, and published in the Federal Register on January 13, 2003. As a result, the final paragraph imposes no incremental costs and affords no savings.

Sensitivity Analysis - Pre-Order Baseline

Relative to the regulations that were in effect before the NRC issued the AAO, the paragraph does not result in any incremental costs. Although the final paragraph adopts provisions from the AAO that require licensees and other entities to ensure that only correct and complete information about individuals is retained and shared with other licensees and other entities, this analysis assumes that this is a standard business practice for licensees and other entities. Therefore, the analysis anticipates that this new requirement will not result in any additional costs.

26.713 Recordkeeping Requirements for Licensees and Other Entities

Paragraphs 26.713(a)

This paragraph of the final rule [including subparagraphs (1)–(4)] requires that records of self-disclosures, employment histories, and suitable inquiries that are required under §§26.55, 26.57, 26.59, and 26.69 as well as those pertaining to denials and granting of authorization, be retained for a period of at least 5 years or until completion of any related legal proceeding, whichever is later. Although extending the period of retention beyond 5 years represents a new requirement, the most substantial costs associated with retaining the records (filing, removal, etc.) do not change as a result of this final paragraph. The incremental burden of maintaining the necessary storage space for those particular records for which legal proceedings continue beyond the 5 year period is insignificant to this analysis. In addition, the ability to store these records

electronically under subparagraph 26.711(b) will likely reduce or offset the potential costs associated with the longer retention period.

Paragraphs 26.713(b)

This paragraph of the final rule [including subparagraphs (1) and (2)] requires that records of trainings conducted under §26.29 as well as audits, audit findings, and corrective actions taken under §26.41, be retained for a period of at least 3 years or until completion of any related legal proceeding, whichever is later. Although extending the period of retention beyond 3 years in the case of legal proceedings represents a new requirement, the most substantial costs associated with retaining the records (filing, removal, etc.) do not change as a result of this final paragraph. The additional burden of maintaining the necessary storage space for those particular records beyond the 3 year period is insignificant to this analysis. In addition, the ability to store these records electronically under subparagraph 26.711(b) will likely reduce or offset the potential costs associated with the longer retention period.

Paragraphs 26.713(c)

This paragraph of the final rule extends to 40 years (or until the NRC deems adequate) the period for which licensees must retain records pertaining to any 5-year denial of authorization under paragraph 26.75(c), (d), or (e)(2) and any a permanent denial of authorization under paragraphs 26.75(b) and 26.75(g). Paragraph 26.71(c) of the former rule imposed similar requirements, but specified a minimum 3-year period for retaining records. Despite this difference, however, removal of records still requires a management determination that the records are no longer needed. The most substantial costs associated with retaining the records (filing, removing, etc.) do not change as a result of the final rule. Although licensees will incur some additional burden to maintain the necessary storage space for 40 years instead of 3 years, these costs are insignificant to this analysis. In addition, the ability to store these records electronically under subparagraph 26.711(b) will likely reduce or offset the potential costs associated with the longer retention period.

Paragraphs 26.713(d)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely revises requirements in §26.20 of the former rule, which pertained to retaining for at least three years records of written, superceded FFD policies and procedures. By contrast, the final rule extends the retention period to 5 years or until completion of all legal proceedings related to the FFD policy violation. The most substantial cost associated with retaining the records (filing, removing, etc.) do not change as a result of the new rule. Although licensees will incur some additional burden to maintain the necessary storage space for 5 years instead of 3 years, these costs are insignificant to this analysis. In addition, the ability to store these records electronically under subparagraph 26.711(b) will likely reduce or offset the potential costs associated with the longer retention period.

Paragraphs 26.713(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely retains the requirement that written agreements between licensees and other entities must be stored for the life of the agreement. The final paragraph also adds that licensees must retain such agreements until the completion of all legal proceedings related to FFD violations that involve those services, if that is later than the life of the agreement. This revision is consistent with long-term licensee practices relating to documents governing FFD-related contracts. Consequently, no incremental cost or saving results.

Paragraphs 26.713(f)

This paragraph of the final rule requires that records of background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel, conducted under §26.31(b)(1)(i) be retained 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. Although this represents a new requirement, the incremental burden associated with retaining the necessary records is insignificant to this analysis. In addition, the ability to store these records electronically under subparagraph 26.711(b) will likely reduce or offset the potential costs associated with the paragraph.

Paragraphs 26.713(g)

This paragraph of the final rule requires that licensees or other entities whose FFD program includes tests for drugs in addition to those specified in the final rule, or uses more stringent cutoff levels than those specified in the final rule, retain documentation certifying the scientific and technical suitability of the assays and cutoff levels used, as required under §§26.31(d)(1)(i) and 26.31(d)(3)(iii)(C). This paragraph of the final rule represents a new requirement, and imposes incremental costs associated with filing and retaining the specified documentation for the length of time the FFD program follows these practices or until the completion of all related legal proceedings, whichever is later. The cost of retaining documentation of these procedures, once filed, is negligible.

The *one-time cost per program* results from clerical support to file and store the forensic toxicologist's evaluation of the FFD program's more stringent cutoff levels.

$$HOURS_{Clerical} \times WAGE_{Clerical} \times PER_{more\ stringent\ cutoffs} \times PER_{non\text{-}report}$$

Parameter	Description
$HOURS_{Clerical}$	Hours of clerical personnel to file and store the forensic toxicologist's evaluation of the FFD program's more stringent cutoff levels per program (as described in assumptions below)

Parameter	Description
$PER_{more\ stringent\ cutoffs}$	Percentage likelihood that the FFD program uses more stringent cutoff levels for drug testing (as described in assumptions below)
$PER_{non\text{-}report}$	Percentage likelihood that the FFD program, if it uses more stringent cutoff levels for drug testing, has not reported to the Commission (as described in assumptions below)
$WAGE_{Clerical}$	Clerical personnel wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Hours of clerical personnel to file and store the forensic toxicologist's evaluation per program: 15 minutes.

- Percentage likelihood that the FFD program will use more stringent cutoff levels for drug testing after the final rule is enacted: 10 percent.

- Percentage likelihood that the FFD program, if it will use more stringent cutoff levels for drug testing after the final rule is enacted, did not previously use these more stringent cutoff levels (and, therefore, has not reported to the Commission): 25 percent.

26.715 Recordkeeping Requirements for Collection Sites, Licensee Testing Facilities, and Laboratories Certified by the Department of Health and Human Services

Paragraphs 26.715(a) and 26.715(b)

These paragraphs of the final rule impose no incremental cost and afford no saving because they merely restate requirements in §26.71 and Appendix A Sections 2.5(f), 2.6(c), and 2.7(n) of the former rule. Specifically, these paragraphs of the former rule required collection sites, licensee testing facilities, and HHS-certified laboratories to maintain documentation concerning all aspects of the testing process (including personnel files for individuals who have been authorized to have access to specimens but are no longer under contract to or employed by the entity) for at least 2 years. The final paragraph adds that collection sites, licensee testing facilities, and HHS-certified laboratories must also retain such records until the completion of any legal proceedings related to an FFD violation, if that is later than the 2-year period. Nonetheless, the most substantial costs associated with retaining the records (filing, removing, etc.) do not change as a result of the new rule. Although licensees will incur some additional burden to store these records for a longer period in certain instances, these costs are insignificant to this analysis.

26.717 Fitness-for-Duty Program Performance Data

Paragraph 26.717(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely restates requirements in paragraph 26.71(d) of the former rule, which pertained to the collection and compilation of FFD program performance data.

Paragraph 26.717(b)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely renumbers requirements in paragraph 26.71(d) of the former rule, which specified the performance data that licensees and C/Vs must compile and collect under paragraph 26.717(a). Although this revised paragraph does add a provision requiring FFD programs to report the number of subversion attempts by type, the rarity of such events makes the incremental cost insignificant.

Paragraph 26.717(c)

This paragraph of the final rule requires licensees and other entities to analyze performance data annually. Incremental costs and savings attributable to this provision are analyzed under related paragraphs 26.717(e) and (f). Licensees and other entities also must retain records of the data, analyses, and corrective actions taken for at least 3 years or until the completion of any related legal proceedings, whichever is later. Although the provision to record corrective actions taken is not contained in the former rule, no incremental costs are expected to result because the burden of recording such events is incidental to that of the corrective actions themselves.

Paragraph 26.717(d)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely restates requirements in paragraph 26.71(d) of the former rule, which addressed how licensees must report information on terminations of authorization or other administrative actions resulting from positive drug tests to the NRC.

Paragraph 26.717(e) and 26.717(f)

These paragraphs of the final rule require FFD programs to report performance data to the NRC every 12 months, rather than every 6 months as specified under the former regulation. The new requirement represents an incremental savings in that it requires licensees to prepare and submit to the NRC only one performance data report (instead of two) each year. Paragraph 26.717(f) allows licensees to submit the FFD program performance data as a consolidated report, provided

that the data are reported separately for each facility. There is no incremental cost or saving associated with this latter report consolidation provision.[1]

The *annual savings per program* associated with eliminating one performance data report per year are calculated as follows:

$$HOURS_{Manager} \times WAGE_{Manager} \times NUM_{Facilities}$$

Parameter	Description
$HOURS_{Manager}$	FFD program manager hours saved in reducing the reporting frequency per facility (as described in assumptions below)
$NUM_{Facilities}$	Number of units at the given facility (as described in Appendix 2, Exhibit A2-14)
$WAGE_{Manager}$	FFD program manager wage rate (as described in Appendix 2, Exhibit A2-11)

Assumption:

- FFD program manager hours saved in reducing the reporting frequency per facility: 20 hours.

The NRC also will experience savings under this final paragraph. Under the former rule, performance reports were submitted twice each year. As the NRC received the performance reports, clerical personnel process and file them in a manner that facilitates annual review by an NRC manager. On an annual basis, the NRC manager reads, reviews, and summarizes the performance reports in an annual industry report. The reduction in the frequency of performance reports will result in savings for the NRC. The *annual savings to the NRC* from processing fewer licensee reports are calculated as follows:

$$(HOURS_{Clerical} \times WAGE_{Clerical}) + (HOURS_{Manager} \times WAGE_{Manager})$$

Parameter	Description
$HOURS_{Clerical}$	NRC clerical hours saved in reducing the reporting frequency per year (as described in assumptions below)
$HOURS_{Manager}$	NRC manager hours saved in reducing the reporting frequency per year (as described in assumptions below)

[1] The analysis assumes that licensees will not opt to change their reporting practices if doing so increases costs. Savings are assumed not to accrue given that licensees must still report data separately for each facility addressed in the consolidated report.

Parameter	Description
$WAGE_{Clerical}$	NRC clerical wage rate (as described in Appendix 2, Exhibit A2-11)
$WAGE_{Manager}$	NRC manager wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- NRC manager hours saved in reducing the reporting frequency per year: 20 hours.

- NRC clerical hours saved in reducing the reporting frequency per year: 24 hours.

Paragraph 26.717(g)

This paragraph of the final rule adds a requirement that includes C/Vs in the reporting of performance data, but precludes duplicate information from being submitted to the NRC. Currently, C/Vs who maintain their own FFD programs are reporting performance data to multiple licensees for whom they work. Incremental savings will result from the paragraph because it will reduce the number of report summaries that C/Vs must distribute each year.

The *annual savings per C/V* program result from the sum of the following savings:

- The final paragraph will reduce the C/V manager labor burden because managers will be able to submit to the NRC a single report that consolidates all performance data that the C/V previously prepared for each licensee. The associated costs are estimated as follows:

  $HOURS_{Manager} \times WAGE_{Manager} \times PER_{Consolidation}$

- The final paragraph will reduce mailing costs because C/Vs will only need to submit a single performance data report to the NRC. The associated savings are estimated as follows:

  $(NUM_{Licenees} - 1) \times COST_{Mailing}$

Parameter	Description
$COST_{Mailing}$	Cost of mailing (express mail) one performance data report to each licensee (as described in Appendix 2, Exhibit A2-10)
$HOURS_{Manager}$	Hours of C/V manager time to compile all licensee performance data reports (as described in assumptions below)
$NUM_{Licensees}$	Number of licensees to whom each C/V submits performance data under the former rule (as described in assumptions below)
$PER_{Consolidation}$	Percentage savings achieved by consolidating performance data into a single report submitted to the NRC (as described in assumptions below)
$WAGE_{Manager}$	C/V manager wage rate (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Number of licensees to whom each C/V submits performance data to under the former rule: 9.
- Hours of C/V manager time to compile all licensee performance data reports: 30 hours.
- Percentage savings achieved by consolidating performance data into a single report submitted to the NRC: 25%.
- Under the former rule, C/Vs submitted performance data reports to each licensee for whom they work, but not to the NRC. Under the final rule, C/Vs will opt to report only to the NRC.

26.719 Reporting Requirements

Paragraphs 26.719(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies that licensees must report to the NRC all significant violations of the FFD policy (as required in §26.73 of the former rule), significant FFD program failures, and errors in drug and alcohol testing (as required in Appendix A, Sections 2.8(e)(4)–(6) of the former rule). The revised paragraph also clarifies that other entities (C/Vs) who have licensee-approved FFD programs must also report significant violations, failures, or errors to the NRC.

Paragraph 26.719(b)

This paragraph of the final rule [including subparagraphs (1)–(4)] lists the significant FFD policy violations and program failures that must be reported to the NRC Operations Center.

Under the clarifications in §26.719(b)(2)(ii), additional reportable FFD policy violations may result in incremental costs per FFD program because of:

- the reduction in the non-negative breath alcohol concentration (BAC) level for initial alcohol testing from 0.04 to 0.02 BAC as discussed in §26.97(b),

- the reduction in the initial cutoff level for marijuana metabolites from 100 ng/mL to 50 ng/mL (somewhat offset by raising of the initial cutoff level for opiate metabolites from 300 ng/mL to 2,000 ng/mL) as discussed in §§26.133 and 26.163(a)(1), and

- the addition of validity testing on all urine specimens as discussed in §§26.131 and 26.161(b).

Incremental costs will result from the added time that the FFD program manager must spend to collect, analyze, and report information concerning the additional events.

The *annual costs per program* associated with the increase in reported FFD events are calculated as follows:

$$NUM_{Events} \times PER_{Staff} \times (HOURS_{Manager} \times WAGE_{Manager}) \times NUM_{Units}$$

Parameter	**Description**
$HOURS_{Manager}$	FFD program manager hours required to investigate, analyze, and report a FFD event (as described in assumptions below)
NUM_{Events}	Annual number of additional non-negative specimen test results for validity and drugs testing per unit under the final rule (as described in Appendix 2)
NUM_{Units}	Number of units at the given facility (described in Appendix 2)
PER_{Staff}	Percentage of tested staff subject to reporting provisions of §26.719(b)(2) (as described in assumptions below)
$WAGE_{Manager}$	FFD program manager wage rate (described in Appendix 2)

Assumptions:

- Percentage of tested staff subject to reporting provisions of §26.719(b)(2): 15%.

- FFD program manager hours required to investigate, analyze, and report an event: 4 hours.

The NRC also will incur incremental costs as a result of the additional reportable events. The increase in the number of reported FFD events will result in additional reports being sent to the NRC, as required by paragraph 26.719(a), thereby increasing the labor burden associated with

processing and reviewing the licensee reports. The NRC's *annual costs* are calculated as follows:

- The NRC manager labor burden will increase as a result of the increased number of reported FFD events. The associated costs are estimated as follows:

$NUM_{Events} \times PER_{Staff} \times (HOURS_{Manager} \times WAGE_{Manager}) \times NUM_{Units}$

Parameter	Description
$HOURS_{Manager}$	NRC manager hours required to review a reported FFD event (as described in assumptions below)
NUM_{Events}	Annual number of additional non-negative specimen test results for validity and drugs testing per unit under the final rule (as described in Appendix 2)
NUM_{Units}	Number of units per program (as described in Appendix 2, Exhibit A2-14)
PER_{Staff}	Percentage of tested staff subject to reporting provisions of 26.719(b)(2) (as described in assumptions below)
$WAGE_{Manager}$	NRC program manager wage (as described in Appendix 2, Exhibit A2-11)

Assumptions:

- Percentage of tested staff subject to reporting provisions of §26.719(b)(2): 15%.
- NRC manager hours required to review a reported FFD event: 3 hours.

Paragraph 26.719(c)

Subparagraph 26.719(c)(1)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely retains and renumbers requirements in Appendix A, Sections 2.8(e)(4)–2.8(e)(6) of the former rule, which stated that licensees must report to the NRC within 30 days of completing an investigation of testing errors or unsatisfactory performance in blind performance testing.

Subparagraph 26.719(c)(2)

This subparagraph of the final rule imposes no incremental cost and affords no saving because it merely clarifies that the requirement in former paragraph 26.73(a) involving the reporting of significant FFD events includes reporting false positive errors on a blind performance test specimen submitted to an HHS-certified laboratory.

Subparagraph 26.719(c)(3)

This subparagraph of the final rule requires licensees to report to NRC within 24 hours in the event of a false negative during quality assurance checks of validity screening tests. Although this represents a new requirement, it imposes no incremental cost and affords no saving for the foreseeable future because there currently are no approved validity screening devices that can be used by licensees (as discussed in more detail under §26.131).

Paragraph 26.719(d)

This paragraph of the final rule requires licensees to document, trend, and correct other non-reportable FFD issues that identify programmatic weaknesses under the licensee's corrective action program in a manner that will not permit the identification of individuals. Although not explicitly required under the former rule, the analysis assumes that licensees and other entities are already tracking and trending FFD program weaknesses in their corrective action programs. As a result, the final paragraph imposes no incremental cost and affords no saving.

Subpart O: Inspections, Violations, and Penalties

26.821 Inspections

This section of the final rule [including paragraphs 26.821(a) and (b)] imposes no incremental cost and affords no saving because it merely retains requirements contained in §26.70 of the former rule, which pertained to inspection of records and written agreements between licensees and C/Vs.

26.823 Violations

Paragraphs 26.823(a) and 26.823(b)

These paragraphs of the final rule impose no incremental cost and afford no saving because they merely renumber and retain the requirements in §26.90 of the former rule as they relate to violations of policy.

26.825 Criminal Penalties

Paragraphs 26.825(a) and 26.825(b)

These paragraphs of the final rule impose no incremental cost and afford no saving because they merely renumber and retain requirements in §26.91 of the former rule, as they relate to criminal penalties.

APPENDIX 2: DATA USED IN THE ANALYSIS

Exhibit A2 - 1
Individuals Subject to the FFD Program

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
FFD Program Personnel Subject to the Rule					**Subpart A**	**26.4(g)**
	These parameters are used in the equations below:					
		Number of MROs per program	NUM mros	2	Assumption	
		% multiplier to spread compliance costs across all programs	PER compliance	25%	Assumption	
	Industry Practices: One-time cost per program to subject MROs to pre-access drug and alcohol testing to comply with the former rule					
			No additional parameters			
	Industry Practices: One-time cost per program to pay for MRO travel to a licensee collection facility to comply with the former rule					
		Hours of MRO travel, waiting, and specimen collection time	HOURS travel	6.0 hr	Assumption	
	Industry Practices: One-time cost per program to conduct FFD training and to administer the comprehensive examination on their MROs to comply with the former rule					
		Length of FFD program training for MROs	HOURS training	2.0 hr	Assumption	
	Industry Practices: Annual cost per program to administer a random drug and alcohol testing program for FFD program personnel to comply with the former rule					
		% tested by a random drug program per year	PER random	50%	Rule requirement	
	Industry Practices: Annual cost per program to pay for MROs selected for random drug and alcohol testing to travel to the specimen collection facility and provide a specimen to comply with the former rule					
		% tested by a random drug program per year	PER random	50%	Rule requirement	
		Hours of MRO travel, waiting, and specimen collection time	HOURS travel	6.0 hr	Assumption	
Individuals Subject to Another Acceptable Program					**Subpart A**	**26.4(j)**
	These parameters are used in the equations below:					
		Annual number of applicants for initial authorization covered by other federal or state program per unit	NUM applicants	10	Assumption	
		% of fed or state programs that qualify	PER covered	50%	Assumption	
	Annual savings per program from bypassing pre-access drug and alcohol testing for the percentage of applicants covered by an acceptable program					
			No additional parameters			
	Annual savings per program from bypassing the training and examination requirement for the percentage of applicants covered by an acceptable program					
		Length of non-supervisory level training	HOURS non-supervisory	2.00 hr	Assumption	
		Length of comprehensive examination	HOURS examination	0.5 hr	Assumption	
	Annual savings per program from requiring fewer contracted trainer hours to conduct trainings and examinations on the percentage of applicants who are covered by an acceptable program					
		Length of non-supervisory level training	HOURS non-supervisory	2.00 hr	Assumption	
		Length of comprehensive examination	HOURS examination	0.5 hr	Assumption	
		Hours of training preparation and examination grading	HOURS preparation	2.0 hr	Assumption	
	Annual savings per program from not conducting remedial training and reexamining the percentage of applicants who are covered by an acceptable program and fail the comprehensive examination					
		Length of remedial supervisory-level training	HOURS remedial	0.75 hr	Assumption	
		Length of comprehensive examination	HOURS examination	0.5 hr	Assumption	
		% failing comprehensive exam	PER failing	10%	Assumption	
	Annual savings per program from requiring fewer contracted trainer hours to conduct remedial training and reexamining those applicants covered by an acceptable program that fail the comprehensive examination					
		Length of remedial supervisory-level training	HOURS remedial	0.75 hr	Assumption	
		Length of comprehensive examination	HOURS examination	0.5 hr	Assumption	
		% failing comprehensive exam	PER failing	10%	Assumption	
	Annual savings per program from not subjecting existing employees who are covered by an acceptable program to a duplicative random drug and alcohol testing program					
		Annual number of existing employees covered by another federal or state program	NUM employees	40	Assumption	
		% tested by a random drug program per year	PER random	50%	Rule requirement	

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Background Checks, Psychological Evaluations, Credit History, Criminal History					**Subpart B**	**26.31(b)(1)(i)**
	Base annual savings per program from eliminating the requirement to update background checks every three years					
		Base number of FFD program personnel per unit for each program	NUM personnel-base	1.5	Assumption	
		Cost of updating background investigation	COST background investigation update	$150	Assumption	
		Factor to adjust the periodic cost (every three years) to an annual cost	PER annualized-1	33.3%	Calculated	
	Additional savings per program from performing fewer background check updates for programs with onsite testing					
		Additional number of FFD program personnel per facility with onsite testing	NUM personnel-onsite testing	1	Assumption	
		Cost of updating background investigation	COST background investigation update	$150	Assumption	
		Factor to adjust the periodic cost (every three years) to an annual cost	PER annualized-1	33.3%	Calculated	
	Additional savings per program from performing fewer background check updates for programs with onsite collection					
		Additional number of FFD program personnel per facility for programs with onsite collection	NUM personnel-onsite collection	0.5	Assumption	
		Cost of updating background investigation	COST background investigation update	$150	Assumption	
		Percentage of facilities with onsite collection per program	PER collection	95.0%	Assumption	
		Factor to adjust the periodic cost (every three years) to an annual cost	PER annualized-1	33.3%	Calculated	
	Base annual savings per program from reducing the frequency of the psychological evaluation and criminal history and credit check update					
		Base number of FFD program personnel per unit for each program	NUM personnel-base	1.5	Assumption	
		Cost of updating psychological evaluation	COST psychological evaluation update	$300	Assumption	
		Cost of updating individual's credit and criminal history	COST criminal/credit update	$50	Assumption	
		Factor to adjust the periodic savings to an annual savings	PER annualized-2	13.3%	Calculated	
	Additional per program savings from reducing the frequency of the psychological evaluation and criminal history and credit check update for programs with onsite testing					
		Additional number of FFD program personnel per facility with onsite testing	NUM personnel-onsite testing	1	Assumption	
		Cost of updating psychological evaluation	COST psychological evaluation update	$300	Assumption	
		Cost of updating individual's credit and criminal history	COST criminal/credit update	$50	Assumption	
		Factor to adjust the periodic savings to an annual savings	PER annualized-2	13.3%	Calculated	
	Additional savings per program from reducing the frequency of the psychological evaluation and criminal history and credit check update for programs with onsite collection					
		Additional number of FFD program personnel per facility for programs with onsite collection	NUM personnel-onsite collection	0.5	Assumption	
		Cost of updating psychological evaluation	COST psychological evaluation update	$300	Assumption	
		Cost of updating individual's credit and criminal history	COST criminal/credit update	$50	Assumption	
		Percentage of facilities with onsite collection per program	PER collection	95.0%	Assumption	
		Factor to adjust the periodic savings to an annual savings	PER annualized-2	13.3%	Calculated	
DOT-Approved Specimen Collection Facilities					**Subpart B**	**26.31(b)(2)**
	Annual savings per program from allowing MROS and other offsite contracted personnel to utilize facilities conforming to DOT requirements					
		Number of MROs per program	NUM mros	2	Assumption	
		% tested by a random drug program per year	PER random	50.0%	Rule requirement	
		% of contracted FFD personnel that live closer to a DOT-approved collection facility than to a licensee's standard collection facility	PER distance	33.3%	Assumption	
		MRO hours of saved travel, waiting and specimen collection	HOURS travel	2.0 hr	Assumption	

Exhibit A2 - 2
Written Policies and Procedures

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Policy and Procedure Revisions - Overall Program					**Subpart B**	**26.27(a)**
	One-time cost per program to account for FFD manager and clerical personnel time and to contract a legal consultant to revise FFD policies and procedures					
		Hours of FFD program manager labor to develop and revise policies and procedures	HOURS manager	370.0 hr	Assumption	
		Hours of clerical personnel support of revision of policies and procedures	HOURS clerical	95.0 hr	Assumption	
		Hours of legal assistance to review and revise policies and procedures	HOURS legal	95.0 hr	Assumption	
	One-time cost per program to account for facility supervisor time to implement the corporate policies at the facility level					
		Hours of facility supervisor time to implement revised corporate policies and procedures	HOURS facility supervisor	40.0 hr	Assumption	
Licensee Testing Facility Policy and Procedure Revisions					**Subpart E**	**26.127**
	One time costs per FFD program with onsite testing					
		Hours FFD manager	HOURS FFD manager	120.0 hr	Assumption	
		Hours Lab supervisor	HOURS lab supervisor	160.0 hr	Assumption	
		Hours Clerical	HOURS clerical	40.0 hr	Assumption	
		Hours Legal	HOURS legal	40.0 hr	Assumption	
NRC Implementation - One-time Revision of Inspection Procedures						
	One-time cost for NRC to revise inspection procedures					
		Time for FFD manager to revise the drug and alcohol testing / access authorization inspection procedures	HOURS FFDmanager	20.0 hr	Assumption	
		Time for FFD manager to write fatigue inspection procedures	HOURS FFDmanager	20.0 hr	Assumption	

Exhibit A2 - 3
Training and Examinations

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Revise and Implement Training, Including Behavioral Observation					**Subpart B**	**26.29(a)**
	These parameters are used in the equations below:					
		Number of training sessions per unit	NUM sessions	50	Assumption	
		% of cost applied to a given facility	PER cost	25%	Assumption	
		% of employees trained at the non-supervisory level under the former rule	PER non-supervisory	85%	Assumption	
		Length of FFD program training	HOURS training	4.00 hr	Assumption	
		Length of comprehensive examination	HOURS examination	0.5 hr	Assumption	
	One-time cost per program associated with revising the training program and training materials to account for new FFD provisions in the final rule					
		Hours of trainer time per program to revise the training program and training materials	HOURStrainer	20.0 hr	Assumption	
		Hours of training manager time per program to revise the training program and training materials	HOURStraining manager	2.0 hr	Assumption	
		Hours of FFD program manager time per program to revise the training program and training materials	HOURSmanager	2.0 hr	Assumption	
		Hours of clerical personnel to support the revision of the training program and training materials	HOURSclerical	4.0 hr	Assumption	
	One-time cost per program associated with revising the training program to include fatigue KAs					
		Hours of FFD program manager time per program revise the training program to include fatigue KAs	HOURS ffd manager-fatigue	60.0 hr	Assumption	
		Hours of clerical personnel to support the revision of the training program to include fatigue KAs	HOURS clerical-fatigue	8.0 hr	Assumption	
	One-time costs per program to retrain existing employees on the fatigue-related KAs					
		Length of training increment addressing the fatigue-related KAs	HOURS training-fatigue	1.00 hr	Assumption	
		Length of comprehensive examination increment addressing the fatigue-related KAs	HOURS examination-fatigue	0.08 hr	Assumption	
	One-time costs per program for trainers to adminster the training on the fatigue-related KAs					
		Length of training increment addressing the fatigue-related KAs	HOURS training-fatigue	1.00 hr	Assumption	
		Length of comprehensive examination increment addressing the fatigue-related KAs	HOURS examination-fatigue	0.08 hr	Assumption	
		Hours of preparation and examination grading	HOURS preparation-fatigue	0.50 hr		
	Annual costs per program for incoming employees to take the training for fatigue-related KAs					
		Length of training increment addressing the fatigue-related KAs	HOURS training-fatigue	1.00 hr	Assumption	
		Length of comprehensive examination increment addressing the fatigue-related KAs	HOURS examination-fatigue	0.08 hr	Assumption	
	Annual costs per program for trainers to administer the training course for fatigue-related KAs					
		Length of training increment addressing the fatigue-related KAs	HOURS training-fatigue	1.00 hr	Assumption	
		Length of comprehensive examination increment addressing the fatigue-related KAs	HOURS examination-fatigue	0.08 hr	Assumption	
	Annual cost per program for employees to take the refresher training increment addressing fatigue-related KAs					
		Length of fatigue-related KA refresher training modules	HOURS training-fatigue	0.50 hr	Assumption	

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
	Annual cost per program for trainers to administer the refresher training increment addressing fatigue-related KAs					
		Length of fatigue-related KA refresher training modules	HOURS training-fatigue	0.50 hr	Assumption	
		Hours of training preparation and examination grading for fatigue-related increment	HOURS preparation-fatigue	1.50 hr		
	Annual costs per program for employees to take the comprehensive challenge examination increment addressing the fatigue-related KAs					
		Length of comprehensive examination increment addressing the fatigue-related KAs	HOURS examination-fatigue	0.08 hr		
		% of employees taking the challenge examination	PER examination	80%	Assumption	
	Annual costs per program for trainers to administer the comprehensive challenge examination					
		Length of comprehensive examination increment addressing the fatigue-related KAs	HOURS examination-fatigue	0.08 hr		
		Hours of examination grading	HOURS grading	0.08 hr		
		% of employees taking the challenge examination	PER examination	80%	Assumption	
	Pre-Order Baseline: One-time cost per program associated with revising the training program					
		Hours of FFD program manager time per program to make knowledge and abilities revisions to training program	HOURS trainer	12.0 hr	Assumption	
		Hours of training manager time per program to review knowledge and abilities revisions to training program	HOURStraining manager	2.0 hr	Assumption	
		Hours of FFD program manager time per program to review knowledge and abilities revisions to training program	HOURS ffd manager	2.0 hr	Assumption	
		Hours of clerical personnel time to support training program revisions process	HOURS clerical	4.0 hr	Assumption	
	Pre-Order Baseline: One-time cost per program for employees not previously trained at the supervisory level to take updated supervisory-level training and a comprehensive examination					
			No additional parameters			
	Pre-Order Baseline: One-time cost per program for trainers to administer supervisory-level training on those employees not previously trained at the supervisory level					
		Hours of training preparation and examination grading	HOURS preparation	2.0 hr	Assumption	
	Pre-Order Baseline: Annual cost per program for incoming employees to take the longer supervisory-level training course					
		Length of supervisory-level training	HOURS supervisory	4.00 hr	Assumption	
		Length of non-supervisory-level training	HOURS non-supervisory	2.00 hr	Assumption	
	Pre-Order Baseline: Annual cost per program for trainers to administer the longer supervisory-level training course on incoming employees					
		Length of supervisory-level training	HOURS supervisory	4.00 hr	Assumption	
		Length of non-supervisory-level training	HOURS non-supervisory	2.00 hr	Assumption	
		Hours of training preparation and examination grading	HOURS preparation	2.00 hr	Assumption	
	Pre-Order Baseline: Annual cost per program for employees to take the longer supervisory-level refresher training					
		% of employees taking the refresher training course	PER refresher	20%	Assumption	
		Length of supervisory-level refresher training	HOURS supervisory	4.0 hr	Assumption	
		Length of non-supervisory-level refresher training	HOURS non-supervisory	2.0 hr	Assumption	
	Pre-Order Baseline: Annual cost per program for trainers to administer the longer supervisory-level refresher training					
		% of employees taking the refresher training course	PER refresher	20%	Assumption	
		Length of supervisory-level refresher training	HOURS supervisory	1.5 hr	Assumption	
		Length of non-supervisory-level refresher training	HOURS non-supervisory	2.0 hr	Assumption	
Urine and Alcohol Collector Training					**Subpart E**	**26.85(a),(b)**
	One time cost per facility					
		Number of collectors per collection site	NUM collectors	4	Assumption	
		Duration of training course	HOURS collector training	8.0 hr	Assumption	
		Number of training courses per facility	NUM courses per facility	1	Assumption	
		On-site Training of Collection Personnel, supplied by commercial vendor	COST training course	$ 1,000	Assumption	
Initial Validity Testing - Onsite Licensee Testing Facilities					**Subpart F**	**26.131(b)**
	One time cost per onsite licensee testing facility					
		Number of laboratory technicians per licensee testing facility	NUM technicians	4	Assumption	
		Duration of training course	HOURS technician training	4.0 hr	Assumption	
		Number of training courses per licensee testing facility	NUM courses per facility	1	Assumption	
		Cost per training course	COST training course	$ 500.00	Assumption	

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Comprehensive Examination					**Subpart B**	**26.29(b)**
	These parameters are used in the equations below:					
		% employees failing exam	PER failing	10%	Assumption	
		% of employees trained at the non-supervisory level under the former rule	PER non-supervisory	85%	Assumption	
		Length of remedial supervisory-level training	HOURS remedial	0.75 hr	Assumption	
	One-time cost per program for employees to take remedial training after failing the initial comprehensive examination when updating their training					
			No additional parameters			
	One-time cost per program for trainers to administer remedial training on those employees who fail the initial comprehensive examination when updating training					
			No additional parameters			
	Annual cost per program for applicants to take remedial training after failing the initial comprehensive examination					
			No additional parameters			
	Annual cost per program for trainers to administer remedial training on applicants who fail the initial comprehensive examination					
			No additional parameters			
Comprehensive Examination in Lieu of Refresher Training					**Subpart B**	**26.29(c)(2)**
	These parameters are used in the equations below:					
		% of employees choosing to take comprehensive refresher exam in lieu of refresher training	PER examination	80%	Assumption	
		Length of comprehensive examination	HOURS exam	0.5 hr	Assumption	
		Trainer time to prepare for training course	HOURS preparation	1.0 hr	Assumption	
		Trainer time to prepare for exam and grade	HOURS grading	0.5 hr	Assumption	
	Annual savings per program for those employees choosing to take the shorter comprehensive examination in lieu of non-supervisory-level refresher training					
		% of employees trained at the non-supervisory level under the former rule	PER non-supervisory	85%	Assumption	
		Length of non-supervisory-level refresher training	HOURS non-supervisory	2.0 hr	Assumption	
	Annual savings per program for those employees choosing to take the shorter comprehensive examination in lieu of supervisory-level refresher training					
		% of employees trained at the supervisory-level under the former rule	PER supervisory	15%	Assumption	
		Length of supervisory-level refresher training	HOURS supervisory	4.0 hr	Assumption	
	Annual savings per program from reduced training costs due to employees choosing to take the shorter comprehensive examination in lieu of non-supervisory-level refresher training.					
		% of employees trained at the non-supervisory-level under the former rule	PER non-supervisory	85%	Assumption	
		Length of non-supervisory-level refresher training	HOURS non-supervisory	2.0 hr	Assumption	
	Annual savings per program from reduced training costs due to employees choosing to take the shorter comprehensive examination in lieu of supervisory-level refresher training.					
		% of employees trained at the supervisory-level under the former rule	PER supervisory	15%	Assumption	
		Length of supervisory-level refresher training	HOURS supervisory	4.0 hr	Assumption	
NRC Implementation - One-time Training						
	Cost to develop NRC staff training workshop					
		Hours of NRC staff time to develop training workshop curriculum and materials	NRC Staff Hours	40.0 hr	Assumption	
	Cost to train NRC staff from Rockville Headquarters					
		Hours to train NRC staff reviewers and inspectors	NRC HQ Staff Hours	24 hr	Assumption	
		Number of local NRC staff participating in training (including instructor)	NUM NRC HQ staff	3	Assumption	
	Cost to train NRC staff from regional NRC offices					
		Hours to train NRC staff reviewers and inspectors	HOUR training	24 hr	Assumption	
		Cost of roundtrip travel	COST travel	$500	Assumption	
		Cost of lodging and per diem per night	COST lodging & food	$150	Assumption	
		Number of nights of lodging for auditor to complete focused audit	NUM nights hotel	3	Assumption	
		Hours of roundtrip auditor travel per audit	HOURS travel	8 hr	Assumption	
		Number personnel from NRC regional offices	NUM NRC regional staff	4	Assumption	

Exhibit A2 - 4

Audits, Inspections, Certifications and Corrective Action

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Audit Frequency					**Subpart B**	**26.41(b)**
	These parameters are used in the equations below:					
		% multiplier to yield annualized savings	PER annualized	50.0%	Calculated	
		Cost of roundtrip travel	COST travel	$300	Assumption	
		Cost of lodging and per diem per night	COST lodging	$150	Assumption	
	Annual base saving per program from the reduced audit frequency					
		Contracted auditor hours at facility with offsite collection and testing	HOURS auditor-base	25.0 hr	NRC staff estimate	
		FFD program manager hours at facility with offsite collection and testing	HOURS manager-base	13.0 hr	NRC staff estimate	
		Clerical personnel hours at facility with offsite collection and testing	HOURS clerical-base	5.0 hr	NRC staff estimate	
	Additional annual savings per program from audit frequency reduction that accrue to programs with onsite testing					
		Contracted auditor hours saved at facility with onsite testing	HOURS auditor-onsite collection	12.0 hr	NRC staff estimate	
		FFD program manager hours saved at facility with onsite testing	HOURS manager-onsite collection	7.0 hr	NRC staff estimate	
		Clerical personnel hours saved at facility with onsite testing	HOURS clerical-onsite collection	0.0 hr	NRC staff estimate	
		Laboratory manager hours saved at facility with onsite testing	HOURS laboratory manager	5.0 hr	NRC staff estimate	
		Laboratory staff hours saved at facility with onsite testing	HOURS laboratory staff	2.0 hr	NRC staff estimate	
	Additional annual savings per program from audit frequency reduction that accrue to programs with onsite collection					
		Contracted auditor hours saved at facility with onsite collection	HOURS auditor-onsite testing	5.0 hr	NRC staff estimate	
		FFD program manager hours saved at facility with onsite collection	HOURS manager-onsite testing	0.0 hr	NRC staff estimate	
		Clerical personnel hours saved at facility with onsite collection	HOURS clerical-onsite testing	0.0 hr	NRC staff estimate	
		Collection manager hours saved at facility with onsite collection	HOURS collection manager	2.0 hr	NRC staff estimate	
		Collection staff hours saved at facility with onsite collection	HOURS collection staff	1.0 hr	NRC staff estimate	
		Percentage of facilities with onsite collection per program		95.0%	Assumption	
	Base annual savings per program from reduced audit frequency					
		Base number of auditors per program audit	NUM auditors-base	1	Assumption	
		Number of auditor overnights saved at facility with offsite collection and offsite testing	NUM nights-base	3	NRC staff estimate	
		Contracted auditor hours traveling	HOURS travel	4.0 hr	Assumption	
	Additional annual savings per program that accrue due to reduced auditor travel to facilities with onsite testing laboratories					
		Additional number of auditors per program with onsite testing laboratories	NUM auditors-onsite testing	1	Assumption	
		Additional number of overnights per program with onsite testing	NUM nights-onsite testing	1	NRC staff estimate	
	Additional annual savings per program that accrue due to reduced auditor travel to facilities with onsite collection facilities					
		Additional number of auditors per program with onsite collection facilities	NUM auditors-onsite collection	0	Assumption	
		Additional number of overnights per program with onsite collection	NUM nights-onsite collection	0	NRC staff estimate	
	Annual cost per program to conduct focused audits addressing problem areas of the FFD program					
		Hours of contracted auditor time conducting a focused audit	HOURS auditor	4.0 hr	NRC staff estimate	
		Hours of FFD program manager time during a focused audit	HOURS manager	3.0 hr	NRC staff estimate	
		Hours of clerical personnel time during a focused audit	HOURS clerical	1.0 hr	NRC staff estimate	
		Number of auditors per program audit	NUM auditors	2	Assumption	
		Cost of lodging and per diem per night	COST lodging	$ 150.00	Assumption	
		Cost of roundtrip travel	COST travel	$ 300.00	Assumption	
		Number of nights of lodging for auditor to complete focused audit	NUM nights-focused	1	NRC staff estimate	
		Hours of roundtrip auditor travel per audit	auditor travel time	4.0 hr	Assumption	

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Elimination of Audit Duplication of HHS-Certified Laboratories					**Subpart B**	**26.41(c)(2)**
	Annual savings per program from eliminating audit duplication					
		Hours of contracted auditor time saved annually per program in elimination of audit duplication	HOURS auditor	7.0 hr	Assumption	
		Hours of FFD program manager time saved annually in elimination of audit duplication	HOURS manager	4.0 hr	Assumption	
		Hours of clerical personnel time saved annually in elimination of audit duplication	HOURS clerical	1.0 hr	Assumption	
Forensic Toxicologist Review of More Stringent Cutoff Levels					**Subpart B**	**26.31(d)(3)**
	One time cost per program to employ more stringent cutoff level(s) for drugs					
		Hours of review by forensic toxicologist of more stringent cut-off levels for drug testing	HOURS toxicologist	3.5 hr	Assumption	
		Hours of time for the forensic toxicologist to produce a certification statement regarding the more stringent cut-off levels	HOURS certification	0.5 hr	Assumption	
		Percentage of FFD programs that use more stringent cut-off levels for drug testing	PERmore stringent cutoffs	10%	Assumption	
		Percentage of FFD programs who use more stringent cut-off levels for drug testing, but have not reported to the Commission	PER non-report	25%	Assumption	
		Hours of time spent by FFD program manager to review the results of the forensic toxicologist's evaluation per FFD program	HOURS manager	0.5 hr	Assumption	
Pre-Award Inspections of HHS-Certified Laboratories					**Subpart G**	**26.153(e)**
	Annual costs per FFD program					
		Hours per pre-award inspection for an HHS-certified lab conducted by licensee personnel or a designate	HOURS inspection	100 hr	Discussion with NEI staff, May 23, 2003	
		Percentage of FFD programs that must change to a new HHS lab because their current HHS-lab loses HHS certification	PER decertification	10%	Assumption	
		Percentage of instances in which a replacement HHS-certified lab is being used by another FFD program (a "known" HHS lab)	PER known	50%	Assumption	

Exhibit A2 - 5
Authorizations

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Initial Authorization						
Self-Disclosure for Initial Applicants					**Subpart C**	**26.55(a)(1)**
		Pre-Order Baseline: Annual savings per program from reduced facility worker labor burden for those initial applicants who qualify for the self-disclosure relaxation				
		% of applicants for initial authorization qualifying for relaxation	PER qualifying	50%	Assumption	
		Facility worker hours saved in foregone self-disclosure	HOURS worker	0.25 hr	NRC staff estimate	
		Pre-Order Baseline: Annual savings per program from reduced clerical personnel labor burden because fewer self-disclosures submitted by initial applicants need to be processed				
		% of applicants for initial authorization qualifying for relaxation	PER qualifying	50%	Assumption	
		Clerical personnel hours saved in foregone self-disclosure	HOURS clerical	0.25 hr	NRC staff estimate	
Suitable Inquiry for Initial Applicants					**Subpart C**	**26.55(a)(2)**
		Pre-Order Baseline: Annual savings per program from not conducting the suitable inquiry on initial applicants qualifying for relaxation				
		% of applicants for initial authorization qualifying for relaxation	PER qualifying	50%	Assumption	
		HR personnel hours saved in exempted suitable inquiry under the former rule, but prior to the AAO	HOURS hr	1.0 hr	NRC staff estimate	
		Pre-Order Baseline: Annual savings per program due to reduced suitable inquiry coverage period and scope for those applicants qualifying for the relaxation				
		HR personnel hours saved due to reduced suitable inquiry coverage period and a reduction in the number of employers that must be contacted	HOURS hr	0.5 hr	NRC staff estimate	
		% of applicants for initial authorization per year who do not qualify for the relaxation under subparagraph 23.63(a) in the final rule	PER not qualifying	50%	Assumption	
		% of initial applicants who have no potentially disqualifying FFD information to disclose	PER non-PDFFDI	95%	Assumption	
		Industry Practices: Annual cost per program to conduct a more thorough suitable inquiry on applicants for initial authorization to comply with the former rule				
		Additional HR personnel hours required to conduct a suitable inquiry compliant with former rule	HOURS hr	0.2 hr	Assumption	
Pre-Access Testing for Initial Applicants					**Subpart C**	**26.55(a)(3)**
		Pre-Order Baseline: Annual savings per program from not administering a pre-access drug and alcohol test on initial applicants covered by a behavioral observation and arrest-reporting program throughout the period of interruption				
		% applicants of applicants for initial authorization qualifying for pre-access drug test relaxation	PER qualifying	25%	Assumption	
		Pre-Order Baseline: Annual savings per program from bypassing required worker labor in the administration of a pre-access drug and alcohol tests for initial applicants covered by a behavioral observation and arrest-reporting				
		Facility worker hours saved at facility with onsite testing laboratory	HOURS onsite	4.0 hr	Assumption	
		Facility worker hours saved at facility with offsite testing laboratory	HOURS offsite	8.0 hr	Assumption	
		% of initial applicants qualifying for pre-access drug test relaxation	PER qualifying	25%	Assumption	
Random Testing Pool for Initial Applicants					**Subpart C**	**26.55(a)(4)**
		Annual costs per program from the implementation of a random drug and alcohol testing program on initial applicants in applicant status				
		% of initial applicants selected for random drug and alcohol testing	PER random	1%	Assumption	
Authorization Updates						
Self Disclosure for Update Applicants					**Subpart C**	**26.57(a)(1)**
		Pre-Order Baseline: Annual savings per program from reduced facility worker labor burden for those applicants for updated authorization who qualify for the self-disclosure relaxation				
		% of applicants for authorization updates qualifying for relaxation	PER qualifying	50%	Assumption	
		Facility worker hours saved in foregone self-disclosure	HOURS worker	0.25 hr	NRC staff estimate	
		Pre-Order Baseline: Annual savings per program from reduced clerical personnel labor burden because fewer self-disclosures submitted by applicants for updated authorization will need to be processed				
		% of applicants for authorization updates qualifying for relaxation	PER qualifying	50%	Assumption	
		Clerical personnel hours saved in foregone self-disclosure	HOURS clerical	0.25 hr	NRC staff estimate	

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Suitable Inquiry for Update Authorization					**Subpart C**	**26.57(a)(2)**
		Pre-Order Baseline: Annual savings per program from not conducting the suitable inquiry on applicants for updated authorization qualifying for the relaxation				
		% of applicants for authorization updates qualifying for relaxation	PER qualifying	50%	Assumption	
		HR personnel hours saved in exempted suitable inquiry under the former rule, but prior to the AAO	HOURS hr	1.0 hr	NRC staff estimate	
		Pre-Order Baseline: Annual savings per program due to reduced suitable inquiry coverage period and scope for applicants for updated authorization qualifying for the relaxation				
		% of applicants for updated authorization not qualifying for relaxation	PER non qualifying	50%	Assumption	
		% of applicants for updated authorization who have no potentially disqualifying FFD information to disclose	PER non-PDFFDI	98%	Assumption	
		HR personnel hours saved due to reduced suitable inquiry coverage period and a reduction in the number of employers that must be contacted	HOURS hr	0.5 hr	NRC staff estimate	
		Industry Practices: Annual cost per program to conduct a more thorough suitable inquiry on applicants for updated authorization to comply with the former rule				
		Additional HR personnel hours required to conduct a suitable inquiry compliant with former rule	HOURS hr	0.2 hr	Assumption	
Pre-Access Testing for Update Applicants					**Subpart C**	**26.57(a)(3)**
		Pre-Order Baseline: Annual savings per program from not administering a pre-access drug and alcohol test on update applicants covered by a behavioral observation and arrest-reporting program throughout the period of interruption				
		% applicants for authorization updates qualifying for pre-access drug test relaxation	PER qualifying	25%	Assumption	
		Pre-Order Baseline: Annual savings per program from bypassing required worker labor in the administration of a pre-access drug and alcohol tests for update applicants covered by a behavioral observation and arrest-reporting				
		Facility worker hours saved at facility with onsite testing laboratory	HOURS onsite	4.0 hr	Assumption	
		Facility worker hours saved at facility with offsite testing laboratory	HOURS offsite	8.0 hr	Assumption	
		% applicants for authorization updates qualifying for pre-access drug test relaxation	PER qualifying	25%	Assumption	
Random Testing Pool for Update Applicants					**Subpart C**	**26.57(a)(4)**
		Annual costs per program from the implementation of a random drug and alcohol testing program on update applicants in applicant status				
		% of initial applicants selected for random drug and alcohol testing	PER random	1%	Assumption	
Authorization Reinstatements with Interruptions						
Self-Disclosure for Reinstatement Applicants with 31-365 Day Interruption					**Subpart C**	**26.59(a)(1)**
		Pre-Order Baseline: Annual savings per program from reduced facility worker labor burden for those applicants for authorization reinstatement who qualify for the self-disclosure relaxation				
		Facility worker hours saved in foregone self-disclosure	HOURS worker	0.25 hr	NRC staff estimate	
		% of applicants for authorization reinstatement qualifying for self-disclosure relaxation	PER qualifying	50%	Assumption	
		Pre-Order Baseline: Annual savings per program from reduced clerical personnel labor burden because fewer self-disclosures submitted by applicants for authorization reinstatement will need to be processed				
		Clerical personnel hours saved in foregone self-disclosure	HOURS clerical	0.25 hr	NRC staff estimate	
		% of applicants for authorization reinstatement qualifying for self-disclosure relaxation	PER qualifying	50%	Assumption	
Suitable Inquiry for Reinstatement Applicants with 31-365 Day Interruption					**Subpart C**	**26.59(a)(2)**
		Pre-Order Baseline: Annual savings per program from not conducting the suitable inquiry on applicants for authorization reinstatement qualifying for the relaxation				
		HR personnel hours saved in exempted suitable inquiry under the former rule, but prior to the AAO	HOURS hr	1.0 hr	NRC staff estimate	
		% of applicants qualifying for the suitable inquiry relaxation	PER qualifying	50%	Assumption	
		Pre-Order Baseline: Annual savings per program due to reduced suitable inquiry coverage period and scope for applicants for authorization reinstatement qualifying for the relaxation				
		HR personnel hours saved due to reduced suitable inquiry coverage period and a reduction in the number of employers that must be contacted	HOURS hr	0.5 hr	NRC staff estimate	
		% of applicants not qualifying for the suitable inquiry relaxation	PER covered	50%	Assumption	
		% of update applicants who have no potentially disqualifying FFD information to disclose on their self-disclosures	PER non-pdffdi	99%	Assumption	
		Industry Practices: Annual cost per program to conduct a more thorough suitable inquiry on applicants for authorization reinstatement to comply with the former rule				
		Additional HR personnel hours required to conduct a suitable inquiry compliant with former rule	HOURS hr	0.2 hr	Assumption	

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Pre-Access Testing for Reinstatement Applicants with 31-365 Day Interruption					**Subpart C**	**26.59(a)(3)**
		Pre-Order Baseline: Annual savings per program from allowing reinstatement applicants covered by a random drug and alcohol testing program throughout the period of interruption to forego pre-access drug and alcohol testing				
		% of applicants for authorization reinstatement covered by a random drug and alcohol testing program	PER qualifying	25%	Assumption	
		Pre-Order Baseline: Annual savings per program from reducing the number of hours of lost worker productivity for reinstatement applicants covered by both a random drug and alcohol testing program and a behavioral observation and arrest reporting program				
		Facility worker hours saved at facility with onsite testing laboratory	HOURS onsite	4.0 hr	Assumption	
		Facility worker hours saved at facility with offsite testing laboratory	HOURS offsite	8.0 hr	Assumption	
		% of applicants for authorization reinstatement covered by a random drug and alcohol testing program	PER qualifying	25%	Assumption	
		Pre-Order Baseline: Annual savings per program resulting from this group of applicants not having to await verification of negative results before granting authorization				
		Facility worker hours saved at facility with onsite testing laboratory	HOURS onsite	4.0 hr	Assumption	
		Facility worker hours saved at facility with offsite testing laboratory	HOURS offsite	8.0 hr	Assumption	
		% of applicants for authorization reinstatement not covered by a random drug and alcohol testing program	PER not qualifying	75%	Assumption	
Random Testing Pool for Reinstatement Applicants with 31-365 Day Interruption					**Subpart C**	**26.59(a)(4)**
		Annual costs per program to conduct random drug and alcohol tests on applicants randomly selected while awaiting the granting of authorization				
		% of initial applicants selected for random drug and alcohol testing	PER random	1%	Assumption	
Self-Disclosure (and Suitable Inquiry) for Reinstatement Applicants with Less than 31 Day Interruption					**Subpart C**	**26.59(c)(1)**
		Pre-Order Baseline: Annual savings per program from reduced facility worker labor burden for those applicants for authorization reinstatement who qualify for the self-disclosure relaxation				
		% of reinstatement applicants qualifying for relaxation	PER qualifying	50%	Assumption	
		Facility worker hours saved in foregone self-disclosure	HOURS worker	0.25 hr	NRC staff estimate	
		Pre-Order Baseline: Annual savings per program from reduced clerical personnel labor burden because fewer self-disclosures submitted by applicants for authorization reinstatement will need to be processed				
		% of reinstatement applicants qualifying for relaxation	PER qualifying	50%	Assumption	
		Clerical personnel hours saved in foregone self-disclosure	HOURS clerical	0.25 hr	NRC staff estimate	
		Pre-Order Baseline: Annual savings per program from not conducting suitable inquiries on applicants for authorization reinstatement with an interruption of not more than 30 days				
		HR personnel hours saved in exempted suitable inquiry under the former rule, but prior to the AAO	HOURS hr	1.0 hr	NRC staff estimate	
		Industry Practices: Annual cost per program for applicants for authorization reinstatement with interruptions of not more than 30 days to submit self-disclosures to comply with self-disclosure requirements				
		Facility worker hours required to complete and submit self-disclosure	HOURS worker	0.25 hr	NRC staff estimate	
		% cost applied to each program	PER cost	50%	Assumption	
		Industry Practices: Annual cost per program for clerical personnel to process additional self-disclosures for applicants for authorization reinstatement with interruptions of not more than 30 days to comply with self-disclosure requirements				
		Clerical personnel hours required to process received self-disclosures	HOURS clerical	0.25 hr	NRC staff estimate	
		% cost applied to each program	PER cost	50%	Assumption	
		Industry Practices: Annual cost per program to conduct suitable inquiries on applicants for authorization reinstatement with an interruption of not more than 30 days to comply with the former rules				
		Additional HR personnel hours required to conduct a suitable inquiry as required by former	HOURS hr	1.0 hr	NRC staff estimate	
		% cost applied to each program	PER cost	50%	Assumption	
		Industry Practices: Annual cost per program to conduct a more thorough suitable inquiry on applicants for authorization reinstatement with an interruption of not more than 30 days to comply with the former rule				
		Additional HR personnel hours required to conduct a suitable inquiry compliant with former rule	HOURS hr	0.2 hr	Assumption	

Pre-Access Testing for Reinstatement Applicants with Less than 31 Day Interruption			Subpart C	26.59(c)(2)
Pre-Order Baseline: Annual savings per program from not administering a pre-access drug and alcohol test on applicants for authorization reinstatement with an interruption of 5 days or less				
No additional Parameters	No Parameters			
Pre-Order Baseline: Annual savings per program from bypassing worker labor in the administration of a pre-access drug and alcohol test for authorization reinstatements with an interruption of 5 days or less				
Facility worker hours saved at facility with onsite testing laboratory	HOURS onsite	4.0 hr	Assumption	
Facility worker hours saved at facility with offsite testing laboratory	HOURS offsite	8.0 hr	Assumption	
Pre-Order Baseline: Annual savings per program from allowing reinstatement applicants who have been covered by a behavioral observation and arrest-reporting program throughout the period of interruption to forego the pre-access drug and alcohol test				
% of applicants qualifying for the relaxation	PER covered	50%	Assumption	
Pre-Order Baseline: Annual savings per program from bypassing required worker labor in the administration of a pre-access drug and alcohol tests for reinstatement applicants who have been covered by a behavioral observation and				
% of applicants qualifying for the relaxation	PER covered	50%	Assumption	
Facility worker hours saved at facility with onsite testing laboratory	HOURS onsite	4.0 hr	Assumption	
Facility worker hours saved at facility with offsite testing laboratory	HOURS offsite	8.0 hr	Assumption	
Pre-Order Baseline: Annual savings per program from allowing reinstatement applicants who have not been covered by a behavioral observation and arrest-reporting program throughout the period of interruption but who have not beer randomly selected for pre-access testing to forego the pre-access drug and alcohol test				
% of applicants not qualifying for the relaxation	PER not covered	50%	Assumption	
% of applicants subject to random testing but not selected	PER not selected	98%	Assumption	
Pre-Order Baseline: Annual savings per program from reducing the number of hours of lost worker productivity for reinstatement applicants who are not covered and are not selected for random pre-access drug and alcohol testing				
% of applicants not qualifying for the relaxation	PER not covered	50%	Assumption	
% of applicants subject to random testing but not selected	PER not selected	98%	Assumption	
Facility worker hours saved at facility with onsite testing laboratory	HOURS onsite	4.0 hr	Assumption	
Facility worker hours saved at facility with offsite testing laboratory	HOURS offsite	8.0 hr	Assumption	
Industry Practices: Annual cost per program to comply with existing pre-access drug and alcohol testing provisions				
Facility worker hours saved at facility with onsite testing laboratory	HOURS onsite	4.0 hr	Assumption	
Facility worker hours saved at facility with offsite testing laboratory	HOURS offsite	8.0 hr	Assumption	
% of cost applied to a given program due to non-compliance	PER compliance	50%	Assumption	
Industry Practices: Annual cost per program of increased lost worker productivity awaiting negative test result verification to comply with existing pre-access drug and alcohol testing provisions				
Facility worker hours saved at facility with onsite testing laboratory	HOURS onsite	4.0 hr	Assumption	
Facility worker hours saved at facility with offsite testing laboratory	HOURS offsite	8.0 hr	Assumption	
% of cost applied to a given program due to non-compliance	PER compliance	50%	Assumption	

Random Testing Pool for Reinstatement Applicants with Less than 31 Day Interruption			Subpart C	26.59(c)(3)
Annual costs per program to subject applicants for authorization reinstatement to one-time random selection for a pre-access drug and alcohol test				
% rate of random test selection	PER randomly selected	2%	Assumption	
% rate of random test selection	PER randomly selected	1%	Assumption	
Annual costs per program from reduced labor productivity to subject applicants for authorization reinstatement to one-time random selection for a pre-access drug and alcohol test				
% rate of random test selection	PER random	2%	Assumption	
Facility worker hours saved at facility with onsite testing laboratory	HOURS onsite	4.0 hr	Assumption	
Facility worker hours saved at facility with offsite testing laboratory	HOURS offsite	8.0 hr	Assumption	

Exhibit A2 - 6

Activities Related to Potential Policy Violations

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Reasonable Effort to Track Randomly Selected Individuals for Testing					**Subpart B**	**26.31(d)(2)**
	Annual costs per program from requiring greater effort to track individuals selected for random drug and alcohol testing					
		% tested by a random drug program per year	PER random	50.0%	Rule requirement	
		% of randomly selected employees per year that are unavailable for the scheduled test	PER unavailable	25%	Assumption	
		Hours of FFD program manager tracking time per randomly selected employee unavailable for the scheduled test	HOURS manager	0.25 hr	Assumption	
Behavioral Observation					**Subpart B**	**26.33**
	This parameter is used in the equations below:					
		% increase in for-cause tests/referrals per year	PERI for-cause	10%	Assumption	
	Annual cost per program to review additional for-cause referrals					
		Hours of FFD program manager review per for-cause referral	HOURS manager	4.0 hr	Assumption	
		Hours of facility worker hours under review per for-cause referral	HOURS worker	4.0 hr	Assumption	
	Annual cost per program to conduct additional drug and alcohol tests due to increased for-cause referrals					
			No additional parameters			
	Annual cost per program to conduct additional pre-access drug and alcohol tests yielding positive results due to increased for-cause referrals					
			No additional parameters			
	Annual cost per program to retest confirmed positive drug test results at a second HHS-certified laboratory at the request of the donor					
		Percentage of urine specimens with confirmed positive, adulterated, substituted, dilute, or invalid validity and/or drug test results retested at the request of the donor at a second HHS-certified laboratory	PER retest	5%	Assumption	
	Annual costs per program for the percentage of workers with confirmed positive test results who initiate an appeals process					
		Percentage of workers with confirmed positive test results that initiate appeals process	PER appeals	1%	Assumption	
Disclosure requirements positive test results					**Subpart B**	**26.37(d)**
	Annual costs per program to provide individuals with easier access to personal documents					
		% of employees with positive test results who request records	PER requesting	50%	Assumption	
		Additional clerical personnel hours copying, packaging, and shipping records per disclosure request	HOURS clerical	1.0 hr	Assumption	
		Cost of mailing (express mail) one performance data report to each licensee	COSTMailing	$ 10.00	Assumption	
Definition of "Potentially Disqualifying Information"					**Subpart H**	**26.189(b)(3)**
	These parameters are used in the equations below:					
		% of applicants for authorization requiring a determination of fitness based on potentially disqualifying FFD information under the former rule	PER PDFFDI-former	10%	Assumption	
		% of applicants for authorization requiring a determination of fitness based on potentially disqualifying FFD information under the final rule	PER PDFFDI-final	5%	Assumption	
	Annual savings per program from the reduction in the number of determinations of fitness requiring SAE review					
		SAE hours of review per determination of fitness	HOURS sae	2.0 hr	Assumption	
	Annual savings per program from the reduction in the number of determinations of fitness requiring FFD program manager review					
		FFD program manager hours of review per determination of fitness	HOURS manager	2.0 hr	Assumption	
	Annual savings per program from the reduction in the number of determinations of fitness requiring clerical personnel support					
		Clerical personnel hours to support determination of fitness	HOURS clerical	2.0 hr	Assumption	
Face-to-Face Determinations of Fitness					**Subpart H**	**26.189(c)**
	Annual costs per program from requiring that a determination of fitness that is conducted for-cause be conducted face-to-face with the individual under review					
		Hours of worker time required per face-to-face determination of fitness	HOURS worker	2.0 hr	Assumption	

Exhibit A2 - 7
Urine Specimen Collections

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Urine Collection: Donors Without Adequate ID					**Subpart E**	**26.89(b)(2)**
	Annual savings per FFD program per year					
		Percentage of individuals without identification	PER no-ID	1.0%	Assumption	
		Time a donor without ID would spend to leave the collection site, obtain appropriate ID, and return to the collection site to be drug and alcohol tested	HOURS worker	0.75 hr	Assumption	
Urine Collection: Eliminate Listing Medications on the CCF Form and add description of testing process					**Subpart E**	**26.89(b)(3)**
	Annual savings per FFD program per year					
		Time per collection to list medications on CCF	HOURS saved	0.033 hr	Assumption	
		Time per collection for collector to explain testing process to donor	HOURS added	0.013 hr		
Urine Collection: Inspecting Contents of Donor's Pockets					**Subpart E**	**26.105(b)**
	Annual costs per FFD program per year					
		Time to inspect contents of a donors pockets per test	HOURS inspection	0.033 hr	Assumption	
Urine Specimen Quantity: Minimum Quantity of 30 mL					**Subpart E**	**26.109(a)**
	Annual savings per FFD program					
		Percentage of collections considered to be of inadequate quantity under the former requirements	PER low quantity	6.7%	4.22.03 Wall Street Journal article, see RA	
		Percentage decrease in the number of inadequate specimens resulting from reduction in the minimum specimen quantity from 60 mL to 30 mL	PERD low quantity	25.0%	Assumption	
		Time per test saved because donor can provide a sufficient specimen under the new rule	HOURS saved	1.50 hr	Assumption	
Urine Specimen: At Least 30 mL, but Less than Predetermined Quantity					**Subpart E**	**26.109(b)(2)**
	Annual costs per FFD program with onsite testing facility					
		Percentage of urine specimens at least 30 mL in volume, but less than the licensee or C/Vs predetermined quantity of urine	PER not predetermined quantity	1.0%	Assumption	
Shy Bladder Medical Evaluation					**Subpart E**	**26.119**
	Annual costs per FFD program					
		Number of urine collections unable to be completed because of inadequate specimen volume per facility per year	NUM shy bladder	1	Assumption	
		Cost of a medical evaluation and written report from a licensed physician (per shy bladder event)	COST medical evaluation	$ 300.00	Assumption	
		Time per medical evaluation (including travel to and from the physician's office)	HOURS medical evaluation	1.50 hr	Assumption	
		Time for a FFD manager per incident where an employee is unable to provide the minimum quantity of urine after 3 hours	HOURS FFD manager	2.0 hr	Assumption	
		MRO time to select a physician, instruct the physician on the medical evaluation that must be conducted, and review and communicate the medical evaluation results	HOURS MRO	2.0 hr	Assumption	

Exhibit A2 - 8
Alcohol Testing

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Blood Collection for Confirmatory Alcohol Testing					**Subpart E**	**26.83(a)**
	Annual savings per FFD program per year					
		Number of blood tests per FFD program per year	NUM blood	1	NEI data	
		Hours MRO to review test result & communicate with employee and donor	HOURS mro	0.75 hour	Assumption	
		Hours lost worker productivity resulting from receiving a blood test	HOURS worker	0.75 hour	Assumption	
Purchase of EBT and Calibration Equipment and Related Training					**Subpart E**	**26.91(b)**
	This parameter is used in the equations below:					
		Percentage of collection sites that will purchase an EBT meeting the specifications in paragraph 26.91(c).	PER purchased	50%	Assumption	
	One time equipment purchases per facility					
		Number of compliant EBTs purchased per collection site	NUM EBTs	2	Assumption	
	One time training cost per facility					
		Cost of alcohol collector training course on purchased EBT	COST training course	$ 250	Assumption	
		Number of alcohol collectors per collection site	NUM collectors	4		
		Length of alcohol collector training course	HOURS collector training	2 hours	Assumption	
Required Use of an EBT on the NHTSA CPL for Confirmatory Testing					**Subpart E**	**26.91(c)**
	Annual savings per FFD program per year					
		Time per test to set-up a second EBTs (locate the EBT, turn on the equipment) to conduct confirmatory testing	HOURS saved	0.033 hour	Assumption	
		Percentage of collections sites that will use a compliant EBT for all collections	PER compliant, final rule	50%	Assumption	
One Breath Specimen Collection for Initial Alcohol Test					**Subpart E**	**26.95(c)**
	Annual savings per FFD program per year					
		Savings in collection time from one fewer breath collection per breath test	HOURS breath collection	0.033 hour	Assumption	
Lowering Initial BAC Requiring Confirmatory Test to BAC 0.02					**Subpart E**	**26.99(b)**
	Annual costs per FFD program per year					
		Percentage increase in number of initial positive alcohol tests under the lower screening level BAC	PERI IPAT	20%	Assumption	
		Time to conduct a confirmatory alcohol test under the final rule	HOURS CAT	0.05 hour	Assumption	
		Hours of FFD manager time associated with personnel activities and administrative actions resulting from a confirmed positive alcohol test result	HOURS FFD manager	2.5 hour	Assumption	
FFD Manager Determines Confirmed Positive Test for Alcohol (BAC 0.02 < 0.04)					**Subpart E**	**26.103**
	Annual costs per FFD program per year					
		% increase in the number of confirmed positive breath alcohol tests per FFD program under the BACs in the final rule	PERI CPAT	20%	Assumption. Note: this is the same rate as in 26.97(b) PERI IPAT	
		Time per test result for FFD manager to determine the length of time an employee has been in work for BACs equal to or greater than 0.02 and less than 0.4	HOURS FFD management	0.25 hour	Assumption	

Exhibit A2 - 9

Drug and validity testing (licensee testing facilities and HHS-certified laboratories)

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Validity Testing (On-site Licensee Testing Facilities and HHS-Certified Laboratories)					**Subpart F**	**26.131(b)**
					Subpart G	**26.161(b)(1)**
	Cost to Conduct Daily Calibration Validity Testing Equipment at Onsite Licensee Testing Facility					
		Number of days per year a licensee testing facility operates	NUMdays	365 days	Assumption	
	Costs for confirmed positive drug tests and confirmed adulterated, substituted, or invalid validity test results					
		Percentage of initial validity tests with dilute, adulterated, substitued, or invalid test results	PER dilute, adulterated, substituted, or invalid - initial valdiity testing	2.69%	Equals the sum of the percentage of dilute, adulterated, and invalid specimens - see Exhibit A2-12)	
		Percentage of Dilute Specimens drug positive at LOD testing	PER positive LOD	33%	Assumption	
		Percentage of initial Adulterated, Substituted (0-<2 mg/dL creatinine), and Invalid test results that remain adulterated, substitued, or invalid on confirmation	PER adulterated, substituted, Invalid confirmed	100%	Assumption	
		Percentage of specimens collected under direct observation as a result of an initial specimen with a confirmatory validity test result of invalid that test positive for drugs	PERdrug positive 2nd collection	33%	Assumption	
Initial Validity Testing - Onsite Licensee Testing Facilities					**Subpart F**	**26.131(b)**
	This parameter is used in multiple equations in 26.131(b) calculations:					
		Percentage of urine specimens with confirmed positive, adulterated, substituted, dilute, or invalid validity and/or drug test results retested at the request of the donor at a second HHS-certified laboratory	PER retest	5.0%	Assumption	
		Percentage of workers with confirmed positive test results that initiate appeals process	PER appeals	1.0%	Assumption	
Change Cutoff Levels for Marijuana and Opiates - Onsite Testing Facilities					**Subpart F**	**26.133**
Change Cutoff Levels for Marijuana and Opiates - HHS-Certified Laboratories					**Subpart G**	**26.163(a)(1)**
		Percentage increase in marijuana positive drug tests resulting from reduced cutoff level in new rule	PERI marijuana	40%	Assumption	
		Percentage decrease in opiate positive drug tests resulting from the increased cutoff level in the new rule	PERD opiate	75%	Assumption	
Quality Control Specimens in Each Analytical Run - Onsite Testing Facilities					**Subpart F**	**26.137(e)(6)**
	Annual costs per unit with onsite testing facilities					
		Percentage cost increase per average urine specimen	PERI cost	10%	Assumption	
Unidentified Interfering Substance/Adulterant - Contact MRO and Specimen Retesting					**Subpart G**	**26.161(g)**
	Annual costs per FFD program					
		Number of urine specimens per facility per year suspected of having a new adulterant or interfering agent that could make a test result invalid that are sent to a second HHS-certified laboratory	NUM new adulterant	1	Assumption	
		Time per specimen for an MRO to speak with the HHS-certified laboratory and determine whether a specimen is to be retested at a second HHS-certified laboratory, and the time to review the results of validity testing at the second HHS-certified laboratory	HOURS MRO	0.50 hr	Assumption	
Retesting of Single Collection Specimens with Confirmed Positive Drug and/or Validity Test Results					**Subpart G**	**26.165(b)**
		Percentage of urine specimens with confirmed positive, adulterated, substituted, dilute, or invalid validity and/or drug test results retested at the request of the donor at a second HHS-certified laboratory	PER retest	5%	Assumption	
		Percentage increase in retesting of confirmed positive urine specimens based on the new rule provision to afford retesting of single specimens	PERI retest	10%	Assumption	

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Blind Sample Testing - 1st Quarter of Contract with a HHS-Certified Laboratory					**Subpart G**	**26.168(a)(1)**
	Annual savings per FFD program which conduct all drug tests at an HHS-certified lab					
		Percentage of urine specimens that must be blind test specimens submitted in initial 90 days of a contract with an HHS-certified lab, former rule	PER blind specimens, initial 90 days, former rule	50%	Former rule requirement, 2.8(e)(2) of Appendix A	
		Maximum number of blind specimens to be submitted in the first 90 days of a contract with an HHS-certified lab, former rule	NUM blinds, max, initial 90 days, former rule	500	Former rule requirement, 2.8(e)(2) of Appendix A	
		Percentage of urine specimens that must be blind test specimens submitted in the first 90 days of a contract with an HHS-certified lab - new rule	PER blind specimens, initial 90 days, new rule	20%	Final rule requirement	
		Maximum number of blind specimens to be submitted in the first 90 days of a contract with an HHS-certified lab, new rule	NUM blinds, max, initial 90 days, new rule	100	Final rule requirement	
		Minimum number of blind specimens to be submitted in the first 90 days of a contract with an HHS-certified lab, new rule	NUM blinds, min, initial 90 days, new rule	30	Final rule requirement	
		Percentage of years that a FFD program enters contracts with a different HHS-certified lab	PER FFD programs change HHS lab	10%	Assumption	
		Number of quarters in a year	NUM quarters	4		
	Annual costs per FFD program which conducts initial drug testing at an on-site licensee testing facility					
		Percentage of specimens analyzed by a licensee testing facility that must be QA specimen	PER QA specimens	10.0%	Licensee testing facilities include 10 percent of total specimens analyzed as controls, complying with former rule 2.7(d) of Appendix A	
		Percentage of QA specimens that must be a blind specimen	PER QA specimens, blinds	10.0%	Assumption	
		Percentage of blind specimens that must be positive under former requirements	PER Blind specimens, positive	20.0%	Former rule requirement, 2.8(e)(3) of Appendix A	
		Percentage of negative initial drug test result specimens submitted to a HHS-certified laboratory for initial drug testing	PER neg. urine specimens to HHS	1.0%	Assumption	
Blind Sample Testing - Contracts with HHS-Certified Laboratories Older Than 90 Days					**Subpart G**	**26.168(a)(2)**
	Annual savings per FFD program which conduct all drug tests at an HHS-certified lab					
		Percentage of urine specimens that must be blind test specimens submitted per quarter for an existing contract with an HHS-certified laboratory - former rule	PER blind specimens, per quarter, former rule	10%	Former rule requirement, 2.8(e)(2) of Appendix A	
		Maximum number of blind specimens to be submitted in the first 90 days of a contract with an HHS-certified lab, former rule	NUM blinds, max, per quarter, former rule	250	Former rule requirement, 2.8(e)(2) of Appendix A	
		Percentage of urine specimens that must be blind performance test specimens submitted per quarter for an existing contract with an HHS-certified laboratory - new rule	PER blind specimens, per quarter, new rule	1%	Final rule requirement	
		Maximum number of blind specimens to be submitted per quarter for an existing contract with an HHS-certified lab, new rule	NUM blinds, max, per quarter, new rule	100	Final rule requirement	
		Minimum number of blind specimens to be submitted per quarter for an existing contract with an HHS-certified lab, new rule	NUM blinds, min, per quarter, new rule	10	Final rule requirement	
		Maximum percentage of urine specimens that must be blind specimens submitted per quarter for an existing contract with an HHS-certified laboratory (if total number of specimens submitted is less than 10 specimens), new rule	PER cap on min. num. blinds per quarter	25%	Final rule requirement. The number of blind specimens per quarter is Final at a minimum of 3 percent (up to a maximum of 25 percent) or 10 blinds specimens, whichever is greater.	
		Increase in the cost per blind performance test specimen due to the change in the mix of the positive to negative ratio of blind specimens in the final rule	PERIcost blind specimen	75%	Assumption, cost increase by 75% because of change in mix of blind performance test samples (former rule required 80% of samples to be negative, final rule requires 60% of samples to be positive, 10% false negative challenge, 10% adulterated, substitued, or dilute)	

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Annual costs per FFD program which conducts initial drug testing at on-site licensee testing facility						
		Percentage of specimens analyzed by a licensee testing facility that must be QA specimens (controls)	PER QA specimens	10.0%	Licensee testing facilities include 10 percent of total specimens analyzed as controls, complying with former rule 2.7(d) of Appendix A	
		Percentage of QA specimens that must be a blind specimen	PER QA specimens, blinds	10.0%	Assumption	
		Percentage of blind specimens that must be positive under former rule	PER Blind specimens, positive, former rule	20.0%	Former rule requirement, 2.8(e)(3) of Appendix A	
		Percentage of negative initial drug test result specimens submitted to a HHS-certified laboratory for initial drug testing	PER neg. urine specimens to HHS	1.0%	Value under Section 26.167(h)(1), cell E727	

Exhibit A2 - 10
Reporting Requirements

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
FFD Programs: Performance Data Reporting and Review					**Subpart N**	**26.717(e), (f)**
	Annual savings per program by reducing reporting requirements					
		FFD program manager hours saved in frequency reduction	HOURS manager	20.0 hr	NRC staff estimate	
	Savings from NRC reviewing fewer licensee reports					
		NRC clerical personnel hours saved in reduction in reporting frequency	HOURS clerical	24.0 hr	NRC staff estimate	
		NRC manager hours saved in reduction in reporting frequency	HOURS manager	20.0 hr	NRC staff estimate	
					Subpart N	**26.717(g)**
		Number of licensee to whom each C/V submits performance data to under the former rule	NUM licensees	9	Assumption	
		Cost of mailing (express mail) per information disclosure request	COSTMailing	$ 10.00	Assumption	
	C/V manager labor burden reduced by only having to produce consolidated report for submission to NRC					
		Hours of C/V manager time to compile one licensee performance data report	HOURS manager	30.0 hr	Assumption	
		% savings achieved by consolidating performance data into a single report submitted to NRC	PER consolidation	25%	Assumption	
	Reduced Mailing costs					
		No Additional Parameters	**No additional parameters**			
Reporting and Review of Reportable Events Due to New Validity Testing Requirements					**Subpart N**	**26.719(b)**
	This parameter is used in the equations below:					
		Percentage of tested staff covered by 26.203(b)(2)	PER staff	15%	Assumption	
	Annual cost per unit due to new validity testing requirements					
		FFD program manager hours required to investigate, analyze, and report an event	HOURS manager	4.0 hr	Assumption	
					Subpart N	**26.719(b)**
	Increase in NRC manager labor to review increased number of reportable events					
		NRC manager hours required to review a reported event	HOURS manager	3.0 hr	NRC staff	
	Increase in NRC clerical labor due to increased number of reportable events					
		NRC clerical hours required to process a reported event	HOURS clerical	1.0 hr	NRC staff	
Filing of Forensic Toxicologist's Evaluation					**Subpart N**	**26.713(g)**
	One-time cost per program from clerical support to file and store the forensic toxicologist's evaluation of the FFD program's more stringent cutoff levels.					
		Hours of clerical personnel to file and store the forensic toxicologist's evaluation of the FFD program's more stringent cutoff levels per program	HOURSClerical	0.25 hr		
		Percentage of FFD programs that use more stringent cut-off levels for drug testing	PERmore stringent cutoffs	10%	Assumption	
		Percentage of FFD programs who use more stringent cut-off levels for drug testing, but have not reported to the Commission	PER non-report	25%	Assumption	
Memorandum to HHS-Certified Laboratory for Incorrect CCF Form					**Subpart G**	**26.153(g)**
	Annual costs per FFD program					
		Number of memoranda per year a collection site used by a facility will write because it uses an expired Federal custody-and-control form or a non-Federal custody-and-control form was used for a specimen collection	NUM memoranda	2	Assumption	
		Time for collection staff to draft a memorandum	HOURS collector	0.25 hr	Assumption	
Licensee Testing Facility Reporting of Testing Data to FFD program (Monthly to Annually)					**Subpart F**	**26.139(d)**
	Annual savings per FFD program with Licensee Testing Facility					
		Time for a laboratory supervisor per licensee testing facility to prepare a monthly statistical summary report of urinalysis testing data	HOURS monthly report	1.50 hr	Assumption	
		Time for a laboratory supervisor per licensee testing facility to prepare an annual statistical summary report of urinalysis testing data	HOURS annual report	4.00 hr	Assumption	
		Number of monthly reports per licensee testing facility per year	NUM monthly reports	12	Number of months in a year.	

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
HHS-Certified Laboratory Reporting of Testing Data to FFD program (Monthly to Annually)					**Subpart G**	**26.169(k)**
		Time to generate and send an annual or monthly statistical summary report per facility	HOURS lab tech	0.50 hour	Assumption	
		Number of reports per month per facility	NUM reports per month	1	former requirement	
		Number of reports that will no longer be sent to a facility	NUM reports	11	Final requirement to move from montly to annual reporting	
		Cost to send an annual or monthly statistical summary report via the U.S. Postal Service	COSTpostage	$ 2.00	Assumption	
NRC Review of Fatigue Information in Annual FFD Performance Reports					**Subpart I**	**26.203(e)**
	Annual cost to NRC to review and summarize annual reports on fatigue					
		NRC clerical hours per year to assist in reviewing and summarizing the additional information addressing fatigue	HOURS Clerical	24.0 hr	Assumption	
		NRC manager hours per year to review and summarize the additional information addressing fatigue	HOURS Manager	24.0 hr	Assumption	

Exhibit A2 - 11:
Hourly Wage Rates

Worker Type	Hourly Wage Rate (2002 $)	Hourly Wage Rate (Adjusted 2006 $)	Source/Comments
C/V manager		$ 50.00 /hour	Assumption
Clerical	$ 15.75 /hour	$ 17.52 /hour	Model Facility Data from NEI Jan to May 2002
Collection Site Supervisor		$ 50.00 /hour	Assumption
Collector or Collection Site Personnel	$ 22.78 /hour	$ 25.34 /hour	Model Facility Data from NEI Jan to May 2002
EAP	$ 28.85 /hour	$ 32.09 /hour	Model Facility Data from NEI Jan to May 2002
Facility Supervisor		$ 70.00 /hour	Assumption
FFD Program Manager	$ 31.98 /hour	$ 35.57 /hour	Model Facility Data from NEI Jan to May 2002
FFD Staff		$ 30.00 /hour	Assumption
Forensic Toxicologist		$ 93.75 /hour	Derived from quote from a drug testing expert
HR personnel		$ 50.00 /hour	Assumption
Contractor/Vendor Worker	$ 58.00 /hour	$ 64.52 /hour	Model Facility Data from NEI Jan to May 2002
Lab supervisor		$ 50.00 /hour	Assumption
Lab Technician	$ 26.54 /hour	$ 29.52 /hour	Model Facility Data from NEI Jan to May 2002
Legal		$ 100.00 /hour	Assumption
MRO	$ 100.00 /hour	$ 111.24 /hour	Model Facility Data from NEI Jan to May 2002
NRC Clerical		$ 40.00 /hour	NRC staff , 2004
NRC Staff		$ 87.00 /hour	NRC staff , 2004
SAE	$ 28.85 /hour	$ 32.09 /hour	Same as SAP wage rate
Trainer		$ 50.00 /hour	Assumption
Training Manager		$ 55.00 /hour	Assumption
Facility Worker (weighted average facility workers & C/Vs)	$ 55.14 /hour	$ 61.34 /hour	Model Facility Data from NEI Jan to May 2002
Facility Worker (not weighted)	$ 36.21 /hour	$ 40.28 /hour	Model Facility Data from NEI Jan to May 2002

2002 dollars have been adjusted to 2006 using implicit price deflators for GDP in the Survey of Current Business, as reported by the U.S. Department of Commerce, Bureau of Economic Analysis. Obtained at http://bea.gov/bea/pubs.htm.

Exhibit A2 - 12:
Testing and Applicant Information

Parameter Description	Value	Source
Drug & Alcohol Testing Information		
Total Number of Drug Tests per year for all FFD Programs	135,702	2005 Information Notice, NRC Table 1. Test results for each test category
Total Number of Drug Tests per Reactor per year	1,280 tests/reactor	Calculated
Total Number of Alcohol Tests per year for all FFD Programs	135,702	2005 Information Notice, NRC Table 1. Test results for each test category (one alcohol test and one drug test conducted for each testing event)
Total Number of Alcohol Tests per year per Reactor	1,280 tests/reactor	Calculated
Total Number of Random Drug and Alcohol Tests per year for all programs	50,286	2005 Information Notice, NRC Table 1. Test results for each test category
Total Number of Random Drug and Alcohol Tests per year per reactor	474 tests/reactor	Calculated
Negative Random Drug and Alcohol Test Rate in 2005	99.71%	Calculated
Positive Random Drug and Alcohol Test Rate in 2005	0.29%	Calculated
Number of confirmed positive alcohol tests per year for all FFD programs	196	2005 Information Notice, NRC Table 5. Number of confirmed positives by substance
Number of confirmed positive alcohol tests per reactor per year	1.85 tests/reactor	Calculated
Number of positive drug test results per year for all FFD programs	755	2005 Information Notice, NRC Table 5. Number of confirmed positives by substance
Number of positive drug test results per reactor	7.12 tests/reactor	Calculated
Positive drug test result rate in 2000	0.56%	Calculated
Number of marijuana positive drug test results per year for all FFD programs	432	2005 Information Notice, NRC Table 5. Number of confirmed positives by substance
Number of marijuana positive drug test results per reactor	4.08 tests/reactor	Calculated
Positive marijuana drug test result rate in 2000	0.32%	Calculated
Number of opiate positive drug test results per year for all FFD programs	16	2005 Information Notice, NRC Table 5. Number of confirmed positives by substance
Number of opiate positive drug test results per reactor	0.15 tests/reactor	Calculated
Positive opiate drug test result rate in 2000	0.01%	Calculated

Exhibit A2 - 12:
Testing and Applicant Information

Parameter Description	Value	Source
Drug & Alcohol Testing Information (continued)		
Annual number of drug and alcohol tests yielding positive results for all programs	979	2005 Information Notice, NRC Table 3. 2005 Test results by test category
Annual number of drug and alcohol tests yielding positive results per reactor	9.24 tests/reactor	Calculated
Annual number of positive pre-access drug and alcohol test results for all programs	648	2005 Information Notice, NRC Table 3. 2005 Test results by test category
Annual number of positive pre-access drug and alcohol test results per reactor	6.11 tests/reactor	Calculated
Annual number of positive random drug and alcohol test results for all programs	147	2005 Information Notice, NRC Table 3. 2005 Test results by test category
Annual number of positive random drug and alcohol test results per reactor	1.39 tests/reactor	Calculated
Annual number of positive post-event drug and alcohol test results for all programs	1	2005 Information Notice, NRC Table 3. 2005 Test results by test category
Annual number of positive post-event drug and alcohol test results per reactor	0.01 tests/reactor	Calculated
Annual number of follow-up drug and alcohol test results for all programs	31	2005 Information Notice, NRC Table 3. 2005 Test results by test category
Annual number of follow-up drug and alcohol test results per reactor	0.29 tests/reactor	Calculated
Annual number of positive other drug and alcohol test results for all programs	47	2005 Information Notice, NRC Table 3. 2005 Test results by test category
Annual number of positive other drug and alcohol test results per reactor	0.44 tests/reactor	Calculated
Annual number of for-cause referrals for all programs	1,161	2005 Information Notice, NRC Table 2 - Test Results for Each Test Category and Work Category
Annual number of for-cause referrals per reactor	10.95 tests/reactor	Calculated
Annual number of for-cause tests yielding positive test results	106	2005 Information Notice, NRC Table 2 - Test Results for Each Test Category and Work Category
Positive for-cause testing rate in 2005	**9.13%**	Calculated

Exhibit A2 - 12:
Testing and Applicant Information

Parameter Description	Value	Source
Validity Test Data		
Percentage of adulterated, substitued, dilute, and invalid validity test results (total)	2.691%	Consists of the sum of dilute (2-5, 5-20 mg/dL), substituted, adulterated, and invalid
Percentage of specimens - Dilute (>5 and <20 mg/dL creatinine)	2.60%	Quest Diagnostics, n=435,309, likely a quarter's data for all Quest Labs (presented 2/2003)
Percentage of specimens - Dilute (2 - 5 mg/dL creatinine)	0.015%	DHHS National Laboratory Certification Program, data from 7/01-6/02 based on n=5,266,000
Percentage of specimens - Substituted (<2 mg/dL creatinine)	0.016%	DHHS National Laboratory Certification Program, data from 7/01-6/02 based on n=5,266,000
Percentage of specimens - Adulterated	0.025%	DHHS National Laboratory Certification Program, data from 7/01-6/02 based on n=5,266,001
Percentage of specimens - Invalid	0.035%	DHHS National Laboratory Certification Program, data from 7/01-6/02 based on n=5,266,002
Applicant information		
Annual number of applicants for authorization for all programs	65,845	NEI Estimate
Annual number of applicants for authorization per reactor	621	Calculated
Annual number of reportable events for all programs	135,702	2005 FFD Performance Reports
Annual number of reportable events per reactor	1,280	Calculated
Annual number of applicants for initial and updated authorization for all programs	20,509	NEI Estimate
Annual number of applicants for initial and updated authorization per reactor	193.48	Calculated
Annual number of applicants for initial authorization for all programs	17,869	NEI Estimate
Annual number of applicants for initial authorization per reactor	168.58	Calculated

Exhibit A2 - 12:
Testing and Applicant Information

Parameter Description	Value	Source
Applicant information (continued)		
Annual number of applicants for updated authorization for all programs	2,640	NEI Estimate
Annual number of applicants for updated authorization per reactor	24.91	Calculated
Annual number of applicants for authorization reinstatement with an interruption of 30 days or less for all programs	26,068	NEI Estimate
Annual number of applicants for authorization reinstatement with an interruption of 30 days or less per reactor	245.92	Calculated
Annual number of applicants for authorization reinstatement with an interruption of 5 days or less	40.99	Calculated
Annual number of applicants for authorization reinstatement with an interruption of 6-30 days	204.94	Calculated
Annual number of applicants for authorization reinstatement with an interruption of between 31 and 365 days for all programs	19,268	NEI Estimate
Annual number of applicants for authorization reinstatement with an interruption of between 31 and 365 days per reactor	181.77	Calculated
Number of applicants per training session	20	Assumption

Exhibit A2 - 13:

Drug and Alcohol Testing Data (in 2006 $)

Drug and Alcohol Specimen Collection - LABOR COSTS (Source: Model Facility Data from NEI Jan to May 2002)

Time per activity for a drug and alcohol collection	Time	Activity	Activity definitions
Worker travel time (to test and back to work)	0.60 hr	w	w= worker
ID Worker	0.03 hr	w, c	c= collector
Complete Initial Paperwork	0.09 hr	w, c	
Perform Alcohol Test	0.09 hr	w, c	
Perform Drug Screen	0.18 hr	w, c	

Labor costs for a drug and alcohol collection	Time for collection (drug & alcohol)	Wage rate	Cost per test
Labor collector - per testing process (one urine collection - initial breath collection)	0.39 hr	$ 25.34	$ 9.84
Labor worker - per testing process (one urine collection - initial breath collection)	0.99 hr	$ 55.14	$ 54.70
Labor costs of drug and alcohol specimen collection (collector & worker)			**$ 64.54**

Time per activity for a drug specimen collection	Time	Activity	Activity definitions
Worker travel time (to test and back to work)	0.60 hr	w	w= worker
ID Worker	0.03 hr	w, c	c= collector
Complete Initial Paperwork	0.09 hr	w, c	
Perform Drug Screen	0.18 hr	w, c	

Labor costs for a drug specimen collection	Time for collection (drug & alcohol)	Wage rate	Cost per test
Labor collector - per testing process (one urine collection)	0.30 hr	$ 25.34	$ 7.59
Labor worker - per testing process (one urine collection)	0.90 hr	$ 55.14	$ 49.81
Labor costs of drug specimen collection (collector & worker)			**$ 57.40**

NEGATIVE TEST RESULTS - SUMMARY OF COSTS (labor, equipment and specimen testing costs)

Negative Result - Alcohol test and Drug test (onsite testing) former rule		Description
Labor costs of drug and alcohol collection (collector & worker)	$ 64.54	Costs include: (1) travel time of worker; (2) collection of drug and alcohol specimens (the labor of collector and worker, collection materials), (3) onsite licensee testing costs per urine specimen for drugs; (4) labor of FFD manager to process negative test results paperwork
Equipment cost for alcohol testing (initial test - 2 breath collections)	$ 0.20	
Initial drug test - onsite licensee testing facility	$ 26.98	
FFD manager labor per negative test result	$ 3.56	
Total per test	**$ 95.28 /test**	

Negative Result - Alcohol test and Drug test (all testing at HHS certified lab), former rule		Description
Labor costs of drug and alcohol collection (collector & worker)	$ 64.54	Costs include: (1) travel time of worker; (2) collection of drug and alcohol specimens (the labor of collector and worker, collection materials), (3) HHS-certified lab costs per urine specimen for drugs; (4) labor of FFD manager to process negative test results paperwork
Equipment cost for alcohol testing (initial test - 2 breath collections)	$ 0.20	
Drug testing (initial & confirmatory when necessary) - HHS certified laboratory (all licensee testing conducted at HHS lab)	$ 22.88	
FFD manager labor per negative test result	$ 3.56	
Total per test	**$ 91.18 /test**	

Negative Result - Alcohol test and Drug & Validity test (onsite testing facility), final rule			Description
Labor costs of drug and alcohol collection (collector & worker)	$	64.54	Costs include: (1) travel time of worker; (2) collection of drug and alcohol specimens (the labor of collector and worker, collection materials), (3) onsite licensee testing costs per urine specimen for drugs & validity; (4) labor of FFD manager to process negative test results paperwork
Equipment cost for alcohol testing (initial test - 1 breath collection)	$	0.10	
Validity Testing (onsite) - Total Labor and Reagents cost per specimen	$	4.22	
Initial drug test - onsite licensee testing facility	$	26.98	
FFD manager labor per negative test result	$	3.56	
Total per test	**$**	**99.40 /test**	

Negative Result - Alcohol test and Drug & Validity test (all testing at HHS lab) - final rule			Description
Labor costs of drug and alcohol collection (collector & worker)	$	64.54	Costs include: (1) travel time of worker; (2) collection of drug and alcohol specimens (the labor of collector and worker, collection materials), (3) HHS-certified lab costs per urine specimen for drugs & validity; (4) labor of FFD manager to process negative test results paperwork
Equipment cost for alcohol testing (initial test - 1 breath collection)	$	0.10	
Validity testing incremental (at HHS-certified lab - initial and confirmatory testing)	$	1.50	
Drug testing (initial & confirmatory when necessary) - HHS certified laboratory (all licensee testing conducted at HHS lab)	$	22.88	
FFD manager labor per negative test result	$	3.56	
Total per test	**$**	**92.58 /test**	

MRO Testing - Negative Result - Alcohol test and Drug & Validity test (at onsite testing facility) - final rule			Description
Labor costs of drug and alcohol collection (collector)	$	9.84	Same cost as: Negative Result - Alcohol test and Drug & Validity test (onsite testing facility), final rule, no MRO labor for travel or the collection process, the labor is accounted for separately
Equipment cost for alcohol testing (initial test - 1 breath collection)	$	0.10	
Validity Testing (onsite) - Total Labor and Reagents cost per specimen	$	4.22	
Initial drug test - onsite licensee testing facility	$	24.25	
FFD manager labor per negative test result	$	3.56	
Total per test	**$**	**41.97 /test**	

MRO Testing - Negative Result - Alcohol test and Drug & Validity test (all testing at HHS lab) - final rule			Description
Labor costs of drug and alcohol collection (collector only)	$	9.84	Same cost as: Negative Result - Alcohol test and Drug & Validity test (all testing at HHS lab) - final rule, no MRO labor for travel or the collection process, the labor is accounted for separately
Equipment cost for alcohol testing (initial test - 1 breath collection)	$	0.10	
Validity testing incremental (at HHS-certified lab - initial and confirmatory testing)	$	1.50	
Drug testing (initial & confirmatory when necessary) - HHS certified laboratory (all licensee testing conducted at HHS lab)	$	22.88	
FFD manager labor per negative test result	$	3.56	
Total per test	**$**	**37.88 /test**	

MRO Testing - Incremental Cost for Alcohol and Drug Specimen Collection at a Non-Licensee Collection Facility			Description
Additional drug and alcohol specimen collection and shipping costs from non-licensee collection facilities	**$**	**30.00**	Twice the labor cost of drug and alcohol collection (collector only) plus shipping cost

Positive (DRUG/VALIDITY/ALCOHOL) TEST RESULT - LABOR COSTS

Subsequent actions - positive drug/validity/alcohol test result	Time	Wage rate	Source
Labor MRO	0.42 hr	$ 111.24	Model Facility Data from NEI Jan to May 2002
FFD manager	2.58 hr	$ 35.57	
Worker	0.47 hr	$ 55.14	
Total cost subsequent actions per confirmed positive drug/validity/alcohol test result		**164.14**	

Appeal of positive drug/validity/alcohol (no change former rule or final rule)	Wage rate	Units	Source
FFD manager (average labor per result)	$ 35.57	12.50 hr	Discussion with NEI staff, May 23, 2003
Worker	$ 55.14	2.00 hr	
Total cost per appeal (positive drug/validity/alcohol test result)		**$555 /appeal**	

Positive (DRUG/VALIDITY/ALCOHOL) TEST RESULT - SUMMARY OF COSTS (labor, equipment and specimen testing costs)

Positive Result - Alcohol/Drug/Validity test - (onsite testing facility), final rule		Description
Labor costs of drug and alcohol collection (collector & worker)	$ 64.54	Costs include: (1) travel time of worker; (2) collection of drug and alcohol specimens (the labor of collector and worker, collection materials), (3) onsite licensee testing costs per urine specimen for drugs; (4) HHS-certified lab cost per specimen for drugs and validity; (5) cost of subsequent actions resulting from a confirmatory positive drug/validity test result.
Equipment cost for alcohol testing (initial test - 1 breath collection)	$ 0.10	
Validity Testing (onsite) - Total Labor and Reagents cost per specimen	$ 4.22	
Initial drug test - onsite licensee testing facility	$ 26.98	
Drug testing (intial & confirmatory when necessary) at HHS-certified lab (after initial positive drug/questionable validity test result at licensee testing facility)	$ 35.25	
Validity testing incremental (at HHS-certified lab - initial and confirmatory testing)	$ 1.50	
Subsequent actions - positive drug/validity/alcohol test result	$ 164.14	
Total per test	**$ 296.73 /test**	

Positive Result - Alcohol/Drug/Validity test - (all testing at HHS certified lab) - final rule		Description
Labor costs of drug and alcohol collection (collector & worker)	$ 64.54	Costs include: (1) travel time of worker; (2) collection of drug and alcohol specimens (the labor of collector and worker, collection materials), (3) HHS-certified lab costs per urine specimen for drugs and validity; (4) cost of subsequent actions resulting from a confirmatory positive drug/validity test result.
Equipment cost for alcohol testing (initial test - 1 breath collection)	$ 0.10	
Validity Testing (onsite) - Total Labor and Reagents cost per specimen	$ 4.22	
Initial and confirmatory (when necessary) drug test	$ 22.88	
Subsequent actions - positive drug/validity/alcohol test result	$ 164.14	
Total per test	**$ 255.89 /test**	

VALIDITY TESTING (labor & equipment) - Onsite Licensee Testing Facility - Final Rule

Validity testing - Lab Techinican Labor costs per urine specimen	time/test	wage rate
Time per urine specimen for validity testing		
pH test	0.02 hr	$ 29.52
creatinine	0.02 hr	$ 29.52
one adulterant assay	0.03 hr	$ 29.52
Validity testing (onsite) - Total Assay Labor cost per specimen		**$ 1.97 /specimen**

Validity testing - Reagants Cost - per urine specimen	Cost per test
Reagent costs of validity testing per urine specimen	
pH test	$ 0.25
creatinine	$ 1.00
one adulterant assay	$ 1.00
Validity Testing (onsite) - Total Reagents cost per specimen	**$ 2.25 /specimen**
Validity Testing (onsite) - Total Labor and Reagents cost per specimen	**$ 4.22 /specimen**

Validity testing - Lab Techinican Labor Costs - Daily Calibration of Equipment	time/calibration	wage rate
Daily calibration of validity testing equipment		
pH test	0.08 hr	$ 29.52
creatinine	0.17 hr	$ 29.52
one adulterant assay	0.17 hr	$ 29.52
Validity Testing (onsite) - Total Labor cost per day to calibrate equipment		**$ 12.30 /day**

Validity testing - Reagants Cost - Daily Calibration of Equipment	Cost per test
Reagent costs of validity testing per urine specimen	
pH test	$ 0.50 / day
creatinine	$ 1.00 / day
one adulterant assay	$ 1.00 / day
Validity Testing (onsite) - Total Reagent Costs per Daily Calibration	**$ 2.50 / day**

Validity Testing - pH meter & accessories per Licensee Testing Facility	Cost	Equipment life	Annualized cost
ph meter	$ 600.00	6.0 years	**$ 100.00**
ph meter probe	$ 150.00	2.0 years	**$ 75.00**

VALIDITY TESTING - HHS-certified laboratory - Final Rule

		Source
Validity testing incremental (at HHS-certified lab - initial and confirmatory testing)	$ 1.50 /test	Assumption, range of testing costs from $0.00 to $3.00.

DRUG TESTING - LICENSEE TESTING FACILITY

			Source
Drug test (initial) - at onsite licensee testing facility	$	26.98 /test	Model Facility Data from NEI Jan to May 2002

DRUG TESTING - HHS- CERTIFIED LABORATORY

Test Type		Cost/test	Source
Drug testing (intial & confirmatory when necessary) at HHS-certified lab (after initial positive drug/questionable validity test result at licensee testing facility)	$	35.25 /test	Model Facility Data from NEI Jan to May 2002
Drug testing (initial & confirmatory when necessary) - HHS certified laboratory (all licensee testing conducted at HHS lab)	$	22.88 /test	Model Facility Data from NEI Jan to May 2002
Dilute Specimen (>=2-20 mg/dL Creatinine) Testing - GC/MS Level of Detection Testing (LOD)	$	75.00 /test	Assumption
Cost of retesting - a confirmed positive drug/adulterated or substitued validity test specimen at second HHS-certified lab (includes specimen preparation and shipping costs)	$	62.50 /test	Assumption, range of testing costs from $50.00 to $75.00
Retesting a specimen at a second HHS lab when the initial HHS lab could not identify a suspected interfering substance/adulterant (includes specimen preparation, packaging, and shipping)	$	125.00 /test	Costs for to analyze for adulterants at a second HHS-certified lab (cost ranges from $50.00 to $200.00 depending on the contract with the lab)

ALCOHOL TESTING EQUIPMENT

Evidential Breath Testing Device (EBT) - purchase			Source	
EBT - compliant with § 26.91(c) in the final rule - included printer and carrying case	$	2,250	Equipment manufacturer of NHTSA certified EBT (fuel cell)	
EBT Calibration Equipment			**Source**	
Regulator (to attach calibration canister to EBT)	$	100.00	Equipment manufacturer of NHTSA certified EBT (fuel cell)	
Calibration canister	$	75.00	Equipment manufacturer of NHTSA certified EBT (fuel cell)	
EBT Exhalent tubes (source: discussion with NEI staff, May 2003)		**Unit cost**	**# of tubes**	**Cost per test**
Exhalent tubes (per test = 2 breath specimens) - former rule	$	0.10 /tube	2	**$ 0.20**
Exhalent tubes (per test = 1 breath specimen) - final rule	$	0.10 /tube	1	**$ 0.10**
Blood Alcohol testing - Existing Rule				
Blood alcohol testing - cost per blood specimen to conduct laboratory analysis	$	31.98	Model Facility Data from NEI Jan to May 2002	
Cost per blood test for a phlebotomist/RN to arrive at the onsite collection site and conduct the blood draw	$	100.00	Assumption	

BLIND PERFORMANCE SAMPLE & TESTING COSTS			Subpart G	26.168(a)(1) 26.168(a)(2)
Cost per blind perfomrance sample & testing - former rule (all testing at HHS-lab)			**Source**	
Cost per blind specimen, former rule: purchased from a vendor, prepared, and shipped to the HHS-certified laboratory for testing, and FFD manager follow-up to check results (former rule)	$	29.34 /test	Model Facility Data from NEI Jan to May 2002	
Drug testing (initial & confirmatory when necessary) - HHS certified laboratory (all licensee testing conducted at HHS lab) (former rule)	$	22.88 /test	Model Facility Data from NEI Jan to May 2002	
Total per test	**$**	**52.22**		
Cost per blind performance sample & testing - final rule (all testing at HHS-lab)			**Source**	
Cost per blind specimen, former rule: purchased from a vendor, prepared, and shipped to the HHS-certified laboratory for testing, and FFD manager follow-up to check results (former rule)	$	29.34 /test	Model Facility Data from NEI Jan to May 2002	
Increase in the cost per blind performance test specimen due to the change in the mix of the positive to negative ratio of blind specimens in the final rule	$	22.00 /test	Assumption, 75 percent increase in cost of blind performance test sample	
Drug testing (initial & confirmatory when necessary) - HHS certified laboratory (all licensee testing conducted at HHS lab)	$	22.88 /test	Model Facility Data from NEI Jan to May 2002	
Validity testing incremental (at HHS-certified lab - initial and confirmatory testing)	$	1.50 /test	Assumption	
Total per test	**$**	**75.72**		
Cost per blind performance sample & testing - former rule (for FFD programs with onsite licensee testing facilities)			**Source**	
Cost per blind specimen, former rule: purchased from a vendor, prepared, and shipped to the HHS-certified laboratory for testing, and FFD manager follow-up to check results (former rule)	$	29.34 /test	Model Facility Data from NEI Jan to May 2002	
Drug testing (intial & confirmatory when necessary) at HHS-certified lab (after initial positive drug/questionable validity test result at licensee testing facility) (former rule)	$	35.25 /test	Model Facility Data from NEI Jan to May 2002	
Total per test	**$**	**64.59**		
Cost per blind performance sample & testing - final rule (or FFD programs with onsite licensee testing facilities)			**Source**	
Cost per blind specimen, former rule: purchased from a vendor, prepared, and shipped to the HHS-certified laboratory for testing, and FFD manager follow-up to check results (former rule)	$	29.34 /test	Model Facility Data from NEI Jan to May 2002	
Increase in the cost per blind performance test specimen due to the change in the mix of the positive to negative ratio of blind specimens in the final rule	$	22.00 /test	Assumption, 75 percent increase in cost of blind performance test sample	
Drug testing (intial & confirmatory when necessary) at HHS-certified lab (after initial positive drug/questionable validity test result at licensee testing facility)	$	35.25 /test	Model Facility Data from NEI Jan to May 2002	
Validity testing incremental (at HHS-certified lab - initial and confirmatory testing)	$	1.50 /test	Assumption	
Total per test	**$**	**88.09**		

PAPER WORK REQUIREMENTS - Drug and Alcohol Testing		
Information Collection Burden Activities - Negative and Positive Test Results		**Source**
File paper work per negative drug and/or alcohol test result	0.05 hr	Assumption
File paperwork per positive drug and/or alcohol test result	0.25 hr	Assumption
File paperwork per appealed positive drug and/or alcohol test result	0.50 hr	Assumption

Exhibit A2 - 14:
FFD Programs

FFD Program/Licensee	Number of Facilities per Program	Number of Units per Program	On-Site or Off-Site Testing	Number of Employees per Unit	Total Number of Employees per Program
Ameren UE	1	1	On-site	949	949
AmerGen Energy Company	3	3	On-site	949	2,846
Arizona Public Service Company	1	3	On-site	949	2,846
Carolina Power & Light	3	4	Off-site	949	3,795
Constellation Energy	3	5	Off-site	949	4,744
Detroit Edison Company	1	1	Off-site	949	949
Dominion Generation	4	7	Off-site	949	6,642
Duke Energy Power Company, LLC	3	7	Off-site	949	6,642
Energy Northwest	1	1	On-site	949	949
Entergy Nuclear Operations, Inc.	8	10	Off-site	949	9,488
Exelon Generation Co., LLC	7	14	On-site	949	13,283
FirstEnergy Nuclear Operating Co.	3	4	Off-site	949	3,795
Florida Power Corp.	1	1	Off-site	949	949
FPL Group	4	6	Off-site	949	5,693
Indiana/Michigan Power Co.	1	2	On-site	949	1,898
Nebraska Public Power District	1	1	Off-site	949	949
Nuclear Management Co.	4	6	Off-site	949	5,693
Omaha Public Power District	1	1	Off-site	949	949
Pacific Gas & Electric Co.	1	2	Off-site	949	1,898
PPL Susquehanna, LLC	1	2	On-site	949	1,898
PSEG Nuclear, LLC	2	3	On-site	949	2,846
South Carolina Electric & Gas Co.	1	1	Off-site	949	949
Southern California Edison Co.	1	2	On-site	949	1,898
Southern Nuclear Operating Co.	3	6	On-site	949	5,693
STP Nuclear Operating Co.	1	2	Off-site	949	1,898
Tennessee Valley Authority	3	5	Off-site	949	4,744
TXU Generation Company, LP	1	2	Off-site	949	1,898
Wolf Creek Nuclear Operating Corp.	1	1	Off-site	949	949
Westinghouse	2	2	Off-site	750	1,500
Inpo	1	1	Off-site	250	250
BWX Technologies	1	1	Off-site	811	811
Nuclear Fuel Services	1	1	Off-site	300	300
MOX Facility	1	1	Off-site	400	400

Exhibit A2-15
Fatigue Inputs

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Policy and Procedures					**Subpart I**	**26.203(a)-(b)**
	One-time costs per program to account for FFD manager and clerical personnel time and to contract a legal consultant to implement fatigue provisions into the written policies and procedures					
		Hours of FFD program staff to develop and revise policies and procedures for fatigue provisions per program	HOURS ffd_staff	80.0 hr	Assumption	
		Hours of labor of various managers to review and approve policies and procedures for fatigue provisions per program	HOURS manager-fatigue	40.0 hr	Assumption	
		Hours of legal assistance to review and revise policies and procedures for fatigue provisions	HOURS legal-fatigue	20.0 hr	Assumption	
		Hours of clerical personnel to support revision of policies and procedures for fatigue provisions	HOURS clerical-fatigue	40.0 hr	Assumption	
	One-time costs per program to provide additional facility supervisor time to implement the corporate policies on the management of fatigue at the facility level					
		Hours of facility supervisor time to implement revised corporate policies and procedures for fatigue	HOURS facility supervisor-fatigue	160.0 hr	Assumption	
Training					**Subpart I**	**26.203(c)**
	The following variables are used in several of the equations in this section					
		Length of training addressing the fatigue-related KAs per session	HOURS Training-Fatigue	1.0 hr	Assumption	
		Length of comprehensive examination increment addressing the fatigue-related KAs	HOURS Examination-Fatigue	0.2 hr	Assumption	
		Hours of incremental preparation and examination grading per session addressing the fatigue-related KAs	HOURS Preparation-Fatigue	0.5 hr	Assumption	
	One-time cost per program associated with revising the training program to include fatigue KAs					
		Hours of industry consultant time per program to develop generic training materials for use by the entire industry	HOURS Consultant	2.6 hr	Assumption	
		Hourly wage for industry consultant to develop generic training materials for use by the entire industry	WAGE Training_Consultant_Loaded	$ 90.00 /hour		
		Hours of training time per program to revise the training materials to address fatigue KAs	HOURS Trainer	8.0 hr	Assumption	
		Hours of training manager time per program to revise the training materials to address fatigue KAs	HOURS Training Manager	2.0 hr	Assumption	
		Hours of FFD proram manager time per program to revise the training program to address fatigue KAs	HOURS Manager	2.0 hr	Assumption	
		Hours of clerical personnel time to support the revision of the training program to address fatigue KAs	HOURS Clerical	4.0 hr	Assumption	
	One-time costs per program to retrain existing employees on the fatigue related KAs					
			No additional parameters			
	One-time costs per program for trainers to administer the training on the fatigue-related KAs					
		Number of workers per training session per facility	NUM Sessions	50	Assumption	
	Annual cost per program for incoming employees to take the training course increment for fatigue-related KAs					
		Turnover Rate (e.g., new hires including outage workers) covered by fatigue provision per facility per year	PER Applicants	25%	Assumption	
	Annual cost per program for trainers to administer training course for fatigue-related KAs					
		Number of workers per training session per facility	NUM Sessions	20	Assumption	
	Annual costs per program for employees to take the refresher training increment addressing fatigue-related KAs					
		Percentage of employees taking refresher training	PER Refresher	20%	Assumption	
		Length of fatigue-related portion of refresher training course	HOURS Fatigue Training	1.00 hr	Assumption	

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
	Annual costs per program for trainers to administer the refresher training increment addressing fatigue-related KAs					
		Number of workers per training session per facility	NUM Sessions	20	Assumption	
		Length of fatigue-related refresher training course	HOURS Fatigue Training	1.00 hr	see Appendix 2, Exhibit A2-3	
Retaining Fatigue Records					**Subpart I**	**26.203(d)**
	Annual cost per program to physically place the documentation required under 26.197(d)(1), (2), (4), and (5) into the appropriate filing cabinets or storage facilities					
		Annual number of hours per facility to store individuals' work hours under final rule	HOURS Work Hours	40.0 hr	Assumption	
		Annual number of hours per facility to store work hour reviews under final rule	HOURS Reviews	4.0 hr	Assumption	
		Annual number of hours per facility to store fatigue assessment documentation under final rule	HOURS Assessments	10.0 hr	Assumption	
	Annual savings per program as a result of fewer waivers being issued					
		Annual number of hours per facility to file deviation authorizations under existing licensee technical specifications	HOURS WaiverTS	12.0 hr	Assumption	
		Annual number of hours per facility to file waivers under final rule	HOURS WaiverNew	1.0 hr	Assumption	
Summarize Waiver Data					**Subpart I**	**26.203(e)(1)**
	Annual cost per program to review documentation for the waived individual work hour controls in 26.199(d)(1)-(4) from the previous calendar year, categorize the instances of waivers as required, and report the data and frequency distribution in the FFD program performance report					
		Annual hours of clerical worker labor to tally the annual number of waivers of each type, separate operating waivers from outage waivers, produce a frequency distribution, and report these data in the FFD program report	HOURS Clerical	10.0 hr	Assumption	
		Annual hours of managerial labor to review the waivers data included in the FFD program report	HOURS Manager	10.0 hr	Assumption	
Summarize Fatigue Assessment Data					**Subpart I**	**26.203(e)(2)**
	Annual cost per program to report the number of fatigue assessments conducted during the previous calendar year, the conditions under which each fatigue assessment was conducted, and the management actions, if any, resulting from each fatigue assessment					
		Annual number of clerical labor hours to review and tally the number of fatigue assessments conducted during the previous calendar year, identify the conditions under which each fatigue assessment was conducted, and report the management actions, if any, resulting from each fatigue assessment included in the FFD program report	HOURS Clerical	20.0 hr	Assumption	
		Annual number of manager labor hours to review the summary information to be sent to NRC	HOURS Manager	10.0 hr	Assumption	
Fatigue Management Audits					**Subpart I**	**26.203(f)**
	Annual cost per program to audit fatigue management as part of the overall FFD program audit required under 26.41					
		Annual number of auditor labor hours to audit the management of worker fatigue	HOURS Auditor	40.0 hr	Assumption	
		Annual number of clerical labor hours to assist with the audit of fatigue management	HOURS Clerical	16.0 hr	Assumption	
		Annual number of manager labor hours to assist with the audit of fatigue management program	HOURS Manager	16.0 hr	Assumption	
		Multiplier to yield annualized costs	PER Annualized	50%	Calculated	

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Calculating Work Hours					**Subpart I**	**26.205(b)**
	One-time cost per program to modify existing timekeeping systems in order to record, track, and document the actual hours worked by individuals covered under the individual work hour controls of paragraph 26.199(d)					
		One-time cost per facility to modify existing timekeeping systems, or develop new systems, to record and track work hour data	COST System	$50,000	Exhibit A2-16	
	Annual costs per program associated with monitoring and managing the hours actually worked by individuals, including filing or backing up work hour records					
		Annual hours of supervisor labor to monitor and manage the hours actually worked by individuals at one facility, including filing or backing up work hour records	HOURS Supervisor_Annual	200.0 hr	Assumption	
		Annual hours for clerical labor to monitor and manage the hours actually worked by individuals at one facility, including filing or backing up work hour records	HOURS Clerical_Annual	50.0 hr	Assumption	
Scheduling Work Hours					**Subpart I**	**26.205(c)**
	One-time cost per program to renegotiate collective bargaining agreements in order to address issues related to the assignment of overtime					
		One-time hours needed for licensee management to work with union representatives in collective bargaining	HOURS Management	60.0 hr	Assumption	
		One-time hours needed for licensee legal staff to work with union representatives in collective bargaining	HOURS Legal	40.0 hr	Assumption	
		Percentage of licensees whose schedule modifications lead to revisions to collective bargaining agreements or to discussions with employee committees	PER Negotiation	100%	Assumption	
	Annual costs per program to prepare modified work schedules on an ongoing basis for all employees covered by the rule					
		Annual hours needed for workers to support supervisors in reviewing, analyzing, and modifying schedules	HOURS Scheduler	2,080 hr	Assumption	
Day-off Requirements					**Subpart I**	**26.205(d)(4)-(6)**
	The following variables are used in several of the equations in this section					
		Number of weeks in modeled refueling outage	WEEKS Outage	6	Exhibit A2-16	
		Adjustment factor to annualize modeled outages that do not occur annually	FACTOR Outage	1	Assumption	
		Number of crews	NUM Crews	2	1 additional day crew plus 1 additional night crew	
	Annual cost per program to pay for in-processing of additional contract operator staff at the time of an outage					
		The average cost to conduct in-processing of one contract operator crew	COST Process_Contract_Ops	$4,500	Assumption	
	Annual cost to pay for additional contract operator staff during an outage					
		The weekly cost of one contract operator crew	WCOST Contract_Ops	$10,260	Is equal to the regular wage * 40 + the overtime wage * 32	
	Annual cost to pay for additional contract maintenance staff during an outage					
		The weekly cost of one contract maintenance crew	WCOST Contract_Maint	$29,640	Is equal to the regular wage * 40 + the overtime wage * 32	
	Annual cost per program to pay for in-processing of additional contract maintenance staff during an outage					
		The average cost to conduct in-processing of one contract maintenance crew	COST Process_Maint	$13,000	Assumption	

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Waivers from Individual Work Hour Limits					**Subpart I**	**26.207**
	Annual cost per program to conduct and document a fatigue assessment					
		Number of weeks per year during which facilities experience outage conditions (refueling and unplanned outages)	WEEKS Outage	8	Exhibit A2-16	
		The costs per week under outage conditions incurred by facilities as a result of their restricted ability to grant waivers	WEEKLYCOSTS Outage	$25,689	Appendix 3	
		Number of weeks per year during which facilities experience full power conditions	WEEKS Power	44	Exhibit A2-16	
		The costs per week under at-power conditions incurred by facilities as a result of their restricted ability to grant waivers	WEEKLYCOSTS Power	$1,087	Appendix 3	
Self-Declarations of Fatigue					**Subpart I**	**26.209**
	The following variables are used in several of the equations in this section					
		Total annual number of persons, per site, granted waivers from the requirements contained in 26.199(d)(1) - (4)	NUM Waivers	15	Assumption	
		Percentage of NUM Waivers that self-declare to a condition of fatigue	PER Self-Declare	10%	Assumption	
	Annual management cost per program to call in replacement workers to substitute for any workers who are sent home to rest following a fatigue assessment					
		Supervisor hours expended to identify and call in a replacement worker	HOURS Supervisor	0.5 hr	Assumption	
	Annual cost per program due to the extra turnover associated with the replacement worker and other lost productivity					
		Labor hours resulting from an additional turnover due to the replacement of a fatigued worker with a substitute worker	HOURS Turnover	1.0 hr	Assumption	
	Annual incremental labor costs associated with the replacement worker					
		Average number of hours worked by the replacement worker per incident	HOURS Substitute	6.0 hr	Assumption	
Work Hour Control Reviews					**Subpart I**	**26.205(e)**
	Annual cost per program to conduct work hour control reviews					
		Annual number of times a facility will review the control of work hours for individuals who are subject to this subpart	NUM Reviews	2	Assumptions	
		Time per participating supervisor to review overtime hours under final rule, per review	HOURS Review	4.0 hr	Assumption	
		Number of supervisors participating in the review	NUM Manager	4	Assumption	
		Annual time for manager to review overtime hours under existing technical specifications	HOURS former_Review	4.0 hr	Assumption	

Activity	Equation	Parameter Description	Parameter	Value	Source	Section
Fatigue Assessments					**Subpart I**	**26.211(a)-(d)**
	The following variables are used in several of the equations in this section					
		Total annual number of fatigue assessments per reactor, including those conducted for-cause, self-declared, post-event, and follow-up	NUM Assessments	50	Assumption	
		Percentage of fatigue assessments that result in a finding of fatigue	PER Fatigue	37.5%	Assumption	
	Annual cost per program to conduct a fatigue assessment for cause, for self-declaration, post-event, and follow-up					
		Hours needed to complete one fatigue assessment	HOURS Assessment	0.5 hr	Assumption	
	Annual cost per program to resolve challenges that may be brought by workers who, after self-declaring to a state of fatigue, object to negative results from their fatigue assessment					
		Annual number of self-declarations of fatigue per facility	NUM Self-Declarations	20	Assumption	
		Percent of annual number of self-declarations of fatigue per facility where the results of the fatigue assessment are negative	PER Not_Fatigued	50%	Assumption	
		Percent of negative fatigue assessment results that are challenged by workers	PER Object	30%	Assumption	
		Amount of worker time to raise and resolve one incident	HOURS Worker	0.5 hr	Assumption	
		Number of hours of Employee Concerns Manager time to raise and resolve one incident	HOURS ECM	2.5 hr	Assumption	
		Number of hours of supervisor time to raise and resolve one incident	HOURS Supervisor	1.0 hr	Assumption	
Post-Fatigue Assessment Controls and Conditions					**Subpart I**	**26.211(e)**
	The following variables are used in several of the equations in this section					
		Total annual number of fatigue assessments per reactor, including those conducted for-cause, self-declared, post-event, and follow-up	NUM Assessments	50	Assumption	
		Percentage of fatigue assessments that result in a finding of fatigue	PER Fatigue	37.5%	Assumption	
	Annual cost per program to call in replacement workers to substitute for any workers who are sent home to rest following a fatigue assessment					
		Supervisory hours expended to identify and call in a replacement worker	HOURS Supervisor	0.5 hr	Assumption	
	Annual cost per program resulting from extra "turnover" of duties to the replacement worker and other lost labor productivity					
		Labor hours resulting from an additional turnover due to the replacement of a fatigued worker with a substitute worker	HOURS Turnover	1.0 hr	Assumption	
	Annual costs per program associated with the replacement worker					
		Average number of hours worked by the replacement worker per incident	HOURS Substituted	6.0 hr	Assumption	
Documenting Fatigue Assessments					**Subpart I**	**26.211(f)**
	Annual costs per program to document the results of any fatigue assessments conducted, the circumstances that necessitated the fatigue assessment, and any controls and conditions that were implemented					
		Total annual number of fatigue assessments per reactor, including those conducted for-cause, self-declared, post-event, and follow-up	NUM Assessments	50	Assumption	
		Time needed to document a fatigue assessment	HOURS Document	0.33 hr	Assumption	

Exhibit A2 - 16:
Fatigue Input Data

FATIGUE - MAINTENANCE COMPENSATION AND HIRING COSTS

Data Element	Estimate	Source
COST/Process_Maint - The average cost to conduct in-processing of one contract maintenance crew	$13,000	Assumption

FATIGUE PROVISIONS - IMPLEMENTATION COST VARIABLES

Cost/System - One-time cost per facility to modify existing timekeeping systems, or develop new systems, to record and track work hour data

PLANT	Estimate	Source Data	Comments
A		$500	Source data were provided by six facilities.
B		$250,000	
C		minimal	
D		TBD	
E		no estimate	
F		$50,000	
Cost/System	**$50,000**		

WEEKS/Outage - Number of weeks in modeled outage (refueling outages only)

Data Element	Estimate	Source Data	Comments
Average U.S. Nuclear Refueling Outage: NEI - Plant Performance data, in weeks		5.71	Accessed 1/5/2005
Rounded Estimate	**6**		

WEEKS/Outage - Number of weeks per year during which facilities experience outage conditions (refueling and unplanned outages)

Data Element	Estimate	Source Data	Comments
Assuming capacity factor of 85%		7.80	Multiply 15% by 52 weeks
Rounded Estimate	**8**		

WEEKS/Power - Number of weeks per year during which facilities experience full power conditions

Data Element	Estimate	Source Data	Comments
Assuming capacity factor of 85%		44.20	Multiply 85% by 52 weeks
Rounded Estimate	**44**		

Crosswalk Index of Subpart Sections and Exhibits

Subpart	Section	Section Description	Exhibits
NA	NA	NRC Implementation - One-time Training	Exhibit A2 - 2: Written Policies and Procedures
NA	NA	NRC Implementation - One-time Revision of Inspection Procedures	Exhibit A2 - 3: Training and Examinations
Subpart A	26.4(g)	FFD Program Personnel Subject to the Rule	Exhibit A2 - 1: Individuals Subject to the FFD Program
Subpart A	26.4(j)	Individuals Subject to Another Acceptable Program	Exhibit A2 - 1: Individuals Subject to the FFD Program
Subpart B	26.27(a)	Policy and Procedure Revisions - Overall Program	Exhibit A2 - 2: Written Policies and Procedures
Subpart B	26.29(a)	Revise and Implement Training, Including Behavioral Observation	Exhibit A2 - 3: Training and Examinations
Subpart B	26.29(b)	Comprehensive Examination	Exhibit A2 - 3: Training and Examinations
Subpart B	26.29(c)(2)	Comprehensive Examination in Lieu of Refresher Training	Exhibit A2 - 3: Training and Examinations
Subpart B	26.31(b)(1)(i)	Background Checks, Psychological Evaluations, Credit History, Criminal History	Exhibit A2 - 1: Individuals Subject to the FFD Program
Subpart B	26.31(b)(2)	DOT-Approved Specimen Collection Facilities	Exhibit A2 - 1: Individuals Subject to the FFD Program
Subpart B	26.31(d)(2)	Reasonable Effort to Track Randomly Selected Individuals for Testing	Exhibit A2 - 6: Activities Related to Potential Policy Violations
Subpart B	26.31(d)(3)	Forensic Toxicologist Review of More Stringent Cutoff Levels	Exhibit A2 - 4: Audits, Inspections, Certifications and Corrective Action
Subpart B	26.33	Behavioral Observation	Exhibit A2 - 6: Activities Related to Potential Policy Violations
Subpart B	26.37(d)	Disclosure requirements positive test results	Exhibit A2 - 6: Activities Related to Potential Policy Violations
Subpart B	26.39(c)	Review of FFD Policy Violations	Exhibit A2 - 6: Activities Related to Potential Policy Violations
Subpart B	26.41(b)	Audit Frequency	Exhibit A2 - 4: Audits, Inspections, Certifications and Corrective Action
Subpart B	26.41(c)(2)	Elimination of Audit Duplication of HHS-Certified Laboratories	Exhibit A2 - 4: Audits, Inspections, Certifications and Corrective Action
Subpart C	26.55(a)(1)	Self-Disclosure for Initial Applicants	Exhibit A2 - 5: Authorizations
Subpart C	26.55(a)(2)	Suitable Inquiry for Initial Applicants	Exhibit A2 - 5: Authorizations
Subpart C	26.55(a)(3)	Pre-Access Testing for Initial Applicants	Exhibit A2 - 5: Authorizations
Subpart C	26.55(a)(4)	Random Testing Pool for Initial Applicants	Exhibit A2 - 5: Authorizations
Subpart C	26.57(a)(1)	Self Disclosure for Update Applicants	Exhibit A2 - 5: Authorizations
Subpart C	26.57(a)(2)	Suitable Inquiry for Update Authorization	Exhibit A2 - 5: Authorizations
Subpart C	26.57(a)(3)	Pre-Access Testing for Update Applicants	Exhibit A2 - 5: Authorizations
Subpart C	26.57(a)(4)	Random Testing Pool for Update Applicants	Exhibit A2 - 5: Authorizations
Subpart C	26.59(a)(1)	Authorization Reinstatements with Interruptions: Self-Disclosure for Reinstatement Applicants with 31-365 Day Interruption	Exhibit A2 - 5: Authorizations
Subpart C	26.59(a)(2)	Authorization Reinstatements with Interruptions: Suitable Inquiry for Reinstatement Applicants with 31-365 Day Interruption	Exhibit A2 - 5: Authorizations
Subpart C	26.59(a)(3)	Authorization Reinstatements with Interruptions: Pre-Access Testing for Reinstatement Applicants with 31-365 Day Interruption	Exhibit A2 - 5: Authorizations
Subpart C	26.59(a)(4)	Authorization Reinstatements with Interruptions: Random Testing Pool for Reinstatement Applicants with 31-365 Day Interruption	Exhibit A2 - 5: Authorizations
Subpart C	26.59(c)(1)	Authorization Reinstatements with Interruptions: Self-Disclosure (and Suitable Inquiry) for Reinstatement Applicants with Less than 31 Day Interruption	Exhibit A2 - 5: Authorizations
Subpart C	26.59(c)(2)	Authorization Reinstatements with Interruptions: Pre-Access Testing for Reinstatement Applicants with Less than 31 Day Interruption	Exhibit A2 - 5: Authorizations
Subpart C	26.59(c)(3)	Authorization Reinstatements with Interruptions: Random Testing Pool for Reinstatement Applicants with Less than 31 Day Interruption	Exhibit A2 - 5: Authorizations

Crosswalk Index of Subpart Sections and Exhibits

Subpart	Section	Section Description	Exhibits
Subpart E	26.83(a)	Blood Collection for Confirmatory Alcohol Testing	Exhibit A2 - 8: Alcohol Testing
Subpart E	26.85(a),(b)	Urine and Alcohol Collector Training	Exhibit A2 - 3: Training and Examinations
Subpart E	26.89(b)(2)	Urine Collection: Donors Without Adequate ID	Exhibit A2 - 7: Urine Specimen Collections
Subpart E	26.89(b)(3)	Urine Collection: Eliminate Listing Medications on the CCF Form and add description of testing process	Exhibit A2 - 7: Urine Specimen Collections
Subpart E	26.91(b)	Purchase of EBT and Calibration Equipment and Related Training	Exhibit A2 - 8: Alcohol Testing
Subpart E	26.91(c)	Required Use of an EBT on the NHTSA CPL for Confirmatory Testing	Exhibit A2 - 8: Alcohol Testing
Subpart E	26.95(c)	One Breath Specimen Collection for Initial Alcohol Test	Exhibit A2 - 8: Alcohol Testing
Subpart E	26.99(b)	Lowering Initial BAC Requiring Confirmatory Test to BAC 0.02	Exhibit A2 - 8: Alcohol Testing
Subpart E	26.103	FFD Manager Determines Confirmed Positive Test for Alcohol (BAC 0.02 < 0.04)	Exhibit A2 - 8: Alcohol Testing
Subpart E	26.105(b)	Urine Collection: Inspecting Contents of Donor's Pockets	Exhibit A2 - 7: Urine Specimen Collections
Subpart E	26.109(a)	Urine Specimen Quantity: Minimum Quantity of 30 mL	Exhibit A2 - 7: Urine Specimen Collections
Subpart E	26.109(b)(2)	Urine Specimen: At Least 30 mL, but Less than Predetermined Quantity	Exhibit A2 - 7: Urine Specimen Collections
Subpart E	26.119	Shy Bladder Medical Evaluation	Exhibit A2 - 7: Urine Specimen Collections
Subpart E	26.127	Licensee Testing Facility Policy and Procedure Revisions	Exhibit A2 - 2: Written Policies and Procedures
Subpart F	26.131(b)	Initial Validity Testing - Onsite Licensee Testing Facilities	Exhibit A2 - 3: Training and Examinations
Subpart F	26.131(b)	Validity Testing (On-site Licensee Testing Facilities and HHS-Certified Laboratories)	Exhibit A2 - 9: Drug and validity testing (licensee testing facilities and HHS-certified laboratories)
Subpart F	26.131(b)	Initial Validity Testing - Onsite Licensee Testing Facilities	Exhibit A2 - 9: Drug and validity testing (licensee testing facilities and HHS-certified laboratories)
Subpart F	26.133	Change Cutoff Levels for Marijuana and Opiates - Onsite Testing Facilities	Exhibit A2 - 9: Drug and validity testing (licensee testing facilities and HHS-certified laboratories)
Subpart F	26.137(e)(6)	Quality Control Specimens in Each Analytical Run - Onsite Testing Facilities	Exhibit A2 - 9: Drug and validity testing (licensee testing facilities and HHS-certified laboratories)
Subpart F	26.139(d)	Licensee Testing Facility Reporting of Testing Data to FFD program (Monthly to Annually)	Exhibit A2 - 10: Reporting Requirements
Subpart G	26.153(e)	Pre-Award Inspections of HHS-Certified Laboratories	Exhibit A2 - 4: Audits, Inspections, Certifications and Corrective Action
Subpart G	26.161(b)(1)	Validity Testing (On-site Licensee Testing Facilities and HHS-Certified Laboratories)	Exhibit A2 - 9: Drug and validity testing (licensee testing facilities and HHS-certified laboratories)
Subpart G	26.161(g)	Unidentified Interfering Substance/Adulterant - Contact MRO and Specimen Retesting	Exhibit A2 - 9: Drug and validity testing (licensee testing facilities and HHS-certified laboratories)
Subpart G	26.163(a)(1)	Change Cutoff Levels for Marijuana and Opiates - HHS-Certified Laboratories	Exhibit A2 - 9: Drug and validity testing (licensee testing facilities and HHS-certified laboratories)
Subpart G	26.165(b)	Retesting of Single Collection Specimens with Confirmed Positive Drug and/or Validity Test Results	Exhibit A2 - 9: Drug and validity testing (licensee testing facilities and HHS-certified laboratories)
Subpart G	26.168(a)(1)	Blind Sample Testing - 1st Quarter of Contract with a HHS-Certified Laboratory	Exhibit A2 - 9: Drug and validity testing (licensee testing facilities and HHS-certified laboratories)
Subpart G	26.168(a)(2)	Blind Sample Testing - Contracts with HHS-Certified Laboratories Older Than 90 Days	Exhibit A2 - 9: Drug and validity testing (licensee testing facilities and HHS-certified laboratories)
Subpart G	26.169(k)	HHS-Certified Laboratory Reporting of Testing Data to FFD program (Monthly to Annually)	Exhibit A2 - 10: Reporting Requirements
Subpart H	26.189(b)(3)	Definition of "Potentially Disqualifying Information"	Exhibit A2 - 6: Activities Related to Potential Policy Violations

Crosswalk Index of Subpart Sections and Exhibits

Subpart	Section	Section Description	Exhibits
Subpart H	26.189(c)	Face-to-Face Determinations of Fitness	Exhibit A2 - 6: Activities Related to Potential Policy Violations
Subpart I	26.203(a)-(b)	Policy and Procedures	Exhibit A2-15: Fatigue Inputs
Subpart I	26.203(c)	Training	Exhibit A2-15: Fatigue Inputs
Subpart I	26.203(d)	Retaining Fatigue Records	Exhibit A2-15: Fatigue Inputs
Subpart I	26.203(e)	NRC Review of Fatigue Information in Annual FFD Performance Reports	Exhibit A2 - 10: Reporting Requirements
Subpart I	26.203(e)(1)	Summarize Waiver Data	Exhibit A2-15: Fatigue Inputs
Subpart I	26.203(e)(2)	Summarize Fatigue Assessment Data	Exhibit A2-15: Fatigue Inputs
Subpart I	26.203(f)	Fatigue Management Audits	Exhibit A2-15: Fatigue Inputs
Subpart I	26.205(b)	Calculating Work Hours	Exhibit A2-15: Fatigue Inputs
Subpart I	26.205(c)	Scheduling Work Hours	Exhibit A2-15: Fatigue Inputs
Subpart I	26.205(d)(4)-(6)	Day-off Requirements	Exhibit A2-15: Fatigue Inputs
Subpart I	26.205(e)	Work Hour Control Reviews	Exhibit A2-15: Fatigue Inputs
Subpart I	26.207	Waivers from Individual Work Hour Limits	Exhibit A2-15: Fatigue Inputs
Subpart I	26.209	Self-Declarations of Fatigue	Exhibit A2-15: Fatigue Inputs
Subpart I	26.211(a)-(d)	Fatigue Assessments	Exhibit A2-15: Fatigue Inputs
Subpart I	26.211(e)	Post-Fatigue Assessment Controls and Conditions	Exhibit A2-15: Fatigue Inputs
Subpart I	26.211(f)	Documenting Fatigue Assessments	Exhibit A2-15: Fatigue Inputs
Subpart N	26.713(g)	Filing of Forensic Toxicologist's Evaluation	Exhibit A2 - 10: Reporting Requirements
Subpart N	26.717(e), (f)	FFD Programs: Performance Data Reporting and Review	Exhibit A2 - 10: Reporting Requirements
Subpart N	26.719(b)	Reporting and Review of Reportable Events Due to New Validity Testing Requirements	Exhibit A2 - 10: Reporting Requirements
Subpart N	26.719(b)	Reporting and Review of Reportable Events Due to New Validity Testing Requirements	Exhibit A2 - 10: Reporting Requirements
Subpart N	26.717(g)	FFD Programs: Performance Data Reporting and Review	Exhibit A2 - 10: Reporting Requirements

Appendix 3: Analysis of Section 26.207

Overview

Section 26.207 of the final worker fatigue provisions establishes new waiver requirements. Among other provisions, the section restricts the granting of waivers from work hour requirement guidelines to cases where the waiver is needed to mitigate or prevent a condition adverse to safety or to maintain security. The rule also clarifies that work hour limits apply only to workers who perform safety-related functions, which will eliminate the need to grant waivers to other staff. This appendix describes a methodology for estimating the incremental costs and savings associated with eliminating waivers that would no longer be permitted under the final rule.

NRC used this methodology to estimate the net cost per week of the new waiver requirements. The resulting estimate of $1,087 per week while at-power and $25,689 per week during plant shutdowns are used as inputs to the cost analysis of §26.207, which is presented in Appendix A2-15. Table 3-1 provides a summary of the waiver data used in this appendix. Table 3-2 provides a breakdown of these data by work-hour provision.

The methodology is based on a review of selected 2003 - 2004 waiver data from six facilities. The analysis categorizes each waiver into one of eight groups and calculates the cost or saving associated with that waiver based on how the situation would be addressed under the final rule. Results for the six facilities are summed and averaged to calculate the net weekly cost of the provision for the average facility (1) while at power, and (2) during an outage.

The remainder of this appendix describes how the analysis estimates the cost or saving of each type of waiver. The discussion is organized into nine sections:

- A3.1 Waivers No Longer Required Under the Final Rule;
- A3.2 Waivers Unaffected by the Final Rule;
- A3.3 Outage Shift Changes that Will Not Meet the New Final Waiver Requirements;
- A3.4 Outage Activities Without Direct Impact on Critical Path;
- A3.5 Outage Activities With Critical Path Impact;
- A3.6 At-Power Costs Associated With Individuals Who Will Not Meet the Final Waiver Requirements;
- A3.7 At-Power Costs Associated With Individuals Involved in Tests or Integrated Evolution Who Will Not Meet the Final Waiver Requirements;
- A3.8 At-Power Costs Associated With Individuals Involved in Return to Full Power Who Will Not Meet the Final Waiver Requirements; and
- A3.9 Generic Costing Assumptions

Table 3-1
Waiver Data Summary

	Description	Total	Plants					
			A	B	C	D	E	F
	Outage Days	295	76	64	30	62	34	29
	At-Power Days	452	30	301	31	30	30	30
A3.1	Waivers No Longer Required*	506	114	81	6	48	25	232
A3.2	Waivers Unaffected*	20	15	1	2	1	0	1
A3.3	Outage Shift Change*	158	133	0	5	18	1	1
A3.4	Outage Activities without Direct Impact on Critical Path*	827	150	6	56	330	112	173
A3.5	Outage Activities with Critical Path Impact*	300	40	4	14	186	36	20
A3.6	At-Power Activities*	28	6	1	5	16	0	0
A3.7	At-Power Activities associated with Test and Integrated Activities*	16	7	7	1	1	0	0
A3.8	At-Power Activities Impacting Return to Full Power*	10	0	1	6	3	0	0
	TOTAL*	1,865	465	101	95	603	174	427

* The numbers in these rows represent the number of personnel with authorized work-hour rule waivers. Consecutively issued waivers for personnel working 12-hour days without an off-day were counted as one occurrence per person for each 7-day period when allowed by the available data.

Table 3-2
Work-hour Provision Breakdown

Provision	Personnel Waived	Percent of Waivers where only a Single Provision is Waived	Percent of Total*
8-hour break	18	6% (1 of 18)	1%
16-hours in 24-hour period	175	28% (49 of 175)	9%
24-hours in a 48-hour period	434	44% (192 of 434)	23%
72-hours in a 7-day period	1536	71% (1333 of 1536)	82%
Total Waived	1865	84% (1575 of 1865)	100%

* Note that since 16% of the waivers address multiple provisions, the sum of provision percentages exceeds 100%.

A3.1 Waivers No Longer Required Under the Final Rule

Numerous work hour waivers that were granted prior to the final rule will no longer be needed (i.e., waivers for engineering staff, waivers that would be eliminated due to the 26-hour in 48-hour rule change and for work not adverse to safety). Licensees will be free to use staff as they did under these waivers, but they will realize incremental savings because they will not have to undertake the administrative exercise of granting the waiver.

The *facility savings per waiver* result from the saved management costs as follows:

$$HOURS_{Manager} \times WAGE_{Management}$$

Parameter	**Description**
$HOURS_{Manager}$	Manager labor saved for each waiver that no longer needs to be processed (described in assumptions below)
$WAGE_{Management}$	Hourly management labor rate (described in Section A3.9)

Assumption:

- Manager labor saved as a result of reduced planning, coordination and administration for each waiver processed: 1 hour.

A3.2 Waivers Unaffected by the Final Rule

Some of the work hour waivers examined will not be affected by the final rule. These are waivers that satisfy the two required elements of the final rule: (a) the activity is necessary to mitigate or prevent a condition adverse to safety or security and (b) there is reasonable assurance that the individual will be able to safely and competently perform his or her duties during the additional work period. There are no incremental costs or savings associated with this category.

A3.3 Outage Shift Changes that Will Not Meet the Final Waiver Requirements

Another group of work hour waivers includes those granted to accommodate a shift schedule change that will not meet the new waiver requirements. This group includes waivers associated with:

- Shifting between day and night schedules or other outage schedule changes; and
- Shifting personnel due to down-staffing.

All but two of the 158 waivers in this category (99%) authorize a variance from the 72-hour work hour control requirement. Due to the limited information provided on many waiver authorization forms, it is often unclear whether the 72-hour limit is exceeded by only a few hours or an entire shift. In addition to the 72-hour limit, about 23% of these waivers also allow individuals to exceed the 16-hours in 24-hour limit.

Contractor - Local Craft

This category estimates the cost associated with eliminating work hour waivers addressing an outage shift change that will not meet the final waiver requirements. The category applies to local contractors supporting an outage that do not require travel or per diem. Activities addressed by this category are not associated with a test or integrated evolution.

The management cost of this section is the additional management burden for planning and coordination. The additional management burden for waivers that address a single person is assumed to be 1 hour. For waivers that address more than one person, this analysis assumes that the additional management burden will be 2 hours.

The *facility cost per waiver* results from the sum of the following factors:

- The labor cost of this waiver is the difference between the cost of labor for the extended period under the final rule and the cost of labor pre-rule. The labor cost is calculated as follows:

  $(NUM_{Local\ Craft} \times HOURS_{Local\ Craft} \times WAGE_{Local\ Craft} \times CONTINGENCY_{Shift\_Schedule\_Change})$
  $- (NUM_{Local\ Craft} \times HOURS_{Local\ Craft} \times WAGE_{Local\ Craft})$

- The management cost of this waiver is the additional management burden for planning and coordination. The management cost is calculated as follows:

  If waiver addresses one person, then $(1\ hour \times WAGE_{Manager})$
  If waiver addresses multiple people, then $(2\ hours \times WAGE_{Manager})$

Parameter	**Description**
$NUM_{Local\ Craft}$	The number of local craft workers impacted by shift schedule changes that will no longer be allowed
$HOURS_{Local\ Craft}$	Hours worked per local craft worker that exceeded the work hour requirements under one waiver
$CONTINGENCY_{Shift\_Schedule\_Change}$	Contingency factor measuring the significance of expected resource loading associated with shift schedule changes (described in assumptions below)
$WAGE_{Local\ Craft}$	The estimated hourly rate of local craft labor (described in Section A3.9)
$WAGE_{Manager}$	Average manager wage rate (described in Section A3.9)

Assumption:

- A scaling factor is used to adjust baseline costs to reflect higher costs under the final waiver provisions. For this equation, the contingency factor value equals 1. Effective management planning should avoid the need for waivers associated with changes in shift schedules.

Contractor - Specialty Vender

This category estimates the cost associated with eliminating work hour waivers addressing an outage shift change. The category is applicable to contractors supporting an outage that are expected to incur transportation and per diem costs.

The labor cost of this waiver is the difference between the cost of labor for the extended period under the final rule and the cost of labor pre-rule. Although transportation and per diem costs are likely for this labor category, these costs are excluded from the cost estimate because it is assumed that effective management planning should avoid such a burden.

The management cost of this section is the additional management burden for planning and coordination. The additional management burden for waivers that address a single person is assumed to be 1 hour. For waivers that address more than one person, this analysis assumes that the additional management burden will be 2 hours.

The *facility cost per waiver* results from the sum of the following factors:

- The labor cost of this waiver is the difference between the cost of labor for the extended period under the final rule and the cost of labor pre-rule. The labor cost is calculated as follows:

  $(NUM_{Specialty\ Vender} \times HOURS_{Specialty\ Vender} \times WAGE_{Specialty\ Vender} \times CONTINGENCY_{Shift\_Schedule\_Change}) - (NUM_{Specialty\ Vender} \times HOURS_{Specialty\ Vender} \times WAGE_{Specialty\ Vender})$

- The management cost of this waiver is the additional management burden for planning and coordination. The management cost is calculated as follows:

  If waiver addresses one person, then $(1\ hour \times WAGE_{Manager})$
  If waiver addresses multiple people, then $(2\ hours \times WAGE_{Manager})$

Parameter	**Description**
$NUM_{Specialty\ Vender}$	The number of specialty venders impacted by shift schedule changes that will no longer be allowed
$HOURS_{Specialty\ Vender}$	Hours worked per specialty vender that exceeded the work hour requirements under one waiver
$CONTINGENCY_{Shift\_Schedule\_Change}$	Contingency factor measuring the significance of expected resource loading associated with shift schedule changes (described in assumptions below)
$WAGE_{Specialty\ Vender}$	The estimated hourly rate of specialty vender labor (described in Section A3.9)
$WAGE_{Manager}$	Average manager wage rate (described in Section A3.9)

Assumption:

- A scaling factor is used to increase baseline costs to reflect higher costs under the final provision. For this equation, the contingency factor value equals 1. Effective management planning should avoid the need for waivers associated with changes in shift schedules.

Utility

This category estimates the cost associated with eliminating work hour waivers addressing an outage shift change. The category is applicable to utility workers supporting an outage. Activities addressed by this category are not associated with a test or integrated evolution that requires a formal job brief.

The management cost represented by this section is the additional management burden for planning and coordination. The additional management burden for waivers that address a single person is assumed to be 1 hour. For waivers that address more than one person, this analysis assumes that the additional management burden will be 2 hours.

The *facility cost per waiver* results from the sum of the following factors:

- The labor cost of this waiver is the difference between the cost of labor for the extended period under the final rule and the cost of labor pre-rule. The labor cost is calculated as follows:

  $$(NUM_{Utility\ Worker} \times HOURS_{Utility\ Worker} \times WAGE_{Utility\ Worker} \times CONTINGENCY_{Shift\_Schedule\_Change}) - (NUM_{Utility\ Worker} \times HOURS_{Utility\ Worker} \times WAGE_{Utility\ Worker})$$

- The management cost represented by this section is the additional management burden for planning and coordination. The management cost is calculated as follows:

  If waiver addresses one person, then $(1\ hour \times WAGE_{Manager})$
  If waiver addresses multiple people, then $(2\ hours \times WAGE_{Manager})$

Parameter	**Description**
$NUM_{Utility\ Worker}$	The number of utility workers impacted by shift schedule changes that will no longer be allowed
$HOURS_{Utility\ Worker}$	Hours worked per utility worker that exceeded the work hour requirements
$CONTINGENCY_{Shift\_Schedule\_Change}$	Contingency factor measuring the significance of expected resource loading associated with shift schedule changes (described in assumptions below
$WAGE_{Utility\ Worker}$	The estimated hourly rate of utility labor (described in Section A3.9)
$WAGE_{Manager}$	Average manager wage rate (described in Section A3.9)

Assumption:

- A scaling factor is used to increase baseline costs to reflect higher costs under the final provision. For this equation, the contingency factor value equals 1. Effective management planning should avoid the need for waivers associated with changes in shift schedules.

A3.4 Outage Activities Without Direct Impact on Critical Path

Contractor - Local Craft

This category estimates the cost associated with eliminating work hour waivers addressing an outage activity that extends beyond a shift. The category is applicable to local contractors supporting an outage that do not require travel or per diem. Activities addressed by this category are not associated with a test or integrated evolution and do not have a direct critical path impact. This group includes waivers associated with:

- Continuation of on-going work activities (not identified or assessed as critical path);
- Equipment de-contamination and temporary shielding activities; and
- Worker contingency actions (personnel on standby).

The management cost of this section is the additional management burden for planning and coordination. The additional management burden for waivers that address a single person is assumed to be 2 hours. For waivers that address more than one person, this analysis assumes that the additional management burden will be 4 hours.

The *facility cost per waiver* results from the sum of the following factors:

- The labor cost of this waiver is the difference between the cost of labor for the extended period under the final rule and the cost of labor pre-rule. The labor cost is calculated as follows:

  $(NUM_{Local\ Craft} \times HOURS_{Local\ Craft} \times WAGE_{Local\ Craft} \times CONTINGENCY_{Non\text{-}Critical\ Path})$
  $- (NUM_{Local\ Craft} \times HOURS_{Local\ Craft} \times WAGE_{Local\ Craft})$

- The management cost of this waiver is the additional management burden for planning and coordination. The management cost is calculated as follows:

  If waiver addresses one person, then $(2\ hours \times WAGE_{Manager})$
  If waiver addresses multiple people, then $(4\ hours \times WAGE_{Manager})$

Parameter	Description
$NUM_{Local\ Craft}$	The number of local craft workers impacted by shift schedule changes that will no longer be allowed
$HOURS_{Local\ Craft}$	Hours worked per local craft worker that exceeded the work hour requirements under one waiver
$CONTINGENCY_{Non\text{-}Critical\ Path}$	Contingency factor measuring the significance of expected resource loading associated with non-critical path resources changes (described in assumptions below)
$WAGE_{Local\ Craft}$	The estimated hourly rate of local craft labor (described in Section A3.9)
$WAGE_{Manager}$	Average manager wage rate (described in Section A3.9)

Assumption:

- A scaling factor is used to increase baseline costs to reflect higher costs under the final provision. The contingency factor value in this equation is assumed to be equal to 2. The contingency factor value is based on an evaluation of special conditions, including individuals' level of specialization, potential difficulty in establishing alternative arrangements, the likelihood of cost premiums like travel per diem and the potential impact to outage duration. In this section of the appendix, the contingency value ranges from 1 to 5. For this category, the contingency factor equals 2 due to the low level of specialization, local availability of labor and limited impact on the outage critical path.

Contractor - Specialty Vender

This category estimates the cost associated with eliminating work hour waivers addressing an outage activity that extends beyond a shift. The category is applicable to contractors supporting an outage that are expected to incur transportation and per diem cost. Activities addressed by this category are not associated with a test or integrated evolution and do not have a direct critical path impact. This group includes waivers associated with:

- Continuation of on-going work activities (not identified or assessed as critical path);
- Motor-operated valve and air-operated valve testing; and
- Worker contingency actions (personnel on standby).

The labor cost of this waiver is the difference between the cost of labor for the extended period under the final rule and the cost of labor pre-rule. The contingency cost includes the expected additional per diem cost. The analysis also assumes that a travel cost of $1,000 per person per waiver will be incurred.

The management cost of this section is the additional management burden for planning and coordination. The additional management burden for waivers that address a single person is

assumed to be 2 hours. For waivers that address more than one person, this analysis assumes that the additional management burden will be 4 hours.

The *facility cost per waiver* results from the sum of the following factors:

- The labor cost of this waiver is the difference between the cost of labor for the extended period under the final rule and the cost of labor pre-rule. The labor cost is calculated as follows:

  $(NUM_{Specialty\ Vender} \times HOURS_{Specialty\ Vender} \times WAGE_{Specialty\ Vender} \times CONTINGENCY_{Non\text{-}critical\ Path}) + (NUM_{Specialty\ Vender} \times COST_{Travel}) - (NUM_{Specialty\ Vender} \times HOURS_{Specialty\ Vender} \times WAGE_{Specialty\ Vender})$

- The management cost of this waiver is the additional management burden for planning and coordination. The management cost is calculated as follows:

  If waiver addresses one person, then $(2\ hour \times WAGE_{Manager})$
  If waiver addresses multiple people, then $(4\ hours \times WAGE_{Manager})$

Parameter	**Description**
$NUM_{Specialty\ Vender}$	The number of specialty venders impacted by shift schedule changes that will no longer be allowed
$HOURS_{Specialty\ Vender}$	Hours worked per specialty vender that exceeded the work hour requirements under one waiver
$CONTINGENCY_{Non\text{-}Critical\ Path}$	Contingency factor measuring the significance of expected resource loading associated with shift schedule changes (described in assumptions below)
$WAGE_{Specialty\ Vender}$	The estimated hourly rate of specialty vender labor (described in Section A3.9)
$COST_{Travel}$	The estimated round trip travel fee used for specialty venders (described in Section A3.9)
$WAGE_{Manager}$	Average manager wage rate (described in Section A3.9)

Assumption:

- A scaling factor is used to increase baseline costs to reflect higher costs under the final provision. The contingency factor value in this equation is assumed to be equal to 4. The contingency factor value is based on an evaluation of special conditions, including individuals' level of specialization, potential difficulty in establishing alternative arrangements, the likelihood of cost premiums like travel per diem and the potential impact to outage duration. In this section of the appendix, the contingency value ranges from 1 to 5. For this category, the contingency factor equals 4 due to the high level of

specialization, potential difficulty in making alternative arrangements, likely need to pay a premium, and the limited impact on the outage critical path.

Utility

This category estimates the cost associated with eliminating work hour waivers addressing an outage activity that extends beyond a shift. The category is applicable to utility workers supporting an outage. Activities addressed by this category are not associated with a test or integrated evolution and do not have a direct critical path impact. This group includes waivers associated with:

- Continuation of on-going work activities (not identified or assessed as critical path);
- Operations outage support (valve manipulations, clearing danger tags, surveillance support, etc.);
- Health Physics survey and job coverage support; and
- Training and qualification support (welders).

The management cost represented by this section is the additional management burden for planning and coordination. The additional management burden for waivers that address a single person is assumed to be 2 hours. For waivers that address more than one person, this analysis assumes that the additional management burden will be 4 hours.

The *facility cost per waiver* results from the sum of the following factors:

- The labor cost of this waiver is the difference between the cost of labor for the extended period under the final rule and the cost of labor pre-rule. The labor cost is calculated as follows:

  $(NUM_{Utility\ Worker} \times HOURS_{Utility\ Worker} \times WAGE_{Utility\ Worker} \times CONTINGENCY_{Non\text{-}critical\ Path}) - (NUM_{Utility\ Worker} \times HOURS_{Utility\ Worker} \times WAGE_{Utility\ Worker})$

- The management cost represented by this section is the additional management burden for planning and coordination. The management cost is calculated as follows:

  If waiver addresses one person, then $(2\ hours \times WAGE_{Manager})$
  If waiver addresses multiple people, then $(4\ hours \times WAGE_{Manager})$

Parameter	Description
$NUM_{Utility\ Worker}$	The number of utility workers impacted by shift schedule changes that will no longer be allowed
$HOURS_{Utility\ Worker}$	Hours worked per utility worker that exceeded the work hour requirements

Parameter	Description
$CONTINGENCY_{Non\text{-}critical\ Path}$	Contingency factor measuring the significance of expected resource loading associated with shift schedule changes (described in assumptions below
$WAGE_{Utility\ Worker}$	The estimated hourly rate of utility labor (described in Section A3.9)
$WAGE_{Manager}$	Average manager wage rate (described in Section A3.9)

Assumption:

- A scaling factor is used to increase baseline costs to reflect higher costs under the final provision. The contingency factor value in this equation is assumed to be equal to 2. The contingency factor value is based on an evaluation of special conditions, including individuals' level of specialization, potential difficulty in establishing alternative arrangements, the likelihood of cost premiums like travel per diem and the potential impact to outage duration. In this section of the appendix, the contingency value ranges from 1 to 5. For this category, the contingency factor equals 2 due to the assignment flexibility of in-house staff and limited impact on the outage critical path.

A3.5 Outage Activities With Critical Path Impact

Contractor - Local Craft

This section estimates the local contractor cost associated with activities that have a critical path impact. The category is applicable to local contractors supporting an outage that do not require travel or per diem. This group includes waivers associated with:

- Support of critical path activities (only 4 waivers were identified as being applicable to the Local Craft portion of this category).

The management cost of this section is the additional management burden for planning and coordination. The additional management burden for waivers that address a single person is assumed to be 2 hours. For waivers that address more than one person, this analysis assumes that the additional management burden will be 4 hours.

The outage portion of this section is used to represent the cost associated with extending the outage as a result of allocating resources without the availability of a waiver. This waiver cost section addresses the potential impact of the job brief on the critical path.

The *facility cost per waiver* results from the sum of the following factors:

- The labor cost of this waiver is the difference between the cost of labor for the extended period under the final rule and the cost of labor pre-rule. The labor cost is calculated as follows:

  $$(NUM_{Local\ Craft} \times HOURS_{Local\ Craft} \times WAGE_{Local\ Craft} \times CONTINGENCY_{Critical\ Path}) - (NUM_{Local\ Craft} \times HOURS_{Local\ Craft} \times WAGE_{Local\ Craft})$$

- The management cost represented by this section is the additional management burden for planning and coordination. The management cost is calculated as follows:

  If waiver addresses one person, then $(2\ hours \times WAGE_{Manager})$
  waiver addresses multiple people, then $(4\ hours \times WAGE_{Manager})$

- The outage portion of this section represents the cost associated with extending the outage as a result of allocating resources without the availability of a waiver. The outage cost is calculated as follows:

  $$HOURS_{Turnover} \times HCOST_{Outage}$$

  If the waiver is associated with the 72-hour provision, then this analysis assumes that there is no cost for critical path turnover. The analysis makes this assumption because the 72-hour provision is typically exceeded for a seventh 12-hour day in 7 days. As a result, a brief would be required regardless of whether this provision is waived or not.

Parameter	**Description**
$NUM_{Local\ Craft}$	The number of local craft workers impacted by shift schedule changes that will no longer be allowed
$HOURS_{Local\ Craft}$	Hours worked per local craft worker that exceeded the work hour requirements
$HOURS_{Turnover}$	The estimated amount of time (in hours) associated with a turnover job briefing (described in assumptions below)
$CONTINGENCY_{Critical\ Path}$	Contingency factor measuring the significance of expected resource loading associated with critical path activities (described in assumptions below)
$WAGE_{Local\ Craft}$	The estimated hourly rate of local craft labor (described in Section A3.9)
$WAGE_{Manager}$	Average manager wage rate (described in Section A3.9)
$HCOST_{Outage}$	The hourly cost of delaying the completion of an outage (described in Section A3.9)

Assumptions:

- A scaling factor is used to increase baseline costs to reflect higher costs under the final provision. The contingency factor value in this equation is assumed to be equal to 3. The contingency factor value is based on an evaluation of special conditions, including individuals' level of specialization, potential difficulty in establishing alternative arrangements, the likelihood of cost premiums like travel per diem and the potential impact to outage duration. In this section of the appendix, the contingency value ranges from 1 to 5. For this category, the contingency factor equals 3 due to the low level of specialization, local availability of labor but a potential impact on the outage critical path.

- The estimated amount of time (in hours) associated with a turnover job briefing: 0.5 hours.

Contractor - Specialty Vender

This section estimates the specialty cost associated with activities that have a critical path impact that will not meet the new waiver requirements. This group includes waivers associated with:

- Refueling path (fuel off-load, on-load, equipment repair, etc.);
- Steam generator eddy current testing;
- Reactor mid-loop operations; and
- Critical path repair/maintenance activities.

The labor cost of this waiver is the difference between the cost of labor for the extended period under the final rule and the cost of labor pre-rule. The cost estimate includes a travel cost of $1,000 per person per waiver.

The management cost of this section is the additional management burden for planning and coordination. The additional management burden for waivers that address a single person is assumed to be 2 hours. For waivers that address more than one person, this analysis assumes that the additional management burden will be 4 hours.

The outage portion of this section is used to represent the cost associated with extending the outage as a result of allocating resources without the availability of a waiver. This waiver cost section addresses the potential impact of the job brief on the critical path.

The *facility cost per waiver* results from the sum of the following factors:

- The labor cost of this waiver is the difference between the cost of labor for the extended period under the final rule and the cost of labor pre-rule. The labor cost is calculated as follows:

$$(NUM_{Specialty\ Vender} \times (HOURS_{Specialty\ Vender} + HOURS_{Turnover} \times 2) \times WAGE_{Specialty\ Vender} \times CONTINGENCY_{Critical\ Path}) + (NUM_{Specialty\ Vender} \times COST_{Travel}) - (NUM_{Specialty\ Vender} \times HOURS_{Specialty\ Vender} \times WAGE_{Specialty\ Vender})$$

- The management cost represented by this section is the additional management burden for planning and coordination. The management cost is calculated as follows:

$$\textit{If waiver addresses one person, then } (2\ hours \times WAGE_{Manager})$$
$$\textit{If waiver addresses multiple people, then } (4\ hours \times WAGE_{Manager})$$

- The outage portion of this section represents the cost associated with extending the outage as a result of allocating resources without the availability of a waiver. The outage cost is calculated as follows:

$$HOURS_{Turnovers} \times HCOST_{Outage}$$

If the waiver is associated with the 72-hour provision, then this analysis assumes that there is no cost for critical path turnover. The analysis makes this assumption because the 72-hour provision is typically exceeded for a seventh 12-hour day in 7 days. As a result, a brief would be required regardless of whether this provision is waived or not.

Parameter	**Description**
$NUM_{Specialty\ Vender}$	The number of specialty vender impacted by shift schedule changes that will no longer be allowed
$HOURS_{Specialty\ Vender}$	Hours worked per specialty vender that exceeded the work hour requirements
$HOURS_{Turnover}$	The estimated amount of time (in hours) associated with a turnover job briefing (described in assumptions below)
$CONTINGENCY_{Critical\ Path}$	Contingency factor measuring the significance of expected resource loading associated with shift schedule changes (described in assumptions below)
$WAGE_{Specialty\ Vender}$	The estimated hourly rate of specialty vender labor (described in Section A3.9)
$COST_{Travel}$	The estimated round trip travel fee used for contractor workers (described in Section A3.9)
$WAGE_{Manager}$	Average manager wage rate (described in Section A3.9)
$HCOST_{Outage}$	The hourly cost of delaying the completion of an outage (described in Section A3.9)

Assumptions:

- A scaling factor is used to increase baseline costs to reflect higher costs under the final provision. The contingency factor value in this equation is assumed to be equal to 5. The contingency factor value is based on an evaluation of special conditions, including individuals' level of specialization, potential difficulty in establishing alternative arrangements, the likelihood of cost premiums like travel per diem and the potential impact to outage duration. In this section of the appendix, the contingency value ranges from 1 to 5. For this category, the contingency factor equals the maximum value of 5 due to the high level of specialization, potential difficulty in making alternative arrangements, likely need to pay a premium, and the potential impact on the outage critical path.

- The estimated amount of time (in hours) associated with a turnover job briefing: 0.5 hours

Utility

This category addresses utility workers and estimates the cost associated with an outage test or integrated evolution that will not meet the new waiver requirements. This group includes waivers associated with:

- Refueling path (fuel off-load, on-load, equipment repair, etc.);
- Steam generator eddy current testing;
- Reactor mid-loop operations;
- Reactor startup activities; and
- Critical path repair/maintenance activities.

The management cost represented by this section is the additional management burden for planning and coordination. The additional management burden for waivers that address a single person is assumed to be 2 hours. For waivers that address more than one person, this analysis assumes that the additional management burden will be 4 hours.

The outage portion of this equation is used to represent the cost associated with extending the outage as a result of allocating resources without the availability of a waiver. This waiver cost section includes the potential impact of the job brief on the critical path. The full weight of this additional activity is included in this cost estimate.

The *facility cost per waiver* results from the sum of the following factors:

- The labor cost of this waiver is the difference between the cost of labor for the extended period under the final rule and the cost of labor pre-rule. The labor cost is calculated as follows:

  $$(NUM_{Utility\ Worker} \times (HOURS_{Utility\ Worker} + HOURS_{Turnover} \times 2) \times WAGE_{Utility\ Worker} \times CONTINGENCY_{Critical\ Path}) - (NUM_{Utility\ Worker} \times HOURS_{Utility\ Worker} \times WAGE_{Utility\ Worker})$$

- The management cost represented by this section is the additional management burden for planning and coordination. The management cost is calculated as follows:

  If waiver addresses one person, then $(2\ hours \times WAGE_{Manager})$
  If waiver addresses multiple people, then $(4\ hours \times WAGE_{Manager})$

- The outage portion of this section represents the cost associated with extending the outage as a result of allocating resources without the availability of a waiver. The outage cost is calculated as follows:

  $$HOURS_{Turnover} \times HCOST_{Outage}$$

  If the waiver is associated with the 72-hour provision, then this analysis assumes that there is no cost for critical path turnover. The analysis makes this assumption because the 72-hour provision is typically exceeded for a seventh 12-hour day in 7 days. As a result, a brief would be required regardless of whether this provision is waived or not.

Parameter	**Description**
$NUM_{Utility\ Worker}$	The number of utility workers impacted by shift schedule changes that will no longer be allowed
$HOURS_{Utility\ Worker}$	Hours worked per utility worker that exceeded the work hour requirements
$HOURS_{Turnover}$	The estimated amount of time (in hours) associated with a turnover job briefing (described in assumptions below)
$CONTINGENCY_{Critical\ Path}$	Contingency factor measuring the significance of expected resource loading associated with shift schedule changes (described in assumptions below)
$WAGE_{Utility\ Worker}$	The estimated hourly rate of utility worker labor (described in Section A3.9)
$HCOST_{Outage}$	The hourly cost of delaying the completion of an outage (described in Section A3.9)
$WAGE_{Manager}$	Average manager wage rate (described in Section A3.9)

Assumptions:

- A scaling factor is used to increase baseline costs to reflect higher costs under the final provision. The contingency factor value in this equation is assumed to be equal to 3. The contingency factor value is based on an evaluation of special conditions, including individuals' level of specialization, potential difficulty in establishing alternative arrangements, the likelihood of cost premiums like travel per diem and the potential impact to outage duration. In this section of the appendix, the contingency value ranges from 1 to 5. For this category, the contingency factor equals 3 due to the assignment flexibility of in-house staff and the potential impact on the outage critical path.

- The estimated amount of time (in hours) associated with a turnover job briefing: 0.5 hours.

A3.6 At-Power Costs Associated with Individuals Who Will Not Meet the Final Waiver Requirements

This category addresses a general estimate of the at-power cost associated with individuals who will not meet the new waiver requirements. This group includes waivers associated with training, meetings and other miscellaneous activities.

The *facility cost per waiver* results from the sum of the following factors:

- The labor cost associated with a shift schedule change that will not meet the new waiver requirements is the difference between the cost of labor for the final rule and the cost of labor pre-rule. The labor cost is calculated as follows:

  $(NUM_{Utility\ Worker} \times HOURS_{Utility\ Worker} \times WAGE_{Utility\ Worker} \times CONTINGENCY_{Power}) - (NUM_{Utility\ Worker} \times HOURS_{Utility\ Worker} \times WAGE_{Utility\ Worker})$

- The management cost associated with a shift schedule change that will not meet the new waiver requirements is the cost of the additional management burden for planning and coordination. The management cost is calculated as follows:

  $(1\ hour \times WAGE_{Manager})$

Parameter	Description
$NUM_{Utility\ Worker}$	The number of utility workers impacted by shift schedule changes that will no longer be allowed
$HOURS_{Utility\ Worker}$	Hours worked per utility worker that exceeded the work hour requirements

Parameter	Description
$CONTINGENCY_{Power}$	Contingency factor measuring the significance of expected resource loading associated with at-power activities (described in assumptions below
$WAGE_{Utility\ Worker}$	The estimated hourly rate of utility worker labor (described in Section A3.9)
$WAGE_{Manager}$	Average manager wage rate (described in Section A3.9)

Assumptions:

- A scaling factor is used to increase baseline costs to reflect higher costs under the final provision. The contingency factor value in this equation is assumed to be equal to 2. The contingency factor value is based on an evaluation of special conditions, including individuals' level of specialization, potential difficulty in establishing alternative arrangements, the likelihood of cost premiums like travel per diem and the potential impact on at-power operation. In this section of the appendix, the contingency value ranges from 1 to 5. For this category, the contingency factor equals 2 due to the assignment flexibility of in-house staff and the lack of impact on at-power operation.

- The estimated level of effort to process an at-power waiver is 1 hour.

A3.7 At-Power Costs Associated With Individuals Involved in Tests or Integrated Evolution Who Will Not Meet the Final Waiver Requirements

This category addresses an estimate of the at-power cost associated with individuals involved in test or integrated evolution who will not meet the new waiver requirements. This group includes waivers associated with testing and other operational activities.

The *facility cost per waiver* results from the sum of the following factors:

- The labor cost associated with a shift schedule change that will not meet the new waiver requirements is the difference between the cost of labor for the final rule and the cost of labor pre-rule. The labor cost is calculated as follows:

  $$(NUM_{Utility\ Worker} \times (HOURS_{Utility\ Worker} + HOURS_{Turnover} \times 2) \times WAGE_{Utility\ Worker} \times CONTINGENCY_{Power\_Test}) - (NUM_{Utility\ Worker} \times HOURS_{Utility\ Worker} \times WAGE_{Utility\ Worker})$$

- The management cost associated with a shift schedule change that will not meet the new waiver requirements is the cost of the additional management burden for planning and coordination. The management cost is calculated as follows:

  $$(1\ hour \times WAGE_{Manager})$$

Parameter	Description
$NUM_{Utility\ Worker}$	The number of utility workers impacted by shift schedule changes that will no longer be allowed
$HOURS_{Utility\ Worker}$	Hours worked per utility worker that exceeded the work hour requirements
$CONTINGENCY_{Power\_Test}$	Contingency factor measuring the significance of expected resource loading associated with at-power test activities (described in assumptions below
$WAGE_{Utility\ Worker}$	The estimated hourly rate of utility worker labor (described in Section A3.9)
$HOURS_{Turnover}$	The estimated amount of time (in hours) associated with a turnover job briefing (described in assumptions below)
$WAGE_{Manager}$	Average manager wage rate (described in Section A3.9)

Assumptions:

- A scaling factor is used to increase baseline costs to reflect higher costs under the final provision. The contingency factor value in this equation is assumed to be equal to 3. The contingency factor value is based on an evaluation of special conditions, including individuals' level of specialization, potential difficulty in establishing alternative arrangements, the likelihood of cost premiums like travel per diem and the potential impact on at-power operation. In this section of the appendix, the contingency value ranges from 1 to 5. For this category, the contingency factor equals 3 due to the assignment flexibility of in-house staff and the increased importance of on-going operational activities.

- The estimated level of effort to process an at-power waiver is 1 hour.

- The estimated amount of time (in hours) associated with a turnover job briefing: 0.5 hours.

A3.8 At-Power Costs Associated With Individuals Involved in Return to Full Power Who Will Not Meet the Final Waiver Requirements

This category addresses an estimate of the at-power cost associated with individuals involved in activities that are associated with the return to full power who will not meet the new waiver requirements. This group includes waivers for individuals involved in repair activities that are not associated with technical specification equipment and that likely result in a power reduction. This analysis assumes that a facility will operate at 75% of its capacity.

The *facility cost per waiver* results from the sum of the following factors:

- The labor cost associated with a shift schedule change that will not meet the new waiver requirements is the difference between the cost of labor for the final rule and the cost of labor pre-rule. The labor cost is calculated as follows:

  $(NUM_{Utility\ Worker} \times (HOURS_{Utility\ Worker} + HOURS_{Turnover} \times 2) \times WAGE_{Utility\ Worker} \times CONTINGENCY_{Return\ to\ Rull\ Power}) - (NUM_{Utility\ Worker} \times HOURS_{Utility\ Worker} \times WAGE_{Utility\ Worker})$

- The management cost associated with a shift schedule change that will not meet the new waiver requirements is the cost of the additional management burden for planning and coordination. The management cost is calculated as follows:

  $(1\ hour \times WAGE_{Manager})$

- The return to power cost associated with operating at a reduced power level is the cost of allocating resources without the availability of a waiver. The return to power cost is calculated as follows:

  $HOURS_{Turnovers} \times REDUCED\_POWER \times HCOST_{Outage}$

Parameter	**Description**
$NUM_{Utility\ Worker}$	The number of utility workers impacted by shift schedule changes that will no longer be allowed
$HOURS_{Utility\ Worker}$	Hours worked per utility worker that exceeded the work hour requirements
$CONTINGENCY_{Return\ to\ Full\ Power}$	Contingency factor measuring the significance of expected resource loading associated with return to full power activities (described in assumptions below)
$WAGE_{Utility\ Worker}$	The estimated hourly rate of utility worker labor (described in Section A3.9)
$HOURS_{Turnover}$	The estimated amount of time (in hours) associated with a turnover job briefing (described in assumptions below)
REDUCED_POWER	Percent of total power lost per hour from operating at a reduced power level (described in assumptions below)
$HCOST_{Outage}$	The hourly cost of delaying the completion of an outage (described in Section A3.9)
$WAGE_{Manager}$	Average manager wage rate (described in Section A3.9)

Assumptions:

- A scaling factor is used to increase baseline costs to reflect higher costs under the final provision. The contingency factor value in this equation is assumed to be equal to 5.

The contingency factor value is based on an evaluation of special conditions, including individuals' level of specialization, potential difficulty in establishing alternative arrangements, the likelihood of cost premiums like travel per diem and the potential impact on at-power operation. In this section of the appendix, the contingency value ranges from 1 to 5. For this category, the contingency factor equals 5 due to the direct impact waivers have on production output.

- The estimated amount of time (in hours) associated with a turnover job briefing: 0.5 hours.
- The estimated level of effort to process an at-power waiver is 1 hour.
- Percent of total power lost per hour from operating at a reduced power level: 25%.

A3.9 Generic Costing Assumptions

- Management labor rate: $100/hour.
- The estimated hourly rate of utility craft labor: $40/hour.
- The estimated hourly rate of specialty contractors: $80/hour.
- The estimated hourly rate of local labor: $25/hour.
- The effectiveness of additional resources relative to those that are being augmented: 100%.
- The hourly cost of delaying the completion of an outage: $10,000.
- The estimated round trip travel fee used for contractor workers: $1,000.
- The estimated level of effort to process a waiver is 1 hour.

Summary and Analysis of Public Comments Received on Proposed Revisions to 10 CFR Part 26 – Fitness for Duty Programs

Comments Received Between August 26, 2005 and June 23, 2006

Prepared by:
ICF International
December 13, 2006

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List of Acronyms

AEP	American Electric Power
CAN	Citizens' Awareness Network
CPL	Conforming Products List
DCS	Duke Cogema Stone & Webster
DOT	Department of Transportation
EAP	Employee Assistance Program-
EBT	Evidential Breath Testing Device
EPRI	Electric Power Research Institute
FENOC	FirstEnergy Nuclear Operating Company
FFD	Fitness for Duty
FMCSA	Federal Motor Carriers Safety Administration
FPL	Florida Power and Light
HHS	US Department of Health and Human Services
IBEW	International Brotherhood of Electrical Workers
LOD	Limit of Detection
MRO	Medical Review Officer
NEI	Nuclear Energy Institute
NHTSA	National Highway Traffic Safety Administration
NMC	Nuclear Management Company
NRC	Nuclear Regulatory Commission
NRSG	Nuclear Regulatory Services Group
NSF	National Sleep Foundation
OMB	Office of Management and Budget
OTC	Over-the-Counter
PBNP	Point Beach Nuclear Plant
PDFFDI	Potentially Disqualifying Fitness-for-duty Information
POCT	Point-of-collection Test
POGO	Project on Government Oversight
PPL	PPL Susquehanna
PROS	Professional Reactor Operator Society
QA/QC	Quality Assurance/Quality Check
SAE	Substance Abuse Expert
SAT	Systems Approach to Training
SAMHSA	Substance Abuse and Mental Health Services Administration
SCE	Southern California Edison
SCE&G	Southern Carolina Electric and Gas Company
SNC	Southern Nuclear Operation Company
STARS	Strategic Teaming and Resource Sharing
TVA	Tennessee Valley Authority
UCS	Union of Concerned Scientists
UWUA	Utility Workers Union of America
VEP	Virginia Electric and Power

Introduction

This document summarizes and responds to the comments received on the NRC's proposed revisions to 10 CFR Part 26 – Fitness for Duty Programs. The NRC accepted 81 written public comments on the proposed rule from August 25, 2005 to June 23, 2006. 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.

The NRC considered comments contained in the transcript of a public meeting held on September 21, 2005 (ADAMS Accession No. ML052420363), in which 18 individuals, excluding NRC staff, spoke. The NRC also considered comments, although not written, from several other public meetings: November 7 and 9, 2005 (ADAMS Accession No. ML052990048) that provided clarification on the proposed rule; and December 15, 2005 (ADAMS Accession No. ML053400002) regarding NEI's proposed alternative approach to the work-hour portion of the proposed rule.

Exhibit 1 identifies the individuals who provided written comments that the NRC received and the organization the individual is affiliated with, if applicable. Exhibit 2 shows the individuals who spoke during the September 21, 2005, public meeting and the organization the individual is affiliated with, if applicable.

Exhibit 1 - Individuals Providing Written Comments	
Robert Althoff	
Andrew Antrassain	UWUA
Jeffrey Archie	SCE&G
Richard Barkely	
Doug Beck	First Energy, Beaver Valley Station
Jim Bradshaw	AEP
Danielle Brian	POGO
Sue Brown	SAMHSA
F.G. Buford	Entergy
Michael Cantor	Waypoint Research Inc
Michael Coyle	NEI
Ethan Darrow	
Jim Davis	NEI
Darrel Drobnich	NSF

Exhibit 1 - Individuals Providing Written Comments	
Marvin Fertel	NEI
Peter Fowler	Duke Energy
C. L. Funderburk	Dominion
Guy Galster	
Ronald W. Gaston	Detroit Edison
Kevin Glidden	
Greg Gorman	First Energy, Beaver Valley Station
Don Grisette	SNC
Gregory Halnon	FENOC
Peter Hammill	PBNP
Daniel Hansen	Exelon
Mark Haywood	First Energy, Beaver Valley Station
Edwin Hill	IBEW
Mike Jolley	
D.M. Jurss	PBNP
Keith R. Jury	Exelon and AmerGen
Deborah Katz	CAN
Kenneth Kolaczyk	
Donald Lenski	Exelon
David Lochbaum	UCS
Charles LoDico	
Brian McCabe	Progress Energy
B.T. McKinney	PPL
Robert M. Meyer	PROS
Glenn W. Morris	TVA
Todd Newkirk	IBEW
Blaine Peters	Exelon

Exhibit 1 - Individuals Providing Written Comments	
Jim Pulley	Clinton Power Station
Barry Quigley	
Brent Rice	
Mark Rosekind	Alertness Solutions
David Sancic	
A. Edward Scherer	SCE
Steven Schildhouse	
Dennis Specha	Dresden Nuclear Power Station
Jim Springfield	IBEW
J A Stall	FPL
Daniel F. Stenger	NRSG
Richard Sweigart	DCS
Anthony Taylor	Exelon
Dan Todhunter	Exelon, Byron Nuclear Power
Ray Wacker	
Jim Waite	Exelon
Edward Weinkam	NMC
Mark J. Wetterhahn	Winston & Strawn
D R Woodlan	STARS
Keith D. Young	AmerenUE

Exhibit 2 - Individuals Providing Comments at the Public Meeting	
Joseph Bower	Exelon
Randy Cleveland	NMC
John P. Cowan	NMC
Jim Davis	NEI
Peter Defillipi	Westinghouse
Nick Depietro	First Energy
John Fee	SCE
Tom Houten	NEI
Dave Lochbaum	UCS
Brian McCabe	Progress Energy
Dana Millar	Entergy
Todd Newkirk	IBEW
Anthony Rizzo	Salem Hope Creek
Pete Stockton	POGO
Susan Techau	Exelon
Getachew Tesfaye	Constellation
Glenn Wilson	Dominion
David Ziebell	EPRI

1. General Issues

1.1 Support

Comments: Several commenters expressed general support for the rulemaking. One commenter stated that NRC, the licensees, and all the stakeholders have a common goal in mind, and the only issue is how to implement the provisions while providing the necessary operational flexibility [Joe Bauer, Exelon].

NRC Response: The comments do not require a response.

1.2 Oppose

No comments generally opposed the rulemaking.

1.3 Legal Basis

Comments: A number of commenters from industry addressed the legal basis of a statement made in the proposed rule *Federal Register* notice. The commenters claimed that the proposed rule package repeatedly stated that licensees have violated NRC requirements in the Policy of Worker Fatigue. Concurrently, the proposed rule package noted that the Policy or guidance documents do not prescribe requirements and are enforceable only when included in licensees' Technical Specifications. Because the NRC Policy on Worker Fatigue is not enforceable by the NRC, the commenters argued that the claimed violation of policy is not an appropriate basis for the reporting requirements contained in proposed Subpart I [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenter that the proposed rule package discussed licensees “violating” the NRC’s Policy on Worker Fatigue. Instead, the rule package addressed a wide variability in how licensees interpreted and implemented the Policy. The NRC found that, in some cases, the use of waivers, in particular, was inconsistent with the Policy, as was discussed in Section IV.D of the proposed rule *Federal Register* notice. The NRC continues to believe that the reporting requirements are justified for the reasons discussed in Sections V and VI of the final rule *Federal Register* notice and Section 11.2.5 of this document.

1.4 Technical and Scientific Basis

<u>Support for Worker-designed Shifts</u>

Comments: One commenter asserted that Subpart I effectively removes rotating 8-hour schedules for most plants, and it presented a scientific paper supporting worker-designed shift

schedules [Todd Newkirk, IBEW].

NRC Response: The NRC understands the commenter's concern to be related to requirement for a 24 hour break in 7 days. In response to this comment, and related comments, the NRC has revised the rest break provisions to provide substantial additional flexibility in the final rule. For further information, see discussion of comments regarding § 26.199(d)(2) in Section 11.3.4 ("Impact on 8-hour Shifts") of this document.

Correlation between Cited Research and Actual Industry Data

Comments: One commenter, supported by many other commenters, raised several issues with the technical basis discussed in the proposed rule package. The commenter disagreed with the "sweeping generalizations" made in Section IV.D (1) and (2) of the proposed rule *Federal Register* notice regarding alertness problems that may occur as a result of fatigue. The commenter stated that the research alluded to in this discussion is not drawn from the nuclear industry, and there is a lack of correlation between the studies and actual nuclear industry data. As a result, the commenter explained that this raises concerns regarding the validity of the NRC's conclusions. The commenter stated that other factors reduce the potential for fatigue (i.e. industry's safety culture, training, work procedures, and attention to details) and these factors make it difficult to apply conclusions from studies conducted outside the nuclear industry [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J.A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG]. Similarly, another commenter expressed concerns about the reasearch included as the basis for the fatigue portion of the proposed rule, as they did not concern workers in the nuclear power industry [Daniel Hansen, Individual].

NRC Response: The NRC agrees with the commenters that Section IV.D (1) of the *Federal Register* notice for the proposed rule provided a general discussion regarding alertness problems that may occur as a result of fatigue as that was the intent of the section. Section IV.D (1) describes the types of impairments that can result from fatigue, specifically impairments of (1) attention, (2) decision-making, (3) problem solving, and (4) communication and teamwork. The discussion includes citations as examples of studies that demonstrate these types of impairments, and the NRC believes that these effects have been well substantiated and broadly accepted by the scientific community. The NRC provided a factual discussion of these effects and related studies and disagrees with the characterization of this discussion as including sweeping generalizations.

Section IV.D (2) of the *Federal Register* notice for the proposed rule provided a discussion of the prevalence of conditions in the nuclear industry that can contribute to worker fatigue. Specifically, the *Federal Register* notice discusses extended work shifts (i.e., 12 or more hours) with five or more consecutive work days, extensive overtime, shiftwork, early start times and extended commutes, and sleep disorders. With regard to the use of more than five consecutive work shifts and extensive use of overtime, the NRC notes that industry and union commenters (further presented and discussed in Section 11.3.4 ("Limited Access to Supplemental Workers" of this document) have asserted that schedules of 6 or more consecutive 12-hour shifts are

necessary to attract supplemental workers and have proposed that the NRC revise the proposed rule requirements to allow such practices. These comments corroborate NRC's assertion of these practices in the U.S. nuclear power industry. Similarly, the NRC considers the proposed rule's *Federal Register* notice discussion of industry use of shiftwork, shift start times beginning at 7 a.m. or earlier, the potential for extended commutes due to the nature of nuclear power plant sites in relationship to major population centers, and the incidence of sleep disorders to be a factual discussion of these conditions and does not overstate their potential to contribute to worker fatigue at nuclear power plants.

Regarding the comment that the NRC cited studies that were based on observations of worker performance outside the nuclear industry, the NRC agrees that it reviewed research from a broad spectrum of industries, in addition to studies of work performance in the nuclear industry. As a result, the NRC believes that it relied upon findings that were demonstrated in multiple settings and that substantiated general principals regarding the relationship between work hours, circadian variations in alertness, and worker performance. In addition, the NRC focused on findings from industries or settings with similar work environments and job demands. Furthermore, in establishing the specific requirements of the final rule, the NRC gave significant consideration to those factors (e.g., level of monitoring and vigilance activities, use of detailed procedures, automated safety systems) and work practices (e.g., use of three-way communications and task verification) that are unique to the nuclear power plant setting.

Accuracy of Data Provided by Industry

Comments: Many commenters from industry argued that the NRC misinterpreted data from an industry survey covering 1997-1999 and that, as a result, the NRC's conclusions regarding the abuse of overtime are not justified. These commenters argued that the NRC overstated overtime hours because the survey was based on pay records, which do not accurately reflect the actual hours worked [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenters that the NRC's conclusions on industry use of overtime are not justified. The basis for the NRC's conclusions is, in part, a survey developed and distributed by NEI to nuclear power plant licensees. The survey provided clear instructions to include only those hours worked and not to include extra hour compensations for working nights, weekends, or holidays. Specifically, the survey stated: "For the purposes of this survey, *Overtime* is defined as those hours worked in excess of a *nominal* 40-hour work-week. Overtime does not include special compensation for working nights, weekends, or holidays unless they are above and beyond the *nominal* 40-hour week-week." The survey also included an example which demonstrated the nominal 40-hour work-week concept for purposes of calculating overtime in response to the survey. If the instructions were followed by the participants of the survey then overtime hours were not based solely on pay records as suggested by the commenters. At the time the NEI submitted a summary of the data by letter, the NEI made no assertion that participants did not follow the survey instructions.

The NRC also notes that the large number of waivers reported from the survey data could only have occurred with excessive amounts of overtime. If overtime is not being worked, waivers are not necessary. Therefore, if actual overtime was much less than pay reports, the number of waivers would have been overreported.

Furthermore, the NRC notes that industry commenters [Michael Coyle, NEI #49; Daniel Hansen, Individual; Donald Lenski, Individual; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG] have asserted that it is necessary to offer large amounts of overtime to prevent the loss of supplemental workers to other industries that can offer overtime without restriction (see Section 11.3.4, "Limited Access to Supplemental Workers"). The premise of this comment is that industry has historically allowed individuals to work large amounts of overtime during outages. The NRC also notes that extensive use of overtime and deviations from Technical Specification work-hour limits has also been documented in NRC inspection reports and in Information Notice 91-36, Nuclear Plant Staff Working Hours. The NRC believes its conclusions regarding industry use of overtime are well founded and consistent with those of many other stakeholders [Kenneth Kolaczyk #33; Michael Jolley, #4; Anonymous, #27, Anonymous #26], including the International Brotherhood of Electrical Workers which observed, "Some of our facilities have done an outstanding job of ensuring a well rested workforce, while other facilities have simply ignored the recommended work hour limitations or relied on other mechanisms to exceed 72 hours per work week" [Edwin Hill, IBEW].

<u>September 11, 2001 Not Valid Justification for Fatigue Provisions</u>

Comments: One commenter, supported by many commenters, stated concern with the following proposed rule package statement: "The inadequacy of the current regulatory framework for addressing cumulative fatigue became particularly apparent in the months following the terrorist attacks of September 11, 2001." The commenters asserted: "Any condition that unexpectedly requires security posture at the highest level of alert is beyond the normal bounds." The commenters claimed that the stress on security officers following the events of September 11, 2001 is not a valid justification for many of the fatigue rule provisions [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees with the commenters that the conditions following the events of September 11, 2001, were beyond normal bounds and resulted from conditions that were largely beyond the control of licensees. However, the NRC maintains that the fatigue of security personnel during this period demonstrated that individuals at nuclear power plants will experience cumulative fatigue, even when those individuals are working hours that are within the NRC's policy guidelines of working not more than 16 hours in any 24-hour period and not more than 72 hours in any 7-day period. Furthermore, such work hours and cumulative fatigue may result from conditions that are within a licensee's control, as in the case of the extended

outage for the Davis Besse reactor head vessel replacement. As a consequence, these examples indicate an inadequacy of the former regulatory framework for addressing cumulative fatigue because plant technical specifications for the control of work hours generally do not place any clear limit on the period of time individuals can work substantially in excess of a 40-hour workweek (e.g., 60 to 72 hours per week).

Adequacy of Former Rule

Comments: A number of industry commenters questioned a contradiction in the proposed rule *Federal Register* notice language. Specifically, the *Federal Register* notice states that former regulatory requirements, orders and the policy statement are adequate. However, in other parts of the rule package, the NRC claims that new provisions will result in significant improvements in public health and safety. These commenters argued that this contradiction shows that the added layers of requirements are not warranted [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenters that the *Federal Register* notice statements described by the commenter are contradictory. Adequate protection of public health and safety and the common defense and security are ensured through the NRC's Policy on Worker Fatigue, licensee technical specification requirements related to this policy statement, and former regulations. However, opportunities exist to improve the former framework regarding to the enforceability and consistency of the former requirements to ensure that all licensees provide reasonable assurance that workers are able to safely and competently perform their duties.

The NRC's Policy on Worker Fatigue does not prescribe requirements and is therefore enforceable only to the extent that licensees incorporate the guidelines into a license condition or technical specification requirements. Further, for the licensees who have incorporated the NRC's Policy on Worker Fatigue into a license condition or technical specifications, it is difficult for the NRC to enforce the worker fatigue requirements and work hour limits in an effective, efficient and uniform way due to the following factors: the predominantly advisory language in the specifications, the lack of key term definitions, inconsistent levels of detail in the technical specifications from one licensee to another, varying scopes of requirements, inconsistent interpretation of the covered personnel, and inconsistent implementation of the basic measures used to determine whether an individual's work hours are within or above the technical specification limits. The NRC believes that by addressing these and other limitations of the former regulatory framework with respect to managing the effects of fatigue on worker FFD, the rule will provide a substantial enhancement to the protection of public health and safety and common defense and security.

24/7 and 48/14 Rest Break Provisions Not Justified

Comments: Several commenters from industry argued that the NRC's justification for a 24-hour break every 7 days and a 48-hour break every 14 days in the proposed rule *Federal*

Register notice is flawed because the proposed rule package discussed the effects of cumulative fatigue without first establishing that cumulative fatigue would exist when every other provision in the proposed rule were observed. The commenters also stated that the lack of industry-specific evidence did not provide adequate justification for these break provisions [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenters that the *Federal Register* notice for the proposed rule discussed the effects of cumulative fatigue without first establishing that cumulative fatigue would exist when every other provision in the proposed rule were observed. As discussed with respect to the comment "September 11, 2001 Not Valid Justification for Fatigue Provisions," the NRC cited operational experience that indicated cumulative fatigue of nuclear power plant personnel at levels of work hours that are lower than those that would be allowed by the other work hour controls. Specifically, the *Federal Register* notice noted that following the terrorists attacks of September 11, 2001, the NRC began to receive a large number of concerns from nuclear power plant security personnel regarding the number of hours they were being required to work and their ability to remain alert and fit for duty. The NRC subsequently reviewed the work hours of security personnel at nuclear power plants and found that the work hours typically did not exceed an average of 60 hours per week. Similarly, the NRC reviewed work hours of personnel at the Davis Besse plant during an extended outage for a reactor vessel head replacement. Although workers had expressed concerns regarding excessive work hours and fatigue, the NRC found that the individual work hours typically did not exceed the guidelines of the NRC's Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors. However, for both the security personnel and the Davis Besse plant staff, the NRC noted that the individuals had worked substantially more than a 40-hour work week for many weeks.

As a result of reviewing this industry experience and related studies concerning cumulative fatigue, the NRC concluded that it was necessary to include controls in the final rule to provide reasonable assurance that the FFD of individuals is not impaired by cumulative fatigue. However, the NRC revised the requirements to address cumulative fatigue in response to comments concerning the impact of these requirements on scheduling flexibility and ability to meet exigent operational demands. For further information on changes to the final rule, see Section 11.3.4, "Opposition to 24/7 and 48/14 Breaks - § 26.199(d)(2)(ii) and (iii)," of this document.

Federal Motor Carrier Safety Administration Precedent

Comments: Several commenters from industry argued that the NRC's proposed rule package did not indicate the same rigor in review and application of studies conducted outside the power reactor industry as that of the Federal Motor Carrier Safety Administration (FMCSA). According to the commenters, the NRC often extrapolated narrow research findings into overly broad assertions. The commenters recommended that the NRC consider the FMCSA precedent, which is based on sound science and takes an integrated approach to managing both acute and cumulative fatigue. The FMCSA analysis was guarded in its extrapolation of narrow

research findings into broad regulatory findings. For example, in many of the studies, a psychomotor vigilance test is used to monitor for fatigue. However, as pointed by FMCSA, this does not necessarily equate to actual performance of assigned tasks. The commenters also explained that the FMCSA rules do not include long-term quarterly, annual or group work hour limits and research data support this regulatory approach [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenters that it extrapolated narrow research findings into overly broad assertions. Although many scientific studies of fatigue cited by the NRC may have considered a limited range of operational conditions, the NRC did not rely on the results of single studies to draw its conclusions. Rather, the NRC relied upon findings that were demonstrated in multiple settings that substantiated general, widely accepted principles regarding the relationship between work hours, circadian variations in alertness, and worker performance. In addition, the NRC focused on findings from industries or settings with similar work environments and job demands. Furthermore, in establishing the specific requirements of the final rule, the NRC gave significant consideration to those factors that are unique to the nuclear power plant setting (e.g., use of detailed procedures, automated safety systems) and work practices (e.g., self-checking, peer verification of tasks), which in some cases justified less stringent work hour controls than would have otherwise been indicated for work environments with greater sensitivity to fatigue induced errors and lapses in attention.

The NRC also acknowledges that the FMCSA rules for commercial vehicle operators do not include long-term quarterly, annual, or group limits and agrees that there is a stronger technical basis for requirements that focus on individual work hours over shorter periods of time. Accordingly, the NRC revised the requirements of the proposed rule to have all work hour limits applicable to individual work hours. In addition, the NRC revised the rule to require an average number of days off per week, for periods when the plant is operating, or a minimum number of days off in a 15-day period, when the plant is shutdown. These requirements focus the control of work hours on shorter time periods than the group work hour controls which established controls for periods up to 13-weeks.

2. Specific Questions for Public Comment

In the *Federal Register* notice for the proposed rule (70 FR 50616), the NRC sought public comment on several specific issues. These issues are addressed below.

2.1 Proposed Drug and Alcohol Provisions

2.1.1 Proposed Sanction for Attempted Subversion of Testing Process (Issue 1 in *Federal Register* Notice)

Issue: "Proposed § 26.75 in Subpart D would increase the sanctions for certain testing-related actions by requiring that: 'Any act or attempted act to subvert the testing process, including refusing to provide a specimen and providing or attempting to provide a substituted or

adulterated specimen, for any test required under this part must result in permanent denial of authorization,' and 'for individuals whose authorization was denied for 5 years ... any subsequent violation of the drug and alcohol provisions of an FFD policy must immediately result in permanent denial of authorization.' The NRC requests comments regarding these proposed changes specifically when compared to the 5-year ban available through the agency's enforcement policy for other acts of deliberate misconduct."

Comments: Several commenters agreed with the proposed requirement and stated that many licensees implemented policies of permanent denial of authorization as a sanction to deter subversion of the testing process. One commenter, supported by other comments, noted that attempted subversion must also be considered by the reviewing official during the trustworthiness and reliability decision required in 10 CFR § 73.56(b). [Randy Cleveland, NMC; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC has adopted the proposed requirement in the final rule. Section 26.75(b) of the final rule states that 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. Also, § 26.75(g) of the final rule states that for individuals whose authorization was denied for 5 years, any subsequent violation of the drug and alcohol provisions of an FFD policy must immediately result in permanent denial of authorization.

2.1.2 Need for "Shy-Lung"' Procedure (Issue 2 in *Federal Register* notice)

Issue: "Proposed § 26.119 [Determining "shy" bladder] would establish a process for determining whether there is a medical reason that a donor is unable to provide a urine specimen of at least 30 mL. The NRC added this proposed section in response to stakeholder requests and adapted the process from the DOT's Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR 40.197). The DOT Procedures also include processes for determining whether there is a medical reason that a donor is unable to provide a specimen of oral fluids (49 CFR 40.263) or a breath specimen (49 CFR 40.265) of sufficient quantity to support alcohol testing. The NRC invites comments on whether the NRC should consider incorporating these processes for insufficient oral fluids and breath specimens in Part 26."

Comments: Several commenters responded to the request for public comments on whether the NRC should consider incorporating these procedures in Part 26. The commenters stated that, based on many years of experience with the former rule requirements, industry sees no need for this provision because there are few, if any, instances where it would apply [Susan Techau, Exelon; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

One commenter suggested that the alcohol collector qualifications in § 26.85(b) are sufficient to address any "shy lung" issues [Susan Techau, Exelon].

NRC Response: Because there is no evidence of a problem requiring a solution in this matter, the NRC has not included these procedures in the final rule.

2.1.3 Forensic Toxicologist (Issue 3 in *Federal Register* notice)

Issue: "Proposed § 26.31(d)(3)(iii)(C) would permit licensees and other entities to specify more stringent cutoff levels for the panel of drugs for which testing is required under this part without informing the NRC within 60 days and without obtaining the written approval of the NRC. Proposed § 26.31(d)(1)(i)(D) and (d)(1)(ii) would also permit licensees and other entities to test for drugs and drug metabolites in addition to those specified in proposed § 26.31(d)(1) without informing or obtaining the written approval of the NRC. However, the proposed paragraphs would require that the scientific and technical suitability of the more stringent cutoff levels and of the assays and cutoff levels used to test for additional drugs or drug metabolites must be evaluated and certified, in writing, by a qualified, independent forensic toxicologist. Certification by a forensic toxicologist would not be required in three circumstances: (1) if the HHS issues more stringent cutoff levels in the HHS Guidelines and the licensee or other entity adopts the revised HHS cutoffs; (2) if the HHS Guidelines are revised to authorize use of the assay in testing for the additional drug or drug metabolites and the licensee or other entity uses the cutoff levels established in the HHS Guidelines for the drug or drug metabolites; and (3) if the licensee or other entity received written approval from the NRC for the lower cutoff levels and/or for testing for the additional drugs or drug metabolites, under former Section 1.1(2) in Appendix A to Part 26. The proposed paragraphs differ from the former requirement in Section 1.1(2) of Appendix A to Part 26. The NRC requests comments regarding these proposed changes."

No comments addressed this issue. However, one commenter referenced proposed 26.31, and that comment is discussed in Section 4.6.4 of this document.

2.1.4 Changes to Opiate Testing (Issue 4 in *Federal Register* notice)

Issue: "Proposed §§ 26.133 and 26.163 would raise the cutoff levels for initial and confirmatory tests for opiates from 300 nanograms (ng) per milliliter (mL) to 2,000 ng/mL. The proposed rule would also require testing for 6-acetylmorphine (6-AM), a metabolite that comes only from heroin, using a 10 ng/mL confirmatory cutoff level for specimens that tested positive on the initial test. The proposed cutoff levels and new test would be consistent with those used by HHS and DOT, and would reduce the number of specimens in Part 26 programs that test positive for opiates at an HHS-certified laboratory but are subsequently determined to be negative by the MRO after consultation with the donor. The NRC invites comment on these proposed changes."

Comments: Several commenters addressed the proposed provision to raise the cut-off levels for initial and confirmatory tests for opiates from 300 nanograms (ng) per mililiter (mL) to 2,000 ng/mL. They stated that industry strongly supports the proposed requirement, as it would increase the efficiency of FFD programs [Pete Defilippi, Westinghouse Electric Company; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA;

Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC has retained the proposed rule cut-off levels and new test (as discussed above) in the final rule.

2.1.5 Specimen Validity Testing (Issue 5 in *Federal Register* notice)

Issue: "In proposed §§ 26.131, 26.137, 26.161, and 26.167, the NRC would add new requirements for validity testing of urine specimens to detect specimens that may have been adulterated, substituted, or diluted. The new requirements are adapted from practices the HHS published in the *Federal Register* on April 13, 2004 (69 FR 19643) as a final rule. The NRC invites public comment on the following issues related to the proposed validity testing requirements."

Comments: One commenter, supported by many commenters, addressed the proposal to add new requirements for validity testing of urine specimens to detect specimens that may have been adulterated, substituted, or dilute. The commenter stated that validity testing requirements should be consistent with established HHS criteria and should not be more stringent [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: Comments received on validity testing are addressed in Sections 8 and 9 of this document regarding Subparts F and G, respectively.

No comments were received on Issues 5a and 5b in *Federal Register* Notice.

2.1.6 MRO Training (Issue 6 in *Federal Register* notice)

Issue: "Proposed § 26.183(a) requires that 'The MRO shall be knowledgeable of this part and of the FFD policies of the licensees and other entities for whom the MRO provides services.' The NRC invites comments on whether Part 26 should establish specific training requirements for the MRO related to this part and the licensee's or other entity's programs for which the MRO provides services."

Comments: Several commenters addressed the issue of whether Part 26 should establish specific training requirements for the MRO related to this part and the licensee's or other entity's programs for which the MRO provides services. The commenters stated that the NRC should not regulate MRO training because MROs are licensed by the states and will be certified as required under the proposed rule. Therefore, additional regulation is not required to ensure that MROs understand licensee policies and procedures [Randy Cleveland, NMC; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC received no public comments supporting the need for specific training requirements for the MRO related to this part and the licensee's or other entity's programs for which the MRO provides services. Therefore, the NRC has retained § 26.183(a) as proposed.

2.1.7 Single or Split Specimen (Bottle B) Retesting (Issue 14 in *Federal Register* notice)

Issue: "Proposed §§ 26.135(b) and 26.165(a)(4) and (b)(1) would prohibit licensees and other entities, the MRO, and the NRC from initiating testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission. The NRC is considering an alternative approach that would permit a licensee or other entity to initiate testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission only if all of the following conditions are met: (1) the first results from testing the specimen were confirmed as non-negative by the MRO; (2) the donor has requested a review under proposed § 26.39 or initiated legal proceedings; and (3) the testing is conducted in accordance with proposed § 26.165(c)–(e), as applicable. Under either the proposed provisions or the alternative approach, the proposed rule would require the licensee or other entity to administratively withdraw the donor's authorization until the results from Bottle B or the retest results are available and to rely only on those results in determining whether the licensee or other entity would be required to take management actions or impose sanctions on the donor. The NRC is seeking an appropriate balance between protecting donors' rights to privacy and due process under the rule and the protection of public health and safety and the common defense and security, and invites public comment on the proposed and alternative approaches."

Comments: One commenter, supported by many commenters, addressed administrative withdrawal of the donor's authorization until the results from Bottle B or the retest results are available. The commenter recommended that the NRC consider the protection of public health and safety and the common defense and security as the primary goal. The commenter further argued that no provisions in the proposed rule negatively impacted the donor's rights, and it appears that only the donor, the MRO, and one employee of the licensee or other entity know the rationale for the administrative withdrawal of the donor's authorization. Thus, it is difficult for industry to envision a smaller number of people with this knowledge, and the donor's right to privacy is protected as much as possible. Therefore, the commenter supported this aspect of the proposed rule [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC addressed comments received on initiating testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission in Section 8.8 of this document with respect to comments regarding § 26.135(b) and in Section 9.8.1 of this document with respect to comments regarding § 26.165(a)(4).

2.2 Rulemaking Issues

2.2.1 Validity Screening Tests (Issue 7 in *Federal Register* notice)

Issue: "The NRC is considering incorporating future changes to the draft HHS Guidelines that were published as a proposed rule for public comment in the *Federal Register* on April 13, 2004 (69 FR 19672) relating to the permission in this proposed Part 26 rule for licensees and other entities to use non-instrumented validity tests to determine whether a urine specimen appears to be adulterated, diluted, or substituted and requires further testing at an HHS-certified laboratory. Proposed Part 26 would permit licensees and other entities to use these devices for validity screening tests, in lieu of the instrumented validity testing required in the April 13, 2004, final version of the HHS Guidelines. Should any changes be made to those draft HHS Guidelines between issuing this proposed rule and issuing the final 10 CFR Part 26 rule, those changes would be considered for incorporation. Any comments related to the potential incorporation of those changes are of interest."

Comments: Several commenters from industry addressed the incorporation of future changes to the draft HHS validity testing guidelines relating to the permission in the proposed rule for licensees and other entities to use non-instrumented validity tests to determine whether a urine specimen appears to be adulterated, dilute, or substituted and requires further testing at an HHS laboratory. The commenters argued that the NRC has offered no justification for bypassing its own processes in the brief discussion of this issue. Thus, they stated that changes to HHS guidelines should not be incorporated into the NRC regulations without going through a complete rulemaking process [Randy Cleveland, NMC; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: In the proposed rule, the NRC stated that it would consider any changes to the draft HHS Guidelines for incorporation in the final FFD rule. HHS has not issued a final rule, and no changes to the draft HHS Guidelines have occurred. Therefore, the NRC is not adopting any changes to the draft HHS Guidelines in the final FFD rule.

2.2.2 Adopting Future Changes to the HHS Guidelines without Backfit (Issue 13 in *Federal Register* notice)

Issue: "The NRC is considering amending 10 CFR 50.109, 70.76, and 76.76 to exclude certain future changes to Part 26 from current backfit requirements. The scope of the exclusions would be limited to only those changes to Part 26 that would be necessary to incorporate relevant revisions to the HHS Guidelines when they are published by HHS as final rules. Examples of changes to the HHS Guidelines that may be incorporated into Part 26 in future rulemakings may include, but would not be limited to (1) adopting changes to the cutoff levels established in the Guidelines; (2) the addition or deletion of drugs and adulterants for which testing would be required; and (3) changes in the specimens, instruments, or assays used in drug and validity testing. The NRC requests comment on excluding such future changes to Part 26 from backfit analysis requirements."

Comments: Several commenters addressed the proposal to amend 10 CFR 50.109, 70.76 and 76.76 to exclude future changes to Part 26 from former backfit requirements. The commenters did not support this proposal and advocated making no changes to § 50.109, § 70.76, and § 76.76 regarding the former backfit requirements. One commenter, supported by many commenters, stated that examples of the changes the NRC would like to make without backfit analyses, given in the comment solicitation, do not appear to provide "… a substantial increase in the overall protection of the public health and safety or the common defense and security …" described in §§ 50.109, 70.76 and 76.76. Therefore, lacking the "substantial increase," industry argued that the NRC should not change these subsections to allow revision of regulations without determining whether the direct and indirect cost of the suggested changes are actually cost beneficial. Further, the commenter argued that the proposed § 26.31(d)(1)(i) allowed licensees and other entities to add other drugs to the panel of substances for testing, such as those popular in their local geographical areas, and to establish appropriate cutoff levels for any additional substances for which testing will be conducted. Thus, industry stated that there is no need to revise §§ 50.109, 70.76 and 76.76, given the proposed rule requirements. Finally, the commenter argued that the NRC has offered no justification for bypassing its own processes in the brief discussion of this issue, and the examples given are not inclusive so the scope of possible changes is boundless [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; Nick DePietro, First Energy; F.G. Burford, Entergy].

NRC Response: Based on the commenters' objections and the lack of support to amend 10 CFR 50.109, 70.76 and 76.76 to exclude future changes to Part 26 from former backfit requirements, the NRC has decided not to pursue modification of the applicability of current backfit requirements relative to Part 26 in the final rule.

2.2.3 Reporting Burden (Issue 15 in *Federal Register* notice)

Issue: "The NRC is seeking comment regarding the administrative reporting burden that the proposed rule provisions would create. Provide any comments as described in Section XIII, Paperwork Reduction Act Statement, of this notice."

Comments: One commenter stated that the reporting requirements associated with the drug and alcohol part of the rule are unnecessary for the NRC to regulate the industry or to protect human health and safety. However, the commenter supported the annual reporting requirements for the purpose of assessing the popularity of specific drug sets. Ultimately, however, the commenter supported the reporting requirements [Jim Davis, NEI].

NRC Response: The NRC considered the comment, but concluded that the reporting requirements associated with the drug and alcohol testing components of the rule are necessary to provide information from which the NRC can monitor the effectiveness of the drug and alcohol testing activities.

2.3 Proposed Fatigue Provisions

2.3.1 Rest Break Provisions (Issue 8a in *Federal Register* notice)

Issue: "Proposed Subpart I, Managing Fatigue, includes many requirements related to worker fatigue at nuclear power plants. The NRC is especially interested in comments on the following provision: Proposed § 26.199(d)(2)(ii) and (d)(2)(iii) would require licensees to provide individuals who are subject to the proposed work hour limits with at least one 24-hour rest break in any 7-day period and at least one 48-hour rest break in any 14-day period, except during the first 14 days of any outage, as well as certain other circumstances for security force personnel."

Impact on 8-hour Shifts

Comments: Several commenters expressed concern about the potential disruption in operations, such as the provision's potential impact on 8-hour shifts and consecutive working days, due to the rest breaks in § 26.199(d)(2)(ii) and (iii). They argued that these rest break provisions do not provide the necessary flexibility and that it would be impossible to build a proper 8-hour rotation without violating the regulations as written. Commenters argued that in response to the inflexible break requirements, licensees with 8-hour shift rotations will adopt 12-hour shift rotations [John Fee, SCE ; Anthony Rizzo Jr., Salem-Hope Creek; Michael Coyle, NEI #49; Todd Newkirk, IBEW; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: In response to this and related comments, the NRC has conducted further analysis of the proposed rule provisions and agrees that the proposed rest break provisions could have significantly disrupted current shift scheduling practices for 8-hour shifts. The NRC has modified the rest break provisions in the final rule to provide substantial additional flexibility. The requirements of the final rule allow licensees greater flexibility in the number of days between days off and whether the days off are provided consecutively or distributed. This flexibility enables licensees to more readily design schedules that meet operation demands while insuring an amount of time off comparable to that which would have been required by the proposed rule. Accordingly the final rule provides comparable assurance that cumulative fatigue from inadequate rest does not impair the ability of workers to safely and competently perform their duties. The revised break and day off provisions are in § 26.205(d)(2)-(5) of the final rule.

2.3.2 Waivers of Work Hour Controls (Issue 8b in *Federal Register* notice)

Issue: "Proposed Subpart I, Managing Fatigue, includes many requirements related to worker fatigue at nuclear power plants. The NRC is especially interested in comments on the following provision: Proposed § 26.199(d)(3) would permit licensees to waive individual work hour limits and rest break requirements only in circumstances in which it is necessary to mitigate or prevent a condition adverse to safety, or to maintain the security of the facility. Proposed § 26.197(e)(1) would require licensees to report the number of waivers granted in a year."

Waivers do not Effect Prior Hours Worked

Comments: One commenter at the September 21, 2005, public meeting disagreed with the provision, stating that waivers have no value when received after the extra hours have been worked, and they do not prevent the utilities from forcing workers to work above the limits [Anthony Rizzo Jr., Salem Hope Creek].

NRC Response: The NRC disagrees with the commenter's assertion that waivers have no value. It is not the NRC's intention that waivers be granted after the fact to account for any excess hours that have already been worked above the work hour limits. As stated in § 26.207(a)(1)(ii) of the final rule, a waiver can only be granted subsequent to a supervisor performing a fatigue assessment. A waiver may be granted only if it is necessary to mitigate or prevent a condition adverse to safety or to maintain the security of the facility and only to address circumstances that the licensee could not have reasonably controlled. In such cases, a fatigue assessment must be performed before the additional hours are worked in order to verify that there is reasonable assurance the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver may be granted. Therefore, the NRC retains the provisions for waiving work hour controls in § 26.207 of the final rule.

Flexibility of Waivers

Comments: Several commenters from industry argued that situations will arise where a waiver is appropriate for the situation even though safety is not challenged. According to the commenters, management should have the ability to grant waivers in these situations. [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenters' concern that granting a waiver is appropriate in situations where safety is not challenged. The potential for worker fatigue in conditions that would require a waiver is substantial. Therefore, the NRC cannot conclude that licensees can reasonably justify the performance of activities on systems, structures, or components (SSC's) that a risk-informed evaluation process has shown to be significant to public health and safety or the performance of functions that are essential for effective response to a fire, plant emergency, or implementation of the site security plan by individuals who have worked hours in excess of the work hour limits on the basis that granting the waiver would not have an adverse impact on safety or security. If the rule were changed for situations such as the example provided above it would be inconsistent with the NRC's goal of providing reasonable assurance that an individual will be able to safely and competently perform his or her duties, and would reduce the likelihood of fatigue-related errors, which could adversely affect public health and safety or the common defense and security. Therefore, the NRC has retained this provision as § 26.207(a)(1)(i) in the final rule.

Agreement with Waiver Provision

Comment: However, another commenter agreed with the NRC's expectations that waivers would only be granted "to address circumstances that the licensee could not have reasonably controlled." The commenter stated that the two circumstances where a waiver can be allowed as proposed in § 26.199(d)(3)(i)(A) – to mitigate or prevent a condition adverse to safety or to maintain the security of the facility – appear to be reasonable and appropriate. The commenter agreed that all use of waivers should be reported to and tracked by the NRC for analysis of unsafe or inappropriate patterns and should be made available to the public where deemed appropriate [Darrel Drobnich, NSF].

NRC Response: The final rule retains the criteria for authorizing a waiver that was specified in § 26.199(d)(3)(i)(A) of the proposed rule. These criteria are in § 26.207(a)(1) and (a)(2) of the final rule. The final rule also retains the requirement for an annual report summarizing the licensee's use of waivers from the work hour limits. The reporting requirement is in § 26.203(e) of the final rule.

2.3.3 48-hour/week Collective Work Hour Limits (Issue 8c in *Federal Register* notice)

Issue: "Proposed Subpart I, Managing Fatigue, includes many requirements related to worker fatigue at nuclear power plants. The NRC is especially interested in comments on the following provision: Proposed § 26.199(f) would prohibit job duty groups that are subject to work hour controls from working more than a maximum collective average of 48 hours per person per week, except during the first 8 weeks of any outage, as well as certain other circumstances for security force personnel."

Removal of Group Work Hour Limits

Comments: One commenter, supported by many commenters, suggested removing the group work hour limits completely for individuals other than security personnel because cumulative fatigue is adequately addressed through many other provisions (layers) built into the rule, such as: inherent alertness abilities that individuals must exhibit, supervisory overviews, individual work hour limits, and rest break provisions. [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG; Anthony Rizzo Jr., Salem Hope Creek; Joe Bauer, Exelon; Jim Davis, NEI].

NRC Response: The NRC disagrees with the commenters that the proposed rule adequately addressed cumulative fatigue through other provisions or layers built into the rule. However, the NRC simplified the rule by eliminating the 48-hour break requirement in the proposed § 26.199(d)(2)(iii) and the collective work hour limits in proposed § 26.199(f) and replaced them with requirements for minimum days off per week averaged over a shift in § 26.205(d)(3) and minimum days off in 15 day blocks in § 26.205(d)(4) of the final rule. This issue is further discussed in detail in Section 11.3.6 of this document. Therefore, the NRC has revised the rule and maintains provisions to address cumulative fatigue on an individual basis and will therefore

provide more uniform assurance of worker fatigue.

2.3.4 Alternate Work-Scheduling Examples (Issue 9 in *Federal Register* notice)

Issue: "As a means of determining the flexibility of the proposed rule work hour controls in § 26.199, the NRC is seeking public comment on work-scheduling examples that meet the requirements of the proposed rule and whether such schedules afford a reasonable degree of flexibility to licensee management."

Request for Prototype 8-hour Shift Schedule

Comment: One commenter requested that the NRC provide a prototype 8-hour rotation because industry could not resolve an alternative shift to fit all the provisions [Todd Newkirk, IBEW].

NRC Response: In response to this and related comments, the NRC conducted further analysis of the proposed rule provisions and agreed that the proposed rest break provisions could significantly disrupt current shift scheduling practices for 8-hour shifts. The NRC has modified the rest break provisions in the final rule to provide substantial additional flexibility in this regard, while providing comparable assurance that cumulative fatigue from inadequate rest does not impair the ability of workers to safely and competently perform their duties. The revised break and day off provisions are in § 26.205(d)(2)-(d)(5) of the final rule.

Example of Shift Based on 24-hour Basis

Comment: One commenter offered an alternative work-scheduling example in response to NRC's request for examples that meet the requirements of the work hour controls in § 26.199 and afford a reasonable degree of flexibility to licensee management. The commenter believed that all schedules and shift lengths need to be based firmly on a 24-hour basis. The commenter also specified additional limits for shift overlap (or turn-over), for currency training and administration, and for overtime. The commenter suggested requirements for the use of fixed (non-rotating) shifts, rapid rotation (no more than 3 contiguous work days on the same shift) or slow rotation (no fewer than 28 contiguous work and free days on the same shift), and, for 8- and 12-hour shifts [Darrel Drobnich, NSF].

NRC Response: The NRC agrees with the concepts provided by the commenter, however the NRC considers the comments to be examples of a good practices that licensees can implement consistent with the requirements of § 26.205(c) of the final rule. The NRC intends to consider the commenter's recommendations for incorporation in the implementation guidance for the final rule. Therefore, no additional changes to the final rule are warranted in response to this comment.

2.3.5 Outage Work Scheduling (Issue 10 in *Federal Register* notice)

Issue: "The NRC is seeking comment on the exclusions from certain work hour controls that would be allowed by proposed § 26.199(d)(2)(iii), (f)(1) and (f)(2) during maintenance and refueling outages, and how these exclusions could affect human error. The NRC is specifically interested in whether a more precisely defined rule scope with more limited outage exclusions

would better meet the stated objectives of the rule."

Definition of an Outage

Comment: One commenter suggested that the rule explicitly define an outage, and asked if "package walk-downs and package preps" are considered part of the outage. The commenter also argued that because outages are planned in advance and workers have a chance to prepare for them, it is unreasonable that workers should be expected to work extra hours during an outage [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenter suggesting that the term "outage" needs to be defined. For the purposes of Part 26, the final rule defines the term "unit outage" to mean that the reactor unit is disconnected from the electrical grid. In response to the commenter's question of whether "package walk-downs and package preps" are considered part of a unit outage, these activities would be considered part of an outage only if they are performed on a unit that is disconnected from the electrical grid.

Work Hour Exclusions During Outages

Comment: One commenter expressed confusion about the rationale for waiving group work hour controls for the first 8 weeks of outages. The commenter did not agree that employees should be encouraged to work more hours during times when significant maintenance and operational functions such as refueling, testing of systems, repair of failed components and structures, plant modifications and regulatory inspections are undertaken. Therefore, the commenter requested that the NRC reconsider all provisions that allow relaxed work hour controls during outages, especially during planned outages [Darrel Drobnich, NSF].

One commenter stated that intensely focused outage periods are a very effective means of assuring and improving overall safety. The commenter further explained that scientific evidence and plant experience show that "super crews" working six 12-hour shifts have been effective during outage periods up to ten weeks with increased plant safety and no increase in performance errors. The commenter also stated that the proposed rule would have impacted 15 percent of the plant outages in 2004, and it will directly impact outages that support major plant improvements in the future. Therefore, the commenter argued that the proposed rule does not need to be more restrictive than the former rule [David Ziebel, EPRI].

NRC Response: The NRC disagrees with the commenter that the NRC should reconsider all provisions that allow relaxed work hour controls during outages, especially during planned outages. Although it would be advantageous for fatigue management to level load all activities on systems, structures, and components (SSC's) that a risk informed process has shown to be significant to public health and safety or activities that are essential for effective response to a fire, plant emergency, or implementation of the site security plan, the nature of work in the nuclear industry requires that work often must be completed during an outage in order to ensure worker safety and public health and safety. The NRC recognizes that individuals are capable of working with limited rest without degraded performance for short periods of time. In addition, the NRC recognizes that plant outages are unique, relatively short-term, and involve levels of activity that are substantially higher than most non-outage operating periods. Therefore, the NRC considers it appropriate to allow flexibility within the work hour

requirements to accommodate limited periods of more intensive work schedules.

In developing the minimum day off requirements for the final rule, the NRC also considered scheduling practices during outages and determined it could not practically extend the same approach used in § 26.205(d)(3) of the final rule because those requirements are based on shift cycles which provide a defined period for implementing the average day off requirement. The length of outages and increased threat conditions are variable and therefore do not provide a consistent averaging period. The NRC further considered establishing the requirement as a minimum 3 days off in any 14-day period because that requirement would have been similar to the requirements it would have replaced. However, the NRC ultimately determined that 3 days off in 15 day periods provided licensees the flexibility of establishing 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 without an excessive number of consecutive 12-hour shifts. 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), nor does the NRC believe it is consistent with providing reasonable assurance that individuals are fit to perform their duties. The minimum day off requirement of § 26.205(d)(4) provides an important protection against cumulative fatigue for individuals who work during unit outages, particularly those working extended periods.

The NRC also disagrees with the commenter that the final rule does not need to be more restrictive than the former rule with regards to a “super crew” working six consecutive 12-hour shifts for up to ten weeks. 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. 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 retains requirements in the final rule which allow for a relaxation from work hour controls for the first 60 days of an outage.

Increase Work Hour Exclusion During Outages to 10 Weeks

Comments: One commenter, supported by many commenters, argued that the outage exclusion should be increased from 8 weeks to 10 weeks. According to the commenter, this change will provide adequate time to complete extended outages involving major equipment replacements. The commenter also claimed that its analysis of human performance data also supports this recommendation because in each outage evaluated, there was a downward trend in human performance errors as the outage progressed [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenter suggesting an increase from 8 weeks to 10 weeks for the plant outage exclusion from work hour controls in § 26.199(f). In

reviewing the frequency of outages, by duration, the NRC found that it would be necessary to increase the exclusion period substantially to address a marginal number of additional outages of longer lengths. This increase in the exclusion period would substantially increase the period of time that individuals would be working extended work hours 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, a rate of 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.

The NRC also disagrees with the conclusion that the commenters' analysis of human performance data supports the recommendation to increase the outage exclusion to 10 weeks because in each outage evaluated there was a downward trend in human performance errors as the outage progressed. The conclusions from that study were subjective and based on visual inspections of graphs of condition reports (CRs) compiled during the outage. The number of CRs were in at least one case actually higher in week 13 compared to week 1. Therefore, the conclusions of the report do not withstand a rigorous analysis and are not evidence that the proposed rule should revised.

However, the NRC has included a provision in the final rule (§ 26.205(d)(6)) that permits licensees to extend the outage exception period by 7 days for each 7-day period during the outage an individual works not more than 48 hours. This provision accommodates longer outages when it is justified by the work history of the individual containing adequate recovery periods. Therefore, the NRC has responded to the commenters' concern in a manner that should not increase cumulative fatigue.

2.3.6 Alternatives for Addressing Cumulative Fatigue (Issue 11 in *Federal Register* notice)

Issue: "The NRC is seeking public comment on alternatives to the group work hour controls that could also address cumulative fatigue, such as individual work hour limits based on a longer term (e.g., monthly or quarterly)."

Comments: Several commenters from industry expressed opposition to long-term individual work hour limits to address cumulative fatigue as an alternative to the group work hour controls. They stated that these limits represent an unnecessary and indefensible layer of regulatory requirements [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenters that requirements to address cumulative fatigue are unnecessary or indefensible, as discussed in the NRC's response to comments on "Collective Work Hour Limits" in Section 11.3.6 of this document. However, the NRC agrees with these commenters' opposition to the use of long-term individual work controls to address cumulative fatigue as an alternative to the group work hour controls (i.e., collective

work hour limits) of the proposed rule. Accordingly, the NRC did not replace the collective work hour limits with long term individual limits. Rather, the NRC eliminated the collective work hour limits and the requirement for a minimum 48-hour break in any 14-day period and addressed cumulative fatigue in the final rule through requirements for a minimum number of days off per week, averaged over a shift cycle, in § 26.205(d)(3), and minimum days off in 15 day blocks, in § 26.205(d)(4) and (d)(5).

2.3.7 Defining Job Duty Groups (Issue 12 in *Federal Register* notice)

Issue: "Proposed § 26.199(a) would require any individual who performs duties within specified job duty groups to be subject to the work hour control provisions in § 26.199. Other individuals, beyond those specified within the scope of § 26.199(a), might substantially impact the outcome of risk-significant work, such as certain engineers (e.g., Shift Technical Advisors). The NRC requests comment on the inclusion of other individuals in the scope of § 26.199(a). The NRC is also seeking comments on an alternative approach for identifying the specific job functions that would be subject to these requirements. Specifically, the NRC is interested in whether, as an alternative, the scope should instead be structured to define attributes of the job functions (e.g., time-critical nature of decisions needed to ensure public health and safety, operational control of risk-important equipment) that would fall within the scope of the proposed work hour control provisions in §26.199. Under such an alternative, the licensee would then be required to identify the specific job functions that fit the defined attributes."

Scope is Appropriate

Comment: One commenter stated that there is not necessarily a need to broaden the scope of individuals subject to work hour controsl; the groups that are already defined are the critical groups [Dana Millar, Entergy].

NRC Response: The NRC agrees with the commenter that the scope is appropriate. The scope includes those job functions that the NRC considers to have the most potential for fatigue to degrade the protection of public health and safety and common defense and security. Although broader application of the work hour limits to other job functions could provide additional safety and security benefits, it is not clear that the additional benefit that could be achieved would justify the substantial cost of broader application of the work hour limits.

Definition of "Directing"

Comments: Several commenters from industry suggested that the NRC clearly define what is meant by the term "directing" in § 26.199(a). The commenters expressed concern that this phrase, along with the definition of "directing" in § 26.5 will subject engineering personnel to work-hour controls, thus increasing the recordkeeping burden on industry [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees with the commenters that NRC should clarify the definition

of the term “directing.” Individuals who are responsible for the correct performance of activities on SSCs that a risk-informed process has shown to be significant to public health and safety or functions that are essential for an effective response to a fire, plant emergency, or implementation of the site security plan should be subject to work hour controls, including engineering and technical support personnel.

The revised definition of “directing” is presented in § 26.5 of the final rule. The revised definition clarifies 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 revised definition more clearly focuses on activities that have the potential to substantively and immediately effect safety.

The definition of "directing" in § 26.5 also applies to the MRO's oversight of MRO staff. In the case of an MRO's direction of MRO staff, the NRC contends that this oversight is necessary because the MRO's direction has the potential to substantively and immediately affect the integrity of the FFD program.

Limit Group Hours to Security Personnel

Comments: Several commenters from industry agreed that armed security officers, anyone carrying a weapon, armed responders, watch persons, and central alarm station (CAS) and secondary alarm stations (SAS) operators should be included in the critical group subject to these provisions [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG]

NRC Response: In response to the comments stating concerns regarding the burden and potential effectiveness of the group work hour controls (i.e., collective work-hour limits) , discussed in Section 11.3.6 of this document, the NRC has replaced the collective work hour limits with individual work hour controls that are applicable to individuals including those security personnel described by the commenters.

Specify Job Functions Instead of Job Duty Groups

Comments: Commenters also suggested that the NRC develop a clear set of job functions which would warrant the added work hour restrictions. They argued that such performance-based criteria would help industry in deciding which individuals must be subjected to work hour restrictions [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger,

NRSG].

NRC Response: The NRC agrees with the commenters that performance-based criteria for the scope of individuals subject to the work hour controls is an appropriate objective and has attempted to establish the requirements accordingly. In this regard the NRC notes that the NRC did not define the scope of individuals subject to the work hour limits in terms of job titles but rather in terms of functions important to the protection of public health and safety and the common defense and security. As an example, the work hour controls do not apply to all operators or maintenance personnel, but rather only to those who operate or maintain systems, structures, or components that a risk-informed evaluation process has shown to be significant to public health and safety. Although the NRC acknowledges that the scope could be defined using more elemental criteria, the NRC notes that the commenters further stated "based on the years of discussions involved in the development of the proposed rule, there appears to be little chance of achieving agreement on this type of performance-based criteria" (Mike Coyle, NEI, #49). Defining the scope in terms of more elemental performance-based criteria presents substantive challenges and may not markedly improve the effectiveness of the rule and may in fact contribute to additional challenges to clear and consistent interpretation of the scope of individuals subject to the work hour controls. Accordingly the final rule retains the approach developed with substantive stakeholder interaction for defining the scope of individuals subject to the work hour controls.

Maintenance Personnel

Comment: One commenter at the September 21, 2005, public meeting stated that industry is struggling with identifying and categorizing maintenance personnel. Industry found that some maintenance organizations are a single multi-tasked organization and others are cross-functional organizations that perform both safety and non-safety related tasks. Therefore, industry finds it difficult to identify a maintenance individual as either safety or non-safety personnel and accordingly categorize them into job duty groups [Jim Davis, NEI].

NRC Response: The NRC agrees that categorizing maintenance personnel could be difficult. The NRC has decided that maintenance personnel are subject to work hour requirements if they are maintaining, or providing onsite direction of maintenance of systems, structures, and components that a risk informed evaluation process has shown to be significant to public health and safety regardless of the organizational structure of the maintenance personnel.

Supplemental Workers

Comment: One commenter stated that transient workers should be included under individual work hour controls, but it would be impractical to include such workers in collective work hour controls [Darrel Drobnich, NSF].

NRC Response: The NRC agrees with this commenter and notes that the final rule does not retain requirements for collective work hour limits. All work hour limits of the final rule are applicable on an individual basis, including § 26.205(d)(4) of the final rule. This requirement ensures that individuals, including transient workers, receive a minimum of 3 days off in each consecutive 15-day period of a unit outage. The minimum day-off requirement of § 26.205(d)(4) will support the final rule's objective of reasonable assurance that transient

workers who perform activities on SSCs that a risk-informed process has shown to be significant to public health and safety or functions that are essential for effective response to a fire, plant emergency, or implementation of the site security plan are not impaired from cumulative fatigue.

Information Sharing

Comment: One commenter agreed with the NRC's proposal as outlined in Subpart C to require licensees and other entities to collect and share greater amounts of information than under the former rule, subject to the protections of individuals' privacy specified in proposed § 26.37. The commenter argued that facilities should be required to share information on the work hours of transient workers at any facility to ensure they that do not exceed the individual work hour control limits [Darrel Drobnich, NSF].

NRC Response: The NRC disagrees with the commenter that licensees should be required to share information on the work hours of transient workers. Although sharing of work hour information among licensees would provide licensees more complete information concerning the work hours of transient workers, such information would not include the hours that these individuals may work for other employers outside of the nuclear power industry. As a result, the accuracy of the information with respect to an individual's total work hours would be substantially diminished and the administrative burden and associated costs would be substantial. As a result, the NRC does not the believe that the potential benefit for management of worker fatigue of sharing this information justifies the significant costs that would be incurred by licensees.

3. Subpart A: Administrative Provisions

3.1 Purpose (§ 26.1)

No comments addressed this section.

3.2 Scope (§ 26.3)

Clarification of § 26.3

Comments: Many commenters addressed the scope of the proposed rule. The majority of these comments focused on § 26.3 and the lack of clarity therein. One commenter at the September 21, 2005, public meeting stated that proposed § 26.3 sufficiently defined the scope until § 26.3(e), which addressed requirements for entities performing construction activities, after which the rule describes program elements and requirements. Industry expressed confusion resolving the requirements here (such as in (e)(1)), "comply with § 26.23, 41 and 189") with the performance objectives described elsewhere in the proposed rule. The commenter also mentioned that industry had difficulty navigating to 10 CFR 52.103 and 50.10(e)(3) and several of the other references mentioned in the language of § 26.3(e) [Jim Davis, NEI].

NRC Response: The NRC agrees with the commenters that the rule language in proposed § 26.3 was unclear about the requirements in Part 26 that apply to each licensee and entity who

is subject to the rule. Therefore, the NRC has reorganized and clarified the provisions in § 26.3 of the final rule and added a description of the licensees and other entities to whom particular sections and subparts of the rule apply (e.g., §§ 26.73 and 26.709).

FFD for Construction

Comments: Several commenters from industry argued that proposed § 26.3(e) was not appropriately written for new plant construction sites [Jim Davis, NEI #48; Tom Houten, NEI; Peter Fowler, Duke Energy; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

The commenters stated that it was unclear what type of FFD program the NRC expect for new plant construction sites. The commenters argued that, by referring to specific sections of the rule which must be met by complying with other sections of the rule, the NRC seemingly applied the entire rule to new construction sites. The commenters stated that it would be difficult for industry to ensure compliance with the referenced sections of the rule without applying the entire rule.

They argued that new plant construction sites should be treated in the same manner as other major, non-nuclear construction sites, which have industrial drug and alcohol programs. The commenters argued that, until fuel arrives on site, there is no reason for public health and safety requirements additional to those applied to large commercial construction facilities [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

They also argued that referring to proposed § 26.23, which required FFD programs to meet the performance objectives of that section, for construction sites was inappropriate because it conflicted with proposed § 26.25. The commenters explained that proposed § 26.25 applied to individuals who have unescorted access to nuclear power plant protected areas, but during the construction phase there will be not yet be any protected areas as cited in proposed § 26.3(e).

Commenters also stated that the application of proposed § 23.23(e) regarding fatigue and degraded alertness was also inconsistent with proposed § 26.195, which applied requirements for managing fatigue only to licensees and other entities identified in proposed § 26.3(a) and (d) but not to (e), the construction phase. [Tom Houten, NEI; Peter Fowler, Duke Energy; Jim Davis NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

They also stated that proposed § 26.41 [Audits and corrective action] and § 26.189 [Determination of fitness] required administrative actions beyond those necessary for a commercial construction site at which there are no protected areas and no nuclear fuel [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn;

Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

To implement these comments, one industry commenter, supported by many other industry commenters, suggested that reference to proposed §§ 26.23, 26.41 and 26.189 in proposed § 26.3(e)(1) should be eliminated, and instead that § 26.3(e) should state: "1) establish a drug-and-alcohol-free workplace policy, including sanctions to be imposed, 2) implement a pre-employment drug and alcohol testing program and a for-cause testing program, and 3) make provisions for the objective and impartial review of sanctions decisions, protection of information and recordkeeping" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: In response to these 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.

Results of NRC 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.

There are 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 NRC believes 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 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.

The NRC acknowledges, 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. 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 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.

FFD Intent for Fuel Fabrication Facilities

Comment: One commenter asserted that under proposed § 26.3 and § 26.195, Subpart I does not apply to fuel fabrication facilities, which is justified due to the lower level of risk at such facilities. The commenter argued that until the NRC authorizes the possession and use of strategic special nuclear material (SSNM) onsite, there is no reason that FFD requirements should be more stringent than those typically applied in non-nuclear large commercial construction facilities [Richard Sweigart, DCS].

NRC Response: The NRC agrees with the commenter that fuel fabrication facilities will not be subject to the requirements in Subpart I. The final rule in § 26.201(a) states that the requirements in Subpart I only apply to licensees and other entities identified in § 26.3(a), and, if applicable, § 26.3(d). These provisions do not identify fuel fabrication facilities.

Correlation with Part 52

Comments: Two commenters at the public meeting noted that there are discrepancies between the proposed rule language and the draft language for Part 52. The commenters suggested that there be coordination between those efforts [Tom Houten, NEI; Peter Fowler, Duke Energy].

NRC Response: The NRC agrees with the commenters and is coordinating the Part 26 and Part 52 rulemakings.

Exception for Long-term Shutdowns

Comment: One commenter stated that the proposed rule contained no provisions for exceptions to the requirements of Subpart I for plants in long-term shutdown status. The commenter stated that there is no reasonable or cost-effective method to comply with the proposed requirements due to the number of personnel being utilized. The commenter suggested that the NRC add subparagraph (g) that states: “Subpart I of this regulation does not apply to plants in long-term shutdown status when fuel has been removed from the reactor vessel and NRC approval is required prior to loading fuel. At the time approval to load fuel is

received, the licensee will be in compliance with all applicable portions of § 26.3 prior to commencement of loading fuel into the reactor vessel." To accompany this change, the commenter suggested that the following phrase be added to § 26.195: "Exceptions are identified in Section 26.3(g)" [Glenn Morris, TVA].

NRC Response: The NRC does not agree with the recommendation to revise the rule text to include a specific exception for plants in long-term shutdown. The NRC notes that § 26.9 of the final rule allows parties to seek exemptions from Part 26 and considers this provision to be a more appropriate means for addressing such infrequent and unique circumstances.

3.3 Definitions (§ 26.5)

"Non-Negative" vs. "Positive"

Comments: Several commenters requested clarification on whether the terms "non-negative" and "positive" had the same meaning in the proposed rule. They suggested use of a consistent term, if usage is interchangeable. One commenter, supported by other commenters, suggested that if these terms were synonymous in the proposed rule, then industry preferred the term "positive." If the NRC did not intend these terms to be synonymous, then the commenter suggested that the NRC give a definition for "positive" as "1) the same as the HHS definition or 2) the result of a confirmatory test that has established the presence of adulterants, drugs, drug metabolites, or alcohol in a specimen at or above cut-off level and that has been deemed positive by the MRO after evaluation." The text of the comment provided many examples of the alleged confusing use of "positive" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters that the terms "non-negative" and "positive" in the proposed rule needed clarification. Therefore, the NRC has deleted "non-negative" from the final rule and replaced it with the more specific terminology of "positive, adulterated, dilute, substituted, or invalid." The final rule uses the term "positive" to refer to results from drug and alcohol testing indicating the presence of drugs or drug metabolites in a urine specimen or alcohol in a specimen of breath or oral fluids, and 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.

"Validity Screening"

Comments: Several commenters requested that the definition of validity screening allow for the use of instrumented devices, in addition to non-instrumented devices [Jim Davis, NEI #48; Brian McCabe, Progress Energy; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comments relating to the use of instrumented devices for validity

screening are addressed below in Section 8.9.2 regarding § 26.137(b) of the final rule.

"Directing"

Comments: Several commenters stated that the proposed rule package discussion significantly expanded who would be included in the area of directing, and industry expressed concern with the lack of clarity of "directing" in the operations and maintenance functional groups. The commenters stated that, for operations, this term is understood to mean individuals with direct authority, such as the Senior Reactor Operator directing the activity of the Reactor Operator.

In the maintenance functional group, the commenters said the NRC staff stated that it was the individual who was at the job site providing direct supervision of the job, had the ability to detect errors and was ultimately responsible for the successful completion of the job. Although the commenters agreed that the group should include management personnel routinely assigned to a shift, they claimed the proposed addition of other individuals who provide periodic support, such as a special outage manager, is unwarranted. They stated that the licensed operator is directly responsible for the safe operation of the plant. The commenters stated that, in the maintenance area, the application of the term "directing" to engineering personnel who provide technical advice is of particular concern.

The commenters argued that the criteria for these two groups should be well-defined and that the term "directing" adds a significant degree of uncertainty as to who should be included in each applicable functional group. The commenters stated that without better definition of expectations in this area, there will be additional disagreement regarding implementation requirements.

The commenters also mentioned that a potential unintended consequence is the distancing of engineering staff from the maintenance and operations staff. Specifically, whenever possible, licensees will define an engineer as an advisor, not a director, of the operations or maintenance groups. In some cases an engineer may not go into the field to give technical advice or participate in troubleshooting for fear that someone will decide he or she is part of a functional group and thus subject to work hour controls. [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees that the proposed definition of "directing" was unclear as used in Subpart I and the scope of personnel who must be subject to work hour controls. Therefore, the NRC has modified the definition in the final rule. The revised definition clarifies the NRC's expectations that a limited scope of personnel providing technical input is subject to the requirements of § 26.205 [Work hours]. The definition explicitly states 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 the revised definition

more clearly focuses on activities that have the potential to substantively and immediately affect safety.

In response to the comment that a licensee may define an engineer as an advisor, the NRC notes that the work hour controls are applicable to individuals who perform the functions specified in § 26.4(a)(1) through (a)(5), regardless of their position title.

In response to the comment that individuals may not go out into the field to provide technical advice, the NRC notes that work hour limits apply to individuals providing "on-site" direction of the functions specified in § 26.4(a)(1) and (a)(2) of the final rule. As a consequence, an individual would not be exempted from the requirements because the direction was provided from a remote on-site location. The NRC defined the requirement in these terms to address the commenters' concern.

"Authorization"

Comments: Another commenter stated that the term "authorization" was used throughout the proposed rule in a number of different contexts, while historically the term has referenced "access authorization." Therefore, the commenter suggested that the NRC clearly define the different uses of the tem "authorization" or utilize unique terms where appropriate [Keith Jury, Exelon].

NRC Response: The NRC agrees with this commenter and has added a definition of the term "authorization" to the final rule. 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 for the FFD program personnel or for individuals who perform construction activities. 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.

"Non-Instrumented Testing Devices"

Comments: One commenter addressed § 26.5 and requested that NRC provide a definition for and some examples of non-instrumented testing devices permitted to perform validity screening tests. The commenter also requested that the definition include examples of acceptable devices to use for validity screening tests [Charles LoDico, Individual].

NRC Response: The NRC agrees, in part, with the commenter's request and has revised the definition of "validity screening test" in § 26.5 of the final rule to clarify the proposed meaning of non-instrumented testing device.[1] In addition, the definition of "validity screening test" has been amended to include instrumented tests, based on another comment received on proposed § 26.137(b), that explained that some instrumented tests could also meet the performance testing criteria in § 26.137. The NRC has revised the definition of a validity screening test in § 26.5 of the final rule to mean the use of a non-instrumented test where the endpoint result is obtained by visual evaluation (i.e., read by human eye), or an instrumented test (machine-read end points), to determine the need for initial validity testing of a urine specimen. The NRC disagrees with the commenter's request to include examples of a non-instrumented test as unnecessary specificity.

"Dilute Specimens"

Comments: One commenter addressed the definition of "dilute specimen" in § 26.5 and stated that the definition did not include the specific gravity, which is necessary to determine if a specimen is dilute or substituted [LoDico, Individual].

NRC Response: The NRC disagrees in part with the commenter. The proposed provision in § 26.5 was consistent with the definition for dilute specimens used in the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. The proposed rule presented the specific gravity cutoffs that HHS-certified laboratories must use to determine if a specimen is dilute in § 26.161(d). Subpart F [Licensee Testing Facilities] of the final rule does not contain a provision on specimen specific gravity testing because NRC is not requiring licensee testing facilities to conduct specimen specific gravity testing. Therefore, the NRC has not amended the definition of "dilute specimen" in the final rule.

"Non-Negative Test Result"

Comments: One commenter stated that the proposed definition of a "non-negative test result" did not include the analytical reporting cutoff for specific gravity to determine whether a specimen is substituted [Charles LoDico, Individual].

NRC Response: As a result of other comments received on the use of the term "non-negative test result" the NRC has eliminated the term in the final rule. The NRC has amended § 26.5 in the final rule to include a new term, "questionable validity," to account for validity screening and initial validity test results from testing conducted at a licensee testing facility that indicate that a specimen may be adulterated, substituted, dilute, or invalid.

3.4 Interpretations (§ 26.7)

No comments addressed this section.

[1]The final rule eliminates the use of the term "device" because of the specific connotation associated with the use of the term identified by another commenter.

3.5 Information Collection Requirements: OMB Approval (§ 26.8)

No comments addressed this section.

3.6 Specific Exemptions (§ 26.9)

No comments addressed this section.

3.7 Communications (§ 26.11)

No comments addressed this section.

4. Subpart B: Program Elements

4.1 Fitness for Duty (§ 26.21)

No comments addressed this section.

4.2 Performance Objectives (§ 26.23)

Comments: One commenter stated that the proposed section (*referring to the performance objectives section*) contained no language to provide reasonable assurance that the program will maintain a level of integrity to ensure the privacy of individuals who are subject to testing, and that the individuals who are subject to testing will not be unjustly or inaccurately portrayed as having violated the FFD requirements. Thus, the commenter suggested that the NRC should include such language in the rule [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenter that the performance objectives in proposed § 26.23 [Performance objectives] did not explicitly address worker protections. Rather, the proposed rule's performance objectives focused on protecting public health and safety and the common defense and security, consistent with the NRC's mission. The final rule retains these performance objectives without change. However, the NRC is concerned that FFD programs maintain an appropriate balance between the needs of the public and those of the individuals who are subject to the rule. Therefore, the final rule contains a variety of provisions that are intended to ensure worker privacy and protection, such as § 26.27 [Written policy and procedures], § 26.29 [Training], § 26.37 [Protection of information], § 26.39 [Review process for fitness-for-duty policy violations], § 26.75 [Sanctions], and § 28.185 [Determining a fitness-for-duty policy violation]. In addition, in response to this comment, the NRC has added or modified several requirements (including §§ 26.37(d), 26.53(h) and (i), and 26.711(c) and (d)) to strengthen the privacy of individuals who are subject to the rule and ensure that individuals are not unjustly or inaccurately portrayed as having violated FFD requirements.

4.3 Individuals Subject to the Fitness for Duty Program (§ 26.25)

No comments addressed this section. However, the NRC has amended and moved the proposed requirements of this section to § 26.4 [FFD program applicability to categories of individuals] in the final rule.

4.4 Written Policy and Procedures (§ 26.27)

Comments: With reference to both this section and proposed § 26.29, one commenter stated that the licensee should not screen for drugs in addition to those listed in the proposed rule without identifying them in advance. The commenter said that if prevention is the true goal, the best way to prevent is to forewarn [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenters 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. Therefore, the NRC has added a new provision in § 26.31(d)(1)(iii) of the final rule to specify that licensees and other entities must document the additional drugs for which testing will be performed in the written policies and procedures. However, the NRC does not agree that a licensee should be prohibited from testing for drugs or drug metabolites in addition to those listed in the rule without identifying them to donors 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 followup, post-event and for-cause testing to detect any drugs listed on Schedules I-IV of the Controlled Substance Act that the individual is suspected of abusing.

4.4.1 General (§ 26.27(a))

No comments addressed this section.

4.4.2 Policy (§ 26.27(b))

Comments: One commenter commended the NRC for considering the impact that untreated sleep disorders have on the health and safety of the workforce at nuclear plants under proposed § 26.27(b)(7). The commenter stated that the NRC has clearly and accurately cited existing information regarding the prevalence of sleep disorders in the United States. The commenter agreed with the NRC that, given the demographics of workers in the nuclear industry, sleep disorders (e.g., sleep apnea) are likely to be prevalent in the workforce and should be diagnosed and treated. The commenter argued that no matter how much time for sleep individuals are afforded, those who suffer from sleep disorders do not accrue the full recuperative benefits from sleep, resulting in an inability to sustain normal levels of alertness and performance throughout the subsequent hours of wakefulness [Darrel Drobnich, NSF].

NRC Response: The comments do not require a response.

4.4.3 Procedures (§ 26.27(c))

Use of the Term “Due Process”

Comments: One commenter, supported by many other commenters, argued that the term "due process" used in proposed § 26.27(c)(1) implied that under this rule, licensee activities will

be subject to judicial review relative to the U.S. Constitution. The commenter suggested replacing "due process rights" with "other rights" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: In a subsequent telephone call, the commenter clarified that the comment was not intended to suggest that due process concerns do not apply to FFD programs and indicated that the proposal to substitute "other rights" for "due process rights" was intended to recognize that an individual's protected rights are not limited to due process. As clarified, the Commission agrees with the commenter that in addition to any due process rights, workers may also have other rights granted by federal and state statutes. Therefore, the NRC has modified the final rule in § 26.27(c)(1) and the preamble to the final rule to refer to "privacy and other rights (including due process) of individuals who are subject to Part 26."

Alcohol Consumption During the Pre-Work Abstinence Period

Comments: Another commenter, supported by many other commenters, stated that the wording in proposed § 26.27(c)(2)(ii) could be interpreted as prohibiting only excess alcohol consumption during the pre-work abstinence period. The commenter suggested that the wording should more clearly express the prohibition against any alcohol consumption during relevant periods, and should be reworded to state: 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 [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with this clarification because it is consistent with the NRC's intent to prohibit any consumption of alcohol, not only excess consumption, during the pre-work abstinence period or while on duty. Therefore, the NRC has modified the final rule accordingly.

Use of the Term "Emergency"

Comments: Another commenter, supported by many other commenters, stated that the language in proposed § 26.27(c)(3) was confusing. Specifically, the commenter argued that the term "emergency" was too limiting. Thus, the commenter recommended changing the section to replace the term "emergency" with "unscheduled working tour" and stated that this wording is consistent with the wording "unscheduled working tour" in proposed § 26.27(c)(3)(ii)(c). [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees with this comment and maintains that the use of the term "emergency" in the second sentence of proposed § 26.27(c)(3) accurately conveyed the NRC's

intent that, if an individual's knowledge and skills are necessary to respond to an emergency, the consumption of alcohol resulting in a BAC that exceeds the cutoff levels in Part 26 does not preclude the licensee from relying on the individual during an emergency. However, the NRC has reorganized the language in the final rule to further clarify the differences between the controls and conditions that apply only to an emergency and those that apply to an unscheduled working tour.

Procedures for Called-In Individuals

Comments: One commenter, supported by many commenters, expressed concern about the wording in proposed § 26.27(c)(3)(i). The commenter stated that the language requiring individuals to report that they meet the fitness-for-duty requirements could have resulted in unintended audit requirements and would require excess documentation. The commenter stated that the intent of this section can be met by having individuals report if they are not fit for duty or have consumed alcohol within the pre-duty abstinence period. Thus, the commenter suggested revising proposed § 26.27(c)(3)(i) to state: "The procedure must require individuals called in to report by exception. The procedure must require individuals called in to declare, as stated in licensee program when they consider themselves unfit for duty or have consumed alcohol within the pre-duty abstinence period stated in the policy" [Randy Cleveland, NMC; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenters. Proposed § 26.27(c)(3)(i), which required each individual who is called to state whether he or she considers himself or herself fit for duty and has consumed alcohol within the pre-duty abstinence period stated in the policy, could create a need for the licensee to document the individual's statement and that such documentation could be the subject of auditing. However, the NRC believes that the alternative suggested by the commenters of having individuals report only if they believe they are not fit for duty or have consumed alcohol within the pre-duty period would be less protective of public health and safety. An affirmative obligation to provide a statement may dissuade individuals who would be tempted to remain silent. It will also provide a clearer record. Therefore, the NRC has not modified the provision in the final rule.

Sanctions for Called-in Individual

Comment: One commenter, supported by many commenters, stated that the language in proposed § 26.27(c)(3)(ii)(C) could be interpreted to mean that an employee who is called in may not be subject to sanctions for any misconduct. The commenter suggested the following word change to the subparagraph: "State that no sanctions may be imposed on an individual who is called in to perform an unscheduled working tour for having consumed alcohol within the pre-duty abstinence period stated in the policy" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenter. The intent of this provision is not to subject an individual to the sanctions that are otherwise required under this part for a confirmed positive alcohol test result when the individual is called in unexpectedly and has a confirmed positive test result for alcohol. The NRC believes that sanctions for the consumption of alcohol in these circumstances would be inappropriate, given that the individual would have been unaware that he or she would be called in to work. Therefore, the NRC has modified the final rule language accordingly.

4.4.4 Review (§ 26.27(d))

No comments addressed this section.

4.5 Training (§ 26.29)

Comments: The comments that concerned training are addressed in section 4.4 "Written Policies and Procedures" of this document.

4.6 Drug and Alcohol Testing (§ 26.31)

Comments: Several commenters supported the majority of provisions of the drug and alcohol portions of the proposed rule. One commenter explicitly supported those provisions that incorporate HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs requirements, reduce unnecessary regulatory burden, and encourage consistency in implementation with the access authorization program [Richard Sweigart, DCS]. One commenter stated that industry supports most of the drug and alcohol testing provisions of the proposed rule because they were developed over a period of many years with due consideration for many improvements recommended by industry groups. The commenter stated that these changes will make FFD programs more efficient and effective [Brian McCabe, Progress Energy].

NRC Response: The comments do not require a response.

4.6.1 General (§ 26.31(a))

No comments addressed this section.

4.6.2 Assuring the Honesty and Integrity of FFD Program Personnel (§ 26.31(b))

Comments: Regarding proposed § 26.31(b)(1)(i), one commenter suggested that the NRC consider consistency of screening frequency between FFD personnel and non-critical group personnel. Because licensees and other entities are not required to update their psychological evaluations of non-critical group personnel, the commenter suggested that the NRC delete the words "...and psychological assessments..." from the last sentence of this section [C. L. Funderburk, Dominion].

NRC Response: The NRC disagrees with the commenter. The NRC believes that FFD program personnel hold unique responsibilities under the rule, given their critical role in maintaining the integrity of the FFD program. The time period for updates of credit and criminal history checks and psychological assessments do not need to align with the update time periods

for individuals who are granted unescorted access authorization under 10 CFR 73.56. Therefore, the NRC has not modified this provision in the final rule.

4.6.3 Conditions for Testing (§ 26.31(c))

Post-Event Testing

Comment: One commenter referenced proposed § 26.31(c)(3) and disagreed with the elimination of the phrase in former § 26.24(a)(3), "if there is reasonable suspicion that the worker's behavior contributed t o the event," from the proposed rule. The commenter stated that in the section-by-section analysis of the proposed paragraph, the NRC claimed that this phrase has long been subject to misinterpretation and that 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. The commenter argued that the NRC presented an incorrect interpretation of the meaning on the former regulation, and that this phrase clearly modified not only the direct antecedent but other types of incidents potentially requiring for-cause testing.

The commenter also argued that the definition of "human error" in proposed § 26.31(c)(3) was too broad, and that there were no limits in defining human error which "may have caused or contributed to the event." The commenter argued that the proposed language would have the unintended consequence of causing individuals not to report medical conditions or to delay seeking treatment to avoid drug and alcohol testing procedures. Therefore, the commenter argued that the agency should not adopt the rule as proposed, and the rule relating to post-event situations should require at least a suspicion that drugs or alcohol affected the individual's actions.

However, the commenter supported language that would include the phrase "within 4 hours after the event" to describe recordable personal injuries and illnesses that would trigger post-event testing [Mark Wetterhahn, Winston and Strawn].

NRC Response: The NRC disagrees with the commenter and believes 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 proposed rule's approach, if one of the events occurs that the regulations define 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.

The proposed rule used 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 (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. This

approach ensures that possible impairment because of substance abuse is always investigated following these significant events, and removes subjectivity from the testing decision.

The NRC believes that the detailed listing in § 26.31(c)(3)(i) through (iii) of situations when post-event testing should be carried out following an accident resulting in injury substantially eliminates the risk of unnecessary testing after "trivial" events mentioned by the commenter. In addition, § 26.31(c)(2) continues to allow "for-cause" testing when its preconditions are met. Section 26.31(c)(3)(i) also limits post-event testing to situations in which the licensee or other entity can determine that an injury or illness meets the threshold within 4 hours after the event has occurred. Therefore, the NRC has not modified § 26.31(c)(3) in the final rule.

Use of the Phrase "Medical Treatment Beyond First Aid"

Comment: Regarding proposed § 26.31(c)(3)(i), one commenter stated that industry believes that the inclusion of the criterion regarding "medical treatment beyond first aid" was an inappropriately low threshold for post-event testing and suggested that this clause be deleted. The commenter expressed concern that setting the for-cause testing threshold this low could have the unintended consequence of increasing the reporting burden associated with industrial safety incidents. The commenter also questioned the benefit of using this threshold because the results of such testing have not identified evidence of substance abuse within the commenter's facilities [F.G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenter. The NRC notes that the phrase regarding "medical treatment beyond first aid" is based on the general criteria contained in 29 CFR 1904.7 of the regulations of the Occupational Safety and Health Administration (OSHA) for recording occupational injuries and illnesses. To clarify, the NRC does not intend that the phrase "medical treatment beyond first aid" should increase the burden of accident reporting by requiring post-event testing in all situations where a personal injury has occurred (i.e., a paper cut or twisted ankle). On the contrary, the NRC intends that this phrase, in addition to the phrase "where the human error may have caused or contributed to the event" in § 26.31(c)(3), should rarely result in testing after such trivial events and should instead cause post-event testing to be undertaken for more significant events caused by human error to determine whether the error was caused by impairment from drugs or alcohol. Therefore, the NRC has not modified § 26.31(d)(3)(i) in the final rule.

Typographical Error

Comments: Many commenters identified a typographical error in proposed § 26.31(c)(3)(i). The commenter stated that the citation of OSHA regulations should refer to 29 CFR 1904.7, not 29 CFR 1907.4 [Jim Davis, NEI #48; F.G. Burford, Entergy; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters that proposed § 26.31(c)(3)(i) contained a typographical error and has modified the final rule accordingly.

4.6.4 General Requirements for Drug and Alcohol Testing (§ 26.31(d))

Lack of Provision for Specimen Dilution

Comments: One commenter, supported by many commenters, suggested a clarification to proposed § 26.31(d)(1)(ii) to properly account for actions that may be taken under § 26.185(g)(2) or (g)(3), when the MRO has reason to believe a donor has diluted a specimen. The commenter suggested that the NRC add a line to the end of the section, stating: "unless the specimen was considered dilute and the licensee or other entity chooses to have the specimen evaluated under § 26.185(g)(2) and (g)(3)" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with this comment. The NRC notes that proposed § 26.185(g)(2) and (g)(3) specified that if an MRO has reason to believe that the donor may have diluted a specimen in a subversion attempt, the MRO may require the laboratory to conduct confirmatory testing of the specimen at the LOD for any drugs as long as they are evaluated under § 26.31(d)(1)(ii) (typographical error in reference corrected in the final rule). As defined in the rule, the LOD is the lowest concentration of an analyte that an analytical procedure can reliably detect, which could be significantly lower than the established cutoff levels. However, § 26.31(d)(1)(ii) specifies that test results that fall below the established cut-off levels may not be considered when making sanction decisions. Therefore, the NRC agrees to add language to § 26.31(d)(1)(ii) to provide consistency with the provisions in § 26.185(g)(3) of the final rule.

Random Testing Requirements

Comments: Another commenter, supported by many commenters, stated that proposed § 26.31(d)(2)(i)(A) limited the unpredictability of specimen collections because it prescriptively required collections on at least 4 days in a calendar week. The commenter argued that this would enable members of the workforce to predict when specimens must be collected during the later days of the week to be in compliance with the regulation. The commenter suggested deleting this language and renumbering § 26.31(d)(2)(i)(B) as § 26.31(d)(2)(i)(A) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenters. Section 26.31(d)(2)(i)(A) states that the FFD program, at a minimum, shall "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." Therefore, the rule does not require licensees and other entities to perform collections on at least four days per week, but only to create an appearance that specimens are being collected. Section 26.31(d)(2)(i)(B)(ii) specifies the actual requirement for specimen collection frequency, which is at a minimum of a nominal weekly frequency.

The NRC believes that the provisions in § 26.31(d)(2)(i) and (d)(2)(i)(B), which specify that random testing must be administered "in a manner that provides reasonable assurance that individuals are unable to predict the time periods during which specimens will be collected" and that licensees shall collect specimens on an "unpredictable schedule," are adequate to ensure that licensees will schedule random testing appropriately. The NRC notes that if a licensee is consistently conducting testing on four consecutive days, or on any predictable schedule, the licensee would not be in compliance with these two provisions.

However, the NRC notes that § 26.31(d)(2)(i)(A) has been clarified to specify the NRC's intent that licensees should reasonable steps to create the appearance of when specimens are being collecte. The NRC has modified this section to require that the portions of each day and the days of the week on which it appears that specimens are being collected must vary in a manner that cannot be predicted by donors.

Testing of Individuals Off-Site/Not Reasonably Available

Comments: One commenter, supported by many commenters, stated that 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 commenter argued that this is inconsistent with NRC-endorsed industry practices and suggested rewording the second sentence of this subparagraph by changing "and" to "or" after "...for testing" to be consistent with NEI 03-01 [Jim Davis, NEI #48;; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters. Proposed § 26.31(d)(2)(iii) and (d)(2)(iv) addressed several circumstances related to selection, notification, and reporting for random testing. These provisions recognized that there will be delays between the points in time at which an individual is selected for random testing, is notified that he or she has been selected, and reports to the collection site for testing. For example, an FFD program may implement its process for selecting individuals for random testing at the beginning of a day shift, but some of the individuals who are selected do not report for work until the mid- or night shift. The NRC expects that FFD program personnel would not notify an individual on the mid- or night shift or his or her supervisor that the individual has been selected for testing until the individual reports for duty to avoid forewarning the individual that testing will occur. Similarly, if an individual has been selected for testing, but the FFD program cannot contact the individual because he or she is on vacation or the individual's supervisor indicates that the individual is suited up and performing work in a radiologically controlled area, the NRC expects that neither FFD program personnel nor the individual's supervisor will notify the individual that he or she must report for testing until the individual has returned to the site or has completed his or her work in the radiologically controlled area. However, the NRC also expects that once an individual has been notified that he or she must be tested, the individual will report to the collection site within the time period specified in the FFD program procedures. The NRC intended proposed § 26.31(d)(2)(iii) to convey these expectations However, the NRC agrees with the commenters that further clarification is necessary. Therefore, the final rule has added the phrase "or who are

on site and are not reasonably available for testing" to § 26.31(d)(2)(v).

Licensees Using LOD Cutoffs

Comment: Another commenter referenced proposed § 26.31(d)(3)(iii)(C) and asked whether the NRC would require licensees already using LOD cutoffs and/or additional substances for testing to submit certification by a forensic scientist or whether they would be grandfathered [Anonymous #18].

NRC Response: The proposed provision stated that one of the circumstances in which certification by a qualified toxicologist is not required under this provisions is if the licensee or other entity received written approval of the NRC to test for lower cut-off levels before the implementation of the final rule. If certification or written approval is required, and the licensee has not received written approval or certification, then the licensee will need toxicologist certification.

Delay of Medical Treatment to Conduct Post-Event Testing

Comments: Two commenters referenced proposed § 26.31(d)(5)(ii) and both agreed that required medical treatment should not be delayed to conduct post-event testing [Todd Newkirk, IBEW; Jim Davis, NEI #48]. However, one of them suggested that the language of this paragraph should state: "treatment *must not* be delayed to conduct drug and alcohol testing" [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenters that medical treatment must not be delayed to conduct drug and alcohol testing. The term "may not" in this provision (and anywhere it appears in the rule) indicates a prohibition. Therefore, the NRC has not modified the provision in the final rule.

Inadequacy of Long-term Random Testing

Comment: One commenter expressed concern that the industry does not adequately test each employee over the long term. The commenter noted that he has not been tested for many years and felt that this trend could compromise the safety of plant operations [Daniel Hansen, Individual].

NRC Response: The NRC disagrees in part with the commenter. If a random drug and alcohol testing program is conducted correctly, each individual who is subject to random testing has an equal probability of being tested each time testing selections are made. However, given the 50% annual testing rate specified in the rule, the NRC acknowledges that it may be possible for an individual not to be tested over a long period of time. The NRC believes that the 50% annual random testing rate is adequate to protect public health and safety because of the continuing low rates of positive test results reported to the NRC in the FFD program performance reports.

4.7 Behavioral Observation (§ 26.33)

No comments addressed this section.

4.8 Employee Assistance Programs (§ 26.35)

Comments: One commenter, supported by many commenters, stated that the language in proposed § 26.35(b) was confusing. Specifically, the rule language did not adequately explain who must be provided EAP services. The commenter suggested rewording the paragraph to state: Licensees and other entities need not provide EAP services to C/V employees *who are working at a licensee's or other entity's facility and are subject to this part. Licensees and other entities need not provide EAP services* to individuals who have applied for, but have not yet been granted, authorization [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with this clarification because it is not NRC's intent that licensees and other entities provide EAP services to C/V employees, even if they work at the licensee's or other entity's facility. Therefore, the NRC has modified the final rule language.

4.9 Protection of Information (§ 26.37)

Comments: One commenter referenced proposed § 26.37(d) and suggested that the donor or representative, with the permission of the donor, should be allowed to access the donor's FFD records at any time and not just in the case of a non-negative test. The commenter expressed that "this is to ensure that no records exist that should not be there," such as records of tests that tested non-negative initially and that the MRO subsequently declared to be negative [Todd Newkirk, IBEW].

NRC Response: The NRC agrees that individuals shall have the right to review FFD information to ensure its accuracy. Therefore, the NRC has added § 26.711(c) to state that licensees and other entities shall inform the individual of his or her right to review information collected under Part 26 to assure its accuracy and provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed by licensees and other entities about the individual. The final rule also requires licensees and other entities to ensure that the information they share with other licensees and entities is correct and complete. This addition is consistent with requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003, and is necessary to protect individual's rights under the rule (including due process).

4.10 Review Process for Fitness-for-Duty Policy Violations (§ 26.39)

Comments: Several commenters referenced proposed § 26.39(c), which stated that the procedure must ensure that more than one individual conduct the review, and that the individuals who conduct the review are not associated with the administration of the FFD program. One commenter, supported by many commenters, suggested 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. The commenter suggested rewording this paragraph to state, "The procedure must ensure that the

review is conducted by *at least one impartial and independent internal management individual* and that the *individual or* individuals who conduct the review are not associated with the administration of the FFD program (see the description of FFD program personnel in § 26.25(a)(4))" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees in part with the commenters. The NRC believes that allowing one person who is not associated with the administration of the FFD program to conduct reviews of FFD policy violations will not compromise an individual's right to an independent and impartial review. Therefore, the NRC has modified the provision in the final rule to clarify this intent.

4.11 Audits and Corrective Action (§ 26.41)

No comments addressed this section.

5. Subpart C: Granting and Maintaining Authorization

5.1 Purpose (§ 26.51)

No comments addressed this section.

5.2 General Provisions (§ 26.53)

No comments addressed this section.

5.3 Initial Authorization (§ 26.55)

No comments addressed this section.

5.4 Authorization Update (§ 26.57)

No comments addressed this section.

5.5 Authorization Reinstatement (§ 26.59)

No comments addressed this section.

5.6 Self-Disclosure and Employment History (§ 26.61)

No comments addressed this section.

5.7 Suitable Inquiry (§ 26.63)

Clarification of Present Employer in § 26.63(c)

Comment: One commenter suggested that the NRC revise the language in proposed § 26.63(c) to state that the licensee or other entity shall conduct the suitable inquiry on a best effort basis by questioning "both the individual's present employer *prior to the day the individual completed the self-disclosure*, and former employers." The commenter argued that this revision would provide more specificity in cases when an individual's current employer changes after the self-disclosure is submitted [Susan Techau, Exelon].

NRC Response: The NRC agrees with the commenter. Licensees and other entities must ensure that a suitable inquiry has been conducted only of those employers that are listed in the self disclosure or employment history. Therefore, the NRC has modified the final rule language in this provision, as well as in § 26.61(c).

Comments: Another commenter, supported by many commenters, stated that the present employer may not be able to answer questions about an individual because of lack of a relationship with the individual in some cases. For example, when a C/V hires the individual on the same day or just a few days before a licensee or other entity processes the individual, the C/V may not be able to answer any questions about the individual. Therefore, the commenter suggested that the NRC add a sentence to the end of proposed § 26.63(c) to state: "If the individual is hired within 3 business days from completion of the self-disclosure, the present employer need not be queried" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenters. The NRC believes that the current employer could have information that is relevant to the suitable inquiry even if the individual's tenure at the current position has been brief. For example, the current employer may have conducted some form of pre-employment drug testing, the results of which would be relevant to the suitable inquiry. Therefore, the NRC has not modified the provision in the final rule

Use of the Term "Presentation" in § 26.63(d)

Comments: Another commenter, supported by many commenters, disagreed with the use of the word "presentation" in proposed § 26.63(d) with regard to an individual's signed release authorizing the disclosure of information. The commenter argued that a licensee should not have to present an individual's signed release authorizing the disclosure of information to another licensee or other entity and should only have to verify that an individual has signed a release authorizing the disclosure of information. Therefore, the commenter suggested changing the first sentence of the paragraph to state: "In response to another licensee's or other entity's inquiry and verification that an individual has signed a release authorizing the disclosure of information" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey

Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy]. Another commenter suggested that the first sentence of § 26.63(d) stating "and presentation of an individual's signed release authorizing" should be changed to "and the individual has signed a release authorizing" [Brian McCabe, Progress Energy].

NRC Response: The NRC agrees with the commenters. Current industry practices allow for verification of a signed release without a licensee "presenting" the actual document. Therefore, the NRC has eliminated the term "presentation" in the final rule and modified the provision to clarify the NRC's intent.

5.8. Pre-Access Drug and Alcohol Testing (§ 26.65)

Comments: Several commenters from industry stated that proposed § 26.65 was generally aligned with current industry practice and recommended that the NRC implement this provision [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comments do not require a response.

5.8.1. Purpose (§ 26.65(a))

No comments addressed this section.

5.8.2. Accepting Tests Conducted within the Past 30 Days (§ 26.65(b))

No comments addressed this section.

5.8.3. Initial Authorization and Authorization Update (§ 26.65(c))

Requirements for Pre-Access Test

Comment: One commenter objected to the language in proposed § 26.65(c)(2) and 26.65(d)(2)(ii). The commenter stated that negative test results from drug and alcohol tests conducted within the past 30 days should qualify as a pre-access test regardless of whether the individual is subject to a behavioral observation and arrest reporting program or is subject to random testing [Anonymous, #16].

NRC Response: The NRC disagrees with the commenter. The NRC intends that if the licensee relies on negative results from drug and alcohol tests that were conducted under the requirements of Subpart C and before the individual applied for authorization, the applicant must also be subject to a behavioral observation and arrest reporting program that meets the requirements of this part. This program must begin on the date the specimens for drug and alcohol testing were collected through the date the individual is granted authorization and throughout their employment. The purpose of this requirement is to minimize the potential for any substance abuse following the test. Behavioral observation provides the necessary deterrence and opportunities to detect any substance abuse during the period that falls between

administration of the pre-access test and the granting of authorization. If the individual is not subject to behavioral observation after the previous test was conducted, it is necessary to conduct a pre-access test to verify that the individual had continued to avoid substance abuse. Therefore, the NRC has not changed the provision in response to this comment. The NRC has also added a requirement that the individual must remain subject to a drug and alcohol testing program that includes random testing in order to be exempt from pre-access testing under § 26.65(c)(2). This measure minimizes the potential for any substance abuse following the drug and alcohol test.

Comments: Another commenter, supported by many commenters, stated that proposed § 26.65(c)(2) and 26.65(d)(2)(ii) contradict § 26.65(b) and 26.65(f). In particular, the commenter argued that licensees should be able to rely on drug and alcohol tests that were conducted before the individual applied for authorization if the individual is subject to a behavioral observation and arrest reporting program and random drug and alcohol testing. Therefore, to improve efficiency the commenter suggested changing § 26.65(c)(2) and (d)(2)(ii) to state, "The licensee or other entity relies upon negative results from drug and alcohol tests that were conducted before the individual applied for authorization, and the individual remains subject to *both a drug and alcohol testing program that includes random testing* and a behavioral observation and arrest reporting program which meet the requirements of this part from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters. The language suggested by the commenter removes the reference to § 26.65(b) in § 26.65(c)(2) and 26.65(d)(2)(ii) to allow licensees to rely on drug and alcohol tests that were conducted more than 30 days before the individual applied for authorization, provided that the individual has been subject to a random drug and alcohol testing program and a behavioral observation program that requires arrest reporting that meet the applicable requirements of this part. The NRC agrees that pre-access testing within 30 days before authorization is granted is unnecessary in these circumstances and has revised the final rule accordingly.

5.8.4. Authorization Reinstatement After an Interruption of More than 30 Days (§ 26.65(d))

The preceding section addresses the comments that related to this section.

5.8.5. Authorization Reinstatement After an Interruption of 30 days or Fewer (§ 26.65(e))

No comments addressed this section.

5.8.6. Time Period for Testing (§ 26.65(f))

Comments: One commenter, supported by many other commenters, disagreed with the

language in proposed § 26.65(f). The commenter stated that licensees currently conduct pre-access drug and alcohol testing within the 30-day period preceding the date the licensee grants authorization. Also, § 26.65(f) only required that licensees collect a sample in this timeframe. The commenter argued that the effort to implement this change exceeds the benefit of the change. Thus, the commenter suggested that the NRC add the 30-day period to conduct testing to § 26.65(c), and delete § 26.65(f) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters. The NRC has deleted§ 26.65(f) from the final rule to eliminate the unnecessary requirements contained therein. However, to accommodate this change, the NRC has clarified § 26.65(c)(1) and (d)(1)(i) to specify that the licensee may only rely on pre-access tests that were conducted within the 30 day period preceding the granting of authorization by the licensee, consistent with the intent of this provision of the rule.

5.8.7. Administrative Withdrawal of Authorization (§ 26.65(g))

No comments addressed this section.

5.8.8. Sanctions for a Confirmed Positive, Adulterated, or Substituted Pre-access Test Result (§ 26.65(h))

No comments addressed this section.

5.9 Random Drug and Alcohol Testing of Individuals Who Have Applied for Authorization (§ 26.67)

No comments addressed this section

5.10. Authorization with Potentially Disqualifying Fitness-for duty Information (§ 26.69)

Comments: Two commenters expressed concern with the requirements in proposed § 26.69. Both commenters stated that reviewing officials are not offered sufficient flexibility under the proposed rule to make rational FFD decisions when there is a single event that is considered potentially disqualifying information (for example, a citation for driving under the influence or an open container violation). These commenters suggested that licensees need more latitude so they may conduct an appropriate level and type of investigation on the individual, depending on the extent of the potentially disqualifying FFD information disclosed [Jim Davis, NEI; Randy Cleveland, NMC].

NRC Response: The NRC disagrees with the commenters and believes that § 26.69(d) in the final rule provides sufficient flexibility to the reviewing official by permitting him or her to decide whether a determination of fitness is required under the circumstances described by the commenters.

5.10.1. Purpose (§ 26.69(a))

No comments addressed this section.

5.10.2. Authorization After a First Confirmed Positive Drug or Alcohol Test Result or a 5-Year Denial of Authorization (§ 26.69(b))

Comments: One commenter stated that industry is already familiar with the role of Substance Abuse Professionals (SAPs) and suggested that the provision in § 26.69(b)(4) allow for use of either an SAE or SAP as it relates to this section. The commenter recommended that the provision be revised to read, "Ensure that SAE *or SAP* conducts a determination of fitness" and that the remaining paragraphs in the section also include the option of using either an SAE or SAP [C.L. Funderburk, Dominion].

NRC Response: The NRC disagrees with the commenter's suggestion. The NRC notes that the SAP training and credentialing process emphasizes knowledge about the SAP role in 10 CFR Part 40 programs. However, although an SAP under Part 40 meets many of the criteria established in the FFD rule, thorough knowledge of Part 26 requirements is also necessary under the final rule. Therefore, the NRC has not modified this provision in the final rule.

5.10.3. Granting Authorization with Other Potentially Disqualifying FFD Information (§ 26.69(c))

Consistency in Self-Disclosure Requirements

Comments: Several commenters at the public meeting on September 21, 2005, addressed these sections of the proposed rule. One commenter addressed § 26.69(c)(1) that required the licensee to verify self-disclosure and employment history. The commenter stated that the proposed language in § 26.69(c)(1) only referenced the self-disclosure time period identified in § 26.61(b)(3). The commenter suggested that the language also reference the employment history time period identified in § 26.61(c) [Susan Techau, Exelon].

NRC Response: The NRC agrees with the commenter that the time periods that must be addressed by the self-disclosure and employment history should be clarified. The NRC has modified the final rule accordingly.

Suitable Inquiry with Potentially Disqualifying FFD Information

Comments: In addition, several commenters expressed confusion about proposed § 26.69(c)(2). One commenter asked if the industry must cover every employer if potentially disqualifying FFD information is discovered or disclosed during the suitable inquiry process. The commenter explained that page 50513 of the *Federal Register* notice contains a discussion of this intent [Randy Cleveland, NMC]. A second commenter stated that it is confusing to move from one section of the regulation (§ 26.69(c)(2)) to another section of the regulation (§ 26.63(f)) when one is conducting an investigation and potentially disqualifying FFD information is discovered or disclosed [Jim Davis, NEI]. These sections of the rule discuss different timeframes for the suitable inquiry, and both commenters asked for an explanation of the NRC's intent.

A commenter at the September 21, 2005, public meeting asked a followup question about the suitable inquiry process for an individual whose period of interruption is 2.5 years. If potentially disqualifying FFD information is discovered or disclosed during this period of time, the commenter asked if the licensee would have to request the individual to provider an additional 2.5 years of employment history to satisfy the 5-year suitable inquiry requirement [Susan Techau, Exelon].

NRC Response: The NRC intends that if potentially disqualifying FFD information is discovered or disclosed during the suitable inquiry, the licensee must contact every employer from the applicable period in § 26.61(b)(3). In the case of an individual whose authorization had been interrupted for 2.5 years, § 26.69(c)(2) requires the licensee or other entity to complete the suitable inquiry with every employer by whom the individual claims to have been employed during that 2.5-year interruption period, and to obtain and review any records pertaining to potentially disqualifying FFD information about the individual from the licensees or other entities who had granted authorization to the individual during the earlier 2.5 years of the 5-year period required. If an individual had not held authorization during the 5-year period and potentially disqualifying FFD information was discovered or disclosed that a previous licensee had not resolved, then the receiving licensee is required to obtain an employment history from the individual that addressed the entire 5-year period and conduct the suitable inquiry with every claimed employer from those 5 years.

5.10.4. Maintaining Authorization with Other Potentially Disqualifying FFD Information (§ 26.69(d))

No comments addressed this section.

5.10.5. Accepting Follow-up Testing and Treatment Plans from Another Part 26 Program (§ 26.69(e))

Comments: Several commenters from industry disagreed with proposed § 26.69(e)(1), which required the FFD program to which an individual was subject 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 administered by the same or different licensee or entity. The commenters argued that the burden of completion, compliance, and follow-up should remain with the individual, not the licensee, to monitor and verify. The commenters asserted that the difficulty and ability to administer such a process would make the requirement ineffective and suggested that § 26.69(e)(1) be deleted from the proposed rule [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees in part with the commenters. The NRC believes that 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 it is appropriate that the granting FFD program develops a comparable treatment plan, with accountability for monitoring the individual's compliance with the plan assumed by the granting licensee or other

entity. Therefore, the NRC has modified the proposed provision accordingly in the final rule.

5.10.6. Sanctions for Confirmed Non-negative Drug and Alcohol Test Results (§ 26.69(f))

No comments addressed this section.

5.11. Maintaining Authorization (§ 26.71)

No comments addressed this section.

6. Subpart D: Management Actions and Sanctions to Be Imposed

6.1. Sanctions (§ 26.75)

Agreement with § 26.75(a)

Comments: Several commenters from industry stated that the industry agrees with proposed § 26.75(a). Each licensee and other entity should view this proposed rule as a continuum from previous versions of the rule and may impose stricter sanctions than the rule requires [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comments do not require a response.

Questionable Justification for § 26.75(b)

Comment: One commenter questioned whether there is adequate justification for proposed § 26.75(b), which stated that refusing to provide a specimen for testing should be considered an act of subversion. The commenter argued that this provision is a significant change from former § 26.27(c), which stated that refusal to provide a specimen for testing must be recorded as a removal for cause [Richard Sweigart, DCS].

NRC Response: The NRC disagrees with the commenter. Refusals to test should be considered an act of subversion and warrant permanent denial of authorization because a refusal to provide a specimen for testing thwarts the testing process, as there is no specimen to test. The NRC believes that those who refuse to provide a specimen for testing 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. Therefore, the NRC has not modified this provision in the final rule.

Sanctions for Withdrawal/Reassignment of Application for Authorization – § 26.75(d)

Comment: One commenter disagreed with proposed § 26.75(d), which stated that any individual who resigns or withdraws his or her application for authorization before authorization is terminated or denied for a first violation of FFD policy shall be subject to a harsher penalty than

a person who does not resign or withdraw. The commenter argued that former § 26.27(c) provided that resignation in such circumstances shall be recorded as a removal for cause [Richard Sweigart, DCS].

NRC Response: The NRC disagrees with the commenter and notes that proposed § 26.75(d) amended the portion of former § 26.27(c) that required licensees to record as removal for cause an individual's resignation that occurs before the licensee removes the individual for violating the FFD policy. Because the former provision raised many questions about the appropriate actions to take in this case, the proposed provision clarified the NRC's intent and provides a more appropriate sanction than the former provision. Therefore, the NRC has not modified the provision in the final rule.

Comment: One commenter referenced proposed § 26.75(d) and suggested that the rule discuss the way the new system of sanctions will handle past violations. The commenter believes that the new system should not consider past violations [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter and believes that an individual's past behavior should not be ignored under the final rule. Therefore, the NRC has not modified this provision in the final rule.

Sanctions for Non-Negative Test Result

Comment: Another commenter asked if the FFD regulations define a required action for positive tests, such as a 1–3 year ban on unescorted access [Brent Rice, Individual].

NRC Response: The NRC notes that the final rule contains several provisions that address required actions for positive test results, as well as adulterated, substituted, and invalid results from specimen validity testing. For example, § 26.65(g) describes the sanctions for a confirmed positive, adulterated, or substituted pre-access test result; § 26.67(c) describes the sanctions if an individual has confirmed positive, adulterated, or substituted random testing results (not a positive test result); and § 26.75(e) describes the sanctions for a confirmed positive drug or alcohol test as an indication of off-site drug or alcohol use.

Clarification of § 26.75(g)

Comments: Another commenter, supported by many commenters, stated that proposed § 26.75(g) applied to § 26.75(e)(2) and not to § 26.75(e)(1). Therefore, the commenter suggested that the NRC change the reference in § 26.75(g) from "(e)" to "(e)(2)" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters that proposed 26.75(g) contained a typographical error and has modified the provision in the final rule to correct the error.

6.2. Management Actions Regarding Possible Impairment (§ 26.77)

No comments addressed this section.

7. Subpart E: Collecting Specimens

7.1 Purpose (§ 26.81)

No comments addressed this section.

7.2 Specimens to Be Collected (§ 26.83)

No comments addressed this section.

7.3 Collector Qualifications and Responsibilities (§ 26.85)

No comments addressed this section.

7.3.1 Urine Collector Qualifications (§ 26.85(a))

No comments addressed this section.

7.3.2 Alcohol Collector Qualifications (§ 26.85(b))

Comments: One commenter noted that proposed § 26.85(b) did not require alcohol collectors to be certified, as required for breath alcohol technicians in U.S. DOT's specimen collector requirements in 49 CFR Part 40. The commenter also stated that the proposed provision did not include documentation requirements for training nor continuing competency training [Sue Brown, Individual].

NRC Response: The NRC agrees that § 26.85(b) in the proposed rule did not require certification of alcohol collectors. The NRC has not required this certification in the proposed and final rule because it believes that certification under the U.S. DOT's specimen collector requirements is unnecessary in Part 26. Licensees currently use the systems approach to training (SAT) breath alcohol collectors. The NRC believes that industry training of breath alcohol collectors in accordance with the SAT provides an adequate level of training to ensure the proper completion of specimen collections. Therefore, the NRC has decided not to require alcohol collectors to be certified as breath alcohol technicians, as required by U.S. DOT. The NRC also agrees with the commenter's statement that proposed § 26.85(b) did not include training documentation requirements for collectors. Therefore, the NRC has revised proposed § 26.85 in the final rule by including a new provision, § 26.85(e), to establish documentation requirements for collectors. Maintaining records to document collector proficiency is necessary for NRC inspection purposes as well as to ensure that the records are available for any administrative and/or legal proceedings challenging an alcohol test result.

7.3.3 Alternative Collectors (§ 26.85(c))

Comments: One commenter disagreed with proposed § 26.85(c) that permitted alternative

collectors (i.e., medical professionals, technologists, technicians) to serve as urine and/or breath collectors without meeting the collector qualification requirements in § 26.85 (a) and/or (b) [Sue Brown, Individual].

NRC Response: The NRC agrees that the intent of the provision as proposed was unclear. The NRC intends that alternative collectors be allowed to conduct specimen collections only in those circumstances, such as post-event testing in a hospital setting, when there is a time period within which a specimen must be collected and a collector who is trained under the requirements of this part cannot reasonably be made available by the licensee or other entity to perform the collection. Therefore, the NRC has reorganized and revised proposed § 26.85(c) in the final rule to clarify this intended meaning.

7.3.4 Personnel Available to Testify at Proceedings (§ 26.85(d))

No comments addressed this section.

7.4 Collection Sites (§ 26.87)

Coloring Agents Cannot Interfere with the Drug and Validity Testing Assays

Comments: One commenter objected to the provision in proposed § 26.87(e)(1) that a coloring agent added to any source of standing water in the stall or room in which a donor provides a specimen cannot interfere with drug and validity testing assays. The commenter stated the proposed provision did not make sense and requested that it be eliminated [Charles LoDico, Individual].

NRC Response: The NRC agrees with the commenter's request and has eliminated the proposed provision that the coloring agent added to standing water in a stall or room to deter specimen tampering must not interfere with drug and validity testing assays. The NRC eliminated the provision because the requirement cannot be effectively implemented. For example, some validity tests use an assay that produces a color result. If a specimen were to contain a coloring agent that an individual had added to their specimen in an attempt to subvert the testing process, the assay could not function correctly and would produce an invalid test result. Therefore, the requirement that a coloring agent added to water not interfere with the drug and validity testing assays is not possible for all validity and drug testing assays used by laboratories.

Same Gender Collector for Specimen Collections in Restrooms with Enclosed Stalls

Comments: One commenter objected to proposed § 26.87(f)(3) that required, in the exceptional instance when a designated collection site is unavailable (e.g., post-event test at a hospital) and a restroom with multiple stalls is used for the collection, that a same-gender collector accompany the donor into the restroom, but remain outside the stall used by the donor. The commenter stated that the proposed provision was contrary to the "normal collection process" that, in the commenter's view, did not require a same gender collector to conduct a specimen collection when a donor provides a specimen in a stall, as long as visual privacy is maintained. The commenter asserted that the proposed provision would be burdensome to implement because it would require that a male and a female collector be present at a collection

site at all times. The commenter also noted that the proposed provision would be especially burdensome to implement during outage situations when a large number of individuals must be subject to testing [Jim Bradshaw, AEP].

NRC Response: The NRC disagrees with the commenter and has retained the proposed requirement in the final rule. This requirement applies only in the exceptional event that a designated collection site is not available (e.g., a post-event test in a hospital setting). Because these circumstances are rare, the NRC does not believe that the requirement imposes an undue burden and that it is necessary to protect donors' privacy rights under the rule. The NRC does not intend to require collectors to be of the same gender as the donor under the "normal collection process."

Comments: Another commenter objected to proposed § 26.87(f)(3) that required a same-gender collector to accompany a donor into a non-dedicated collection site (e.g., a public restroom with multiple stalls) but remain outside the stall used by the donor to provide a specimen. The commenter stated that the proposed provision was inconsistent with the proposed observed specimen collection requirements that do not require a same-gender collector [Charles LoDico, Individual].

NRC Response: The NRC disagrees with the commenter. The circumstance addressed in § 26.87(f)(3) is not an observed collection situation. This provision addresses an exceptional circumstance in which a designated site is not available for specimen collection. In addition, § 26.87(f)(3) is consistent with the same requirement in Section 2.4(g)(10) in Appendix A to Part 26 of the former rule. Therefore, the NRC has not modified the proposed provision in the final rule.

7.5 Preparing to Collect Specimens for Testing (§ 26.89)

Notification of Selection for Testing

Comments: One commenter addressed proposed § 26.89(a) and stated that because a licensee or other entity can "arbitrarily determine" that an employee has attempted to subvert the testing process by failing to appear for testing at a collection site in a timely manner, the provision should have required that each employee receive a "positive contact" of their selection for testing. The commenter suggested that an employee's FFD supervisor be required to notify the employee via face-to-face communication because it is impossible to verify the notifier's identity over the telephone. The commenter further suggested that any FFD supervisor who notifies an employee to appear for testing should be subject to the same subversion of testing provisions as those applicable to donors [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter's request to require licensees and other entities to notify, in person, an individual selected for required testing. Requiring a face-to-face notification of testing would be unnecessarily burdensome on licensees and other entities and could delay required testing. The NRC further disagrees with the commenter's assertion that a licensee or other entity can arbitrarily determine whether an individual has attempted to subvert the testing process because the individual did not arrive at the collection site within the required time period. In order to determine that an individual has not reported in a timely manner for testing, the licensee or other entity must maintain a record of the time that an

individual was notified to proceed for testing. Therefore, to conclude that an individual has refused to submit to testing, the licensee must implement a defensible method to document the time that the employee was notified for testing. Although one acceptable notification method would be a face-to-face communication between an FFD program supervisor and the individual selected for testing, the licensee or other entity may meet the rule's requirements by employing other secure methods to notify an individual that he or she has been selected for testing. Therefore, the NRC has not modified the proposed provision in the final rule.

The NRC agrees with the commenter that individuals who notify donors that they have been selected for testing must be subject to sanctions for any attempt or act to subvert the testing process, as required under § 26.75(b) of the final rule. To clarify the applicability of this sanction to FFD program personnel, the final rule specifically states that the sanctions in Subpart D [Management Actions and Sanctions To Be Imposed] apply to the individuals listed in § 26.4(g).

Time Limit to Appear for Testing at a Collection Site

Comments: One commenter requested that proposed § 26.89(a) specify the acceptable time period within which a donor must appear at the designated collection site for testing [Charles LoDico, Individual].

NRC Response: The NRC disagrees with the commenter's request. The types and physical circumstances of licensees and other entities subject to Part 26 vary widely. Accordingly, acceptable time limits for donors to appear for testing at collection sites also vary widely among licensees and other entities. A time limit appropriate at one licensee may be entirely unreasonable at another licensee. Therefore, NRC has chosen to continue to allow each licensee's or other entity's FFD program to establish the acceptable time limit within which a donor must appear at the designated collection site for testing.

FFD Supervisor - Method to Identify a Donor Without Photo Identification

Comments: One commenter suggested that proposed § 26.89(b)(2) be revised to allow an additional method to confirm the identity of a donor. The commenter recommended that FFD supervisors be permitted, except for pre-access testing, to positively identify employees that arrive at a collection site without acceptable photo identification. The commenter reasoned that if an FFD supervisor is trusted to observe a donor, the FFD supervisor should be considered sufficiently trustworthy to verify the donor's identity [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.89(b)(2) in the final rule. For tests other than pre-access tests, this section in the final rule directs FFD management, upon being informed by the specimen collector that the donor did not present acceptable identification, to contact the donor's supervisor to verify the donor's identity. If the donor's supervisor is not available, FFD management must take other steps to establish the donor's identity and determine whether the lack of identification was an attempt to subvert the testing process. This revision is consistent with the former requirement in Section 2.4(g)(2) in Appendix A to Part 26 that permitted a collector to positively identify a donor "through the presentation of a photo identification or identification by the employer's representative."

Pre-access Testing Prohibition Without Valid Photo Identification

Comments: One commenter addressed proposed § 26.89(b)(2) and requested clarification on the intent of words "may not" in the sentence, "If the donor is scheduled for pre-access testing and cannot produce acceptable identification, the collector may not proceed with the collection." (This wording now appears in § 26.89(b)(3) of the final rule.) The commenter stated that by using the words "may not" it appeared as though a licensee or other entity has a choice of whether or not to permit testing. The commenter suggested replacing "may not" with "shall not" to emphasize that no collection is permitted [C.L. Funderburk, Virginia Electric and Power].

NRC Response: The NRC disagrees with the commenter's request. The NRC requires that rule text must use the phrase "may not" to describe a prohibited activity. Therefore, the phrase "may not" is used throughout the final rule instead of the phrase "shall not."

Comments: One commenter addressed proposed § 26.89(b)(2) and disagreed with the permission for a specimen collection to proceed even if the donor's identity cannot be confirmed by the collector. The commenter reasoned that the proposed provision is inconsistent with Section 2.2(f)(2) in the HHS Mandatory Guidelines for Federal Workplace Drug Testing which prohibits a collector from proceeding with a specimen collection if a donor's identity cannot be verified [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. The final rule permits a specimen collection for any testing that is required under Part 26 other than pre-access testing to proceed when a donor does not have acceptable identification. Individuals subject to FFD program requirements must have identification with them at all times while at a licensed facility and, therefore, cases in which a donor does not have an acceptable form of identification will be infrequent. However, the NRC has revised proposed § 26.89(b)(2) in the final rule to explicitly require FFD management to take steps to verify the individual's identity or take other necessary actions. In instances where the donor does not present acceptable identification, § 26.89(b)(2) now requires FFD management to contact the donor's supervisor to verify in person the donor's identity. If the supervisor is not available, FFD management must take other steps to investigate the reason the donor was unable to present acceptable identification and to prevent a donor attempt to subvert the testing process by having another individual provide a specimen for him or her. Steps that FFD program management could take to investigate the reason an individual could not present acceptable identification at the collection site could include assigning a security officer to accompany the individual to his or her car or locker to obtain identification that verifies the individual's claim while ensuring that the individual does not have the opportunity to bring an adulterant or substitute urine back to the collection site. FFD program management could also request collection site personnel to photograph any individual who is unable to present acceptable identification for the FFD manager's use in the investigation.

Informing a Donor of Refusal to Test Actions

Comments: One commenter addressed proposed § 26.89(c) that required urine collectors to inform each donor, before beginning a specimen collection, that leaving the collection site before the collection is completed or refusing to cooperate with the specimen collection process will be considered a refusal to test. The commenter stated that solely relying on the collector to verbally inform the donor of the actions considered to be a refusal test under the rule is inadequate

because the collector may forget to convey the information. The commenter requested that a description of the refusal to test actions be included on the donor consent-to-test form or be posted in a conspicuous location at the collection site. [Todd Newkirk, IBEW].

NRC Response: The NRC has declined to grant the commenter's request. The beginning of the testing process is not the first or only time when the rule requires licensees and other entities to inform donors of the actions that will be considered a refusal to test and the consequences of a refusal to test. Section 26.27(b) requires licensees and other entities to inform all individuals subject to the provisions of their FFD program of the program policies. This section also requires licensees and other entities to ensure that a written FFD policy statement is readily available to all covered individuals that includes 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. Among these details are "the consequences of subverting or attempting to subvert the testing process" in proposed and final § 26.27(b)(3). Likewise, § 26.29(a)(1) requires licensees and other entities to provide training that addresses the FFD policy and the consequences of violating the policy. With regard specifically to a donor's refusal to test, the NRC has revised proposed § 26.27(b)(3) in the final rule to explicitly require that the FFD policy statement describe donor actions considered to be a refusal to test, and the consequences of refusals to test. These various requirements, considered together, ensure that individuals subject to FFD program drug and alcohol testing are adequately informed of the licensee's or other entity's policy regarding refusals to test.

7.6 Acceptable Devices for Conducting Initial and Confirmatory Tests for Alcohol and Methods of Use (§ 26.91)

7.6.1 Acceptable Alcohol Screening Devices (§ 26.91(a))

No comments addressed this section.

7.6.2 Acceptable Evidential Breath Testing Devices (§ 26.91(b))

No comments addressed this section.

7.6.3 EBT Capabilities (§ 26.91(c))

Comments: Several commenters addressed the provision in proposed § 26.91(c)(2) that specified the criteria that evidential breath testing (EBT) devices must meet to be acceptable for use in confirmatory alcohol testing. The commenters disagreed that these EBTs should have to display a unique number that can be read before each test. The commenters asserted that some EBTs on the NHTSA Conforming Products List (CPL) do not have this capability. The commenters stated that to implement the proposed provision, some licensees would have to purchase new equipment, even though their current equipment is on the NHTSA CPL. Finally, the commenters suggested that the proposed provision would have a significant economic impact on small entities that manufacture EBTs [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenters' request. Section 26.91(c)(2) in the proposed and final rule specifically applies only to EBTs used to conduct confirmatory alcohol tests (designated on the NHTSA CPL without an asterisk) and not to EBT models identified on the NHTSA CPL that may be used only to conduct initial alcohol tests (designated with an asterisk on the NHTSA CPL). The majority of EBT models appearing on the NHTSA CPL without an asterisk have the capability to display a unique test number before each test and to print the same unique test number with the alcohol test result once the test is completed. Requiring an EBT that is used for confirmatory testing to display and print a unique test number establishes the chain of custody for the test result and ensures that the result is legally defensible. For example, if the same EBT is used to conduct both initial and confirmatory testing, a unique test number for each test provides the documentation necessary to establish that the individual has actually been tested two different times. Therefore, if the EBTs used by the commenters do not meet the functional requirements specified in § 26.91(c)(2), test results from these EBTs may not be legally defensible if challenged. The final rule permits a licensee or other entity to continue to use any approved EBT model on the most current NHTSA CPL to perform initial alcohol tests. However, confirmatory alcohol tests must be conducted using an EBT meeting the specifications in § 26.91(c) of the final rule. In addition, industry affirmed that the cost estimate in the regulatory analysis of the proposed rule provision is consistent with projected new equipment purchases by some FFD programs. The NRC also deems it unlikely that this requirement will have any significant impact on EBT manufacturers. Because other Federal agencies have similar EBT requirements, most notably the U.S. DOT, this NRC requirement should have no appreciable impact on the EBT market.

7.6.4 Quality Assurance and Quality Control of ASDs (§ 26.91(d))

No comments addressed this section.

7.6.5 Quality Assurance and Quality Control of EBTs (§ 26.91(e))

External Calibration Definition

Comments: One commenter addressed proposed § 26.91(e) and noted that the term "external calibration check" was not defined. The commenter suggested eliminating "external" from the term "external calibration check." [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenter's request. The term "external calibration check" has a specific meaning for EBT devices and is a commonly used term for describing the quality assurance measures taken by a collection site to evaluate the performance of an EBT. A collection site must ensure the each EBT used for FFD program alcohol testing is functioning within the acceptable tolerance limits specified in the quality assurance plan of the equipment manufacturer by conducting a specific accuracy check on the equipment, which is called an external calibration check.

Frequency of External Calibration Checks on EBTs

Comments: One commenter addressed proposed § 26.91(e)(1) that required, at a minimum, that an external calibration check must be performed on an EBT according to the time interval specified in the manufacturer's quality assurance plan (QAP). The commenter requested that the NRC revise this section to require an external calibration check to be performed more frequently because a donor could be sanctioned for a positive test result that would be later overturned if the EBT was malfunctioning (i.e., fails the next external calibration check). Specifically, the commenter requested that an external calibration be performed on each EBT used for testing at the start and end of each testing day. [Todd Newkirk, IBEW].

NRC Response: The NRC agrees, in part, with the commenter's request. The QAPs for many EBTs require only monthly external calibration checks and/or external calibration checks more frequently, if a specific number of tests have been performed. The NRC considered requiring more frequent external calibration checks, but could find no reasonable basis for establishing schedules that would be more appropriate for every EBT on the NHTSA list than those recommended by EBT manufacturers. To address this concern, § 26.91(e)(4) in the final rule provides two optional procedures that licensees or other entities must choose from for reacting to an EBT's failure of an external calibration check. The first option directs that, if an EBT fails an external calibration check, the licensee or other entity is to cancel every confirmed positive test result that was obtained using the EBT from any tests that were conducted after the EBT passed its last external calibration test. Alternatively, collection sites are directed to conduct an external calibration check on the EBT in the presence of the donor after every confirmed positive test result using that EBT. If the EBT fails the external calibration check, the rule requires the collector to cancel the donor's test result and immediately conduct a second specimen collection (initial and, if necessary, confirmatory test) using another EBT. Performing the external calibration check while the donor is still present ensures that, if an EBT is malfunctioning, another EBT that meets the requirements in § 26.91(c) can be used to perform additional alcohol testing in a timely manner. Under either of these options, performing external calibration checks at the start and end of each testing day would be unnecessary and both ensure that donors will not be subject to sanctions based on erroneous test results.

<u>EBT Calibrations and Cancellation of Positive Test Results</u>

Comments: One commenter, supported by other commenters, disagreed with the provision in proposed § 26.91(e)(3) pertaining to an EBT that fails an external check of calibration. The commenter objected to the proposed requirement to cancel all positive breath alcohol test results from the point the EBT last passed an external calibration check to the point the EBT failed the external calibration check and was taken out of service. The commenter argued that "since fitness for duty has traditionally been considered an aspect of physical plant security, it causes one to make a comparison to those situations when security equipment fails, and that comparison yields contradictory results. For instance, if access screening equipment fails, all personnel in the protected area are not required to be re-searched because there is not an automatic assumption made that the machine was inoperative and everyone in the plant was improperly screened. In the same manner, personnel within a vital area are not required to leave the area when the access device or door alarm fails because there is not an automatic assumption made that they were able to obtain unauthorized or undetected access. In each of these instances, the assumption is that the equipment failed in the testing officer's presence and compensatory measures are implemented, to include an investigation. . . The same line of thinking should be applied across the spectrum of security, including FFD. Unless evidence can

be provided that can demonstrate failure occurred immediately following the last successful test, the assumption should not be that the equipment was not working, it should be that it worked properly until the failing test was performed." The commenter also asserted that having to "negate all positives since the last successful test will probably cause an increase in the frequency of testing to minimize the impact from this occurring. The implied test frequency exceeds the required frequency, adding burden to FFD staff and increased costs not calculated in the regulatory analysis." [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees that a positive confirmed breath alcohol test result should not be overturned when the EBT used during the test fails an external calibration check. Each donor must receive a fair and accurate test result. A donor should not be subject to sanctions based on a test result produced by a malfunctioning EBT. However, the NRC has revised § 26.91(e) in the final rule to provide licensees and other entities with two options to respond to EBT external calibration check failures. This section retains the proposed § 26.91(e)(3) requirement (in § 26.91(e)(4)(i) in the final rule) that any positive confirmatory alcohol test results that were obtained from an EBT that fails an external calibration check must be cancelled and also that the results of any tests that were conducted with that EBT subsequent to its last successful external calibration check must be cancelled. Section 26.91(e)(4)(ii) in the final rule adds a second option. This 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 collector must cancel the donor's test result and perform another initial and confirmatory alcohol test, if necessary, using a different EBT. The NRC finds no basis for the commenter's conclusion that the proposed provision would cause additional burden and costs. Given that the positive rate for alcohol testing is low, the likelihood that many test results would be required to be overturned by any FFD program is insignificant.

Copy of the External Calibration Records for EBTs

Comments: One commenter addressed the quality assurance and quality control provisions contained in proposed § 26.91(e)(3) and requested that a provision be added to permit a donor or donor representative to receive a copy of the external calibration check record performed on the EBT used to test the donor [Todd Newkirk, IBEW].

NRC Response: The NRC's expansion of donors' right to obtain their FFD-related records in § 26.37(d) of the final rule addresses this comment. This section in the final rule stipulates that individuals subject to Part 26 requirements, or their designated representatives, have the right to request and receive "…all FFD records pertaining to the individual, including, but not limited to,…drug and alcohol test results…." This information includes records of external calibration checks on EBTs from a collection site. The NRC believes that access to this information is necessary to protect donors' rights, including due process, under the rule.

7.7 Preparing for Alcohol Testing (§ 26.93)

No comments addressed this section.

7.8 Conducting an Initial Test for Alcohol Using a Breath Specimen (§ 26.95)

No comments addressed this section.

7.9 Conducting an Initial Test for Alcohol Using a Specimen of Oral Fluids (§ 26.97)

No comments addressed this section.

7.10 Determining the Need for a Confirmatory Test for Alcohol (§ 26.99)

Comments: One commenter requested that proposed § 26.99 be revised to specifically prohibit any further licensee actions or sanctions against a donor with a breath alcohol concentration result of less than 0.02 percent BAC [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter's request. Section 26.23(b) in the final rule stipulates that FFD programs must "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…." Moreover, when an individual appears to be impaired or the individual's fitness appears to be questionable, § 26.77(b) in the final rule requires a licensee or other entity to take immediate action to prevent the person from performing activities that would make him or her subject to Part 26 requirements. Although an individual may have an initial alcohol test result of less than 0.02 percent BAC, other indicators may suggest possible impairment. In these cases, the licensee or other entity must take action consistent with the § 26.77(b) to assure the individual's ability to safely and competently perform duties covered by Part 26.

7.11 Conducting a Confirmatory Test for Alcohol (§ 26.101)

No comments addressed this section.

7.12 Determining a Confirmed Positive Test Result for Alcohol (§ 26.103)

Comments: One commenter, supported by many commenters, stated that proposed § 26.103 would improve the effectiveness of FFD programs in detecting alcohol misuse by ensuring that confirmatory alcohol testing identifies employees who have either consumed alcohol while on duty or before duty and may pose a risk to public health and safety. [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters that § 26.103 improves FFD program effectiveness and has retained this provision without change in the final rule.

Scientific Basis for Assigning a Positive Alcohol Test Result for 0.02 and 0.03 BAC Levels

Comments: One commenter addressed proposed § 26.103(a)(2) and (a)(3) by questioning the scientific validity of assigning a positive test result for an individual with a BAC of 0.03 percent and work status of at least 1 hour, or a BAC of 0.02 percent and work status of at least 2 hours. The commenter asked, "Due to differences in metabolism how can a straight line cutoff be established?" The commenter suggested that several breath specimens should be collected to calculate the decay ratio for the individual being tested [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter. Individual metabolism rates for alcohol may be influenced by an individual's weight, the number of metabolizing enzymes present in an individual's liver (a healthy liver vs. a diseased liver), and other factors, such as food consumption. However, individual differences in metabolism should not impact the procedures for back-extrapolation in § 26.103(a). The final rule requires individuals to abstain from alcohol use for at least 5 hours before reporting for duty. Back-extrapolation would be conducted for the first, second, or third hour after an individual has reported for duty. These procedures provide an alcohol-free period of 6 to 8 hours before an alcohol test, which is more than an adequate period of time for all alcohol consumed by even a moderately heavy drinker (3 to 4 drinks per episode) to have been metabolized from the body under normal conditions. Further, if a heavy drinker (5 or more drinks per episode) consumed significant amounts of alcohol just before the beginning of the pre-work abstinence period and had tested positive under these procedures, removal from duty would be warranted not only for the alcohol remaining in the individual's body, but also for the likely carry-over effects (e.g., hangovers) that could affect concentration and cognitive skills. 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. The NRC is confident that use of this average metabolic rate, in conjunction with back-extrapolation, will result in fair and accurate alcohol test determinations. Thus, if a donor's BAC is measured as 0.03 percent after he or she has been at work for 1 hour, he or she would have had a BAC of approximately 0.04 percent when reporting for work an hour before the test. 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 before the test. These requirements ensure that confirmatory alcohol testing will identify workers who may have posed a risk to public health and safety by being impaired from alcohol use while on duty.

Comments: One commenter stated that the provisions in proposed § 26.103(a) conflict with the FFD policy requirement in proposed § 26.27(c)(3) that pertained to unscheduled working tours. Specifically, § 26.27(c)(3) stated that "no sanctions may be imposed on an individual called in to perform an unscheduled working tour and has consumed alcohol within the pre-duty abstinence period stated in the policy." [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees that there is a conflict between the requirements in §§ 26.103(a) and 26.27(c)(3). Section 26.27(c)(3) requires licensees and other entities to maintain procedures "to ensure that individuals who are called in to perform an unscheduled working tour are fit for duty." In cases where an individual indicates that he or she has consumed alcohol within the pre-duty abstinence period, § 26.27(c)(3)(ii)(A) specifies that this procedure must "Require a determination of fitness by breath alcohol analysis or other

means…." The NRC has revised proposed §26.27(c)(3) by adding specific directives in the final rule regarding whether or not the individual may be assigned to Part 26-related duties, including emergency response duties, depending on whether the determination of fitness indicates that the individual is fit to safely and competently perform his or her duties. Section 26.27(c)(3)(ii)(E) in the final rule further stipulates 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."

Section 26.103(a) in the final rule, on the other hand, establishes the cutoff levels for confirmatory alcohol test results that licensees and other entities must declare as positive test results. These requirements are to be used in the "…determination of fitness by breath alcohol analysis or other means…" required in § 26.27(c)(3)(ii)(A) as in any other Part 26 testing for alcohol. Section 26.103(a) does not, however, contain any requirements related to sanctions. Thus, there is no conflict between the § 26.103(a) test result requirements and the § 26.27(c)(3)(ii)(E) stipulation 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. Therefore, the NRC has not modified these provisions in the final rule.

7.13 Preparing for Urine Collection (§ 26.105)

Comments: One commenter addressed proposed § 26.105(b) that required each urine specimen donor to empty the contents of his or her pockets so that the collector can inspect the items to ensure that the donor does not possess items that could be used to tamper with, adulterate, or substitute a urine specimen. The commenter requested that the proposed provision be revised to require collection sites to post a list of items that a collector could consider to be used to attempt to subvert the testing process. The commenter expressed concern that the proposed provision was ambiguous in that the collector may determine if an "item appears to have been inadvertently brought to the collection site" or may determine if an item was brought by the donor to the collection site "with the intent to adulterate the specimen." The commenter also expressed concern that an employee might bring a harmless substance such as a bottle of eye drops to the collection site and the collector might wrongly accuse the donor of attempting to subvert the testing process. The commenter suggested that an alternative to a posted list would be to require each donor to place all items on his or her person in a locker outside the collection area. The donor would be provided with the key to the locker which he or she would keep during the collection process [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter. The commenter's suggestion regarding a list of items that potentially could be used to subvert alcohol testing is untenable because collection site personnel would have no effective way to identify all possible items. Further, § 26.105 in the final rule provides for urine collection preparation procedures that protect against unjust determinations of subversion attempts. In particular, § 26.105(b) requires that if a collector identifies an item that the collector determines the donor brought to the collection site with the intent of adulterating or substituting a urine specimen, the collector must contact the MRO or FFD program manager to determine if further action must be taken. This review will ensure that a collector makes an accurate determination of whether or not the donor had intended to subvert the testing process. Also, the final rule requires urine collectors to receive training on collection procedures to ensure that correct decisions regarding the contents of a donor's pockets can be made. Finally, if a collector determines that a donor has

inadvertently brought something to the collection site (e.g., eye drops), the collector is required, by proposed and final § 26.105(b), to secure the item(s) outside the stall or enclosure used by the donor to provide a specimen before beginning a specimen collection. The NRC believes that these provisions provide adequate protections for each donor and ensure the integrity of the testing process. Therefore, the NRC has not modified this provision in the final rule.

Refusal to Test Action - Donor Refusal to Display the Contents of their Pockets

Comments: One commenter addressed proposed § 26.105(b) that stated a donor's refusal to show the collector the items in his or her pockets is an action considered to be a refusal to test. The commenter stated that solely relying on a collector to verbally inform the donor of the actions considered a refusal test is inadequate because the collector may forget to convey the information. The commenter requested that a description of the refusal to test actions be included on the donor consent-to-test form or be posted in a conspicuous location at the collection site. [Todd Newkirk, IBEW].

NRC Response: The NRC agrees, in part, with the commenter's request. Section 26.89(c) in the final rule requires that a collector must inform a donor that having an item that could be used to interfere with providing an actual urine specimen is a refusal to test. Individuals subject to Part 26 drug and alcohol testing are also informed of refusal to test actions in other ways. All individuals subject to the provisions of a licensee's or other entity's FFD program must be informed of the program policies under § 26.27(b) and must receive training on the FFD policy and consequences of violating the policy under § 26.29(a)(1). Section 26.27(b) requires that a written FFD policy statement be readily available to all covered individuals and include "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." One of the minimum FFD policy statement elements in § 26.27(b) is to "describe the actions that constitute a refusal to test, the consequences of refusals to provide a specimen for testing, as well as the consequences of subverting or attempting to subvert the testing process." The NRC believes that individuals subject to Part 26 urine testing will receive adequate notice of the actions that are considered a refusal test through this combination of access to FFD policy statements, training, and being informed at the urine collection site that having an item that could be used to interfere with providing an actual urine specimen is a refusal to test.

7.14 Collecting a Urine Specimen (§ 26.107)

Comments: Two commenters addressed proposed § 26.107(a)(3). One commenter, supported by many others, agreed with the proposed provision that permitted a collector to use professional judgement to determine an acceptable time limit for a donor to void. The commenter stated that the provision provided flexibility for a collector to accommodate a donor who needs additional time, when appropriate, but also ensured that the collector can prevent a donor from disrupting the testing process by attempting to delay the testing process [Jim Davis].

Another commenter requested that the proposed provision be revised to specify the time limit that is considered a "reasonable time limit for voiding." The commenter requested that a time limit be specified to remove possible subjectivity as to what a collector may deem as a reasonable time limit for voiding [Todd Newkirk, IBEW].

NRC Response: The first comment does not require a response. The NRC disagrees with the second commenter's request to establish a specific time limit that is acceptable for a donor to void. Collectors need flexibility to allow some donors additional time to provide a specimen (e.g., an individual with a disability). In addition, during public meetings some stakeholders reported incidents in which some donors delayed the testing process and challenged the collector's authority to set a time limit on a specimen provision. The intent of § 26.107(a)(3) in the final rule is to provide collectors with the necessary authority to set a reasonable time limit for voiding and to prevent a donor from disrupting the testing process. The collector should rely on his or her professional judgment in setting this time limit. Section 26.85(a) specifies new training and qualification requirements for collectors to ensure that they are able to exercise this professional judgment appropriately. Section 26.107(a)(3) is also consistent with other Federal agency requirements (e.g., U.S. DOT). Therefore, the NRC has not modified the proposed provision in the final rule.

7.15 Urine Specimen Quantity (§ 26.109)

Comments: One commenter addressed proposed § 26.109(b)(1) that permitted a donor to consume up to 24 ounces of fluid in situations where the donor fails on an initial attempt to provide the minimum quantity of urine. The commenter stated that the proposed provision was consistent with the HHS Guidelines, but not the U.S. DOT's provision to permit a donor up to 40 ounces of fluid [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.109(b)(1) to permit donors to consume up to 40 ounces of liquid over a 3-hour period if they fail on their initial attempt to provide the minimum quantity of urine. This is consistent with the quantity of fluid that other Federal testing programs (i.e., U.S. DOT) permit a donor in a shy-bladder situation to consume. The NRC believes that this amount will give donors a better chance than under the proposed rule's 24-ounce limit to provide a urine specimen of the required quantity while at the same time ensuring that individuals who may be subject to water intoxication will not be placed at risk.

<u>Specify That a Collector Must Discard a Specimen that is Less Than 30 mL in Quantity</u>

Comments: One commenter stated that proposed § 26.109(b) did not clearly state that if the quantity of urine collected from a donor is less than 30 mL the collector must discard the specimen and collect another. The commenter suggested that the NRC revise proposed § 26.109(b)(1) to state: "The collector shall discard the specimen and a second specimen shall be collected" and delete the second sentence under proposed § 26.109(b)(1) [Sue Brown, Individual].

NRC Response: NRC disagrees with the commenter's request. Section 26.109(b)(4) in the final rule addresses the commenter's concern because it states that "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 . . ." Therefore, the NRC has not modified the proposed provision in the final rule.

7.16 Checking the Validity of the Urine Specimen (§ 26.111)

Acceptable Temperature Range of a Urine Specimen

Comments: One commenter, supported by other commenters, agreed with the proposed provision to expand the acceptable temperature range of a urine specimen in § 26.111. [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comment does not require a response.

Comments: One commenter requested the NRC to clarify proposed § 26.111 by specifying whether validity screening (including specific gravity testing) is to be performed at the point of collection or at the point of testing [Anonymous].

NRC Response: Comments received on point of collection testing and specific gravity testing are addressed in Subpart F.

Timing of Measuring a Donor's Temperature

Comments: One commenter addressed proposed § 26.111(a) that required a collector to measure the temperature of a specimen sooner than the 4-minute limit from the point the specimen is provided to the collector, if the ambient temperature was low or the specimen quantity was small. The commenter stated that the proposed provision would be difficult to monitor and would be subject to legal challenge. The commenter recommended that the provision be eliminated from the final rule [Charles LoDico, Individual].

NRC Response: The NRC agrees with the commenter and has eliminated the wording in § 26.111(a) of the proposed rule to which the commenter objected. The normal collection process is that the collector immediately measures the temperature of the specimen once the donor presents the specimen to the collector. The intent of the proposed provision was to serve as guidance to collectors, directing them to take special care to quickly measure the temperature of a specimen under specific circumstances. However, the NRC recognizes that obtaining an accurate temperature reading on specimens smaller than 15 mL can be difficult. Thus, § 26.109(b)(4) in the final rule requires collectors to discard these small specimens. This section also directs collectors to discard specimens of 15 mL or more, but less than 30 mL, unless they have a reason to believe that these specimens have been diluted, adulterated, substituted, or otherwise altered. In these cases, § 26.109(b)(4) directs collectors to transfer the suspect specimens to an HHS-certified laboratory and contact FFD program management to determine whether a directly observed collection is required. It should also be noted, however, that when a small specimen's temperature falls outside the temperature range specified in § 26.111(b), MROs and FFD program managers have the authority, under the § 26.111 provisions, to decide that the low temperature is not a reason to believe that attempted subversion has occurred and they are not required to order a directly observed collection in every instance.

Comments: One commenter, supported by many others, addressed proposed § 26.111(a) regarding measuring the temperature of a specimen within 4 minutes of the specimen collection. The commenter stated that the temperature difference between a donor's specimen and a donor's body temperature as specified in § 26.115(a)(2)(ii) lacked a scientific basis without a time consideration. The commenter stated that a donor's specimen will begin to cool immediately and will continue to cool until it reaches temperature equilibrium with the surrounding air. Because the cooling rate of a specimen is largely a function of the temperature difference between the specimen and the surrounding air and the temperature difference is typically significant (approximately 25 degrees F), the commenter suggested that a donor's body temperature be taken as soon as possible after the specimen is determined to be outside the acceptable temperature range. [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees in part with this commenter's requests. The NRC has eliminated the provision in proposed § 26.115(a)(2)(ii) that would have authorized comparing the donor's body temperature and specimen temperature as part of a reason for requiring a subsequent collection of a urine specimen under direct observation. Public comments at stakeholder meetings indicated that the U.S. DOT's experience shows that there are often discrepancies when comparing the temperature provided by a specimen container temperature slip and the temperature provided by a device that measures body temperature. Somewhat contrary to the commenter's second suggestion, however, the NRC has decided to eliminate the option for the donor to volunteer to provide a measurement of body temperature that appeared in proposed § 26.111(b). As compared to the former rule, § 26.111 in the final rule creates a wider range of acceptable specimen temperatures. With this increase in acceptable temperature range, measurement of body temperature is less useful to counter a reason to believe that the donor has altered the specimen. This change is consistent with the testing regulations for other Federal agencies (U.S. DOT, and HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs). It should also be noted that § 26.111(c) in the final rule allows the donor to volunteer to submit a second specimen under direct observation. This provides the donor with an opportunity to counter any reason to believe that he or she may have altered or substituted the first specimen.

Comment: One commenter addressed proposed § 26.111(b) that allowed a donor to volunteer to have his or her body temperature measured by the collector in the circumstance when the specimen that a donor provides is outside the acceptable temperature range. The commenter suggested that NRC reconsider permitting the measurement of a donor's body temperature given that a temperature measuring device is a better indicator of body temperature than the temperature strips used on specimen collection containers [Charles LoDico, Individual].

NRC Response: The NRC agrees with the commenter's request. The NRC has eliminated the proposed provision in § 26.111(b) that, in cases when the specimen is out of the acceptable temperature range, would have allowed the donor to volunteer to have his or her body temperature taken to provide evidence to counter a reason to believe that the donor may have altered or substituted the specimen. As compared to the former rule, § 26.111 in the final rule creates a wider range of acceptable specimen temperatures. With this increase in acceptable

temperature range, measurement of body temperature is less useful to counter a reason to believe that the donor has altered the specimen. The elimination of the option to measure a donor's body temperature is also consistent with the testing regulations for other Federal agencies (U.S. DOT, and HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs).

Comments: One commenter addressed proposed § 26.111(b) and stated that if the temperature of a specimen is outside the acceptable range, a form should be used by the collector so that the actual temperature of the donor can be recorded or the donor can sign the form refusing to permit his or her body temperature to be measured [Todd Newkirk, IBEW.]

NRC Response: The NRC has addressed this commenter's concern by eliminating this provision in the final rule, as discussed with respect to the preceding comment.

Use of the Word "Validity" in the Title for § 26.111

Comments: One commenter, supported by other commenters, requested that the word "validity" in the heading for proposed § 26.111, "Checking the validity of the urine specimen," be changed to "acceptability." The commenter recommended the word change to reduce possible confusion that may arise given that three definitions in § 26.5 (initial validity testing, screening validity testing, confirmatory validity testing) already include the word "validity." The commenter suggested using the word "acceptability" given its use in proposed § 26.111(g), which stated that an acceptable specimen is within the acceptable temperature range, is at least 30 mL in quantity, and is free of any apparent contaminants [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with this request and has revised the heading of § 26.111 in the final rule to improve the clarity of the heading used to describe the provisions in this section.

7.17 Splitting the Urine Specimen (§ 26.113)

Comments: One commenter disagreed with proposed § 26.113(b)(1) that required a donor to urinate into either a specimen bottle or a specimen container. The commenter asserted that the proposed process might produce conflicting results for Bottle A and Bottle B, especially if a donor successfully adulterates one bottle and the laboratory identifies the adulterant. The donor could challenge the laboratory result by requesting Bottle B specimen testing which would produce a different test result (if no adulterant were added to the Bottle B specimen) that would result in the cancellation of the test result. The commenter recommended that for all specimen collections, a urine specimen be collected in a collection cup and that the collector transfers the urine specimen into the A and B bottles [Charles LoDico, Individual].

NRC Response: The NRC agrees with the commenter's reasoning and has eliminated the proposed provision that a donor may urinate into a specimen bottle. The final rule requires the collector to direct the donor to urinate into a specimen container. Once the donor provides a specimen that is within the acceptable temperature range, is at least 30 mL in quantity, and is

free of any apparent contaminants, the collector will split the specimen into Bottle A and Bottle B under § 26.113(b)(2) and (3) of the final rule.

Comments: One commenter addressed proposed § 26.113(b)(2) and suggested that the phrase "a minimum of" be added to the requirement that "Bottle B must contain 15 mL." [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's request and has revised § 26.113(b)(2) in the final rule. This provision now requires the collector to pour a minimum of 15 mL of urine into Bottle B or all urine that remains after pouring 30 mL into Bottle A. As revised, this section of the final rule more clearly specifies 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 made this clarification 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. The NRC intends that licensees and other entities subject to Part 26 do not adopt this burdensome practice.

Comments: One commenter addressed proposed § 26.113(b)(2) and suggested that the provision appeared to suggest that a collector would not send Bottle B to either the HHS-certified laboratory or to a licensee testing facility if the quantity of the specimen in Bottle B is less than 15 mL. The commenter suggested that the provision be revised to read: "If there is less than 15 mL of urine available for Bottle B, all remaining urine must be poured into Bottle B. Bottle A and Bottle B must be sent to the HHS-certified laboratory." [Sue Brown, Individual]

NRC Response: NRC agrees with the commenter's request to clarify the proposed requirement and has revised § 26.113(b)(2) in the final rule to require the collector to send both Bottles A and B to the HHS-certified laboratory in circumstances where there is less than 15 mL of urine available for Bottle B. In this circumstance, forwarding the Bottle B specimen to a licensee testing facility is unnecessary, because there is insufficient urine for conducting any testing at the licensee testing facility. This requirement is also consistent with other provisions of the final rule that require collectors to forward specimens with other unusual characteristics to the HHS-certified laboratory.

7.18 Collecting a Urine Specimen under Direct Observation (§ 26.115)

Comments: One commenter requested that NRC define the terms "EC" and "EF" in proposed § 26.115(a)(2)(ii) that stated: "The donor's measured body temperature varies by more than 1EC/1.8EF from the temperature of the specimen." [Charles LoDico, Individual]. Another commenter recommended that NRC replace the letter "E" in the terms "EC" and "EF" with the word "degrees" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC has eliminated the requirement in proposed § 26.115(a)(2)(ii) because U.S. DOT's experience shows that there are often discrepancies when comparing the temperature provided by a specimen container temperature slip and the temperature provided by

a device that measures body temperature. Also, § 26.111(b) of the final rule no longer permits a body temperature measurement in instances where a donor provides a specimen that is outside of the acceptable temperature range. Therefore, it is unnecessary for the NRC to make the commenters' suggested change.

7.19 Preparing Urine Specimens for Storage and Shipping (§ 26.117)

Specimen Chain of Custody

Comments: One commenter addressed proposed § 26.117(g) and requested that the provision be revised to more precisely describe what a break in the chain of custody is and what specific actions must be taken [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenter's request. The NRC has added provisions to § 26.129(b) in Subpart F and § 26.159(b) in Subpart G of the final rule to identify the circumstances that require the MRO to cancel the testing of a specimen as a result of conditions that demonstrate the specimen's chain of custody is unverifiable (e.g., the identification numbers on the specimen bottle seal(s) do not match the identification numbers on the custody-and-control form). The requirements included in the final rule are consistent with the related drug testing provisions of the U.S. DOT and are necessary to protect the integrity of the testing process.

Specimen Storage Requirements - Cooling to Not More than 6 Degrees Celsius:

Comments: One commenter addressed proposed § 26.117(j) that required a specimen to be stored at not more than 6 degrees Celsius if the specimen is not shipped to an HHS-certified laboratory or licensee testing facility within 24 hours of the specimen collection or if a specimen is suspected of being tampered with, adulterated, or substituted. The commenter stated that the HHS Guidelines do not contain the specimen storage requirements in the proposed provision [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. The NRC has chosen to maintain the former rule's refrigerated specimen storage requirement. This requirement improves FFD programs' ability to reduce the likelihood of specimen degradation that can lead to erroneous test results and improves the ability of the FFD program to detect and deter prohibited drug use. Therefore, the NRC has not modified the proposed provision in the final rule.

7.20 Determining "Shy" Bladder (§ 26.119)

Comments: One commenter addressed proposed § 26.119(a) and stated that the proposed 5-business day time limit for a donor to receive a medical evaluation after failing to provide the minimum quantity of urine within the 3-hour time limit for a specimen collection is inadequate. The commenter asserted that obtaining an appointment with a medical doctor, especially if the doctor is a specialist, is highly unlikely within the proposed 5-day time limit [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenters request. The provision was consistent with other federal testing programs (U.S. DOT). It also accounted for the likelihood

that most doctors' offices do not offer appointments during weekends or holidays. The NRC established the time limit of 5 business days as a trade-off between the need to provide the donor with sufficient time to locate a qualified physician and obtain an appointment, and for the physician to complete the evaluation (i.e., the donor's right to due process), and the public's interest in a rapid determination of whether the donor had attempted to subvert the testing process by refusing to provide a sufficient specimen. The U.S. DOT's experience indicates that 5 days is sufficient to complete the evaluation. Therefore, the NRC has not modified the proposed provision in the final rule.

Comments: One commenter addressed § 26.119(a) and inquired as to why a medical doctor who conducts the "shy-bladder" evaluation on a donor must be acceptable to the MRO [Todd Newkirk, IBEW].

NRC Response: The NRC has retained the requirement in § 26.119(a) that a licensed physician who evaluates the donor must be acceptable to the MRO. This is necessary to ensure that the physician is qualified because not all physicians may have the requisite expertise specific to this particular medical condition. MROs will be qualified to assess the expertise of other physicians as a result of the training required to obtain certification under § 26.183(a).

Comments: One commenter addressed proposed § 26.119 and stated that the NRC should consider the use of alternate specimen testing in situations where a donor fails to provide the minimum quantity of urine necessary for specimen testing within the permitted 3-hour time limit. The commenter suggested that alternate specimen testing be considered an option for shy-bladder situations, given that proposed § 26.31(d)(5) allowed for alternate specimen testing if an MRO determines that a donor has a medical condition that precludes urine drug testing [Todd Newkirk, IBEW].

NRC Response: The NRC agrees, in part, with the commenter's request. Testing alternate specimens may be necessary in shy-bladder situations. However, it is imperative that a valid medical condition is confirmed and that only the MRO has the authority to order alternate testing. The NRC disagrees that using an alternate specimen for testing in these situations should be a standard procedure to be routinely implemented by specimen collectors. The MRO must be involved in making or reviewing the medical diagnosis, determining the specimens that are to be collected and tested based on the most recent information available about the accuracy and sensitivity of testing methods for alternate specimens, and directing how the collection and testing procedures must be performed. The MRO's involvement in this process is necessary to ensure that testing of alternate specimens will provide valid and legally defensible results. Section 26.31(d)(5) addresses circumstances when it may be impossible or inadvisable to perform urine drug testing on an individual and 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. This subsection makes clear that only the MRO is permitted to authorize an alternative evaluation procedure, which may include, but is not limited to blood testing for alcohol. Therefore, the NRC has not modified the proposed provision in the final rule.

8. Subpart F: Licensee Testing Facilities

8.1 Purpose (§26.121)

No comments addressed this section.

8.2 Testing Facility Capabilities (§ 26.123)

Comments: One commenter suggested that each licensee testing facility be required to meet the Initial Instrumented Testing Facility (IITF) specifications described in the proposed revisions to the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (69 FR 19672) [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's suggestion. The proposed revisions to the HHS Mandatory Guidelines for Federal Workplace Drug Testing have yet to be finalized to allow for consideration during the completion of this rulemaking effort and may be revised. The NRC will review the provisions regarding Initial Instrumented Testing Facility specifications once the finalized HHS Guidelines have been published and determine if additional revisions to Part 26 may be warranted at that time.

8.3 Licensee Testing Facility Personnel (§ 26.125)

Comments: Two commenters objected to the proposed elimination of the requirement that licensee testing facilities retain records on color blindness testing of their laboratory personnel. The commenters stated that because some non-instrumented validity tests require testing personnel to evaluate the color of the assay to determine the result, color blindness testing is necessary to ensure laboratory technician competency [Sue Brown, Individual; Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenters and has revised § 26.125(c) in the final rule to require that licensee testing facilities retain color blindness test results for laboratory testing personnel conducting specimen validity testing. The ability of laboratory personnel to identify the color of test results is a necessary job requirement.

8.4 Procedures (§ 26.127)

Comments: One commenter, supported by many others, affirmed that the proposed provision in § 26.127(b) would ensure that licensees and other entities take appropriate corrective actions if an issue is identified with the chain-of-custody for any specimen [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comment does not require a response.

Comments: One commenter requested that proposed § 26.127(b) be revised to specify the required actions that must be taken if the chain of custody for a specimen is "broken" [Todd Newkirk, IBEW]

NRC Response: The NRC has revised proposed § 26.129(b) in the final rule to include a description of the required actions to be taken by a licensee testing facility if the testing laboratory believes 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 provisions also describe procedures to address instances where either the Bottle A or Bottle B specimen leaks in transport from the collection site to the testing facility. Further, the revisions to § 26.129(b) include specific instances that would require the cancellation of the testing of a donor's urine specimen. These revisions are consistent with U.S. DOT's requirements.

8.5 Assuring Specimen Security, Chain of Custody, and Preservation (§ 26.129)

Licensee testing facility security

Comments: One commenter, supported by many others, affirmed the adequacy of the proposed security requirements for licensee testing facilities [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comment does not require a response.

Comments: One commenter requested that proposed § 26.129(a) be revised to specify the personnel who must maintain the security of licensee testing facilities and what actions must be taken if facility security is determined to be compromised [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter. The NRC believes that the requirements in this provision are adequate to protect the security of a licensee testing facility. Adding greater specificity with respect to personnel and actions would unnecessarily limit licensees' and other entities' flexibility. Testing facility staffing and physical and operational characteristics vary substantially among licensees and other entities. This variability makes it impractical for the NRC to devise specific language that would be appropriate at all testing facilities. Therefore, the NRC is leaving it to each individual licensee and other entity to determine the personnel who must maintain the security of licensee testing facilities and the actions to be taken if facility security is determined to be compromised.

Specimen Integrity

Comments: One commenter, supported by many others, supported the requirements in proposed § 26.129(b) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comment does not require a response.

Comments: One commenter suggested that proposed § 26.129(b) be revised to state that a specimen "must not be tested if the integrity or identity" is in question, instead of the proposed language that a specimen "may not be tested if the integrity or identity" of a specimen is in question [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter's request. The NRC requires that rule text use the phrase "may not" to describe a prohibited activity.

Correcting Custody and Control Form Errors

Comments: One commenter suggested that proposed § 26.129(b) be revised to stipulate that when attempting to resolve any discrepancies with information entered on the specimen custody-and-control form, licensee testing facility personnel should attempt to obtain a "memorandum for the record" from the specimen collector instead of making any corrections to the original custody-and-control form. The commenter stated that obtaining a memorandum for the record is a forensically acceptable means to correct discrepancies found on a custody-and-control form while permitting a collector to modify the original custody-and-control form is not [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter. Corrections to the original custody-and-control form should be made only by the collector during the specimen collection process and in the presence of the donor. Once the donor leaves the collection site, any errors identified on the custody-and-control form must be corrected using a memorandum for the record and not on the original custody-and-control form. Therefore, the NRC has revised § 26.129(b) in the final rule to include a description of the process for obtaining a memorandum for the record from the collector to correct any custody-and-control form errors identified after the specimen collection process has been completed and the donor has departed from the collection site.

Other Appropriate Methods to Track Aliquot Custody and Control

Comments: One commenter objected to the provision in proposed § 26.129(c) permitting licensee testing facilities to use "other appropriate methods of tracking aliquot custody and control." The commenter stated that HHS has always required written documentation on a chain-of-custody form to track specimens and aliquots in certified laboratories. The commenter noted that while bar coding is an effective tracking method used in HHS-certified laboratories, a bar code list generated by a tracking device or instrument is always associated with a custody-and-control form that documents the personnel handling each specimen or aliquot. The commenter stated that written documentation ensures the security of each specimen and aliquot during the testing process [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. The NRC is not aware of any instances where the custody and control of a specimen has been jeopardized or called into question as a result of the specimen tracking methods used by a licensee testing facility. Therefore, the NRC has not modified the proposed provision in the final rule.

Bottle B Retention Location

Comments: One commenter addressed proposed § 26.129(f) and recommended that for split specimen collections, both Bottles A and B should be maintained together at all times and that both bottles should be sent to the HHS-certified laboratory if Bottle A has any non-negative test result. The commenter suggested that keeping both bottles together would reduce the chance that a specimen could be lost and would improve the timeliness in testing Bottle B [Charles LoDico, Individual]. Another commenter noted that the proposed provision would create a cumbersome requirement because the licensee testing facility must maintain proper custody and control for Bottle A and Bottle B separately. In addition, the licensee testing facility must ensure that Bottle B is moved from refrigeration to frozen storage, or discarded. The commenter suggested that the probability than an error could occur with the custody-and-control documentation would increase given the number of times Bottle B could be moved at the licensee testing facility [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenters. The NRC is not aware of any instances where the custody and control of a Bottle B specimen has come into question or a Bottle B specimen has been lost in an attempt to maintain the specimen at a licensee testing facility. Licensee testing facilities have successfully maintained Bottle B specimens and industry experience fails to provide evidence that current practices have been unsuccessful in securing and storing specimens. Therefore, the NRC has not modified § 26.129(f) of the final rule.

Emergency Backup Power

Comments: One commenter addressed proposed § 26.129(f) and disagreed with the NRC's decision not to require each licensee testing facility to have emergency power equipment available in case of a prolonged power failure. The commenter stated that emergency power equipment is necessary to maintain specimens in long-term frozen storage if a licensee testing facility is permitted to retain specimens rather than transferring them to an HHS-certified laboratory [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.135(c) in the final rule to require that licensee testing facilities electing to retain Bottle B specimens at the testing facility rather than forwarding the specimens to an HHS-certified laboratory with Bottle A, must ensure that proper storage conditions be maintained (i.e., specimens stored at a temperature of -20^{o} Celcius or less) in the event of a prolonged power failure.

Location of Original Custody-and-Control Form

Comments: One commenter stated that the proposed § 26.129(g) requirement that a licensee testing facility must send the original custody-and-control form with the Bottle A specimen to the HHS-certified laboratory leaves the specimen in Bottle B maintained at the licensee testing facility without the original custody-and-control form. The commenter noted that the proposed procedure was not in agreement with the HHS Mandatory Guidelines for Federal Workplace Drug Testing which require the original custody-and-control form to be maintained with the specimen Bottle A, and if the specimen in Bottle B is to be sent to a second HHS-certified laboratory, a copy of the original custody-and-control form is to be sent. The commenter

recommended both Bottle A and Bottle B be sent to the HHS-certified laboratory instead of maintaining Bottle B at the licensee testing facility [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. The NRC is not aware of any instances where the custody and control of a specimen has been jeopardized or called into question as a result of the specimen tracking procedures currently used by licensee testing facilities. Therefore, the NRC has not modified the proposed provision in the final rule.

8.6 Cutoff Levels for Validity Screening and Initial Validity Tests (§ 26.131)

Validity Testing at Licensee Testing Facility if Sending All Specimens to HHS-certified Laboratory?

Comments: One commenter asked if proposed § 26.131 required validity testing to be conducted at a licensee testing facility even if the licensee does not conduct immunoassay drug screening onsite at a licensee testing facility (i.e., the FFD program sends all specimens to an HHS-certified laboratory for testing) [Anonymous, #15].

NRC Response: A licensee or other entity may choose to send all urine specimens to an HHS-certified laboratory for all required testing (i.e., validity and drug testing) under this part.

Conducting Initial Validity and Validity Screening Testing

Comments: One commenter addressed proposed § 26.131(a) and requested the NRC to clarify whether initial validity testing must be conducted if a licensee testing facility conducts validity screening tests [Susan Techau, Exelon].

NRC Response: The NRC does not intend to require licensee testing facilities to perform initial validity testing if they the use validity screening tests. Section 26.131(a) of the final rule requires that all validity test results from licensee testing facilities 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. In other words, a licensee testing facility may conduct either a validity screening test or an initial validity test on each specimen. The NRC is also permitting licensee testing facilities to perform validity screening testing first and then initial validity testing on specimens that yield questionable validity test results from validity screening tests, at their discretion. Either validity screening or initial validity testing will accomplish the NRC's objective of identifying specimens of questionable validity that must be transferred to an HHS-certified laboratory for additional testing. Therefore, the agency is permitting licensees and other entities to choose which of these validity testing procedures, or a combination of procedures, they will implement at a licensee testing facility.

Conduct Validity Testing at Collection Site as Soon a Specimen is Received

Comments: One commenter addressed proposed § 26.131(b) and suggested that specimen validity testing be performed at the collection site as soon as the donor presents a urine specimen to the collector and before the donor leaves the collection site. The commenter stated that immediate validity testing of a specimen would protect the donor from being accused of

attempting to subvert the testing process and would also allow for an immediate observed second collection if the initial specimen did not pass the validity test. [Todd Newkirk, IBEW]

NRC Response: The NRC disagrees with the commenter's suggestion. The NRC believes that licensees or other entities must conduct all specimen testing at a licensee testing facility and/or at an HHS-certified laboratory. Specimen collectors do not have the appropriate level of training to use validity screening tests. In addition, the commenter's suggested revision would permit the individual who tests the specimen to be aware of the identity of the donor. Since Part 26 was first promulgated, the NRC has maintained that the individuals who perform urine testing must not be aware of a donor's identity to protect against any potential biases that knowledge could introduce into the testing process. This policy is consistent with a similar HHS policy which has always prohibited testing facility employees from collecting specimens if they could link the donor's identity to test results. Therefore, the NRC has not modified the proposed provision in the final rule.

Use of the Term "Cutoff Levels"

Comments: One commenter suggested revising proposed § 26.131 by replacing the term "cutoff levels" with "decision points" for validity screening and initial validity testing. The commenter suggested the change because validity testing is based on decision points and not cutoff levels [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request. The term "cutoff levels" is consistent with testing terminology familiar to licensees and other entities subject to Part 26. To maintain consistency with terminology used by industry, the NRC has decided not to modify the proposed provision in the final rule. However, the NRC has revised the definition of "cutoff level" in § 26.5 in the final rule to address the commenter's concern. The definition of "cutoff level" has been revised to mean "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)."

Use of the Term "Non-negative"

Comments: One commenter stated that use of the term "non-negative" in proposed § 26.131(a) to describe some validity screening and initial validity test results was inaccurate. Instead of "non-negative," the commenter recommended using "presumptive adulterated, substituted, or invalid" for validity screening and initial validity test result reporting [Sue Brown, Individual].

NRC Response: The NRC agrees, in part, with the commenter's request. Throughout the final rule, the NRC has replaced the term "non-negative test result" with a new term to address validity screening and initial validity test 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 chosen this term, rather than a term that would directly reference possible adulteration, substitution, dilution, or an invalid specimen, because licensee testing facilities will not be conducting the specific gravity testing that is required to establish these specimen characteristics.) The NRC has added a definition of "questionable validity" in § 26.5 of the final rule. Adding the term "questionable validity"

addresses the commenter's concern and improves the clarity of the language used in the final rule.

Validity Screening Testing

Comments: One commenter addressed proposed § 26.131(a) and stated that licensee testing facilities are only capable of performing validity screening testing. The commenter asserted that validity screening tests usually do not have the same sensitivity as initial validity tests and therefore could not meet the cutoff levels listed in proposed § 26.131(b). The same commenter also stated that validity screening tests, at a minimum, should meet the cutoff criteria for an "invalid" specimen in the HHS Guidelines. [Sue Brown, Individual]

NRC Response: The NRC disagrees that licensee testing facilities should be authorized to perform only validity screening tests and is continuing to permit initial validity testing at licensee testing facilities. However, the NRC agrees with the commenter that validity screening tests must be able to meet the invalid specimen criteria in the HHS Guidelines. The NRC has revised the specimen criteria for pH and nitrite concentration in the final rule to identify potentially invalid specimens, consistent with the HHS Guidelines, as specimens with a pH less than 4.5 or a nitrite concentration equal to or greater than 200 mcg/mL. The provisions accounting for invalid specimens have been included in § 26.131(b)(2) and (b)(3) of the final rule.

Required Tests for Validity Screening Testing

Comments: One commenter addressed proposed § 26.131(b) and asked if a licensee testing facility could meet the validity screening testing requirements by only conducting instrumented specimen testing for pH and creatinine [Anonymous, #15].

NRC Response: A licensee testing facility will not meet the validity screening testing requirements if each urine specimen is tested only for pH and creatinine. Section 26.131(b) of the final rule requires licensee testing facilities to test each urine specimen for creatinine, pH, and one or more oxidizing adulterants.

Specific Gravity Testing at Licensee Testing Facilities

Comments: One commenter noted that proposed § 26.131(b) did not include requirements for specific gravity testing at a licensee testing facility. The commenter stated that the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs require specific gravity testing for any specimen with a creatinine concentration less that 20 mg/dL. The commenter further added that because specific gravity testing is not currently permitted at licensee testing facilities, the NRC has not properly defined specimen dilution and substitution criteria, which both require specific gravity test results [Charles LoDico, Individual].

NRC Response: In contrast to the HHS Guidelines requirements for initial validity testing, the final rule does not require licensee testing facilities to test specimens' specific gravity. Instead, § 26.131(b) of the final rule requires licensee testing facilities to forward specimens having a creatinine concentration of less than 20 mg/dL to the HHS-certified laboratory which will measure these specimens' specific gravity. The NRC has chosen this course because of the high costs of refractometers, the instruments that the HHS Guidelines require for measuring

specimens' specific gravity. Although some licensee testing facilities are currently measuring specific gravity, the new HHS Guidelines specific gravity cutoff levels require more sensitive measurement than those licensee testing facilities are currently capable of doing. They would have to purchase new equipment to meet these new cutoff levels. Rather than require licensees to incur the resulting expense, the final rule does not require licensee testing facilities to test specimens' specific gravity nor does it include cutoff levels for specific gravity or quality control requirements for measuring specific gravity.

Licensee Testing Facilities Reporting Negative and Dilute Specimen Result

Comments: One commenter addressed proposed § 26.131(b)(1) and asked if a licensee testing facility would be permitted to report a specimen as negative and dilute. The commenter noted that if a licensee testing facility were permitted to report a specimen as negative and dilute, the facility would have to perform an initial creatinine test with a calibrator at 2.0 mg/dL, and perform a specific gravity test, using a 3-place refractometer. The licensee testing facility would then forward any specimen with a creatinine less than 5.0 mg/dL to an HHS-certified laboratory for additional testing. The commenter also noted that for a licensee testing facility that performs only validity screening testing for creatinine, all specimens with a creatinine concentration less than 20 mg/dL must be forwarded to an HHS-certified laboratory for further testing [Sue Brown, Individual].

NRC Response: Section 26.131(b) in the final rule does not require licensee testing facilities to conduct specific gravity testing. Therefore, licensee testing facilities are not permitted to report a specimen as negative and dilute. The NRC agrees that any specimen this is determined by a licensee testing facility to have a creatinine concentration less than 20 mg/dL as a result of either validity screening testing and/or initial validity testing must be forwarded to an HHS-certified laboratory for further testing under the final rule.

Specimen pH Testing Levels

Comments: One commenter addressed proposed § 26.131(b)(2)(i) and stated that the proposed specimen pH criteria did not account for specimens meeting the "invalid" criteria specified in the HHS Mandatory Guidelines for Federal Workplace Drug Testing programs. The commenter recommended revising the provision in the final rule to account for invalid specimen criteria from "pH less than 3" to "pH less than 4.5." This change would provide decision points for both presumptive invalid and adulterated specimens that would require additional specimen testing at an HHS-certified laboratory [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.131(b)(2) in the final rule to read "pH less than 4.5" to be consistent with Section 2.4(h)(7)(ii) in the HHS Guidelines.

Specimen Validity Testing - pH Range

Comments: One commenter suggested that proposed § 26.131(b)(2) be revised from "Using either a colorimetric pH test or pH meter" to read "Using either a colorimetric pH test with a dynamic range of 2 to 12 or pH meter." The commenter asserted that the change to include the dynamic pH range is necessary to identify invalid specimens (as defined in the HHS Mandatory

Guidelines for Federal Workplace Drug Testing Programs as a specimen with pH greater than or equal to 3 and less than 4.5, or greater than or equal to 9 and less than 11). The commenter stated that the recommended change would be necessary only if NRC did not revise § 26.131(b)(2)(i) to read “pH less than 4.5” [Sue Brown, Individual].

NRC Response: Because the NRC has revised § 26.131(b)(2) in the final rule to read “pH less than 4.5," the comment does not require a response.

Specimen Validity Testing - Nitrite Concentration

Comments: One commenter stated that the proposed nitrite concentration of “equal to or greater than 500 mcg/mL” in proposed § 26.131(b)(3) would not identify invalid specimens. Specifically, the commenter referenced the criteria in the HHS Guidelines that identify a specimen as possibly invalid when the specimen has a nitrite concentration “greater than or equal to 200 mcg/mL but less than 500 mcg/mL.” The commenter suggested revising the proposed nitrite concentration to be equal to or greater than 200 mcg/mL so that invalid specimens would be detected [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised the nitrite concentration in § 26.131(b)(3) in the final rule to read “nitrite or other oxidant concentration equal to or greater than 200 mcg/mL.” This change incorporates the invalid specimen criteria in Section 2.4(h)(7)(iii) of the HHS Guidelines to ensure that potentially invalid specimens are detected through validity screening tests and/or initial validity testing at a licensee testing facility.

Specimen Validity Testing - Nitrite Concentration General Oxidant Colorimetric Test

Comments: One commenter addressed proposed § 26.131(b)(3) and suggested that the reference to the “general oxidant colorimetric test” include an additional reference that the test must have a “cutoff equal to or greater than 200 mcg/mL nitrite-equivalents.” The commenter suggested that the additional information would emphasize that the general oxidant test must be calibrated with a 200 mcg/mL nitrite solution in order to ensure that the test could identify invalid specimens [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.131(b)(3) in the final rule to state that the general oxidant colorimetric test must have a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents. The revision improves consistency with the HHS Guidelines to ensure that potentially invalid specimens are detected through validity screening tests and/or initial validity at a licensee testing facility.

Specimen Validity Testing - Presence of Chromium (VI)

Comments: One commenter addressed proposed § 26.131(b)(4) and suggested that “Presence of chromium (VI) is indicated” should be revised to read “The possible presence of chromium (VI) is determined using . . .” The commenter recommended the change because neither the general oxidant colorimetric test nor the chromium (VI) colorimetric test is the confirmatory test for the presence of chromium (VI). The commenter noted that the recommended change is consistent with the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.131(b)(4) in the final rule to improve the accuracy of the language used in the final rule and its consistency with the HHS Guidelines.

Specimen Validity Testing - Halogen Adulterants

Comments: One commenter addressed proposed § 26.131(b)(5) and suggested that "Presence of halogen . . . is indicated" should be revised to read "The possible presence of halogen (e.g., bleach, iodide, fluoride) is determined using . . ." The commenter recommended the change because neither the general oxidant colorimetric test nor the halogen colorimetric test is the confirmatory test for the presence of halogen. The commenter noted that the suggested change is consistent with the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.131(b)(5) in the final rule to improve the accuracy of the language used in the final rule and its consistency with the HHS Guidelines.

Specimen Validity Testing - Halogen Adulterants, Additional Test

Comments: One commenter suggested that NRC consider adding the odor of the specimen as an additional criterion to evaluate a specimen for the possible presence of halogen. The commenter noted that the suggested revision is consistent with criteria used in the HHS Guidelines to detect the possible presence of halogen [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and revised § 26.131(b)(5) in the final rule to add the suggested method to evaluate the possible presence of halogen. Section 26.131(b)(5) now includes a statement that the possible presence of halogen can be determined using the "odor of the specimen as the initial test." Including specimen odor as a method to detect the possible presence of halogen is consistent with Section 2.4(h)(7)(v) of the HHS Guidelines.

Validity Testing Criteria for Adulterants, Glutaraldehyde

Comments: One commenter addressed proposed § 26.131(b)(6) and suggested replacing "Presence of glutaraldehyde is indicated" with the phrase "The possible presence of glutaraldehyde is determined using. . ." The commenter noted that neither the aldehyde test nor the characteristic immunoassay response is the confirmatory test for the presence of glutaraldehyde. The commented noted that the suggested change is consistent with wording in the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.131(b)(6) in the final rule to improve the accuracy of the language used in the final rule and its consistency with the HHS Guidelines.

Validity Testing Criteria for Adulterants, Oxidants

Comments: One commenter suggested revising proposed § 26.131(b)(7) to be consistent with the related provision in the HHS Guidelines. Specifically, the commenter stated that the general oxidant colorimetric test and the chromium (VI) colorimetric test can detect only the possible presence of an oxidizing adulterant and cannot specifically identify pyridine as suggested by the proposed requirement [Sue Brown, Individual].

NRC Response: The NRC agrees, in part, with the commenter's request. The NRC has consolidated proposed § 26.131(b)(4) and (b)(7) in § 26.131(b)(4) of the final rule, given that both provisions in the proposed rule use the same general oxidant colorimetric test and chromium (VI) colorimetric test to detect the possible presence of an oxidizing adulterant.

Validity Testing Criteria for Adulterants, Surfactants

Comments: One commenter stated that proposed § 26.131(b)(8) incorrectly identified the surfactant colorimetric test as the confirmatory test for surfactant. The commenter also asserted that by using the wording "presence of surfactant is indicated" in the proposed rule text implied that the colorimetric test can identify surfactant, which it cannot. The commenter requested that the proposed rule be revised to state the "possible presence of surfactant is determined. . .." In addition, the commenter requested that the final rule be revised to include a "foam/shake test" as an additional method to identify the possible presence of surfactant and noted that the HHS Guidelines permit a "foam/shake test" to identify possible invalid specimens that result from surfactant [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's requests. Section 26.131(b)(7) in the final rule now states,"The possible presence of surfactant is determined by using. . ." It also includes the "foam/shake test" as an additional method to identify the possible presence of surfactant. Including this additional test is consistent with Section 2.5(h)(7)(viii) of the HHS Guidelines.

Validity Testing Criteria, Specimen Shows Signs of Adulterants

Comments: One commenter suggested that the phrase "on separate aliquots" in proposed § 26.131(b)(9)(iii) should be revised to read "on two separate aliquots." The commenter noted that the suggested change is consistent with the HHS Guidelines which require testing of two separate aliquots to demonstrate the inability to obtain a valid immunoassay drug test result and for a specimen to be considered possibly an invalid specimen [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.131(b)(9)(iii) (§ 26.131(b)(9) in the final rule) to clarify the intent of the provision and improve the consistency of the final rule with the HHS Guidelines.

8.7 Cutoff Levels for Drugs and Drug Metabolites (§ 26.133)

No comments addressed this section.

8.8 Split Specimens (§ 26.135)

Specimen Retention at the Licensee Testing Facility

Comments: One commenter addressed proposed § 26.135(a) and suggested that the licensee testing facility should be required to forward both Bottle A and Bottle B from split specimen collections to an HHS-certified laboratory for any specimen yields a non-negative test result from testing at a licensee testing facility. The commenter stated that the proposed system appeared cumbersome and open to possible errors at the licensee testing facility that might affect the security and integrity of a specimen in Bottle B. The commenter suggested that HHS-certified laboratories currently have processes in place to ensure the security and integrity of specimens in Bottles A and B [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. The NRC is unaware of instances that demonstrate that the security and integrity of a specimen has been affected by licensee testing facilities maintaining Bottle B onsite, while Bottle A is sent to an HHS-certified laboratory for further testing. Therefore, the NRC has not modified the proposed provision in the final rule.

Support for the Proposed Provision

Comments: One commenter, supported by many other commenters, stated that the industry supports the requirement in proposed § 26.135(b) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comment does not require a response.

Written Request for Bottle B Specimen

Comments: One commenter stated that the requirement in proposed § 26.135(b) that a donor must submit a written request to the MRO to direct Bottle B specimen testing at a second HHS-certified laboratory was not consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. Specifically, the commenter noted that the HHS Guidelines do not prescribe any specific method of notification for the donor to direct the MRO to contact the HHS-certified laboratory to request that the donor's Bottle B specimen be sent for testing at another HHS-certified laboratory [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has eliminated the proposed requirement that a donor must provide a written request to the MRO to direct the retesting of an aliquot of a single specimen or the testing of the Bottle B specimen at a second HHS-certified laboratory. Section 26.165(b) in the final rule provides a donor with more flexibility in communicating with the MRO. The NRC modeled the revised provisions on the regulations of the U.S. DOT in 49 CFR 40.171(a) and related provisions in the HHS Guidelines to increase the consistency of Part 26 with other Federally mandated workplace drug testing programs.

MRO Instructions to Donor for Bottle B Specimen Testing

Comments: One commenter suggested that proposed § 26.135(b) should be revised to require the MRO to provide each donor with an instruction form to use to request Bottle B specimen testing. The same commenter also requested that the rule specify whether the 3 business day limit could be met with a postmark date or if the written request must be received by the MRO within 3 business days [Todd Newkirk, IBEW].

NRC Response: The NRC agrees, in part, with the commenter's requests and has added a provision in § 26.165(b)(2) of the final rule to require the MRO to provide the donor with specific instructions for making a request for a retest of an aliquot of a single specimen or the testing of the Bottle B specimen. It also stipulates that the request, whether written or oral, must be received by the MRO within the 3 business days. The revised provision is based on the U.S. DOT's drug testing regulations in 49 CFR 40.171 and therefore enhances the consistency of Part 26 with advances in other relevant Federal rules and guidelines. However, the NRC has not revised § 26.165(b)(2) in the final rule to address postmarking or receipt of a written request by the MRO because the final rule no longer requires a written request, as discussed with respect to the previous comment on this section.

Other Parties Requesting Bottle B Specimen Testing

Comment: One commenter addressed proposed § 26.135(b) and stated that the requirement to prohibit any entity (e.g., licensee, MRO, NRC) from ordering the testing of a Bottle B specimen without a donor's written permission conflicts with Section 2.6(e)(4) of the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. The HHS Guidelines permit a Federal agency to have a single or split (Bottle B) specimen retested "as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result." The commenter recommended that NRC should include the HHS Guideline provision [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's recommendation. The NRC intentionally diverged from the HHS Guidelines when former Part 26 was first published by permitting split specimen procedures, which the HHS Guidelines did not permit at the time. The NRC's intent when permitting, but not requiring, split specimen procedures was to enhance donors' confidence in the drug testing process imposed by the rule and provide one means for donors to defend against possible administrative and/or methodological errors in testing the specimen in Bottle A, if a licensee or other entity chose to implement split specimen procedures. The NRC's experience has been that its objectives of detecting and deterring substance abuse can be met with testing a single specimen, but it has permitted split specimen procedures solely for the potential benefits to donors, who are private citizens under Part 26 by contrast to the Federal employees who are subject to testing under the HHS Guidelines and may have a reduced expectation of privacy. The NRC is concerned that permitting testing of the specimen in Bottle B of a split specimen or retesting of a single specimen without the donor's permission in order to defend against a donor's legal or administrative challenge to a drug test result would decrease donors' confidence in the FFD program. In addition, this testing or retesting would also conflict with the principle embodied in § 26.31(d)(6) of the final rule that the donor must retain control over his or her biological specimens for privacy reasons. Section 26.185(l) of the final rule continues to permit an MRO to order retesting an aliquot of a single specimen or

testing of the specimen in Bottle B if he or she questions the accuracy and scientific validity of a test result and believes that this additional testing will aid him or her in determining whether the donor has violated the FFD policy. The NRC believes that permitting the MRO to order this testing or retesting is necessary to meet the rule's objective to improve the effectiveness and efficiency of FFD programs. However, permitting testing of the specimen in Bottle B or retesting of a single specimen for other purposes without the donor's permission would conflict with the NRC's intent for permitting split specimen procedures. Therefore, the NRC has not revised the final rule.

Three Business Day Requirement to Request Testing of Bottle B

Comments: One commenter addressed proposed § 26.135(b) and stated that industry experience suggests that the 3 business day time limit for a donor to request Bottle B testing is adequate, given that donors typically request Bottle B specimen testing on the same day as the MRO notification of a positive test result [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy]. However, another commenter disagreed with the 3 business day time limit and suggested 10 business days instead. The commenter stated that some shift workers may have difficulty meeting the 3 business day time limit [Todd Newkirk, IBEW].

NRC Response: The NRC believes that the 3 business day time limit in proposed § 26.135(b) provides a donor with sufficient time to direct the MRO to request the retesting of single specimen or the testing of the Bottle B specimen. In addition, this 3 business day time limit provides more flexibility than permitted in Section 2.6(e)(2) of the HHS Guidelines which provide a donor with only 72 hours (i.e., 3 calendar days) after being notified by the MRO of a positive, adulterated, or substituted test result to request Bottle B testing. Therefore, the NRC has not modified the proposed provision in the final rule.

Emergency Backup Power for Long-term, Frozen Storage of Specimens

Comments: One commenter addressed proposed § 26.135(c) and stated that licensee testing facilities should be required to maintain emergency backup power to ensure that specimens in long-term, frozen storage remain at the required temperature during power outages [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and added this requirement to § 26.135(c) in the final rule. Licensee testing facilities must provide emergency backup power to ensure that Bottle B specimens that have been retained by the licensee testing facility and placed in long-term frozen storage remain at the required temperature during power outages. This provision is consistent with former Section 2.7(c) in Appendix A to 10 CFR Part 26 which required a licensee testing facility to have emergency power equipment available in case of a prolonged power failure.

8.9 Quality Assurance and Quality Control (§ 26.137)

Comments: One commenter addressed proposed § 26.137 and noted that the provisions did not require a licensee testing facility to conduct quality assurance testing on performance testing samples [Sue Brown, Individual].

NRC Response: The NRC is not aware of any problems that have arisen in the past related to the quality control and performance testing samples used by licensee testing facilities and does not, at this time, believe that there is a need to require quality assurance testing of performance testing samples by licensee testing facilities. The NRC believes the quality control provisions included in § 26.137 of the final rule will effectively identify any testing issues related to performance testing samples.

8.9.1 Quality Assurance Program (§ 26.137(a))

No comments addressed this section.

8.9.2 Performance Testing and Quality Control Requirements for Validity (§ 26.137(b))

FDA Cleared Point-of-Collection Testing Device

Comments: One commenter addressed proposed § 26.137(b)(1)(i) and stated that a drug point-of-collection tests (POCT) is a "device" in FDA terminology and approved by FDA while a specimen validity POCT is not required to be cleared by FDA and should not be referred to as a "device." The commenter suggested that NRC delete this proposed requirement [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has eliminated the requirement for FDA approval of a specimen validity POCT from § 26.137(b)(1)(i) in the final rule. The NRC also agrees with the commenter's request to eliminate the use of the term "device" with respect to validity screening tests given the specific connotation of the use of the term with FDA approval of tests.

Drug and Validity Point of Collection Testing Requirements

Comments: One commenter addressed proposed § 26.137(b) and stated that HHS proposed amendments to the HHS Guidelines (April 13, 2004, FR19673-19732) included a new category of specimen drug and validity tests called point-of-collection tests (POCT) that differed from those proposed for validity testing by the NRC. Unlike the proposed provisions in § 26.137(b), the proposed amendments to the HHS Guidelines did not separate the drug and specimen validity testing requirements. The proposed HHS Guidelines included quality assurance, device validation, annual validation, training and re-training of testers, provision for performance testing, provision for failures of the device, and reporting of results. The commenter stated that it would be difficult to permit only the use of validity POCTs, as proposed by the NRC.

NRC Response: The NRC was aware of the differences between the proposed Part 26 provisions and those published by the HHS. However, the NRC is also aware that specimen validity tests now commercially available can meet the stringent quality assurance and

performance testing requirements established in the final rule. Furthermore, the NRC is satisfied that licensees' and other entities' processes for ensuring that testing facility personnel are properly trained to conduct drug testing will be adequate when applied to training personnel to conduct validity screening tests. In response to this comment, the NRC has reviewed the provisions that addressed quality assurance, device validation, re-validation, training, performance testing, provisions for testing failures, and reporting results in the proposed amendments to the HHS Guidelines. On the basis of this review, the NRC has made several changes in the final rule to further strengthen the requirements related to validity screening tests in Part 26. The specific changes and their bases are discussed in Section VI of the Federal Register Notice publishing the final rule.

Non-instrumented Devices for Validity Screening Tests

Comments: One commenter addressed proposed § 26.137(b) and suggested that permitting licensee testing facilities to use only non-instrumented testing devices to perform validity screening tests is unduly restrictive. The commenter stated that some instrumented tests can successfully meet the performance testing requirements for validity screening tests as described in § 26.137(b). The commenter provided two examples of instrumented tests. The proposed requirement in § 26.137(b)(5) for colorimetric pH tests that have a narrow dynamic range and do not support the 2-12 pH cutoffs can be met using an instrumented test (as most HHS-certified laboratories use for pH screening). The commenter also stated that the proposed requirement in § 26.137(b)(6) for a general oxidizing adulterant test or one or more specific oxidizing adulterant tests for validity screening can be performed using an instrumented test (as HHS-certified laboratories use for initial validity testing) [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter that some instrumented tests can meet the performance testing requirements for validity screening tests. Therefore, the NRC has revised the definition of "validity screening test" in § 26.5 of the final rule to include "a test that is instrumented to the extent that results are machine-read." The NRC has also eliminated the term "non-instrumented" from the discussion in § 26.137(b) of the final rule and instead simply references validity screening tests.

Eliminate Provision to Permit Licensee Testing Facilities to Use Specimen Validity POCTs

Comments: One commenter addressed proposed § 26.137(b) and suggested that the NRC reconsider permitting licensee testing facilities to use POCTs to conduct validity screening tests. Instead, the commenter suggested that the NRC permit screening validity tests currently permitted in the HHS Guidelines. The commenter stated that licensee testing facilities would most likely follow the current HHS-certified laboratory practice for specimen validity testing (e.g., use of pH paper, dipstick tests for pH, dipstick tests for oxidants, dipstick tests for nitrite, and instrumented colorimetric pH tests with a narrow dynamic range) [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request. The NRC is permitting licensee testing facilities to use POCTs to conduct validity screening and/or initial validity testing. This provides licensee testing facilities with flexibility in conducting validity testing. However, the NRC has revised proposed § 26.137(b)(1)(i) and (b)(1)(ii) to require that licensee testing facilities use only validity screening tests that either have been placed on the SAMHSA list of POCT

devices that are certified for use in the Federal Workplace Drug Testing Program as published in the Federal Register, or that meet § 26.137(b)(1)(ii) performance testing criteria.

Test Results for POCT Devices That Include Both Drug and Specimen Validity Tests on the Same Device

Comments: One commenter addressed proposed § 26.137(b) and identified a possible concern related to permitting licensee testing facilities to use POCT devices to perform validity screening testing. Because many of the current POCT devices available include both drug and specimen validity tests, the commenter asked what the licensee testing facility would do with drug tests results [Sue Brown, Individual].

NRC Response: Section 26.137(e) in the final rule prohibits licensees and other entities from taking management actions on the basis of any drug test results obtained from non-instrumented devices that may be used for validity screening tests. The NRC is aware that several non-instrumented devices are currently 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 the use of such combination tests for validity screening. However, the drug testing capabilities of these tests are not yet sufficiently accurate and sensitive for Part 26 drug testing purposes. In the future the NRC may consider accepting the use of initial drug test results from non-instrumented tests if and when the 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 licensee testing facilities using these tests for drug testing.

Validity Screening Testing - Specific Gravity

Comments: One commenter addressed proposed § 26.137(b) and suggested that NRC consider adding specific gravity testing using a three-place refractometer so that licensee testing facilities could report dilute specimens [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. The NRC is not requiring licensee testing facilities to conduct specific gravity testing on urine specimens as discussed in Section 8.6 of this document in response to a comment received on proposed § 26.131(b). Therefore, the NRC has not revised the proposed provision in the final rule.

Personnel Conducting Performance Testing of Specimen Validity Devices

Comments: One commenter suggested that proposed § 26.137(b)(1)(ii)(A) be revised to require that licensee testing facility personnel who use specimen validity devices be the ones to conduct performance testing of those devices. The commenter stated that HHS-certified laboratory personnel will not be using these types of devices and would therefore not be trained in the performance testing procedures [Sue Brown, Individual]. Another commenter stated that HHS-certified laboratories do not perform performance testing on non-instrumented validity testing devices [Charles LoDico, Individual].

NRC Response: The NRC agrees, in part, with the commenters. The NRC has added § 26.137(b)(1)(ii)(E) in the final rule to require that if a validity screening test is not approved by SAMHSA as a point-of-collection test, the licensee testing facility must 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 § 26.137. The NRC believes that the manufacturer of each validity screening test is the most appropriate entity to conduct initial performance testing before a licensee uses the test in a Part 26 testing program. These revised performance testing requirements will reduce the burden on licensees and other entities while ensuring that validity screening tests provide accurate and consistent test results.

SAMHSA Certified List for Validity Screening Devices

Comments: Two commenters addressed proposed § 26.137(b)(1)(i) and stated that SAMHSA does not currently have a list of certified POCTs acceptable for validity screening testing for use in the Federal Workplace Drug Testing Program [Sue Brown, Individual; Charles LoDico, Individual]. One of the two commenters noted that although HHS has proposed guidelines (April 13, 2004, FR19673-19732) for the use of POCTs, the rule has yet to be finalized [Sue Brown, Individual].

NRC Response: The NRC is aware that SAMHSA has yet to publish a list of approved POCTs and that the proposed HHS Guidelines are not yet finalized. The final rule's § 26.137(b)(i) references a SAMHSA list of certified POCTs so that licensee testing facilities may rely on that list when it becomes available. To enable licensee testing facilities to begin using validity screening tests before the SAMHSA publishes its list, the NRC has added § 26.137(b)(1)(ii) to the final rule which creates stringent validity screening test performance testing requirements. These requirements will both protect donors' interests in having accurate test results and provide licensee testing facilities with flexibility in conducing validity testing.

Clarify the Meaning of pH Tests That Have a Narrow Dynamic Range

Comments: One commenter requested that the NRC clarify the phrase in proposed § 26.137(b)(5) that stated "pH tests that have a narrow dynamic range and do not support the 2-12 pH cutoffs" [Charles LoDico, Individual].

NRC Response: The NRC agrees with this comment and has eliminated the proposed provision from the final rule. Instead, the final rule in § 26.137(b)(1)(ii)(B) clarifies that 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.

Initial Performance Testing of a Device to Be Used for Specimen Validity Testing

Comments: One commenter addressed § 26.137(b)(1)(ii) and stated that the proposed requirement for a licensee or other entity to ensure, before using a validity screening device for specimen testing, that the device effectively determines the validity of the specimen would be overly burdensome [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenters and has revised the performance testing provisions in § 26.137(b)(1)(ii) of the final rule to reduce the burden that the proposed rule would have imposed on licensees and other entities. This section as revised requires validity screening test manufacturers to demonstrate the performance characteristics of their tests. The NRC believes that the manufacturer is best qualified to demonstrate the effectiveness of each test because the manufacturer, rather than a person with limited training at an HHS-certified laboratory, has the greatest knowledge of correct testing procedures. The final rule continues to require licensee testing facilities to challenge the validity screening tests they intend to use. It requires licensee testing facilities to submit three consecutive sets of performance test samples (6 samples in each round) to the manufacturer for performance testing rather than submitting to an HHS-certified laboratory at least one out of every 10 specimens that test negative using the non-instrumented validity screening device, as proposed § 26.137(b)(1) required. The revised requirement reduces the number of performance test samples that an FFD program must submit to meet the minimum performance testing requirements for creatinine, pH, and one oxidizing adulterant, while at the same time ensuring that the accuracy and sensitivity of the each validity screening test have been successfully evaluated. The revised requirements in the final rule will continue ensure that validity screening tests used in Part 26 programs meet the NRC's objective of detecting specimens of questionable validity that require further testing at an HHS-certified laboratory.

Performance Testing of Validity Screening Tests - Nitrite

Comments: One commenter addressed proposed § 26.137(b)(1)(ii)(B) and asserted that a validity POCT for nitrite should be able to identify invalid specimens that have a nitrite concentration equal to or greater than 200 mcg/dL. In the commenter's view, the proposed requirement to validate a device with samples with nitrite concentrations in the range of 650 to 800 mcg/mL or 250 mcg/mL to 400 mcg/mL would not evaluate a device at the 200 mcg/mL cutoff [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter that the nitrite concentrations specified in the proposed rule would not evaluate a validity screening device at the nitrite concentration that meets the HHS Guidelines criteria for an invalid specimen. Therefore, the proposed nitrite concentrations are contrary to the NRC's intent. Because the NRC has reorganized the performance testing and quality control requirements for validity screening tests in the final rule, § 26.137(b)(1)(ii)(E) now establishes requirements for nitrite performance testing samples and incorporates the commenter's suggestion. This provision of the final rule states that "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 . . . ."

Performance Testing of Validity Screening Tests - Creatinine

Comments: One commenter addressed proposed § 26.137(b)(1)(ii)(B) and stated that validity screening POCTs will not be able to distinguish creatinine concentrations in the proposed ranges of 5-20 and 1-5 mg/dL. The commenter noted that a validity screening POCT, at best, would have a creatinine concentration cutoff of 20 mg/dL and should be able to distinguish between a sample with a creatinine concentration of 15 mg/dL from a sample with a creatinine concentration of 25 mg/dL [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter that validity screening tests need only measure the concentration of creatinine in a specimen to a cutoff of 20 mg/dL. In addition, because the final rule requires licensee testing facilities to send any specimen with a creatinine concentration less than 20 mg/dL to an HHS-certified laboratory for further testing, creatinine testing specificity beyond the 20 mg/dL cutoff is unnecessary. Therefore, the NRC has revised the proposed provision to require that a validity screening device must be able to distinguish the creatinine concentration of a specimen at a 20 mg/dL cutoff. Because the NRC has reorganized the proposed performance testing and quality control requirements for validity screening tests, this requirement appears in § 26.137(b)(1)(ii)(A) of the final rule,

Reconsider the Use of Non-instrumented Validity Testing Devices

Comments: One commenter referenced proposed § 26.137(b)(1)(iii) and requested that the NRC reconsider permitting the use of non-instrumented validity testing devices given that the current SAMHSA Federal Workplace Drug Testing Program does not have any rules or regulations permitting the use of non-instrumented validity screening tests [Charles LoDico, Individual].

NRC Response: The NRC is aware that SAMHSA has not yet published a list of certified POCTs. However, when it publishes such a list, SAMHSA will require that a POCT to meet the same or very similar performance testing requirements as those contained in § 26.137(b)(1)(ii) of the final rule. Incorporating these performance testing requirements in the rule now permits licensee testing facilities to conduct the required performance testing and begin using any devices that meet the criteria before SAMHSA publishes its list. Therefore, the NRC disagrees with the commenter's request to eliminate the option of using non-instrumented validity screening tests. However, in response to other comments received on the performance testing provisions for validity screening tests, the NRC has revised proposed § 26.137(b) in the final rule, as discussed with respect to previous comments on this topic.

Licensee Testing Facility Personnel to Perform Quality Control Sample Testing

Comments: One commenter addressed proposed § 26.137(b)(2) and suggested that licensee testing facility personnel performing validity screening tests should also be responsible for testing quality control samples. The commenter reasoned that because non-instrumented tests have visually read endpoints, the test result must be interpreted by the tester. Therefore, each tester must be able to interpret the quality control samples correctly before conducting tests on donor specimens [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's reasoning and has amended § 26.137(b)(2)(i) in the final rule to require that licensee testing facility personnel who conduct validity screening tests must also conduct the required quality control testing. This testing, which is essential to ensuring accurate and reliable test results, is intended 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.

Validity Screening Tests, Creatinine Concentration Measure to 1 Decimal Place

Comments: One commenter addressed proposed § 26.137(b)(4) and stated that validity screening tests must measure specimen creatinine concentration to 1 decimal place [Charles LoDico, Individual]. Another commenter stated that no validity screening tests can measure to 1 decimal place and that, at best, a dipstick method to measure creatinine has a cutoff of 20 mg/dL. This commenter suggested deleting the requirement to measure creatinine to 1 decimal point [Sue Brown, Individual].

NRC Response: The NRC disagrees with the comment that validity screening tests must measure specimen creatinine concentration to 1 decimal place and agrees with the comment suggesting that validity screening devices can only measure creatinine concentration at the 20 mg/dL cutoff required in the final rule. The final rule does not require licensee testing facilities to conduct validity screening testing for creatinine concentration to 1 decimal place or the specific gravity testing that is necessary for HHS-certified laboratories to report substituted, dilute, or invalid validity test results. Rather, licensee testing facilities are only required to identify specimens of questionable validity in Part 26. Therefore, measuring specificity beyond the 20 mg/dL creatinine cutoff is unnecessary. The NRC has revised the proposed provision accordingly at § 26.137(b)(1)(ii)(A) in the final rule. This change reflects the current capabilities of validity screening tests and supports the NRC's intent that licensee testing facilities need only be able to identify whether a specimen has a creatinine concentration of less than 20 mg/dL.

General Oxidizing Test - Nitrite Cutoff Level

Comments: One commenter addressed proposed § 26.137(b)(6) and stated that the proposed nitrite cutoff level of 500 mcg/mL was for adulterated specimens and did not provide the ability to identify possible "invalid" specimens. The commenter suggested revising the cutoff level to 200 mcg/mL of nitrite [Sue Brown, Individual].

NRC Response: The NRC agrees with the comment. The final rule requires using a nitrite cutoff level of 200 mcg/mL to account for invalid specimens in § 26.137(b)(1)(ii)(C) of the final rule. The 200 mcg/mL nitrite cutoff is consistent with the nitrite decision point for a general oxidizing test in Section 2.4(h)(7)(iii) of the HHS Guidelines.

8.9.3 Non-Negative Validity Screening (§ 26.137(c))

Comments: One commenter noted that the words "may be adulterated, substituted, dilute, or invalid" in proposed § 26.137(c) appeared to be inconsistent with use of the term "non-negative" in other sections of the proposed rule [Sue Brown, Individual].

NRC Response: Based on this and other comments received, the NRC has eliminated the use of the term "non-negative" in the final rule. Instead, the NRC has replaced the term "non-negative" with a new term "questionable validity" to describe the results of validity screening or initial validity testing at a licensee testing facility. A definition for "questionable validity" has been added in § 26.5 of the final rule and states that "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." The NRC has chosen this term, rather than a term that would directly reference adulterated, substituted, dilute or invalid

specimens, because licensee testing facilities will not be conducting specific gravity testing that would determine these specimen characteristics. Using the term "questionable validity" addresses the concern expressed in the comment and improves the clarity of the final rule.

Comments: One commenter recommended that proposed § 26.137(c) refer only to validity screening test results that indicate a specimen may be adulterated (because of pH or an oxidizing adulterant) or substituted (because of creatinine concentration less than 20 mg/dL). The commenter suggested eliminating references to dilute and invalid specimens given that the requirements in proposed § 26.131(b) did not provide for the ability to determine if a specimen is dilute or invalid [Sue Brown, Individual].

NRC Response: The NRC agrees, in part, with the commenter's request. Instead of using the specific test results that a licensee testing facility may report for an individual specimen, the NRC has created a new term, "questionable validity," to apply to specimens that have a creatinine concentration of less than 20 mg/dL or the specimen exhibits characteristics of adulteration, such as an abnormal pH or the possible presence of an oxidant. In addition, the NRC has revised other sections in the final rule to address the commenter's statement that the proposed rule did not provide licensee testing facilities with the capability to identify a specimen that may be invalid. Specifically, § 26.131(b)(2)(i) and (b)(3) in the final rule provide licensee testing facilities with the ability to identify specimens that may be invalid based on pH less that 4.5 or greater than or equal to 9 or a nitrite concentration equal to or greater than 200 mcg/dL.

8.9.4 Quality Control Requirements for Performing Initial Validity Tests (§ 26.137(d))

Quality Control Requirements for Initial Validity Tests at Licensee Testing Facilities - Creatinine

Comments: One commenter recommended that proposed § 26.137(d)(1) be revised in the final rule to be consistent with the HHS Guidelines by adding a creatinine calibrator at 2 mg/dL and a control in the range of 1.0 mg/dL to 1.5 mg/dL [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request. The calibrators specified in proposed § 26.137(d)(1) pertain to initial validity testing for creatinine and need to ensure only that the test can determine if a specimen's creatinine concentration is less than 20 mg/dL. Because the final rule does not require licensee testing facilities to conduct specific gravity testing or report substituted specimen test results, calibrators at lower creatinine concentrations are unnecessary. Therefore, the NRC has not modified the proposed provision in the final rule.

Incorrect Reference in Section-by-Section Analysis in Proposed Rule

Comments: One commenter addressed the section-by-section analysis of substantive rule changes in the proposed rule (page 50550 of the Federal Register notice). The commenter stated that although the discussion referred to a proposed § 26.137(d)(7), that section did not exist in the proposed rule [Sue Brown, Individual].

NRC Response: The NRC agrees with the comment and has revised the section-by-section analysis of substantive rule changes in the Federal Register notice publishing the final rule to reference the section on blind performance test samples, § 26.137(e)(6)(v).

8.9.5 Quality Control Requirements for Initial Drug Tests (§ 26.137(e))

POCTs for Validity Testing

Comments: One commenter recommended that the second and third sentences of proposed § 26.137(e)(1) should be deleted, because the NRC should not permit licensee testing facilities to use POCTs for validity testing [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's suggestion. The NRC is permitting licensee testing facilities to use validity screening tests that meet the specifications in § 26.137(b) of the final rule. Therefore, the NRC not modified the proposed provision in the final rule.

Donor Information for Negative Urine Specimens Pooled for Internal QC Program

Comments: One commenter recommended that proposed § 26.137(e)(2) be revised to clarify that donor-specific information should be disassociated from samples pooled to be used in the laboratory internal quality control program [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with this comment and revised § 26.137(e)(2) in the final rule to prohibit licensee testing facilities from retaining any information linking donors to specimens pooled for use in the internal quality control program. No reason exists for a laboratory to retain donor-specific information for negative urine specimens used in the internal quality control program. This change further protects the privacy of individuals who are subject to Part 26. A similar provision has been added to § 26.159(j) that applies to HHS-certified laboratories.

Performing Multiple Initial Drug Tests on a Specimen

Comments: One commenter asked the NRC to clarify the intent of proposed § 26.137(e)(3) that permitted licensee testing facilities to perform multiple initial drug tests on a specimen for the same drug or drug class provided that all tests meet the cutoffs and quality control requirements in Part 26. The commenter asked if the provision permitted multiple analyses of a donor specimen for the same drug class. The commenter also asserted that NRC was promoting individual licensee testing instead of a standard applying to all licensee testing facilities [Charles LoDico, Individual].

NRC Response: The NRC agrees with this comment and has revised proposed § 26.137(e)(3) in the final rule to include a more precise description of when multiple initial drug tests on a specimen (also know as rescreening) are permitted. A similar revision was made to proposed § 26.167(d)(2) in the final rule to apply to HHS-certified laboratories. These revisions are consistent with the related provision in the HHS Guidelines and limit the potential variability in testing of concern to the commenter.

Quality Control Requirements for Initial Drug Tests, Quality Control Samples

Comments: One commenter stated that the requirements in proposed § 26.137(e)(6) for quality control samples were consistent with the HHS Guidelines except for one excluded provision in Section 2.5(b)(4) of the Guidelines. The commenter recommended revising the proposed rule

by adding the requirement, “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.” [Sue Brown, Individual]

NRC Response: The NRC agrees with the comment and has added the recommended provision in § 26.137(e)(6)(iv) of the final rule. This change enhances quality control procedures at licensee testing facilities and increases the consistency of Part 26 with related provisions in the HHS Guidelines.

Comments: One commenter suggested deleting “a” in the phrase “. . . at least one control fortified with a drug or drug metabolite targeted at 25 percent . . .” in proposed § 26.137(e)(6)(ii) because “a” implies that the control may have only one drug or drug metabolite. The commenter stated that a positive control must be positive for all drugs and drug metabolites and that a positive control must be analyzed with each analytical run [Sue Brown, Individual].

NRC Response: The NRC agrees with the comment and has revised § 26.137(e)(6)(ii) in the final rule to more clearly state the intent of the provision.

Comments: One commenter suggested deleting “a” in the phrase “. . . at least one control fortified with a drug or drug metabolite targeted at 75 percent . . .” in proposed § 26.137(e)(6)(iii) because “a” implies that the control may have only one drug or drug metabolite. The commenter stated that a control below the cutoff for each drug and drug metabolite must be analyzed with each analytical run [Sue Brown, Individual].

NRC Response: The NRC agrees with the comment and has revised § 26.137(e)(6)(iii) in the final rule to more clearly state the intent of the provision.

Comments: One commenter suggested reorganizing one of the provisions in proposed § 26.137(e)(7). The commenter noted that because the second sentence in proposed § 26.137(e)(7) discussed a quality control sample requirement, the provision should be moved to § 26.137(e)(6) which described the quality control sample requirements for each analytical run [Sue Brown, Individual].

NRC Response: The NRC agrees with this request. The NRC has renumbered the provisions in proposed § 26.137(e)(7) as § 26.137(e)(6) and (e)(6)(v) in the final rule to improve the rule’s clarity.

Blind Performance Testing Samples

Comments: One commenter asked how the proposed § 26.137(e)(7) requirement to include blind performance tests samples in each run could be met for non-instrumented testing devices when a donor must be present. The commenter also questioned how a blind performance test sample could be introduced into the batch during this testing process [Charles LoDico, Individual].

NRC Response: Section 26.137(e)(7) proposed requirements for quality control samples for initial specimen drug testing at a licensee testing facility. The NRC is not permitting drug or

validity testing to be performed at the collection site using POCTs. Rather, the NRC is restricting the use of non-instrumented validity screening tests to licensee testing facilities. Because all specimen validity testing would be conducted at a licensee testing facility and/or at an HHS-certified laboratory, a donor would never be present during specimen validity testing and the issue raised by this comment does not apply. Therefore, the NRC has not modified the proposed provision in the final rule.

Blind Performance Testing Samples - Example

Comments: One commenter addressed the section-by-section analysis of substantive changes in proposed § 26.137(e)(7). The commenter suggested that the example incorrectly presented the number of quality control samples that must be included in an analytical run. The section-by-section analysis stated, "For example, if an analytical run tested 50 donor specimens, the licensee testing facility would include 5 quality control samples in the run. At least one of the 5 would be required to be a blind test sample, and it could be either a blank or a sample fortified with a drug or metabolite at either 25 percent above the FFD program's cutoff level or at 75 percent of the cutoff level. The remaining 4 samples could include any combination of blanks and fortified samples." The commenter also suggested clarifying the following section-by-section discussion: "The blind test sample may be either a blank (certified negative urine), or a sample with drug or drug metabolite, usually targeted at 50% or greater above the cutoff." Specifically, the commenter stated that this discussion appeared to imply that the "fortified" quality control samples may have varied concentrations of drugs or drug metabolites, conflicting with the requirements in proposed § 26.137(e)(6)(ii) and (iii). The commenter recommended that the example explaining the quality control samples be revised in the final rule as follows: "For example, if an analytical run tested 45 donor specimens, the licensee testing facility would include 5 additional samples, all of which are quality control samples. The total number of samples in the analytical run would then be 50. At least one of the 5 quality control samples must be a control that appears as a donor sample to the initial testing technician. This blind test sample could be either a certified drug negative sample or a sample with drug or drug metabolite above the cutoff. The other 4 quality control samples must meet the requirements of § 26.137(e)(6)(i)-(iii)" [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's request and has revised the example used to explain quality control sample requirements in the section-by-section analysis of substantive rule changes for § 26.137(e)(6), where these requirements appear in the final rule. The example more precisely explains the requirement that 10 percent of all specimens tested in each analytical run must be quality control samples. Although the section-by-section analysis was technically accurate for an analytical run of 50 donor specimens, the discussion should have more clearly stated that 10 percent of the number of donor specimens or 5 additional specimens, must be quality control samples. The total specimens in the example analytical run would be 55 specimens.

8.9.6 Errors in Testing (§ 26.137(f))

No comments addressed this section.

8.9.7 Accuracy (§ 26.137(g))

No comments addressed this section.

8.9.8 Calibrators and Controls (§ 26.137(h))

No comments addressed this section.

8.10 Reporting Initial Validity and Drug Test Results (§ 26.139)

No comments addressed this section.

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

9.1 Purpose (§ 26.151)

No comments addressed this section.

9.2 Using Certified Laboratories for Testing Urine Specimens (§ 26.153)

More Stringent Cutoff Levels and/or Testing for Other Substances - Oversight

Comments: One commenter addressed proposed § 26.153(d) and requested that, in situations where a licensee or other entity chooses to use more stringent cutoff levels than those specified in Part 26 and/or chooses to test for substance not mandated by Part 26, that the NRC and not the licensee or other entity should ensure that the HHS-certified laboratory takes measures consistent with Part 26 to ensure that test results are valid and defensible [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with this comment. The NRC believes that the evaluations of assays and cutoff levels by an independent forensic toxicologist, as required in § 26.31(d)(1)(i)(D) and (d)(1)(ii), and the auditing activities required under § 26.41 provide adequate assurance that any testing conducted under this subpart will provide results that are valid and defensible. Therefore, the NRC has not modified the proposed provision in the final rule.

Laboratory Personnel Appearing for Administrative/Disciplinary Hearings

Comments: One commenter suggested revising proposed § 26.153(f)(2) by implementing "more stringent provisions" to compel laboratory personnel to appear to testify at an administrative and disciplinary proceeding against an individual when the proceeding is based on urinalysis results reported by an HHS-certified laboratory. The commenter stated that if laboratory personnel fail to appear at an administrative or disciplinary proceeding, the case against the donor should be dropped [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the comment. The licensee or other entity is responsible, through its contract with the HHS-certified laboratory, for ensuring that the

appropriate personnel from the HHS-certified laboratory are available to testify in an administrative or disciplinary proceeding when that proceeding is based on urinalysis results reported by the HHS-certified laboratory. If the licensee does not ensure that the appropriate individuals are available, or the HHS-certified laboratory does not make the individuals available, both the licensee and HHS-certified laboratory could be subject to NRC enforcement action. However, the rule does not require laboratory personnel to appear in person. Therefore, the NRC believes these provisions adequately protect donors' rights to a fair and objective review and are sufficiently stringent. The NRC also does not agree that dropping the case against an individual is acceptable if laboratory personnel are not made available. The NRC requires reviewing officials to make a positive determination that individuals are fit for duty and trustworthy and reliable, as demonstrated by the avoidance of substance abuse, in order for licensees or other entities to grant or maintain an individual's authorization. If test results are received that call into question an individual's fitness for duty and trustworthiness and reliability, the individual's authorization must be terminated to protect public health and safety and the common defense and security until the question can be resolved. The licensee or other entity is responsible for ensuring that sufficient information is available for the reviewing official to make either a positive or negative determination. Therefore, the NRC has not modified the proposed provision in the final rule.

Conflict of Interest Between HHS-Certified Laboratory and MRO

Comments: One commenter, supported by other commenters, addressed proposed § 26.153(f)(5) and requested the NRC to provide specific examples of relationships between HHS-certified laboratories and MROs that the NRC considers to be conflicts of interest. The commenter suggested including the conflict of interest examples specified in the U.S. DOT's drug and alcohol testing regulations in 49 CFR 40.101(b). The commenter also requested that the NRC specifically exempt a potential conflict of interest situation in which a medical doctor uses an HHS-certified laboratory for services in his or her private practice and who also serves as the MRO to a licensee that uses the same HHS-certified laboratory [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees, in part, with the commenter's request and has revised proposed § 26.183(b) in the final rule to include specific examples of conflict of interest relationships between MROs and HHS-certified laboratories. As requested, the basis for the examples is 49 CFR 40.101(b) of the U.S. DOT's Procedures for Transportation Workplace Drug and Alcohol Testing Programs.

The NRC disagrees with the commenter's request to specifically exempt as a potential conflict of interest the situation where a medical doctor uses an HHS-certified laboratory for services in his or private practice and also serves as the MRO to a licensee or other entity that uses the same HHS-certified laboratory. Under certain circumstances, this relationship could be construed as a potential conflict of interest. For example, an MRO could negotiate lower pricing for specimen testing with the same laboratory a licensee uses by suggesting that he/she could persuade the licensee to take its business elsewhere. This could be considered a possible conflict of interest situation because the MRO could potentially influence a licensee's decision on changing to a

different HHS-certified laboratory and thereby gain leverage in reducing pricing for the MRO's private practice. Therefore, the NRC has not modified the proposed provision in the final rule to include the requested exemption.

Access to Donor Testing Records and Laboratory Records

Comments: Several commenters supported proposed § 26.153(f)(4) and stated that the industry agreed that access to laboratory records, beyond that required for licensee or other entity FFD program functions, should be restricted to individual donors viewing their own records [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The commenters' reading of proposed § 26.153(f)(4) was contrary to the NRC's intended meaning of that section. The NRC intends that an employee of a licensee or other entity who is subject to a drug test shall have the right to designate a representative to review the HHS-certified laboratory's records related to the employee's validity and drug test as well as any records related to the results of any certification, review, or revocation-of-certification proceedings relevant to the employee. This right to designate a representative is consistent with § 26.37(d) of the proposed and final rules which permits an individual, as well as a designated representative, consistent with the former rule requirements in § 26.29(b), to request and receive copies of all records pertaining to a determination that the individual has violated the FFD policy. The NRC has revised proposed § 26.153(f)(4) in the final rule to clarify the ambiguity in the proposed rule.

Comments: One commenter suggested that the NRC revise proposed § 26.153(f)(4) to permit authorized employee representatives to have access to an HHS-certified laboratory's records pertaining to an employee's validity and drug test results, as well as laboratory records of relevant certification, review, and revocation-of certification proceedings [Todd Newkirk, IBEW].

NRC Response: The NRC intended that proposed § 26.153(f)(4) would authorize employee representatives to have access to the records mentioned by the commenter. The NRC has revised proposed § 26.153(f)(4) in the final rule to clarify the ambiguity in the proposed rule. This revision makes § 26.153(f)(4) consistent with § 26.37(d) in the final rule which permits the employee, and his or her designated representative, to request copies of all records pertaining to the determination of a violation of the FFD policy, including test results, from an HHS-certified laboratory.

9.3 Laboratory Personnel (§25.155)

No comments addressed this section.

9.3.1 Day-to-Day Management of the HHS-Certified Lab (§ 26.155(a))

Comments: One commenter disagreed with the NRC's decision in proposed § 26.155(a)(4) to eliminate the requirement for an HHS-certified laboratory to maintain laboratory operating procedures in a "procedure manual" as specified in Sections 2.5(a)(5) and 2.7(o)(1) in Appendix

A to Part 26. The commenter stated that no longer requiring laboratories to maintain a procedure manual would be inconsistent with the requirements in Section 2.4(q)(1) of the HHS Guidelines. For consistency with the HHS Guidelines, the commenter suggested including the requirement for laboratory operating procedures to be maintained in a manual [Sue Brown].

NRC Response: The NRC agrees with the comment. The NRC has revised proposed § 26.155(a)(4) in the final rule to require an HHS-certified laboratory to maintain laboratory operating procedures in a procedure manual, consistent with the former rule and the related requirement in the HHS Guidelines.

9.3.2 Certifying Scientist (§ 26.155(b))

Comments: One commenter addressed the section-by-section analysis of substantive changes in proposed § 26.155(b). The section-by-section analysis stated that "the proposed rule would provide more detailed requirements with respect to the individual who validates test results at the HHS-certified laboratory." The commenter recommended that the word "validates" should be replaced by the word "certifies" because test results at HHS-certified laboratories are certified and not validated [Sue Brown, Individual].

NRC Response: The NRC agrees with the recommendation and has revised proposed § 26.155(b)(1) in the final rule to state that "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."

9.3.3 Day-to-Day Operations and Supervision of Analysts (§ 26.155(c))

No comments address this section.

9.3.4 Other Personnel (§ 26.155(d))

No comments addressed this section.

9.3.5 Training (§ 26.155(e))

No comments addressed this section.

9.3.6 Files (§ 26.155(f))

No comments addressed this section.

9.4 Procedures (§ 26.157)

No comments addressed this section.

9.5 Assuring Specimen Security, Chain of Custody, and Preservation (§ 26.159)

Comments: One commenter addressed proposed § 26.159(f) that directed an HHS-certified testing laboratory to include the original custody-and-control form with a specimen that is

transferred to a second HHS-certified laboratory for additional testing. The commenter recommended that the proposed requirement be revised to conform to the chain-of-custody procedures used at HHS-certified laboratories. Specifically, HHS-certified laboratories provide a copy, rather than the original custody-and-control form, with a specimen that is transferred to a second HHS-certified laboratory for additional testing [Sue Brown, Individual].

NRC Response: The NRC agrees with the recommendation. The NRC has revised § 26.159(f) in the final rule to require that a copy of the custody-and-control form is packaged with an aliquot of a single specimen or a Bottle B specimen that is transferred to a second HHS-certified laboratory for testing. This revision makes the final rule consistent with the procedures used by HHS-certified laboratories.

Pooling of Urine Specimens Used for Laboratory QC Program

Comments: One commenter stated that proposed § 26.159(j) should be revised to require donor-specific information to be disassociated from valid samples that test negative on initial or confirmatory drug tests and that the laboratory chooses to pool for use in the internal quality control program at the laboratory [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the comment and has revised § 26.159(j) in the final rule to prohibit HHS-certified laboratories from retaining any information linking donors to specimens pooled for use in the internal quality control program. No reason exists for a laboratory to retain donor-specific information for negative urine specimens used in the internal quality control program. This change further enhances the privacy of individuals who are subject to Part 26. A similar provision has been added to § 26.137(e)(2) that applies to licensee testing facilities.

9.6 Cutoff Levels for Validity Testing (§ 26.161)

No comments addressed this section.

9.6.1 Validity Test Results (§ 26.161(a))

No comments addressed this section.

9.6.2 Initial Validity Testing (§ 26.161(b))

Specific Gravity Testing Instrumentation

Comments: One commenter addressed proposed § 26.161(b) and asked that the final rule specify the type of instrument to be used to perform specific gravity testing. The commenter stated that the HHS Mandatory Guidelines require specific gravity testing to be performed using a four-place refractometer [Charles LoDico, Individual].

NRC Response: The type of equipment that an HHS-certified laboratory must use to perform specific gravity testing of urine specimens is described in § 26.167(c)(2)(i) in the proposed and final rule. Therefore, the NRC has not modified § 26.161(b) in the final rule in response to this comment.

Redundancy with Subpart F Discussion in 26.131(c)

Comments: One commenter addressed proposed § 26.161(b)(2) and noted the redundancy between the initial validity testing requirements in proposed § 26.131(c) through (f) of Subpart F for licensee testing facilities and the requirements in proposed § 26.161(b)(2) for HHS-certified laboratories. The commenter suggested deleting the requirements in proposed § 26.161(b)(2). [Sue Brown, Individual]

NRC Response: The NRC agrees with the suggestion and deleted the proposed requirements in § 26.161(b)(2) because they are captured in § 26.161(c) through (f) of the final rule.

Include Invalid Specimens

Comments: One commenter suggested amending proposed § 26.161(b)(2) to include invalid specimens in the statement "there is a reason to believe the donor may have diluted, substituted, or adulterated the specimen" [Sue Brown, Individual].

NRC Response: The NRC has eliminated proposed § 26.161(b)(2) from the final rule in response to an earlier comment.

9.6.3 Results Indicating an Adulterated Specimen (§ 26.161(c))

Quality Controls for Unidentified Adulterants

Comments: One commenter addressed proposed § 26.161(c)(8) and inquired about what, if any, quality controls exist when testing specimens where "any other adulterant" is reported as the test result. The commenter inquired as to how an HHS-certified laboratory is to identify and quantify the substance [Todd Newkirk, IBEW].

NRC Response: If a specimen is identified as containing "any other adulterant," the adulterant identified by the HHS-certified laboratory is a substance other than those described in § 26.161(c)(1) through (c)(7) of the final rule. An instance that might warrant a laboratory testing for an adulterant not specified in §26.161(c)(1) through(c)(7) may arise when a specimen has an invalid test result (e.g., interference occurs on the immunoassay drug tests on two separate aliquots and a valid immunoassay drug test result cannot be obtained). If an HHS-certified laboratory conducts testing for "any other adulterant," the laboratory must perform two types of testing techniques (as specified in § 26.161(c)(8)). Also, in order to validate the accuracy of the adulterant tests used, the laboratory must use standard controls containing known concentrations of the substance (i.e., "the adulterant that the test identifies"). Further, proposed and final § 26.169(d) requires the laboratory to report the numerical value of a test result to the MRO for a specimen with an adulterated test result. Therefore, the NRC has not modified the proposed provision in the final rule.

Addition of Hyphens for Chromium (VI), Nitrite, and Sulfonate Equivalents

Comments: One commenter addressed proposed § 26.161(c)(3) through (c)(7) and requested that hyphens be inserted before the word "equivalents' in "chromium (VI) equivalents," "nitrite equivalents," and "sulfonate equivalents." The commenter stated that the suggested changes

would be consistent with HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.161(c)(3) through (c)(7) in the final rule by adding hyphens before the word “equivalents” to clarify the accuracy of the language in Part 26 and improve consistency with the HHS Guidelines.

Support for Proposed Provision

Comments: Several commenters stated that industry supports the requirements in proposed § 26.161(c)(8) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comment does not require a response.

9.6.4 Results Indicating a Substituted Specimen (§ 26.161(d))

Comments: One commenter addressed a statement in the section-by-section analysis of substantive changes in proposed § 26.161(d). The commenter said that the discussion incorrectly stated that a refractometer must measure to 3 decimal places (e.g., specimen specific gravity levels of 1.001 and 1.020). The commenter asserted that a refractometer must measure to 4 decimal places (e.g., specific gravity levels of 1.0010 and 1.0200) in order to report a specimen as substituted [Sue Brown, Individual].

NRC Response: The NRC agrees with the comment and has revised the section-by-section analysis of § 26.161(d) in the final rule to correct the specific gravity range for a substituted specimen by referencing specimen specific gravity levels of 1.0010 and 1.0200.

9.6.5 Results Indicating a Dilute Specimen (§ 26.161(e))

Comments: One commenter addressed a statement in the section-by-section analysis of substantive changes in proposed § 26.161(e). The commenter stated that the discussion incorrectly specified the specific gravity range for a dilute specimen as “less than or equal to 1.001 or equal to or greater than 1.020.” The commenter stated that the correct specific gravity range is “greater than 1.0010 but less than 1.0030." [Sue Brown, Individual]

NRC Response: The NRC agrees with the comment and has revised the section-by-section analysis of § 26.161(d) in the final rule to correct the specific gravity range for a dilute specimen to “greater than 1.0010 but less than 1.0030.”

9.6.6 Results Indicating an Invalid Specimen (§ 26.161(f))

Specimen Testing Criteria for Invalid Test Result

Comments: One commenter inquired about testing criteria used to determine that a specimen

is invalid. The commenter asked why a substance could not be identified and suggested that the possibility that a laboratory testing problem might also provide an invalid test result [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter. Proposed and final § 26.161(f) specify the initial validity testing criteria that HHS-certified laboratories must use to determine whether a specimen is invalid. To ensure that each validity test performed on a specimen functions correctly, § 26.167(b) and (c) require HHS-certified laboratories to evaluate the accuracy of the assays performed using calibrators and controls in each analytical run of specimen testing performed. Each analytical run of specimens must also include blind performance testing samples under § 26.168 of the final rule. Given that sufficient controls exist in the final rule to ensure that initial validity tests function correctly, the NRC not revised proposed § 26.161(f) in the final rule.

General Oxidant Colorimetric Testing

Comments: One commenter suggested that the requirement "equal to or greater than 200 mcg/mL nitrite equivalents using a general oxidant colorimetric test" in proposed § 26.161(f)(3) was inconsistent with the intended meaning in the HHS Guidelines and should be revised to state "equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test." The commenter stated that the intended meaning of the HHS Guideline requirement is that the general oxidant test must be positive with an equivalent of 200 mcg/mL of nitrite. The commenter noted that the general oxidant test can be calibrated with a 200 mcg/mL nitrite calibrator or with a 50 mcg/mL chromium (VI) calibrator. If calibrated with the 50 mcg/mL chromium (VI) calibrator, the general oxidant test would produce a positive result for specimens with nitrite concentrations much less than 200 mcg/mL; not the intended cutoff for nitrite in the proposed provision. [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.161(f)(3) in the final rule to clarify the intent of the provision. That section now reads "equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test."

Addition of Hyphens for Chromium (VI), Nitrite, and Sulfonate Equivalents

Comments: One commenter requested that proposed § 26.161(f)(7) and (f)(8) be revised by adding hyphens before the word "equivalents" in the terms "nitrite equivalents," "chromium (VI) equivalents," and "sulfonate equivalent." The commenter noted the suggested revisions are consistent with HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.161(f)(7) and (f)(8) in the final rule by adding hyphens before the word "equivalents" to improve consistency between the HHS Guidelines and these Part 26 provisions.

9.6.7 Additional Testing by a Second Lab (§ 26.161(g))

Support for Proposed Provision

Comments: Several commenters stated that the industry supported proposed § 26.161(g) [Jim

Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comment does not require a response.

HHS-Certified Laboratory Contacting MRO, Specimens with Possible Interfering Substances/ Adulterants

Comments: One commenter addressed the requirement in proposed § 26.161(g) that HHS-certified laboratories must consult with a licensee's or other entity's MRO to receive approval to send a specimen to a second HHS-certified laboratory for additional testing if the laboratory suspects the presence of an interfering substance/adulterant that could make a specimen test result invalid. The commenter stated that the specimen should be automatically sent to a second HHS-certified laboratory for additional testing. The commenter reasoned that no employee should suffer or be accused of attempting to subvert the testing process because of an unidentified substance [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the request to eliminate the required consultation between the HHS-certified laboratory and the licensee's or other entity's MRO to determine if additional testing should be conducted at a second HHS-certified laboratory to try to identify whether an interfering substance/adulterant is present in a donor's specimen. This consultation is important because not all HHS-certified laboratories have the same testing capabilities to identify additional types of interfering substances and "new" adulterants. Therefore, sending a specimen to any second HHS-certified laboratory without first requiring the MRO and laboratory to confer on the test results from the first laboratory and determine whether an appropriate laboratory exists that has the capabilities to conduct additional types of test may not automatically improve the likelihood that the substance will be identified. Specifically, the HHS-certified laboratory must confer with the MRO to determine if additional testing of the specimen might identify the unidentified substance in a donor's urine specimen that is preventing a valid test result. The commenter need not be concerned that a donor would suffer or be accused of attempting to subvert the testing process. These procedures do not result in an employee being accused of subverting the testing process. No sanctions are imposed on anyone for an invalid test result. As required by § 26.185(f), the MRO must contact the donor to determine if an acceptable medical explanation exists that may cause an invalid specimen test result. Depending on the results of this enquiry, the MRO will require the donor to give another specimen, either under direct observation or not. Therefore, the NRC has not modified the proposed provision in the final rule.

Comments: One commenter stated that the provision in proposed § 26.161(g) that required the HHS-certified laboratory to contact a licensee's or other entity's MRO conflicted with Section 2.4(h)(12) in the HHS Guidelines. Specifically, the HHS Guidelines permit HHS-certified laboratories to report an "invalid" specimen test result using the same initial test on two separate aliquots. The commenter stated that most HHS-certified laboratories have eliminated their confirmatory tests for adulterants, and have been reporting more invalid results. The commenter argued that the proposed provision would impose a burden on HHS-certified laboratories to

contact the MRO for every invalid test result and suggested that the proposed provision be eliminated [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request to eliminate the proposed provision in the final rule. Section 26.161(g) in the proposed and final rule is consistent with Section 2.4(h)(12) in the HHS Guidelines. For invalid specimen test results, a discussion between the HHS-certified laboratory and the MRO is critical because of differences between laboratories in their capabilities to identify interfering substances or "new" adulterants. The intent of this requirement is to deter individuals from attempting to subvert the testing process by introducing interfering substances or adulterants to mask the presence of prohibited drugs and to increase the likelihood of detection if they do. Reporting a specimen as invalid, rather than conducting confirmatory testing for a suspected adulterant when a laboratory is available that is capable of confirming the presence of an adulterant, does not achieve the NRC's objectives in requiring specimen validity testing for adulterants. Therefore, the NRC has not modified the proposed provision in the final rule.

9.6.8 More Stringent Validity Test Cutoff Levels are Prohibited (§ 26.161(h))

No comments addressed this section.

9.7 Cutoff Levels for Drugs and Drug Metabolites (§ 26.163)

No comments addressed this section.

9.7.1 Initial Drug Testing (§ 26.163(a))

Dilute Specimen Testing, Limit of Detection (LOD) Testing

Comments: One commenter addressed proposed § 26.163(a)(2) and suggested revising the provision that permitted an MRO to direct an HHS-certified laboratory to test a specimen for drugs and/or drug metabolites "down to the confirmatory assay's limit of detection (LOD)." The commenter stated that HHS Guidelines do not use the term "limit of detection" and suggested replacing the provision with the phrase "using the laboratory's confirmatory assay" [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request because it is contrary to the intent of the proposed provision. The NRC is well aware that there are many legitimate reasons for specimens being dilute. However, dilution is also a method some donors use to subvert the testing process. Dilution may decrease the concentration of a drug or drug metabolites sufficiently that applying Part 26 cutoff levels, or a licensee's or other entity's more stringent cutoff levels, would produce false negative drug test results. The special processing of dilute specimens required by §26.163(a)(2) increases the likelihood that any drugs and drug metabolites in the specimen will be detected. Therefore, the final rule continues to permit licensees and other entities to conduct confirmatory testing to the assay's limit of detection for dilute specimens.

Conducting Initial Drug Testing for Dilute Specimens to LOD

Comments: One commenter addressed proposed § 26.163(a)(2) and stated that the requirement "to conduct initial drug testing of dilute specimens using FDA-approved analytical kits that have the lowest concentration levels available for the initial testing technologies" would be overly burdensome to HHS-certified laboratories. The commenter said the requirement would be burdensome because, in her experience, a large category five HHS-certified laboratory may have as many as 10 percent of specimens tested with dilute results. The commenter stated that many health-conscious individuals may have dilute specimen test results simply because they consume large quantities of water, not because they are attempting to conceal drug use. The commenter also stated that the proposed provision would be burdensome because an HHS-certified laboratory would need to have more than one FDA-approved analytical kit for a drug or metabolite to fulfill the proposed requirement. For example, the initial drug test cutoff level for marijuana metabolite is 50 ng/mL. The initial drug test kit manufacturers market a kit for use at the 50 ng/mL cutoff and at the 20 ng/mL cutoff. To meet the proposed requirement, a laboratory would need to re-screen the dilute specimen with the 20 ng/mL cutoff kit, using different controls. The commenter noted that some kit manufacturers also offer lower cutoffs for opiate metabolites and amphetamines. By using the lower cutoff levels, the NRC would effectively be lowering the initial test cutoff levels for these drugs and, by doing so, treating donors with dilute specimens differently.

If the NRC were to decide not to eliminate this proposed § 26.163(a)(2) requirement, the commenter recommended that the laboratory not be required to re-screen the identified dilute specimen and, instead, be permitted to compare the initial drug test immunoassay response for the specimen to the initial drug test immunoassay response for the cutoff calibrator with the initial drug test kit used for testing. If the specimen's response is within 50 percent of the response of the cutoff calibrator, the laboratory would report this to the licensee's or other entity's MRO on the final report. The commenter noted that an additional burden would be imposed on the laboratory to capture the initial test immunoassay response number and report it on the report form. The commenter suggested that the HHS-certified laboratory could accomplish this reporting using the laboratory's information system [Sue Brown, Individual].

NRC Response: The NRC agrees, in part, with the commenter's request and has eliminated from the final rule proposed § 26.163(a)(2) that required HHS-certified laboratories to use an FDA -approved analytical kit with the lowest concentration levels marketed for the technology(ies) being used to conduct initial drug testing of specimens with dilute initial validity test results. The NRC has accepted the commenter's recommended approach to conduct initial drug testing of each dilute specimen and evaluate the immunoassay response for each drug test such that if the quantitative test result is equal to or greater than 50 percent of the cutoff calibrator for the drug tested, the laboratory would consider the result as an initial positive drug test result. The NRC disagrees with the commenter's assertion that further testing is unnecessary. Given the consequences for donors of a positive drug test result, the NRC believes that confirmatory drug testing to the limit of detection is necessary to confirm the initial drug test result.

Dilute Specimen Testing, Eliminate the Word Confirmatory

Comments: One commenter suggested eliminating the word "confirmatory" in the sentence "If confirmatory validity testing indicates that a specimen is dilute . . ." in proposed § 26.163(a)(2). The commenter reasoned that a dilute specimen test result may be reported by testing a single aliquot of a specimen [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's reasoning and has eliminated the word "confirmatory" in § 26.163(a)(2)(i) of the final rule. This change also increases the consistency of Part 26 with the related provision in the HHS Guidelines.

9.7.2 Confirmatory Drug Testing (§ 26.163(b))

No comments addressed this section.

9.8 Testing Split Specimens and Retesting Single Specimens (§ 26.165)

No comments addressed this section.

9.8.1 Split Specimens (§ 26.165(a))

No Discussion on Disposal of Negative Bottle A Specimens

Comments: One commenter noted that, while proposed § 26.165(a)(3) permitted the HHS-certified laboratory to discard the Bottle B specimen if the Bottle A specimen is determined to be a valid specimen free of any drugs or drug metabolites, it did not also specify that the Bottle A specimen may be discarded [Sue Brown, Individual].

NRC Response: The NRC agrees with the comment and has revised proposed § 26.165(a)(3) in the final rule to specify that an HHS-certified laboratory may also discard the specimen in Bottle A once the specimen is determined to be valid and free of any drugs or drug metabolites.

Written Request to Test Bottle B Specimen or Retest Aliquot of Single Specimen

Comments: Two commenters stated the prohibition in proposed § 26.165(a)(4) on any entity (e.g., licensee, MRO, NRC) ordering the testing of a Bottle B specimen without a donor's written permission conflicted with Section 2.6(e)(4) of the HHS Guidelines. The HHS Guidelines permit a Federal agency to have a single or split (Bottle B) specimen retested "as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result." The commenters recommended that the NRC should include the HHS Guideline provision [Sue Brown, Individual; Charles LoDico, Individual].

NRC Response: The NRC disagrees with the commenters' recommendation. The requirements for testing split specimens in the former, proposed, and now final rule ensure that each donor receives fair and accurate testing under Part 26. The NRC's intent in the original rule, when permitting split specimen testing, was to enhance donors' confidence in the drug testing process imposed by the rule and provide one means for donors to defend against possible administrative and/or methodological errors in testing the specimen in Bottle A.

Because the NRC's intent in permitting split specimen testing has been to protect donors, and because the NRC believes that testing an individual's biological specimen without his or her permission infringes on an individual's privacy, the NRC declines to adopt the commenter's proposed revision.

Clarity of Requirement for Requesting Bottle B (Split Specimen) Testing

Comments: One commenter suggested that the NRC revise the proposed § 26.165(a)(4) that provided a donor with the opportunity to request the testing of a Bottle B specimen. The commenter stated that the proposed provision is lengthy, confusing, and does not specify that MROs must first verify that an HHS-certified laboratory test result is drug positive, adulterated, or substituted before informing donors that they have the right to request testing of the Bottle B specimen. The commenter recommended that § 26.164(a)(4) be revised to be consistent with proposed § 26.165(b)(1), which allows a donor to request a retest of a single specimen at a second HHS-certified laboratory. The commenter suggested using Section 2.6(e) in the HHS Guidelines as an example when considering the suggested revisions. The same commenter also suggested that the first sentence in proposed § 26.165(a)(4) be relocated to the results reporting section of the rule, given that the sentence instructs the laboratory to report test results to the MRO [Sue Brown, Individual].

NRC Response: The NRC agrees with the comments. The NRC has revised the proposed provision in § 26.165(a)(4) and moved it to § 26.165(b) in the final rule to improve the rule's clarity and intent. In addition, the NRC has consolidated the proposed provisions on retesting of an aliquot of a single specimen and the testing of Bottle B specimens into a single section (§ 26.165(b)(1) through (b)(6)) to improve the organization and clarity of the final rule.

Sending Bottle B Specimen to Second HHS-Certified Laboratory

Comments: One commenter stated that proposed § 26.165(a)(5) did not allow for the possibility that a licensee testing facility, rather than the HHS-certified laboratory, may retain Bottle B specimens as allowed under proposed § 26.135(a) and would have to forward Bottle B specimen to a second HHS-certified laboratory. The commenter also noted that in situations where a Bottle B specimen is located at a licensee testing facility, the one business day requirement to send the specimen to a second HHS-certified laboratory may not be sufficient time [Sue Brown, Individual].

NRC Response: Section 26.135(b) in the final rule addresses the issue raised by the commenter. If a licensee testing facility maintains a Bottle B specimen, the licensee or other entity must ensure that the donor's specimen is forwarded to a second HHS-certified laboratory if directed to do so by the MRO, at the specific request of the donor. The NRC believes that the one business day time limit for a licensee testing facility to send a Bottle B specimen to a second HHS-certified laboratory is reasonable. It should be noted that the NRC has relaxed this requirement from the "same-day" requirement for these situations in the former rule. The NRC made this revision because logistical difficulties sometimes created obstacles to FFD program compliance with the former rule's same-day requirement. For example, commenters at public meetings with stakeholders cited communication delays among donors, MROs, and FFD program personnel, particularly on weekends and holidays, as one such difficulty. They also noted that the time required to identify a second laboratory with the appropriate capability to test

the split specimen sometimes made compliance difficult. The NRC is confident that allowing one business day will be sufficient to overcome these logistical obstacles. In response to other comments received on proposed § 26.165(a) and (b), the NRC has revised and consolidated the provisions pertaining to donor requests for the retesting of an aliquot of a single specimen and Bottle B split specimen testing.

Personnel Responsible for Directing a Laboratory to Send a Bottle B Specimen for Testing

Comments: One commenter addressed proposed § 26.165(a)(5) and stated that the phrase "If the donor requests that the specimen in Bottle B be tested . . ." did not accurately reflect the notification process for split specimen testing. The commenter noted that the MRO, at the request of a donor, directs the HHS-certified laboratory to send the Bottle B specimen to a second HHS-certified laboratory for testing [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.165(b) in the final rule to clarify that, at the request of the donor, it is the MRO who directs the HHS-certified laboratory to send the Bottle B specimen for testing at another HHS-certified laboratory. In response to other comments received on proposed § 26.165(a) and (b), the NRC has revised and consolidated the provisions pertaining to donor requests for the retesting of an aliquot of a single specimen and testing of a Bottle B specimen into § 26.165(b) in the final rule to improve the clarity and organization of rule.

Providing Quantitative Values of Specimen Retest Results

Comments: One commenter addressed proposed § 26.165(a)(6) and asked why the NRC was proposing to allow the MRO to provide a donor with the quantitative values of a specimen retest result. The commenter noted that the proposed requirement was inconsistent with Section 2.6(h) in the HHS Guidelines [Sue Brown, individual].

NRC Response: The proposed provision requiring the MRO to provide a donor with the quantitative values of positive test results was consistent with Section 2.7(j) in Appendix A of the former rule. The NRC has retained this provision in the proposed and final rule to maintain donors' rights to this information and has intended to differ from the HHS Guidelines on this issue since Part 26 was first published. Therefore, the NRC has not modified the proposed provision in the final rule.

9.8.2 Donor Request to the MRO for Retest of Single Specimen (§ 26.165(b))

Comments: One commenter recommended that proposed § 26.165(b) be combined with proposed § 26.165(a)(4) and the heading of the combined section to be titled "Donor request to MRO for a retest." The commenter further suggested that the combined paragraph be modeled after the discussion in Section 2.6(e) of the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has consolidated the proposed provisions on retesting of an aliquot of a single specimen and the testing of Bottle B specimens into a single section (§ 26.165(b)(1) through (b)(6) in the final rule) to clarify the NRC's intent in the final rule.

Comments: One commenter noted that the first sentence in proposed § 26.165(b)(2) prohibited a donor from requesting a retest for an invalid specimen test result and that this was consistent with the HHS Guidelines. However, the commenter thought that the second sentence in the proposed provision was confusing and appeared to allow a donor to request a retest of a specimen with an invalid test result [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised and consolidated the provisions in proposed § 26.165(a) and (b) to improve the clarity of the final rule. Section 26.165(b)(1) in the final rule now clearly states that a donor is not permitted to request the retesting of an aliquot of a single specimen or a split specimen (Bottle B) that the laboratory's testing had determined to be invalid. The NRC is imposing this prohibition because some invalid specimens create a risk of damaging laboratory equipment and because retesting invalid specimens would not provide useful information.

9.8.3 Retesting a Specimen for Drugs (§ 26.165(c))

Use of the Phrase "Standard Confirmatory Drug Test"

Comments: One commenter addressed proposed § 26.165(c)(1) and stated that the phrase "The second laboratory shall use its standard confirmatory drug test when retesting . . ." is not an accurate description of the test. The commenter requested that the word "standard" be deleted from the proposed provision since no "standard confirmatory drug test" is used by an HHS-certified laboratory [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter that HHS-certified laboratories do not use a standard confirmatory drug test and has eliminated the word "standard" from proposed § 26.165(c)(1) in the final rule.

Limit of Detection (LOD) Testing

Comments: One commenter suggested that the NRC eliminate the requirement in proposed § 26.165(c)(2) that confirmatory drug testing be performed down to the an assay's LOD for the retesting of an aliquot of a single specimen or for Bottle B split specimen testing. The commenter noted that the HHS Guidelines do not contain a similar provision [Sue Brown, Individual].

NRC Response: The NRC disagrees with this request. Section 26.163(a)(2) in the final rule allows licensees and other entities, at their discretion, to require the HHS-certified laboratory to conduct special analyses of dilute specimens, including confirmatory testing down to the LOD, for those drugs and/or drug metabolites for which the response was equal to or greater than 50 percent of the cutoff. The NRC is aware that this provision differs from the HHS Guidelines. However, testing at the LOD may be necessary to confirm the presence of drugs or metabolites in a dilute specimen. Therefore, requiring the second HHS-certified laboratory to use LOD testing is appropriate.

9.8.4 Retesting a Specimen for Adulterants (§ 26.165(d)

Comments: One commenter addressed proposed § 26.165(d) and suggested changing the word "appropriate" in the phrase "A second laboratory shall use the appropriate confirmatory validity test and criteria . . ." to "required." The suggested change would improve the consistency of the proposed provision with the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter that the word "required" more accurately characterizes the confirmatory validity test and criteria and has revised § 26.165(d) in the final rule accordingly.

9.8.5 Retesting a Specimen for Substitution (§ 26.165(e))

Comments: One commenter recommended deleting the second sentence of proposed § 26.165(e), suggesting that the sentence was confusing and redundant. Specifically, the commenter noted that if the second HHS-certified laboratory does not find creatinine and specific gravity values that meet the substituted specimen criteria, the laboratory would report the result to the MRO as "failed to reconfirm" and not as stated in the proposed provision as "non-confirmed." The commenter also suggested deleting the phrase "exceed the original test cutoff parameters" because it was redundant with the first sentence of the proposed requirement [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's recommendations and has eliminated the second sentence of proposed § 26.165(e) in the final rule to improve the clarity of the requirement to meet Goal 6 of the rulemaking, which is to improve the clarity of the rule's language.

9.8.6 Management Actions and Sanctions (§ 26.165(f))

Donor Compensation While Awaiting Results of Split Specimen Testing

Comments: One commenter stated that the NRC should prohibit a licensee or other entity from withholding an employee's compensation and benefits during the time period when an employee is awaiting the test results of split specimen (Bottle B) testing [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the comment. Section 26.75(i)(2) in the final rule prohibits a licensee or other entity from withholding an individual's compensation and benefits during the time period his or her authorization has been administratively withdrawn following a positive initial drug test result for marijuana and/or cocaine metabolites at a licensee testing facility pending an HHS-certified laboratory specimen test result verified by the MRO. However, the NRC does not agree that this prohibition should be applied when a donor is waiting for the results of split specimen testing at a second HHS-certified laboratory. The difference is that, for § 26.75(i)(2), the donor's specimen has not been subject to initial or, if necessary, confirmatory testing at an HHS-certified laboratory and the result has not been confirmed by the MRO. Section 26.75(i)(2) prohibits action stronger than administrative withdrawal of authorization because the initial and confirmatory testing that could show culpability and justify stronger action have not been conducted. In the situation described by the commenter, the donor's specimen has already been subject to an HHS-certified laboratory's sophisticated testing procedures and

the MRO has confirmed the result as positive, adulterated, or substituted. Unlike the first situation, there is ample test result evidence that would indicate an FFD violation that should lead to sanctions, such as withholding of compensation and benefits. Split specimen testing or retesting of an aliquot of a single specimen is a right that a donor may choose to exercise to verify the accuracy of the first HHS-certified laboratory test result. If the second laboratory's testing fails to reconfirm the initial laboratory test result, the MRO, as required by § 26.186(n)(3) and (n)(4) of the final rule, would report that no FFD policy violation had occurred. Because of the significant difference in indicators of culpability in these two situations, the NRC has chosen not to revise proposed § 26.165(f) of the final rule.

Cancel Test Result If Donor Request Retest and Specimen Is Insufficient for Testing

Comments: One commenter stated that proposed§ 26.165(f)(2) conflicted with the HHS Guidelines. The proposed provision required that an MRO cancel an initial confirmed test result if the donor requests a retest and testing by the second laboratory cannot be performed because of circumstances outside of the donor's control (e.g., insufficient quantity of single specimen to permit retesting, or a courier, the HHS-certified laboratory, or a licensee testing facility loses Bottle B). In this instance, the HHS Guidelines also require the MRO to direct that the donor must submit a second specimen under direct observation [Charles LoDico, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.165(f)(2) in the final rule. That section now requires the MRO to inform the licensee or other entity that a second specimen collection under direct observation must occur if a donor requests the retesting of an aliquot of a single specimen or the testing of the Bottle B specimen after a confirmed positive, adulterated, or substituted test result, but the second HHS-certified laboratory is unable to test the specimen because of circumstances outside of the donor's control. Without this revision, it would have been be possible for a donor to test positive for a drug but, because the single specimen or the specimen in Bottle B of a split specimen could not be retested, the first confirmed positive test result would be cancelled and the licensee or other entity would not be required to take any further action. However, if the same donor did not request a retest of his or her specimen, the first confirmed positive test result would have stood and the licensee or other entity would impose the appropriate sanctions on the individual. By requiring a second collection under direct observation, this section as revised ensures that the individual is not using prohibited drugs whether or not he or she requests the first specimen be retested. Including this provision in the final rule also increases the consistency of Part 26 with the drug testing requirements of other Federal agencies.

Additional Reason Why a Bottle B Specimen Could Not Be Tested

Comments: One commenter addressed proposed § 26.165(f)(2) and noted that an additional reason that a Bottle B specimen could not be tested for split specimen testing is because of insufficient volume to permit testing or no volume at all.

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.165(f)(2) in the final rule to include insufficient volume in Bottle B as an additional reason why a split specimen (Bottle B) could not be tested.

Reporting of Test Results from an HHS-Certified Laboratory

Comments: One commenter addressed the section-by-section analysis of substantive changes in proposed § 26.165(f)(1). The commenter stated that the phrase "If the test results from the second laboratory confirm any non-negative test results from the first HHS-certified laboratory, the proposed paragraph would require the licensee . . ." was inconsistent with the HHS Guidelines. The commenter suggested that the word "confirms" should be revised to "reconfirms" [Sue Brown].

NRC Response: The NRC agrees with the commenter's request and has revised proposed §26.165(f)(1) in the final rule accordingly. In addition, in response to other comments received on the use of the term "non-negative test result," the NRC has replaced that term in this provision with "positive, adulterated, substituted, or invalid test result," as applicable.

9.9 Quality Assurance and Quality Control (§ 26.167)

Quality Control Testing

Comments: One commenter addressed proposed § 26.167 and recommended that quality control tests be conducted at the start of the testing period. If a specimen tests positive during the analytical run, the commenter recommended that a quality control test should be performed immediately after the positive test result was obtained to ensure that the testing equipment was functioning properly (i.e., the equipment is not reporting false positive results). A copy of the tests results for quality control testing performed at the start of the testing period along with the test results from the quality control test performed immediately after the positive specimen test should be provided to the MRO for each specimen that has a positive result. The commenter also recommended that, if back-to-back positive test results occur during a batch run, the second of the two samples should be tested again to ensure that carryover did not occur [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter's request. The NRC believes that the quality assurance and quality control provisions in the final rule provide enhanced measures to evaluate the performance of HHS-certified laboratory testing processes when compared to the commenter's suggestion because the rule requires that a variety of quality control samples must be included in every analytical run of specimens. Including quality control samples in each analytical run ensures that they are subject to the same testing conditions as any donor specimens that yield positive results. If quality control samples are tested only before and after each analytical run, it would be more difficult to conclude that any errors in testing identified also affected donor specimens because the conditions under which testing occurred differed. The purpose of including these quality control samples is to verify the accuracy of the testing process while it is occurring. Therefore, the NRC has not modified the proposed provisions in the final rule.

Replace Hyphens in Control Ranges with "to"

Comments: One commenter addressed proposed § 26.167 and suggested that the NRC should replace the hyphens used when identifying control ranges (e.g., 1-1.5 mg/dL creatinine)

with “to.” The suggested change would make the text consistent with the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has replaced the hyphens used in the control ranges specified in proposed § 26.167 with the word “to” in the final rule. The NRC also made this change in proposed § 26.137, where applicable.

9.9.1 Quality Assurance Program (§ 26.167(a))

No comments addressed this section.

9.9.2 Calibrators and Controls Required (§ 26.167(b))

No comments addressed this section.

9.9.3 Quality Control Requirements for Performing Initial and Confirmatory Validity Testing (§ 26.167(c))

Comments: One commenter addressed proposed § 26.167(c)(1)(iv) and stated that the creatinine concentration for the lower control should be revised from 1 to 1.0. The commenter indicated that the decimal place is important at the low end of the linear range [Charles LoDico, Individual].

NRC Response: The NRC agrees with the commenter and has revised the creatinine concentration from 1 to 1.0 in § 26.167(c)(1)(iv) of the final rule to improve accuracy in the language of the rule.

Reorganization of Requirements for pH Tests to Match HHS Guidelines

Comments: One commenter recommended that proposed § 26.167(c)(3)(i) through (c)(3)(v) addressing pH testing should be reorganized to be more consistent with the HHS Guidelines. Specifically, the commenter requested that proposed § 26.167(c)(3)(ii) be moved to the end of § 26.167(c)(3) and renumbered as (c)(3)(vi) and that the last sentence in proposed § 26.167(c)(3)(i) be moved to a new provision as § 26.167(c)(3)(ii) [Sue Brown, individual].

NRC Response: The NRC agrees with the commenter and has reorganized § 26.167(c)(3) accordingly. These changes enhance the organizational of the final rule and increase its consistency with related provisions in the HHS Guidelines.

Comments: One commenter recommended that the sentence structure of proposed § 26.167(c)(3)(iii) through (c)(3)(v) should be revised to be more consistent with the sentence structure used in the HHS Guidelines for the related provisions. The commenter suggested that the NRC should reverse the order of the clauses in the proposed provisions to present the requirements in these provisions before presenting the conditions under which each requirement applies [Sue Brown, Individual]

NRC Response: The NRC disagrees with the commenter’s recommendation. The NRC believes that presenting the antecedent conditions for a requirement before presenting the

requirement in a sentence is clearer than presenting the consequents first. Therefore, the NRC has not modified these provisions.

§ 26.167(c)(4) - Add References to Cutoff Concentration Sections

Comments: One commenter suggested revising proposed § 26.167(c)(4)(i) that stated, "Initial tests for oxidizing adulterants must include a calibrator at the appropriate cutoff concentration for the compound of interest . . ." to also include a reference to the sections in proposed § 26.161(c) that specified the cutoff concentrations. The commenter suggested that the recommended change would improve consistency with the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.167(c)(4)(i) in the final rule to include references to § 26.161(c) and (f). These provisions specify the cutoff concentrations for initial tests for oxidizing adulterants. The NRC made similar revisions to proposed § 26.167(c)(4)(ii) in the final rule. These changes improve the clarity in the language of the proposed rule.

Comments: One commenter recommended that the phrase in proposed § 26.167(c)(4)(ii) that states, "Each confirmatory analytical run. . " should be replaced with the phrase, "Each confirmatory test batch" to be consistent with Section 2.5(h)(2) of the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request and believes that the clarity of the proposed language adequately conveyed the testing requirement. Therefore, the NRC has not modified the proposed provision in the final rule.

9.9.4 Quality Control Requirements for Performing Initial Drug Tests (§ 26.167(d))

Comments: One commenter addressed § 26.167(d)(2) and (d)(3) and suggested that the wording in the proposed provisions should be reorganized to be consistent with proposed § 26.137(e)(6) [Sue Brown, Individual].

NRC Response: The NRC agrees, in part, with the commenter's suggestion. The NRC has revised § 26.167(d)(3) in the final rule to be consistent with the organization of § 26.137(e)(6). The NRC disagrees with the commenter's request to reorganize § 26.167(d)(2) because the proposed provision clearly stated the intent of the requirement.

9.9.5 Quality Control Requirements for Performing Confirmatory Drug Test (§ 26.167(e))

Comments: One commenter addressed proposed § 26.167(e)(1) and recommended that because the provision did not describe quality control samples, it should be deleted [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. Section 26.167(e)(1) presents quality control requirements for performing confirmatory drug testing, not only requirements for quality control samples to be included in each analytical run of specimens subject to confirmatory testing, as indicated by the commenter. Therefore, the NRC has not modified the proposed provision in the final rule.

9.9.6 Blind Performance Testing (§ 26.167(f))

Criteria for Positive Samples May Not Result in a Positive Test Result

Comments: One commenter addressed proposed § 26.167(f)(3) and stated that the drug or drug metabolite level for blind performance testing samples at "60-80 percent of the initial cutoff values for the panel of drugs" would not produce a positive result. The commenter also noted that proposed drug or drug metabolite levels were inconsistent with those proposed for blind performance testing samples for licensee testing facilities in § 26.137(f)(6) [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.167(f)(9)(ii) to require that a drug positive blind performance testing sample must contain a measurable amount of the target drug or analyte between 150 and 200 percent of the initial cutoff value. This requirement appears in § 26.168(g)(2) of the final rule. In addition, the NRC has revised proposed § 26.167(f) to include specific criteria that each blind performance test sample type (i.e., negative, drug positive, adulterated, dilute, substituted, and false negative challenge) must meet. The final rule's § 26.168(g) contains these criteria. These criteria ensure that each licensee and other entity sufficiently challenges the testing assays of HHS-certified laboratories to ensure accurate and reliable test results, thus improving the effectiveness and efficiency of FFD programs. The blind performance testing provisions in proposed § 26.167(f) were reorganized into a new section in the final rule, § 26.168(g), to improve the clarify of the final rule.

Blind Performance Testing Sample - Dilute

Comments: One commenter addressed proposed § 26.167(f)(3) that required a licensee or other entity to submit blind performance testing samples to an HHS-certified laboratory meeting the criteria for a dilute specimen. The commenter stated that the HHS Guidelines contain no such requirement [Sue Brown, Individual].

NRC Response: The NRC has chosen to challenge HHS-certified laboratories with blind performance testing sample types beyond those required by the HHS Guidelines. Because the NRC is permitting licensees and other entities to subject dilute specimens to testing at the LOD under § 26.163(a)(2) in the final rule, the NRC believes that challenging the laboratory's ability to detect dilute specimens is necessary. Therefore, the NRC has not modified the proposed provision in the final rule.

Comments: One commenter noted that proposed § 26.167(f)(5) did not include reference to dilute specimens, as required by proposed § 26.167(f)(3).

NRC Response: The NRC agrees with the commenter and has revised § 26.168(e) in the final rule to require FFD programs to submit dilute blind performance testing samples to the HHS-certified laboratory for testing each quarter. Because the NRC is permitting licensees and other entities to subject dilute specimens to testing at the LOD under § 26.163(a)(2) in the final rule, the NRC believes that challenging the laboratory's ability to detect dilute specimens is necessary. The blind performance testing provisions in proposed § 26.167(f) were reorganized into a new section in the final rule, § 26.168(g), to improve the clarify of the final rule.

Eliminate Specific Concentrations for Drug and Validity Performance Testing Samples

Comments: One commenter addressed proposed § 26.167(f)(5)(i)and (f)(5)(ii) and argued that listing the specific concentrations for drug and validity performance testing samples may be confusing and restrictive. The commenter also noted that because proposed § 26.167(f)(5) listed the criteria for performance testing samples, the requirements in proposed § 26.167(f)(5)(i) and (f)(5)(ii) should be deleted [Sue Brown, Individual].

NRC Response: NRC agrees with the commenter's recommendations and has revised proposed § 26.167(f)(5)(i) and (f)(5)(ii) in the final rule. Specifically, the NRC replaced the proposed provisions with revised provisions in § 26.168(g) of the final rule that specify the criteria that each type of blind performance test sample must meet. The specimen criteria in the final rule are less restrictive to ensure that FFD programs have the maximal flexibility to challenge the testing capabilities of HHS-certified laboratories. The blind performance testing provisions in proposed § 26.167(f) were reorganized into a new section in the final rule, § 26.168(g), to improve the clarify of the final rule.

Blind Performance Testing Samples

Comments: One commenter addressed the drug performance testing sample provisions in proposed § 26.167(f)(5)(i)(A) and stated that samples at the proposed "20 percent above the designated cutoff for the initial drug test" may produce a negative result. The commenter stated that to ensure a drug positive on the initial drug test, the drug or drug metabolite concentration should be between 1.5 and 2 times the initial drug test cutoff concentration [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter. The NRC moved proposed § 26.167(f)(5)(i)(A) to § 26.168(g)(2) of the final rule and revised it to require that drug positive blind performance testing samples must contain a measurable amount of the target analyte between 150 and 200 percent of the initial cutoff value for each drug tested. This revision will ensure that the accuracy of drug testing at HHS-certified laboratories is effectively evaluated. The blind performance testing provisions in proposed § 26.167(f) were reorganized into a new section in the final rule, § 26.168(g), to improve the clarify of the final rule.

Comments: One commenter addressed proposed § 26.167(f)(5)(i)(C) and asked why a drug performance testing "routine sample" would need to be below the cutoff for "special purposes." The commenter stated that the initial drug tests performed on a routine sample submitted to an HHS-certified laboratory would produce a negative test result because the drug concentration was below the initial cutoff level. The commenter recommended clarifying the statement or deleting the requirement from the final rule [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's request and has eliminated § 26.167(f)(5)(i)(C) from the final rule.

Comments: One commenter identified an inconsistency between proposed § 26.167(f)(5)(i)(D) and the related provision in the HHS Guidelines. Specifically, the HHS Guidelines require a negative sample to contain no drug, while the proposed provision stated, "A negative sample

may not contain the target drug analyte at a concentration greater than 10 percent of the confirmatory cutoff" [Sue Brown, Individual].

NRC Response: The NRC agrees with the comment. The blind performance test sample criteria have been revised in § 26.168(g)(1) of the final rule. That section requires that a negative blind performance test sample may not contain a measurable amount of a target analyte and must be certified by immunoassay and confirmatory testing. The blind performance testing provisions in proposed § 26.167(f) were reorganized into a new section in the final rule, § 26.168(g), to improve the clarify of the final rule.

Comments: One commenter addressed proposed § 26.167(f)(5)(i)(E) and recommended that the phrase "fortified with" be replaced with the word "contain." [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's request. The NRC has eliminated proposed § 26.167(f)(5)(i)(E) in the final rule in response to another comment. Therefore, no action is necessary to respond to this comment. However, the word "fortified" has been eliminated in the final rule in §26.137(d) and § 26.167(d) and (e) to improve the clarity of the final rule provisions.

Comments: One commenter suggested that the NRC combine proposed § 26.167(f)(5)(ii)(D) and (f)(5)(ii)(E) to ensure that blind performance testing samples meet the requirements for substituted or dilute specimens required in proposed § 26.167(f)(3) [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter. To improve the clarity and intent of the proposed provisions in § 26.167(f)(5)(ii)(D) and (ii)(E), the NRC has revised the blind performance test sample criteria for dilute samples in § 26.168(g)(5) of the final rule and for substituted samples in § 26.168(g)(6) in the final rule.

9.9.7 Errors in Testing (§ 26.167(g))

Comments: One commenter stated that the proposed provision in § 26.167(g)(3) incorrectly identified the title of the individual at an HHS-certified laboratory who is responsible for overseeing any corrective action required as a result of a false positive error. The commenter stated that position title should be the "responsible person" and not the "certifying scientist" was specified in the proposed provision [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.167(f)(3) in the final rule to refer to the individual at an HHS-certified laboratory who oversees any corrective action required as a result of a false positive error as the "responsible person." This change clarifies the intent of the rule.

9.9.8 Accuracy (§ 26.167(h))

No comments addressed this section.

9.10 Reporting Results (§ 26.169)

Comments: One commenter stated that the provision in proposed § 26.169(a) that HHS-certified laboratories must report for each specimen tested "any indications of tampering, adulteration, or substitution that may be present" was redundant given that laboratories will report validity test results as adulterated, substituted, invalid, or dilute. In addition, the commenter noted that any notation made on the custody-and-control form by the specimen collector also will be reported by the HHS-certified laboratory in the test result documentation. The commenter suggested that NRC delete the proposed provision [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. Tampering may occur after a specimen has been collected and before it arrives at the HHS-certified laboratory that cannot be detected only through testing. For example, physical evidence may exist to suggest that a shipping container containing donor specimens had been opened in transit. If the proposed provision were eliminated from the final rule, the laboratory may not inform the licensee or other entity of the physical evidence and the possibility that tampering had occurred would not then be investigated, as required under § 26.159(b) of the final rule. Therefore, the NRC has not modified the proposed provision in the final rule.

Invalid Specimens Not Included as a Non-Negative Test Result

Comments: One commenter addressed the proposed provision in § 26.169(b) that specified the non-negative test results that an HHS-certified laboratory must report to the MRO. The commenter noted that the provision did not include invalid specimen test results [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has amended proposed § 26.169(c)(1) in the final rule to include an invalid specimen test result as a result that must be reported by HHS-certified laboratories to MROs. This change clarifies the NRC's intent that HHS-certified laboratories must report test results for invalid specimens to the MRO.

Reporting Numerical Values of Specimen Test Results

Comments: One commenter addressed proposed § 26.169(d) and stated that by including the phrase "when applicable" in the provision for reporting of numerical values for dilute, adulterated, and substituted test results, it appeared that HHS-certified laboratories may have the option of providing this information for specimens with substituted and adulterated test results. The commenter stated that the HHS Guidelines require laboratories to report to the MRO the numerical values for specimens with substituted and adulterated test results [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.169(c)(3) in the final rule to clarify the intent of the provision. This change clarifies the NRC's intent that HHS-certified laboratories must report to the MRO the numerical values for specimens with substituted and adulterated test results.

Reporting of Numerical Values for Dilute Specimens

Comments: One commenter addressed proposed § 26.169(d) and stated that the provision requiring HHS-certified laboratories to report numerical values for substituted, adulterated, and dilute specimen test results "when applicable" made it appear that the laboratory would have to provide numerical values for dilute specimens. Because the HHS Guidelines do not require laboratories to report the numerical values for dilute specimens, the commenter suggested that NRC revise the proposed provision to be consistent with the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised the reporting requirements for substituted and adulterated specimen test results in § 26.169(c)(3) of the final rule to clarify the intent of the proposed provision. The NRC is requiring HHS-certified laboratories to report the numerical values to the MRO for only adulterated and substituted test results.

Reporting of Creatinine Result, Substituted Specimens

Comments: One commenter stated that the requirement in proposed § 26.169(d), "If 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," was inconsistent with the HHS Guidelines. Specifically, the commenter stated that if the creatinine concentration for a specimen is below the LOD, the HHS-certified laboratory will report a result of "creatinine: none detected" along with the numerical value of the specific gravity test [Sue Brown, Individual]

NRC Response: The NRC agrees with the commenter. The NRC has revised § 26.169(c)(3) in the final rule to specify that for a specimen with a creatinine test result below the LOD, the HHS-certified laboratory will report the result as "creatinine: none detected" along with the specific gravity test result for the specimen. The revision improves consistency between the HHS Guidelines and the related Part 26 provisions.

Reporting of Numerical Values for Drug Positive, Adulterated, and Substituted Test Results

Comments: One commenter suggested that proposed § 26.169(f) requiring the HHS-certified laboratories to "provide numerical values for non-negative confirmatory test results when the MRO requests such information" was redundant, given the reporting requirement in proposed § 26.169(d). The commenter suggested that perhaps the intent of the provision was to require the laboratory to provide numerical values for drug positive test results to the MRO [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter. The NRC has revised § 26.169(c)(2) in the final rule to require an HHS-certified laboratory to provide the quantitative test results for positive test result from confirmatory testing when requested by the MRO. This change clarifies the NRC's intent in the proposed provision.

Reporting of Test Results, Number of Rejected Specimens

Comments: One commenter recommended adding two data elements to the reporting requirements in proposed § 26.169(k). To be consistent with the HHS Guidelines, the commenter suggested that HHS-certified laboratories also report the number of specimens reported as rejected for testing because of a fatal flaw and the number of specimens rejected for testing because of an uncorrected flaw [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's recommendation and has added a requirement to § 26.169(h) of the final rule for HHS-certified laboratories to report the number of specimens "rejected for testing and the reason for the rejection." The NRC added this reporting requirement to account for specimens where testing has been canceled by the MRO because of circumstances specified in § 26.159(b)(2) of the final rule.

Reporting of Test Results, Number of Specimens Received or Reported

Comments: One commenter stated that the requirement in proposed § 26.169(k)(1) for an HHS-certified laboratory to report the "total number of specimens received" at the laboratory was inconsistent with HHS Guidelines which require the reporting of only the number of "specimen results reported" [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request. The NRC considers having HHS-certified laboratories report the total number of specimens received to be a necessary component of NRC oversight of licensee testing programs because it permits the NRC to determine how many specimens licensees and other entities send to HHS-certified laboratories for testing. Therefore, the NRC has not modified the proposed provision in the final rule.

10. Subpart H: Determining FFD Policy Violations and Determining Fitness

10.1. Purpose (§ 26.181)

No comments addressed this section.

10.2. Medical Review Officer (§ 26.183)

No comments addressed this section.

10.2.1. Qualifications (§ 26.183(a))

No comments addressed this section.

10.2.2. Relationships (§ 26.183(b))

Comments: One commenter, supported by many comments, stated that additional guidance is needed in proposed § 26.183(b) to clarify conflict-of-interest relationships between MROs and HHS-certified labs. The commenter suggested that the NRC add language from DOT's 49 CFR 40.101(b) which provides examples of MRO conflicts of interest. The commenter noted that this

suggestion is consistent with Goal 1 of the rulemaking [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenter's request to add specific examples of conflict-of-interest relationships between MROs and HHS-certified laboratories. Therefore, the NRC has clarified the final rule to include specific examples of conflict-of-interest relationships between MROs and HHS-certified laboratories. The basis for the examples is 49 CFR 40.101(b) of the U.S. DOT's Procedures for Transportation Workplace Drug and Alcohol Testing Programs.

10.2.3. Responsibilities (§ 26.183(c))

No comments addressed this section.

10.2.4. MRO Staff (§ 26.183(d))

MRO Staff Performing Other Duties

Comments: One commenter, supported by many commenters, requested that the NRC revisit the requirements of proposed § 26.183(d)(1)(i) because they limit the flexibility of MRO staff who are licensee employees. The commenter requested that the licensee staff who perform MRO functions on a part-time basis be allowed to perform other duties for, and take direction from, the licensee while not working to support the MRO. This change would allow licensees to avoid needless increases to staff size. The commenter recommended that licensees and other entities be allowed to continue assigning individuals to the MRO staff on a part-time basis in accordance with current practices. The commenter suggested that the NRC add the following language to the end of the proposed section: "Employees of licensees and other entities may function as MRO staff. When functioning as MRO staff they shall take direction from the MRO only" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

Two commenters in the public meeting requested clarification on how the new rule applies in certain situations. For example, under the former rule, if a site has MRO staff that are licensee employees and an MRO that is a contractor, the licensee maintains authority over performance evaluations, hiring, and firing. The commenters were confused as to how to implement the new rule in such situations. In this case, the commenters stated that the proposed rule would force the licensee to either have an employee that is an MRO, have the MRO staff as employees, or make them all contractors. The commenters argued that in all cases, there will be a cost burden on industry [Nick Depietro, First Energy; Susan Techau, Exelon].

NRC Response: The NRC agrees with the first comment. It is not the NRC's intent to require MRO staff to be employees of an MRO. Rather, the intent of these provisions was to permit licensee staff who perform MRO functions on a part-time basis be allowed to perform other

duties for the licensee while not working to support the MRO. Therefore, the NRC has added a sentence to § 26.183(d) in the final rule to specifically state this intent.

The NRC agrees with the second set of comments that the rule requires MRO staff to be employees of the licensee or other entity, employees of the MRO, or employees of a C/V. The rule also requires an MRO to be directly responsible for the administrative, technical, and professional activities of individuals who perform MRO staff duties subject to the MRO's authority, and that the MRO's direction of staff must be meaningful. Meaningful direction involves, among other things, providing input to an individual's performance evaluation.

MRO Staff Function

Comments: Several commenters from industry addressed proposed § 26.183(d)(2)(iii) and requested that MRO staff, not exclusively the MRO, be allowed to validate prescription medication information as an administrative function. The commenters believed that this change would better allow MRO staff to assist the MRO in obtaining the information necessary to make decisions about specimens [Jim Davis, NEI #48; Brian Mc Cabe, Progress Energy; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees with this comment. The medications that a donor has taken or is taking is personal information that only a professional who meets the requirements to serve as an MRO is qualified to discuss with the donor and evaluate. Therefore, the NRC has retained the prohibition on permitting MRO staff to request information about prescription medications from donors to protect individuals' privacy under the rule.

Restrictions on MRO Staff

Comments: One commenter, supported by many commenters, disagreed with the language in proposed § 26.183(d)(2)(iv) that prohibited MRO staff from discussing test results with licensees and other entities. The commenter stated that clarification is needed to permit the MRO staff to relate confirmed results and to discuss those results with licensee and other entity personnel. The commenter stated that it is ineffective and inefficient to have only the MRO discuss results with the licensee or other entity personnel. The commenter recommended the following revised language for this subparagraph: "Staff may not report nor discuss any non-negative test results received from the HHS-certified laboratory with any individual other than the MRO and *individuals designated by licensees and other entities*" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenters that MRO staff should be permitted to discuss test results with licensee or other entity personnel because it is inefficient to prohibit the staff from doing so. The intent of this provision is to ensure that test results are not revealed to licensee or other entity personnel until the MRO has reviewed and confirmed them. This

prohibition is necessary to ensure that donors' privacy is protected if there is a legitimate medical explanation for a positive, adulterated, substituted, or invalid initial or confirmatory test result from the HHS-certified laboratory. It is also necessary to avoid any questions that could arise about the donor's fitness or trustworthiness and reliability based on test results that have not been confirmed by the MRO. The former, proposed, and final rules have consistently reflected the NRC's intent in this matter. The NRC intends that MRO staff may not communicate or discuss any positive, adulterated, substituted, invalid, or dilute test results received from the HHS-certified laboratory that have not been reviewed and confirmed by the MRO (i.e., unconfirmed test results) with any person other than other MRO staff or the MRO. Furthermore, the NRC does not believe that MRO staff are qualified to answer questions about an individual's medical condition, the bases for an MRO decision either to confirm an adverse confirmatory test result from an HHS-certified laboratory or to declare the test result as negative, or the meaning of any quantitative confirmatory test results reported by the HHS-certified laboratory. Those discussions must be conducted only by the MRO.

Proposed § 26.183(d)(2)(iv) referred to test results "received from the HHS-certified laboratory," which the NRC intended to be interpreted as meaning test results that have not been confirmed through MRO review. The NRC has modified this provision to more fully explain its intent in the final rule.

10.3. Determining a FFD Policy Violation (§ 26.185)

"Referral Physician"

Comments: One commenter also asked for clarification of "referral" physician in proposed § 26.185(h)(1) and (i)(1). The commenter argued that if it means the donor must be referred to him by the MRO, the commenter asked: "Why can't the donor pick his own specialist, especially if he already has the proof from the specialist in his possession?" [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenter that the term "referral" is ambiguous and has deleted it from § 26.185(h)(1) and (i)(1) in the final rule. The NRC intends the MRO to have sole responsibility to determine whether or not the donor has provided legitimate medical evidence and whether the specialist selected and/or the documentation provided meets the criterion of legitimate medical evidence. However, the rule does not prohibit a donor from selecting his or her own specialist or providing any documentation that the donor possesses.

Providing Legitimate Medical Evidence within Five Days

Comments: With regard to proposed § 26.185(h)(1) and (i)(1), one commenter argued that five days is not enough time to get an appointment to see a specialist. The commenter suggested that it may be better to show proof of appointment with a specialist within five days and have the clearance placed on administrative hold, pending the results from the doctor. Further, the commenter suggested that the MRO should contact the specialist to expedite the appointment. The commenter also stated that if the specialist exonerates the donor, the licensee should be liable for the costs of testing. However, the commenter stated that if the specialist cannot confirm that a medical explanation exists, then the costs should be the responsibility of the donor [Todd Newkirk, IBEW].

Several commenters from industry stated that five business days are sufficient for the donor to have medical records sent to the MRO from the donor's physician who is familiar with the donor's medical issues and recommend that the NRC implement this paragraph as proposed [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenter who does not support the proposed provision. Five business days is not an onerous time limitation. The DOT reports that individuals who have legitimate medical evidence related to the circumstances addressed in these provisions have not had difficulty in providing their medical records to an MRO within the 5-day time period required under DOT's procedures. Therefore, the NRC has not modified this provision in the final rule.

10.3.1. MRO Review Required (§ 26.185(a))

Comments: Several commenters from industry stated that the proposed rule language calling for the MRO to determine whether the donor has violated the FFD policy was onerous for the MRO, whose expertise is medical. The commenters stated that MROs should not be required to interpret whether the FFD policy has been violated. Rather, MROs should only be responsible for reviewing non-negative test results before reporting the result to licensees. Therefore, the commenters suggested the NRC strike the phrase "to determine whether the donor has violated the FFD policy" from this proposed section [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC does not agree with the commenters. According to § 26.183(a), the MRO must be knowledgeable of the FFD policies of the licensees or other entities for whom the MRO provides services. Also, according to § 26.185(a), the MRO shall have detailed knowledge of alternate medical explanations for a positive, adulterated, substituted, invalid, or dilute test result. Because the MRO has both detailed medical knowledge and knowledge of the licensee's FFD policies, the NRC believes that review by an MRO is a key element in determining FFD policy violations. Therefore, the NRC has not modified the provision in the final rule.

10.3.2. Reporting of Initial Test Results Prohibited (§ 26.185(b))

No comments addressed this section.

10.3.3. Discussion with the Donor (§ 26.185(c))

No comments addressed this section.

10.3.4. Donor Unavailability (§ 26.185(d))

Comments: One commenter addressed donor unavailability (i.e., to talk to the MRO, or MRO staff) and stated that proposed § 26.185(d)(1) through (3) should be re-written to improve the notification requirements. For example, a night shift worker may not have an answering machine or it may be broken. This situation could make notification impossible, unless the contact is made at work. However, if the MRO were to contact the individual at work and the individual was out of the plant, the commenter asked: "what happens if the message gets lost? What happens if the worker is on vacation, in the hospital, or on a long set of weekday ST days, like 12-hour workers get, and what if the MROs can't make contact?"

This commenter suggested that the licensee should be responsible for contacting the individual's supervisor and making arrangements for the worker to contact the licensee, who would then schedule a time for the MRO discussion. Because the supervisor is aware of the employee's schedule and health status, this would avoid the donor being declared as violating the FFD program simply because he was unavailable due to perfectly innocent reasons [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter and believes that the three paragraphs in question give adequate opportunity for the donor to be contacted. The first two paragraphs of this section pertain to situations in which contact with the donor has been made and documented, and which are not the subject of this comment. The third subparagraph clarifies that the MRO may confirm a test result as an FFD policy violation if the MRO is unable to make contact with the donor after the MRO makes all "reasonable efforts" to do so. A reasonable effort is described in this paragraph, which also makes clear that the MRO may go beyond the stated efforts to make contact with the donor.

In response to the commenter's specific examples, the MRO is required to attempt to contact the donor at day and evening phone numbers at least three times spaced reasonably over a 24-hour period. The NRC believes that contacting the donor at work is encompassed within "reasonable" efforts. If the donor is on vacation or in the hospital, reasonable efforts by the MRO will likely uncover this information.

The NRC believes that naming the donor's supervisor, instead of the donor, as the point of contact for the MRO, is inefficient and will not address the issues raised by the commenter because the MRO may face the same challenges in contacting the supervisor as in contacting the donor. In addition, MRO contact with the supervisor has the potential to violate the donor's privacy. However, § 26.185(e) provides donors with an opportunity to contact the MRO and request additional discussion of the test result(s) in the event of circumstances such as those described by the commenter.

In the rare event that a donor is unable to either receive or respond to an MRO's call, § 26.185(e) grants the donor an opportunity to re-open the discussion with the MRO by documenting the reason(s) he or she was unable to contact the MRO to discuss the adverse MRO determination. After the donor has been notified that the MRO has determined the donor violated the FFD policy without discussion, the donor has 30 days to present information to the MRO that documents the unavoidable circumstances which prevented the donor from

establishing contact with the MRO or a representative of the licensee or other entity. After evaluating the information provided by the donor, the MRO may modify the initial determination.

The NRC believes that these provisions adequately protect donors' privacy and other rights (including due process) in the circumstances described by the commenter and has not modified the provisions in the final rule.

10.3.5. Additional Opportunity for Discussion (§ 26.185(e))

No comments addressed this section.

10.3.6. Review of Invalid Specimens (§ 26.185(f))

MRO Judgement

Comments: One commenter addressed proposed § 26.185(f)(2), (f)(3), (g)(1), (h)(1) and (i)(1) and asked what constitutes an "acceptable" or "legitimate" explanation for the drug test result. The commenter argued that the provision should specify that if the individual presents testimony or certification from a medical doctor (especially a specialist), the MRO must accept it as a valid reason [Todd Newkirk, IBEW].

Several commenters from industry stated that industry believes MRO judgement is adequate and appropriate when a donor submits medical evidence to the MRO, and thus recommends that the NRC implement § 26.185(f)(2), (f)(3), (g)(1), (h)(1), and (i)(1) as proposed [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters who support the proposed provisions, and believes it is appropriate and adequate to rely on MRO judgement to determine if there is an acceptable medical explanation for drug test results, based upon his or her medical knowledge, the qualifications and training required under § 26.183(a), and any information that the donor provides. Accordingly, the NRC has not modified the proposed provisions in the final rule.

10.3.7. Review of Dilute Specimens (§ 26.185(g))

Grounds Constituting Reason to Suspect Specimen Dilution

Comments: Another commenter, supported by many commenters, objected to the proposed language in § 26.185(g)(2) that included the specific reasons the MRO may use to determine that a donor has attempted to dilute a specimen. The commenter stated that these reasons were too restrictive, did not afford the opportunity for changes in medical knowledge, and may have negatively impacted the effectiveness of the FFD program. The commenter suggested deleting the last sentence in this paragraph as well as the three paragraphs that follow [(g)(2)(i)-(iii)] [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn

Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with commenter that the words "exclusive grounds" in the proposed provision were too restrictive. Therefore, the NRC has added language to the final rule clarifying that MROs shall consider the circumstances specified in § 26.185(g)(2)(i) through (g)(2)(iii) as applicable in making the determination required under this paragraph.

Typographical Error

Comments: Several commenters from industry identified a typographical error in proposed § 26.185(g)(2) and (g)(3): instead of citing § 26.31(c)(1)(ii), the NRC should cite § 26.31(d)(1)(ii) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC has revised proposed 26.185(g)(2) in the final rule and has eliminated the need for reference to 26.31(d)(1)(ii). However, the NRC agrees with the commenter that proposed § 26.185(g)(3) contained a typographical error and has revised the final rule accordingly.

MRO Judgement

Comments that addressed MRO judgment are documented in Section 10.3.6 of this document.

10.3.8. Review of Substituted Specimens (§ 26.185(h))

MRO Judgement

Comments that referenced this section are addressed in Section 10.3.6 of this document.

10.3.9. Review of Adulterated Specimens (§ 26.185(i))

Typographical Error

Comments: One industry commenter, supported by many commenters, addressed § 26.185(i)(3) and noted that there is a typographical error in the proposed language. To resolve this issue, the commenter suggested the following language: “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 the test is negative”[Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with this comment. The error in the proposed rule resulted in an inconsistent provision. The NRC has revised the final rule accordingly.

MRO Judgement

Comments that addressed MRO judgment are documented in Section 10.3.6 of this document.

10.3.10. Review of Opiates, Prescription and Over-the-Counter Medications (§ 26.185(j))

Donor Responsibility to Determine if Medication is Controlled Substance

Comments: One commenter referenced proposed § 26.185(j)(6) and stated that if a doctor prescribes medication legally as treatment for a medical condition, it should not be the employee's responsibility to determine if this medication is on the list in Schedule I of section 202 of the Controlled Substances Act [21 U.S.C. 812]. The commenter stated that although § 26.21(b)(6) references the "use of prescription and over-the-counter medications that could cause impairment," no mention is made requiring the individual to report the use of prescription and OTC medications to a supervisor. This would be an invasion of the individual's privacy and a supervisor wouldn't be qualified to determine whether use of the medication would cause impairment. The commenter also argued that there is also no requirement for the employee to list his or her prescription and OTC medications when taking an FFD test; this is only required when the employee is called in for the MRO interview after a positive test occurs [Todd Newkirk, IBEW].

Several commenters from industry also referenced § 26.185(j)(6) and stated that industry agrees with the proposed paragraph because the use of drugs contained in Schedule I is a fitness-for-duty policy violation [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: NRC agrees with the commenters who support the proposed provision. The drugs on Schedule I, by definition, do not have legitimate medical uses and, except in very rare circumstances, are not prescribed by licensed physicians. Therefore, donors will not be required to determine whether a medication resides on Schedule I.

Also, the NRC agrees that requiring an individual to report the use of prescription medications would be an invasion of the individual's privacy. Therefore, there is no requirement in the rule for a donor to list his or her prescription and OTC medications when taking an FFD test. 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 in the former rule to list medications before 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 or drug test results in order to enhance their rights to privacy under the rule. This revised requirement is also consistent with the procedures of other Federal agencies.

Review for Over-the-Counter (OTC) Medications

Comments: One commenter made three OTC-related arguments:

1) Anyone taking prescription and OTC medications may be doing so legally, but may be impaired nonetheless. Therefore, there should be a point of contact in the licensees testing program, available at all times that coincide with shift workers' starting hours, who can ensure that the medication being taken does not jeopardize the safety of the individual, coworkers, or the plant.

2) If the workers FFD file contained prescription and OTC medication information, it would eliminate the need for the worker to endure the stress of the MRO review if the medication were the cause of the non-negative test.

3) If the employee forgets about his or her OTC or prescription medications, and an FFD test were to identify them, the employee should be designated, "Not fit for duty due to accepted medical reasons," until the MRO deems that the medication is no longer being taken. [Todd Newkirk, IBEW]

NRC Response: The NRC disagrees with the commenter's first argument that there should be an available point of contact for those individuals taking prescriptions and OTC medications because the final rule contains other provisions that address this topic. Language has already been included in the final rule for such provisions. Specifically, licensees and other entities must establish the FFD program requirements for addressing these issues in their policy (§ 26.27(b)(6)) and in their procedures (§ 26.27(c)(4)).

The NRC also disagrees with the second argument that employees' FFD file should contain information about their OTC prescription medications. Requiring employees to include medication information that is linked to the positive, adulterated, substituted, or invalid test result would be an invasion of the individuals' privacy. Also, MRO's require current medication information, and the information contained in a donor's personnel file may be outdated.

The NRC disagrees with the commenter's final argument. Section 26.185(k) already addresses the commenter's concern that an employee may forget about his or her prescription or OTC medication only to have the medications identified in the FFD test. That provision states that the donor has not violated the FFD policy if an MRO determines that there is legitimate medical explanation for a positive drug test result, 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.

10.3.11. Results Consistent with Legitimate Drug Use (§ 26.185(k))

No comments addressed this section.

10.3.12. Retesting Authorized (§ 26.185(l))

No comments addressed this section.

10.3.13. Result Scientifically Insufficient (§ 26.185(m))

No comments addressed this section.

10.3.14. Evaluating Results from a Second Lab (§ 26.185(n))

No comments addressed this section.

10.3.15. Reauthorization after a First Violation for a Drug-Positive Test Result (§ 26.185(o))

No comments addressed this section.

10.3.16. Time to Complete MRO Review (§ 26.185(p))

Comments: One commenter, supported by many commenters, suggested a clarification for proposed § 26.185(p), and stated that in this paragraph, the NRC did not specify "business days." The commenter argued that the proposed language should be revised to say "business days" to conform to proposed § 26.169(a) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters that modifying the rule to state "business days" would improve consistency with other provisions. Therefore, the NRC has revised the final rule accordingly.

10.4. Substance Abuse Expert (§ 26.187)

No comments addressed this section.

10.4.1. Implementation (§ 26.187(a))

Comments: One commenter, supported by many commenters, stated that proposed § 26.187(a) needed clarification. Specifically, the commenter said the language should be revised to give the MRO, if qualified, the option to function as the SAE. This would avoid any unnecessary financial burden for licensees that have an MRO that can make SAE determinations. The commenter suggested adding a second sentence to § 26.187(a) that stated the following: "One person who qualifies as both an MRO as required in § 26.183 and an SAE as required by this section may perform the functions of both positions" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, EntergyÅ].

NRC Response: The NRC agrees with the commenters that the final rule should specify that an MRO who meets the applicable requirements may serve as both an MRO and as an SAE. Therefore, the NRC has revised this provision in the final rule accordingly.

10.4.2. Credentials (§ 26.187(b))

No comments addressed this section.

10.4.3. Basic Knowledge (§ 26.187(c))

No comments addressed this section.

10.4.4. Qualification Training (§ 26.187(d))

No comments addressed this section.

10.4.5. Continuing Education (§ 26.187(e))

No comments addressed this section.

10.4.6. Documentation (§ 26.187(f))

Comments: One commenter addressed documentation and stated that SAE documentation should be provided to the individual or designated representative upon request [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenter. Documentation of the credentials, knowledge, and training of the SAE should be available upon request to individuals as well as to NRC representatives, licensees, or other entities. The NRC has added a cross-reference to this provision of the final rule to specify that these types of documents shall be made available in accordance with the protection of information requirements in § 26.37.

10.4.7. Responsibilities and Prohibitions (§ 26.187(g))

Comments: One commenter addressed proposed § 26.187(g)(2) and stated that, in order to best prevent a conflict of interest, once the SAE has made the recommendation for the best treatment of the individual, the individual should be allowed to select the entity that will provide the treatment if the entity meets the credential requirements for the course of treatment provided. The commenter argued that, because personality conflicts may interfere with treatments, the individual should be allowed to change treatment providers (with SAE concurrence) during the course of treatment [Todd Newkirk, IBEW].

NRC Response: The NRC does not agree with the commenter. The NRC notes that nothing in this paragraph prohibits an SAE from considering a donor's preferences, among the other considerations specified, in identifying a treatment provider. However, "personality conflicts" with a treatment provider may be clinically meaningful and changing providers may not represent the most effective resolution to the issues. The NRC is confident that an SAE will be qualified to address such circumstances, and, therefore, has not modified this provision in the final rule.

10.5. Determination of Fitness (§ 26.189)

Definition of Determination of Fitness

Comments: One commenter, supported by other commenters, stated that proposed § 26.189(a) was confusing. The commenter suggested rewording the first sentence of the paragraph to clarify what a determination of fitness is: "A determination of fitness is 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" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters. A determination of fitness is conducted after indications that the individual may be in violation of the FFD policy are discovered, not to determine whether there are such indications. Therefore, the NRC has modified the provision in the final rule to clarify this intent.

Language Clarification

Comments: Another commenter, supported by many commenters, stated that the proposed language in § 26.189(b)(3) was confusing and suggested the following minor word change: "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 part..." [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters that this edit will clarify the intent of the provision. A determination of fitness is intended to be conducted before an individual is granted authorization when potentially disqualifying fitness-for-duty information (PDFFDI) is identified that has not been previously evaluated by another licensee or entity who is subject to this part. Therefore, the NRC has modified the provision in the final rule to address this comment.

Requirement for Face-to-Face For-Cause Determination of Fitness

Comments: One commenter, supported by many commenters, addressed the proposed language in § 26.189(c) and stated that face-to-face interaction is not always required to make a "for cause" determination of fitness. The commenter stated that the determination of the appropriate approach to this determination should be left to the professional making the determination. The commenter argued that, in other parts of the rule, the qualified professional would be expected to make that determination using techniques that are generally acceptable in the professional community and these may not include face-to-face interaction in all circumstances. For example, if the ultimate issue is whether a certain psychoactive medication will prevent an individual from performing assigned duties, the commenter argued that a clinical

psychologist may be able to provide the needed determination of fitness without a face-to-face interaction. Thus, the commenter suggested deleting this paragraph, renumbering (d) as (c), and moving the subparagraphs in the previous (c) under the new (c) [Randy Cleveland, NMC; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: A for-cause determination of fitness shall be conducted in response to an individual's observed behavior or physical condition indicating that they are in violation of the FFD policy or otherwise unable to safely and competently perform his or her duties. The NRC believes that the assessment should include immediate sensory observation (such as the smell of alcohol or the individual's physical appearance or behavior) that can only be available during a face-to-face interaction. However, the NRC has clarified the final rule to reflect NRC's intent that a for-cause determination of fitness is not required 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).

Second Determination of Fitness

Comment: Regarding proposed § 26.189(d), one commenter stated that this provision appeared to eliminate the use of a second MRO to evaluate additional information supplied by an individual after an initial determination of fitness has been made. The commenter argued that this creates the situation where an individual's fitness cannot subsequently be evaluated if the deciding MRO is unavailable because only that MRO can change his or her initial determination. The commenter also stated that this section appeared to conflict with the review process in § 26.39. Therefore, the commenter suggested that this section be removed from the rule [C.L. Funderburk, Dominion].

NRC Response: The NRC disagrees with the commenter that the provision would lead to situation in which an individual's fitness cannot subsequently be evaluated if the deciding professional is unavailable in the long-term, given that the provision specifically states "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." In the short-term, if the professional is on vacation or sick leave, the professional may evaluate any new or additional information upon his/her return to duty.

The NRC also disagrees with the statement that the provision conflicts with § 26.39, as §§ 26.189 and 26.39 contain provisions for differing types of reviews. Section 26.189 contains provisions for a determination of fitness, which is a method of determining whether an individual has violated the FFD policy or is fit to safely and competently perform his or her duties. The review process in § 26.39 establishes provisions for the review of a determination that an individual has violated the FFD policy. This section specifically states that the reviewers cannot be associated with the administration of the FFD program (i.e., those who make a determination of fitness in 26.189). Therefore, the NRC has not modified the proposed provision in the final rule.

11. Subpart I: Managing Fatigue

Many commenters referenced the fatigue provisions in Subpart I of the proposed rule. There appeared to be an equal amount of support for and disagreement with the proposed rule.

Support for Subpart I

Comments: Many commenters supported Subpart I. For example, several commenters ardently supported the fatigue provisions for various reasons, including the prevention of worker injuries and forced-overtime, as well as increased opportunity for time workers will have to spend with their families [Anonymous #26; Anonymous #27; Anonymous #28; Anonymous #29; Mark Haywood, First Energy; Greg Gorman, First Energy; Richard Barkley, Individual]. Some commenters argued that the new rules will force the owners/operators of power plants to increase staffing levels and reduce overtime [Mike Jolley, Individual; Anonymous #19; Richard Barkley, Individual]. Another commenter stated that the fatigue provisions are also beneficial from a security standpoint, [Anthony Rizzo Jr, Salem Hope Creek]. Two commenters argued that if fatigue is left unchecked, problems will worsen due to regulation, downsizing, and the aging workforce [Anonymous #29, Anonymous #75]. Another argued that this rule may increase the experience level of current personnel while reducing the operating costs of licensees, as fewer resources will need to be dedicated to the training of replacement personnel [Kenneth Kolaczyk, Individual].

Several commenters supported the fatigue provisions in this Subpart by discrediting industry arguments against it. They disagreed with industry's argument that worker fatigue has not yet led to a significant reactor event, hence, there is no problem to be resolved via the rulemaking [David Lochbaum, UCS; Deborah Katz, CAN; Anonymous #75]. Two commenters explained that this argument is "intellectually bankrupt" for at least two reasons. First, past evaluations of plant events do not parse human performance finely enough to dismiss fatigue as either a primary or contributing factor. The commenters argued that there are indeed events where "failure to follow procedure" is identified as a cause, and this could be a result of fatigue. Second, the commenters argued that "it would be imprudent public policy and unwise business judgement to tolerate an unsafe practice until it caused mayhem." The commenters stated that although NEI data showed that excessive working hours was not rampant in the industry and that most plant owners were responsibly managing working hours, the data also revealed that some plant managers worked employees beyond reason. Thus, the commenters argued that this rulemaking is necessary to control those owners who cannot responsibly manage work hours and to provide adequate protection against impairment from fatigued workers [David Lochbaum, UCS; Deborah Katz, CAN].

Another commenter stated that because the safety of nuclear power plants is predicated upon the proper implementation of programs and procedures by qualified personnel, and studies have shown that fatigued personnel are less likely to conduct activities properly, the proposed work hour restrictions would be a "prudent NRC action" [Kenneth Kolaczyk, Individual].

One commenter supports the inclusion of education and fatigue assessment as compliments to the explicit work-hour policies, as this represents a progressive approach that acknowledges the complexity of managing fatigue in the nuclear generating industry. The commenter stated that although a duty-hour approach to controlling fatigue cannot fully address fatigue factors, it is

essential to provide a reasonable assurance that the risk of fatigue-related events are being managed. However, the commenter stated that while federal duty-hour policies provide a critical and central structure for managing fatigue, there should also be consideration of the need to respond to unforseen circumstances and operational flexibility [Mark Rosekind, Alertness Solutions].

NRC Response: The comments do not require a response.

Individuals' Recognition of Fatigue

Comments: Some commenters stated that workers should be able to recognize when they are fatigued and should be able to correct the issue themselves via the former rule provisions, thus the proposed NRC fatigue regulation is burdensome and unnecessary [Jim Waite, Exelon; Blaine Peters, Exelon; Danny Todhunter, Exelon; Donald Lenski, Individual; Robert Althoff, Individual]. Some commenters suggested that the only change to the FFD program should be the prohibition of forced overtime, and voluntary overtime should be allowed [Jim Waite, Exelon; Donald Lenski, Individual; Guy Galster, Individual].

NRC Response: The NRC agrees in part with the commenters concerning the workers ability to recognize when they are fatigued. However, although individuals are able to make relative judgements regarding their level of fatigue, there have been several studies that noted the tendency for individuals to underestimate their level of impairment from fatigue as discussed in the *Federal Register*, Vol. 70, No. 165, on page 50458. More recently, research has suggested that individuals may not take necessary safety precautions despite a recognition that they are impaired by fatigue (Nabi et al., 2006). The NRC has also received allegations from nuclear power plant workers expressing fear of adverse actions from employers for reporting that they are unfit for duty because of fatigue. As a consequence, the NRC does not believe there is reasonable assurance workers can reliably address excessive fatigue solely through their own actions under the former requirements applicable to worker fatigue or that only a prohibition on forced overtime would be adequate. Therefore, the NRC retains the requirements in the final rule concerning fatigue management.

New Provisions Add Cost and Only Facilitate Regulatory Oversight

Comment: Another commenter stated that, unless the NRC is finding frequent excessive work hours, providing "additional layers of bureaucracy" is adding costs and seems to only facilitate regulatory oversight [David Sancic, Individual].

NRC Response: The NRC disagrees that the NRC is only adding costs to facilitate regulatory oversight. The NRC has documented concerns regarding frequent excessive use of work hours in SECY-01-0113, "Fatigue of Workers at Nuclear Power Plants," and SECY 05-0074, "Proposed Rule to Amend the Fitness-For-Duty Requirements in 10 CFR Part 26." Therefore, establishing clear and enforceable requirements for the management of worker fatigue is necessary to ensure against worker fatigue adversely affecting public health and safety and the common defense and security.

Lack of Correlation between Impacts of Fatigue and Performance at Reactors

Comments: One commenter, supported by other commenters, stated that there has been no correlation between the claimed impacts of fatigue and actual human performance at power reactor sites. As a result, the commenter suggested that there is no need to significantly expand fatigue requirements beyond those contained in Generic Letter 82-12. The commenter also explained that after reviewing facilities' human performance measures, the data showed no adverse trend in a performance for longer outages and beyond the sixth day of work. Therefore, the commenter disagreed with the rule package's contention that increased fatigue after long outages and after the sixth day of work affects human performance [Andrew Antrassian, UWUA; Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the conclusions of the report, “Work Hour Rule Data Summary,” submitted by the commenters. The report concludes that human performance does not suffer in longer outages with greater work schedules and that there is not an adverse trend in human performance for work beyond six straight days. The conclusions of the report do not withstand a rigorous analysis and therefore cannot support leaving fatigue requirements as those stated in Generic Letter 81-12.

According to the text of the report the plot of the number of human performance errors and Corrective Action Reports (CRs) which occurred over a 13 week period has a downward trend (in the data) during an outage. However, both human performance errors and CRs, while declining between weeks 4 and 10, are actually increasing for weeks 11 through 13. (There is no data provided after week 13). Moreover, the number of CRs is actually higher after week 13 compared to week 1 (60 versus 40). The later illustrates a problem generally associated with visual inspection of time series data, namely scale values. If only data for weeks 1 and 13 were shown, then the visual inspection of the data would have led to the observation that human performance errors increase over time during an outage, while CRs are roughly constant.

Several plants submitted data for human performance errors by day of work for seven straight days. Again, the report stated that the data demonstrated that there was either a downward or no trend in human performance errors as a function of the day of shift. Again, there was not a rigorous analysis of the data but rather a subjective conclusion drawn out by visual inspection of graphs.

The NRC recognizes that the analysis of the data collected by licensees to evaluate human performance error during periods of normal operating and outages is of anecdotal value. However, the NRC disagrees that the report is evidence that the proposed rule should be revised. In contrast, the overwhelming body of evidence, as discussed in Section IV.D of the preamble to the final rule, supports the need for periodic days off to prevent cumulative fatigue and human error. Therefore, the final rule language retains provisions to address cumulative fatigue. However, in response to comments regarding the proposed rule provisions concerning the minimum break requirements in § 26.199(d)(2) of the proposed rule and the collective work hour limits in § 26.199(f) of the proposed rule, the NRC has revised the provisions to address

cumulative fatigue. These revised provisions are presented in § 26.205 (d)(2) through (a)(6) of the final rule.

Questionable Data

Comment: Another commenter claimed that the justification for the fatigue provisions is based on speculative and politically skewed data, rather than sound scientific data. [Daniel Hansen, Individual].

NRC Response: The NRC disagrees with the commenter and notes that the commenter provided no basis for this assertion. The studies used by the NRC as the basis for the proposed requirements are largely from refereed journals and the findings of those studies were consistent with the broader research literature and widely accepted fatigue management guidelines. Therefore, the NRC retains the Subpart I requirements for the management of fatigue.

Inconsistency with Goals of the Rulemaking

Comments: Some commenters stated that the proposed work hour provisions in Subpart I are inconsistent with some of the stated goals of the rulemaking. They stated that Subpart I introduces new inefficiencies and unnecessary requirements which are contrary to rulemaking Goals 3 and 5, and suggested that broader application of performance-based principles and fewer prescriptive limits would more effectively meet the Commission's intent in Generic Letter 82-12. [Michael Coyle, NEI #49; Gregory Halnon, First Energy; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees in part with the comments on the proposed work hour provisions. Therefore, the NRC has eliminated the collective work hour controls that would have been required by the proposed rule and has restructured the break and day off requirements in the final rule in a manner that will reduce the burden on licensees and place more emphasis on performance-based requirements. The revised break and day off requirements are presented in § 26.205(d)(2) through (d)(6) of the final rule.

Napping Policies

Comment: One commenter noted studies that show that napping at the workplace is especially effective for workers who need to maintain a high degree of alertness, attention to detail, or make quick decisions. Thus, it encouraged the NRC to include a provision regarding the inclusion of sound napping policies in the fatigue management plans developed by licensees. These napping policies should include the designation of quiet, dark and accessible areas (e.g., rooms in EAP or wellness units) to be used as napping facilities. The use of these facilities should be encouraged especially during outages, the use of heavy overtime, and when waivers are granted [Darrel Drobnich, NSF].

NRC Response: The NRC agrees that napping is a particularly effective fatigue management strategy. The rule does not require licensees to use napping, or address napping in their fatigue management policy, so that licensees have the flexibility to use the methods they consider most appropriate and effective in the specific circumstances they are addressing. However, the NRC notes that § 26.205(b)(2) of the final rule will allow licensees to exclude within-shift break times from work hour calculations if the licensee provides reasonable opportunity and accommodations for sleep. Although this provision does not require licensees to use napping as a fatigue mitigation strategy, allowing licensees to exclude time used for napping from work hour calculations removes a potentially significant disincentive for using this strategy. In addition, § 26.203(c) of the final rule requires licensee FFD training programs to address "the effective use of fatigue countermeasures" and verify worker knowledge and abilities through a comprehensive examination as required by § 26.29(b). As a consequence, the NRC expects that licensees who choose to use napping as a fatigue mitigation strategy will have associated training to ensure effective implementation.

11.1. Applicability (§ 26.195)

No comments addressed this section.

11.2. General Provisions (§ 26.197)

Comments: One commenter supported § 26.197(a), (b), and (c) [Brian McCabe, Progress Energy]. Other commenters expressed support for the provisions in § 26.197(a) through (d). These commenters agreed that establishing clear policies, procedures, training and records will be a significant improvement for the management of work hour requirements [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The comments do not require a response.

11.2.1. Policy (§ 26.197(a))

Comments: Several commenters from industry supported this section of the rule and stated that setting clear expectations for individuals to self-declare and establishing a process for dealing with fatigue are key features of the proposed rule [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The comments do not require a response.

11.2.2. Procedures (§ 26.197(b))

Support for Procedures

Comments: Some commenters supported the procedure requirements of Subpart I, specifically proposed § 26.197(b)(1), which requires that the licensee's FFD program explicitly describe the process for making and handling fatigue self-declarations by all workers. The commenters stated that this language is "absolutely vital to the efficacy and integrity of the program." They also stated the proposed language assures that appropriate checks and balances are in place to limit abuses both in the case of management forcing fatigued workers to stay on the job, as well as workers using fatigue self-declaration to supplement their sick/vacation time [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The comments do not require a response.

Rest Break Procedures

Comment: One commenter suggested that the NRC add to proposed § 26.197(b)(1) subparagraph (iv) and (v) a requirement for a licensee procedure that would describe criteria for workers to activate the 24 or 48 hour optional rest period. The commenter suggested the following language for subparagraph (v): "For individuals working a nominal rotation shift cycle containing a majority of 8 hour shifts for 7 work days not to exceed 8 work days of continuous duty with each work shift providing a break period as described in § 26.199(d)(2)(i); describe the process to be followed when an individual requests to observe a 24 Hour and/or a 48 Hour break period prior to the licensee soliciting or assigning further work to an individual exceeding the last scheduled day containing the 7 or 8 continuous work days as allowed by § 26.199(d)(2)(ii), § 26.199(d)(2)(iii) and § 26.199(d)(4)." The commenter also suggested the following language for subparagraph (v): "Describe the process to be followed when an individual requests to observe a 48 Hour break period for individuals working a nominal rotation shift cycle containing a majority of scheduled hours above 8 hours per shift as allowed by § 26.199(d)(2)(iii)(a) and § 26.199(d)(4) [Edwin Hill, IBEW].

NRC Response: The NRC agrees in part with the commenter, however, it did not conclude that it was appropriate to establish a requirement for optional rest periods. The NRC has revised the final rule text by establishing minimum day off requirements in § 26.205(d)(3) through (d)(6) of the final rule that allow increased flexibility in the specific timing of the breaks. This increased flexibility allows licensees and workers to address personal and work schedule needs while continuing to provide reasonable assurance that individuals do not become impaired from fatigue because of excessive work hours. Therefore, the commenter's concerns have been addressed through alternative requirements.

Self-Declaration Procedures

Comment: One commenter expressed concern that § 26.197(b)(1) would mandate prescriptive requirements for the content of licensee procedures with respect to worker self-declarations of fatigue. The commenter stated that the proposed rule appears to intrude unnecessarily into the employer-employee relationship and may have the effect of establishing new responsibilities and procedural rights beyond existing collective bargaining agreements. The commenter argued that

the rule should not rely on self-declarations as the primary means of identifying fatigue, and the training of shift workers that would be required as part of the fatigue management program under proposed § 26.197(c) should be sufficient. Thus, in view of the adequacy of training, the commenter recommended that the NRC eliminate the requirement for a detailed self declaration process procedure [Daniel Stenger, NRSG].

NRC Response: The NRC disagrees that the proposed rule intrudes unnecessarily into the employer-employee relationship and that the NRC should eliminate the requirement for a self-declaration process. Section 26.197(b)(1) of the final rule requires licensees to develop, implement, and maintain a procedure for self-declaration. It further requires that the procedure describe the individual's and licensee's rights and responsibilities related to self-declaration, the 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, and the process to be followed if the individual disagrees with the results of a fatigue assessment. The rule does not establish the individual's rights and responsibilities, does not prescribe the controls and conditions that must be established, and does not prescribe the process to be followed if an individual disagrees with the results of a fatigue assessment. As a consequence, the NRC does not believe that the requirement for a procedure intrudes unnecessarily into the employer-employee relationship. However, in light of the allegations that the NRC has received concerning self-declaration of fatigue, it appears that there has been a lack of understanding by licensees and workers regarding the applicability of the requirements of Part 26 and 10 CFR 50.7 to these circumstances, and that a procedure that addresses the self-declaration process is necessary to ensure that self-declaration is an effective means for detecting impairment from fatigue. Therefore, the NRC retains the proposed requirements regarding self-declaration in § 26.203(b)(1) of the final rule.

11.2.3. Training and Examinations (§ 26.197(c))

Comments: One commenter fully endorsed this provision because comprehensive education and training on the promotion of good quality sleep and the mitigation of fatigue is essential to the promotion of safety in the nuclear industry. The commenter also suggested that some education and training on sleep, sleep disorders and the consequences of sleep deprivation, although not necessarily examinations, should be required for all personnel, whether or not they are in safety sensitive positions or covered under work hour controls in proposed § 26.199(a). The commenter stated that education of all personnel, including (and perhaps especially) upper management, is key to fostering a culture that embraces alertness and effective fatigue management [Darrel Drobnich, NSF].

With regard to proposed § 26.197(c)(1), the commenter stated that the NRC should provide specific guidance regarding topics that should be covered in fatigue training and education modules and examinations. The commenter suggested that the NRC take the lead in developing uniform curriculum and examination materials in order to ensure the accuracy and uniformity of information provided. The commenter also argued that all MROs should receive education and training regarding the signs and symptoms of sleep disorders as well as effective treatment options, and that information on the prevention of drowsy driving should be included in any materials that are developed [Darrel Drobnich, NSF].

NRC Response: The NRC agrees with the commenter's general support for this provision. The NRC notes that this training requirement is applicable to all licensee personnel subject to the FFD program, not just workers subject to the work hour controls. Consequently, managers and MROs, who have an important role in fostering an effective fatigue management culture, would be subject to the training requirements. With regard to the commenter's suggestion that the NRC should provide specific guidance regarding the specific topics that should be addressed in fatigue management training, the NRC notes that § 26.203(c)(1) of the final rule requires licensees to include specified knowledge and abilities concerning fatigue management in the content of the FFD training program. Establishing training requirements at the knowledge and abilities level allows licensees the flexibility to update their existing FFD training programs, as necessary and in a manner that efficiently achieves the fundamental objective of the training. Although the NRC agrees that a uniform curriculum may help ensure the accuracy of the information provided, and notes the NRC may participate in the development and review of guidance concerning fatigue management training, it is the responsibility of individual licensees to ensure that training materials are technically correct and support trainee attainment of the required knowledge and abilities. Therefore, the NRC retains the proposed training requirements in § 26.203(c) of the final rule.

11.2.4. Recordkeeping (§ 26.197(d))

Support for Recordkeeping Provisions

Comments: One commenter agreed with the recordkeeping requirements of Subpart I, especially the three year record retention requirement because it is consistent with the inspection cycle of the reactor oversight process (ROP) [David Lochbaum, UCS; Deborah Katz, CAN]

Several commenters from industry said the provision that requires licensees to maintain records, combined with proposed § 26.199(j), provide an additional performance-based provision to the rule and provides assurance that performance expectations are met [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The comments do not require a response.

Records of Rest Breaks

Comment: Another commenter suggested that the NRC add § 26.197(d) subparagraph (6) that states: "Documentation of individual requested rest breaks and final licensee disposition of the requested break in accordance with § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii)" [Edwin Hill, IBEW].

NRC Response: The NRC disagrees with the comment that individual requested rest breaks should be documented. Optional rest breaks alone do not provide reasonable assurance that nuclear power plant workers will obtain an adequate amount of rest. Consequently, the NRC does not believe that recordkeeping of such requests is warranted. However, the NRC has

modified the final rule to include rest break requirements that largely meet the commenter's objective of providing workers increased flexibility in the distribution of their rest breaks. Therefore, the commenters concerns have been addressed. The revised break and day off requirements are presented in § 26.205(d)(2) through (d)(6) of the final rule.

11.2.5. Reporting (§ 26.197(e))

NRC's Justification of Reporting Requirements is Flawed

Comments: Many commenters addressed the reporting requirements for the fatigue provisions. Several commenters from industry argued that the reporting requirements in § 26.197(e) 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 for the NRC power reactor licensees [Marvin Fertel, NEI]. A similar comment stated that (e)(1) and (e)(3) should be deleted for these reasons, and § 26.199(e)(2) should be revised to apply only to the job duty group comprised of security personnel as defined in § 26.199(a)(5) [Michael Coyle, NEI #49;, Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

One commenter expanded upon the argument that the requested information is not required for the NRC to ensure public health and safety. The commenter argued that the NRC's FFD rule package does not demonstrate that the industry would fail to comply with the requirements of the revised rule without the imposition of these reporting requirements. Additionally, the commenter stated that the NRC has an effective oversight process that does not depend on extensive data collection from licensees. Thus, the commenter argued that the existing regulatory process is adequate to ensure compliance with regulatory requirements with the reporting provisions in question. The commenter also argued that the NRC's claim that reporting requirements are needed to "focus the NRC inspection resources" is flawed. The commenter stated that the NRC staff will be able to gauge the adequacy of reactor licensees' fatigue management programs without this information collection. With the NRC's baseline inspection program and resident inspectors assigned to each site, the commenter argued that there is adequate attention to a broad range of performance indicators that would indicate any degradation in performance well in advance of a public health and safety issue. Also, the commenter stated this claim is inconsistent with the NRC staff's approach in other areas, such as the corrective action program [Marvin Fertel, NEI].

Some commenters argued that the reporting requirement ignores the significant duplication in licensee efforts that the proposed language creates. For example, § 26.197(d) requires that licensees retain adequate records of waivers and assessments, and § 26.197(j) requires periodic reviews by licensees to assess the effectiveness of the work hour controls, including waivers and fatigue assessments. These reviews are documented and trended under the licensee's corrective action program, and the corrective action program is periodically inspected by the NRC. Thus, industry commenters argued that reporting this data to the NRC under fatigue management on an annual basis is an unnecessary duplication of these requirements

with no attendant increase in protection of public health and safety [Marvin Fertel, NEI; F.G. Burford, Entergy].

NRC Response: The NRC does not agree with comments that the requirements for reporting 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 for the NRC power reactor licensees. In choosing to retain reporting requirements regarding the use of waivers the NRC considered several aspects of the work hour requirements in § 26.205 of the final rule: (1) The NRC established the work hour limits in the final rule at levels such that the potential for worker fatigue is substantive for individuals working in excess of those limits; (2) 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; and (3) the rule only requires a waiver if the individual is operating or maintaining a system, structure, or component (SSC) that a risk-informed evaluation process has shown to be significant to the protection of public health and safety, or if the individual is performing specified functions that are essential for effective response to a fire, plant emergency, or implementation of the site security plan. As a result, information concerning licensee use of waivers provides an indication of: (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 the NRC that is relevant to the NRC'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 for 4 conditions: (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. In regard to fatigue assessments following self-declarations, the NRC notes that individuals are only assessed when a licensee denies a worker request for relief from duty (i.e., a rest break). In all other instances the individual will be allowed time off duty in accordance with the licensee's administrative practices and the rule will not require a fatigue assessment. Given these requirements of the final rule, licensee annual reporting of information pertaining to fatigue assessment will provide an indication of 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 they are unfit, 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 to the NRC that is relevant to the NRC's mission, particularly when considered in conjunction with information concerning the licensee's use of waivers from the work hour limits.

The NRC also disagrees with the comments that the reporting requirement ignores significant duplication in licensee efforts. The NRC agrees that § 26.205(e) of the final rule requires periodic reviews by licensees to assess the effectiveness of the work hour controls, and that

these reviews will be documented and trended under the licensee's corrective action program, which is periodically inspected by the NRC. However, as noted previously, the NRC considers the burden of the annual report to be limited, and that relative to a review that is limited to evaluation of reports in a licensee's corrective action program, the annual reports will enable the NRC to provide more effective and consistent oversight and achieve other objectives described herein for the effective implementation of the requirements in Subpart I.

The comment recommending that the NRC revise the proposed § 26.197(e)(2) to apply only to security personnel is not applicable to the final rule because collective work hour limits have been removed from the rule and the NRC eliminated the requirement for reporting information pertaining to collective work hours as a conforming change. Therefore the NRC retains the reporting requirements in the final rule with the exception of those related to collective work hour limits.

Intent of Reporting Information

Comments: Some commenters stated that the reports the rule would require do not provide a meaningful indicator of the overall quality of how a licensee manages work hours because there are a number of valid conditions that may warrant waivers of work-hour controls. For example, the series of hurricanes that occurred in 2004 could have resulted in a number of waivers for licensees of nuclear power plants located in Florida and along the Gulf Coast. Thus, the commenter argued that as a result of the way that FFD work-hour waivers are counted and maintained under the NRC regulations, the data requested in these reports would not provide an accurate picture of conditions that may have warranted the waiver [Marvin Fertel, NEI]. To address this issue, another commenter argued that the waivers data should be kept onsite for the NRC inspection so that the data may be accompanied by the plant-specific cause for the waivers [John Cowan, NEI].

Two commenters suggested that the rulemaking should also require licensees to report the number of workers covered under § 26.199(a) to provide appropriate context for the annual reporting of waivers [David Lochbaum, UCS; Deborah Katz, CAN].
A commenter at the public meeting, after acknowledging that the reporting is intended to get management's attention, expressed confusion about the philosophy of the waivers. The commenter asked what the NRC will do with the reports and how many waivers will be considered "too many" [Nick DePietro, First Energy].

NRC Response: The NRC disagrees with the comment that the required reports are not a meaningful indicator of the performance of a FFD program. The NRC agrees in part with the comment that information concerning waivers should be considered in context. The requirements in proposed § 26.197(e)(1) and (e)(3) were revised in response to comments that the required information would not provide a meaningful indicator of licensee performance in managing work hours because there are a number of valid conditions that may warrant waivers of work-hour controls. Through reviews 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 requirements for reporting waivers of the work hour requirements in § 26.205 such that the report shall indicate whether or not the waiver was associated with an outage activity. The requirement for reporting information pertaining to fatigue assessments was also similarly revised such that the report will indicate

whether or not the individual was engaged in an outage related activity at the time of the event or condition that resulted in the need for the licensee to conduct a fatigue assessment.

As a result of these changes, the NRC will be better able to interpret changes in waiver use over time at a site and understand why certain annual reports for a given site may indicate a heightened level of waiver use relative to other reports for that site. The NRC recognizes that outages are not the only cause of waivers, however, the NRC expects that most other causes of waiver use will be for substantially shorter periods of time or smaller groups of workers such 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 would expect to be aware of, or be able to identify, such conditions if they were to significantly affect waiver use. Furthermore, it is the NRC's intent to consider waiver use in conjunction with the reported fatigue assessment information. Therefore, the NRC will be able to assess 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. In this regard 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) provides an indication of 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 control of the licensee.

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 that received just one waiver during the year, the number of operators that received two waivers during the year, etc. The NRC incorporated this requirement in the final rule in response to comments that the rulemaking should also require licensees to report the number of workers covered under § 26.199(a) of the proposed rule to provide appropriate context for the annual reporting of waivers. The NRC understood 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 whether the waivers are concentrated among individuals performing a certain duty and whether the waiver use within a duty group is concentrated within a relatively few individuals or distributed among many.

Reporting Requirements Do Not Satisfy the Paperwork Reduction Act

Comments: The commenters 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 has failed to adequately justify the need for these provisions to achieve the objectives of the proposed FFD rule, and has also failed to objectively support its estimate of the burden created on affected licensees.

The commenters note that the NRC rule package estimate for reporting in § 26.197(e)(1) is two hours of clerical and one hour of management time for each facility's annual report. The estimate for § 26.197(e)(2) is two hours management time. The estimate for § 26.197(e)(3) is estimated as 12 hours clerical and two hours management time. The commenters argued that this is a significant understatement of the actual time effort required to prepare, check and review an annual report. The industry estimates that preparing the total report will require at least 30 clerical hours and 20 management hours (and these estimates must be multiplied times the more than sixty nuclear plant sites in the U.S). The commenters argued that the management time required to prepare this report could more effectively be devoted to other activities with a closer nexus to public health and safety.

Accordingly, industry believes that OMB should not approve the data collection proposed in this section of the proposed rule and remand proposed § 26.197(e) to the NRC for its further consideration in light of these inadequacies [Marvin Fertel, NEI; Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with commenters' statement 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). The NRC expects that the information provided by licensees in response to the annual reporting requirements in Subpart I will facilitate NRC oversight of licensee implementation of the requirements through several means:

(1) 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 oversight of the implementation of the requirements in Subpart I and in enforcement of those requirements. Without the reporting requirements, NRC 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. Such 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 for the individual inspectors conducting the oversight process and maintain consistency in NRC's oversight process. In addition, information in the annual report can enhance the efficiency of NRC inspection by providing a basis for the NRC to focus inspection resources on duty groups (e.g., security or maintenance) or issues (e.g., self-declaration) that the annual report indicates may be areas warranting review. The report will enable NRC to achieve a greater focus during preparation for the inspection, enabling the NRC to reduce the burden of on-site inspection hours and potentially reduce the total number of hours required for the baseline inspection. Furthermore, the annual reporting will help achieve a more complete and continuous assessment of licensee performance given that the NRC intends to conduct the baseline inspection of FFD programs only once every 2 years.

(2) Evaluation of rule implementation for lessons learned – Although the NRC and stakeholders made extensive efforts to ensure clear and enforceable requirements that are effective and practical, by establishing new requirements 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 reports can provide important future 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, in this final rule, the random testing rate for drugs and alcohol.

(3) Consistent interpretation of waiver criterion – The final rule provides licensees the discretion to use waivers to exceed the work hour limits and thereby allow levels of work hours that create substantial potential to adversely affect worker fitness for duty. 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 these exigent circumstances. The annual reporting of waiver use, in conjunction with the reporting of information concerning fatigue assessments will enable NRC to ensure that licensees use this discretion 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 in which 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 that the high levels of waiver use at some sites was abuse. These commenters suggested that differences in licensee waiver practices could be attributed to the NRC allowing the policy statement to be subject to a number of interpretations during the many years 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 this 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 for why the reporting requirements are necessary for the effective and efficient oversight of the implementation of the rule, the NRC considers the reporting requirements to be justified and beneficial for several additional reasons:

(1) Consistency with Part 26 requirements and performance objectives – The final rule retains the long-standing requirements for the reporting of results of licensee drug and alcohol testing and the performance objective for reasonable assurance that individuals are not impaired from any cause (§§ 26.719 and 26.23(b) of the final rule). In addition, several studies discussed in detail in Section IV.D of the preamble to the final rule have demonstrated that worker fatigue can produce levels of impairment that are comparable to blood alcohol concentrations above 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 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 consistent with the requirements for reporting information pertaining to drug and alcohol testing, consistent with the performance objective of this rulemaking for licensees to implement a comprehensive FFD program, and consistent with NRC's belief that the management of worker fatigue is no less important to worker fitness for duty than the effective detection and deterrence of drug and alcohol use.

(2) Public confidence -- Public interest stakeholders such as the Union of Concerned Scientists and the Project on Government Oversight have commented at public meetings that much 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 would be publicly available and provide public stakeholders reassurance 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.

(3) The burden is limited and justified – Section 26.203(e) requires the information concerning waiver use and fatigue assessments to be reported as part of the annual FFD program report. As a consequence, 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 that § 26.203(e) requires licensees to report is largely information that licensees would already have generated in order to comply with other provisions of Subpart I. As a result, the burden associated with the report would largely be associated with compiling the information in a form appropriate for the report and reviewing that compilation. The NRC has reviewed the public comments asserting that the NRC underestimated the number of clerical and management hours associated with this requirement, and have 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 justified for the reasons described in this and the preceding paragraphs concerning the annual report requirements in § 26.203(e). Therefore, the NRC has retained requirements for an annual report containing information pertaining to fatigue management in § 26.203(e) of the final rule.

11.3. Work Hour Controls (§ 26.199)

Support for Work Hour Controls

Comments: Several commenters generally addressed the work hour control provisions. One commenter stated that the work-hour limits are reasonable, and will ensure that fatigue will be managed at facilities where the heavy use of overtime for extended periods has become routine. It noted that the work-hour limits will only impose a regulatory burden on licensees commensurate with the safety backfit achieved [Richard Barkley, Individual].

NRC Response: The comments do not require a response.

Layers of Requirements are Ineffective and Burdensome

Comments: The commenters argued that short term individual work hour limits address acute and cumulative fatigue, so additional "layers" of prescriptive requirements would be ineffective and burdensome to industry [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the comment that short-term individual work hour limits are adequate to address cumulative fatigue. The short-term individual limits allow up to 72 hours of work per week, excluding turnover time and time worked under waivers, and require only a minimum 10-hour break between successive work periods. The minimum break period of 10 hours does not provide reasonable assurance that individuals will obtain adequate rest when

individuals are working long work days with few days off. Cumulative fatigue will result from the extended work periods combined with reduced sleep periods as individual forego sleep to attend to daily living obligations. Such fatigue effects were reported by security personnel in the months following the terrorists attacks of September 11, 2001. In those instances the NRC found that the security personnel were typically working fewer hours than would be allowed by the short-term individual limits. However, the NRC agrees with the objective of reducing burden and eliminating unnecessary layers of requirements in the rule. In this regard the NRC notes that the NRC eliminated the requirements for a minimum 48-hour break and collective work hour limits that would have been required by § 26.199(d)(2)(iii) and 26.199(f) of the proposed rule and replaced these requirements with the minimum day off requirements of § 26.205(d)(3) of the final rule. The revised provisions will reduce burden and limit the potential for cumulative fatigue by preventing excessive use of the maximum work hours and minimum rest breaks permitted by the individual work hour controls.

11.3.1. Individuals Subject to Work Hour Controls (§ 26.199(a))

Expanding the Scope of Workers Subject to Subpart I

Comments: Some commenters stated that proposed § 26.199(a) limits the scope of the individuals subject to work hour controls to a subset of the work force; thus, those workers outside the scope of this section have no limits on their individual or collective work hours. They suggested that all workers should be subject to work hour controls [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC disagrees, in part, with the comment stating that all workers should be subject to work hour controls. Work hour controls are only a subset of the requirements included in this rule. Individuals who are not covered by the work hour controls in this subpart are still subject to broader fatigue management requirements. Section 26.203 establishes fatigue management requirements for licensees' FFD programs. Section 26.203(a) 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. Section 26.203(b)(1) requires licensees to develop, implement, and maintain procedures that describe the process to be followed any time an individual who is subject to the licensee's FFD program reports to a supervisor that he or she is unfit for duty because of fatigue (i.e., makes a self-declaration). These broad policy and procedure requirements, which apply to all workers, will provide clear expectations for all workers. In addition, § 26.203(c) requires licensees to train all individuals subject to the licensee's FFD program in fatigue management, including shift work strategies for obtaining adequate rest and effective use of fatigue countermeasures.

For the subset of requirements covering work hour controls, subjecting all workers to work hour controls, regardless of job function, would be impractical, burdensome to both individuals and licensees, and would not significantly improve public health and safety or the common defense and security. In determining the scope of personnel who would be subject to the proposed work hour controls, the NRC considered the burdens on individuals and licensees associated with the practical control of work hours in conjunction with the potential for individuals' work activities to affect public health and safety or the common defense and security if their performance is degraded by fatigue. The NRC also considered the nature of these individuals' work activities

and work environments relative to their potential to induce or exacerbate fatigue, 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, only the individuals who perform the types of job duties specified in § 26.4(a)(1) through (a)(5) must be subject to the proposed work hour controls.

Therefore, the NRC retains the requirements for the work hour controls for the narrower scope of workers. The NRC also retains in § 26.203 the requirements for management of fatigue, including the policy and procedure and training requirements for all workers. Therefore, no additional changes are warranted in response to this comment.

"On-Site Directing" and the Inclusion of Engineering Personnel

Comments: Another commenter, supported by many commenters, raised concerns regarding the use of "on-site directing" in § 26.199(a)(1) and (a)(2). The commenter stated that the term "directing" has added uncertainty to who should be included in the functional work groups and suggested that the NRC clarify the definition of this term. Also, by using "on-site directing" in these subparagraphs, the commenter argued that this definition could be interpreted to include engineering and technical support personnel, and maintaining records on this group in addition to the job duty groups that are clearly defined could present a burden to utilities. Thus, the commenter recommended changing "on-site" to "job-site" in subparagraphs § 26.199(a)(1) and (a)(2). The commenter argued that this change would make these provisions consistent with the definition of "directing," which clearly focuses on individuals directly involved with the performance of the work activity [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees with the commenter that the definition of the term "directing" should be clarified. Individuals who are responsible for the correct performance of risk-significant work should be subject to work hour controls, including engineering and technical support personnel.

The revised definition of "directing," is presented in § 26.5 of the final rule. The revised definition clarifies 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 revised definition more clearly focuses on activities that have the potential to substantively and immediately affect safety.

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, decision-making, communications) and are susceptible to fatigue-induced errors, as described in Section IV.D of the preamble to the final rule. Incorrect technical direction provided to operators can significantly challenge licensed operators and increase the possibility of errors or events, especially when the direction is provided by an individual who supervises the operators, or an individual who the operator reasonably expects to have specialized technical knowledge of the system or component being operated.

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, such as during key outage maintenance activities. These individuals perform tasks that are often highly dependent on cognitive skills (e.g., problem-solving, decision-making, communications) that are susceptible to fatigue, as discussed in Section IV.D of the preamble to the final rule. Incorrect technical direction provided to maintenance technicians can significantly challenge maintenance technicians and increase the possibility of errors or events, especially when that direction is provided by an individual who supervises them, or an individual who the maintenance technician reasonably expects to have specialized technical knowledge of the system or component being maintained.

The NRC disagrees with the comment that the rule language should be revised to change "on-site" to "job-site." Whether the directing is occurring at the job site or in a nearby room by phone is not relevant. Another commenters regarding the definition of "directing" asserted that engineers will not go out into the field to troubleshoot, for fear of being subject to work hour controls, and this is also a reason why work-hour controls should apply to individuals providing "on-site" direction.

In summary, the NRC has revised the definition for "directing" in § 26.5 of the final rule and clarify to whom the requirement should apply.

Expansion of Scope for Work Hour Limits

Comments: Other commenters stated that the proposed work-hour limits should be imposed on all licensee employees and supervisors who perform safety-related work instead of being limited to the work groups listed in the proposed rule. The commenter argued that all workers who perform safety-related work, as well as the individuals who supervise that work, be fit for duty [Barry Quigley, Individual; Anonymous #75]. One commenter stated that if such an expansion of the rule is not possible, then at a minimum, system engineers be included in the scope of this rule, as their job task assignments often require prompt response to the facility and decision-making that can immediately affect the ability to operate safety-related equipment [Richard Barkley, Individual]. Another commenter also addressed this issue and argued that engineering personnel performing or directing safety-related work be included in the scope of the rule [Barry Quigley, Individual].

NRC Response: The NRC disagrees, in part, that the proposed work-hour limits should be imposed on all licensee employees and supervisors who perform safety-related work instead of being limited to the work groups listed in the proposed rule. (See NRC response to comment

"Expanding the Scope of Workers Subject to Subpart I" at the beginning of Section 11.3.1). However, the NRC agrees that engineers directing safety-related work be included in the scope of this rule, as their job task assignments often require prompt response to the facility and decision-making that can immediately affect the ability to operate safety-related equipment.

The NRC revised the definition of "directing," which is presented in § 26.5 of the final rule. The revised definition clarifies 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."

These individuals include engineers who provide onsite technical direction to operations and maintenance personnel, such as test directors or reactor engineers. These individuals perform tasks that are often highly dependent on cognitive skills (e.g., problem-solving, decision-making, communications) and are susceptible to fatigue-induced errors, as described in Section IV.D of the preamble to the final rule. Incorrect technical direction provided to operators or maintenance personnel can significantly challenge licensed operators and increase the possibility of errors or events, especially when the direction is provided by an individual who the operator reasonably expects to have specialized technical knowledge of the system or component being operated.

Therefore, the NRC retains the requirements for the scope of the working hour controls and the scope of the requirements in § 26.203 for the management of fatigue, including the policy, procedure, and training requirements for all workers. In addition, the NRC has revised the definition for "directing" so that the definition as applied to the direction of operations and maintenance personnel appropriately includes a limited scope of engineering functions that can have an immediate effect on the safe operation of the plant.

Fire Brigade

Comments: Several commenters from industry expressed disagreement with § 26.199(a)(4). Specifically, the commenters stated that the fire brigade member who is responsible for understanding the effects of fire and fire suppressants on safe shutdown capability should not be subject to work hour controls because of the administrative burden. The commenter recommended that § 26.199(a)(4) be deleted from the draft rule [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the comment that fire brigade members should be deleted from the work hour controls because of the administrative burden. In response to other comments, the NRC has eliminated group work hour controls from the final rule. Thus, fire brigade members' work hours are no longer required to be analyzed as a group. The NRC expects this change will eliminate any excess administrative burden. However, fire brigade members remain subject to the individual work hour controls specified in proposed § 26.199(d).

Fire brigade members must retain the cognitive ability to be able to think and determine the best way to suppress a fire to prevent additional damage to safety-related equipment, evaluate equipment affected by a fire to report to control room operators concerning equipment availability, make decisions concerning smoke ventilation to prevent the fire effects from affecting other plant operations, and coordinate all activities with control room operators. 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."

Fatigue can substantially degrade a worker’s decision-making and communication abilities, cause a worker to take more risks, and cause a worker to maintain faulty diagnoses throughout an event. These abilities are key to the duties of the fire brigade members who are responsible for understanding the effects of fire and fire suppressants on safe shutdown capability for the reactor. Degradations of these abilities could have significant consequences on the outcome of an event involving a fire. For instance, a fatigued worker could incorrectly decide to vent smoke or toxic gas to an area required for alternate shutdown, which could prevent or impair access to equipment needed for safe shutdown of the plant. In addition, a fatigued worker could incorrectly apply the wrong fire suppressant, which could affect additional equipment in the plant. Further, impaired decision-making could lead a worker to improperly control flooding, which could impact other needed equipment, or could incorrectly determine whether an area contains critical equipment and improperly apply a suppressant in that area. Impaired communications could also lead to incomplete disclosure of information to licensed operators in the control room, which could adversely impact the decision-making of those operators. If information known to the impaired worker is not properly communicated, operators may not initiate appropriate actions to mitigate the fire effects, or effects of suppressant activities, on critical equipment.

Ensuring that the ability of fire brigade members to safely and competently assess the effects of a fire and fire suppressants on safe shutdown capability is essential to the overall success of the fire mitigation strategy and the protection of public health and safety. Therefore, because the comment does not present new information or any explanation of unique administrative burden, the NRC will continue to subject fire brigade members to the requirements of Subpart I in the final rule.

11.3.2. Calculating Work Hours (§ 26.199(b))

Support for Exclusion of Turnover Time

Comments: Several commenters from industry supported the exclusion of turnover time as discussed in the rule package [Michael Coyle, NEI #49; Danny Todhunter, Exelon; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The comments do not require a response.

Definition of Shift Turnover

Comments: A commenter stated that the exclusion of shift turnover time from individual work hours was abused in the past, and defining shift turnover time is a step in the right direction. However, the commenter stated that proposed § 26.199(b)(1)(i) would define shift turnover as only those activities that are "necessary to safely transfer information and responsibilities between two or more individuals between shifts." The commenter argued that activities considered to be "necessary" is open to interpretation, and, as a result, there will be continued abuse of shift turnover. Also, the commenter explained that the language appears to allow both on-coming and off-going time to be subtracted; in essence allowing the licensee to "double dip" on how much turnover time can be subtracted. Thus, the commenter felt that the turnover language was not clear and should be revised [Peter Hammill, PBNP].

Another commenter asked why turnover times are not counted as work hours, and argued that turnover is "work" [Anonymous #29].

NRC Response: The NRC agrees in part with these comments. The NRC recognizes that shift turnovers are important for communicating plant status information between work crews. However, the NRC also recognizes that shift turnovers routinely add time to the length of a shift and workweek, and including shift turnovers in work hour calculations may cause indirect pressure on individuals to abbreviate shift turnovers in order to ensure that they do not violate work hour limits. This pressure may compromise the quality of shift turnovers and have unintended adverse safety consequences. Therefore, although the commenter and other stakeholders believe that turnover is part of the workday and should be included in work hour calculations, the NRC believes the benefit of including turnover for managing worker fatigue would be outweighed by the potential adverse consequences on the quality of shift turnovers, if turnovers were subject to time limits.

Section 26.205(b)(1) of 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. In addition, § 26.205(b) provides specific examples of activities that licensees may and may not exclude as part of turnover to provide clear exceptions regarding NRC's intent. Although questions or differences in opinion may arise regarding what transfer of information is necessary to support safe operations, the rule will limit the potential for individuals and/or licensees to use the proposed shift turnover exclusion to perform other unnecessary work activities and addresses 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."

In order 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.

Post-Turnover Technical Assistance

Comment: One commenter suggested that the NRC add the following sentence after the third sentence in the subparagraph § 26.199(b)(1)(i): "Relieved individuals observing rest break(s)

contained in § 26.199(d)(2) that are contacted by telephone to discuss job continuity and/or technical assistance by the licensee is considered shift turnover and is excluded for work hours accounting purposes." The commenter argued that the need for offsite technical assistance contact needs to be addressed because turnover does not always capture every detail that may cause a question to arise later after the worker has been relieved [Edwin Hill, IBEW].

NRC Response: The NRC agrees in part with the commenter's concern and has modified the final rule to allow short periods of technical assistance to be considered turnover and may be excluded from the work hour calculations. This provision is in § 26.205(b)(5) of the final rule. 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 duration of the work does not exceed a nominal 30 minutes. For the purposes of compliance with the final rule minimum break requirements of § 26.205(d)(2) and minimum day off requirements of (d)(3), such duties do not constitute work periods or work shifts. This provision provides flexibility in the work hour controls to obtain expert advice or details on recent operating experience that may not have been included in a turnover without the burden that would be imposed by resetting the clock to account for the disruption in a break period. The nominal 30 minute duration of such 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.

The revised requirements on post-turnover technical assistance are in § 26.205(b)(5) of the final rule.

Beginning/Resuming Job Duties in Calculation Period

Comment: With reference to § 26.199(b)(1)(iii), other commenters stated that the first sentence must be revised to read "Licensees *shall not* calculate the work hours of an individual ... [who] has not performed such duties during the applicable calculation period." The commenters argued that, as presently worded, this requirement would allow a licensee to pad the group work hour limit with workers qualified to perform duties but never actually performing said duties [David Lochbaum, UCS; Deborah Katz, CAN].

Another commenter, supported by many commenters, disagreed with the proposed language in § 26.199(b)(1)(iii). Specifically, the commenter stated that the proposed language is overly burdensome and too restrictive because it requires that a licensee include all hours worked by an individual who joins a functional work group at some point during the monitoring period. The commenter suggested that work hour controls should be applied once the individual starts to perform activities within the functional group. The commenter recommended changes to the rule language, striking the phrase "include in the calculation of the individual's work hours all work hours worked, including hours worked performing duties that are not listed in paragraph (a) of this section, and" from § 26.199(b)(1)(iii). [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG]. One other commenter argued that the individual limits of paragraph (d)

will be sufficient to meet the intent of § 26.199(b)(1)(iii) without the additional qualification [Brian McCabe, Progress Energy].

NRC Response: The NRC has not retained the collective work hour limits in the final rule. As a result the comment concerning the need to revise the wording of proposed § 26.199(b)(1)(iii) to prevent padding of collective work hour limit calculations is not applicable to the final rule. The NRC disagrees with the comment that when an individual resumes performing duties subject to the work hour controls, the calculation of work hours should not include all hours worked for the licensee. Section 26.205 of the final rule permits licensees to assign individuals, who are qualified to perform the duties listed in § 26.4(a), to other duties than those listed in proposed § 26.4(a), without controlling their work hours in accordance with the work hour controls contained in proposed § 26.205(d). 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 the individual worked when calculating the individual's work hours and to subject the individuals to the work hour controls in § 26.205(d).

Section 26.205(b)(3) requires licensees 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 the relationship of the work to maintaining plant safety or security. Therefore, including the hours worked performing other duties provides assurance that fatigue does not compromise that individual's ability to safely and competently perform the duties that are specified in § 26.4(a).

Therefore the NRC retains the requirements of proposed § 26.199(b)(1)(iii) in § 26.205(b)(3) of the final rule.

Calculating Collective Work Hours

Comment: One commenter, supported by many commenters, recommended revisions to § 26.199(b)(2)(ii) and (iii) to replace "individuals" with "security personnel" and "any job duty group" with "the security job duty group." [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC has eliminated the referenced requirements, therefore the comment is not applicable to the requirements of the final rule.

11.3.3 Work Hours Scheduling (§ 26.199(c))

Support for Work Hours Scheduling Provision

Comments: Several commenters addressed work hour scheduling and stated that the work hour guidance in proposed § 26.199(c) is an important feature of the proposed rule. They explained that this section represents a performance-based requirement that allows licensees to

design effective fatigue management programs. In addition, the commenters stated that the importance of this provision is not adequately expressed in the rule package [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees with the commenters' support for this provision and notes that the requirement is retained in the final rule as § 26.205(c). During the development of the proposed rule the NRC had intended this requirement to be limited to the development of work schedules. However, 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 § 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 because of 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.

Opposition to Work Hours Scheduling Provision

Comments: A commenter argued that § 26.199(c) should be eliminated because it lacks the clarity necessary for consistent implementation and enforcement, and it is unnecessary given the numerous layers of prescriptive work hour limits which accomplish the same objective of preventing impairment from fatigue because of the duration, frequency, or sequencing of successive shifts [Brian McCabe, Progress Energy].

One commenter stated that the proposed rest break provisions and individual work hour controls, if implemented at the upper limits of what would be allowed, could result in work schedules that are not based on the 24-hour biological clock. The commenter argued that if these upper limits of scheduling were allowed in the final rules, there could be facilities that misinterpret these limits as being the established upper boundaries for safe operational performance, and as a result, impose work schedules on employees that actually produce unsafe levels of fatigue – at the plant or when the employee drives home. Therefore, the commenter suggested that the NRC make an additional effort to provide clear guidance regarding the systematic scheduling of 24/7 operations that are consistent with a 24-hour day. Additionally, the commenter suggested that the NRC take steps to add provisions that would encourage licensees to make shift rotations that are not only in keeping with the basics of sleep and human performance research, but are predictable and stable [Darrel Drobnich, NSF].

Two commenters argued that because of the way the proposed rule was written, it is difficult to comply with both proposed § 26.199(c) and § 26.199(d). The commenters stated that there is no mechanism in place in Subpart I for NRC review and approval of routine shift schedules that meet the intent of § 26.199(c). Thus, licensees will have to default back to the guidance of § 26.199(d) and develop schedules that would meet the requirements of this section even though the NRC stated that they are not intended as guidelines or limits for routine work scheduling [D.M. Jurss and Peter Hammill, PBNP].

NRC Response: The NRC agrees in part that § 26.199(c), retained as § 26.205(c) in the final rule, establishes a high level objective for scheduling without providing prescriptive requirements. The maximum work hour and minimum break and day off requirements that are specified in § 26.205(d) are intended for infrequent, temporary circumstances, and not as guidelines or limits for routine work scheduling. In addition, the work hour controls in proposed § 26.205(d) would not address several elements of routine schedules that can significantly affect worker fatigue, such as shift length, the number of consecutive shifts, the duration of breaks between blocks of shifts, and the direction of shift rotation. Therefore, § 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 circadian rhythms are the result of changes in physiology outside the control of the individual. Work may be scheduled, and the consequent timing of periods of sleep and wakefulness, in a manner that either facilitates an individual's adaptation to the work schedule or challenges the individual's ability to get adequate rest. Therefore, the duration, frequency, and sequencing of shifts, particularly for personnel who work rotating shifts, are critical elements of fatigue management. The effect of circadian rhythms on worker fatigue is also discussed in Section IV. D. The importance of these elements for fatigue management is reflected in guidelines for work scheduling, such as, 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). 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.

During the development of the proposed rule the NRC had intended this requirement to be limited to the development of work schedules. However, 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 because of 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.

Because there are many ways to construct schedules, the industry and the NRC acknowledge that it would be more appropriate to put details in a guidance document. This guidance would make it clear that meeting maximum work hour limits or minimum break requirements by themselves would not satisfy § 26.205(c). Industry stakeholders have proposed that guidance be developed, which would assist in the interpretation and implementation of § 26.205(c). A letter from J. W. Davis, Nuclear Energy Institute, to D. R. Desaulniers, dated March 8, 2006, suggested the development of such guidance and proposed draft criteria or metrics to use in a guidance document (ADAMS Accession No. ML060680403). Such guidance would also support the implementation of § 26.205(e)(1), which requires licensees to review the work hours

and performance of individuals subject to the work hour requirements for consistency with the requirements of § 26.205(c). The NRC will consider endorsing the proposed guidance.

Site-Specific Schedule Approval

Comment: One commenter at the public meeting asked if the NRC has considered approving schedules on a site-specific basis [Anthony Rizzo, Jr, Salem Hope Creek].

NRC Response: The NRC disagrees with the comment that the NRC should consider approving schedules on a site-specific basis. In developing this rulemaking, the intent was to establish requirements that allow for a variety of approaches at a site-specific level, and still meet the overall requirements of § 26.205(c) and (d). In the draft industry guidance applicable to § 26.205(c), (ADAMS Accession No. ML060680403), some example schedules are included as appendices. The NRC will consider endorsing the proposed guidance, however, because of the complexities associated with establishing schedules, it is unlikely that the NRC will specifically endorse those examples. It will be the responsibility of the licensee to establish a schedule that meets the intent of § 26.205(b) through (d) and adhere to that schedule in accordance with endorsed criteria included in the guidance.

11.3.4. Work Hour Controls for Individuals (§ 26.199(d))

Support for Work Hour Controls

Comments: Several commenters from industry supported the individual work hour limits in proposed § 26.199(d)(1) because they are effective in preventing both acute and cumulative fatigue [Michael Coyle, NEI #49; John Cowan; NEI; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees with the comments that support these provisions. However, the NRC does not agree with the assertion that the individual work hour controls in § 26.205(d)(1) are adequate to address cumulative fatigue caused by excessive overtime. To address cumulative fatigue, the final rule includes requirements for rest breaks in § 26.205(d)(2) and the minimum number of days off averaged over a shift cycle in § 26.205(d)(3) and the minimum days off per 15-day block in § 26.205(d)(4) and (5). These provisions will prevent excessive use of the maximum work hours and minimum rest breaks that would be permitted under the proposed individual work hour controls and ensure that the potential for cumulative fatigue, which would otherwise adversely affect the abilities of individuals to perform functions that are important to maintaining the safety and security of the plant, is managed.

Switching between Day and Night Shifts

Comment: One commenter referenced the changing of shifts between night and day and asked: “Do the new rules specify switching between nights, days, nights and then back to days all in one week?” The commenter also suggested that the rule should include language about

changing between shifts to prevent fatigue. Specifically, the commenter suggested "only one switch between nights and days ... in a seven day period when a worker is working 12-hour [shifts]" [Ethan Darrow, Individual].

NRC Response: NRC agrees that some shift schedules can exacerbate fatigue. Section 26.205(c) in the final rule addresses the sequencing of work shifts to prevent impairment from fatigue. Consistent with that provision and anticipated guidance, the NRC expects licensees to develop shift schedules that prevent impairment from fatigue associated with switching between day and night shifts. The final rule also includes additional flexibility in the break and day-off requirements such that licensees will be better able to develop shift schedules that minimize the circadian cycle disruption caused by rotating shifts. Specifically, licensees are not required to provide two consecutive days off, which reduces the potential for adversely affecting circadian adjustment to night shifts.

Negative Impact on Nuclear Power Workers

Comment: Several commenters stated that the proposed rule work-hour limits will have a significant negative financial impact on nuclear power workers by limiting the hours they are allowed to work. One commenter also argued that the proposed rule would produce an out-flow of experienced workers from nuclear facilities to other industries where work hours are not limited, and this loss of experienced workforce will result in the reduction of public health and safety and common defense and security. Further, the commenter argued that this rule language will result in increased contract work to outside entities, which constitutes "union busting" at its most basic level and will contribute to the creation of a hostile work environment at nuclear power facilities [Andrew Antrassian, UWUA]. Another commenter stated that he is re-evaluating his retirement plan because it was based on his previous work during outages. The commenter argued that the work hour provisions will limit the amount of time he will be able to work on outages, thus decreasing his income [Daniel Hansen, Individual].

NRC Response: The NRC disagrees with these comments. The NRC has documented concerns regarding frequent excessive use of work hours in SECY-01-0113, Fatigue of Workers at Nuclear Power Plants," and SECY 05-0074, Proposed Rule to Amend the Fitness-For-Duty Requirements in 10 CFR Part 26. Therefore, establishing clear and enforceable requirements for the management of worker fatigue is indeed necessary to ensure against worker fatigue adversely affecting public health and safety and the common defense and security. Further, the requirements provide a significant amount of flexibility when establishing schedules and they do not dictate or endorse any specific schedule. Therefore, the requirements should not unduly restrain collective bargaining agreements. The NRC also notes that the work hour limits allow for substantial amounts of overtime, allowing approximately a 20% overtime rate when a plant is operating and approximately a more than 50% overtime rate when a plant is in an outage. Furthermore, these limits are only applicable to individuals who are performing duties on systems, structures, or components that a risk-informed evaluation process has shown to be significant to public health and safety, or are performing critical emergency or fire response duties, or are members of the site security force performing duties necessary for execution of the site security plan. The rule does not limit the hours of individuals who are not performing these specified functions.

Limited Access to Supplemental Workers

Comments: Other commenters stated that the work hour restrictions would limit industry's access to supplemental workers. The commenters explained that the break requirements would encourage supplemental workers to seek out jobs in other industries that offer more overtime. Therefore, the commenters stated that this unintended consequence of the break requirements would harm licensees' ability to attract qualified workers. Without a consistent supply of experienced workers, the commenters warned that jobs would be delayed and turnovers would increase. In addition, the commenters predicted that more workers would seek second jobs to supplement their hours. As a result, total hours worked would not necessarily decrease [Michael Coyle, NEI #49; Daniel Hansen, Individual; Donald Lenski, Individual; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the comments and notes that the work hour requirements in Subpart I require the licensee to manage fatigue by limiting work hours, not compensation, as well as ensuring periodic breaks to enhance safety without unduly limiting overtime. The requirements allow for substantial amounts of overtime, up to 32 hours in a week, in excess of 400 hours per year for years without outages, and substantially more hours of overtime in years with outages. Also, in contrast to the commenters' concerns, the NRC believes that limiting work hours may attract and retain workers who perceive former work hours practices as excessive. Furthermore, the limits of the final rule are not substantially different from the limits in Generic Letter 82-12 and most licensees' Technical Specifications. In addition the work hour limits of Subpart I only apply to individuals who are performing duties on systems, structures, or components that a risk-informed evaluation process has shown to be significant to public health and safety, or are performing critical emergency or fire response duties, or are members of the site security force performing duties necessary for execution of the site security plan. The rule does not limit the hours of individuals who are not performing these specified functions.

Generic Letter 82-12

Comments: Commenters also stated that the individual work hour limits of proposed § 26.199(d)(1) are similar to the work-hour limits that are outlined in Generic Letter 82-12, and industry appreciates the minor change that was made to these limits, as it should eliminate inconsistency in the application of these limits [F.G. Burford, Entergy; Brian McCabe, Progress Energy; Jim Davis, NEI].

NRC Response: The comments do not require a response.

Impact on 8-hour Shifts

Comments: Many commenters opposed certain work hour controls because they decrease scheduling flexibility for the 8-hour shifts and will encourage 12-hour shifts [D.M. Jurss, PBNP; Peter Hammil; PBNP; John Cowan, NEI, Kevin Glidden, Individual; Jim Davis, NEI; Todd

Newkirk, IBEW; James Springfield, IBEW; Dennis Specha, Individual; Anonymous #34; Brian McCabe, Progress Energy; Gregory Halnon, First Energy; Anonymous #75; Ray Wacker, Individual]. Other commenters argued that 8-hour shifts allow adequate amounts of sleep between shifts, so the move to 12-hour shifts would be detrimental to nuclear plant workers in terms of preventing fatigue. [D.M. Jurss; PBNP; John Cowan, NEI; Doug Beck, First Energy]. One commenter argued that working 10 or 12 hour shifts would decrease the amount of time workers will be able to spend with their families [Doug Beck, First Energy].

To address this issue, one commenter suggested that the language of § 26.199(d)(2)(iii) be changed to: "A 48-hour break in any 14-day period, except during the first 14 days of any plant outage if the individual is performing the job duties listed in paragraph (a)(1) through (a)(4) of this section." The commenter also recommended adding subparagraph (iv) that states "A 24-hour break in any 8-day period if work hours scheduled under § 26.199(c) is based on an 8-hour shift schedule" [D.M. Jurss, PBNP].

NRC Response: In response to these and related comments, the NRC has conducted further analysis of the proposed rule provisions and agrees that the proposed rest break provisions could significantly disrupt current shift schedules and rotations. The NRC has modified the rest break provisions in the final rule to provide substantial additional flexibility in this regard, while providing comparable assurance that cumulative fatigue from inadequate rest does not impair the ability of workers to safely and competently perform their duties. The revised break and day off provisions are in § 26.205(d)(2)-(5) of the final rule.

Limit Consecutive Hours Worked to Ten

Comments: Another commenter stated that the proposed changes only address the "tail end" of the fatigue cycle, and the commenter suggested that the language limit the number of consecutive hours worked to ten [Jim Pulley, Clinton Power Station].

NRC Response: The NRC disagrees with the comment that the number of consecutive hours worked should be limited to ten hours. Limiting consecutive hours worked to 10 hours would effectively limit schedules providing 24-hour coverage to 8-hour shift lengths. A 10-hour shift length would not be practical and would not be based on a 24-hour clock and therefore would cause significant disruption of worker circadian shift cycles and worker fatigue. Although studies of worker fatigue in other industries have demonstrated deteriorating performance after 9 hours of duty, 12-hour shifts allow more tasks to be completed without a turnover, reduce the number of turnovers between shifts, and frequently allow individuals to turnover to the individuals that they relieved. As a result, 12-hour shifts improve job continuity and reduce the potential for error that can be introduced through the turnover process. The NRC considers these factors to mitigate, to some extent, the degradation in performance that may occur as a result of shift lengths in excess of 8 hours. In addition, many licensees have implemented 12-hour shifts for years and the NRC does not have information to indicate that the performance of individuals at sites with 12-hour shifts is substantively different from the performance of individuals at sites with using 8-hour shifts. As a consequence the NRC concluded that the information available at this time regarding the potential fatigue management benefit of limiting consecutive hours worked to 10 hours does not justify the substantial burden that would result from eliminating 12-hour shifts as a schedule option.

16 Work Hours in any 24 Hour Period – § 26.199(d)(1)

Comment: One commenter expressed concern about the individual work hour control in (d)(1)(i) that would allow 16 hours of work in any 24-hour period. The commenter acknowledged that 12 hour shifts have become increasingly common at U.S. nuclear power plants and that the NRC has proposed provisions (§ 26.199(d)(1)(ii), § 26.199(d)(2)(i)) that would restrict or dissuade the use of 16-hour days. However, the commenter stated that allowing the possibility of 16-hour days for personnel in safety-sensitive positions is counterproductive and potentially hazardous. The commenter stated that the proposed 16-hour value appears to imply that (1) fewer than 8 hours of sleep will be acquired between work shifts, which is insufficient as the NRC itself has noted, or (2) the report time will slip from day to day causing circadian instability, which should not be acceptable. Therefore, the commenter suggested that the maximum number of work hours should be 10 hours per 24 hours for people on 8-hour shifts and 14 hours per 24 hours for people on 12-hour shifts [Darrel Drobnich, NSF]. Another comment stated that workers should not be working more than 8 hours per day [Anonymous #76].

NRC Response: The NRC agrees in part with the commenterers in that the routine use of 16 hour shifts is inappropriate for fatigue management. Attachment 1 to SECY-01-0113 provides the basis for this proposed limit, which is summarized as follows: Studies have shown that task performance declines after 12 hours on a task (Folkard, 1997; Dawson and Reid, 1997; Rosa, 1991). Other studies have shown that the relative risk of having an accident increases dramatically after 9 consecutive hours on the job (Hanecke, et al.,1998; Colquhoun, et al.,1996; U.S. DOT, 49 CFR Parts 350, et al., Proposed Rule, May 2, 2000, 65 FR 25544). Further, a maximum of 12 work hours per day was the limit recommended by nine experts who met in 1984 to develop recommendations for NUREG/CR-4248. Therefore, in originally developing the NRC's Policy on Worker Fatigue, the NRC had planned a 12-hour maximum limit, but revised it to 16 hours in response to practical concerns from industry that the 12-hour limit required personnel who worked 8-hour shifts to split shifts when they work overtime. Those practical concerns remain valid, and the final rule retains a 16-hour limit in § 26.205(d)(1)(i).

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. Because of this the final rule has requirements that will substantially limit their use. Specifically, the 10-hour break requirement in § 26.205(d)(2)(i) will be applicable to all individuals subject to work hour controls. As a consequence, an individual would not be eligible to return for the beginning of the next normally-scheduled shift without a 10-hour break, and therefore would likely have a day off following a 16-hour shift.

Support for Ten Hour Between-Shift Rest Break – § 26.199(d)(2)(i)

Comments: Many commenters supported the mandatory rest break provision in § 26.199(d)(2)(i) that increases minimum break time from eight hours to ten hours because it will effectively remove the potential for cumulative fatigue by improving operator alertness levels and providing an opportunity to meet an individual's sleep requirement and minimize any acute sleep loss [Kevin Glidden; Individual; Mike Jolley, Individual; Mark Rosekind, Altertness Solutions; Michael Coyle, NEI #49; Ethan Darrow, Individual; D.M. Jurss, PBNP; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory

Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG]. One commenter suggested that the rule package understates the importance of this provision [Michael Coyle, NEI #49].

NRC Response: The NRC agrees with the commenters' support for this provision, but does not agree that the 10-hour break is adequate for preventing impairment from cumulative fatigue. Inadequate rest breaks between shifts not only contribute to a long work day but also cause increased pressure for 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. Therefore, the NRC has included other rest break and day off requirements in the final rule to effectively manage the effects of cumulative fatigue. The provision in proposed § 26.199(d)(2)(i) has been retained as § 26.205(d)(2)(i) of the final rule.

Opposition to Ten Hour Between-Shift Rest Break

Comments: One commenter stated the issue of off-duty time is one of the most important issues considered by the NRC. It said that ten hours off between shifts is the very minimum that should be allowed to provide employees the opportunity to get adequate sleep. The commenter encouraged the NRC to consider raising this provision to at least 12 hours off between shifts [Darrel Drobnich, NSF].

One commenter suggested that the 10-hour break requirement has little value. The commenter explained that the few times when workers are applicable to the minimum 8-hour breaks are during "call-outs" or shift changes, but the new 10-hour requirement makes an exception for shift changes [Anonymous #75].

NRC Response: The NRC agrees that a 10 hour rest break is the minimum that should be allowed between work periods. The NRC disagrees that the minimum break period should be increased to 12-hours. In most cases at nuclear power plants, workers are allowed at least a twelve hour break, exclusive of turnover. Therefore, the NRC acknowledges that this provision is applied infrequently. However, in instances of extended shifts (holdovers) or unscheduled shifts ("call-outs"), the 10-hour between-shift break requirement is very important to protect against the effects of acute fatigue. Also, the NRC notes that the 10-hour break exception for shift changes is intended for entire crews when they change shift schedules or shift durations, and is not to be used on an individual or frequent basis. Such transitions may occur at the beginning or end of an outage or when new shift schedules are adopted. As a result, the NRC expects that these instances will be infrequent.

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) in the final rule 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. Accordingly the NRC retains the proposed rule provision for a minimum 10-hour break between work shifts in § 26.205(d)(2)(i) of the final rule.

Opposition to 24/7 and 48/14 Breaks – § 26.199(d)(2)(ii) and (iii)

Comments: Many commenters disagreed with some aspects of the rest break provisions in § 26.199(d)(2)(ii) and (iii). They stated that the 24-hour and the 48-hour rest breaks are unnecessary, duplicative of requirements in § 26.199(c), do not address practical implementation issues, will be disruptive of normal shifts, and would negatively impact industry [Michael Coyle, NEI #49; James Springfiled, IBEW; Keith Young, Ameren UE; D.M. Jurss, PBNP; Mark Rosekind, Alertness Solutions; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG; Ray Wacker, Individual].

One commenter, supported by many commenters, 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. For example, the commenters stated that the break requirements would make it difficult to assign teams to provide 24-hour coverage to complete critical maintenance activities, or to restore inoperable safety equipment, which would result in longer outage times. The commenter also explained that the break requirements will make emergency plan and security drills more difficult to schedule and carry-out. If an individual has to participate on a required day off, there would be limitations on who could participate and there would be an increased need for waivers. According to the commenter, this would add another layer of complexity to planning drills [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

One commenter stated that while the rest breaks of § 26.199(d)(2) are intended to provide opportunities to recover from any cumulative sleep debt from preceding consecutive work periods, the ten-hour break provision would be adequate to obtain sufficient sleep and eliminate or minimize any potential acute sleep loss. Therefore, artificially requiring a 24 hour break every

7 days or a 48 hour break every 14 days is arbitrary and there is no scientific justification to support these specific numbers. [Mark Rosekind, Alertness Solutions].

Several commenters from industry stated that the "recovery concept" is scientifically supported, but the approach used to prevent cumulative fatigue should take into consideration existing work schedules and scheduling practices. The commenter explains that there is a problem with focusing on days off when facilities use 12-hour and 8-hour rotation schedules. Further, the commenter stated that there is no scientific basis for linking recovery breaks to any number of days less than 14 consecutive days. The commenter finds fault with focusing on days off without considering the number of hours worked in a particular day and the breaks between work periods. The commenter illustrates this point in a series of work-hour rotation schedule examples [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

A commenter, supported by many commenters, suggested that § 26.199(d)(2)(ii) should be revised to provide more equitable breaks during periods of normal operations. The commenter argued that a single set of break limits cannot be applied without undermining the viability of eight hour shift rotations, which industry supports. The commenter recommended deleting proposed § 26.199(d)(2)(ii) and replacing it with the following language:

(ii) During periods of normal operations:

(A) For a crew in a predominately 12-hour work schedule, an average of two 24-hour breaks per week over the nominal rotation cycle.

(B) For a crew in a predominately 8-hour or 10-hour work schedule, an average of one 24-hour break per week over the nominal rotation cycle.

(C) The nominal rotation cycle shall be between 4 and 6 weeks.

(D) Individuals are exempt from this requirement for the first 10 weeks of an outage in which the requirements of paragraph (d)(2)(iii) are applied.

[Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

Many commenters raised the issue of work schedule disruption as a result of the 48-hour break requirement in § 26.199(d)(2)(iii). They argued 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 two-day break. According to the commenters, some workers have stated that having two 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, they requested that the 48-hour break requirement during outage periods be deleted. One commenter, supported by many other commenters, suggested that NRC replace this provisions with the following language: "During outage periods, in which the requirements of (d)(2)(ii) above are not applied [see above text for commenter suggestion for (d)(2)(ii) language], a 24-hour break in any 7-day period." [Dennis Specha, Individual; Danny

Todhunter, Exelon; Jim Waite, Exelon; Daniel Hansen, Individual; Jim Davis, NEI #48; Michael Coyle, NEI #49; Andrew Antrassain, UWUA; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG; C.L. Funderburk, Dominion].

NRC Response: The NRC agrees that alternative requirements can prevent and mitigate cumulative fatigue while providing licensees increased scheduling flexibility. A significant amount of research has shown that adequate rest breaks are necessary to ensure that licensees provide individuals with sufficient time off between work periods to permit the individuals to recuperate from fatigue and provide reasonable assurance that acute and cumulative fatigue do not compromise the abilities of these individuals to safely and competently perform their duties. However, the NRC has conducted further analysis of the proposed provisions and has concluded that alternative break and day off requirements can effectively support fatigue management while providing greater scheduling flexibility. Therefore, the NRC has modified the work hour controls applicable to periods of normal operations in the final rule.

In response to comments on the break requirement in § 26.199(d)(2)(ii) of the proposed rule, the NRC has revised the maximum number of days between the breaks. The revised requirement is in § 26.205(d)(2)(ii) of the final rule and requires a minimum 34-hour break in any 9-day period. In revising the requirement the NRC considered that although the final rule allows more consecutive work shifts for 8-hour and 10-hour shift schedules, the additional flexibility allowed by the final rule allows licensees to more readily optimize 8-hour shift schedules to minimize 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 therefore do not experience the disruption of their circadian cycle that exacerbates the cumulative fatigue effects of consecutive work shifts. 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 requirement also provides flexibility to accommodate other practical considerations such as scheduling training on a Monday thru Friday basis and allows a contingency day for 8-hour shift schedules that include a series of 7 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)(ii) of the proposed rule, to a minimum 34-hour break in § 26.205(d)(2)(ii) of the final rule. The revision more clearly states NRC's intent to require a periodic "day off" in which individuals have the opportunity for 2 consecutive sleep periods without an intervening work period. The 34-hour break duration provides opportunity for 2 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.

In response to comments on the proposed 48-hour break requirement (§ 26.199(d)(2)(iii)) and the collective work hour limit (§ 26.199(d)(2)(iii)) of the proposed rule, the NRC has not retained these requirements in the final rule. Rather, the NRC has replaced these requirements with alternative provisions in § 26.205(d)(3) for normal operations and § 26.205(d)(4)-(5) for unit outages, planned security system outages or increased threat conditions.

To address cumulative fatigue during periods when a plant is operating, § 26.205(d)(3) requires each individual subject to the work hour requirements to have a minimum average number of days off per week. This rule provision addresses comments on the 48-hour break requirement and collective work hour limits by addressing cumulative fatigue on an individual basis; by tailoring the breaks to the duration of the shift; by establishing a limit that allows the flexibility of distributing the minimum days off over a shift cycle of up to 6 weeks; and by establishing requirements that are practical and should impose less administrative burden on licensees than would have been required by the collective work hour limits.

These final rule provisions also address those comments on the 48-hour break that were applicable to outage periods, as follows:

(1) The minimum day off requirements of § 26.205(d)(4) and (d)(5) do not require licensees to schedule 2 consecutive days off as would have been required by the 48-hour break requirement. As a consequence licensees are better able to establish schedules that minimize the potential for circadian disruption for individuals on fixed night shifts.

(2) The minimum day off requirements of § 26.205(d)(4) and (d)(5) allow licensees substantial flexibility in scheduling the required days off within the 15 day outage period. As a consequence, licensees are able to implement a range of scheduling options to meet known outage schedule demands and have the flexibility to revise schedules as may be necessary to address emergent needs.

(3) The minimum day off requirements of § 26.205(d)(4) allow licensees to use a predictable repeating schedule. The requirement permits a schedule of 4 consecutive 12 hour shifts followed by 1 day off. This 5 day sequence can repeat 3 times in each 15-day period creating a schedule that is predictable and repeating, characteristics desired by workers and schedulers. It also limits the number of consecutive work shifts to prevent cumulative fatigue and includes sufficient periodic days off to mitigate fatigue.

(4) The minimum day off requirements of § 26.205(d)(4), in conjunction with the other requirements in § 26.205, allow a maximum work week of 72 hours and an average work week of 67.2 hours for a period up to 60 days. As a consequence, the requirement allows licensees to offer, within these limits, substantial amounts of overtime 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 work hour limits of § 26.205 are applicable to only those duties that have the most direct impact on the protection of public health and safety and common defense and security. As a consequence, the requirements do not prevent individuals from working more than 72 hours per week unless those individuals are performing duties on systems, structures, or components that a risk-informed evaluation process has shown to be significant to public health and safety, or are performing critical emergency or fire response duties, or are members of the site security force performing duties necessary for execution of the site security plan. Accordingly the NRC has replaced the requirements in proposed § 26.199(d)(2)(ii) and (d)(2)(iii) with the requirements in § 26.205(d)(3) of the final rule. The NRC also notes that the final rule includes provisions to accommodate licensees performing unannounced emergency preparedness drills and security drills in response to comments that the break requirements would have made it difficult for licensees to schedule these activities. These provisions are in §§ 26.205(b)(4) and 26.207(b) of the rule, respectively.

Suggested Change to Rest Breaks

Comment: The commenter suggests that, rather than mandatory breaks, individuals should have the discretion to decline or exercise their right to a minimum break period. Specifically, the commenter suggested that NRC modify § 26.199(d)(2)(ii) to state: "A 24-hour break in any 7-day period; *or*" and § 26.199(d)(2)(ii)(A) to state: “During licensee normal operations for individuals identified in § 26.199(d)(4), a 24-hour break after completing 7 or 8 consecutive days of scheduled 8-hour shifts in any 14-day period activated as an individual option requiring reasonable notice by individuals to the licensee to observe the break period. Individuals who do not exercise this option do not require the licensee to adhere to individual waiver requirements in § 26.199(c)(3) unless subject to § 26.199(d). During plant outages § 26.199(d)(2)(ii)(A) is not applicable and § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii) is applicable to § 26.199(d)(4) individuals” [Edwin Hill, IBEW].

Similarly, the commenter suggested that NRC modify § 26.199(d)(2)(iii) to state: “A 48-hour break in any 14-day period activated as an individual option requiring reasonable notice by individuals to the licensee to observe the break period. Individuals who do not exercise this option do not require the licensee to adhere to individual waiver requirements in § 26.199(c)(3) unless subject to § 26.199(d), or” and § 26.199(d)(2)(iii)(A) should state: “During licensee normal operations for individuals identified in § 26.199(d)(4), a 48-hour break in any 14-day period during licensee normal operations. During plant outages § 26.199(d)(2)(iii)(A) is not applicable and § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii) is applicable to § 26.199(d)(4) individuals” [Edwin Hill, IBEW].

NRC Response: The NRC agrees in part with these comments. The break and day off provisions of the final rule in § 26.199(d)(2) through (d)(5) largely meet the commenter’s objective of providing workers and licensees increased flexibility in the distribution of breaks and days off, while allowing the licensee to retain scheduling authority.

Clarification of Rest Breaks

Comment: Another commenter stated that in the proposed rule, it is unclear whether the 24 and 48 hours off could be additive in 14-day period. The commenter asked: “would an individual get 24 hours off in a 7-day period and 48 hours off in a 14-day period, for a total of 72 hours off in the 14-day period?” The commenter suggested that the intent be clarified in the explicit language [Mark Rosekind, Alertness Solutions].

NRC Response: It was not NRC’s intent that the rest break provisions be additive in a 14 day period. Clarification of the NRC’s intent regarding these provisions is unnecessary, as the requirements for a minimum 24-hour break and a minimum 48-hour break have been modified in the final rule in § 26.205(d)(2)(ii) and § 26.205(d)(3) for normal operations and § 26.205(d)(4) through (5) for various outage conditions and these provisions provide a clearer set of requirements.

Exception During Outage

Comments: Other commenters expressed concern about the lack of work hour regulation during outage periods [Ethan Darrow, Individual; Anonymous #75]. In contrast, another

commenter argued the need for an exception from § 26.199(d)(2)(ii) to allow individuals to work for 14 consecutive days during the first two weeks of an outage or during other periods of high work activity [Daniel Stenger, NRSG].

NRC Response: The NRC does not agree that the work hour requirements applicable during outage periods should be made any more or less stringent as recommended by the commenters. Outages are unique, relatively short-term, and involve levels of activity that are substantially higher than most non-outage operating periods. Section 26.205(d)(4) and (d)(5) of the final rule establishes minimum day off requirements applicable to outages that accommodate the increased level activity of outages, but generally limits this more intensive scheduling to a period of 60 days to limit cumulative fatigue. Section 26.205(d)(6) allows an extension of the 60 day periods, but only for individuals who have had periods of less intensive scheduling during the outage. Although more restrictive requirements could perhaps provide greater assurance of worker fitness for duty, the NRC believes the burden on licensees would be excessive relative to the additional fatigue mitigation or prevention that would be gained. Regarding the recommendation to allow 14 consecutive days of work during outages or periods of high work activity, such a provision would allow work schedules with substantial potential for impairment of individuals from fatigue. Accordingly the NRC has not adopted the commenter's recommendation for the final rule.

Outage Length

Comment: One commenter stated that the former regulations allowed personnel to work hours over the guidelines with only a waiver and the ample use of turnover time. The commenter also argued that if the NRC is going to attempt to further limit work hours, then the NRC should mandate the length of an outage, and the commenter suggested a mandated 35 day outage. The commenter argued that if the NRC limits the hours of qualified in-house personnel but does not set a standard outage length, then companies will further rely on non-qualified contractor personnel to do critical work [Anonymous #dpr25].

NRC Response: The NRC does not agree with the comment that the NRC should mandate the length of an outage. The fatigue management provisions of § 26.207 establish criteria for the use of waivers that should substantially limit their use to conditions where warranted by safety or security considerations. Use of turnover time is limited by § 26.205(b)(1) so as to prevent abuse of the exclusion of turnover time from the work hour limits. The suggestion that the NRC limit outage length to prevent excessive work hours could effectively prevent licensees from completing maintenance necessary for the continued safe operation of the facility or create undue pressure to complete such activities within the allowed outage period. The NRC does not agree that the proposed limits will cause increased reliance on contractors, since the limits will also apply to contract personnel.

Conditions for Granting Waivers

Comment: One commenter argued that the process of extending work hours should be difficult for the utility, such that it will only occur under very unusual circumstances [Ethan Darrow, Individual].

NRC Response: The NRC agrees that waivers should only be granted in very unusual circumstances as originally stated in the NRC's Policy on Worker Fatigue. 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 provision in proposed § 26.199(d)(3) and as retained in § 26.207(a)(1)(i) of the final rule, clearly articulate that licensees must limit the granting of waivers to circumstances in which it is necessary to prevent or mitigate a condition adverse to safety or to maintain the security of the plant.

Also, as stated in § 26.207(a)(2) of the final rule, waivers can be granted only when such circumstances could not reasonably have been controlled. 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. 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 would not be limited to, equipment failures or a sudden increase in the personnel attrition rate.

Waiver in Lieu of Adequate Staffing

Comment: A commenter stated that § 26.199(d)(3)(ii) would prohibit the use of a waiver in lieu of adequate staffing, but then gives licensees an "out" by citing a sudden increase in personnel attrition rate as an example of a circumstance that the licensee could not have reasonably controlled, providing further justification for a licensee to stay at inadequate staffing levels [Peter Hammill, PBNP].

NRC Response: The NRC agrees that the waiver provisions allow licensees to use waivers to address a sudden decrease in plant staffing, if the conditions meet the waiver requirements. Specifically, the work to be conducted under the waiver must be necessary to prevent or mitigate a condition adverse to plant safety or security (as required by § 26.207(a)(1)(i) of the final rule), the individual to work under the waiver must be assessed face-to-face, and found fit to perform his or her duties during the additional work period (as required by § 26.207(a)(1)(ii) of the final rule), and, in this example, the sudden decrease in staffing could not have been reasonably controlled (as required by § 26.207(a)(2) of the final rule).

A licensee can reasonably assert that filling a position required by minimum staffing requirements is necessary to prevent or mitigate a condition adverse to safety or security. However, it is not the NRC's intent to allow waivers to compensate for deficiencies in staffing levels or other conditions that a licensee can reasonably control. Nevertheless, the NRC believes that it is reasonable to expect waivers to be used on a temporary basis to meet minimum staffing requirements if the loss of personnel could not have been reasonably controlled by the licensee. The rule would not allow the use of waivers for such conditions for an unlimited period of time because the licensee would eventually have time to respond to the condition and the NRC would consider the condition to be within reasonable control of the licensee. Given these considerations the NRC believes that the rule provision provides appropriate flexibility for conditions beyond the reasonable control of the licensee without providing licensees a blanket exception to use waivers to compensate for inadequate staffing. Accordingly the NRC has retained the provision in § 26.199(d)(3)(ii), which is presented in § 26.207(a)(2) of the final rule.

Insufficient Flexibility of Waivers

Comments: Several commenters from industry suggested that the waiver requirements in proposed § 26.199(d)(3) do not provide sufficient flexibility to grant a waiver to specific workers based on operational needs. They explained that there will be cases where a waiver would allow the completion of important work in a timely manner and would not result in any safety or security impact, and urged that management should have the flexibility to approve waivers in these cases. With the inclusion of the fatigue assessment and allowance for the individual to make a fatigue self-declaration, the commenters stated that this limitation is excessive and may represent a financial burden to the facilities. As a result, one commenter, supported by many commenters recommended adding "or a determination that the waiver is necessary for plant operations" to the end of § 26.199(d)(3)(i)(A) [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

Another commenter recommended that proposed § 26.199(d)(3)(i)(A) be modified to say: "An operations shift manager determines that the waiver is necessary to mitigate or prevent a condition adverse to safety or to support plant operational needs..." [Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenters' concern that the criterion that must be met in order to grant a waiver in proposed § 26.199(d)(3)(i)(A) may be 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. The potential for worker fatigue in conditions that would require a waiver is substantial. Therefore, the NRC cannot conclude that licensees can reasonably justify the performance of risk-significant activities by individuals who have worked hours in excess of the work hour limits on the basis that granting the waiver would not have an adverse impact on safety or security. This would be inconsistent with the NRC's goal of providing reasonable assurance that an individual will be able to safely and competently perform his or her duties, and therefore this provision has not been substantially modified and is retained as § 26.207(a)(1)(i) in the final rule.

Approval Authority for Waivers

Comment: One commenter stated that the language in the rule implies that the operations manager is the approval authority. The commenter stated that the operations manager should be evaluating the situation and individual, however, the plant manager should be the authority "signing off" on the waiver because of the impact of work hours on fatigue [Ethan Darrow, Individual].

NRC Response: The NRC disagrees with the commenter. The final rule states in § 26.207(a)(1)(i) that the operations shift manager would make the determination of whether the waiver is necessary to mitigate or prevent a condition adverse to safety and the security shift manager would make the determination if the waiver is necessary to maintain the security of the plant. 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.

Before the waiver is granted, a face-to-face assessment by a supervisor who is qualified to direct the work to be performed is also required by the final rule in § 26.207(a)(1)(ii) to determine that there is reasonable assurance that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver will be granted. These determinations 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.

In addition, § 26.207(a)(3) of the final rule requires that the waiver assessment be performed no more than four hours before the individual begins performing any work under that waiver, which will ensure that the individual will be fit-for-duty at the time the waiver is needed. Using the plant manager as the approval authority may increase the time that it takes for the waiver to get approved. Thus, using the operations or security shift manager, instead of the plant manager, as the approval authority will ensure that the appropriate personnel make the important waiver approval decisions and that the waiver process will not be abused.

Counting of Waivers

Comment: Another commenter stated that in many cases, waivers include a whole department or crew, so the counting of waivers does not give an accurate indication of how many workers are exceeding the work hour limits [Anonymous #75].

NRC Response: The NRC disagrees with the comment because the proposed rule required that a waiver may be granted to a particular individual under the circumstances outlined in proposed § 26.199(d)(3) only after that individual has undergone a face-to-face assessment to determine whether or not the individual will be able to safely and competently perform his or her duties during the additional period for which the waiver will be granted. As noted in SECY-01-0113, it has never been the NRC's intent in its Policy on Worker Fatigue or in the proposed rule that blanket waivers be granted for a large group of individuals. In addition, proposed § 26.199(d)(3)(iii) establishes a maximum period of four hours before the individual begins working under the waiver as the period within which the supervisory assessment must be performed. Finally, the reporting requirements in proposed § 26.197(e)(1) state that licensees must report waivers of work hour controls for individuals, not groups of individuals. Accordingly the final rule retains these reporting requirements in § 26.203(e)(1), and the waiver requirements in § 26.207(a)(1), (a)(3), and (a)(4).

Qualification of Supervisor Performing Face-to-Face Assessment

Comment: Referencing § 26.199(d)(3)(i)(B), one commenter stated that the phrase "qualified to direct the work to be performed" could inappropriately be linked to the definition of directing included in paragraph § 26.5, Definitions. The commenter further noted: "If, for example, an instrumentation calibration is required during the night and the Shift Manager determines that the adjustment is needed to prevent or mitigate a condition adverse to safety, an I&C supervisor would be notified to request at least one, probably two task qualified individuals to report to the

plant. The individual will report to the control room supervisor, who assumes oversight responsibilities during the performance of the task. The control room supervisor, although trained on the system and system interactions, may not be able to provide technical input for the calibration function that is being performed. As such, if the phrase "qualified to direct the work to be performed" is linked to the definition of directing, the I&C supervisor would also have to report to the site just to perform the fatigue assessment. This would result in an unnecessary prolonged interruption in the sleep cycle of more individuals than seems appropriate." Therefore, the commenter suggested that the wording "A supervisor, who is qualified to direct the work to be performed" be changed to "A supervisor, who is qualified to provide oversight of the work to be performed..." [F.G. Burford, Entergy]

NRC Response: The NRC agrees that requiring a supervisor to report to the site in the middle of the night for the purpose of conducting a fatigue assessment would be a significant burden and would be counterproductive for managing the fatigue of the supervisor. The proposed rule would have required that a supervisor, who is qualified to direct the work to be performed, assess the individual face-to-face to determine that there is reasonable assurance that the individual will be able to safely and competently perform the tasks during the period covered by the waiver. The purpose of the proposed requirement was to ensure that these determinations are made by individuals with 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 effectively 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. In response to this comment the NRC revised the requirement to accommodate situations in which there is no supervisor on site who is qualified to direct the work. Accordingly, § 26.207(a)(1)(ii) of the final rule states that the assessment can be performed by a supervisor who is qualified to provide oversight of the work to be performed by the individual. 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 that 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. The NRC also notes that in all instances, the supervisor performing the assessment shall have the training required by §§ 26.29 and 26.203(c), which provide knowledge and abilities 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.

The final rule retains the requirements in proposed § 26.199(d)(3)(i)(B), with the changes recommended by the commenter, in § 26.207(a)(1)(ii) of the final rule.

Face-to-Face Assessments for Waivers

Comment: One commenter stated that performing face-to-face fatigue assessments as proposed in the rule will be very difficult, no matter how well trained supervisors may become. The commenter noted that even sleep professionals would not rely on observation to determine how fatigued a person may be, and research demonstrates that most people experience cognitive decrements long before they start to exhibit physical manifestations of fatigue that may be observed by a supervisor or co-workers. The commenter argued that without some objective instrument or measure of fatigue, the system as proposed would be vulnerable to error and/or

abuse. The commenter suggested that NRC develop appropriate guidance for the implementation of training programs in relation to performing fatigue assessments [Darrel Drobnich, NSF].

NRC Response: The NRC agrees in part with the comments but notes that current technology for assessing fatigue has not matured to the state where it has been validated for regulatory use and has its own set of limitations in its ability to reliably detect impairment from fatigue. In lieu of such objective measure, the proposed rule would have required that the supervisor who will be conducting the face-to-face assessment to be trained in accordance with the requirements of § 26.29 and § 26.203(c), and must meet other minimum criteria necessary to effectively assess the potential for acute or cumulative fatigue. These requirements have been retained in § 26.29 and § 26.203(c) of the final rule. The required training will provide the knowledge and abilities 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.

Section 26.207(a)(1)(ii) of the final rule requires that supervisors must perform the assessment face to face with the individual that he or she is assessing for the waiver. This requirement ensures that the supervisor who is performing the assessment has the opportunity to observe the individual's appearance and behavior to note indications of fatigue (e.g., decreased facial tone, rubbing of eyes, slowed speech) and interact with the individual to assess the individual's ability to continue to safely and competently perform his or her duties during the period for which the waiver will be granted.

Section 26.207(a)(1)(ii) of the final rule 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 the individual will have worked by the end of the work period for which the waiver is being considered. The potential for cumulative fatigue can be practically assessed by reviewing the individual's work schedule during the past 14 days to determine (1) whether the individual had adequate opportunity to obtain sufficient rest, considering the length and sequencing of break periods; (2) whether the available sleep periods occurred during the night or at other times when sleep quality may be degraded; and (3) the potential for transitions between shifts (e.g., from days to nights) to have interfered with the individual's ability to obtain adequate rest. The potential for circadian degradations in alertness and performance can be practically assessed by considering the time of day or night during which the work would be performed, as well as the times of day of the individual's recent shift schedules.
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 recognizes 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 must 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.

The NRC also notes that the NEI has initiated development of an implementation guide for the rule, including a checklist that addresses the criteria for authorizing a waiver. Therefore it is anticipated that this will be the subject of further development. The NRC notes that these are minimum criteria, and the requirements do not prevent a licensee from developing a tool that may more effectively make this determination.

Comment: Referring to the last sentence in § 26.199(d)(3)(i)(B)(iii), one commenter expressed uncertainty about how this requirement would apply to a case where the face-to-face supervisory assessment allows an individual to cover a work period in excess of four hours. The commenter presented the example of the case where an individual is called in to cover an 8-hour shift because of sickness of another individual. The commenter asked: "Does the face-to-face supervisory assessment conducted immediately prior to the individual assuming the shift cover the entire 8-hour shift or only the first four hours of it?" The commenter argued that a strict reading of the requirement as presently written might preclude that individual from beginning to perform any work under the waiver more than four hours after the face-to-face supervisory assessment [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC disagrees with the commenter's description of the intent of the subparagraph. Proposed § 26.199(d)(3)(iii) requires that a face-to-face supervisory assessment must be conducted sufficiently close in time (four hours) to the period during which the individual "begins performing any work under the waiver" to ensure that the individual's condition will not substantively change before work is performed under the waiver. This provision is not intended to address the length of the extended work period that the waiver would "cover," and only requires that the assessment is conducted within four hours of the start of the extended work period.

<u>Proposal to Amend Break Requirements</u>

Comment: One commenter argued that work groups/crews who want to work rotating 8-hour shifts should be afforded the opportunity to do so without § 26.199(d)(2)(ii) vetoing existing 8-hour shifts at facilities. The commenter suggested that the NRC add § 26.199(d)(4) that states: "During licensee normal operations for individuals working 7 or 8 days of consecutive work periods scheduled for 8 hours each contained in a nominal shift rotation cycle of 14 days or more § 26.199(d)(2)(ii)(A) and § 26.199(d)(2)(iii)(A) is applicable for rest periods with § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii) being inapplicable for normal operations rest periods. For plant outages § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii) are applicable to individuals scheduled

for 8 hour shift rotations for rest periods with § 26.199(d)(2)(ii)(A) and § 26.199(d)(2)(iii)(A) being inapplicable for plant outage rest breaks." In this case, the commenter suggested that § 26.199(d)(1) should state the following: "Except as permitted under paragraph (d)(3) *and/or (d)(4)* of this section, licensees shall ensure that any individual's work hours do not exceed the following limits" because (d)(4) allows consideration of licensees who work 8-hour shift rotations for 7 or 8 days consecutively for a nominal rotation cycle of 14 days or more [Edwin Hill, IBEW].

NRC Response: The NRC agrees in part with this comment and has revised the final rule to eliminate the requirements for a minimum 24-hour break in any 7 days and a 48-hour break in any 14 days. The new requirements in the final rule are for a 34-hour break in any 9 days and a minimum number of days off per week averaged over a shift cycle. These requirements, which accommodate 8-hour shift schedules, are in § 26.205(d)(2)(ii) and § 26.205(d)(3), respectively, of the final rule.

Impact on Rate of Pay

Comment: One commenter suggested that the NRC review the impact on those workers who have negotiated a rate of pay on their second day off as a double-time day instead of a time-and-a-half day. The commenter argued that this provision negatively affects worker morale not only because workers have less control of their weekly schedule, but also because their rate of pay would be reduced when working overtime [James Springfield, IBEW].

NRC Response: The NRC disagrees with this comment since § 26.205(d)(3)-(6) of the final rule provides break and day off requirements that largely meet the commenter's objective of providing increased flexibility in the distribution of breaks and control of weekly schedules. The intent of Subpart I is to limit fatigue not compensation. The increased flexibility of the final rule allows for negotiation between workers and the licensee while providing the necessary controls to reduce the likelihood of fatigue-related errors adversely affecting public health and safety or the common defense and security.

TVA Overtime Agreement

Comment: One commenter referenced the 1991 Overtime Agreement utilized at all nuclear facilities of the Tennessee Valley Authority (TVA). The commenter stated that this agreement addressed the idea that the "16/24, 24/48, and 72/7 had little if any real safety basis when coupled with the volunteering of overtime." The commenter argued that the NRC, TVA and IBEW were satisfied by the results of this agreement, and this agreement has been successfully utilized without challenge for fifteen years. Hence, the commenter questioned the NRC's attempt to override this settlement and formally requested the settlement to be reopened if the NRC disregards it [James Springfield, IBEW].

NRC Response: The NRC disagrees with the comment that individual work hour limits have little safety basis when individuals volunteer for overtime. Although individuals may be able to make relative judgements regarding their level of fatigue, there have been several studies that have noted the tendency for individuals to underestimate their level of impairment from fatigue (Nabi et al, 2006; Wylie, et al., 1996; Dinges, 1995; Rosekind and Schwartz, 1988). The NRC has also received allegations from nuclear power plant workers expressing fear of adverse actions from employers for reporting that they are unfit for duty because of fatigue. As a

consequence, the NRC does not believe there is reasonable assurance workers can reliably address excessive fatigue through their own actions under the former requirements applicable to worker fatigue.

The NRC also notes that limiting hours and fatigue of employees engaged in licensed activities is an exercise of NRC statutory authority to regulate nuclear safety. Such regulation may affect labor agreements between a licensee and a union. If the parties to a labor contract believe that the contract has been made obsolete by subsequent events, e.g., this final rule, the parties to the contract are responsible for renegotiating their contract. The NRC has no authority to compel parties to a labor contract to renegotiate the contract.

11.3.5. Self-Declarations During Extended Work Hours (§ 26.199(e))

Support for Self-Declarations

Comments: Two commenters supported the self-declaration provision in proposed § 26.199(e) [Jim Davis, NEI; Todd Newkirk, IBEW].

NRC Response: The comments do not require a response.

Suggestion for Increased Implementation Guidance

Comment: One commenter commended the NRC for proposing this self declaration provision to provide employees with a process to declare when they might be too fatigued, for whatever reason, to conduct certain tasks. However, while the concept of self declaration is a worthy one in theory, the commenter argued that its use may be impractical since (a) employees may fear reprisal, directly or indirectly; and (b) chronically sleep deprived individuals and individuals with certain sleep disorders are not capable of accurately self-assessing their level of alertness and capacity to perform. The commenter therefore encouraged the NRC to put forward very clear guidance regarding the implementation of this rule to make sure that the potential for abuse for both self-declaration and face-to face assessments is minimized. The commenter also encouraged the NRC and the nuclear industry to support the development and utilization of objective assessment tools and predictive software models currently being tested [Darrel Drobnich, NSF].

NRC Response: The NRC agrees with the comment for implementation guidance. 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, indicates that there is a need for individuals to clearly understand their fatigue management responsibilities and those of the licensee.

The Nuclear Energy Institute has agreed to develop implementation guidance for the rule. The NRC will review the guidance and, as appropriate, recommend changes or endorse the guidance in an NRC Regulatory Guide. Through this process implementation guidance will be made available to licensees. Regarding the comment that the NRC and industry should encourage the development of objective assessment tools and predictive software models, the

NRC would support industry development of tools and methods that would facilitate effective implementation of the requirements of this rule.

Oversight of the Self-Declaration Process

Comments: Other commenters argued that the NRC should closely oversee the self-declaration process. They cited examples of self-declaring workers who are afraid to self-declare and forced to work under duress due to the threat of being fired, sent to psychiatrists, and given undesirable schedules. The commenters argued that if there is evidence of retaliation for self-declaration, then the NRC should take enforcement action and levy significant fines against the utilities [Pete Stockton and Danielle Brian, POGO].

NRC Response: The NRC agrees that oversight of the self-declaration process should be part of the NRC's oversight of licensee implementation of the requirements in Subpart I. The NRC will revise the baseline inspection procedure for fitness for duty programs, IP71130.08, as part of the NRC's implementation activities for this rule. The revision will include requirements for the inspection of licensee fatigue management, including the implementation of the self-declaration requirements. In addition, § 26.203(e) of the final rule requires licensees to report information pertaining to fatigue assessments, including self-declarations. This will enable the NRC to monitor licensee use of the self-declaration process. Furthermore, the NRC notes that the NRC's allegation program is available to all licensee employees. Individuals who believe that they are being forced to work when they are unfit for duty because of fatigue may report these concerns through the NRC's allegation process.

Regarding the commenters' recommendation that NRC should take enforcement action against utilities that retaliate against individuals for self-declaration, the NRC notes that 10 CFR 50.7 prohibits retaliation for the reporting of nuclear safety concerns. The NRC has addressed the applicability of this requirement with respect to self-declarations in RIS-2002-007, "Clarification of NRC Requirements Applicable to Worker Fatigue and Self-Declarations of Fitness-For-Duty." In summary, the NRC has several mechanisms for the oversight of the self-declaration process and, therefore, the commenters concerns are adequately addressed through this rulemaking and existing NRC regulations and programs.

11.3.6. Collective Work Hour Limits (§ 26.199(f))

Support for Collective Work Hour Limits

Comment: One commenter stated that cumulative limits are important controls for the long-term mitigation of fatigue, and thus supports their inclusion in the final rule [Barry Quigley, Individual]

NRC Response: The NRC agrees with the commenter's statement supporting provisions that address cumulative fatigue. Although the NRC has eliminated collective work hour limits from the final rule, those limits have been replaced with requirements for minimum number of days off per week averaged over a shift cycle in § 26.205(d)(3) and minimum days off in 15 day blocks in § 26.205(d)(4) that have the same objective of preventing cumulative fatigue. Therefore, the NRC has revised the final rule and maintains provisions to address cumulative fatigue.

Opposition to Collective Work Hour Limits

Comments: Many commenters addressed collective work hour limits, with the majority of them opposing some portion of the provisions. Some commenters stated that the collective work hour limit approach is inconsistent with the rest of the FFD rule and dangerous when coupled with the provision limiting the scope of work hour limits to only those workers with hands-on responsibilities [David Lochbaum, UCS; Deborah Katz, CAN]. Another commenter recommended that the NRC eliminate the specific policies regarding collective work hour limits, because they are not an effective means to address the known physiological fatigue risks contributed by individual operators [Mark Rosekind, Alertness Solutions]. One commenter stated that the group hours should not be adopted for the further reason that the NRC's backfitting analysis does not adequately justify imposing this new requirement (See Section 14.2) [Daniel Stenger, NRSG]. Another one disputed the validity of surveys referenced by the NRC staff to imply that the limits are consistent with worker desires regarding overtime. To the contrary, the commenter believes that the predominant opinion of workers in the nuclear industry is overwhelming opposition to the work-hour limits [Andrew Antrassian, UWUA].

Many commenters from industry stated that the proposed collective work hour limits are unnecessary to mitigate the effects of cumulative fatigue and limit the flexibility to increase work hours in a job-duty group based on operational needs. They expressed that cumulative fatigue is adequately addressed by other rule provisions, such as the work schedule, individual work hour limits, individual break requirements, the fatigue assessment and the self-declaration process. Therefore, the commenters asserted that the inclusion of cumulative work hour controls is unnecessary and should be eliminated for any functional group except security [Michael Coyle, NEI #49; John Cowan, NEI; Jim Davis, NEI, Richard Sweigart, DCS, Keith Jury, Exelon; Keith Young, Ameren UE; Richard Sweigart, DCS; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG; Pete Stockton, POGO]. One commenter suggested that the NRC adopt a more performance-based rulemaking approach that better recognizes the complexity of work scheduling practices at nuclear power plants and allows for more flexibility [Daniel Stenger, NRSG].

Some commenters expressed concern that the utility companies will be able to "fudge" how many armed security officers they have on shift by including the unarmed officers, trainers, and in some cases clerical and managerial staff into the group with the armed responders. Therefore, these commenters suggest that the group hour limits are irresponsible and should be deleted from the rule [Danielle Brian, POGO; Anthony Rizzo Jr, Salem Hope Creek]. One commenter also asserted that the only way to ensure that the collective work hour limit will achieve adequate shift coverage without routine heavy use of overtime is to remove leave hours from the averaging process [Peter Hammill, PBNP].

One commenter stated that collective work hours will allow licensees to force workers to work overtime [Dennis Specha, Individual]. To address this, one commenter suggested that the NRC require that a licensee cannot force someone to work over 48 hours, but an individual may volunteer to work up the 72 hours in a week if it relieves another individual from a forced overtime situation [Guy Galster, Individual]. Another commenter stated that the 48-hour

collective work hour limit will not prevent individuals from working up to the limits of § 26.199(d) on a frequent basis. The commenter argued that the time frame between outages is the time frame when § 26.199(f) will apply, and it is also the period of highest vacation usage. The commenter argued that since overtime is used to cover for vacation or illness, it is possible that during these times one could be working up the limits of § 26.199(d) repeatedly to cover for absences [Peter Hammill, PBNP].

A commenter also noted that the maximum limits for group work hour averages may not be consistent with existing collective bargaining agreements (CBA's), and may result in variations among work groups at a site [Daniel Stenger, NRSG].

Several commenters from industry stated that one of the challenges surrounding the collective work hour limits is the recruitment of supplemental workers past the eight-week point in an outage when the work hours are limited. The commenters argued that, for many individuals, the availability of overtime is a key factor in where they decide to work, and attracting the same individuals to work subsequent outages and retaining them for the duration of the outage significantly improves the quality of the work process. Thus, the commenters suggested that the 8 week outage exemption be increased to 10 weeks because licensees will face the unintended consequence of the loss of supplemental workers in the final stages of an outage [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees in part with the statements made by many commenters concerning collective work hour limits. In response to these comments the NRC has replaced proposed rule requirements for collective work hour limits with the minimum day off requirements in § 26.205(d)(3) of the final rule. The NRC expects that the minimum day off requirements in the final rule will be equally effective in addressing cumulative fatigue, while addressing the commenters' concerns. The requirements of the final rule address cumulative fatigue on an individual basis and therefore provide more uniform assurance against worker fatigue while eliminating the burden of defining and tracking individual membership in job duty groups. The final rule requirements also eliminate the potential that the calculation of collective work hours would not be representative of the hours worked by all individuals in a group or are in some other way biased.

Clarification of Individuals Subject to Collective Work Hours

Comment: Another commenter at the public meeting expressed confusion over which workers were considered to be in the "group" [Pete Stockton and Danielle Brian, POGO]. Others stated that the provision must explicitly state that only those individuals who meet one or more of the criteria in § 26.199(a) shall be included in the group hour calculations [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC agrees that the rule requirements should be clear regarding the individuals to whom they are applicable and the NRC's intent for the collective work hour limits was that these limits would be applicable to only those individuals who met at least one of the

criteria specified in § 26.199(a) of the proposed rule. However, the final rule does not retain the requirements for collective work hour limits. The NRC replaced the collective work hour limits with individual work hour limits and the calculation of work hours for purposes of compliance with the final rule requirements does not depend upon group membership.

Collective Work Hours for Security Personnel

Comments: One commenter, supported by many commenters, recommended revisions to § 26.199(f) to replace "individuals" with "security personnel" or "any job duty group" to "the security job duty group." [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

One commenter suggested that the language in § 26.199(f)(1) and (f)(3) should reference (a)(1) and (a)(5) instead of only "(a)" because collective group hour management will not be the best fatigue management for groups (a)(2), (a)(3) and (a)(4) due to the burdensome tracking of average collective work hours for these groups that have a high occurrence of mobility within the industry. The commenter argued that the recommended provision language focuses on security and operations. [Edwin Hill, IBEW].

NRC Response: The NRC agrees with the comment that licensees could experience a greater burden implementing the collective work hour limits for groups that have a high occurrence of mobility within the industry. The NRC eliminated the requirements for collective work hour limits from the final rule. As a consequence, all fatigue management provisions are applicable on an individual, rather than group, basis. The final rule therefore eliminates the burden associated with tracking group membership for individuals in jobs that are highly mobile in the nuclear power industry.

Exclusions During Plant Outages

Comments: Regarding § 26.199(f)(1), one commenter, supported by many commenters, also recommended that the 8 week exclusion for outages be increased to 10 weeks throughout the rule package to accommodate anticipated upcoming outages of longer duration. The commenter argued that review of recent outages shows an increase in the number of outages that exceed 8 weeks. The commenter also argued that equipment replacements show a number of outages that exceed 8 weeks that could be managed with a 10 week outage [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

Some commenters strongly opposed the relaxation of collective work hour limits during the first eight weeks of a plant outage [David Lochbaum, UCS; Deborah Katz, CAN]. However, another commenter stated that industry is supportive of this exemption [John Cowan, NEI]. Another

commenter argued that this exemption should continue for longer than the first eight weeks of an outage [Todd Newkirk, IBEW].

NRC Response: The NRC does not agree with the commenters' recommendations that the exemption period from the collective work hour limits for unit outages should be either extended or eliminated. Although the NRC has replaced the collective work hour limits of the proposed rule with the minimum day off requirements in § 26.205(d)(3) of the final rule, the requirements of the final rule that are applicable to unit outages are comparable to those of the proposed rule. As a consequence the NRC has retained a comparable exemption period, limiting the exemption from the requirements of § 26.205(d)(3) to the first 60 days of a unit outage or planned security system outage. The relaxation of individual work hours during these specific times accommodates the short-term demand for increased work hours associated with these outages while limiting cumulative fatigue. The NRC considers the burden on licensees of eliminating the exemption period for these conditions to be excessive for the additional assurance that could be gained in worker fitness for duty relative to that achieved by the limited exemption period of the proposed rule.

In setting the maximum duration of the exclusion period, the NRC not only considered the duration of typical and longer term outages, but also 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)–(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 would be a reduction of 60 percent 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. As a result the NRC did not consider it appropriate to extend the exception period without assurance individuals obtained sufficient rest to prevent cumulative fatigue. However, the NRC has included a provision in the final rule (§ 26.205(d)(6)) that permits licensees to extend the outage exception period by 7 days for each 7-day period during the outage an individual works not more than 48 hours. This provision accommodates longer outages when it is justified by the work history of the individual containing adequate recovery periods.

13-Week Averaging Period

Comments: Other commenters stated that the proposed rule is not clear in how the 8-week outage suspension of the collective work hour limits per § 26.199(f)(1) gets reconciled with the 13-week averaging period specified per § 26.199(b)(2) [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC did not retain the proposed collective work hour limits in the final rule. This change to the requirements eliminates the 13-week averaging period. Therefore, the final rule renders moot comments concerning the 13-week averaging period.

Fatigued Individuals

Comments: Commenters stated that the rule must not allow an individual who is already chronically fatigued from entering the collective work hour limit pool, especially when that entry coincides with the 8-week outage "free pass." They suggested that the NRC revise § 26.199(b)(1)(iii) to require a formal, documented check before an individual begins or resumes performing any of the job duties listed in paragraph (a). The commenters stated that the licensee should assess the person's work hour history over at least the prior 13 weeks to verify that the individual is not already likely to be chronically fatigued [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC agrees that chronically fatigued individuals should not be allowed to perform duties covered in proposed § 26.199(a). The NRC does not agree that the rule should be revised to include a formal documented check of a worker's work hour history over at least the prior 13 weeks. The NRC considered methods for licensees to track the work hours of individuals that work for other licensees and other employers and determined that the burden of tracking work hours was substantial and that the ability to verify work hours from other employers was limited. However, the NRC determined that the potential for cumulative fatigue was substantial for individuals who work outages in close succession and that licensees can reasonably track and verify the hours of individuals that may move from outage to outage among their own power plant sites. Accordingly, the NRC revised § 26.199(g) of the proposed rule to provide more effective controls to prevent cumulative fatigue of individuals that work successive outages for the same licensee. The revised requirement is in § 26.205(d)(7) of the final rule. In addition, the NRC notes in the event an individual becomes chronically fatigued, § 26.211(a)(1) of the final rule requires licensees to conduct fatigue assessments for-cause when individuals appear not to be fit for duty because of fatigue and § 26.203(b)(1) requires licensees to establish procedures for the self-declaration of fatigue. The NRC considers that collectively these requirements provide reasonable assurance that individuals will not perform duties that are subject to the work hour controls when they are chronically fatigued or otherwise are not fit to safely and competently perform those duties.

Ensuring Adequate Staffing Levels

Comment: One commenter argued that § 26.199(f)(3)(i) provides an "out" to licensees, in effect telling them that they do not need to maintain adequate staffing when it is not reasonably controllable. Thus, if the intent is to ensure adequate staffing levels, the commenter urges the NRC to define adequate staffing levels [Peter Hammill, PBNP].

NRC Response: The NRC agrees that proposed § 26.199(f)(3)(i) permitted a limited exception from the collective work hour limits for conditions that the licensee could not have reasonably controlled. However, the NRC has not retained the collective work hour requirements for the final rule and has eliminated the provision in proposed § 26.199(f)(3)(i) as part of the elimination of the collective work hour limits.

Collective Work Hour Limits for Security Personnel During Outages

Comments: Regarding § 26.199(f)(2)(i), one commenter expressed concern that security personnel would be allowed to work more hours during outages. The commenter stated that, for

the reasons stated by the NRC in its reasoning in relation to § 26.199(a)(5), work controls should be in place for security personnel, especially during times of increased activity such as planned security system outages or under threat conditions. Thus, the commenter stated that security personnel must be under more stringent work hour controls and should not be included in any provisions that allow waivers during outages or other circumstances other than, possibly, during attack or emergency situations [Darrel Drobnich, NSF].

Other commenters argued that armed security officers should be limited to 48 hours a week, and the only instances in which hours should reach 60 are refueling and heightened security [Pete Stockton and Danielle Brian, POGO].

NRC Response: The NRC agrees, in part, with the commenters. The NRC agrees that the work hour controls for nuclear power plant security personnel should be stringent for the reasons described in the section-by-section analysis of this rule with respect to § 26.205(a) of the final rule. The NRC also agrees that the work hours of armed security guards should not routinely exceed 48 hours per week. However, the NRC does not agree that the rule should not permit limited periods of increased work hours for security personnel during outages or increased threat conditions. The collective work hour requirements in proposed § 26.199(f)(2)(i) have been eliminated from the final rule. However, the alternative requirements in the final rule for individual work hours in § 26.205(d)(5) prescribe less stringent day off requirements than those required by § 26.205(d)(3) during the first 60 days of a plant outage, security system outage, or increased threat condition.

Outages and increased threat conditions are unique, relatively short-term, and involve levels of activity that are substantially higher than most non-outage operating periods. It is not practical to expect licensees to maintain sufficient supplemental security staff to maintain 48-hour weeks under all conditions. A rule that imposed such a requirement would place an exceptionally high burden on licensees and result in a security staff that would not be fully employed under most circumstances. The relaxation of individual work hours for security personnel accommodates the short-term demand for increased work hours associated with these outages and increased security threat conditions. The minimum day off requirements in § 26.205(d)(5) of the final rule, in conjunction with the other provisions in Subpart I, ensure individuals have sufficient days off during these periods of more intensive work schedules to provide reasonable assurance that security personnel are not impaired by fatigue. However, the NRC agrees that such increased periods of work hours create the increased potential for cumulative fatigue. As a result, § 26.205(d)(5) limits the exception period to generally not more than 60 days.

<u>"Hard Cap" on Collective Work Hours</u>

Comments: A couple of commenters noted that § 26.199 (f)(3)(ii) imposes a cap of 54 hours per person per week under certain circumstances and § 26.199 (f)(2)(i) and other sections impose a cap of 60 hours per person per week for security personnel under other circumstances. To rectify this, the commenters suggested that the NRC provide a "hard cap" on collective work hours [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC has revised the rule such that collective work hour limits are eliminated from the final rule, including the provision in § 26.199 (f)(2)(i) of the proposed rule. The comment is therefore not applicable to the requirements of the final rule.

Approval to Exceed Collective Work Hour Limits

Comment: One commenter stated that the requirement in § 26.199(f)(5) for prior NRC approval of a written request by a licensee to exceed any collective work hour limits for any job group is overly restrictive and could have unintended consequences, such as delayed site response and corrective actions to emerging issues [Daniel Stenger, NRSG].

NRC Response: The NRC has revised the rule such that collective work hour limits are eliminated from the final rule, including the requirement in § 26.199(f)(5). As a result of these changes the comment is not applicable to the requirements in the final rule.

11.3.7. Successive Plant Outages (§ 26.199(g))

Multi-Site Licensees

Comments: A couple of commenters stated that the proposed rule is written under the implicit assumption that there are unique licensees for each reactor site, and that assumption is false. They explained 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. The commenters included an example of when the sustained outage provision of § 26.199(g) does not apply, and argued that the rule must not permit this [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC agrees in part with the comment that certain individuals work successive outages and, therefore, the NRC 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 rule provision was limited to successive outages at a licensee's site. The commenter 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) of the final rule 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 provision 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 rule 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 no different for these individuals than for those 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 the burden was not warranted given the expected benefit. The revised requirements applicable to individuals who work in outages in close succession are in § 26.205(d)(7) of the final rule.

Successive Outage Calculations

Comments: Several commenters also stated that § 26.199(g) "tosses out" the collective work hour limits when outages are separated by at least two weeks but less than 13 weeks. They

argued that § 26.199(b)(2) requires collective work hours to be calculated "within an averaging period that may not exceed 13 weeks." Thus, if the licensee specifies 13 weeks as the averaging period and the end of an outage resets the clock for starting an averaging period, then the collective work hour calculation does not become meaningful until 13 weeks after the end of an outage. The commenters argued that, in the interim, the only real limits on working hours are the individual limits in § 26.199(d), and this allows a licensee to use the collective work hour limits “free pass” for an eight week outage as often as possible during a year, as long as the outages are separated by at least two weeks [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC agrees that § 26.199(g) of the proposed rule allows licensees to use the outage exception multiple times in a year if outages are separated by at least 2 weeks. The NRC does not agree that this provision has the effect of “tossing out” the work hour controls generally applicable to routine plant operations. 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. Accordingly, § 26.199(g) of the proposed rule ensures that individuals have at least a 2 week period during which their work hours are subject to the requirements applicable to routine plant operations before the individuals are eligible for control of their work hours in accordance with an outage exception. A minimum of 2 weeks under normal workloads provides reasonable assurance that individuals have the opportunity for successive days of rest to reduce the potential for cumulative fatigue. Although consecutive outages separated by more than 2 weeks may create some potential for cumulative fatigue, particularly if individuals are working more than 2 consecutive outages, the NRC considers the 2 week minimum to be adequate to substantively reduce the potential for cumulative fatigue. In addition, the NRC expects that the likelihood of individuals working more than 2 consecutive extended duration outages separated by just 2 weeks is low given that the time period that licensees conduct unit outages is typically limited to periods of low demand for electricity. In this regard the NRC also notes that it also revised this requirement in the final rule to be 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. As a result the final rule provision 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. Accordingly, § 26.205(d)(7) retains, with limited changes, the requirements in § 26.199(g) of the proposed rule.

Work Schedules During Extended Outages

Comments: One commenter, supported by many commenters, argued that during an extended outage, if a functional work group returned to normal operations for a period in excess of two weeks, the elapsed outage period should be recalculated based on when the functional work group returned to an outage work schedule. Therefore, the commenter said the criteria for successive plant outages could be applied to these situations. It recommended revising proposed § 26.199(g) by adding the following to the end of the proposed paragraph: "If an outage is scheduled such that a functional group returns to a normal operational schedule for at least two weeks, the number of days may be restarted from the date outage manning is resumed" [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey

Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC does not agree with the recommendation to revise the requirement in proposed § 26.199(g). The proposed revision would allow licensees to schedule individuals in accordance with the requirements applicable to outages, which the NRC intends for temporary use, for more than 40 weeks of a year. Although a 2 week period of routine scheduling would substantively reduce cumulative fatigue, a repeated sequence of outage scheduling with only 2 weeks of routine scheduling intervening would not provide reasonable assurance that personnel do not become impaired by cumulative fatigue. However, the NRC has revised the proposed rule to include a provision that allows a 7-day extension of the relaxed outage work hour controls for each independent 7-day period during which the individual has worked not more than 48 hours during the plant or security system outage or increased threat condition. Instead of re-calculating the outage period as the commenters suggested, this provision will essentially give "credit" to an individual for every week that the individual works not more than 48 hours per week, thus allowing the outage to be extended. This provision limits the total duration an individual is scheduled at the relaxed limits applicable to outages but provides licensees flexibility in scheduling the periods of high and low levels of work hours and does not require that the 2 weeks of "normal operational scheduling" be consecutive. The provision allowing 7-day extensions of the outage exception is contained in § 26.205(d)(6) of the final rule. The requirements in § 26.199(g) are retained, with limited changes, as § 26.205(d)(7) of the final rule.

11.3.8. Common Defense and Security (§ 26.199(h))

Comments: One commenter recommended that the wording in proposed § 26.199(h) be changed from "..when informed in writing by the NRC..." to "...when informed verbally and followed up in writing by the NRC..." or some similar wording that would allow the NRC to verbally state that the licensee does not have to meet the requirements of this section and at a later date the NRC could provide written confirmation of that verbal statement. This is similar to the approval of exemptions from code requirements [F.G. Burford, Entergy].

NRC Response: The NRC does not agree that verbal approval is needed to facilitate exemption of requirements in § 26.205 of the final rule. If there is a security emergency in which the licensee must immediately react to assure the common defense and security, the licensee need not meet the requirements of § 26.205 (c) and (d) as stated in § 26.207(d). In all other cases that do not meet the condition of § 26.207(d), the NRC considers timely written consent to be adequate. The final rule retains the requirements of proposed § 26.199(h), without change, in § 26.207(c) of the final rule.

11.3.9. Plant Emergencies (§ 26.199(i))

Comments: One commenter praised the clarity contained in proposed § 26.199(i) [F.G. Burford, Entergy].

NRC Response: The comment does not require a response.

11.3.10. Reviews (§ 26.199(j))

Comments: One commenter argued that the periodic reviews are not consistent with the desired information for the annual report described in § 26.197(e). As previously stated, industry suggested the deletion of § 26.197(e). However, if the data requested in § 26.197(e) is valuable to the NRC, then the commenter suggested that the information be moved to § 26.199(j). The documentation of the periodic review would be available to the NRC resident inspector upon request, and there remains no need to provide an annual submittal to the NRC [F.G. Burford, Entergy].

Analysis: The NRC disagrees with the commenter that the periodic reviews required by proposed § 26.199(j) are inconsistent with the reporting requirements of proposed § 26.197. The requirements of proposed § 26.199(j) are now contained in § 26.205(e) of the final rule and the requirements of proposed § 26.197 are contained in § 26.203 of the final rule. The NRC acknowledges that both the reviews and reports required by the final rule focus on the use of waivers and fatigue assessments. However, the NRC considers the differences in the review and reporting requirements to be consistent with the licensee's responsibility for fatigue management and the NRC's oversight of the licensee's performance in this regard. Therefore the NRC has not revised the final rule to eliminate or move the requirements in proposed § 26.197(e).

11.4. Fatigue Assessments (§ 26.201)

Further Development of Fatigue Assessment Requirements

Comment: One commenter stated that an effective practice of fatigue assessments will add a significant dimension to overall fatigue management activities and further extend efforts beyond just a work hour limits policy. The commenter stated that some aspects are already well defined, such as situations where fatigue assessments would be used and some of the procedures (e.g., done by properly trained personnel, free of bias, and with privacy protections). However, the specific details of what will be assessed, how the information is summarized and analyzed, and the interpretation of findings require further development. The commenter suggested that one approach to explore is how fatigue factors are examined in accident investigations. This provides a structured approach to examining the known physiological factors that underlie fatigue and could be extrapolated and tailored for use in the context of the NRC proposed fatigue assessments [Mark Rosekind, Alertness Solutions].

NRC Response: The NRC agrees that implementation guidance for the fatigue assessments requirements for Subpart I would be beneficial. The Nuclear Energy Institute has agreed to develop implementation guidance for Subpart I. The NRC intends to review the implementation guidance and ensure that the guidance addresses fatigue assessments and supports valid assessments that can be practically implemented by supervisors trained in accordance with § 26.29 and § 26.203(c) of the final rule.

Clarification of "Impaired Alertness"

Comment: One commenter also stated that the rule language should provide a clear definition of "impaired alertness" within the meaning of proposed § 26.201(a)(1) to bound the conditions

that trigger the need for initiating a fatigue assessment. The commenter recommended that the following point should be clarified in the final rule: if a covered employee is found to be in a state of impaired alertness, including unintentionally falling asleep on duty (e.g., nodding off), a fatigue assessment should be performed to identify the root cause before management actions are taken such as disciplinary action [Daniel Stenger, NRSG].

NRC Response: The NRC does not agree that the rule language should be revised to further define “impaired alertness” as used in § 26.201(a) of the final rule. Proposed § 26.201(a)(1) would have required a fatigue assessment to be conducted in response to an observed condition of impaired alertness “creating a reasonable suspicion that an individual is not fit to safely and competently perform his or her duties.” This threshold for action is consistent with the requirements for management action in response to possible impairment as described in § 26.77(b)(1) of the final rule. The NRC also notes that the nature of the duties (for example, whether a job is monotonous), and the sensitivity of the job from impairment from fatigue (e.g., whether lapses in attention or degraded cognitive function affect the individual’s ability to perform safely and competently) will affect the criteria for this determination. As a consequence, the NRC believes that the criteria of “reasonable suspicion that an individual is not fit to safely and competently perform his or her duties” adequately defines the conditions that trigger the need for initiating a fatigue assessment. Furthermore, an example such as “unintentionally falling asleep on the job,” may be interpreted as the threshold for performing assessments. Although the NRC agrees that fatigue assessments should be performed in such cases, the onset of impairment from fatigue begins prior to an individual falling asleep and reasonable suspicion of fatigue can occur through observation of other behavioral and cognitive impairments, before sleep onset. Accordingly, the NRC has retained the requirements in proposed § 26.201(a)(1) as § 26.211(a)(1) of the final rule.

Affects of Fatigue Assessment on Rule Implementation

Comment: After recognizing that the fatigue assessment is a valuable element of the rule package, one commenter stated that the time needed to develop and establish a fatigue assessment program, which includes training, may be the most time consuming aspect of implementing this rule. Therefore, industry requested a one year implementation period from the date of approval of the rule [F.G. Burford, Entergy].

NRC Response: The NRC agrees that training of personnel to conduct fatigue assessments may require a one-year period for all personnel to receive the training in the course of their normal training cycle for the FFD program. Accordingly, the NRC intends to establish a one-year implementation period for this provision.

Personnel Authorized to Conduct Fatigue Assessment

Comment: Referencing proposed § 26.201(b), one commenter recommended that the words "Either a supervisor or a staff member of the FFD program, who is...” should be revised to "Either a supervisor or a FFD program staff member, who is ... " to clarify that the supervisor need not be a member of the FFD program to conduct the fatigue assessment [Brian McCabe, Progress Energy].

NRC Response: The NRC agrees that the recommended wording provision more clearly states the individuals authorized to conduct fatigue assessments and has revised § 26.201(b) accordingly. The revised rule provision is contained in § 26.211(b) of the final rule.

12. Subpart J: Recordkeeping and Reporting Requirements

12.1. General Provisions (§ 26.211)

Comments: One commenter stated that the proposed rule contained various new or amended information collection requirements, most of which industry supports [Marvin Fertel, NEI].

NRC Response: These comments do not require a response.

12.2. Recordkeeping Requirements for Licensees and Other Entities (§ 26.213)

No comments addressed this section.

12.3. Recordkeeping Requirements for Collection Sites, Licensee Testing Facilities, and Laboratories Certified by the Department of Health and Human Services (§ 26.215)

No comments addressed this section.

12.4. Fitness-for-Duty Program Performance Data (§ 26.217)

Comments: One commenter stated that industry supports the need for reporting to the NRC certain drug and alcohol-related information as proposed here [Jim Davis, NEI].

NRC Response: These comments do not require a response.

12.5. Reporting Requirements (§ 26.219)

No comments addressed this section.

13. Subpart K: Inspections, Violations, and Penalties

No comments addressed this subpart.

14. Other Comments

14.1. Regulatory Analysis

Requirements are Too Prescriptive

Comment: One commenter, supported by many commenters, stated that the new requirements are needlessly prescriptive and the regulatory analysis fails to justify the rigid approach. According to the commenters, the NRC's Regulatory Analysis Guidelines (§ 4.2, NUREG/BR-0058, Rev. 4) state that requirements should be performance based unless there is good cause for highly prescriptive rules. Therefore, the commenters suggested that the

regulatory analysis should better justify the prescriptive approach. [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: Although the comment was not specific with regard to which particular provisions might be needlessly prescriptive, the NRC did consider this issue during the development of the rule. The NRC agrees that the rule's drug and alcohol testing provisions are prescriptive when compared to some other NRC regulations. This approach was intentional, however, as discussed in the preamble to the proposed rule (e.g., see 70 FR 50451-50452). As discussed there, the prescriptive approach is intended to improve clarity and enhance effectiveness and, in part, is a response to the requests of industry stakeholders. Therefore, the NRC believes there is good cause for the prescriptive approach and that the basis for the approach is adequately justified. The regulatory analysis accounted for the cost of each provision, and also discussed the effects of improved clarity in Section 4.1.2.2.

With respect to the rule's fatigue management provisions, the NRC agrees that it adopted a prescriptive approach for certain work hour limits. This approach addressed stakeholder concerns, as discussed in SECY-01-0113, Fatigue of Workers at Nuclear Power Plants, related to the clarity and enforceability of NRC's regulatory framework concerning worker fatigue. However, the NRC notes that although certain requirements may be prescriptive, the requirements provide licensees substantial flexibility. As discussed in greater detail with respect to other, more specific comments addressing the relevant provisions, the final rule adopts an approach that is more flexible and considerably less prescriptive. The NRC has revised the regulatory analysis to address the more flexible approach.

Regulatory Analysis Does Not Account for Interaction of Requirements

Comment: One commenter, supported by many commenters, stated that the Regulatory Analysis looks at each provision in isolation and does not allow for a comparison of various portions of the draft rule and the interaction of the various requirements. According to the commenters, the Regulatory Analysis was performed on a section-by-section basis, which makes it difficult to compare the incremental impact of each section given the existence of other proposed requirements. Therefore, the commenters stated that the analysis is deficient because it fails to justify that each section included is essential to the rule and multiple layers were not accounted for properly. [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees that the regulatory analysis was conducted on a section-by-section basis but does not agree that the provisions were considered in isolation. In fact, the cost analysis specifically accounted for the effects of interacting provisions as appropriate, both with respect to drug and alcohol provisions and to fatigue management

provisions. Although it is considerably more difficult to analyze the benefits associated with individual provisions that interact with other provisions, the regulatory benefits analysis of the proposed rule's fatigue management provisions (at which the NRC believes this comment was targeted) was informed by a side-analysis (presented as an addendum to the regulatory analysis), which sought to consider the interaction between key provisions. Nevertheless, the NRC has modified the fatigue management provisions that appear in the final rule in response to other public comments. In light of those rule changes, the NRC believes that this comment is not likely to remain a concern to stakeholders.

Justification for Subpart I Costs

Comment: One commenter, supported by many commenters, claimed that the work hour limits and break requirements in the proposed rule had a disproportionately higher cost than the training, self-declaration, and fatigue assessment provisions. Further, the commenters stated that the Regulatory Analysis did not provide a convincing cost justification for these work hour controls. Also, the commenters stated that the Regulatory Analysis included an extensive analysis of the cost of implementing Subpart I, but the justification for the implementation burden was deficient. [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenters. The NRC has modified the fatigue management provisions that appear in the final rule in response to other public comments. In addition, based on insights provided in public comments, the NRC believes that if the proposed fatigue management provisions were not being modified by the final rule then it would be necessary to revise the regulatory analysis to reflect a higher implementation burden associated with certain fatigue management provisions. In light of the rule changes, however, the NRC believes that this comment is not likely to remain a significant concern to stakeholders. In addition, the regulatory analysis has been revised in accordance with the final rule. With respect to the findings of the regulatory analysis for the final rule, the NRC believes there is not a disproportionately higher cost for work hour limits and break requirements than for training, self-declaration, and fatigue assessment provisions.

Disagreement with Safety Goal Evaluation

Comment: One commenter, supported by many commenters, also argued with the Safety Goal Evaluation in section 4.5 of the Regulatory Analysis. According to the commenter, the Safety Goal Evaluation did not fully satisfy the standards set forth in the NRC's Regulatory Analysis Guidelines. Specifically, the commenters stated that in situations where it is not possible to develop adequate quantitative supporting information, "qualitative analysis and perspective" should be provided for the proposed new requirement, and these insights should be "related to the safety goal screening criteria." The commenters argued that the Regulatory Analysis did not address any such criteria. In this regard, the commenter stated that the staff's finding that the proposed changes "may qualify ... as generic safety enhancements because they may affect the likelihood of core damage," and its statement that the rule will reduce the probability of accidents and damages, was cursory and unsubstantiated.

The commenters stated that the Safety Goal Evaluation highlighted the overall lack of rigor and precesion in the entire Regulatory Analysis. The commenter felt that the staff's acknowledgement that its evaluation failed to quantify the "magnitude" of the claimed change in liklihood of core damage, or the claimed added assurance provided by the rule, is significant. Further, the commenter claimed that the generality of the staff's findings undermined the NRC's assertions in the rule package the implementation of Subpart I will "result in substantial non-quantified benefits related to safety and security." [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC's evaluation followed agency guidance in the Regulatory Analysis Guidelines and in Appendix D of the CRGR Charter. Therefore, the NRC disagrees with the comments on the Safety Goal Evaluation and believes that the analysis presented in Section 4.5 of the regulatory analysis was appropriate for this rule. As discussed there, the NRC believes the action is a generic safety enhancement which does not lend itself to a Safety Goal Analysis. The rulemaking provides added assurance that individuals working at nuclear facilities are fit for duty and, consequently, the rule reduces safety and security risks ranging from workplace safety incidents up to radiological damage to the reactor core. A safety goal evaluation generally focuses on the change in likelihood of core damage. However, the magnitude of the change for this rule is not readily quantifiable due to uncertainties regarding the types, frequencies, and results of damage that occurred pre-rule and will occur post-rule. A more dominant effect of the rule will be to reduce the probability of other types of accidents and damages associated with a wide array of acts related to drug and alcohol abuse and fatigue, although this effect is equally difficult to quantify. Because the change in safety associated with the rulemaking cannot be quantified, the rule provisions cannot be compared to the NRC's safety goals. The NRC also disagrees that there was a lack of rigor and precision in the entire regulatory analysis. Nevertheless, in response to other public comments, the NRC has replaced several of the proposed fatigue management provisions (at which the NRC believes this comment was targeted) in the final rule. In light of those rule changes, the NRC believes that this comment is not likely to remain a concern to stakeholders.

14.1.1. Addendum

Comments: In the public meeting, one commenter addressed the Addendum 1 to the Regulatory Analysis, which quantified some of the benefits associated with selected fatigue management provisions in the proposed rule. Industry was confused about the purpose of this addendum and whether the quantitative analysis is considered in the backfit justification of the rule. The commenter did not believe that it should be included in the rule package [Jim Davis, NEI].

One commenter, supported by other commenters, also addressed this issue, expressing disagreement with Addendum 1 to the Regulatory Analysis. Specifically, the commenters stated that the analysis failed to show any correlation between its findings and actual performance and conditions in the commercial nuclear power reactor industry. According to the commenters, this made the "seemingly precise calculations meaningless." The commenters also disagreed with

Addendum 1's conclusions regarding reduced rework. The commenters stated that this conclusion was incorrect because it ignored the many measures in place in the industry, such as use of detailed procedures, supervision and quality assurance measures. [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: It is not the NRC's intent that the quantitative analysis in the addendum be considered in the backfit analysis determination. The addendum was provided only as information related to the rulemaking, as the NRC determined in the regulatory analysis and the backfit analysis that the rulemaking would result in substantial additional benefits beyond those captured in the addendum. The addendum has not been revised to address the final rule and has not been included in the final rulemaking package.

14.2. Backfit Analysis

Comments: Several commenters from industry stated that the backfit analysis for the proposed rule was deficient. The commenters suggested that the backfit analysis did not include a meaningful discussion of the proposed rule's actual improvements in public health and safety. Specifically, the commenters explained that the qualitative statement that each element examined will provide substantial improvement to public health and safety was not supported by facts, and did not consider the diminished impact when other rule provisions are considered. The commenters argued that, considering the rule as whole, the protection of public health and safety will not be diminished if cumulative work hour limits are only applied to security personnel and a flexible approach is used for break requirements. Therefore, The commenters argued that the backfit analysis did not meet the intent of § 50.109 [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

Other commenters supplemented this argument, specifically arguing that the collective work hour limits of the proposed rule should have been subjected to a separate backfitting analysis to assess whether this aspect of the rule would produce a cost-justified substantial increase in safety as required by the NRC's Backfit Rule. The commenters noted that § 50.109(c) requires a backfitting analysis to consider the potential impact of new requirements on plant "operational complexity" and the cost of facility downtime. The commenter argued that because of the "aggregate" backfitting analysis performed for the entire rule, it was not clear that the full impact of the collective work hour limits was considered [Daniel Stenger, NRSG; Brian McCabe, Progress Energy].

NRC Response: The NRC disagrees with the commenters. Although the NRC believes that neither the proposed rule's backfit analysis nor its underlying approach was deficient based on available information, the NRC has gained additional insights from public comments suggesting that the backfit analysis would need to be revised to account for additional operational

complexity if the fatigue management provisions were to be finalized as proposed. However, the NRC has replaced several of the proposed fatigue management provisions at which the NRC believes that comment was targeted in the final rule in response to other public comments. Therefore, the backfit analysis has been revised as appropriate based on the final rule. In light of the rule changes, the NRC believes that it has resolved the concern.

14.3. Paperwork Burden Analysis

Support for Drug and Alcohol Reporting Requirements

Comments: Several commenters from industry found the reporting requirements associated with the drug and alcohol portion of the rule to be appropriate [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: These comments do not require a response.

Paperwork Reduction Act Obligation

Comments: Several commenters argued 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 claimed that the NRC has failed to adequately justify the need for these provisions to provide useful information for making a determination on the adequacy of a facility's fatigue management program and help the NRC assign inspection resources, and has also failed to objectively support its estimate of the burden created on affected licensees. Therefore, the commenters urged OMB to remand proposed § 26.197(e) to the NRC for its further consideration in light of these inadequacies [Marvin Fertel, NEI; Michael Coyle, NEI #49; F.G. Burford; Brian McCabe, Progress Energy; Gregory Halnon, First Energy; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC has reviewed its Paperwork Burden Analysis in light of the comments, and has revised certain burden estimates based on information provided by the commenters as well as additional analysis conducted by the staff. The NRC remains convinced, however, that the information collection requirements in the proposed rule are necessary to ensure that the NRC has the information necessary to effectively implement and enforce the FFD program, including its fatigue management requirements, increase consistency of rule enforcement, increase public confidence, and facilitate rule improvement. Section 11.2.5 of this document provides a detailed discussion of the NRC's justification for including these reporting requirements. (Note that the reporting requirements of proposed § 26.197(e) are now contained in § 26.203(e) of the final rule.)

Clarification of OMB Process

Comment: One commenter also asked the question of how the OMB process and the NRC rulemaking process come together with respect to the reporting provisions [Brian McCabe, Progress Energy].

NRC Response: As described in Section XIII of the Supplementary Information for the Proposed Rule (70 FR 50618-50619), under the Paperwork Reduction Act of 1995, the Office of Management and Budget (OMB) must review and approve all new or amended information collection requirements included in the proposed rule. No information collection may be conducted without OMB approval. Thus, the OMB paperwork burden approval process is a key component of the rulemaking process.

14.4. Regulatory Flexibility Analysis

No comments addressed this analysis.

14.5. Implementation

Implementation Process

Comments: Two commenters requested information about the process if the NRC concurred with alternative means of meeting the rule and changed a significant portion of the rule [Brian McCabe, Progress Energy; David Lochbaum, UCS].

NRC Response: Throughout the rulemaking process, the NRC has made efforts to inform stakeholders of significant changes to the proposed rule that resulted from the NRC's consideration of public comment. For example, the NRC held public meetings in March 2006 to discuss changes to the proposed fatigue management provisions and FFD provisions relating to the construction of power reactors. These meetings provided opportunities for the NRC and stakeholders to exchange their views on the proposed provisions. The NRC also published revised rule text on its website in August and October 2006 for public review and to apprise stakeholders of the status of the rulemaking process. In general, changes to the proposed rule that appear in the final rule are clarifications or extensions of the relevant provisions in the proposed rule and were made in response to public comments on the proposed rule.

Implementation Period

Comments: Commenters stated that a significant amount of work will be required to train workers on the provisions of this rule, and asked how long industry will have to implement the final rule. Several commenters from industry argued that, given the significant changes involved in this rulemaking, 12 months will be required for implementation of a majority of the new requirements once the final rule is published [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

One commenter argued that there is an urgency to push this rulemaking without a thought of the impact on industry. The commenter argued that the implementation of any changes needs to be phased in gradually to give the workforce time to adjust [Daniel Hansen, Individual].

Another commenter asked if the NRC would consider giving the fatigue subpart a different implementation date than the rest of the rule [Dana Millar, Entergy].

NRC Response: The NRC agrees that implementation of the final rule will require time. Therefore, the agency has determined that licensees and other applicable entities may defer implementation of this rule, except for Subparts I and K, until 365 days from the publication of the final rule in the *Federal Register*. Subpart I must be implemented by licensees and other applicable entities no later than 18 months from the publication of the final rule in the *Federal Register*. Additionally, licensees and other applicable entities shall comply with the requirements of Subpart K as of 30 days from the publication of the final rule in the *Federal Register*.

Topics for the Final Rule Package

Comments: One commenter, supported by many commenters, argued that the final rule package must address several issues regarding the implementation process. These issues include:

- Addressing licensees that have work hour limits in their Technical Specifications
- Addressing the process to cancel the security work hour order
- Addressing portions of the Access Authorization Order that may conflict with 10 CFR Part 26

[Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: With regard to the first bullet, as stated in the *Federal Register* notice for the final rule, the implementation period for the rule is 365 days from the date of publication in the *Federal Register*. The NRC considers this period sufficient to support an orderly transition from control of work hours in accordance with order EA-03-038, which requires compensatory measures for the control of work hours for security personnel, and unit technical specification requirements for the administrative control of work hours for personnel performing safety-related functions. The NRC expects that, during this period, licensees will submit applications to amend unit technical specifications to remove requirements pertaining to the administrative control of work hours for personnel performing safety-related functions.

With regard to the 2nd and 3rd bullets, the NRC intends, on verification that licensees have met requirements set forth in the final rule, to rescind the portions of the orders that are superceded by the final rule.

14.6. Other Miscellaneous Comments

Comment: One commenter recommended that the NRC conduct a formal study of this rulemaking [Jim Davis, NEI].

NRC Response: The NRC does not believe that a formal study of this rulemaking is warranted. However, the staff acknowledges that there were numerous lessons learned that will be beneficial for future NRC rulemaking efforts.

Comment: Another commenter proposed a third-party FFD assessment tool to assist the NRC with this rulemaking [Michael Cantor, WayPoint].

NRC Response: The NRC does not endorse third-party products and will continue to follow formal rulemaking processes.

Comment: One commenter fully supported the NRC's efforts to address the self-disclosure of sleep disorders by operators through other regulatory documents such as the Regulatory Guide 1.134, (Medical Evaluation of Licensed Personnel at Nuclear Power Plants) (see 70 FR 50445). The commenter argued that no employee should be afraid to seek treatment for a sleep disorder that can be effectively diagnosed and treated and the NRC should take appropriate steps to ensure that all MROs receive proper training regarding the signs and symptoms of sleep disorders as well as effective treatments. The commenter stated that the NRC should take appropriate steps to see that uniform education and training materials for MROs are developed to ensure that appropriate topics are covered accurately [Darrel Drobnich, NSF].

NRC Response: The NRC agrees that the assessment of sleep disorders for licensed operators should be addressed through Regulatory Guide 1.134, Medical Evaluation of Licensed Personnel at Nuclear Power Plants, and is revising that guidance through a separate effort. The NRC intends to revise the guidance to communicate its expectations that the evaluation considers sleep disorders among the potential factors that can affect the ability of an operator to remain alert. Regarding the commenters recommendation for uniform education and training materials, the final rule establishes training and examination requirements applicable to all individuals subject to the licensees FFD program, and specifically requires licensees to add "knowledge of . . . indications and risk factors for common sleep disorders, shiftwork strategies for obtaining adequate rest, and the effective use of fatigue countermeasures" to the content of their FFD training and examinations. Although it is common for industry groups such as the Nuclear Energy Institute or the Institute for Nuclear Power Operations to voluntarily develop generic guidance documents for common use by licensees, the final rule does not require uniform training materials. The NRC notes that it the licensee's responsibility to develop and ensure the accuracy of training materials to meet these requirements.

14.7. Comments Outside the Scope of the Rulemaking

No comments addressed this issue.

SUPPORTING STATEMENT
FOR
10 CFR PART 26, FITNESS-FOR-DUTY PROGRAM,
Final Rule
(OMB Clearance No. 3150-0146)

COMPLETE REVISION OF 10 CFR PART 26

DESCRIPTION OF THE INFORMATION COLLECTION

Part 26 of Title 10 of the Code of Federal Regulations contains the Nuclear Regulatory Commission's requirements and standards for the establishment, implementation, and maintenance of fitness-for-duty (FFD) programs. The Part 26 requirements and standards apply to the following: licensees who are authorized to operate a nuclear power reactor; licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under 10 CFR Part 70; corporations, firms, partnerships, limited liability companies, associations, or other organizations that obtain a certificate of compliance or an approved compliance plan under 10 CFR Part 76, but only if the entity elects to engage in activities involving formula quantities of SSNM; and contractor/vendors (C/Vs) who implement FFD programs or FFD 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 10 CFR Part 26. Certain more limited information collection requirements apply to the following: holders of a combined operating license under 10 CFR Part 52, Subpart C, before the Commission has made the finding under §52.103, combined license applicants who have received authorization to construct under §50.10(e)(3), construction permit holders (under 10 CFR Part 50), construction permit applicants who have received authorization to construct under §50.10(e)(3), and holders of manufacturing licenses (under 10 CFR Part 52).

The 103 operating nuclear power reactors in the United States are located at 65 facilities, with each facility consisting of one or more reactor units. Several facilities may be owned and operated by the same licensee. A licensee may administer the FFD activities at one or more facilities through a single FFD program (i.e., the same FFD policy and procedures apply, a single FFD staff administers the drug and alcohol testing program, one medical review officer performs the MRO functions, etc.) This information collection supporting statement estimates the burden associated with reporting and recordkeeping activities for 52 FFD programs, as follows: 28 FFD programs for 65 facilities with a total of 103 nuclear power reactors; 2 fuel-cycle facilities; 2 contractor/vendors; 1 mixed-oxide fuel fabrication facility; and 19 construction FFD programs.

The fatigue management provisions in Subpart I of Part 26 apply to a smaller group of licensees and other entities, and be implemented through 30 programs (28 FFD programs covering nuclear power reactors and 2 programs covering contractor/vendors, who are required to implement fatigue management provisions if their personnel provide services to nuclear power reactors in the appropriate job duty groups).

With respect to nuclear power plant construction, Part 26 requires all individuals who, at the location where the nuclear power plant will be constructed and operated, serve as a security officers, perform quality assurance activities, are designated by a licensee or other entity to perform fitness monitoring under Subpart K, of have responsibility for determining that all or parts of inspections, tests, and analyses have been successfully completed, to be subject to a

FFD program that meets all the requirements of Part 26 except Subparts I and K. Those individuals who perform construction activities, defined as the tasks involved in building the safety-related structures, systems, and components (SSCs) of a nuclear power reactor that are required to be described in the final safety analysis report (FSAR), including receiving, evaluating, assembling, installing, constructing, and testing the safety-related SSCs, must either be subject to an FFD program that meets the requirements of Subpart K or an FFD program that meets all of the requirements of Subparts A through H of Part 26. Licensees and other entities may either subject these individuals to random drug and alcohol testing and behavioral observation, or they may subject them to a fitness monitoring program. This analysis assumes that 12 of the 19 FFD programs at nuclear power plant construction sites will be closely associated with FFD programs at existing nuclear power reactors and will adopt random testing and behavioral observation, and that the remaining 7 FFD programs will adopt fitness monitoring.

The rule described in this clearance package constitutes a complete revision of Part 26.

The recordkeeping and reporting requirements in the rule include provisions requiring licensees and other entities to develop and maintain policies and procedures; retain records of training, qualification and authorization of individuals; retain records related to drug and alcohol collections and tests; retain other records related to the collection, testing and review processes; report FFD program performance and significant violations, program failures and testing errors; and retain records related to employee assistance programs. Records and reports are also required under the fatigue management component of the FFD program. The recordkeeping and reporting requirements are mandatory for licensees and other entities subject to the rule. The NRC uses the reports to assess the effectiveness of FFD programs for those subject to the rule, and whether the provisions are implemented as the NRC intends.

The recordkeeping and reporting requirements of Part 26 are largely centralized into Subpart I - Managing Fatigue (§26.203) and Subpart N - Recordkeeping and Reporting Requirements (§§26.711-26.719), and Subpart K - FFD Programs for Construction (§§ 26-405, 26.411, and 26.417). Cross references to the recordkeeping and reporting requirements in Subpart N appear in other related portions of the Part 26 rule, but these cross references do not constitute additional recordkeeping or reporting requirements.

The burden for the recordkeeping and reporting requirements is captured against the specific requirement rather than in the general sections for recordkeeping and reporting (primarily §§26.713, 26.715, 26.717, and 26.719) to facilitate determining the burden impacts when a specific requirement is modified.

The estimated annual burden for the final rule of 738,129 hours for one-time recordkeeping (annualized), annual recordkeeping, and annual reporting exceeds NRC's estimate for the previous rule of 61,143 hours (as estimated in the final clearance renewal published in the Federal Register on October 3, 2005 (70 FR 57625)) by 676,986 hours. Of this,132,965 hours are for one-time recordkeeping requirements. The increase in burden is explained by several differences between the former rule and the final rule. In particular, the final rule creates more detailed requirements pertaining to the FFD authorization process for individuals to ensure consistency with the NRC's access authorization requirements for nuclear power plants established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003. The final rule includes more detailed requirements pertaining to the specimen collection and testing process, to increase consistency with other relevant Federal rules and guidelines, including the U.S. Department of Health and Human Services (DHHS)

Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines). The final rule also includes a new subpart addressing requirements for HHS-certified laboratories, adds requirements for confirmatory drug and alcohol testing and verification testing, and expands and makes more explicit the requirements for licensee testing facilities. The burden estimate for the final rule captures significant third-party collections associated with the reporting and recordkeeping associated with the drug and alcohol testing activities that were not captured in the previous rule. Experience from the implementation of the current FFD rule, information obtained from stakeholders, and information obtained from sources such as the DHHS National Laboratory Certification Program has led the NRC to revise its estimates of the burden of certain activities. The final rule contains new fatigue management provisions that include reporting and recordkeeping burdens that were not part of previous estimates. The final rule also contains new requirements for an FFD program for construction that includes reporting and recordkeeping burdens, some of which were not part of previous estimates, for an estimated 19 new FFD programs involving individuals constructing new nuclear power reactors.

A. JUSTIFICATION

As provided by the Atomic Energy Act (AEA), as amended, and the Energy Reorganization Act of 1974, in order to provide for the protection of public health and safety, including the radiation safety of workers and the general public, and the common defense and security, the NRC licenses and regulates the owners and operators of nuclear power plants, entities that are authorized to construct nuclear power plants, entities that are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM), and holders of combined licenses and manufacturing licenses under 10 CFR Part 52. NRC provides in 10 CFR Part 26 that the owners and operators of nuclear power plants, entities that are authorized to construct nuclear power plants, entities that are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM), and holders of combined licenses and manufacturing licenses under 10 CFR Part 52 must ensure that certain individuals whose job duties require them to have access to the protected areas of nuclear power plants or to perform certain specified duties are subject to fitness-for-duty programs.

The fitness-for-duty programs must provide reasonable assurance that such individuals are trustworthy, reliable, and fit for duty, as demonstrated by the avoidance of substance abuse; are not under the influence of legal or illegal drugs or alcohol, or mentally or physically impaired from any cause that in any way adversely affects their ability to safely and competently perform their duties; and that the effects of fatigue and degraded alertness on individual's abilities to safely and competently perform their duties are managed commensurate with maintaining public health and safety. The fitness-for-duty programs must also provide reasonable measures for the early detection of individuals who are not fit to perform the job duties that require them to be subject to the program and provide reasonable assurance that the workplaces subject to Part 26 are free from the presence and effects of illegal drugs and alcohol.

The reporting and recordkeeping provisions of 10 CFR Part 26 (listed below) support the following important functions of the fitness-for-duty program: (1) they provide a record of the authorization process through which individuals become authorized to have or maintain access to the protected areas of nuclear power plants or to perform certain specified duties; (2) they provide a record of the drug and alcohol testing procedures and the chain of custody of samples to be available in case a determination of fitness is necessary and/or if a determination of fitness is challenged under either the procedures specified by Part 26 or through litigation; and (3) they provide records for both self-assessments by licensees and other entities and

audits and inspections by the NRC of FFD programs. Because fitness-for-duty programs are required for key functions at nuclear power reactors, and because FFD programs can impose significant consequences on individuals who violate the FFD requirements, access to detailed records concerning the individuals covered by the programs is particularly important.

1. Need for and Practical Utility of the Collection of Information

These information collections are necessary to properly manage fitness-for-duty programs. Licensees must perform certain tasks, maintain records, and prepare reports to demonstrate their fulfillment of regulatory requirements. Certain events are of such significance that they must be reported to the NRC. Collection of this information pertaining to significant fitness-for-duty events is necessary to permit timely evaluation of events that might become problems and that may require a timely response by the NRC staff to ensure that the health and safety of the public is not endangered.

Section 26.9, Specific Exemptions, provides that the Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 26, and specifies that exemption requests must meet the provisions of 10 CFR 50.12 or 10 CFR 70.17.

This reporting requirement is necessary to ensure that licensees seeking exemptions from the requirements of 10 CFR Part 26 provide the information needed to enable the NRC to determine if the criteria for granting an exemption listed in §§50.12 or 70.17 have been met.

Section 26.11, Communications, provides that all communications, applications, and reports may, except where otherwise specified, be sent to the Commission either by mail or, where practicable, by electronic submission.

This section contains no information collections and merely specifies acceptable means for submitting information under Part 26.

Section 26.27, Written Policy and Procedures

> Paragraph 26.27(a) requires each licensee or other entity subject to Part 26 to establish, implement, and maintain written policies and procedures designed to meet the general performance objectives and specific requirements of Part 26.

The written FFD policy and procedures are the primary means by which a licensee or other entity communicates its FFD policy and procedures to individuals who are subject to the policy and procedures. These requirements are also necessary to ensure that the due process rights of individuals are protected by informing them in sufficient detail about licensee FFD rules, what is expected of them, and what consequences may result from a lack of adherence to the FFD policy. Because the consequences of lack of adherence to the FFD policy can be very severe, including inability to perform certain functions in the industry, it is particularly important that all individuals who are potentially subject to them know their details. The one-time burden for the initial development of the policy is shown under this paragraph.

> Paragraph 26.27(b) requires the current FFD policy statement to be readily available to all individuals subject to the policy and specifies the minimum mandatory contents of the written policy statement, which include a description of the consequences of prohibited actions, reporting for testing requirements, alcohol abstinence requirements, the factors

that could affect fitness-for-duty, employee assistance programs, and responsibilities to report FFD violations or concerns.

This requirement ensures that the FFD policy is included and maintained in the licensee's compendium of policies, where it can be reviewed by any individual who is subject to the FFD program. The burden for incorporating and maintaining the policy statement in the policy compendium is shown under this paragraph.

Paragraph 26.27(c) requires each licensee or other entity to prepare, implement, and maintain written procedures that describe the methods to be used in implementing the FFD policy and requirements of Part 26. It specifies the mandatory contents of the procedures, including procedures to be used in testing for drugs and alcohol; procedures for protecting the employee and the integrity of the specimen; procedures to ensure that the test results are valid and attributable to the correct individual; procedures to describe the immediate and follow-up actions that will be taken in those cases when individuals are determined to have been involved in the use, sale, or possession of illegal drugs, consumed alcohol to excess as determined by a test that measures blood alcohol content (BAC), attempted to subvert the testing process, refused to provide a specimen, or had a legal action taken relating to drug or alcohol consumption; procedures to ensure that individuals who are called in to perform an unscheduled working tour are fit to perform the task assigned; and procedures to describe the process to be followed if an individual's behavior raises a FFD concern.

This requirement is necessary to ensure that individuals who manage and implement the FFD program and individuals subject to that FFD program are provided specific detailed information about how testing for the use of drugs and alcohol are conducted, including the cutoff levels used in drug and alcohol testing and the time periods within which an individual who has been selected for random testing must report to the collection site; how and why behavioral observation is conducted; and how authorization is granted, maintained, reinstated, and withdrawn. They also provide a description of programs that are available to personnel desiring assistance in dealing with drug, alcohol, or other problems that could adversely affect their performance. These requirements also partially meet the legal necessity of protecting the due process rights of individuals who are subject to Part 26, and also proving "prior notice" and having it documented for evidence in legal proceedings. The one-time burden for initial preparation of the procedures and the recurring burden for updating and amending the FFD procedures are shown under this paragraph.

Paragraph 26.27(d) specifies that the NRC may at any time review the written policy and procedures to ensure that they meet the performance objectives of Part 26.

This requirement is necessary to ensure that the NRC can carry out timely evaluations of whether the policies or procedures of particular licensees or other entities fail to include necessary FFD program elements or do include elements that are not consistent with the requirements of an effective FFD program. The recurring burden for providing the policy or procedure to the NRC, when it is reviewed as part of the inspection process or when it is otherwise requested, is shown under this paragraph.

Recordkeeping requirements for current policies and procedures under §26.27(b), (c), and (d) are established by that section. Recordkeeping requirements for superseded procedures are established by §26.715(b)(4).

Section 26.29, Training

Paragaraph 26.29(a) requires licensees and other entities to ensure that individuals who are subject to Part 26 have specified knowledge and abilities.

The one-time burden for developing a training course, including the development of an initial question bank, that reflects the requirements of Part 26, including both drug and alcohol testing and fatigue management provisions, is shown under this paragraph.

Paragraph 26.29(b) requires all individuals subject to Part 26 to demonstrate successful completion of training by passing a comprehensive examination about the knowledge and abilities specified in §26.29(a)(1) through (10).

The one-time burden of testing all personnel subject to the FFD program when the Part 26 rule becomes effective is shown under this paragraph, and includes the burden of FFD management personnel to prepare the computerized examination from the question bank, to grade the examinations, to notify individuals of results, and to maintain records of the examination results.

In addition, the recurring burden of testing individuals who become subject to the FFD programs of licensees or other entities at a later time is shown under this paragraph. The recurring burden includes the time required for preparation of the computerized examination, to grade the examinations, to notify individuals of results, and to maintain records of the examination results.

Paragraph 26.29(c)(1) requires training for all personnel to be completed before FFD program authorization may be granted to a licensee or other entity.

The one-time burden of providing training to those staff of licensees and other entities when the Part 26 rules become effective is shown under this paragraph.

Paragraph 26.29(c)(2) requires refresher training to be completed on a nominal 12-month frequency, and allows individuals who pass a comprehensive annual examination to forgo refresher training.

The recurring burden of providing refresher training, which includes training for new staff who are hired after the initial training, and administering a comprehensive annual examination, is shown under this paragraph. The burden of keeping FFD training updated, maintaining a question bank and developing examinations to be given to new staff and to existing staff as an alternative to refresher training, is also shown under this paragraph.

Paragraph 26.29(d) allows a licensee or other entity to accept the training of individuals who have been subject to another training program that meets the requirements of this section and who have, within the previous 12 months, either had initial or refresher training or have successfully passed a comprehensive examination specified in §26.29(b).

The requirements in §26.29 are necessary to ensure that individuals assigned to activities within the scope of Part 26 are provided with appropriate training so that they understand the methods used to implement the FFD policy, the personal and public health and safety hazards associated with abuse of drugs or alcohol, the effects of prescription and over-the-counter drugs and dietary conditions on drug test results, their roles and responsibilities in the

implementation of the fitness-for-duty program, the role of the Medical Review Officer (MRO), and the Employee Assistance Program (EAP) services available; that they are sufficiently skilled to detect conditions that arise from abuse or presence of drugs or alcohol, and that they know the proper action to be initiated. Licensees or other entities are required to prepare appropriate examination questions and maintain a question bank, develop and administer examinations, assess whether individuals pass or fail the examinations, and communicate examination results to the individuals and to the FFD program managers. FFD programs are expected to administer and grade examinations and communicate results by means of their computer networks. These requirements also partially meet the legal necessity of providing "prior notice" and having it documented (by training and examination records) for evidence in legal proceedings.

Recordkeeping requirements for §26.29 are established by §26.713(b)(1).

Section 26.31, Drug and alcohol testing

Paragraph 26.31(a) requires licensees and other entities to implement drug and alcohol testing programs for individuals who are subject to this subpart.

The reporting and recordkeeping requirements associated with the drug and alcohol testing programs are described under subsequent subparts of Part 26, including Subparts E, F, G, H, and N.

Paragraph 26.31(b)(1)(i) requires licensees and other entities to complete background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel before their assignment to tasks directly associated with administration of the FFD program. The background investigations, credit and criminal history checks, and psychological investigations conducted under a nuclear power plant's access authorization program [10 CFR Part 25] are acceptable to meet the requirement. Section 26.31(b)(1)(i) requires the credit and criminal history checks and psychological assessments to be updated nominally every 5 years.

Paragraph 26.31(b)(1)(v) requires FFD program personnel to 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 are also subject to behavioral observation.

These requirements are necessary to ensure the honesty and integrity of persons who directly administer the FFD program. Assuring their fitness for duty is important because the FFD program determines those persons who are granted unescorted access to protected areas in nuclear power plants or who possess, use, or transport formula quantities of SSNM. The written procedures for the behavioral observation program are part of the FFD program procedures required to be developed by §26.27.

Recordkeeping requirements for §26.31(b)(1)(i) are established by §26.713(f). The current rule, by relaxing the previous requirement in Section 2.3(2) of Appendix A to Part 26 that requires background checks and psychological evaluations of FFD program personnel to be conducted at least once every three years and providing instead that credit and criminal history checks and updated psychological assessments must be conducted nominally every 5 years, reduces the number of such records that are created. However, the retention period for such records is not affected.

Paragraph 26.31(c) requires licensees and other entities to implement drug and alcohol testing programs that administer tests under the following conditions:

(1) Pre-access. In order to grant initial, updated, or reinstated authorization to an individual;

(2) For cause. In response to an individual's observed behavior or physical condition indicating possible substance abuse or after receiving credible evidence that an individual is engaging in substance abuse as defined in §26.5.

(3) Post-event. The licensee takes action as soon as practical after an event involving a human error that was committed by an individual who is subject to Part 26, where the human error may have caused or contributed to the event. The licensee or other entity shall test the individual(s) who committed the error(s), and need not test individuals who were affected by the event but whose actions likely did not cause or contribute to the event. The individual(s) who committed the human error(s) shall be tested if the event resulted in: (i) a significant illness or personal injury to the individual to be tested or another individual, which within 4 hours after the event is recordable under the Department of Labor standards contained in 29 CFR 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; (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 and security of the plant;

(4) Followup. As part of a followup plan to verify continued abstention from the use of substances covered under Part 26.

(5) Random. On a statistically random and unannounced basis such that all individuals in the population subject to testing have an equal probability of being selected and tested.

No records are required by this paragraph. Records of the drug and alcohol testing programs are required in Subparts C, D, E, F, G, and N of Part 26.

Paragraph 26.31(d)(1)(i)(A),(B) and (C) allows licensees and other entities to add other drugs to the panel of substances for testing, but only if the additional drugs are listed in Schedules I-V of section 202 of the Controlled Substances Act; the licensee or other entity establishes appropriate cutoff limits for these substances; and the licensee or other entity establishes rigorous testing procedures for these substances, so that the MRO can evaluate the use of these substances.

This requirement is necessary to ensure that adequate procedures are established for the testing of additional drugs. Those procedures are additions to the FFD procedures required to be developed under §26.27.

Paragraph 26.31(d)(1)(i)(D) allows licensees and other entities to conduct an analysis for a drug or drug metabolite not listed in §26.31, if 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. Certification 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.

This section allows licensees and other entities to add to the panel of drugs for which testing is required in §26.31(d)(1). It eliminates the reporting requirement in the previous Section 1.1(2) in Appendix A to Part 26 that required licensees to obtain written approval from the Commission to test for additional drugs. However, the current rule requires that the assay and cutoff levels to be used in testing for the additional drugs be certified in writing as scientifically sound and legally defensible by an independent forensic toxicologist. This requirement is necessary to ensure that the NRC can verify that the assays and cutoff levels are appropriate.

The licensee or other entity is required to maintain a copy of each certification under §26.31(d)(1)(i)(D). Recordkeeping requirements for §26.31(d)(1)(i)(D) are established by §26.713(g).

Paragraph 26.31(d)(1)(ii) allows licensees and other entities that are conducting post-event, follow-up, or for cause testing to test for drugs listed on Schedules I-V of secton 202 of the Controlled Substances Act [21 U.S.C. 812] that an individual is suspected of having abused. If the drug or metabolites tested are not included in the FFD program's drug panel, the assay and cutoff levels to be used must be certified in writing by an independent qualified forensic toxicologist in accordance with paragraph §26.31(d)(1)(i)(D).

Paragraph 26.31(d)(1)(iii) requires licensees or other entities to document and describe the additional drugs for which testing will be performed in written policies and procedures.

This section allows licensees and other entities to add to the panel of drugs for which testing is required in §26.31(d)(1). It ensures that the NRC can verify that the assays and cutoff levels used in testing for the additional drugs are scientifically sound and legally defensible by requiring an independent forensic toxicologist to perform this evaluation and so certify in writing.

The licensee or other entity is required to maintain a copy of each certification under §26.31(d)(1)(ii). Recordkeeping requirements for §26.31(d)(1)(ii) are established by §26.713(g).

Paragraph 26.31(d)(3)(ii) provides that licensees and other entities may conduct validity screening and initial validity and drug tests of urine aliquots to determine which specimens are valid and negative and need no further testing, provided that the licensee's or other entity's staff possesses the necessary training and skills for the tasks assigned, the staff's qualifications are documented, and adequate quality controls for testing are implemented.

This requirement is necessary to ensure that validity screening and initial validity and drug tests of urine aliquots are performed correctly. Documentation of the qualifications of the personnel

of licensee testing facilities and quality controls for testing are addressed under Subpart F, "Licensee Testing Facilities," §§26.125, 26.127, 26.129, and 26.137.

Paragraph 26.31(d)(3)(iii)(A) requires a licensee or other entity that uses more stringent cutoff levels than the cutoff levels specified in §26.163 to document the cutoff levels in any written policies and procedures in which cutoff levels for drug testing are described.

Paragraph 26.31(d)(3)(iii)(C) requires the scientific and technical suitability of more stringent cutoff levels to be evaluated and certified, in writing, by a forensic toxicologist, unless the HHS Guidelines are revised to lower the cutoff levels used for the drug or drug metabolites in Federal workplace 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 the implementation of the final rule.

These requirements are necessary to ensure that individuals receive prior notice of the cutoff levels that are used, and that those cutoff levels are certified by an appropriate expert as meeting the criteria of scientific and technical suitability. The cutoff levels used in a licensee or other entity's testing program are available to individuals subject to the FFD program through the written FFD program policies developed pursuant to §26.27. Recordkeeping requirements for FFD policy and procedures are described under §26.27. The licensee or other entity is required to maintain a copy of each certification under §26.31(d)(3)(iii)(C).

Recordkeeping requirements for §§26.31(d)(3)(iii)(A), and 26.31(d)(3)(iii)(C) are established by §26.713(g).

Paragraph 26.31(d)(6) specifies that specimens collected under NRC regulations may only be designated or approved for testing as described in Part 26 and may not be used to conduct another analysis or test without the written permission of the donor.

This requirement is necessary to ensure that specimens are not used for such testing as DNA testing, serological typing, or other forms of genetic or medical tests for diagnostic or specimen identification purposes without the express written permission of the donor.

Recordkeeping requirements for the third-party collection under §26.31(d)(6) are established by this section.

Section 26.33, Behavioral observation, requires all individuals who are subject to Part 26 to report FFD concerns about other individuals subject to this part to the entity designated in the FFD policy.

This section is necessary to increase the likelihood that if impairment or other adverse behaviors are detected they will be brought to the attention of the licensees or other entities who are subject to the rule so that they can be appropriately addressed. The burden for third-party reports of FFD concerns is covered under this section. Actions in response to reports of FFD concerns are taken under §26.31(c)(2), which provides that licensees and other entities shall administer drug and alcohol tests for cause, in response to any observed behavior indicating possible substance abuse or after receiving credible information that an individual is abusing drugs or alcohol, and under §26.211(a)(1), which provides for fatigue assessments in response to an observed condition of impaired alertness creating a reasonable suspicion that an individual is not fit to safely and competently perform his or her duties. Records of reports

received pursuant to §26.33 are maintained as part of the records of for-cause tests under §§26.31 or 26.211.

Recordkeeping requirements, including the third-party burden for the initial behavioral observation reports, for §26.33 are established by §§26.203(d)(5) or 26.713(a)(2).

Section 26.35, Employee assistance programs

> Paragraph 26.35(a) requires each licensee and other entity to maintain an employee assistance program (EAP) to 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.

This requirement is necessary to define the scope and activities of the EAP. The written description of the EAP program forms part of the FFD program policy and procedures to be developed pursuant to §26.27. The burden for the EAP program procedures is covered under this section.

> Paragraph 26.35(c) requires the EAP staff to 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. Licensees and other entities are prohibited from requiring the EAP to routinely report the names of individuals who self-refer to the EAP or the nature of the assistance the individuals sought. However, if EAP personnel determine that an individual poses or has posed an immediate hazard to himself or herself or others, EAP personnel are required to 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 are reportable under §26.719(b)(1) through (b)(3).

The EAP program helps to prevent harm through early intervention. This requirement is necessary to ensure confidentiality for individuals who seek EAP services, thus encouraging use of the EAP; except if the individual waives the right to privacy in writing or if EAP personnel determine that the individual poses or has posed an immediate hazard to himself or others. The requirement that the individual waive the right to privacy in writing is necessary to ensure that there is a clear record of the waiver. The requirement that the EAP staff inform the FFD program management if the EAP personnel determine that the individual poses or has posed an immediate hazard to himself or others is necessary to increase the likelihood that impairment and other adverse behaviors are appropriately addressed by the licensees and other entities who are subject to the rule.

Recordkeeping requirements for §26.35(a) policy and procedures are established by this section and by §26.27(a). Recordkeeping requirements for §26.35(c) third-party collections for the written waiver by the individual and the communications between the EAP and FFD program management are established by this section.

Section 26.37, Protection of information

Paragraph 26.37(a) requires each licensee or other entity subject to Part 26 that collects personal information on an individual for the purpose of complying with Part 26 to establish and maintain a system of files and procedures to protect the personal information.

The one-time burden to confirm that the FFD files and procedures are adequate to protect personal information is covered under this section.

Paragraph 26.37(b) requires each licensee or other entity to obtain a signed consent that authorizes the disclosure of personal information to persons other than the subject or his or her representative, assigned MROs and MRO staff, NRC representatives, appropriate law enforcement officials under court order, licensee or other entity personnel who have a need to have access to the information to performi their assigned duties under the FFD program, the presiding officer in judicial or administrative proceedings initiated by the individual, persons deciding under review in §26.39, and other persons pursuant to court order.

Paragraph 26.37(b)(1) requires an individual to designate in writing his or her representative for specified FFD matters.

This third-party collection is required if an individual desires representation by a union official, attorney, or other person with a need to review personal information about the individual. The one-time burden to confirm that the signed consent and designation of a personal representative have been obtained is covered under this section.

Paragraph 26.37(c) requires disclosure to other licensees or entities who are legitimately seeking the information as required by Part 26 for authorization decisions and who have obtained a signed release from the subject individual.

Paragraph 26.37(d) requires the FFD program, including the collection site, HHS-certified laboratory, substance abuse expert, or MRO, upon receipt of a written request by the subject individual or his or her designated representative, to 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. This paragraph also requires the licensee or other entity to obtain records related to the results of any relevant laboratory certification, review, or revocation-of-certification proceeding from the HHS-certified laboratory and provide them to the subject individual or his or her designated representative upon request.

These third-party collection requirements are necessary to ensure the protection of personal information collected and maintained about individuals, and to ensure that such information is not disclosed to persons other than assigned MROs, other licensees legitimately seeking the information as required by Part 26 for employment decisions and who have obtained a release from current or prospective employees or C/V personnel, NRC representatives, appropriate law enforcement officials, the individual subject or his or her representative, or those licensee personnel who have a need to have access to the information in performing assigned duties.

Recordkeeping requirements for §§26.37(c) and (d) are established in this section.

Recordkeeping requirements for §26.37(b) are established by §26.713(a)(3).

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

Paragraph 26.39(a) requires each licensee and other entity subject to this subpart to establish procedures for the review of a determination that an individual has violated FFD policy.

Paragraph 26.39(b) requires that the procedures for the review of a determination that an individual has violated FFD policy provide for giving notice to the individual of the grounds for the determination that the individual has violated the FFD policy and provide for an opportunity for the individual to respond and submit additional information.

These one-time requirements are necessary to ensure that there are written procedures that specify how each FFD program ensures that the criteria for determining that an individual has violated FFD policy have been met and provides individuals with a specified process for reviewing and appealing determinations that the individual has violated FFD policy. The requirements are necessary to ensure that the due process rights of individuals who are subject to the rule are protected by informing them with sufficient detail about licensee review procedures, what is expected of the individual, and what consequences may result from a lack of adherence to the policy. The requirements also partially meet the legal necessity of proving "prior notice" and having it documented for evidence in legal proceedings.

Recordkeeping requirements for §§26.39(a) and (b) are established by §26.715(a).

Paragraph 26.39(d) requires that if a review of a determination that an individual has violated FFD policy finds in favor of the individual, the licensee or other entity must update the relevant records to reflect the outcome of the review and delete or correct all information found to be inaccurate.

This third-party collection requirement is necessary to ensure that the records of licensees and other entities do not contain incorrect information concerning FFD determinations pertaining to particular individuals. An increase in the number of transient personnel who work solely in the nuclear industry but who travel from site to site and work at several different sites has led to increased information sharing among licensees and C/Vs about individuals in the workforce. This requirement helps to ensure that incorrect information does not enter and proliferate throughout this information-sharing network.

Recordkeeping requirements for §26.39(d) are established by §26.713(a)(2).

Paragraph 26.39(e) requires that 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 by §26.39 is provided to the individual.

The requirements are necessary to ensure that individuals who are subject to the rule are protected by informing them with sufficient detail about licensee review procedures, what is expected of the individual, and what consequences may result from a lack of adherence to the policy. The requirement also partially meets the legal necessity of proving "prior notice" and having it documented for evidence in legal proceedings.

Recordkeeping requirements for §26.39(e) are established by §26.713(a)(2).

Section 26.41, Audits and corrective action

Paragraph 26.41(a) requires licensees and other entities to ensure that the FFD program elements 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 upon whom the licensee or other entity and its C/Vs rely is audited and corrective actions are taken to resolve any problems identified.

Paragraph 26.41(b) requires licensees and other entities to ensure that the FFD program is audited as needed, and at least nominally every 24 months.

Paragraph 26.41(c)(1) requires licensees and other entities to ensure that 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, are audited on a nominal 12-month frequency.

The burden for documenting audit records is shown under §26.41(f).

Paragraph 26.41(d) requires contracts by licensees or other entities with C/Vs and HHS-certified laboratories to reserve the right of licensees to review all information and documentation that is reasonably relevant to audits of FFD program elements provided by C/Vs, the program elements of any C/Vs that are accepted by the licensee or other entity, and the programs of HHS-certified laboratories, and to obtain copies of and take away any documents 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.

Paragraph 26.41(f) requires the results of any audits required by §§26.41(a), (b), and (c) to be documented and reported to senior corporate and site management. C/Vs who have licensee-approved FFD programs must provide the licensees to whom they provide services with copies of the audit report.

Paragraph 26.41(g) allows licensees and other entities to jointly conduct audits or to accept audits conducted by other licensees, but requires them to review audit records and reports to identify any areas that were not covered by the shared or accepted audit and to maintain a copy of the shared audit and inspection records, including findings, recommendations, and corrective actions.

These requirements for audit documentation, maintenance of audit records, and access to audit information are necessary to help ensure identification and resolution of program weaknesses and to help licensees and other entities, including C/Vs and HHS-certified laboratories, determine what corrective actions are necessary and carry out necessary corrective actions. The requirements help to ensure that necessary information is available for NRC inspections.

Third-party collection requirements for obtaining copies of audit records under §26.41(d) and distribution of audit records and reports to management under §26.41(f) and (g) are established in these sections.

Recordkeeping requirements for retention of audit records in §§26.41(f) and (g) are established by §26.713(b)(2).

Section 26.53, General Provisions

> Paragraph 26.53(d) requires the FFD program of a licensee or other entity that is seeking to grant authorization to an individual who is maintaining authorization under another FFD program to ensure that the program elements to which the individual is subject under the transferring FFD program remain current.

This third-party collection requirement requires communications between the two FFD programs to ensure that the necessary information is transferred between them concerning the individual.

> Paragraph 26.53(e)(2) requires a C/V to inform a licensee or other entity if the C/V's FFD program denies or unfavorably terminates an individual's authorization and the individual is performing any duties for the 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). The licensee or other entity is required to deny or unfavorably terminate the individual's authorization to perform those duties on the day that it receives information from the C/V, or to implement the process in §26.69 to maintain the individual's authorization.

This third-party collection requirement requires communications between the C/V and the licensee or other entity to ensure that the necessary information is transferred between them concerning the individual.

> Paragraph 26.53(g) requires the licensees and C/Vs specified in §26.4(a) and, as applicable, (d) to identify any violation of any requirement of Part 26 to any licensee who has relied on or intends to rely on the FFD program element that is determined to be in violation of Part 26.

This third-party collection requirement requires communications between the C/V and the licensee or other entity to ensure that the necessary information is transferred between them concerning the violation.

> Paragraph 26.53(h) requires licensees and other entities to obtain the knowledge and written consent of the subject individual before initiating any actions under Subpart C [Granting and Maintaining Authorization]. The individual may withdraw consent at any time. If consent is withdrawn, the licensee or other entity may not initiate any elements of the authorization process that were not in process at the time the consent was withdrawn but may conplete and document any elements in progress at the time consent is withdrawn. The licensee or other entity is required to record the individual's application for authorization; withdrawal of consent; the reason given for the withdrawal, if any; and any pertinent information gathered from the elements that were completed. The licensee or other entity shall inform the individual that withdrawal of consent will withdraw the individual's current application for authorization; and other licensees and entities will have access to information documenting the withdrawal.

This third-party collection requirement requires the licensee or other entity to obtain and retain a written consent from the individual.

Paragraph 26.53(i) requires licensees and other entities to inform, in writing, any individual who is applying for authorization that the following actions are sufficient cause for denial or unfavorable termination of authorization: refusal to provide written consent for the suitable inquiry; refusal to provide or falisification of any personal information required under Subpart C of Part 26; refusal to provide written consent for the sharing of personal information with other licensees or C/Vs; and failure to report any legal actions, as defined by §26.5.

This third-party collection requirement requires the licensee or other entity to provide a written notice to the individual.

Section 26.55, Initial Authorization

Paragraph 26.55(a)(1) requires the licensee or other entity to obtain and review a self-disclosure and employment history from an individual before granting authorization to the individual.

Paragraph 26.55(a)(2) requires the licensee or other entity to complete a suitable inquiry before granting authorization to the individual.

Requirements for the contents of the self-disclosure and employment history are established by §26.61. These requirements are necessary to help provide reasonable assurance that any individual who has never previously held authorization or whose authorization has been interrupted for a period of three years or more is trustworthy, reliable, and fit for duty, as demonstrated by avoiding substance abuse, as well as aspects of the individual's character and reputation other than substance abuse covered by the self-disclosure and suitable inquiry.

Recordkeeping requirements for §§25.55(a)(1) and (a)(2)
are established by §§26.61 and 26.63 and by §§26.713(a)(1) and (a)(3).

Section 26.57, Authorization Update

Paragraph 26.57(a)(1) requires the licensee or other entity to obtain and review a self-disclosure and employment history from an individual before granting authorization to the individual.

Paragraph 26.57(a)(2) requires the licensee or other entity to complete a suitable inquiry before granting authorization to the individual.

These requirements are necessary to help provide reasonable assurance that any 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 who is granted reauthorization is trustworthy, reliable, and fit for duty, as demonstrated by avoiding substance abuse, as well as aspects of the individual's character and reputation other than substance abuse covered by the self-disclosure and suitable inquiry.

Recordkeeping requirements for §25.57(a)(1) and (a)(2) are established by §§26.61 and 26.63 and by §§26.713(a)(1) and (a)(3).

Section 26.59, Authorization Reinstatement

Paragraph 26.59(a)(1) requires the licensee or other entity to obtain and review a self-disclosure and employment history from 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 before granting authorization to the individual.

Paragraph 26.59(a)(2) requires the licensee or other entity to complete a suitable inquiry for 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 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 another 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.

These requirements are necessary to help provide reasonable assurance that any individual whose authorization has been interrupted for more than 30 days but no more than 365 days and whose last period of authorization was terminated favorably who is granted authorization reinstatement is trustworthy, reliable, and fit for duty, as demonstrated by avoiding substance abuse, as well as aspects of the individual's character and reputation other than substance abuse covered by the self-disclosure and suitable inquiry.

Paragraph 26.59(b) provides that if a licensee or other entity administratively withdraws an individual's authorization, 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 Chapter 10 of the Code of Federal Regulations, 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.

This requirement is necessary to ensure that information about an administrative withdrawal of authorization that is subsequently reversed does not become disseminated to licensees or other entities.

Paragraph 26.59(c)(1) requires the licensee or other entity to obtain and review a self-disclosure from 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 before granting authorization to the individual.

This requirement is necessary to help provide reasonable assurance that any individual whose authorization has been interrupted for no more than 30 days and whose last period of authorization was terminated favorably who is granted authorization reinstatement is trustworthy, reliable, and fit for duty, as demonstrated by avoiding substance abuse, as well as aspects of the individual's character and reputation other than substance abuse covered by the

self-disclosure. Because the authorization has been interrupted for a period of no more than 30 days, no suitable inquiry is required.

Recordkeeping requirements for §§26.59(a)(1) and (a)(2), including records of administrative withdrawal of authorization and subsequent termination of the withdrawal of authorization or unfavorable termination of authorization under §26.59(b), are captured by §§26.61 and 26.63 and by §§26.713(a)(1) and (a)(3).

Recordkeeping requirements for §26.59(c)(1) are established by §26.61 and by §§26.713(a)(1) and (a)(3).

Section 26.61, Self-disclosure and employment history

Paragraph 26.61(a) requires a licensee or other entity to obtain a written self-disclosure and employment history from an individual who is applying for authorization, except in specified circumstances.

Paragraph 26.61(a)(1) specifies that if the individual previously held authorization under Part 26, the licensee or other entity must verify that the individual's last period of authorization was terminated favorably, and that the individual has been subject to a behavioral observation and arrest-reporting program throughout the period since the individual's last authorization; if so, the licensee or other entity need not obtain the self-disclosure or employment history in order to grant authorization.

Paragraph 26.61(a)(2) specifies that 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.

These sections create the requirement for submission of self-disclosures and employment histories by individuals seeking authorization. FFD programs require individuals to sign a statement at the conclusion of the self-disclosure statement and employment history that the information provided by the individual is, as far as they are aware, correct, and the burden for the self-disclosures, employment histories, and signed certification is included here. These sections relax the requirements in §§26.55, 26.57, and 26.59 when the specified conditions above indicate that the self-disclosure and/or employment history are unnecessary and reduce the number of situations in which a licensee or other entity must obtain and review the documents from those otherwise required by §§26.55, 26.57, and 26.59. Verification that the last previous period of authorization was terminated favorably and that the licensee was subject to a behavioral observation and arrest-reporting program is obtained from the nuclear reactor industry's Personnel Access Data System (PADS), to which plants send information concerning individuals.

Recordkeeping requirements for §26.61(a) are established by §26.713(a)(1).

Paragraph 26.61(b) specifies the information to be included in the written self-disclosure, and includes information on FFD policy violations; authorization denials; unfavorable terminations of authorization; use, sale, or possession of illegal drugs; abuse of legal drugs or alcohol; subversion or attempted subversion of a drug or alcohol testing program; refusal to take a drug or alcohol test; substance abuse treatment (except for self-referral); and legal or employment action taken for alcohol or drug use.

Paragraph 26.61(c) requires the individual to provide an employment history listing employers and dates of employment.

These requirements are necessary to ensure that the written self-disclosure and employment history are sufficiently complete and comprehensive to allow licensees and other entities to rely upon them for determinations concerning the trustworthiness, reliability, and fitness for duty of individuals, as demonstrated by avoiding substance abuse. They do not establish any information collection requirements in addition to those included in §26.61(a), but they do specify the types of information that must be included in the self-disclosure and employment history required by §26.61(a).

These sections specify the information to be reported or recorded in support of authorization determinations under §§26.55, 26.57, and 26.59.

Section 26.63, Suitable inquiry

Paragraph 26.63(a) requires the licensees or other entities to ensure a suitable inquiry has been conducted unless the individual was previously authorized, the licensee has verified that the last authorization was terminated favorably, and the individual was subject to a behavioral observation and arrest-reporting program throughout the period of interruption.

Paragraphs 26.63(b), (c), and (f) specifies that to meet the suitable inquiry requirement, licensees and other entities may rely upon the information that other licensees and entities who are subject to this subpart have gathered for previous periods of authorization and specifies the information to be included, e.g., reasons for termination, eligibility for rehire, and other information that could reflect on the individual's fitness to be granted authorization.

Paragraph 26.63(c)(2) specifies that if a claimed period of employment was military service, the licensee or other entity may accept a copy of the DD 214 presented by the individual or provided by the custodian of military records.

These sections specify the information to be reported or recorded in support of authorization determinations under §§26.55, 26.57, and 26.59. In addition, they specify limitations on the scope of the reporting and recordkeeping necessary in support of the authorization determinations under §§26.55, 26.57, and 26.59. Sections 26.63(b), (c), and (f) specify that licensees and other entities may rely on third-party communications, but do not create any additional recordkeeping requirement.

Paragraph 26.63(c)(2) creates an exception to the requirement for an employment history by allowing submission of an already existing record of military service.

Recordkeeping requirements for §26.63(a) and (c)(2) are established by §26.713(a)(1).

Paragraph 26.63(c)(3) specifies that 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 within 3 business days of the request, the licensee or other entity shall document this refusal, inability, or unwillingness in the record of the investigation and obtain a confirmation of employment or educational enrollment and attendance from at least one alternate source. If the licensee or other entity uses an

alternate source but the response is received after 3 business days, the response should be evaluated and documented.

This third-party requirement is necessary to ensure that a record is created explaining gaps and absences in the information otherwise required by §§26.55, 26.57, and 26.59, so that an individual is not charged with responsibility for such gaps and denied authorization on that basis. This requirement also helps to ensure that licensees and other entities can grant authorization, even if the information requested but not received from another company, previous employer, or educational institution, is not available.

Recordkeeping requirements for §26.63(c)(3) are established by §26.713(a)(1).

Paragraph 26.63(d) requires, if a licensee or other entity presents to another licensee or other entity an individual's signed release authorizing the disclosure of information, that other licensee or entity shall disclose whether the individual's authorization was denied or terminated unfavorably as a result of a violation of an FFD policy and the information upon which the denial or unfavorable termination of authorization was based and any other information that is relevant to an authorization decision.

This requirement is necessary to ensure that information about individuals can be transferred from one licensee or other entity to another licensee or other entity for FFD determinations, because individuals who belong to the much more transient workforce that is currently employed in the nuclear industry frequently move from one licensee or other entity to another. The individual signs a release when first applying for authorization, and the release is placed in the licensee's record of the suitable inquiry. The owners and operators of nuclear power reactors have established and maintain a private system of information known as the Personnel Access Data System (PADS) that contains data on personnel. Each participant is contractually obligated to supply updated information to PADS concerning individual authorizations, employment, and FFD violations.

Paragraph 26.63(e) specifies that in conducting a suitable inquiry, the licensee or other entity may obtain information and documents by electronic means, including but not limited to telephone, facsimile, or email. The licensee or other entity shall make a record of the contents of the telephone call and shall retain that record and any documents or electronic files obtained electronically.

This requirement is necessary in light of the use of PADS and other electronic means of information transfer by licensees and other entities to ensure that a record is made and retained of the information secured by electronic means.

Recordkeeping requirements for §26.63(d) and (e) are specified by §§26.711 and 26.713(a), (b), and (c).

Paragraph 26.63(f) specifies the time periods that a suitable inquiry must cover for initial authorization, authorization update, and authorization reinstatement after an interruption of more than 30 days.

While paragraph 26.63(f) does not require information collection, it does affect the burden attributable to §26.63. An average burden has been used for those estimates.

Section 26.65 Pre-access drug and alcohol testing

Paragraphs 26.65(d)(1) and (e)(2) provides that a licensee or other entity may reinstate authorization for an individual whose authorization has been interrupted for more than 30 days but less than 365 days, or for less than 30 days, respectively, if the individual has negative results from alcohol testing and a specimen for drug testing is collected before authorization is reinstated. Paragraphs 26.65(d)(1)(ii) and (e)(2)(iii)(B) further provide that unless the licensee or other entity verifies that the drug test results are negative within 5 business days of specimen collection, it must administratively withdraw authorization until the drug test results are received.

These sections clarify the required testing where an individual's authorization is terminated less than a year, or less than 30 days. The sections assure that an individual with reinstated authorization maintains the FFD requirements.

Recordkeeping responsibilities for §§26.65(d)(1) and 26.65(e)(2) are established by §26.713(a)(3).

Paragraph 26.65(f) specifies that if a licensee or other entity administratively withdraws an individual's authorization under paragraphs (d)(1)(ii) or (e)(2)(iii)(B), and until the drug results are known, the licensee or other entity may not record the administrative action to withdraw authorization as an unfavorable termination. Immediately upon receipt of negative test results, the licensee or other entity shall ensure that any matter that could link the individual to the temporary administrative action is eliminated from the donor's personnel record and other records.

This requirement is necessary to ensure that any administrative action to withdraw authorization is not permanently recorded as an unfavorable termination of the individual, or communicated to another licensee or other entity as an unfavorable termination, unless and until such a record and such communication is correct and appropriate.

Recordkeeping requirements for §26.65(f) are specified by §26.713(a)(2).

Section 26.67, Random drug and alcohol testing of individuals who have appliced for authorization

Paragraph 26.67(a) specifies that 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, the licensee or other entity shall subject the individual to random testing under §26.31(d)(2), except if the licensee or other entity does not grant authorization to the individual or the licensee or other entity relies on drug and alcohol tests that were conducted before the individual applied for authorization.

Paragraph 26.67(b) provides that if an individual is selected for one or more random tests after a requirement for pre-access testing under §§26.65 or 26.69 has been met, the licensee may grant authorization before the random testing is completed.

Paragraph 26.67(c) provides that if an individual has a confirmed positive, adulterated, or substituted test result from any drug, validity, or alcohol test required under this section, the licensee or other entity may deny authorization, terminate the individual's authorization if it has been granted, or grant authorization to the individual under §26.69.

These third-party collections involve notice to the individual rafarding the status of their authorization (granted or not granted) and placement of information in PADS concerning the individual.

Recordkeeping requirements for §26.67 are specified by §26.713(a)(2).

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

Paragraph 26.69(b) specifies that for an individual seeking authorization after a first confirmed positive drug or alcohol test result or a 5-year denial of authorization, a licensee or other entity must obtain and review a self-disclosure and employment history and complete a suitable inquiry with every employer by whom the individual claims to have been employed during the period addressed in the self-disclosure and must obtain and review any records that other licensees or entities who are subject to Part 26 may have developed related to the unfavorable termination or denial of authorization.

Paragraph 26.69(c)(1) requires the licensee or other entity to obtain and review a self-disclosure and employment history for the shortest of the following periods: the past five years, since the individual's eighteenth birthday, or since the individual's last period of authorization was terminated.

Paragraph 26.69(c)(2) requires the licensee or other entity to complete a suitable inquiry with every employer by whom the individual claims to have been employed during the period addressed in the employment history. If the individual held authorization within the past 5 years, the licensee or other entity must obtain and review any records that other licensees or entities who are subject to Part 26 may have developed with regard to potentially disqualifying FFD information about the individual within the past 5 years.

Paragraph 26.69(c)(3) requires, where potentially disqualifying FFD information is discovered that is not a first confirmed positive drug or alcohol test nor a 5-year denial of authorization, that the licensee verify that a professional qualified under §26.187(a) has indicated the individual is fit for duty.

Paragraph 26.69(c)(4) requires the licensee to ensure the individual is in compliance with, or has completed, plans for treatment and drug and alcohol testing.

Paragraph 26.69(c)(5) requires the licensee to verify that results of pre-access drug and alcohol testing are negative before granting authorization, and that the individual is then subject to random testing.

Paragraph 26.69(d) provides that 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 ensure that a reviewing official completes a review of the circumstances associated with the potentially disqualifying FFD information; decide whether a determination of fitness is required; verify that if a determination of fitness is required that a professional with the appropriate qualifications has indicated that the individual is fit to safely and competently perform his or her duties; and implement any recommendations for treatment and followup drug and alcohol testing from the determination of fitness.

Paragraph 26.69(e) allows licensees and other entities to 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 subject to Part 26.

Paragraph 26.69(e)(1) requires licensees or other entities that imposed treatment and/or followup testing for an individual to ensure that information documenting the treatment and/or followup plan is identified to any subsequent licensee or other entity who seeks to grant authorization to the indivdual.

These requirements are necessary to ensure that the information upon which an authorization decision is made about an individual who has had a first confirmed positive drug or alcohol test or a 5-year denial of authorization is fully complete and comprehensive for the period being covered. They require review of appropriate records, including the written treatment plan, records of drug and alcohol testing of the individual, and records of any potentially disqualifying FFD information that is disclosed or discovered. These third-party collections involve notice to the individual rafarding the status of their authorization (granted or not granted) and placement of information in PADS concerning the individual.

Recordkeeping requirements for §§26.69(b), (c)(1), (c)(2) and (c)(3) are specified by §26.713(a)(1).

Recordkeeping requirements for §§26.69(c)(4) and (5) and for §26.69(d) are specified by §26.713(a)(3).

Section 26.75, Sanctions

Paragraphs 26.75(a), (b), (c), (d), (e) and (g) specifies the minimum sanctions that licensees and other entities must impose upon individuals who are determined to have violated the drug and alcohol provisions of an FFD policy. Paragraph 26.75(d) specifies that 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 Part 26 had the individual not resigned or withdrawn his or her application for authorization.

These requirements, which establish a uniform set of sanctions for FFD violations, are implemented through the creation of records of the sanction imposed. This ensures that a record is created and maintained of the sanction that is available for later reference if the individual seeks authorization after the passage of time or at another facility. Records of sanctions are shared among FFD programs through the industry's Personnel Access Database System (PADS), to which the licensees send information concerning employment dates, approvals of access authorization, withdrawals of access authorization, violations of FFD policy, and other subjects.

Recordkeeping requirements for §§26.75(a), (b), (c), (d), (e)(2), and (g) are established by §26.713(c).

Paragraph 26.75(h) specifies that 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 postive test result from any initial drug test, other than positive initial test reslults for marijuana or cocaine metabolites from a specimen that is reported to be valid

on the basis of either validity screening or inidial validity testing performed at a licensee testing facility, unless other evidence indicates the individual is impaired or might otherwise pose a safety hazard.

This requirement does not create any reporting or recordkeeping requirements. However, it triggers the requirements in the following paragraphs.

Paragraph 26.75(i) allows a licensee testing facility to inform licensee or entity management of initial, non-negative marijuana or cocaine test results with a valid specimen. Licensees or other entities may administratively withdraw the donor's authorization or take lesser administrative actions against the donor, provided that certain conditions specified in §§26.75(i)(1) - (4) are met.

Paragraph 26.75(i)(3) requires that the licensee or other entity eliminate any matter from the individual's personnel record and other records that could link the individual to the temporary administrative action immediately upon receipt of a negative report from the HHS-certified laboratory or the Medical Review Officer.

This requirement is necessary to ensure that any administrative action to withdraw authorization is not permanently recorded as an unfavorable termination of the individual, or communicated to another licensee or other entity as an unfavorable termination, unless and until such a record and such communication is correct and appropriate.

The recordkeeping requirements for this section are established by §26.713(a)(2).

Paragraph 26.75(i)(4) requires that 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 FFD policy in response to a suitable inquiry conducted under §26.63, a background investigation conducted under Part 26, or to any other inquiry or investigation. The licensees or other entities must provide access to the system of files and records to personnel who are conducting reviews, inquiries into allegations, audits under §26.41, and to NRC inspectors, to ensure that no records are retained. The licensees or other entities 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.

This requirement is necessary to ensure that any administrative action to withdraw authorization is not permanently recorded as an unfavorable termination of the individual, or communicated to another licensee or other entity as an unfavorable termination, unless and until such a record and such communication is correct and appropriate. This provision, in addition, ensures that an individual, the individual's personal representatives, and the NRC are allowed to review the records to ensure that no inappropriate records are retained, and that a written confirmation that the temporary administrative action will not be disclosed, and that the individual need not disclose the action, is provided to the individual.

The recordkeeping requirements for this section are established by §26.713(a)(2).

Section 26.77, Management actions regarding possible impairment

Paragraph 26.77(c) requires a licensee or other entity that 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, to immediately notify the appropriate Regional Administrator by telephone, followed by written notification to document the verbal notification, or, if the Regional Administrator cannot be reached, to notify the NRC Operations Center.

This requirement is necessary to ensure that the NRC receives immediate notification by telephone, followed by written notification, that an NRC employee or NRC contractor may be under the influence of a substance or is otherwise unfit for duty, so that the NRC can take action to remove the employee from duty and to take any other appropriate actions.

Reporting requirements for §26.77(c) are established by §26.719(a).

Section 26.85, Collector qualifications and responsibilities

Paragraph 26.85(a) requires qualification training for urine collectors on the requirements of Part 26, the FFD policy and procedures of the licensee or other entity for whom collections are performed, all steps necessary to complete a collection correctly and the proper completion and transmission of the custody-and-control form; methods to address problem collections, how to correct problems in collections, and the collector's responsibility for maintaining the integrity of the specimen collection and transfer process, ensuring the modesty and privacy of the donor, and avoiding conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

Paragraph 26.85(b) requires qualification training for alcohol collectors on the requirements of Part 26, the FFD policy and procedures of the licensee or other entity for whom collections are performed, and any changes to alcohol collection procedures, the alcohol testing requirements of Part 26, operation of the particular alcohol testing device(s) or evidential breath testing devices (EBTs) to be used, consistent with the most recent version of the manufacturer's instructions, methods to address problem collections, how to correct problems in collections, and the collector's responsibility for maintaining the integrity of the specimen collection and transfer process, ensuring the modesty and privacy of the donor, and avoiding conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

This requirement is necessary to ensure that individuals assigned to perform collection activities under Part 26 are provided with appropriate training so that they understand the methods that are used to implement the FFD policy. The burden for one-time training for collectors and the ongoing burden for training new collectors are both shown under these sections.

Recordkeeping requirements for §26.85(a) and (b) are established by §§26.715(a) and (b)(1).

Paragraph 26.85(c)(4) requires any medical professional, technologist or technician who serves as an alternative collector without meeting the training criteria otherwise required to be provided with detailed, clearly-illustrated, written instructions for collecting specimens in accordance in Subpart E of Part 26.

This third-party information collection requirement is necessary to ensure that alternative collectors have detailed instructions on how to perform the collections.

Recordkeeping requirements for §26.85(c)(4) are established by §26.715(a).

Paragraph 26.85(e) requires collection site personnel files to include each individual's resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluations and advancement; incident reports, if any; results of tests that establish employee competency for the position he or she holds; and appropriate data to support determinations of honesty and integrity conducted in accordance with §26.31(b).

These requirements are necessary to ensure that the training, competency of the collection site personnel a licensee testing facility to correctly use the instruments and devices that the licensee testing facility has selected can be verified This is an important support for the review process underlying determinations of fitness. In addition, records of training and competency may be important evidence in any litigation that may occur with respect to test results. Records of training and competency of collection site personnel also will supports reliance by licensees and other entities on test results from testing that was performed by another Part 26 program.

Recordkeeping requirements for §26.85(e) are established by §26.715(a) and (b)(1).

Section 26.87, Collection Sites

Paragraph 26.87(d)(3) specifies that 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 allowed only for authorized personnel.

Paragraph 26.87(f)(1) provides that if a public rest room is used as a collection site, a sign must be posted, or an individual assigned, to ensure that no unauthorized personnel are present during the entire collection procedure.

These requirements are necessary in order to ensure that specimen collection sites are clearly identified to prevent unauthorized access to the collection site that could compromise the integrity of the collection process or the specimens, and to protect donor privacy.

The recordkeeping requirements for §26.87(c)(4) are established by §26.715(b)(3).

The paperwork burden for the posting required by §§26.87(d)(3) and (f)(1) is established by those sections.

Paragraph 26.87(f)(3) requires the person who accompanies the donor into the specimen collection area to be instructed on the collection procedures and his or her identity must be documented on the custody-and-control form.

Paragraph 26.87(f)(4) requires the collector to instruct the donor to participate with the collector in completing the chain-of-custody form.

Paragraph 26.87(f)(5) requires the authorized collector to maintain control of the specimen until the specimen is prepared for transfer, storage, or shipping, and to document his or her custody of the specimen on the custody and control form.

The requirements in §§26.87(f)(3), (f)(4), and (f)(5) are necessary to ensure a chain-of-custody form is prepared that identifies the origin of the specimen and associates the specimen with the correct donor.

Recordkeeping requirements for §§26.87(f)(3) and (f)(5) are established by §26.715(b)(2).

Section 26.89, Preparing to collect specimens for testing

Paragraph 26.89(a) requires collectors to inform FFD program managers when an individual fails to appear for drug testing.

Paragraph 26.89(b)(1) and (b)(2) requires that individuals show proper identification before testing, and, if they cannot produce acceptable identification the collector must notify FFD program management. 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.

Paragraph 26.89(b)(3) provides that 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.

Paragraph 26.89(b)(4) requires the collector to 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.

Paragraph 26.89(c) requires that the collector inform the donor that the donor must remain present at the collection site until the collection is complete. In the event the donor leaves the test site prematurely, the collector is required to report this to FFD management.

Paragraphs 26.89(a), (b)(1), (b)(2), and (b)(3) create third-party collection requirements. Notice to FFD program management is necessary to ensure that appropriate actions are undertaken under the FFD procedures to determine of authorization of the person should be denied or other management actions taken. Paragraph 26.89(b)(4) creates a third-party collection requirement. Explanation of the testing procedure and obtaining a signed consent-to-test form are necessary to ensure that the due process rights of the individual are protected and there is a record that the individual understood the testing procedure and consented. Paragraph 26.89(c) creates a third-party collection requirement. Informing the donor that the donor must remain present until the collection is complete protects the due process rights of the donor. Notice to FFD program management if the donor leaves or is uncooperative is necessary to ensure that appropriate actions are undertaken under the FFD procedures to determine of authorization of the person should be denied or other management actions taken.

The recordkeeping requirements for §§26.89(a), (b), and (c) are established by §26.715(b)(6).

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

Paragraph 26.91(c)(1) - (3) provides that an evidential breath testing device must provide a printed result of each breath test, assign a unique number to each completed test that is

printed on each copy of the test result, and print on each copy of the test result the manufacturer's name for the device, its serial number, and the time of the test.

This requirement is necessary to establish the specifications for evidential breath testing devices that may be used in FFD programs and to ensure that the results provided by evidential breath testing devices can be confirmed by the individual to whom the test is administered and that it is possible to confirm that no test results have been discarded or ignored. It may be necessary in some cases for licensees and other entities to obtain new evidential breath testing devices (EBTs) with the capability of providing printed results, but most FFD programs are expected to already possess such devices. This requirement helps to ensure that information is available for reviews of determination of fitness and legal proceedings, if any, addressing determinations of fitness. This requirement also helps to ensure that information is available with which to track the performance of each EBT. This requirement does not directly create any records, but describes the types of records that must be created through the use of EBTs in FFD programs.

Recordkeeping requirements for the records created using EBTs that meet the specifications of §26.91(c)(1)-(3) are established by §26.715(b)(12).

Paragraph 26.91(e)(4) requires the licensee or other entity 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: 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 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.

Paragraph 26.91(e)(5) requires that the inspection, maintenance, and calibration of the EBT be performed by the manufacturer or a certified representative of the manufacturer.

Paragraph 26.91(e)(5) creates a third-party collection requirement to create an internal record of the inspection, maintenance, and calibration. This requirement is necessary to ensure that past inspection, maintenance, and calibration activities can be reviewed and confirmed.

The recordkeeping requirements for §26.91(e)(4) and §26.91(e)(5) are established by §26.715(b)(14).

Section 26.93, Preparing for alcohol testing

Paragraph 26.93(a)(6) requires that prior to collecting a specimen for alcohol testing the collector must document that certain questions about substance ingested and instructions about the testing process as specified in §26.93(a)(1) - (a)(5) were communicated to the donor.

This third-party collection requirement is necessary to ensure that the donor understands how the test will be conducted and what the donor must and must not do in order to ensure that the test result is valid and that the testing process is not subverted. This requirement also partially meets the legal necessity of protecting the due process rights of individuals who are subject to

Part 26, and also proving "prior notice" and having it documented for evidence in legal proceedings.

Recordkeeping requirements for §26.93(a)(6) are established by §26.715(b)(6).

Section 26.95, Conducting an initial test for alcohol using a breath specimen

Paragraph 26.95(b)(5) requires a collector conducting an initial breath test for alcohol to ensure that the test result can be associated with the donor and is maintained secure.

This requirement is necessary to help ensure that the test result is an accurate and correct record with respect to the individual who is being tested. This requirement also partially meets the legal necessity of protecting the due process rights of individuals who are subject to Part 26, and also proving "prior notice" and having it documented for evidence in legal proceedings.

Recordkeeping requirements for §26.95(b)(5) are established by §26.715(b)(6).

Section 26.97, Conducting an initial test for alcohol using a specimen of oral fluids

Paragraph 26.97(b)(2) requires that, if the steps required to use the device correctly could not be completed successfully, the collector must record the reason for a new test.

Paragraph 26.97(c)(1) requires that, if a second attempt at collection fails following the failure of the initial attempt, the collector must document the reasons the collection could not be completed.

These requirements are necessary to ensure that if tests cannot be completed because the alcohol testing device cannot be used correctly, that fact must be provided as an explanation of the need for a new test. This helps to ensure that the need for a new test is not incorrectly attributed to the actions of the individual donor. These requirements also partially meet the legal necessity of protecting the due process rights of individuals who are subject to Part 26, and also proving "prior notice" and having it documented for evidence in legal proceedings.

Recordkeeping requirements for §26.97(b)(2) and (c)(1) are established by §26.715(b)(6).

Paragraph 26.97(d) requires the collector, when using a testing device, to show the device and its reading to the donor, record the result, and record that an alcohol screening device (ASD) was used.

This requirement is necessary so that the donor can verify that a particular device was used and confirm the result and the fact that the result was recorded correctly. This record is important for a determination of fitness, if any. The record of the use of the ASD and the result of the test also provide important information for tracking the activities of the FFD program, and help to ensure that information is available for audits and NRC inspections. This requirement also partially meets the legal necessity of protecting the due process rights of individuals who are subject to Part 26, and also proving "prior notice" and having it documented for evidence in legal proceedings.

Recordkeeping requirements for §26.97(d) are established by 26.715(b)(6).

Section 26.99, Determining the need for a confirmatory test for alcohol

> Paragraph 26.99(b) requires the collector to ensure that the time when an initial test whose result is 0.02 percent Blood Alcohol Content (BAC) or higher was concluded (i.e., the time at which the test result was known) is recorded.

This requirement is necessary to ensure that the length of time the donor had been in work status when the initial test was conducted can be determined, in order to calculate the actual level while the individual was in work status, which is one factor under §26.103 in determining whether to declare a confirmed positive test result. In addition, by recording the time of the initial test, the FFD program can demonstrate that the 15-minute waiting period required by §26.93(a), if necessary, has occurred before the initial alcohol test was done. This requirement also is necessary to ensure that the confirmatory test is done, as required by §26.101, no more than 30 minutes after the conclusion of the initial test.

Recordkeeping requirements for §26.99(b) are established by §26.715(b)(6).

Section 26.101, Conducting a confirmatory test for alcohol

> Paragraph 26.101(b)(7) requires the collector to show the donor the result displayed upon or printed by the EBT, record the result, and document the time at which the confirmatory test result was known.

This requirement is necessary so that the donor can personally know that a particular device was used for the confirmatory test, the indicated confirmatory test result, and the fact that the confirmatory test result was recorded correctly. The record of the result of the confirmatory test and the time at which the result was known also provide important information for determining whether or not a confirmed positive test result for alcohol must be declared. This requirement also provides important information for tracking the activities of the FFD program, and help to ensure that information is available for audits and NRC inspections. This requirement also partially meets the legal necessity of protecting the due process rights of individuals who are subject to Part 26, and also proving “prior notice” and having it documented for evidence in legal proceedings.

Recordkeeping requirements for §26.101(b)(7) are established by §26.715(b)(6).

Section 26.103, Determining a confirmed positive test result for alcohol

> Paragraph 26.103(b) requires the collector to declare test results as negative where the results show BAC below .02 but at or above .01, if the donor has been at work status for 3 hours or more. The collector informs FFD management and the licensee or other entity prohibits the donor from duties subject to Part 26 until a determination of fitness is made.

This third party collection requirement is necessary to ensure that FFD management is notified so that appropriate actions, including a determination of fitness, can be undertaken under the FFD procedures.

Recordkeeping requirements for §26.103(b) are established by §26.715(b)(6).

Section 26.107, Collecting a urine sample

Paragraph 26.107(b) requires the collector to document on the custody-and-control form any conduct that clearly indicates an attempt to tamper with a specimen.

This requirement is an integral part of the collection procedure and is essential to documenting the chain of custody for the specimens collected. Because it is expected to be an infrequent occurrence, it does not create a significant additional burden. However, it is necessary to ensure that an immediate record of any attempt to tamper with a specimen is prepared and accompanies the specimen, such as an attempt to bring an adulterant or urine substitute into the room or stall used for urination.

Recordkeeping requirements for §26.107(b) are established by §26.715(b)(6).

Section 26.109, Urine specimen quantity

Paragraph 26.109(b)(3) requires that, if the donor has not provided a specimen of at least 30 mL within 3 hours of the first unsuccessful attempt, the collector shall discontinue the collection and notify the FFD program manager or MRO to initiate the “shy bladder” procedures in §26.119.

Paragraph 26.109(b)(4) requires the collector to discard specimens less than 30mL, unless the collector has reason to believe that the donor had diluted, adulterated, substituted, or otherwise tampered with the specimen. In that event, if the sample is greater than 15mL and less than 30mL, the collectoris required to prepare the specimen for shipping to the HHS-certified lab and contact FFD management to determine whether a directly observed collection is required.

These third-party collection requirements are necessary to ensure that the FFD program manager or MRO is informed to collection problems involving a particular donor so that the FFD program manager or MRO can initiate alternative procedures for which their approval is required.

Recordkeeping requirements for §26.109(b)(4) are established by §26.715(b)(6).

Section 26.111, Checking the validity of the urine specimen

Paragraph 26.111(b) requires the collector to inspect the urine specimen and to note any unusual findings on the custody-and-control form.

This requirement is an integral part of the collection procedure and is essential to documenting the chain of custody for the specimens collected. Because it is expected to be an infrequent occurrence, it does not create a significant additional burden. However, the information provided could be useful to a laboratory conducting testing and ensures the scientific supportability of the test results in case of a review in support of a determination of fitness and/or legal proceedings.

Recordkeeping requirements for §26.111(b) are established by §26.715(b)(2).

Paragraph 26.111(c) requires the collector to contact the designated FFD manager if the collector has the reasonable belief, based on observation, that the donor may have

attempted to dilute, substitute or adulterate the specimen. The FFD manager may require the donor to provide a second specimen under supervision.

This third-party collection requirement is necessary to ensure that the FFD program manager is informed of the possibility that a donor may have attempted to dilure, substitute, or adulterate a specimen, so that the FFD program manager can examine the circumstances and determine whether to initiate appropriate management actions, including notification to the NRC if the facts of attempted dilution, substitution, or adulteration of a specimen are confirmed.

Recordkeeping requirements for §26.111(c) are established by §26.715(b)(6).

Section 26.113 Splitting the urine specimen

Paragraph 26.113 (b)(3) requires the collector to prepare custody-and-control forms for both specimens when the urine specimen is split into two specimen bottles.

This requirement is an integral part of the collection procedure and is essential to documenting the chain of custody for the specimens collected. Chain of custody, in turn, is a fundamental procedure for sample analysis, because it ensures that there is a record demonstrating that the specimens analyzed by the laboratory are the same specimens that were obtained from the donor. When the sample is split into two specimen bottles, a chain-of-custody form must be prepared to accompany each bottle to properly identify each testing result.

Recordkeeping requirements for §26.113(b)(3) are established by §26.715(b)(2).

Section 26.115, Collecting a urine specimen under direct observation

Paragraph 26.115(b) requires that, before collecting a urine specimen under direct observation, the collector must obtain the agreement of the FFD program manager or MRO.

This requirement is necessary because of the intrusive nature of collection of a urine specimen under direct observation. Therefore, a person qualified in making the determination that direct collection should be used must make that decision and document it.

Recordkeeping requirements for §26.115(b) are established by §26.715(a).

Paragraph 26.115(d) requires the collector to complete a new custody-and-control form for a specimen obtained from a directly observed collection, and to record on the form that the collection was observed and the reason(s) for the observed collection.

The third-party collection requirement in §26.115(b) is necessary to ensure that the FFD program manager or MRO is informed of the need for a collection under direct observation, so that the FFD program manager or MRO can examine the circumstances and approve or deny the request for a collection under direct observation. The FFD program manager or MRO, not the collector, are qualified and assigned the duty of making the determination. The requirement to complete a new custody-and-control form, and record the basis for the collection, is an integral part of the collection procedure and is essential to documenting circumstances of collection in case of subsequent legal proceedings.

Recordkeeping requirements for §26.115(d) are established by §26.715(b)(2).

Paragraph 26.115(f)(3) requires that, if someone other than the collector observed the collection, the collector must record the observer's name on the custody-and-control form.

This requirement is an integral part of the collection procedure and is essential to documenting the identity of the observer in case of subsequent legal proceedings.

Recordkeeping requirements for §26.115(f)(3) are established by §26.715 (b)(2).

Section 26.117, Preparing urine specimens for storage and shipping

Paragraph 26.117(c) requires the collector to place an identification label containing the date, the donor's specimen number, and any other identifying information provided or required by the FFD program securely on each specimen container.

Paragraph 26.117(d) requires the donor to initial the identification label(s) on the specimen bottle(s) and 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 the donor provided.

Paragraph 26.117(e) requires the collector to complete the custody-and-control form (or forms for both Bottle A and Bottle B, if split specimens procedures were followed) and certify proper completion of the collection.

Paragraph 26.117(k) requires that custody accountability of shipping containers during shipment by couriers, express carriers, and the postal service must be maintained by a tracking system provided by the courier, express carrier, or postal service.

The requirements in §§26.117(c), (d), and (e) are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The provision in §26.117(k) is not intended to create a third-party recordkeeping requirement. Use of such tracking systems by couriers, express carriers, and the postal service is an ordinary business practice and relied upon for all shipments. The provision is intended to notify licensees and other entities that they may rely upon the tracking system provided by the courier, express carrier, or postal service.

Recordkeeping requirements for §26.117(c), (d), and (e) are established by §26.715(b)(2).

Section 26.119, Determining "shy" bladder

Paragraph 26.119(a) requires a donor who has not provided a specimen of at least 30 mL within the 3 hours permitted for urine collection to obtain, within 5 business days, an evaluation from a licensed physician, or from the MRO if the MRO has the appropriate expertise.

This requirement is necessary to ensure that a qualified MRO or licensed physician prepares an evaluation of whether the medical condition of the donor was or could have with a high probability been the basis for the donor's failure to provide a specimen.

Paragraph 26.119(b) requires the MRO, if the MRO is not performing the evaluation, to provide the physician who is performing the evaluation with information about the donor

and the testing requirements, and instructions about the determination to be made by the physician.

Paragraph 26.119(e) requires a physician who performs an evaluation of the donor's failure to provide a sufficient specimen to prepare a written statement of his or her determination and the basis for it and to provide the statement to the MRO.

Paragraph 26.119(f) requires the physician, if he or she 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, to set forth this determination and the reasons for it in the written statement to the MRO.

These requirements are necessary to ensure that if a donor does not provide a specimen within the specified time, then a medical evaluation, based on specified information and instructions, is prepared and provided in writing to the MRO. The medical evaluation, in part, provides an opportunity to the donor to demonstrate that the failure to provide the specimen is not an attempt to subvert the testing process but is, instead, the result of a valid medical condition, and helps to ensure that the licensee or other entity does not inappropriately impose sanctions on the individual.

Recordkeeping requirements related to maintaining a record of the donor's testing results for §26.119(a), (b), (e) and (f) are established by §26.715(b)(6).

Third-party recordkeeping requirements related to providing instructions and making a written determination for §§26.119(a), (b) (e), and (f) are established by §26.119 itself.

Section 26.125, Licensee testing facility personnel

Paragraph 26.125(b) requires technicians who perform urine specimen testing to have documented proficiency in operating the testing instruments and devices used at the licensee testing facility.

Paragraph 26.125(c) requires licensee testing facility files to include each individual's resume of training and experience, certification of license, if any; references; job descriptions; records of performance evaluations and advancement; incident reports, if any; results of tests that establish the employee's competency for the position he or she holds, includiing certification that personnel are proficient in conducting testing; and appropriate data to support determinations of honesty and integrity required by Part 26.

These requirements are necessary to ensure that the training, competency of the technicians and staff of a licensee testing facility to correctly use the instruments and devices that the licensee testing facility has selected can be verified This is an important support for the review process underlying determinations of fitness. In addition, records of training and competency may be important evidence in any litigation that may occur with respect to test results. Records of training and competency of licensee testing facility personnel also supports reliance by licensees and other entities on test results from testing that was performed by another Part 26 program.

Recordkeeping requirements for §26.125(b) and (c) are established by §26.715(a) and (b)(1).

Section 26.127, Procedures

Paragraph 26.127(a) requires licensee testing facilities to develop, implement, and maintain clear and well-documented procedures for accession, receipt, shipment, and testing of urine specimens.

Paragraph 26.127(b) requires licensee testing facilities to have written chain-of-custody procedures describing 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.

Paragraph 26.127(c) requires licensee testing facilities to develop, implement, and maintain written standard operating procedures for each assay performed for drug and specimen validity testing. If the licensee testing facility performs validity screening tests, the facility is also be required to develop, implement, and maintain written standard operating procedures for each device. The procedures must include detailed descriptions of the principles of each test; preparation of reagents, standards, and controls; calibration procedures; derivation of results; linearity of the methods; cutoff values; mechanisms for reporting results; controls; criteria for unacceptable specimens and results; reagents and expiration dates; and references.

Paragraph 26.127(d) requires licensee testing facilities to develop, implement, and maintain written procedures for instrument and device setup and normal operation that include a schedule for checking critical operating characteristics for all instruments and devices; tolerance limits for acceptable function checks; and instructions for major troubleshooting and repair.

Paragraph 26.127(e) requires licensee testing facilities to develop, implement, and maintain written procedures for remedial actions to be taken when systems and instrumented and non-instrumented testing devices (if used for validity screening tests) are out of acceptable limits or errors are detected. Each facility is required to maintain documentation that these procedures are followed and that all necessary corrective actions are taken. In addition, all facilities are required to have systems in place and to verify all stages of testing and reporting and to document the verification.

These requirements are an integral part of the quality assurance/quality control process for every testing facility and are essential to documenting the procedures to be followed to ensure that all steps in the testing and analysis process, including chain-of-custody for the specimens collected, are carried out in an appropriate manner by all personnel conducting the activities.

Recordkeeping requirements for §26.127(a), (b), (c), (d) and (e) are established by §26.715(a).

Section 26.129, Assuring specimen security, chain of custody, and preservation

Paragraph 26.129(a) requires each licensee testing facility to limit access to secured areas only to specifically authorized individuals whose authorization is documented.

This requirement, which involves the collection of signatures of persons visiting the secured areas of testing facilities and a check of their credentials or other authorization for such entry, is

necessary to ensure that unauthorized persons do not gain access to testing areas, where they might seek to subvert the testing process.

Paragraph 26.129(b) requires licensee testing facility personnel to inspect each package when specimens are received for evidence of possible tampering and to compare the information on the specimen containers within each package to the information on the accompanying custody-and-control forms, and to attempt to resolve any discrepancies. When resolving any discrepancies, licensee testing facility personnel are required to obtain a memorandum for the record from the specimen collector to document correction of the discrepancy. The memorandum must accompany the specimens and custody-and-control forms if the specimens must be transferred.

This requirement is necessary to ensure that a record of the resolution of any discrepancies involving information about specimens is prepared and accompanies the specimens following the resolution of the discrepancy. This will avoid duplicative efforts to resolve discrepancies and will ensure that the information accompanying the specimen is correct.

Paragraph 26.129(b)(1) requires licensee testing facilities to report to licensee senior management any indications of tampering with specimens in transit from the collection site or at a testing facility, or discrepancies in the information on specimen bottles or on the accompanying custody-and-control forms. Such reports are required to be made as soon as practical and no later than 8 hours after the indications are identified.

This requirement is necessary because confirmed reports of tampering must be reported to the NRC as required by §26.719(b).

Paragraph 26.129(d) requires licensee testing facilities's procedures for tracking custody and control of specimens to protect the identity of the donor. The facilities are required to provide documentation of the testing process and each transfer of custody of the specimen, along with the date and purpose and every individual in the chain of custody.

Paragraph 26.129(h) requires that custody accountability of shipping containers during shipment by couriers, express carriers, and the postal service must be maintained by a tracking system provided by the courier, express carrier, or postal service.

These requirements are an integral part of the quality assurance/quality control process for every testing facility and are essential to ensuring the security from tampering of the specimens collected and appropriate and timely actions if possible tampering is suspected. These requirements are necessary to protect donors from inaccurate results, to provide assurance that specimens of questionable validity are detected, and to ensure the integrity of the testing process.

The provision in §26.129(h) is not intended to create a third-party recordkeeping requirement. Use of such tracking systems by couriers, express carriers, and the postal service is an ordinary business practice and relied upon for all shipments. The provision is intended to notify licensees and other entities that they may rely upon the tracking system provided by the courier, express carrier, or postal service.

Third-party recordkeeping requirements for §26.129(a) are established by §26.715(b)(13).

Third-party recordkeeping requirements for §26.129(b) are established by §26.715(b)(2).

Third-party recordkeeping requirements for §26.129(b)(1) are established by §26.715(b)(3).

Third-party recordkeeping requirements for §26.129(d) are established by §26.715(b)(2).

Section 26.135, Split Specimens

Paragraph 26.135(b) allows, upon a non-negative result, the donor to request that a split specimen (if the FFD program follows split specimen procedures as described in §26.113 be tested at another HHS-certified laboratory. The donor provides his or her written permission for the testing of bottle B.

This requirement is necessary in order to ensure that a record exists of the donor's approval of a second test, in case of subsequent legal proceedings.

Third-party recordkeeping requirements for §26.135(b) are established by §26.715(b)(6).

Section 26.137, Quality assurance and quality control

Paragraph 26.137(a) requires each licensee testing facility to develop and implement a quality assurance program and quality assurance procedures encompassing all aspects of the testing process.

These requirements are an integral part of the quality assurance/quality control process for all testing and laboratory facilities. The requirements are necessary to protect donors from inaccurate results and to provide assurance that specimens of questionable validity are detected.

Paragraph 26.137(b)(1)(ii) requires the licensee or other entity before using the test, to ensure that the validity screening test, by lot number, effectively identifies specimens of questionable validity by meeting the performance testing and quality control requirements listed in this section.

Paragraph 26.137(b)(1)(iii) requires a licensing testing facility that has placed a validity screening test in service to either verify that the device remains on the SAMHSA-approved list or if the list is unavailable, ensure the manufacturer's documentation documents the test's validity and that the licensee conducts performance testing at a nominal annual frequency.

These requirements are necessary to ensure that all point-of-collection testing devices used by a licensee testing facility meet certain minimum performance criteria. This will protect donors from inaccurate test results and provide assurance that specimens of questionable validity are detected.

Recordkeeping requirements for §26.137(a) are established by §26.715(b)(3).

Recordkeeping requirements for §26.137(b)(1)(ii) and (iii) are established by §26.715(b)(7).

Paragraph 26.137(b)(3) requires licensee testing facilities to submit at least one specimen out of every 10 that test negative using each validity screening test to an HHS-certified laboratory as part of the licensee testing facility's quality assurance program.

This requirement is an integral part of the quality control/quality assurance process and protects donors from inaccurate test results as well as providing assurance that specimens of questionable validity are detected.

Reporting requirements for §26.137(b)(3) are established by §26.719(c)(3).

Paragraph 26.137(e)(7) requires licensee testing facilities to document the implementation of procedures to ensure that carryover [i.e., materials from a previous test that have not been adequately purged from the apparatus] does not contaminate the testing of a donor's specimen.

Paragraph 26.137(f)(5) requires licensee testing facilities to prepare a record of findings and corrective actions taken, where applicable, for all investigations of 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 or MRO reviews. The record must be signed and dated by the individuals who are responsible for the day-to-day management of the licensee testing facility and reported to appropriate levels of management.

Paragraph 26.137(h) requires standards and controls to be labeled with dates of when received, when prepared or opened, when placed in service, and when scheduled for expiration.

These requirements are an integral part of the quality assurance/quality control process for all testing and laboratory facilities. The requirements are necessary to protect donors from inaccurate results and to provide assurance that specimens of questionable validity are detected.

Recordkeeping requirements for §26.137(e)(8) are established by §26.715 (b)(3).

Recordkeeping requirements for §26.137(f) are established by §26.715(b)(8).

Recordkeeping requirements for §26.137(h) are established by §26.715(b)(5).

Section 26.139, Reporting initial validity and drug test results

Paragraph 26.139(d) requires licensee testing facilities to prepare information for annual reports to the NRC, as required in §26.717.

This requirement is necessary to ensure that the NRC can monitor testing program effectiveness. The NRC has concluded that annual reporting creates the appropriate balance between reporting burden and the NRC's need for information. Section 26.717 of the rule specifies the program performance data to be included in the annual report.

Reporting requirements under §26.139(d) are established by §26.717(b) and (e).

Section 26.153, Using certified laboratories for testing urine specimens

Paragraph 26.153(e) requires a licensee or other entity, before awarding a contract to an HHS-certified laboratory, to conduct a pre-award inspection and evaluation of the procedural aspects of the laboratory's drug testing operations.

Paragraph 26.153(f) requires licensees' and other entities' contracts with HHS-certified laboratories to implement all applicable obligations of Part 26 and specifies minimum requirements.

The third-party recordkeeping of the pre-award inspection and evaluation in the form of documentation of the inspection and evalution ensures that FFD program personnel and managers not personally participating in the inspection and evaluation can review and assess the qualifications of the laboratory and make informed decisions about contracting with that laboratory.

Recordkeeping requirements for §26.153(e) are established by §26.715(b)(9).

Recordkeeping requirements for §26.153(f) are established by §26.713(e).

Paragraph 26.153(g) requires licensees or other entities who use a form other than the current Federal custody-and-control form to provide a memorandum to the HHS-certified laboratory explaining why a non-Federal form was used, and to ensure that the form used contains all the required information on the Federal custody-and-control form.

This requirement is consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. 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's and other entity's specimens from being rejected.

Recordkeeping requirements for §26.153(g) are established by §26.715(b)(2).

Section 26.155, Laboratory personnel

Paragraph 26.155(a)(1) requires day-to-day management of the HHS-certified laboratory to be performed by an individual with documented scientific qualifications in analytic forensic toxicology.

Paragraph 26.155(a)(3) requires the individual to ensure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

Paragraph 26.155(a)(4) requires the day-to-day manager to review, sign, and date procedures to be followed by laboratory personnel whenever the procedures are first placed into use or changed or when a new individual assumes responsibility for management of the laboratory, and to ensure that copies of all procedures are maintained.

Paragraph 26.155(a)(5) requires the day-to-day manager to maintain a quality assurance program that, among other things, documents the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

Paragraph 26.155(b) requires that each HHS-certified laboratory have at least one certifying scientist to certify test results. The paragraph specifies the requirements for the certifying scientist.

Paragraph 26.155(c) requires that each HHS-certified laboratory assign at least one individual to be responsible for day-to-day operations and supervision of the technical analysts. The paragraph specifies the requirements for the analysts' supervisor.

Paragraph 26.155(e) requires that HHS-certified laboratories make available continuing education programs for personnel.

Paragraph 26.155(f) requires each laboratory personnel file to include a resume, any professional certifications or licenses, a job description, and documentation to show that the individual has been properly trained to perform his or her job function.

These requirements are consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, Sections 11.2 and 11.3. HHS explains (69 FR 19691, April 13, 2004), that these recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. As standard business practices, they are not considered a burden for this analysis.

Recordkeeping requirements for §§26.155(a)(1), (a)(3), (b), and (c) are established by §26.155(f).

Recordkeeping requirements for §26.155(a)(4) are established by §26.157.

Recordkeeping requirements for§26.155(a)(5) are established by §26.715(b)(3).

The recordkeeping burden for §26.155(e) and (f) is captured under HHS OMB control number 0930-0158.

Section 26.157, Procedures

Paragraph 26.157(a) requires HHS-certified laboratories to develop, implement, and maintain clear and well-documented procedures for accession, receipt, shipment, and testing of urine specimens.

Paragraph 26.157(b) requires HHS-certified laboratories to have written chain-of-custody procedures describing 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 the specimens.

Paragraph 26.157(c) requires HHS-certified laboratories to develop, implement, and maintain a written standard operating procedures manual for each assay performed for drug and specimen validity testing. If the licensee testing facility performs validity screening tests with non-instrumented devices, the facility is also required to develop, implement, and maintain written standard operating procedures for each device.

Paragraph 26.157(d) requires HHS-certified laboratories to develop, implement, and maintain written procedures for instrument and device setup and normal operation.

Paragraph 26.157(e) requires HHS-certified laboratories to develop, implement, and maintain written procedures for remedial actions to be taken when systems and non-instrumented testing devices (if used for validity screening tests) are out of acceptable

limits or errors are detected. Each facility is required to maintain documentation that these procedures are followed and that all necessary corrective actions are taken. In addition, all facilities are required to have systems in place and to verify all stages of testing and reporting and to document the verification.

These requirements are consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, Section 11.1. These recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. As standard business practices, they are not considered a burden for this analysis.

The recordkeeping burden for §26.157(a), (b), (c), (d) and (e) is captured under HHS OMB control number 0930-0158 .

Section 26.159, Assuring specimen security, chain of custody, and preservation

Paragraph 26.159(a) requires each HHS-certified laboratory to limit access to secured areas only to specifically authorized individuals whose authorization is documented.

Paragraph 26.159(b) requires HHS-certified laboratories to inspect each shipment of specimens for evidence of possible tampering and to compare information on specimen bottles within each package to the information on the accompanying custody-and-control forms. Any direct evidence of tampering or discrepancies in the information on the specimen bottles and the custody-and-control forms attached to the specimen bottles 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.

Paragraph 26.159(c) requires laboratory personnel to use aliquots and laboratory internal custody-and-control forms when conducting initial and confirmatory tests, and that these forms remain in secure storage.

Paragraph 26.159(d) requires each HHS-certified laboratory's internal custody-and-control form to allow for identification of the donor, and documentation of the testing process and transfers of custody of the specimen.

Paragraph 26.159(e) requires each HHS-certified laboratory's personnel to document the date and purpose each time a specimen is handled or transferred within the laboratory on the custody-and-control form, and to identify every individual in the chain. Authorized technicians are required to sign and complete custody-and-control forms for each specimen or aliquot as they are received.

Paragraph 26.159(f) requires that, when transferring a specimen to a second HHS-certified laboratory, the original custody-and-control form is packaged with its associated urine specimen bottle.

Paragraph 26.159(i) requires that, unless otherwise authorized in writing, specimens be retained in proper storage for 1 year.

These requirements are consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, Sections 11.7, 11.8., and 16.1. These requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. As standard business practices, they are not considered a burden for this analysis.

The recordkeeping burden for §26.159(a) is captured under HHS OMB control number 0930-0158.

Recordkeeping requirements for §26.159(b) are established by §26.715(b)(3).

Recordkeeping requirements for §26.159(c), (d), (e), (f), and (i) are established by §26.715(b)(2).

Reporting requirements for reports of tampering to NRC under §26.159(b) are established by §26.719(b)(3).

Section 26.163, Cutoff levels for drugs and drug metabolites

Paragraph 26.163(a)(2) specifies that if initial validity testing indicates that a specimen is dilute, and any response is equal to or greater than 50 percent of the cutoff, the HHS-certified laboratory shall test the specimen for those drugs and/or drug metabolites down to the confirmatory assay's limit of detection (LOD). The laboratory shall report the numerical values obtained from this special analysis to the MRO.

This requirement is necessary to validate a dilute result to protect donors from inaccurate results, to provide assurance that specimens of questionable validity are detected, and to ensure the integrity of the testing process.

The recordkeeping requirements for §26.163(a)(2) are established by §26.715(b)(6).

Section 26.165, Testing split specimens and retesting single specimens

Paragraph 26.165(b)(1) requires that 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.

Paragraph 25.165(b)(2) requires the MRO to 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 re-testing 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 is required to 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. .

Paragraph 25.165(b)(3) requires the donor to provide his or her permission for re-testing an aliquot of the single specimen or the testing of Bottle B.

Paragraph 25.165(b)(4) provides that if the donor has not requested a retest of an aliquot of a single specimen or a test of the split specimen 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, or other circumstances unavoidably prevented the donor from making a timely request. If the MRO concludes that there was a legitimate reason for the donor's failure to contact the MRO within 3 business days, the MRO shall direct the retesting take place, as if the donor had made a timely request.

Paragraph 26.165(b)(6) requires the HHS-certified laboratory that re-tests an aliquot of a single specimen or tests the specimen in Bottle B to provide the test results to the MRO and the MRO to provide the test results to the donor.

Paragraph 25.165(c)(4) provides that a second laboratory conducting retesting shall report all results to the licensee's or other entity's MRO.

Paragraph 26.165(f)(1) specifies that a licensee or other entity may administratively withdraw an individual's authorization on the basis of a first confirmed positive, adulterated, or substituted test result until the results of testing Bottle B or retesting an aliquot of a single specimen are available and have been reviewed by the MRO. Paragraph 26.165(f)(1) requires that 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 FFD policy in response to a suitable inquiry conducted under §26.63, a background investigation conducted under Part 26, or to any other inquiry or investigation. The licensees or other entities must provide access to the system of files and records to personnel who are conducting reviews, inquiries into allegations, audits under §26.41, and to NRC inspectors, to ensure that no records are retained. The licensees or other entities 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.

Paragraph 26.165(f)(1)(ii) requires that the licensee or other entity eliminate any matter from the individual's FFD record and other records that could link the individual to the temporary administrative action immediately upon receipt of a negative report from the testing of Bottle B or retesting the aliquot of a single specimen.

Paragraph 26.165(f)(1)(iv) requires that the licensee or other entity 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.

Paragraph 26.165(f)(2) requires that if the donor requests that either Bottle B be tested or an aliquot of a single specimen be retested and either is not available, 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) or any temporary administrative action.

These requirements are necessary to provide donors with the opportunity to request that either Bottle B of a split specimen or an aliquot of a single specimen be tested if an initial non-

negative test result is obtained, and to ensure that no records of a temporary administrative action taken as a result of an initial non-negative test result are retained if a negative report is received from the testing of Bottle B or retesting of an aliquot of a single specimen. These requirements are, in part, consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, Section 15.1. The requirements are necessary to protect donors from inaccurate results and to provide assurance that specimens of questionable validity are detected. They also assure to the donor the confidential nature of temporary administrative actions.

Recordkeeping requirements for the test result collections in §26.165(b)(1), (b)(6), and (c)(4) are established by §26.715(b)(6).

Recordkeeping requirements for third-party collections for notifications to the donor, permissions by the donor, and access to records by the NRC inspectors under §26.165(b)(1), (b)(2), (b)(3), (b)(4), (b)(6), (f)(1), (f)(1)(ii), (f)(1)(iv), and (f)(2) are established in this section.

Section 26.167, Quality assurance and quality control

> Paragraph 26.167(a) requires each HHS-certified laboratory to have a quality assurance program encompassing 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, limit of detection (LOD), limit of quantitation (LOQ), specificity) of each test must be validated and documented for each test. Validation 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.

This requirement is consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. These recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing, and to ensure the scientific legitimacy of test results. As standard business practices, they are not considered a burden for this analysis.

> Paragraph 26.167(c)(2)(i) requires a refractometer used by an HHS-certified laboratory to report and display the specific gravity to 4 decimal places and to be interfaced with a laboratory information management system or computer and/or to generate a hard copy or digital electronic display to document the numerical result.

This requirement is necessary to establish the specifications for refractometers used in HHS-certified laboratories to perform tests for FFD programs. The section does not create any separate records, but determines the types of records that will be created under other sections of Part 26. The section is consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. This requirement also is necessary to protect donors from inaccurate results, to allow donors to see the result, and to ensure the integrity of the testing process.

Recordkeeping requirements for the records created meeting the specifications of §26.167(c)(2)(i) under other sections of Part 26 are established by §26.715(b)(14).

Paragraph 26.167(f) requires the licensee or other entity to ensure that the HHS-certified laboratory investigates any testing errors or unsatisfactory performance. Paragraph 26.167(f)(1) requires sufficient records to be maintained to furnish evidence of activities affecting quality. The identification of the significant condition, the cause of the condition, and the corrective action taken are required to be documented and reported to appropriate levels of management Paragraph 26.167(f)(3) requires, if a false positive error occurs on a blind performance test sample and the error is determined to be technical or methodological, that the licensee or other entity instruct the laboratory to provide all quality control data from the batch or analytical run of specimens that included the false positive sample. If retesting is required, the retesting must be documented by a statement signed by the laboratory's certifying scientist.

These requirements are consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs and with 10 CFR Part 50, Appendix B, Quality Assurance Requirements for Nuclear Power Plants and Fuel Reprocessing Plants, Criterion XVI, Quality Assurance Records. These requirements are necessary to protect donors from inaccurate results, to provide assurance that specimens of questionable validity are detected, and to ensure the integrity of the testing process.

Paragraph 26.167(h) requires laboratory calibrators and controls to be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions that are obtained from commercial manufacturers and that are properly labeled as to content and concentration. The standards and controls must be labeled with the dates when they are received, when prepared or opened, when placed in service, and when scheduled for expiration.

These requirements are consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs and are standard business and laboratory practices necessary for any laboratory to conduct forensic drug testing, and to ensure the scientific legitimacy of test results. As standard business practices, they are not considered a burden for this analysis.

Recordkeeping requirements for §§26.167(a), (c)(2)(i), and (f) are established by §26.715(b)(7).

Recordkeeping requirements for §26.167(h) are established by §26.715(b)(3).

Section 26.168, Blind performance testing

Paragraph 26.168(a) requires each licensee or other entity to submit blind performance test samples to the HHS-certified laboratory. Sixty percent of the blind performance test samples submitted to the laboratory must be positive for one or more drugs.

This third-party collection requirement involves the use of a simple standard form, and is a standard business practice of laboratories that prepare blind performance test samples.

Paragraph 26.168 (h)(2) requires each licensee or other entity to ensure that the supplier of blind performance test samples provides the expiration date for each test sample.

This third-party collection requirement is a standard business practice of laboratories that prepare blind performance test samples.

Paragraph 26.168(i)(2) requires each licensee or other entity to 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 speciemn is a blind performance test sample.

This third-party collection requirement is a standard business practice for blind performance test samples.

Section 26.169, Reporting results

Paragraph 26.169(a) requires HHS-certified laboratories to report test results to the licensee's or other entity's MRO within 5 business days after receiving the specimen. Before reporting any test result, the laboratory's certifying scientist must 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.

Paragraph 26.169(c)(1) requires HHS-certified laboratories to report all positive, adulterated, substituted, dilute, and invalid test results to the MRO.

Paragraph 26.169(c)(2) requires HHS-certified laboratories to report to the MRO numerical values for all positive test results if the MRO requests them. 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.

Paragraph 26.169(c)(3) requires HHS-certified laboratories to report to the MRO numerical values for all adulterated or substituted test results.

Paragraph 26.169(c)(4) requires the HHS-certified laboratory to 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.

Paragraph 26.169(c)(5) an HHS-certified 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.

Paragraph 26.169(e) requires the HHS-certified laboratory to transmit results by electronic means (e.g., teleprinter, facsimile, or computer) in a manner designed to ensure the confidentiality of the information, and would prohibits transmitting results verbally by telephone.

Paragraph 26.169(f) requires the HHS-certified laboratory to 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.

Paragraph 26.169(g) requires the HHS-certified laboratory for a specimen that has a positive, adulterated, substituted, dilute, or invalid result, to 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.

Paragraph 26.169(h) requires the HHS-certified laboratory to prepare an annual statistical summary report of urinalysis testing results for that year. To avoid sending data from which it is likely that information about an individual donor's test result can be inferred, the laboratory is not permitted to send a report if the licensee or other entity has fewer than 10 specimen test results in a one-year period. The summary report is required to be sent within 14 calendar days after the end of the one-year period covered by the report. Information that is required to be included in the summary report is listed in §§26.169(k)(1) - (8).

These requirements are necessary to ensure that licensees and other entities receive all necessary reports of test results and testing-related information from HHS-certified laboratories performing services for the licensees or other entities. This information is necessary for implementation of the licensee or other entities' FFD programs and for submission in annual FFD program reports to the NRC. The recordkeeping and reporting requirements under §26.169 are established by contract between licensees and other entities and HHS-certified laboratories. Such records and reports are generally consistent with the requirements for HHS-certified laboratories in the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, as well as with usual and customary business practices for such laboratories.

Recordkeeping requirements for §26.169 are established by §26.715(b)(2), (b)(3), (b)(5), (b)(6), and (b)(8).

Section 26.183, Medical Review Officer

Paragraph 26.183(a) establishes the required qualifications of the MRO and requires a record of the degree held by the MRO and the results of the MRO examination administered by a nationally-recognized MRO certification board or subspeciality board.

This requirement is necessary to ensure that if questions are raised about the qualifications of the MRO a record is available that indicates that the MRO meets the requirements specified in Part 26 to serve as an MRO.

Paragraph 26.183(c)(1) requires the MRO to examine alternate causes of a positive, adulterated, substituted, invalid and, at the licensee's or other entity's discretion, dilute result, including reviewing records made available by the donor, and documented medical conditions.

Paragraph 26.183(d)(1)(ii)(D) requires the MRO to maintain the confidentiality of records and other donor personal information, except for those releases permitted under Part 26; to ensure the security of data transmission; and to ensure that drug test results are reported to the licensee's or other entity's designated reviewing official only in accordance with the requirements of Part 26.

These requirements and records are necessary to specify how the MRO performs certain duties.

Paragraph 26.183(d)(2)(i) allows MRO staff, under the direction of the MRO, to receive, review, and report negative test results to the licensee's or other entity's designated representative.

Paragraph 26.183(d)(2)(ii) requires that the staff reviews of positive, adulterated, substituted, invalid, or 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 that require corrective action(s), but must forward the custody-and-control forms to the MRO for review and approval of the resolution.

These requirements are necessary to ensure the protection of personal information, except as necessary for the ongoing implementation of the FFD program. These requirements define the limits of the duties that the staff of the MRO may perform, and require the staff to make third-party communications with the MRO to inform the MRO about actions proposed by the staff. Review of chain-of-custody errors and review of test results by an independent MRO is a key due process protection for individuals. These requirements therefore partially meet the legal necessity of protecting the due process rights of individuals who are subject to Part 26.

Recordkeeping requirements for §§26.183(a) are established by this section or, for MROs no longer employed by the licensee, by §26.715(b)(1).

Recordkeeping requirements for §§26.183(c)(1), (d)(1)(ii), (d)(2)(i) and (d)(2)(ii) are established by §26.713(a)(2).

Section 26.185, Determining a fitness-for-duty violation

Paragraph 26.185(a) requires the MRO to review all positive, adulterated, substituted, dilute, or 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.

Paragraph 26.185(c) prohibits the MRO from determining that a positive, adulterated, substituted, dilute, or invalid result or other occurrence is a FFD policy violation and reporting it to the licensee or other entity without giving the donor an opportunity to discuss the test result or other occurrence with the MRO, if, after discussion, the MRO determines the result or occurrence is FFD violation, the MRO shall notify the licensee.

These requirements are necessary to ensure that before the licensee or other entity is notified of a possible FFD violation the MRO has reviewed the positive, adulterated, substituted, dilute, or invalid result and, before reporting it as a violation, has discussed the result with the donor.

Paragraph 26.185(d) allows the MRO to 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 three instances (1) if the MRO had made and documented contact with the donor and the donor expressly declined the opportunity to discuss the test result or other occurrence that might constitute an FFD policy violation; (2) a representative of the licensee or other entity, or a MRO staff member, has successfully made and documented contact with the donor and has instructed him or her to contact the MRO; 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.

Paragraph 26.185(e) allows a donor, within 30 days of notification, to present to the MRO information documenting circumstances that 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 to request that the MRO reopen the procedure for determining whether the donor's test result or other occurrence is an FFD policy violation.

The requirements in §§26.185(c), (d), and (e) partially meet the legal necessity of protecting the due process rights of individuals who are subject to Part 26, and also proving "prior notice" and having it documented for evidence in legal proceedings.

Paragraph 26.185(f)(1) requires the MRO to consult with an HHS-certified laboratory that reports an invalid result, to determine if additional testing by another HHS-certified laboratory would be useful.

This requirement is necessary to protect donors from inaccurate results, to provide assurance that specimens of questionable validity are detected, and to ensure the integrity of the testing process.

Paragraph 26.185(f)(2) requires the MRO, if additional testing is not useful, to contact the donor to determine whether there is an acceptable medical explanation for the invalid result, and, if there is, to report to the licensee that the test result is not an FFD policy violation.

Paragraph 26.185(h)(1) requires the MRO, if the HHS-certified laboratory reports a specimen as substituted, to contact the donor and offer the donor an opportunity to provide an acceptable medical explanation for the substituted result. The donor must provide credible medical evidence within 5 business days that he or she produced the specimen for which the HHS-certified laboratory reported a substituted result. Any medical evidence must be submitted through a referral physician who is experienced and qualified in the medical issues involved.

Paragraph 26.185(h)(2) requires the MRO, if the MRO determines there is no acceptable medical explanation for the substituted test result, to report to the licensee or other entity that the specimen was substituted.

Paragraph 26.185(h)(3) requires the MRO, if the MRO determines there is an acceptable medical explanation for the substituted test result, to report to the licensee or other entity that no FFD policy violation has occurred.

Paragraph 26.185(i)(1) requires the MRO, if the HHS-certified laboratory reports a specimen as adulterated, to contact the donor and offer the donor an opportunity to provide an acceptable medical explanation for the adulterated result. The donor is required to provide creditable medical evidence within 5 business days that he or she produced the adulterated result through normal human physiology.

Paragraph 26.185(i)(2) requires that, if the MRO determines there is no acceptable medical explanation for the adulterated test result, the MRO must report to the licensee or other entity that the specimen is adulterated.

Paragraph 26.185(i)(3) requires that, if the MRO determines there is an acceptable medical explanation for the adulterated test result, the MRO must report to the licensee or other entity that there was no FFD policy violation.

Paragraph 26.185(j)(3) requires that, if the MRO determines that the donor has used another individual's prescription medication and evidence of drug abuse is found, the MRO must report to the licensee that the donor has violated the FFD policy.

Paragraph 26.185(k) requires, 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, the MRO to report to the licensee or other entity that no FFD policy violation has occurred.

Paragraph 26.185(m) provides that, 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.

Paragraph 26.185(n) provides that, if a second laboratory reconfirms any drug-positive test results or reconfirms any adulterated, substituted, or invalid validity test results, the MRO may report an FFD policy violation to the licensee or other entity; if the second laboratory does not reconfirm any drug-positive test results, the MRO shall report that no FFD policy violation has occurred; or if the second laboratory does not reconfirm any adulterated, substituted, or invalid validity test results, the MRO shall report that no FFD policy violation has occurred.

Paragraph 26.185(o) requires the MRO to review drug test results from an individual whose authorization was terminated or denied following a first violation of FFD policy. 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.

Paragraph 26.185(p) requires the MRO to complete the MRO's review of positive, adulterated, substituted, and invalid test results and, in those instances in which the MRO determines that the donor has violated the licensee's or other entity's FFD policy, to notify the licensee or other entity's designated representative in writing within 10 business days of an initial positive, adulterated, or substituted test result.

The requirements in §§26.185(h)(1), (h)(2), (h)(3), (i)(1), (i)(2), (i)(3), (m), (n), (o) and (p) are necessary to partially meet the legal necessity of protecting the due process rights of individuals who are subject to Part 26, and also proving "prior notice" and having it documented for evidence in legal proceedings. The requirements also protect donors from inaccurate results, to provide assurance that specimens of questionable validity are detected, and to ensure the integrity of the testing process.

Recordkeeping requirements for §26.185 are established by §26.713(a)(2).

Section 26.187, Substance Abuse Expert

Paragraph 26.187(d) requires the Substance Abuse Expert (SAE) to receive qualification training on the background, rationale, and scope of Part 26; key drug testing requirements of Part 26, including specimen collection, laboratory testing, MRO review, and problems in drug testing; key alcohol testing requirements of Part 26, including specimen collection, laboratory testing, MRO review, and problems in alcohol tests; SAE qualifications and prohibitions; 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; procedures for SAE consultation and communication with licensees or other entities, MROs, and treatment providers; reporting and recordkeeping requirements of Part 26; and issues that SAEs confront in carrying out their duties under Part 26.

This requirement is necessary to ensure that SAEs are aware of the special requirements associated with their position. Some aspects of the SAE training are covered in the FFD training given to all individuals who are subject to the FFD program. Additional training in topics specific to the SAE will also be prepared and given.

Paragraph 26.187(f) requires the Substance Abuse Expert to maintain documentation showing that he or she currently meets all credentials, knowledge, and training requirements for a Substance Abuse Expert established by §26.187, and to provide this documentation upon request to NRC representatives, licensees, or other entities who are relying upon or contemplating relying upon the substance abuse expert's services and to other individuals and entities, in accordance with the requirements of § 26.37.

This requirement is necessary to ensure that the training and competency of the Substance Abuse Expert can be verified by NRC inspectors, license auditors, or other staff of the licensee or other entity conducting self-assessments or other activities. Records of training and competency may be important evidence in any litigation that may occur with respect to test results and/or FFD program management actions or sanctions. In addition, records of training and competency of Substance Abuse Experts will support reliance by licensees and other entities on FFD program results from other Part 26 programs.

Recordkeeping requirements for §§26.187(d) and (f) are established by this section, or for SAEs no longer employed by the licensee by §715(b)(1).

Reporting requirements for §26.187(f) are established by this section.

Section 26.189, Determination of Fitness

Paragraph 26.189(a) provides that a determination of fitness, the process entered when there are indications that an individual in § 26.4(a) through (e), and, at the licensee's or other entity's discretion, § 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, 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 written record of the determination of fitness must be prepared.

Paragraph 26.189(c) provides that a determination of fitness that is conducted "for cause" must be conducted through face-to-face interaction between the subject individual and the professional making the determination. 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 Part 26 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 is required to 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. A written record of the determination of fitness conducted "for cause" must be prepared.

These requirements are necessary to specify the procedures to be followed in making determinations of fitness of individuals under Part 26. Licensees must ensure that certain individuals whose job duties require them to have access to the protected areas of nuclear power plants or to perform certain specified duties are fit-for-duty. The determinations of fitness-for-duty must provide reasonable assurance that such individuals are trustworthy and reliable, as demonstrated by the avoidance of substance abuse, are not under the influence of legal or illegal drugs or alcohol, or mentally or physically impaired from any cause that in any way adversely affects their ability to safely and competently perform their duties, and that the effects of fatigue and degraded alertness on individual's abilities to safely and competently perform their duties are managed commensurately with maintaining public health and safety, common defense, and security. The fitness-for-duty determinations must also provide reasonable measures for the early detection of individuals who are not fit to perform the job duties that require them to be subject to the program and provide reasonable assurance that the workplaces subject to Part 26 are free from the presence and effects of illegal drugs and alcohol. These requirements also partially meet the legal necessity of protecting the due process rights of individuals who are subject to Part 26, and also proving "prior notice" and having it documented for evidence in legal proceedings.

Paragraph 26.189(d) provides that after the initial determination of fitness has been made, the professional making the determination may modify his or her evaluation and recommendations based on new or additional information from other sources.

This requirement is necessary to ensure that if additional information is received that causes the determination of fitness to be modified, the determination is modified and records pertaining to the determination are changed to reflect the new determination.

Recordkeeping requirements for §26.189 are established by §26.713(a)(4).

Section 26.203, General provisions

Paragraph 26.203(a) requires each licensee or other entity subject to Part 26, Subpart I, to establish a policy for the management of fatigue for all individuals who are subject to the licensee's FFD program and to incorporate it into the written policy required in §26.27(b).

Paragraph 26.203(b) requires each licensee or other entity subject to Part 26, Subpart I, to develop, implement, and maintain written procedures that describe the process to be followed when an individual subject to Part 26 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; describe the process for implementing the controls required under

§26.205; describe the process for conducting fatigue assessments; and describe the sanctions, if any, that the licensee may impose on an individual following a fatigue assessment and the conditions and consierations for taking those sanctions.

These requirements are necessary to ensure that written policies and procedures are available to individuals that indicate how each FFD program subject to Subtitle I meets the general objectives of Part 26, Subpart I, and that describe any allowable variations in the program. The policy and procedures are necessary to ensure that individuals who are covered by Subpart I are aware of their responsibilities and rights by informing them with sufficient detail about licensee FFD rules, what is expected of them, and what consequences may result from a lack of adherence to the FFD policy. The requirements also partially meet the legal necessity of proving "prior notice" and having it documented for evidence in legal proceedings.

The policy and procedures for fatigue management are included in the overall policy and procedures for FFD. Therefore, the burdens for the written policy and procedures required under §26.203 are included under §§26.27(b) and (c) for the overall policy and procedures.

Paragraph 26.203(c) requires licensees to add specific knowledge and abilities (KAs) to the content of the training that is required in §26.29(a) and the comprehensive examination required in §26.29(b) relating to knowledge of and ability to identify symptoms of work fatigue and contributors to decreased alertness in the workplace.

This requirement is necessary to ensure that individuals assigned to activities within the scope of Part 26 Subpart I are provided with appropriate training with respect to fatigue so that they are sufficiently skilled to detect conditions that arise from fatigue, they know the proper action to be initiated, and that they understand the methods that will be used to implement the FFD policy, the personal and public health and safety hazards associated with fatigue, their roles and responsibilities in the implementation of the fitness-for-duty program as it addresses fatigue, the role of the Medical Review Officer (MRO), and the EAP services available. The requirement also partially meets the legal necessity of providing "prior notice" and having it documented for evidence in legal proceedings.

Paragraph 26.203(d) requires all licensees and other entities to retain the following records for at least 3 years or until the completion of all related legal proceedings, whichever is later:

- Paragraph 26.203(d)(1): Records of work hours for individuals subject to the work hour controls in §26.205;
- Paragraph 26.203(d)(2): Records of shift schedules and shift cycles of individuals who are subject to the work hour controls in §26.205;
- Paragraph 26.203(d)(3): Documentation of waivers that is required in §26.207(a)(4), including the basis for granting the waivers.
- Paragraph 26.203(d)(4): Documentation of work hour reviews that is required in §26.205(e)(3) and (e)(4); and
- Paragraph 26.203(d)(5): Documentation of fatigue assessments that is required in §26.211(f).

These requirements are necessary to ensure that licensees and other entities establish and properly implement fatigue management programs. Licensees and other entities must maintain records to demonstrate the fulfillment of regulatory requirements for self-assessments and to support the preparation of annual reports, and to provide information to the NRC to be used in evaluating the effectiveness of the fatigue management programs required by Part 26.

Paragraph 26.203(e) requires that the following information in a standard format is included in the annual FFD program performance report required under §26.717:

- Paragraph 26.203(e)(1): Summaries for each nuclear power plant site of all instances during the previous calendar year in which 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: 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; 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; and 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.).

- Paragraph 26.203(e)(2) requires licensees to summarize instances of fatigue assessments for each NPP site during the previous calendar year, for any individual indentified in § 26.4(a) through (c). The summary must include: the conditions under which each fatigue assessment was conducted (i.e., self-declaration, for cause, post-event, followup); 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; 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 the management actions, if any, resulting from each fatigue assessment.

These requirements are necessary to ensure that licensees and other entities provide information to the NRC to demonstrate their fulfillment of regulatory requirements for fatigue management and to allow the NRC to assess the effectiveness of the fatigue management requirements. Collection of this information pertaining to significant fatigue-management topics, events, and actions is necessary to permit self-assessments and internal reviews and audits by licensees and to permit timely evaluation of events that might become problems and that may require action by the NRC staff to ensure that the health and safety of the public is not endangered.

Recordkeeping requirements for §26.203 are established by this section.

Reporting requirements for §§26.203(e)(1), and (e)(2) are established by this section.

Section 26.205, Work hours

Paragraph 26.205(b) requires licensees to calculate the work hours of individual's 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.

Paragraph 26.205(c) requires licensees to 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.

Paragraph 26. 205 (d)(1) requires licensees to implement work hour controls for individuals to ensure that, except as permitted by the waiver provisions in §26.207, individual's work hours do not exceed 16 work hours in any 24-hour period, 26 work hours in any 48-hour period, and 72 work hours in any 7-day period.

Paragraph 26. 205 (d)(2) requires licensees to ensure that individuals have adequate rest breaks between successive work periods, during which the individual does not perform any duties for the licensee other than one shift turnover, either at the beginning or the end of a shift, but not both. Except as permitted in § 26.207, at a minimum, licensees are required to ensure that individuals subject to Subpart I have a 10-hour break between successive work periods or an 8-hour break when a break of less than 10 hours is necessary to accomodate a crew's scheduled transition between work schedules or shifts; and a 34 - hour break in any 9 - day period.

Paragraph 26. 205(d)(3) requires licensees to 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 in 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. Individuals who are working 8-hour shift schedules shall have at least 1 day off per week, averaged over the shift cycle; individuals who are working 10-hour shift schedules shall have at least 2 days off per week, averaged over the shift cycle; 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 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.

Paragraph 26.205(d)(4) exempts licensees from the requirements of paragraph (d)(3) of this section for individuals specified in § 26.4(a)(1) through (a)(4) for the first 60 days of an outage, while the individuals are working on unit outage activities. However, the licensee is required to ensure that these individuals have at least 3 days off in each successive (i.e., non-rolling) 15-day period.

Paragraph 26.205(d)(5) exempts licensees from the requirements of paragraph (d)(3) of this section for individuals specified in § 26.4(a)(5) for the first 60 days of a unit outage, security system outage, or increased threat condition. However, licensees shall ensure that these individuals have at least 4 days off in each successive (i.e., non-rolling) 15-day period; and 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.

Paragraph 26.205(d)(6) extends the 60-day periods in paragraphs (d)(4) and (d)(5) of this section 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, as applicable.

Paragraph 26.205(d)(7) requires the licensee to implement the requirements in paragraphs (d)(4) through (d)(6) of this section based upon the number of days that have elapsed since the first outage in the series began 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.

Paragraph 26. 205(e)(1) and (2) requires licensees to review the effectiveness of their control of work hours for individuals who are subject to Part 26, Subpart I, at a minimum twice per calender year. The two reviews need not cover periods of equal duration but must collectively cover the entire calendar year. The reviews evaluate the effectiveness of the work hour controls and assess staffing adequacy for all jobs subject to the work hour controls.

Paragraph 26. 205(e)(3) requires licensees to document the methods used to conduct the reviews and the results of the reviews.

Paragraph 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.

These requirements are necessary to ensure that licensees and other entities are properly implementing work hour controls, including waivers of those controls, for personnel performing activities on systems, structures, and components that a risk-informed evaluation process has shown to be significant to public health and safety. These records are necessary to enable licensees and other entities to review and correct any problems in maintaining control of work hours, to enable the NRC to inspect the licensee's and other entities' fatigue management programs, and to provide information for periodic audits.

Recordkeeping requirements for §26. 205(c) and (d)(1) are established by §26.203(d)(1).

Recordkeeping requirements for §26.205(d)(2) through (d)(7) are established by §26.203(d)(2).

Recordkeeping requirements for §25.205(e)(1) through (e)(3) are established by §26.203(d)(4).

Recordkeeping requirements for §26.205(e)(4) are established by this section.

Section 26.207, Waivers and exceptions

Paragraph 26.207(a)(4) requires licensees to 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.

Recordkeeping requirements for §25.207 are established by §26.203(d)(3).

Section 26.211, Fatigue assessments

Paragraph 26.211(f) requires licensees to document the results of any fatigue assessments conducted, the circumstances that necessitated the fatigue assessment, and any controls and conditions that were implemented.

This requirement is necessary to ensure that fatigue assessments of individuals are conducted in appropriate circumstances and in an appropriate manner. This requirement is necessary to ensure that the due process rights of individuals who are subject to the fatigue management requirements are protected. It will support internal licensee self-assessments of fatigue-management programs. This requirement also will enable the NRC to review and audit the licensees' and other entities' fatigue management programs.

Recordkeeping requirements for §26.211(f) are established by §26.203(d)(5).

Section 26.401, General

Paragraph 26.401(b) requires licensees and other entities who elect to implement an FFD program under Subpart K to submit an FFD program plan to the NRC for review and approval as part of the license or permit application.

This requirement is necessary to ensure licensees develop a plan to ensure worker fitness for duty prior for the start of construction of a nuclear reactor.

Section 26.403, Written Policy and Procedures

Paragraph 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. 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.

Paragraph 26.403(b) requires FFD programs under this Subpart K to develop, implement, and maintain written procedures that address drug and alcohol testing program methods and techniques and procedures for ensuring valid results attributable to the correct individual, actions taken and procedures used for FFD violations, and the process to be followed for behavior that may raise concerns of possible FFD violations or impairment.

The written FFD policy and procedures required by Subpart K are the primary means by which a licensee or other entity communicates its FFD policy and procedures to individuals who are subject to the policy and procedures. These requirements are also necessary to ensure that individuals are protected by informing them in sufficient detail about licensee FFD rules, what is expected of them, and what consequences may result from a lack of adherence to the FFD policy. Because the consequences of lack of adherence to the FFD policy can be very severe, including inability to perform certain functions in the industry, it is particularly important that all individuals who are potentially subject to them know their details. The one-time burden for the initial development of the policy is shown under this paragraph.

Section 26.405, Drug and alcohol testing

Paragraph 26.405(b) provides that if a licensee or other entity elects to impose random testing for drugs and alcohol, the random testing must meet certain specified criteria.

Paragraph 26.405(c)(1) requires licensees to conduct pre-assignment testing before employees are assigned to perform activities specified in § 26.4(f).

Paragraph 26.405(c)(2) requires licensees to conduct for-cause testing 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.

Paragraph 26.405(c)(3) requires licensees to conduct post-accident testing as soon as practical after an event involving human error committed by individuals specified in § 26.4(f), where the human error may have caused or contributed to the accident. The individual(s) who committed the human error(s) shall be tested if the event resulted in: a significant illness or personal injury to the individual to be tested or another individual, which is recordable under the Department of Labor standards contained in 29 CFR 1904.7, 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; or, even if it does not result in death, if it results in days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness; or significant damage to SSCs that are required to be described in the FSAR.

Paragraph 26.405(c)(4) requires licensees to conduct followup testing as part of a followup plan to verify an individual's continued abstinence from substance abuse.

Paragraph 26.405(d) requires licensees and other entities to test for specified drugs, adulterants, and alcohol, at the cutoff levels specified in Part 26, and requires urine specimens collected for drug testing to be subject to validity testing.

Paragraph 26.405(e) requires the specimen collection and drug and alcohol testing procedures of FFD programs under Subpart K to protect the donor's privacy and the integrity of the specimen, and to 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 requriements of 49 CFR Part 40.

Paragraph 26.405(f) requires 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 an HHS-certified laboratory. Any initial drug test performed by a licensee or other entity must use an immunoassay that meets FDA requlirements for commercial distribution. 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.

Paragraph 26.405(g) requires FFD programs under this subpart to provide for an MRO review of positive, adulterated, substituted, and invalid drug and validity test results from the HHS-certified laboratory 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.

These requirements are necessary to ensure testing occurs under all necessary circumstances. In order to ensure proper FFD is maintained testing must occur in pre-assignment, for cause, post accident, followup, and random circumstances.

Section 26.406, Fitness Monitoring Program

Paragraphs 26.406(a), (b), and (d) require licensees and other entities that do not implement random testing under § 26.405(b) to establish 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 on site or while on duty; impairment from any cause that if left unattended may result in a risk to public health and safety or the common defense and security, and any actions or other indications that call into question an individual's trustworthiness and reliability under Part 26. To ensure that the fitness of individuals is monitored effectively, licensees and other entities must consider the number and placement of monitors requlried, the necessary ratio of monitors to individuals specified in §24.4(f), and the frequency with which observations must be conducted.

Paragraph 26.406(c) requires licensees and other entities that do not elect to establish a random testing program to establish instead a fitness monitoring program and to establish procedures that fitness monitors shall follow and to train the monitors to implement the program.

These requirements are necessary to ensure that fitness monitors know and understand the procedures established for the fitness monitoring program if the licensee or other entity elects to establish a fitness monitoring program.

Section 26.407, Behavioral Observation

Paragraph 26.407 requires a licensee or other entities who implement an FFD program under this subpart to ensure that the individuals who are specified in §26.4(e) perform behavioral observation of the individuals listed in §26.4(f), unless those persons are subject to a fitness monitoring program under §26.406.

This requirement is necessary to ensure that if licensees and other entities elect to implement a random drug and alcohol testing program under §26.405, they also implement behavioral observation under this section to deter substance abuse and detect indications of possible use, sale, or possession of illegal drugs, use or possession of alcohol on site, 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.

Section 26.411, Protection of Information

Paragraph 26.411(a) requires FFD programs that collect personal information about an individual for the purpose of complying with this subpart to establish and maintain a system of files and procedures to protect the personal information. FFD programs shall maintain and use such records with the highest regard for individual privacy.

Paragraph 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 this subpart before disclosing the personal information.

These information collection requirements are necessary to ensure the protection of personal information collected and maintained about individuals, and to ensure that such information is not disclosed to persons other than assigned MROs, other licensees legitimately seeking the information as required by Part 26 for employment decisions and who have obtained a release from current or prospective employees or C/V personnel, NRC representatives, appropriate law enforcement officials, the individual subject or his or her representative, or those licensee personnel who have a need to have access to the information in performing assigned duties.

Section 26.413, Review Process

Paragraph 26.413 requires FFD programs to 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.

These one-time requirements are necessary to ensure that there are written procedures that specify how each FFD program ensures that the criteria for determining that an individual has violated FFD policy have been met and will provide individuals with a specified process for reviewing and appealing determinations that the individual has violated FFD policy. The requirements are necessary to ensure that the due process rights of individuals who are subject to the rule are protected by informing them with sufficient detail about licensee review procedures, what is expected of the individual, and what consequences may result from a lack of adherence to the policy. The requirements also partially meet the legal necessity of proving "prior notice" and having it documented for evidence in legal proceedings.

Section 26.415, Audits

Paragraph 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 are provided by C/Vs, and the FFD programs of C/Vs that are accepted by the licensee or other entity.

These requirements for audit documentation, maintenance of audit records, and access to audit information are necessary to help ensure identification and resolution of program weaknesses and to help licensees and other entities, including C/Vs and HHS-certified laboratories, determine what corrective actions are necessary and carry out necessary corrective actions. The requirements help to ensure that necessary information is available for NRC inspections.

Section 26.417, Recordkeeping and Reporting

Paragraph 26.417(a) requires FFD programs to 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.

Paragraph 26.417(b)(1) requires licensees and other entities who implement FFD programs to make 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.

Paragraph 26.417(b)(2) requires licensees and other entities who implement FFD programs to make annual program performance reports for the FFD program.

These requirements are necessary to ensure that records are maintained by licensees and other entities that maintain collection sites and/or testing facilities, and by laboratories certified by the Department of Health and Human Services that provide services to licensees and other entities, that demonstrate that drug and alcohol testing requirements are implemented properly. Such records are generally consistent with the requirements for HHS-certified laboratories in the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, as well as with usual and customary business practices for such laboratories. These records are also necessary to enable licensees and other entities to review and correct any problems in implementing FFD drug and alcohol testing programs, and to enable the NRC to inspect the licensees' and other entities' drug and alcohol testing programs. This section groups recordkeeping requirements that apply to collection sites, testing facilities, and laboratories certified by the Department of Health and Human Services that provide services to licensees or other entities in one section in the rule, in order to improve clarity in the organization of the rule and to respond to requests from stakeholders.

These requirements are also necessary to ensure that licensees and other entities provide information about significant violations of FFD policy, testing errors, and other events affecting the performance of their FFD programs that will enable the NRC to ensure that those programs are adequately protecting public health and safety, common defense, and security. These reports are necessary to enable licensees and other entities to review and correct any problems in implementing FFD programs, and to enable the NRC to inspect the licensee's and other entities' FFD programs and to obtain information necessary to evaluate the effectiveness of the FFD programs. Collection of information pertaining to significant FFD events is necessary to permit evaluations of events that might become problems and that may require timely response by the NRC staff to ensure that the health and safety of the public is not endangered.

Section 26.711, General provisions [Recordkeeping and Reporting Requirements]

Paragraph 26.711(a) provides that each licensee and other entity shall maintain records and submit certain reports to the NRC. Records that are required by the regulations in Part 26 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 license, certificate, or other regulatory approval.

Paragraph 26.711(b) provides that each licensee and entity may store and archive records electronically, provided that the record is an accurate representation of the original, cannot be altered once it has been committed to storage, and can be easily retrieved and recreated.

Although no records or reports are required by this paragraph, this section influences how the records and reports required by Part 26 will be made, stored, and archived. This section provides licensees and other entities with the opportunity to use electronic records and makes the requirements in Part 26 consistent with access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plants dated January 7, 2003.

Section 26.713, Recordkeeping requirements for licensees and other entities

Paragraph 26.713(a)(1) requires the retention of records of self-disclosures and suitable inquiries conducted under §§26.55, 26.57, 26.59, and 26.69 that result in the granting of authorization 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.

Paragraph 26.713(a)(2) requires the retention of records pertaining to any determination of a violation of the FFD policy and related management actions 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.

Paragraph 26.713(a)(3) requires the retention of records of documentation of the granting and termination of authorization 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.

Paragraph 26.713(a)(4) requires the retention of records of any determinations of fitness conducted under §26.189 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.

Paragraph 26.713(b)(1) requires that licensees and other entities retain records of FFD training and examinations conducted under §26.29 for at least 3 years or until the completion of all related legal proceedings, whichever is later.

Paragraph 26.713(b)(2) requires that licensees and other entities retain records of FFD audits, audit findings, and corrective actions taken under §26.41 for at least 3 years or until the completion of all related legal proceedings, whichever is later.

Paragraph 26.713(c) requires that licensees and other entities 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 denials of authorization under §§26.75(b) and (g) for at least 40 years or until, upon application, the NRC determines that the records are no longer needed.

Paragraph 26.713(d) requires that licensees and other entities 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.

Paragraph 26.713(e) requires that licensees and other entities retain written agreements for the provision of services under Part 26 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.

Paragraph 26.713(f) requires that licensees and other entities retain records of the background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel, conducted under §26.31(b)(1), 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.

Paragraph 26.713(g) requires that if a licensee's and other entity's FFD program includes tests for drugs in addition to those specified in Part 26, the licensee or other entity shall retain the documentation certifying the scientific and technical suitability of the assays and cutoff levels used, as required under §26.31(d)(1) and (d)(3)(iii)(C) respectively, for the period of time during which the FFD program follows those practices of until the completion of all related legal proceedings, whichever is later.

These requirements are necessary to ensure that licensees and other entities collect and maintain records that demonstrate they are properly implementing FFD regulatory requirements in a manner adequate to protect public health and safety and the common defense and security. These records are also necessary to enable licensees and other entities to review and correct any problems in implementing FFD programs, and to enable the NRC to review and audit the licensee's and other entities' FFD programs. This section groups recordkeeping requirements that apply to licensees and other entities in one section in the rule, in order to improve clarity in the organization of the rule and thereby to reduce the information collection burden associated with this recordkeeping.

Section 26.715, Recordkeeping requirements for collection sites, licensee testing facilities, and laboratories certified by the Department of Health and Human Services

Paragraph 26.715(a) requires collection sites providing services to licensees and other entities who are subject to this subpart, licensee testing facilities, and HHS-certified laboratories to maintain and make available documentation of all aspects of the testing process for at least two years or until the completion of all legal proceedings related to the determination of an FFD violation, whichever is later, and also provides that the 2-year period may be extended upon written notification by the NRC or by any licensee or other entity for whom services are being provided.

Paragraph 26.715(b) specifies that the records that must be retained pursuant to §26.715(a) include the following:

- Paragraph 26.715(b)(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;
- Paragraph 26.715(b)(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 approriate summary information has been recorded for program administration purposes);
- Paragraph 26.715(b)(3): Quality assurance and quality control records;
- Paragraph 26.715(b)(4): Superseded procedures;
- Paragraph 26.715(b)(5): All test data (including calibration curves and any calculations used in determining test results);
- Paragraph 26.715(b)(6): Test reports;
- Paragraph 26.715(b)(7): Records pertaining to performance testing;
- Paragraph 26.715(b)(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;
- Paragraph 26.715(b)(9): Performance records on certification inspections;
- Paragraph 26.715(b)(10): Records of preventative maintenance on licensee testing of facility instruments;
- Paragraph 26.715(b)(11): Records that summarize any negative test results based on scientific insufficiency;
- Paragraph 26.715(b)(12): Printed or electronic copies of computer-generated data;
- Paragraph 26.715(b)(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
- Paragraph 26.715(b)(14): Records of the inspection, maintenance, and calibration of EBTs.

These requirements are necessary to ensure that records are maintained by licensees and other entities that maintain collection sites and/or testing facilities, and by laboratories certified by the Department of Health and Human Services that provide services to licensees and other entities, that demonstrate that drug and alcohol testing requirements are implemented properly. Such records are generally consistent with the requirements for HHS-certified laboratories in the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, as well as with usual and customary business practices for such laboratories. These records are also necessary to enable licensees and other entities to review and correct any problems in implementing FFD drug and alcohol testing programs, and to enable the NRC to inspect the licensees' and other entities' drug and alcohol testing programs. This section groups recordkeeping requirements that apply to collection sites, testing facilities, and laboratories certified by the Department of Health and Human Services that provide services to licensees or other entities in one section in the rule, in order to improve clarity in the organization of the rule and to respond to requests from stakeholders.

Section 26.717, Fitness-for-duty program performance data

Paragraph 26.717(a) requires licensees and other entities to collect and compile FFD program performance data.

Paragraph 26.717(b) specifies that the FFD program performance data must include the following information:

- Paragraph 26.717(b)(1): The random testing rate;
- Paragraph 26.717(b)(2): Drugs tested for and cutoff levels, including results of tests using lower cutoff levels tests for drugs not included in the HHS panel, and tests of dilute specimens tested at the level of detection (LOD);
- Paragraph 26.717(b)(3): Populations tested;
- Paragraph 26.717(b)(4): Number of tests administered and results of those tests sorted by population tested;
- Paragraph 26.717(b)(5): Conditions under which the tests were performed;
- Paragraph 26.717(b)(6): Substances identified;
- Paragraph 26.717(b)(7): Number of subversion attempts by type; and
- Paragraph 26.717(b)(8): Summary of management actions.

Paragraph 26.717(c) requires any licensee or other entity who has a licensee-approved FFD program to analyze the FFD program performance data at least annually and to retain records of the data, analyses, and corrective actions taken for at least 3 years or until the completion of any related legal proceedings, whichever is later.

Paragraph 26.717(d) requires 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 to report those test results in the annual summary by processing stage and to include the number of terminations and administrative actions taken against individuals in the reporting period.

Paragraph 26.717(e) requires licensees and other entities to submit the FFD program performance data (for January through December) to the Commission annually, before March 1 of the following year.

Paragraph 26.717(f) permits licensees and other entities to submit FFD program performance data in a consolidated report, if the report presents the data separately for each site.

Paragraph 26.717(g) specifies that each C/V who maintains a licensee-approved drug and alcohol testing program is subject to the reporting requirements of §26.717 and shall submit the required information either directly to the NRC or through the licensee(s) or entities to whom the C/V provided services during the year. Licensees, C/Vs, and other entities are required to share information to ensure that the information is reported completely and is not duplicated in reports submitted to the NRC.

These requirements are necessary to ensure that licensees and other entities provide information about the performance of their FFD programs that will enable the NRC to ensure that those programs are adequately protecting public health and safety. These reports also are necessary to enable licensees and other entities to review and correct any problems in implementing FFD programs, and to enable the NRC to inspect the licensees' and other entities' FFD programs and to obtain information necessary to evaluate the effectiveness of the programs. Collection of information pertaining to significant FFD events is necessary to permit evaluations of events that might become problems and that may require actions by the NRC staff to ensure that the health and safety of the public and the common defense and security are not endangered. The rule requires licensees and other entities to submit program performance data to the NRC every 12 months, rather than every 6 months as required by the previous rule, to reduce reporting burden and to make the reporting time consistent with the NRC's need for the information.

Section 26.719, Reporting requirements

Paragraph 26.719(a) requires licensees and entities subject to Part 26 to report significant violations of the FFD policy, significant FFD program failures, and errors in drug and alcohol testing, and to report under §26.719 rather than §73.71.

Paragraph 26.719(b) requires licensees and entities subject to Part 26 to report the following significant violations of the FFD policy and significant FFD program failures to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers the violation:

- Paragraph 26.719(b)(1): The use, sale, distribution, possession, or presence of illegal drugs, or the consumption or presence of alcohol within a protected area or by an individual while performing duties within the scope of Part 26.
- Paragraph 26.719(b)(2): Any acts by any person who is 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 Part 26; 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; 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.
- Paragraph 26.719(b)(3): Any intentional act that casts doubt on the integrity of the FFD program; and
- Paragraph 26.719(b)(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 assigned to perform duties that require them to be subject to the FFD program.

Paragraph 26.719(c)(1) requires the licensee or other entity to submit to the NRC a report within 30 days following completion of 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 report is required to include a report of the incident and corrective action taken or planned.

Paragraph 26.719(c)(2) requires the licensee or other entity to notify the NRC within 24 hours following discovery of a false positive error on a blind performance test sample submitted to an HHS-certified laboratory.

Paragraph 26.719(c)(3) requires the licensee or other entity to notify the NRC within 24 hours following discovery of a false negative error on a quality assurance check of validity screening tests required by §26.137(b).

Paragraph 26.719(d) requires the licensee or other entity to document, trend, and correct non-reportable indicators of FFD programmatic weaknesses under the licensee's or other entity's corrective action program, but prohibits the tracking or trending of drug and alcohol test results in a manner that permits the identification of any individuals.

These requirements are necessary to ensure that licensees and other entities provide information about significant violations of FFD policy, testing errors, and other events affecting the performance of their FFD programs that will enable the NRC to ensure that those programs are adequately protecting public health and safety, common defense, and security. These reports are necessary to enable licensees and other entities to review and correct any problems in implementing FFD programs, and to enable the NRC to inspect the licensee's and other entities' FFD programs and to obtain information necessary to evaluate the effectiveness of the FFD programs. Collection of information pertaining to significant FFD events is necessary to permit evaluations of events that might become problems and that may require timely response by the NRC staff to ensure that the health and safety of the public is not endangered. The rule

groups these reporting requirements into one section in order to improve clarity in the organization of the rule and to respond to requests of stakeholders.

Section 26.821, Inspections

Paragraph 26.821(a) requires licensees and other entities to permit duly authorized NRC representatives to inspect, copy, or take away copies of its records as necessary to accomplish the purposes of Part 26.

This requirement is necessary to enable the NRC to obtain copies of documents for additional review and analysis at the offices of the NRC and for the development of a written record on topics involving Part 26. Such copies of records may be necessary to enable the NRC to evaluate the licensee's and other entities' FFD programs and to obtain information necessary to develop public policy.

Paragraph 26.821(b) requires licensees and other entities to enter into written agreements with their C/Vs that permit duly authorized NRC representatives to inspect, copy, or take away copies of the 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.

This requirement is necessary because C/Vs may administer components of the licensee's or other entities' FFD program or may have their own FFD programs pertaining to their employees who work under contract to licensees or other entities in situations in which they are subject to FFD requirements. This requirement is necessary to enable the NRC to obtain copies of documents for additional review and analysis at the offices of the NRC and for the development of a written record on topics involving Part 26. Such copies of records may be necessary to enable the NRC to evaluate the C/Vs' FFD programs and to obtain information necessary to develop public policy.

The recordkeeping requirement for §26.821(b) is established by §26.713(e).

2. Agency Use of Information

The NRC will use the information included in the records and reports required in this part for one or more of the following purposes:

- to monitor compliance with Part 26 and ensure that licensees' and other entities' FFD programs are adequate to protect public health and safety and minimize danger to life and property, common defense, and security;

- to determine if there are problems requiring timely response by the NRC staff (NRC actions might vary depending on the circumstances, but include immediate telephone contact with the licensee or other entity to discuss the event or followup at the site);

- to perform empirical evaluations of drug and alcohol testing and fatigue management in support of any future considerations, including analysis of trends and lessons learned.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use information technology when it is beneficial to them. Most licensees collect, store, and format fitness-for-duty data electronically. The NRC issued a regulation on October 10, 2003 (68 FR 58792), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. It is estimated that none of the potential responses are filed electronically, because the licensees and other entities have concluded that they do not wish to do so.

4. Efforts to Identify Duplication and Use Similar Information

Certain records referenced in Subpart G of Part 26 belonging to HHS-Certified laboratories are required to be kept under the standards for a National Laboratory Certification Program established by the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, and also are consistent with usual and customary business practices for forensic laboratories. Licensees for nuclear power reactors maintain a system of records on individuals subject to access authorization requirements called the Personnel Access Database System (PADS), to which the licensees send information concerning employment dates, approvals of access authorization, withdrawals of access authorization, violations of FFD policy, and other subjects. All other records maintained by licensees are not duplicated by other Federal information collection requirements and are not available from any other source. NRC has in place an on-going program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

5. Effort to Reduce Small Business Burden

The NRC has determined that the affected entities are not small entities or businesses as those terms are used in the Regulatory Flexibility Act.

6. Consequences to Federal Programs or Policy Activities if the Collection is Not Conducted or is Collected Less Frequently

The records required by the rule pertaining to drug and alcohol testing, including data about the performance of specimen collection sites, licensee testing facilities, and HHS-Certified laboratories, the chain of custody of specimens, laboratory test results, quality assurance and quality control procedures, the inspection, maintenance, and calibration of laboratory instruments, training and qualifications of FFD program personnel, and security of specimen collection, storage, and testing facilities, are standard components of all forensic specimen collection and testing programs. If these records are not made in a comprehensive manner at the time that specimen collection and testing occurs, the scientific accuracy of test results cannot be assessed or verified and neither the performance objectives of the FFD program nor the protection of the rights of individuals subject to the program can be attained. Collection of information pertaining to individuals' past employment, past periods of authorization, if any, including authorization denial or unfavorable termination, past arrest record, and other potentially disqualifying FFD information also must be complete and must take place at the time that FFD authorization decisions are made, or inappropriate authorizations may be granted. The annual report on the performance of licensees' and other entities' programs provides data that is necessary for the NRC to assess whether the FFD programs are meeting the program requirements. The rule reduces the frequency of the current FFD performance report from semi-annually to annually. Receiving FFD program performance data at least annually is necessary because any longer period of time could result in substantial program deterioration

that would result in potential threats to public health and safety and danger to common defense and security.

7. Circumstances which Justify Variation from OMB Guidelines

Section 26.77(c) requires a licensee or other entity that 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, to immediately notify the appropriate Regional Administrator by telephone, followed by written notification (e.g., email or fax) to document the verbal notification. If the Regional Administrator cannot be reached, the licensee or other entity must notify the NRC Operations Center. The immediate notification is necessary to inform the NRC of potential FFD violations by NRC staff, so that the appropriate NRC managers can address the situation immediately.

Section 26.165 (b)(3) requires written permission from the donor before additional testing may occur if the initial sample had positive, adulterated, or substituted results. If a donor wants retesting, he or she must request it in writing within 3 business days. The time requirement is needed to ensure that the specimen(s) are retested quickly and do not deteriorate before retesting. The requirement protects the due process rights of donors.

Section 26.169(a) requires HHS-certified laboratory to report test results to the licensee's or other entity's MRO within 5 business days after receiving the specimen. The requirement for reporting within 5 business days ensures that the FFD program can take prompt action if the test results indicate that the authorization of the individual should be withdrawn or that there is evidence of tampering, adulteration, or substitution that should be investigated that must be investigated promptly to ensure that the results of other tests are not affected in the same way.

Section 26.169(h) requires the HHS-certified laboratory to provide to the licensee's or other entity's official responsible for coordination of the FFD program an annual statistical summary of urinalysis testing within 14 calendar days after the end of the 1-year period covered by the report. This requirement provides information from which the NRC can monitor the effectiveness of drug testing activities.

Section 26.185(p) requires an MRO to complete a review of positive, adulterated, substituted, and invalid test results and notify the licensee or other entity's designated representative within 10 business days of the an initial non-negative test result. Notification within 10 days is necessary so that the licensee or other entity can take prompt action concerning the non-negative result.

Section 26.203(d) requires that specified records pertaining to fatigue management should be kept for at least three years, which is consistent with the OMB Guidelines, "or until the completion of all related legal proceedings, whichever is later:" The latter requirement is necessary to ensure that records pertaining either to an enforcement action against a licensee or other entity for failure to comply with the fatigue management requirements of Subpart I of Part 26 or to an individual are available. The requirement protects the due process rights of licensees and other entities and of individuals.

Section 26.417(b)(1) requires licensees and other entities to report 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 Subpart K FFD program and any programmatioc failure, degradation, or discovered vulnerability of the Subpart K FFD program that may permit undetected durg or alcohol use or abuse by individuals subject to Subpart K of Part 26. This

requirement is necessary to ensure that the NRC is informed promptly so that the appropriate NRC managers can address the situation immediately.

Section 26.711(a) requires that if a retention period is not otherwise specified in the appropriate section of Part 26, records must be retained until the Commission terminates the facility license. This requirement is necessary to ensure that records are 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.

Section 26.713(a) requires that records of self-disclosures, employment histories, and suitable inquiries, records pertaining to the determination of a violation of the FFD policy and related management actions, documentation of the granting and termination of authorization, and records of any determinations of fitness conducted under §26.189 must be retained 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. The requirement to retain records for at least five years, which is consistent with the previous rule, is necessary to ensure that licensees and other entities who may be considering granting authorization to an individual can obtain these records for review as part of the authorization decision-making process. The NRC considers that retention of these records for only three years will not be sufficient to ensure that individuals will be identified who seek reauthorization with a licensee or other entity after previously having violated an aspect of the FFD program. The requirement to retain records until the completion of all related legal proceedings was added at the suggestion of stakeholders during public meetings. 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 previous rule requires these records to be retained and that adding a requirement to retain the records until all legal proceedings are complete protects individuals' right to due process under the rule.

Sections 26.713(b)(1) and (b)(2) requires that licensees and other entities retain records of FFD training and examinations, and of FFD audits, audit findings, and corrective actions for at least three years, which is consistent with OMB guidelines, or until the completion of all related legal proceedings, which is later. The NRC again added the requirement to retain records until the completion of all related legal proceedings at the suggestion of stakeholders during public meetings to address the possibility of protracted legal proceedings.

Section 26.713(c) requires that licensees and other entities ensure the retention and availability of records pertaining to any 5-year denial of authorization and any permanent denial of authorization for at least 40 years or until, upon application, the NRC determines that the records are not longer needed. Because of the extremely serious nature of the actions that cause an individual to receive either a 5-year denial of authorization or a permanent denial of authorization, the 40-year retention requirement is intended to cover the longest expected working life of an individual, so that the record is available over the individual's entire working life. Requiring the record to continue to be available, even if the license is terminated of the licensee or other entity that had denied the individual's authorization, is necessary because the individual whose authorization was denied for 5 years or permanently denied under that licensee's FFD program would not necessarily leave the industry. Requiring retention and availability 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.

Section 26.713(d) requires that licensees and other entities retain superseded FFD policies and procedures for at least 5 years or until they no longer need to respond to a legal challenge. The period of time that superseded materials are retained has been increased from 3 to 5 years to ensure that the materials are available if subsequent licensees and other entities require the information in validating a determination of fitness made at the time the procedures were in effect. The requirement to retain the policy and procedures related to any matter under legal challenge until the matter is resolved has been added to ensure that the materials remain available, should an individual, the NRC, a licensee, or another entity who is subject to this rule require access to them in a legal or regulatory proceeding.

Section 26.713(e) requires licensees and other entities to retain the written agreement for the life of the agreement (as in the current rule) or until completion of all legal proceedings related to an FFD violation that involved the services, whichever is later. The requirement to retain the written agreements for any matter under legal challenge until the matter is resolved has been added to ensure 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.

Section 26.713(f) requires 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. The retention period 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 should an individual, the NRC, a licensee, or another entity who is subject to this rule require access to them in a legal or regulatory proceeding. However, the rule establishes a limit on the period during which the records must be retained in order to reduce the burden associated with storing such records indefinitely.

Section 26.713(g) requires licensees and other entities to retain records of the certification of the scientific and technical suitability of any assays and cutoff levels used for drug testing that are not addressed in Part 26, provided by a qualified forensic toxicologist, as required under §26.31(d)(1)(i) and (d)(3)(iii)(C). The licensee or other entity is required to retain these records for the period of time during which the FFD program continued to test for drugs for which testing is not required under Part 26, uses more stringent cutoff levels than those specified in Part 26, or until the completion of all related legal proceedings, whichever is later. The retention period is necessary to ensure the NRC's access to the records for inspection purposes and that the records remain available should an individual, the NRC, a licensee, or another entity who is subject to this rule require access to them in a legal or regulatory proceeding.

Section 26.715(a) requires collection sites providing services to licensees and other entities, licensee testing facilities, and HHS-certified laboratories to maintain and make available documentation of all aspects of the testing process for at least two years, which is consistent with OMB guidance, or until the completion of all legal proceedings related to the determination of an FFD violation, whichever is later. The section also provides that the 2-year period may be extended upon written notification by the NRC or by any licensee or other entity for whom services are being provided. This requirement is necessary to ensure access to the records by the NRC or by a licensee or other entity securing services from the collection site or the HHS-certified laboratory for inspection purposes and that the records remain available should an

individual, the NRC, a licensee, or another entity who is subject to this rule require access to them in a legal or regulatory proceeding.

Section 26.717(c) requires a licensee and any other entity that has a licensee-approved FFD program to analyze the FFD program performance data at least annually and to retain records of the data, analyses, and corrective actions taken for at least three years, which is consistent with OMB guidelines, or until the completion of any related legal proceedings, whichever is later. This retention is necessary to ensure that the records remain available should an individual, the NRC, a licensee, or another entity who is subject to this rule require access to them in a legal or regulatory proceeding.

Section 26.719(b) requires licensees or other entities to report significant FFD policy violations or programmatic failures to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers the violation. This requirement is necessary to ensure that the NRC is informed promptly so that the appropriate NRC managers can address the situation immediately.

Section 719(c)(2) requires licensees or other entities to report a false positive error that occurs on a blind performance test sample submitted to an HHS-certified laboratory within 24 hours of the discovery of the error. Because positive test results can result in significant actions taken by FFD programs, it is important that a false positive experienced by one FFD program be reported to the NRC immediately so that actions can be taken to provide notice to other FFD programs that a particular laboratory may be experiencing analytic problems.

Section 719(c)(3) requires licensees or other entities to report a false negative error that occurs on a blind performance test sample submitted to an HHS-certified laboratory within 24 hours of the discovery of the error. Because negative test results can result in significant actions taken by FFD programs, it is important that a false negative experienced by one FFD program be reported to the NRC immediately so that actions can be taken to provide notice to other FFD programs that a particular laboratory may be experiencing analytic problems.

8. Consultations Outside the NRC

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

In 2000, the Office of Management and Budget commented on the information collection clearance document submitted by the NRC in support of a proposed revision of the FFD rule. The NRC has prepared responses to those comments, the majority of which dealt with issues aside from reporting and recordkeeping. The NRC's responses are presented in Section V.A. of the Federal Register notice announcing the proposed rule and the availability of this supporting statement for public comment. Between 2001 and 2004, the NRC staff conducted 11 stakeholder meetings on the drug and alcohol testing portions of Part 26 and held 13 stakeholder meetings on a proposed draft rule to incorporate provisions to manage worker fatigue. Subsequent to the Commission's decision in May 2004 to combine the two rulemaking efforts, the staff held one stakeholder meeting on the combined rule in July 2004, and two meetings on the fatigue portions of the combined rule in August and September 2004. During the meetings the staff discussed with the stakeholders the proposed reporting and recordkeeping requirements along with other topics pertaining to the proposed FFD

requirements. At the July 2004 stakeholders meeting, the stakeholders received a detailed description of the estimated reporting and recordkeeping burdens associated with the proposed rule provisions as they existed at that time. Stakeholders provided verbal commentary on a few sections, but in general the stakeholders stated that they preferred to comment on the reporting and recordkeeping burden estimates when the proposed rule was published. The NRC offered to review and, consistent with the rulemaking schedule outlined to stakeholders at the public meetings, consider comments sent in following the meeting and received prior to September 15, 2004. However, no comments were received. Subsequent to the July 2004 stakeholders meeting, the NRC also requested and received data from six nuclear power plants pertaining to certain fatigue management provisions in the proposed Subpart I. Throughout this period of time, the staff made the draft proposed rule language available to the public through the agency's internet-based interactive rulemaking website at http://ruleforum.llnl.gov. All comments received between 2001 and September 15, 2004, were considered in developing this burden estimate.

An opportunity for public comment on the information collection requirements contained in the proposed rule published in the Federal Register on August 26, 2005, (70 FR 50442) elicited comments from several commenters. Stakeholders objected to the proposed annual reporting requirements that would have required licensees to report, as part of their annual FFD program performance report, information concerning implementation of their fatigue management program. Several commenters asserted that the NRC should delete the reporting requirements from the rule because they would not provide new or unique information, are unnecessary to protect public health and safety, are unnecessary to facilitate NRC oversight of implementation of the revised rule, and are unduly burdensome. Commenters also stated that the NRC has not met its obligation under the Paperwork Reduction Act with respect to the information collection requirements in the proposed reporting requirement. They argued that the NRC failed to adequately justify the need for these provisions to achieve the objectives of the proposed FFD rule and to objectively support the agency's estimate of the burden created for 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 these public comments, the staff revised the reporting requirements to ensure that annual reports provided meaningful information regarding licensee management of worker fatigue. However, the staff does not agree with comments suggesting that the requirements to include fatigue management information in annual FFD program performance reports should be deleted from the rule. The staff concludes that the industry-estimated 50 hours of licensee staff effort to include fatigue management information in the annual report is justified for the following reasons:

- The report will contain information that is central to effective oversight of licensee fatigue management— Licensee annual reports summarizing waivers from the work-hour limits will indicate how often a licensee relies on individuals who are at increased potential for impairment from fatigue to mitigate or prevent a condition adverse to safety or security when these conditions are associated with risk-significant SSCs or functions that are essential for effective response to a fire, plant emergency, or implementation of the site security plan. Frequent reliance on personnel with a high potential for impairment to resolve these conditions indicates a lack of effective management of worker fatigue and plant risk. The annual reports will also include information pertaining to licensee fatigue assessments that will provide an indication of 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, and (3) individuals are required to remain on duty

following their declaration that they are not fit for duty because of fatigue. When this information is considered in conjunction with information concerning the licensee's use of waivers from the work hour limits, it will provide the NRC an indication of the extent to which these conditions may be the result of licensee's work scheduling practices.

- Consistency of NRC oversight— Annual FFD program performance reports concerning fatigue management will enable the NRC to achieve a higher level of consistency in the oversight of the implementation of the requirements in Subpart I and in the enforcement of those requirements. By enabling ready access to the fatigue management information (e.g., waiver use) for all plants, the annual reports provide NRC inspectors a common basis and perspective when inspecting licensee FFD programs and thereby maintain consistency in NRC's oversight of licensee FFD programs.

- Efficiency of NRC oversight— Information in the annual reports will enhance the efficiency of the NRC inspection process by providing the information necessary to allow the agency to better focus inspections of licensee fatigue management on specific categories of workers (e.g., security or maintenance) or issues (e.g., self-declaration). Accordingly, the staff expects that the annual reports will enable the NRC to be better focused in preparing for the inspection, thereby reducing the burden of onsite inspection hours and potentially reducing the total number of hours required for a baseline inspection.

- Evaluation of rule implementation— Changes in the size and composition of the nuclear industry, and staffing demands from possible new plant construction may have significant and unforeseen implications for site staffing and fatigue management at the existing nuclear power plants. As a result, industry trend and normative information obtained through the annual reports will provide important insights regarding potential opportunities to amend the rule to improve its effectiveness.

- Consistent interpretation of the waiver criteria— Based on experience with licensee use of waivers from work hour limits in plant technical specifications[1], the staff considers it prudent to provide a level of oversight through the annual reporting requirement that will ensure consistent implementation of the waiver criteria in the future. The NRC's policy guidance is for waivers to be used for "very unusual circumstances." Consistent with the guidance, the final rule provides licensees the discretion, in limited circumstances, to use waivers to exceed the work hour limits. 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 managing worker fatigue, and not as a means to compensate for a lack of adequate staffing.

- Consistency with Part 26 requirements and performance objectives—The final rule retains the requirement of the former rule for reporting results of drug and alcohol testing and the performance objective for reasonable assurance that individuals are not impaired from any cause. In addition, several studies discussed in detail in Section IV of Enclosure 1 have demonstrated that worker fatigue can produce levels of impairment that are comparable to blood alcohol concentrations above levels permitted by Part 26. Accordingly, a requirement for annual reporting of information pertaining to licensee management of worker fatigue is consistent with the requirements for reporting information pertaining to

[1] In SECY-01-0113, the staff reported extensive use of waivers by some licensees.

drug and alcohol testing, consistent with the Part 26 performance objective for licensees to implement a comprehensive FFD program, and consistent with the staff'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 Union of Concerned Scientists (UCS) and the Project on Government Oversight have commented that the NRC has withheld much relevant information regarding worker fatigue to either protect an alleger's 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 would be publicly available and reassure public stakeholders that the NRC is appropriately cognizant of licensee actions regarding fatigue management. In essence, these reports would make the NRC's oversight of this issue transparent to all stakeholders

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

Sections 26.31, 26.33, 26.35, 26.39, 26.61 through 26.70, 26.75, 26.77, 26.85, 26.115, 26.117, 26.119, 26.165, 26.183, 26.185, 26.189, 26.211, 26.411, 26.713, and 26.719 require each licensee or other entity to collect personal information for the purpose of complying with Part 26. Section 26.37(a) of the rule requires each licensee or other entity who collects personal information about an individual for the purpose of complying with Part 26 to establish and maintain a system of files and procedures to protect the personal information, and to maintain and use such records with the highest regard for individual privacy. Section 26.37(b) permits disclosure of personal information concerning an individual only pursuant to a signed consent from the individual, except for disclosures to the following: 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 have access to the information in performing assigned duties, including determinations of fitness, audits of FFD programs, and human resources functions; the presiding officer in a judicial or administrative proceeding that is initiated by the subject individual; persons deciding matters under review for FFD policy violations under §26.39; and other persons pursuant to court order. Section 26.37(c) provides that personal information that is collected under Part 26 must be disclosed to other licensees or other entities, including C/Vs, or their authorized representatives, who are legitimately seeking the information for authorization decisions as required by Part 26 and who have obtained a signed release from the subject individual. Section 26.37(d) provides that upon receipt of a written request by the subject individual or his or her designated representative, the licensee, other entity, HHS-certified laboratory, or MRO possessing such records shall promptly provide copies of all records pertaining to the determination of a violation of the FFD policy, including test results, MRO reviews, and management actions pertaininig to the subject individual.

Information identified as proprietary or confidential will be handled in accordance with 10 CFR 2.390 of the NRC regulations.

11. Justification for Sensitive Questions

Sections 26.31, 26.33, 26.35, 26.39, 26.61 through 26.70, 26.75, 26.77, 26.85, 26.115, 26.117, 26.119, 26.165, 26.183, 26.185, 26.189, 26.211, 26.411, 26.713, and 26.719 require each licensee or other entity to collect personal information for the purpose of complying with Part 26. It is necessary to obtain sensitive personal information to accomplish the performance objectives of Part 26, which include providing reasonable assurance that individuals who are subject to Part 26 are trustworthy and reliable as demonstrated by the avoidance of substance abuse; providing 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 affects their ability to safely and competently perform their duties, that the workplaces subject to Part 26 are free from the presence and effects of illegal drugs and alcohol, and 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; and to provide reasonable measures for the early detection of individuals who are not fit to perform the job duties that require them to be subject to Part 26.

12. Estimate of Industry Burden and Costs

The burden associated with the information collections are given in Table 1 for one-time burden, Table 2 for annual recordkeeping burden, Table 3 for annual reporting burden, and Table 4 for third-party collections. Because the new rule constitutes a complete revision of Part 26, estimates are included for all sections that affect the information collection requirements and establish a new baseline. These estimates are based, in part, on discussions with nuclear utility employees, staff of the Nuclear Energy Institute, and on estimates made by NRC personnel who are familiar with the records and reports required by 10 CFR Part 26.

13. Estimates of Other Additional Costs

The quantity of records to be maintained is roughly proportional to the recordkeeping burden (excluding third-party communication requirements that are not specifically recordkeeping) and therefore can be used to calculate approximate records storage costs. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to .0004 times the recordkeeping burden cost. Therefore, the storage cost for this clearance is estimated to be $5,627 (576,428 recordkeeping hours - 507,795 third-party hours = 68,633 recordkeeping hours x $205 per hour x .0004).

Approximately 50 percent of FFD programs, or 20 programs, are expected to purchase an average of 2 evidentiary breath testing (EBT) devices per program at a cost of approximately $3,000 per device for a total of $120,000 (20 x 2 x $3,000).

14. Estimated Annualized Cost to the Federal Government

Table 5 describes the estimated annual cost to the NRC for administration of the reporting and recordkeeping requirements in Part 26. The cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Change in Burden or Cost

The estimated annual burden of 645,861 hours for one-time recordkeeping (annualized), annual recordkeeping, and annual reporting of the rule exceeds NRC's estimate for the current rule of 61,143 hours (as estimated in the final clearance renewal published in the Federal Register on October 3, 2005 (70 FR 57625)) by 584,718 hours. Of this, 128,701 hours are for one-time recordkeeping requirements. Therefore, the burden increase will be reduced by about 20 percent once the one-time requirements are complete. The final rule is a complete revision of Part 26, and as such the burden increase or decrease cannot be associated with changes in the estimate for particular rule sections from the former rule to the final rule.

The factors that account for the increased estimate are the following: the rule creates more detailed requirements pertaining to the FFD authorization process for individuals to ensure consistency with the NRC's access authorization requirements for nuclear power plants established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003. The rule includes more detailed requirements pertaining to the specimen collection and testing process, to increase consistency with other relevant Federal rules and guidelines, including the U.S. Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines). The rule adds requirements for confirmatory drug and alcohol testing and verification testing, and makes more explicit the requirements for licensee testing facilities. The burden estimate for the rule captures significant third-party collections associated with the reporting and recordkeeping associated with the drug and alcohol testing activities that were not captured in the previous rule. Experience from the implementation of the previous FFD rule, information obtained from stakeholders, and information obtained from sources such as the DHHS National Laboratory Certification Program has led the NRC to revise its estimates of the burden of certain activities. Finally, the rule contains new fatigue management provisions that include reporting and recordkeeping burdens that were not part of previous estimates, and it contains new requirements for FFD programs for individuals involved in the construction of new nuclear power reactors. The fatigue management requirements pertain to 30 programs; the FFD requirements for individuals involved in the construction of new reactors are expected to apply to 19 new nuclear power reactor construction activities.

16. Publication for Statistical Use

Not applicable.

17. Reasons for Not Displaying the Expiration Date

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

18. Exceptions to the Certification Statement

None.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical Methods are not used in this information collection.

Attachments:

1. Table 1 – One-Time Recordkeeping Burden
2. Table 2 – Annual Recordkeeping Burden
3. Table 3 – Annual Reporting Burden
4. Table 4 – Annual Third-Party Burden
5. Table 5 – Annualized NRC Reporting and Recordkeeping Burden

Table 1
One-Time Recordkeeping Requirements
(Annualized)

Section	Number of Programs	Burden Hours per Program (Annualized)	Total Burden Hours (Annualized)
26.27(a): Prepare FFD policy statement	33 programs	321.0	3,531
26.27(a): Prepare FFD procedures	33 programs	213.0	7,029
26.29(a): Prepare FFD training course	33 programs	83.0	2,739
26.29(b): Prepare FFD exam	33 programs	13.3	440
26.29(b): All current staff take FFD exam	33 programs	283.3	9,350[2]
26.29(b): FFD staff mgmt grade FFD exam	33 programs	283.3	9,350[3]
26.29(c)(1): FFD training for current staff	33 programs	2,266.7	74,800[4]
26.31(b)(1)(v): Prepare behavioral observation procedures for FFD program personnel	Burden shown under §§26.27		
26.31(d)(1)(iii): Document additional drugs being tested	33 programs	0.3	11
26.37(a): Confirm files and procedures protect personal information	33 programs	2.7	88
26.37(b): Obtain signed consent for release of information	33 programs	141.7	4,675[5]
26.39(a) and (b): Prepare procedure for review of determination of FFD violation	33 programs	13.3	440
26.85(a): Prepare and deliver qualification training for urine collectors	33 programs	5.3	176

[2]Estimate assumes 1,700 employees per program take the FFD exam. The FFD exam is estimated to take 0.5 hours to complete per employee.

[3]Estimate assumes 1,700 employees per program take the FFD exam. The FFD exam is estimated to take 0.5 hours to grade per employee.

[4]Estimate assumes 1,700 employees per program that require FFD training. The FFD training is estimated to take 4.0 hours per employee.

[5]Estimate assumes 1,700 employees per program that must consent to the release of information. The collection is estimated to take 0.25 hours per employee.

Section	Number of Programs	Burden Hours per Program (Annualized)	Total Burden Hours (Annualized)
26.85(b): Prepare and deliver qualification training for alcohol collectors	33 programs	5.3	176
26.127(a): Prepare procedures for handling specimens at licensee testing facilities	33 programs	13.3	440
26.127(b): Prepare written chain-of-custody procedures for licensee testing facilities	33 programs	13.3	440
26.127(c): Prepare written procedures for assays performed by licensee testing facilities	33 programs	13.3	440
26.127(d): Prepare written procedures for instrument and test setup by licensee testing facilities	33 programs	13.3	440
26.127(e): Prepare written procedures for remedial actions for systems and tests at licensee testing facilities	33 programs	13.3	440
26.137(a): Develop QA/QC program and procedures for licensee testing facilities	33 programs	13.3	440
26.155(a)(1), (3), (4), (5); (b),(c), (e), and (f): Confirm that HHS requirements for laboratory personnel qualifications and procedures already in place pursuant to HHS requirements also meet Part 26 requirements	26 HHS labs	2.7	69
26.157(b), (c), (d), and (e): Confirm that laboratory procedures already in place pursuant to HHS requirements also meet Part 26 requirements	26 HHS labs	2.7	69
26.159(a), (c), (e), (f): Confirm that specimen security, chain of custody, and preservation procedures already in place pursuant to HHS requirements also meet Part 26 requirements	26 HHS labs	2.7	69
26.203(a): Prepare fatigue management policy (In addition to §§26.27 burden)	30 programs	2.7	400
26.203(b): Prepare fatigue management procedures (In addition to §26.27 burden)	30 programs	13.3	400

Section	Number of Programs	Burden Hours per Program (Annualized)	Total Burden Hours (Annualized)
26.203(c): Prepare training on fatigue management.	30 programs	22.7	680
26.205(b): Develop work hour tracking system	30 programs	133.3[6]	4,000
26.205(c): Develop individual work scheduling system	30 programs	33.3	1,000
26.401(b): Prepare FFD program plan	19 programs	60.0	1,140
26.403(a): Prepare construction FFD policy statement	19 programs	107.0	2,033
26.403(a): Distribute FFD policy statement to all individuals	19 programs	5.0	95
26.403(b): Prepare construction FFD policy procedures	19 programs	213.0	4,047
26.406(a), (b), and (d): Establish a fitness monitoring program	7 programs	26.7	187
26.406(c): Establish procedures for fitness monitors	7 programs	40.0	280
26.407: Establish procedures for behavioral observation	12 programs	40.0	480
26.413: Develop procedures for review of determinations of FFD violations	19 programs	120.0	2,280
Table 1: Total			**132,965**

[6]Based on Regulatory Analysis estimate of $50,000 to develop revised timekeeping and tracking system.

Table 2
Annual Recordkeeping Burden

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.27(b): Make FFD policy statement available to staff subject to FFD reqs.	33 programs	2.0	66
26.27(c): Update policy & procedures	33 programs	2.0	66
26.27(d): Provide policy and procedures for NRC review	33 programs	2.0	66
26.29(b): FFD exams	33 programs	1.0	33
26.29(c)(2): Refresher FFD training or testing	33 programs	250.0	8,250
26.29(d): Accept FFD training from other licensees' programs	33 programs	17.5	576
26.31(b)(1)(i): Background checks for FFD personnel	33 programs	17.5	576
26.31(b)(1)(v): Behavioral observation for FFD program personnel	33 programs	80.0	2,640
26.31(d)(1)(i)(D): Analysis and certification for unlisted drugs	8 programs	4.0	32
26.31(d)(1)(ii): Licensee additions to tested drugs	33 programs	8.0	264
26.31(d)(3)(iii)(A): Document more stringent cutoff levels	8 programs	8.0	64
26.31(d)(3)(iii)(C): Evaluation and certification of more stringent cutoff levels	8 programs	8.0	64
26.31(d)(6): Written permission of donor to conduct another analysis or test with specimen	8 programs	1.0	8
26.33: Records of behavioral observations	33 programs	436.4	14,400
26.35(a): Employee assistance program records	33 programs	16.0	528
26.35(c): Written waiver of right to privacy from individual given to EAP	33 programs	2.0	66
26.35(c): EAP disclosure to FFD mgmt.	16 programs	1.0	16
26.37(b)(1): Signed designation of personal representative for FFD matters	33 programs	117.8	3,888
26.37(c): Disclosure to other licensees	33 programs	108.0	3,564

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.37(d): Obtain lab results and provide result to individual	33 programs	32.7	1,080
26.39(a): Maintain procedures for review of determinations of FFD	33 programs	120.0	3,960
26.39(d): Update records to reflect outcome of review of determination of fitness	33 programs	43.6	1,440
26.39(e): Provide review procedure to individual	33 programs	14.8	490[7]
26.41(a), (b), and (c): Conduct audits	Burden shown under §§26.41(f)		
26.41(d): Review C/V audit results	33 programs	38.0	1,254
26.41(f): Document and report audit results	33 programs	38.0	1,254
26.41(g): Share audit results with mgmt and with other FFD programs	32 programs	40.0	1,320
26.53(e)(2): Inform licensee of the termination of an individual's authorization	2 programs	120.0	240
26.53(g): Inform licensee of Part 26 requirement violations	8 programs	8.0	64
26.53(h): Obtain the knowledge and written consent of the subject individual before initiating any actions under Subpart C	33 programs	1,197.0	39,503[8]
26.53(i): Inform, in writing, any individual applying for authorization of the causes for denial or termination of authorization	33 programs	19.6	648[9]
26.55(a)(1) and (a)(2): Obtain and review self-disclosure and empl. history and complete suitable inquiry	Burden shown under §§26.61 and 26.63		
26.57(a)(1) and (a)(2): Obtain and review self-disclosure and empl. history and complete suitable inquiry	Burden shown under §§26.61 and 26.63		

[7]Estimate is based on 979 positive test results from NRC's "Summary of Fitness-for-Duty Program Performance Reports for 2005," (henceforth, "FFD 2005 program performance data)". http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/performance-reports.html

[8]Estimate is based on 79,005 pre-access tests from NRC's 2005 FFD program perforance data. One-half burden hour is estimated for each test.

[9]Estimate is based on 648 positive pre-access test results from NRC's 2005 FFD program perforance data. One hour is estimated for each positive test result.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.59(a)(1) and (a)(2): Obtain and review self-disclosure and empl. history and complete suitable inquiry	Burden shown under §§26.61 and 26.63		
26.59(c)(1): Obtain and review self-disclosure	Burden shown under §§26.61		
26.61(a): Written self-disclosure and employment history	33 programs	1,096.4	36,180
26.63(a) and (e): Suitable inquiry	33 programs	1,723.6	56,880
26.63(c): Confirm contents of employment history	33 programs	1,096.4	36,180
26.63(c)(2): Receive and file DD 214	33 programs	7.6	252
26.63(c)(3): Document refusal to supply employment information	33 programs	5.5	180
26.63(d) & (e): Obtain and maintain documentation of reinstated authorization from other FFD programs	33 programs	1.0	33
26.65(d)(1) and (e)(2): Prepare record of reinstatement or administrative withdrawal of authorization	33 programs	193.1	6,372
26.65(f): Adjust personnel records	33 programs	1.0	33
26.67 Random drug and alcohol testing of persons who have applied for authorization	33 programs	0.5 [10]	25,000
26.69(c)(1): Obtain and review written self-disclosure and employment history	Burden shown under §§26.713(a)(1)		
26.69(b) and (c)(3): Obtain and review employee records to confirm potentially disqualifying FFD situation resolved	33 programs	81.8	2,700
26.69(c)(2): Complete a suitable inquiry on previous employers	Burden shown under §§26.63		
26.69(c)(4): Verify drug/alcohol treatment & testing completed	33 programs	3.0	99
26.69(c)(5): Verify pre-access drug/alcohol testing completed	33 programs	1.0	33
26.69(d): Verify reviewing officer's review completed	33 programs	24.0	792

[10]NRC's 2005 FFD program perforance data reported approximately 50,000 total random drug tests.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.69(e): Provide information on testing and treatment plans to other FFD programs	33 programs	8.0	264
26.75(a), (b), (c), (d), (e), and (g): Record of sanctions for FFD violation	33 programs	12.0	396
26.75(h):Record additional evidence indicating impairment	33 programs	18.0	594
26.75(i): Inform licensee of non-negative initial test result	33 programs	80.0	2,640
26.75(i)(3) and (i)(4): Eliminate references to temporary administrative action and provide written statement that records expunged	33 programs	1.0	33
26.85(a), (b), & (c): Training collectors	33 programs	4.0	132
26.85(c)(4): Written instructions for alternate collectors	33 programs	16.0	528
26.85(e): Maintain personnel files	33 programs	4.0	132
26.87(d)(3) and (f)(1): Signage/security at test site	11 programs	0.3	3
26.87(f)(3), (f)(4), and (f)(5): Prepare custody-and-control form	11 programs	0.5	6
26.89(a): Report absence of donor	33 programs	1.0	33
26.89(b)(1) and (b)(2): Obtain ID and consent form	33 programs	1.5	50
26.89(b)(3): Inform FFD program management that individual did not present identification	33 programs	4.0	132
26.89(c): Report premature departure	33 programs	3.3	108
26.91(c)(1), (c)(2), and (c)(3): Record of EBT test results	Burden shown under §26.715(b)(12)		
26.91(e)(4): Cancel results after EBT calibration check failure	8 programs	6.0	48
26.91(e)(5): Prepare record of EBT maintenance	33 programs	6.0	198
26.93(a)(6): Document alcohol pre-test questions asked and answered	33 programs	322.9	10,656
26.95(b)(5): Record donor identity for initial alcohol breath test	33 programs	322.9	10,656

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.97(b)(2): Record reason for new oral fluid alcohol test	33 programs	5.5	180
26.97(c)(1): Document reason for failure of 2nd collection attempt	33 programs	2.7	90
26.97(d): Record results and alcohol screening device used	33 programs	67.6	2,232
26.99(b): Record test time of initial test with 0.02% or higher BAC	33 programs	17.1	565
26.101(b)(7): Indicate time on EBT printout of alcohol test result	33 programs	17.1	565
26.103(b): Inform FFD mgmt of result between 0.01 and 0.02 when donor in work status 3 or more hours	33 programs	0.3	11
26.107(b): Document tampering attempt on c & c form	33 programs	1.4	47
26.109(b)(3): Notify FFD mgt. or MRO of “shy bladder” problem	33 programs	0.5	18
26.109(b)(4): Notify FFD mgmt. if observed collection required	33 programs	0.3	11
26.111(b): Note unusual findings on c & c form	33 programs	1.4	47
26.111(c):Report tampering attempts to FFD mgr.	33 programs	0.3	11
26.113(b)(3): Prepare c & c forms for both parts of split sample	33 programs	0.3	11
26.115(b): Obtain approval for collection under direct observation from FFD mgr. or MRO	33 programs	0.5	18
26.115(d): Prepare c & c form for directly observed collection	33 programs	0.3	11
26.115(f)(3): Record name of observer	33 programs	0.3	11
26.117(c), (d), and (e): Prepare ID labels and c & c forms for specimen shipment	33 programs	65.5	2,160
26.119(a), (e), and (f): Obtain evaluation from MRO or physician evaluating “shy bladder” claim	33 programs	6.0	198

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.119(b): MRO provides information to physician as background for evaluation of “shy bladder” claim	33 programs	2.2	72
26.125(b) and (c): Proficiency and qualifications records of testing facility personnel	33 programs	16.4	540
26.127(a): Procedures for handling specimens by licensee testing facilities	33 programs	40.0	1,320
26.127(b): Written chain-of-custody procedures for licensee testing facilities	33 programs	40.0	1,320
26.127(c): Written procedures for assays performed by licensee testing facilities	33 programs	40.0	1,320
26.127(d): Written procedures for instrument and device setup by licensee testing facilities	33 programs	40.0	1,320
26.127(e): Written procedures for remedial actions for systems and testing devices at licensee testing facilities	33 programs	40.0	1,320
26.129(a): Limit access to testing site	33 programs	2.5	83
26.129(b): Inspect specimen packages, custody control forms, and obtain memorandum from specimen collector	33 programs	0.5	17
26.129(b)(1): Report to senior mgmt. attempts to tamper with specimens in transit	33 programs	1.0	33
26.129(d): Procedures for tracking c & c of specimens	33 programs	95.0	3,135
26.135(b): Donor’s written permission for retest second part of split sample	33 programs	2.2	72
26.137(a): Maintain QA/QC program and procedures for licensee testing facility	33 programs	4.0	132
26.137(b)(1)(ii): Document performance of testing device not on SAMHSA list	2 programs	40.0	80
26.137(b)(1)(iii): Document results of annual test of device not on SAMHSA list	2 programs	20.0	40
26.137(b)(3): Submit 1 in 10 negative specimens for validity screening	33 programs	40.0	1,320
26.137(e)(7): Document procedures to protect against carryover material	33 programs	2.0	66

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.137(f)(5): Record finding of testing errors	33 programs	26.2	864
26.137(h): Label standards and controls	33 programs	65.0	2,145
26.139(d): Prepare information for FFD annual report on activities of licensee testing facility	33 programs	40.0	1,320
26.153(e): Inspect HHS-certified labs	33 programs	40.0	1,320
26.153(f): Include specified requirements in contracts with HHS labs	33 programs	40.0	1,320
26.153(g): Supply memo to HHS labs explaining use of non-federal c & c form	33 programs	0.5	17
26.155(a)(1): Document qualifications for lab mgr of HHS-certified lab.	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(a)(3): Lab mgr. documents training of lab personnel	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(a)(4): Lab mgr. reviews and signs lab procedures	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(a)(5): Lab mgr. maintains QA program	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(b): Certifying scientist to certify test results from HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(c): Supervise technical analysts at HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(e): Continuing education for staff of HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(f): Lab personnel records	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.157(a): Written procedures for accession, receipt, shipment, and testing of urine specimens by HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.157(b): Written chain-of-custody procedures for HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.157(c): Written procedures manual for each assay performed by HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.157(d): Written procedures for device set-up and operation	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.157(e): Written procedures for remedial actions to address systems and instrument errors	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.159(a): Documented restriction to access to HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.159(b): Report evidence of tampering with specimens in transit to FFD program mgr. of licensee or other entity	33 programs	1.0	33
26.159(c), (d), and (e): Use and storage of c & c forms	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.159(f): Use of c & c form when shipping specimen to another HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.159(i): Obtain written authorization to store specimens other than 1 year	33 programs	0.5	17
26.163(a)(2): Inform licensee of dilute specimen and report confirmatory validity test result to MRO	33 programs	3.3	108
26.165(b)(1): Donor requests aliquot or split specimen to be tested by a second HHS-certified laboratory	33 programs	10.9	361[11]
26.165(b)(2): MRO informs donor of opportunity for re-test of aliquot or test of Bottle B of split sample	33 programs	3.3	108

[11]Estimate is based on 361 donors and one burden hour per donor.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.165(b)(3): Donor gives written permission for re-test of aliquot or test of Bottle B of split sample	33 programs	10.9	361[12]
26.165(b)(4): Donor presents documentation for reason unable to complete timely retest request	33 programs	0.2	6[13]
26.165(b)(6): Provide results of re-test of aliquot or test of Bottle B to MRO and to donor	33 programs	6.5	216
26.165(c)(4): Report retesting results to MRO	26 laboratories	13.9	361[14]
26.165(f): Adjustments to personnel files and written notifications regarding test results, including temporary administrative action	33 programs	6.5	216
26.165(f)(1)(iv) and (f)(2): Written notice that records purged of references to temporary administrative action	33 programs	8.7	288
26.167(a): Document quality assurance program of HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.167(c)(2)(i): HHS-certified laboratory's refractometer must display specific gravity to 4 decimals and be interfaced with laboratory information management system or computer and/or document result by hard copy or electronic display	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.167(f)(3): Certification by HHS lab that retesting requested by licensee or other entity has occurred	26 laboratories	1.0	26
26.167(h): Labeling of standards and controls	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		

[12]Estimate is based on 361 donors and one burden hour per donor.

[13]Estimate is based on 6 donors and one burden hour per donor.

[14]Estimate is based on 361 donors and one burden hour per donor.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.168(a): Preparer certifies contents of blind performance test samples submitted to HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.168(h)(2): Ensure supplier provides expiration date for test sample	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.168(i)(2): Use c & c form, place fictional initials on specimen labels, and indicate blind performance test samples	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.169(a): Reports of test results by HHS lab	Burden covered under §§26.169 (c)(1) through (c)(5)		
26.169(c)(1): HHS lab reports positive, adulterated, substituted, dilute, and invalid test results to the MRO	26 laboratories	350.0	9,100
26.169(c)(2): HHS lab reports quantitative test results as requested by MRO	5 laboratories	1.0	5
26.169(c)(2): HHS lab reports quantitative test results for opiates to MRO	16 laboratories[15]	1.0	16
26.169(c)(3): HHS lab reports quantitative test results for adulterated or substituted test results	26 laboratories	20.0	520
26.169(c)(4): HHS contact with MRO to discuss whether testing by another HHS lab should be done	26 laboratories	2.0	52
26.169(c)(5): HHS lab may report concentration exceeding linear range	5 laboratories	1.0	5
26.169(f): HHS lab transmits copy of the c & c form for negative results to the MRO	26 laboratories	0.3	7
26.169(g): HHS lab transmits original of c & c form for positive, adulterated, substituted, dilute or invalid results to the MRO	26 laboratories	100.0	2,600
26.169(h): HHS lab prepares and submits annual statistical summary report of urinalysis testing results	26 laboratories	40.0	1,040
26.183(a): Documentation of MRO qualifications	33 programs	3.5	116

[15]Estimate based on 16 total positive opiate drug tests listed in NRC's 2005 FFD program perforance data.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.183(c)(1): MRO review of records for positive, adulterated, substituted, invalid, or, at the licensees or other entity's discretion, dilute test results	33 programs	26.2	864
26.183(d)(1)(ii)(D): MRO report of drug test results to licensee's designated reviewing official	33 programs	24.0	792
26.183(d)(2)(i): MRO staff review and reporting of negative test results	33 programs	12.0	396
26.183(d)(2)(ii): MRO staff review c & c forms and forward changes to MRO	33 programs	13.1	432
26.185(a) MRO review of all positive, adulterated, substituted, dilute, or invalid test results and report to licensee or other entity	33 programs	54.5	1,800
26.185(c): MRO discussion of test results with the donor	33 programs	2.2	72
26.185(c): MRO report to licensee, following discussion with donor, of FFD violation	33 programs	2.2	72
26.185(d)(1): Documentation that donor declined to discuss test results	33 programs	2.2	72
26.185(e): Documentation that donor was unavoidably prevented from discussing test results and request to reopen proceeding	33 programs	0.3	11
26.185(f)(1): MRO consultation with HHS lab to determine whether additional testing needed	33 programs	0.5	17
26.185(f)(2): MRO contact with donor regarding medical explanation for test result	33 programs	0.5	17
26.185(h)(1): MRO contact with donor to offer opportunity to provide medical evidence regarding substituted specimen	33 programs	1.0	33
26.185(h)(1): Donor presents medical explanation for substituted result	33 programs	1.0	33
26.185(h)(2): MRO notification to licensee that no valid medical explanation presented	33 programs	2.0	66
26.185(h)(3): MRO notification to licensee that valid medical explanation presented	33 programs	1.0	33

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.185(i)(1): MRO contact with donor to offer opportunity to provide medical evidence regarding adulterated specimen	33 programs	1.0	33
26.185(i)(1): Donor presents medical explanation for adulterated result	33 programs	1.0	33
26.185(i)(2): MRO notification to licensee that no valid medical explanation presented	33 programs	2.0	66
26.185(i)(3): MRO notification to licensee that valid medical explanation presented	33 programs	1.0	33
26.185(j)(3): MRO notification to licensee where evidence of drug abuse	33 programs	1.0	33
26.185(j)(3): MRO report to licensee that donor has violated FFD policy by use of another individual's prescription medication	33 programs	0.5	17
26.185(k): MRO report to licensee that no FFD policy violation has occurred	33 programs	1.0	33
26.185(m): MRO review of inspection and audit reports, quality control data, multiple specimens, and other data to determine if positive, adulterated, substituted, or invalid result is scientifically insufficient for determination of FFD policy violation	33 programs	1.0	33
26.185(n): MRO report to licensee on result of analysis by second laboratory	33 programs	2.0	66
26.185(o): MRO request for quantitation of test results	33 programs	0.5	17
26.185(o): Lab provides quantitation of test results	33 programs	1.0	33
26.185(p): MRO notice to licensee of determination of FFD policy violation	33 programs	8.7	288
26.187(d): SAE training requirements	33 programs	20.0	660
26.187(f): Documentation of SAE credentials and training	33 programs	1.0	33
26.189(a): Written record of determination of fitness	33 programs	74.2	2,448
26.189(c): Written record of "for cause" determination of fitness	33 programs	13.1	432

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.189(d): Modification of an initial determination of fitness	33 programs	1.0	33
26.203(d)(1): Records of work hours	Burden shown under §26.205(c), (d)(1), and (e)(4)		
26.203(d)(2): Records of shift schedules and shift cycles	Burden shown under §26.205(c), (d)(1), and (e)(4)		
26.203(d)(3): Documentation of waivers	Burden shown under §26.207(a)(4)		
26.203(d)(4): Documentation of work hour reviews	Burden shown under §26.205(d)(2), (e)(3) and (e)(4)		
26.203(d)(5): Documentation of fatigue assessment	Burden shown under §26.211(f)		
26.205(b): Calculate work hours	30 programs	176.0	5,280
26.205(c): Schedule work hours	30 programs	2,288.0	68,640
26.205(d)(1): Implement work hour controls	30 programs	50.0	1,500
26.205(d)(2): Ensure adequate rest breaks	30 programs	50.0	1,500
26.205(e)(1) and (2): Review of control of work hours twice per calendar year	30 programs	40.0	1,200
26.205(e)(3): Document methods for reviews	30 programs	20.0	600
26.205(e)(4): Record and trend problems in regarding work hours	30 programs	20.0	600
26.207(a)(4): Document bases for waiver	3 programs	6.0	18
26.211(f): Document results of fatigue assessments	30 programs	50.0	1,500
26.405(a) Random drug and alcohol testing	12 programs	875.0	10,500[16]
26.405(c)(1): Document pre-assignment testing	19 programs	1,750.0	33,250[17]
26.405(c)(2) and (c)(3): Document for-cause and post accident testing	19 programs	38.0	722

[16]Value based on estimate of 12 construction programs choosing to conduct random testing (rather than fitness monitoring), 1,750 workers per construction site subject to the FFD program, a 50% test rate, and one hour of burden per test. This one hour burden per random test is larger than the 0.5 hours per random test for operating reactor sites, due to the large size of a construction site and the associated travel time necessary to reach the testing site.

[17]Estimate based on one hour per person to document pre-assignment testing for 1,750 workers at the construction site subject to the FFD program.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.405(c)(4): Document follow up testing	19 programs	190.0	3,610
26.405(d): Test for specified drugs, adulterants, and alcohol, at Part 26 specified cutoff levels	Burden shown under §26.405(a) - (c)(4)		
26.405(e): Ensure privacy and quality control	19 programs	40.0	760
26.405(f): Ensure testing conducted at an HHS-certified laboratory	19 programs	40.0	760
26.405(g): MRO review of positive, adulterated, substituted, and invalid drug and validity test results	19 programs	50.0	950
26.406(c): Maintain fitness monitoring procedures (programs that do not adopt random testing and behavioral observation)	7 programs	80.0	560
26.411(a): Maintain a system of files and procedures to protect personal information	19 programs	4.0	76
26.411(a): Collect personal information	19 programs	1,750.0	33,250[18]
26.411(b): Obtain signed consent form	19 programs	1.5	29
26.413: Document results of review process	19 programs	80.0	1,520
26.415: Document and report audit results	19 programs	40.0	760
26.417(a): Retain program records	19 programs	20.0	380
26.713(a)(1): Retain records of self-disclosure	33 programs	80.0	2,640
26.713(a)(2): Retain records on FFD violations	33 programs	80.0	2,640
26.713(a)(3): Retain records of authorization	33 programs	80.0	2,640
26.713(a)(4): Retain records of FFD determinations	33 programs	80.0	2,640
26.713(b)(1): Retain records of FFD training	33 programs	160.0	5,280
26.713(b)(2): Retain records of audits	33 programs	80.0	2,640
26.713(c): Retain records on 5-year authorization denial and permanent denial	33 programs	40.0	1,320

[18]Estimate based on one hour per person to collect personal information for 1,750 workers at the construction site subject to the FFD program.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.713(d): Retain superseded FFD policy	33 programs	80.0	2,640
26.713(e): Retain written agreements for services under Part 26	33 programs	16.0	528
26.713(f): Retain records of background investigations	33 programs	80.0	2,640
26.713(g): Retain documentation regarding additional drugs tested	33 programs	40.0	1,320
26.715(a): Maintain documentation of all aspect of testing process (not otherwise specified in 26.715(b))	33 programs	40.0	1,320
26.715(b)(1): Retain personal files	33 programs	20.0	660
26.715(b)(2): Retain chain-of-custody documents	33 programs	240.0	7,920
26.715(b)(3): Retain quality assurance records	33 programs	120.0	3,960
26.715(b)(4): Retain superseded procedures	33 programs	40.0	1,320
26.715(b)(5): Retain all test data	33 programs	240.0	7,920
26.715(b)(6): Retain test reports	33 programs	240.0	7,920
26.715(b)(7): Retain performance test records	33 programs	80.0	2,640
26.715(b)(8): Retain testing error investigation records	33 programs	40.0	1,320
26.715(b)(9): Retain certification inspection records	33 programs	40.0	1,320
26.715(b)(10): Retain records on preventative maintenance	33 programs	40.0	1,320
26.715(b)(11): Retain records summarizing scientific insufficiency	33 programs	20.0	660
26.715(b)(12): Retain computer-generated data	33 programs	120.0	3,960
26.715(b)(13): Retain records on visitors	33 programs	20.0	660
26.715(b)(14): Retain records on EBT maintenance	33 programs	20.0	660
26.717(a) and (b): Collect FFD performance data	33 programs	200.0	6,600
26.717(c): Analyze FFD data annually	33 programs	80.0	2,640

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.717(d): Test results leading to termination	2 C/Vs	1.0	2
26.717(g): Sharing of required FFD information by C/V with licensee to ensure information is reported completely and is not duplicated in reports submitted to the NRC	2 C/Vs	120.0	240
26.719(d): Document non-reportable indicators of FFD program weaknesses	33 programs	20.0	660
26.821(a): Allow NRC to inspect and copy records	33 programs	4.0	132
26.821(b): Written agreement between C/Vs and licensees to permit authorized NRC representatives to inspect, copy, or take away copies of C/Vs documents, records, and reports	5 C/Vs	4.0	20
Table 2 Total			**576,428**

Table 3
Annual Reporting Burden

Section	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Total Burden Hours
26.9: Application to NRC for exemption	2 programs	1	2	16.0	32
26.77(c) Report FFD-impaired NRC employee	33 programs	None	None	1.0	None
26.137(b)(2)(iii): Report false negative QC test result	Burden shown under §26.719(c)(3)				
26.137(b)(3): Report false negative QC lab result	Burden shown under §26.719(c)(3)				
26.139(d): Prepare information for annual report	Burden shown under §26.717(c)				
26.187(f): Provide SAE quals documentation to NRC	1 program	1	1	1.0	1
26.203(e)(1): Report work hour controls waivers to NRC	30 programs	1	30	20.0	600
26.203(e)(2): Report number of fatigue assess. to NRC	30 programs	1	30	30.0	900
26.417(b)(1): Report to NRC by telephone with 24 hours programmatic failures	1 program	1	1	4.0	4
26.417(b)(2): Annual construction FFD report	19 programs	1	19	80.0	1,520
26.717(d): Report termination test results in the annual summary by processing stage	33 programs	30	979	1.0	979[19]
26.717(e) and (f): Annual report of FFD program performance	33 programs	1	33	120.0	3,960

[19]Estimate is based on 979 positive test results in NRC's 2005 FFD program perforance data and one burden hour per positive test result.

Section	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Total Burden Hours
26.719(a): Reports of signif. FFD violations, program failurs, and errors in testing	Burden reported under 26.719(b) and (c)				
26.719(b): Report signif. FFD violations by phone w/in 24 hrs	33 programs	1	33	2.3	74
26.719(c)(1): Report results of testing error investigation to NRC w/in 30 days	2 programs	1	2	1.0	2
26.719(c)(2): Notify NRC of false pos. on blind performance sample w/in 24 hrs	33 programs	155	5,112	4.0	20,448
26.719(c)(3): Notify NRC of false neg. on QA check w/in 24 hrs	33 programs	7	216	1.0	216
Table 3 Total			**6,458**		**28,736**

TOTAL PART 26 BURDEN: 738,129 hours (132,965 hours one-time recordkeeping annualized, 576,428 hours recordkeeping + 28,736 hours reporting)
TOTAL RESPONSES: 6,510 (6,458 responses + 52 recordkeepers)
NUMBER OF RESPONDENTS: 52 (28 reactor programs, 2 contractor/vendors, 2 fuel cycle facilities, 1 mixed-oxide fuel fabrication facility, and 19 construction FFD programs)

Table 4
Annual Third - Party Burden

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.27(b): Make FFD policy statement available to staff subject to FFD reqs.	33 programs	2.0	66
26.29(b): FFD exams	33 programs	1.0	33
26.29(b): All current staff take FFD exam	33 programs	283.3	9,350
26.29(b): FFD staff mgmt grade FFD exam	33 programs	283.3	9,350
26.29(c)(1): FFD training for current staff	33 programs	2,266.7	74,800
26.29(c)(2): Refresher FFD training or testing	33 programs	250.0	8,250
26.29(d): Accept FFD training from other licensees' programs	33 programs	17.5	576
26.31(b)(1)(i): Background checks for FFD personnel	33 programs	17.5	576
26.31(b)(1)(v): Behavioral observation for FFD program personnel	33 programs	80.0	2,640
26.31(d)(1)(i)(D): Analysis and certification for unlisted drugs	8 programs	4.0	32
26.31(d)(1)(ii): Licensee additions to tested drugs	33 programs	8.0	264
26.31(d)(3)(iii)(A): Document more stringent cutoff levels	8 programs	8.0	64
26.31(d)(3)(iii)(C): Evaluation and certification of more stringent cutoff levels	8 programs	8.0	64
26.31(d)(6): Written permission of donor to conduct another analysis or test with specimen	8 programs	1.0	8
26.33: Records of behavioral observations	33 programs	436.4	14,400
26.35(a): Employee assistance program records	33 programs	16.0	528
26.35(c): Written waiver of right to privacy from individual given to EAP	33 programs	2.0	66
26.35(c): EAP disclosure to FFD mgmt.	16 programs	1.0	16
26.37(b): Obtain signed consent for release of information	33 programs	141.7	4,675

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.37(b)(1): Signed designation of personal representative for FFD matters	33 programs	117.8	3,888
26.37(c): Disclosure to other licensees	33 programs	108.0	3,564
26.37(d): Obtain lab results and provide result to individual	33 programs	32.7	1,080
26.39(a) and (b): Maintain procedures for review of determinations of FFD	33 programs	120.0	3,960
26.39(d): Update records to reflect outcome of review of determination of fitness	33 programs	43.6	1,440
26.39(e): Provide review procedure to individual	33 programs	14.8	490[20]
26.41(d): Review C/V audit results	33 programs	38.0	1,254
26.41(f): Document and report audit results	33 programs	38.0	1,254
26.41(g): Share audit results with mgmt and with other FFD programs	32 programs	40.0	1,320
26.53(e)(2): Inform licensee of the termination of an individual's authorization	2 programs	120.0	240
26.53(g): Inform licensee of Part 26 requirement violations	8 programs	8.0	64
26.53(h): Obtain the knowledge and written consent of the subject individual before initiating any actions under Subpart C	33 programs	1,197.0	39,503[21]
26.53(i): Inform, in writing, any individual applying for authorization of the causes for denial or termination of authorization	33 programs	19.6	648[22]
26.55(a)(1) and (a)(2): Obtain and review self-disclosure and empl. history and complete suitable inquiry	Burden shown under §§26.61 and 26.63		

[20]Estimate is based on 979 positive test results from NRC's 2005 FFD program perforance data. 0.5 burden hours is estimated for each positive test result.

[21]Estimate is based on 79,005 pre-access tests from NRC's 2005 FFD program perforance data. 0.5 burden hours is estimated for each test.

[22]Estimate is based on 648 positive pre-access test results from NRC's 2005 FFD program perforance data. 1 burden hour is estimated for each positive test result.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.57(a)(1) and (a)(2): Obtain and review self-disclosure and empl. history and complete suitable inquiry	Burden shown under §§26.61 and 26.63		
26.59(a)(1) and (a)(2): Obtain and review self-disclosure and empl. history and complete suitable inquiry	Burden shown under §§26.61 and 26.63		
26.59(c)(1): Obtain and review self-disclosure	Burden shown under §§26.61		
26.61(a): Written self-disclosure and employment history	33 programs	1,096.4	36,180
26.63(a) and (e): Suitable inquiry	33 programs	1,723.6	56,880
26.63(c): Confirm contents of employment history	33 programs	1,096.4	36,180
26.63(c)(2): Receive and file DD 214	33 programs	7.6	252
26.63(c)(3): Document refusal to supply employment information	33 programs	5.5	180
26.63(d) and (e): Obtain and maintain documentation of reinstated authorization from other FFD programs	33 programs	1.0	33
26.65(d)(1) and (e)(2): Prepare record of reinstatement or administrative withdrawal of authorization	33 programs	193.1	6,372
26.65(f): Adjust personnel records	33 programs	1.0	33
26.67: Random drug and alcohol testing of persons who have applied for authorization	33 programs	0.5 [23]	25,000
26.69(c)(1): Obtain and review written self-disclosure and employment history	Burden shown under §§26.713(a)(1)		
26.69(b) and (c)(3): Obtain and review employee records to confirm potentially disqualifying FFD situation resolved	33 programs	81.8	2,700
26.69(c)(2): Complete a suitable inquiry on previous employers	Burden shown under §§26.63		
26.69(c)(4): Verify drug/alcohol treatment & testing completed	33 programs	3.0	99
26.69(c)(5): Verify pre-access drug/alcohol testing completed	33 programs	1.0	33

[23]NRC's 2005 FFD program perforance data reported approximately 50,000 total random drug tests.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.69(d): Verify reviewing officer's review completed	33 programs	24.0	792
26.69(e): Provide information on testing and treatment plans to other FFD programs	33 programs	8.0	264
26.75(a), (b), (c), (d), (e), and (g): Record of sanctions for FFD violation	33 programs	12.0	396
26.75(h):Record additional evidence indicating impairment	33 programs	18.0	594
26.75(i): Inform licensee of non-negative initial test result	33 programs	80.0	2,640
26.75(i)(3) and (i)(4): Eliminate references to temporary administrative action and provide written statement that records expunged	33 programs	1.0	33
26.85(a), (b), and (c): Training collectors	33 programs	4.0	132
26.85(c)(4): Written instructions for alternate collectors	33 programs	16.0	528
26.85(e): Maintain personnel files	33 programs	4.0	132
26.87(d)(3) and (f)(1): Signage/security at test site	11 programs	0.3	3
26.87(f)(3), (f)(4), and (f)(5): Prepare custody-and-control form	11 programs	0.5	6
26.89(a): Report absence of donor	33 programs	1.0	33
26.89(b)(1) an (b)(2): Obtain ID and consent form	33 programs	1.5	50
26.89(b)(3): Inform FFD program management that individual did not present identification	33 programs	4.0	132
26.89(c): Report premature departure	33 programs	3.3	108
26.91(c)(1), (c)(2), and (c)(3): Record of EBT test results	Burden shown under §26.715(b)(12)		
26.91(e)(4): Cancel results after EBT calibration check failure	8 programs	6.0	48
26.91(e)(5): Prepare record of EBT maintenance	33 programs	6.0	198
26.93(a)(6): Document alcohol pre-test questions asked and answered	33 programs	322.9	10,656

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.95(b)(5): Record donor identity for initial alcohol breath test	33 programs	322.9	10,656
26.97(b)(2): Record reason for new oral fluid alcohol test	33 programs	5.5	180
26.97(c)(1): Document reason for failure of 2nd collection attempt	33 programs	2.7	90
26.97(d): Record results and alcohol screening device used	33 programs	67.6	2,232
26.99(b): Record test time of initial test with 0.02% or higher BAC	33 programs	17.1	565
26.101(b)(7): Indicate time on EBT printout of alcohol test result	33 programs	17.1	565
26.103(b): Inform FFD mgmt of result between 0.01 and 0.02 when donor in work status 3 or more hours	33 programs	0.3	11
26.107(b): Document tampering attempt on c & c form	33 programs	1.4	47
26.109(b)(3): Notify FFD mgt. or MRO of “shy bladder” problem	33 programs	0.5	18
26.109(b)(4): Notify FFD mgmt. if observed collection required	33 programs	0.3	11
26.111(b): Note unusual findings on c & c form	33 programs	1.4	47
26.111(c):Report tampering attempts to FFD mgr.	33 programs	0.3	11
26.113(b)(3): Prepare c & c forms for both parts of split sample	33 programs	0.3	11
26.115(b): Obtain approval for collection under direct observation from FFD mgr. or MRO	33 programs	0.5	18
26.115(d): Prepare c & c form for directly observed collection	33 programs	0.3	11
26.115(f)(3): Record name of observer	33 programs	0.3	11
26.117(c), (d), and (e): Prepare ID labels and c & c forms for specimen shipment	33 programs	65.5	2,160
26.119(a), (e), and (f): Obtain evaluation from MRO or physician evaluating “shy bladder” claim	33 programs	6.0	198

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.119(b): MRO provides information to physician as background for evaluation of "shy bladder" claim	33 programs	2.2	72
26.125(b) and (c): Proficiency and qualifications records of testing facility personnel	33 programs	16.4	540
26.129(a): Limit access to testing site	33 programs	2.5	83
26.129(b): Inspect specimen packages, custody control forms, and obtain memorandum from specimen collector	33 programs	0.5	17
26.129(b)(1): Report to senior mgmt. attempts to tamper with specimens in transit	33 programs	1.0	33
26.129(d): Procedures for tracking c & c of specimens	33 programs	95.0	3,135
26.135(b): Donor's written permission for retest second part of split sample	33 programs	2.2	72
26.137(a): Maintain QA/QC program and procedures for licensee testing facility	33 programs	4.0	132
26.137(b)(1)(ii): Document performance of testing device not on SAMHSA list	2 programs	40.0	80
26.137(b)(1)(iii): Document results of annual test of device not on SAMHSA list	2 programs	20.0	40
26.137(b)(3): Submit 1 in 10 negative specimens for validity screening	33 programs	40.0	1,320
26.137(e)(7): Document procedures to protect against carryover material	33 programs	2.0	66
26.137(f)(5): Record finding of testing errors	33 programs	26.2	864
26.137(h): Label standards and controls	33 programs	65.0	2,145
26.153(e): Inspect HHS-certified labs	33 programs	40.0	1,320
26.153(f): Include specified requirements in contracts with HHS labs	33 programs	40.0	1,320
26.153(g): Supply memo to HHS labs explaining use of non-federal c & c form	33 programs	0.5	17
26.155(a)(1): Document qualifications for lab mgr of HHS-certified lab.	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.155(a)(3): Lab mgr. documents training of lab personnel	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(a)(4): Lab mgr. reviews and signs lab procedures	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(a)(5): Lab mgr. maintains QA program	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(b): Certifying scientist to certify test results from HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(c): Supervise technical analysts at HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(e): Continuing education for staff of HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(f): Lab personnel records	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.157(a): Written procedures for accession, receipt, shipment, and testing of urine specimens by HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.157(b): Written chain-of-custody procedures for HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.157(c): Written procedures manual for each assay performed by HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.157(d): Written procedures for device set-up and operation	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.157(e): Written procedures for remedial actions to address systems and instrument errors	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.159(a): Documented restriction to access to HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.159(b): Report evidence of tampering with specimens in transit to FFD program mgr. of licensee or other entity	33 programs	1.0	33
26.159(c), (d), and (e): Use and storage of c & c forms	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.159(f): Use of c & c form when shipping specimen to another HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.159(i): Obtain written authorization to store specimens other than 1 year	33 programs	0.5	17
26.163(a)(2): Inform licensee of dilute specimen and report confirmatory validity test result to MRO	33 programs	3.3	108
26.165(b)(1): Donor requests aliquot or split specimen to be tested by a second HHS-certified laboratory	33 programs	10.9	361[24]
26.165(b)(2): MRO informs donor of opportunity for re-test of aliquot or test of Bottle B of split sample	33 programs	3.3	108
26.165(b)(3): Donor gives written permission for re-test of aliquot or test of Bottle B of split sample	33 programs	10.9	361[25]
26.165(b)(4): Donor presents documentation for reason unable to complete timely retest request	33 programs	0.2	6[26]
26.165(b)(6): Provide results of re-test of aliquot or test of Bottle B to MRO and to donor	33 programs	6.5	216
26.165(c)(4): Report retesting results to MRO	26 laboratories	13.9	361[27]

[24]Estimate is based on 361 donors and one burden hour per donor.

[25]Estimate is based on 361 donors and one burden hour per donor.

[26]Estimate is based on 6 donors and one burden hour per donor.

[27]Estimate is based on 361 donors and one burden hour per donor.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.165(f): Adjustments to personnel files and written notifications regarding test results, including temporary administrative action	33 programs	6.5	216
26.165(f)(1)(iv) and (f)(2): Written notice that records purged of references to temporary administrative action	33 programs	8.7	288
26.167(a): Document quality assurance program of HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.167(c)(2)(i): HHS-certified laboratory's refractometer must display specific gravity to 4 decimals and be interfaced with laboratory information management system or computer and/or document result by hard copy or electronic display	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.167(f)(3): Certification by HHS lab that retesting requested by licensee or other entity has occurred	26 laboratories	1.0	26
26.167(h): Labeling of standards and controls	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.168(a): Preparer certifies contents of blind performance test samples submitted to HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.168(h)(2): Ensure supplier provides expiration date for test sample	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.168(i)(2): Use c & c form, place fictional initials on specimen labels, and indicate blind performance test samples	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.169(a): Reports of test results by HHS lab	Burden covered under §§26.169 (c)(1) through (c)(5)		
26.169(c)(1): HHS lab reports positive, adulterated, substituted, dilute, and invalid test results to the MRO	26 laboratories	350.0	9,100
26.169(c)(2): HHS lab reports quantitative test results as requested by MRO	5 laboratories	1.0	5

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.169(c)(2): HHS lab reports quantitative test results for opiates to MRO	16 laboratories[28]	1.0	16
26.169(c)(3): HHS lab reports quantitative test results for adulterated or substituted test results	26 laboratories	20.0	520
26.169(c)(4): HHS contact with MRO to discuss whether testing by another HHS lab should be done	26 laboratories	2.0	52
26.169(c)(5): HHS lab may report concentration exceeding linear range	5 laboratories	1.0	5
26.169(f): HHS lab transmits copy of the c & c form for negative results to the MRO	26 laboratories	0.3	7
26.169(g): HHS lab transmits original of c & c form for positive, adulterated, substituted, dilute or invalid results to the MRO	26 laboratories	100.0	2,600
26.169(h): HHS lab prepares and submits annual statistical summary report of urinalysis testing results	26 laboratories	40.0	1,040
26.183(a): Documentation of MRO qualifications	33 programs	3.5	116
26.183(c)(1): MRO review of records for positive, adulterated, substituted, invalid, or, at the licensees or other entity's discretion, dilute test results	33 programs	26.2	864
26.183(d)(1)(ii)(D): MRO report of drug test results to licensee's designated reviewing official	33 programs	24.0	792
26.183(d)(2)(i): MRO staff review and reporting of negative test results	33 programs	12.0	396
26.183(d)(2)(ii): MRO staff review c & c forms and forward changes to MRO	33 programs	13.1	432
26.185(a) MRO review of all positive, adulterated, substituted, dilute, or invalid test results and report to licensee or other entity	33 programs	54.5	1,800

[28]Estimate based on 16 total positive opiate drug tests listed in NRC's 2005 FFD program perforance data.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.185(c): MRO discussion of test results with the donor	33 programs	2.2	72
26.185(c): MRO report to licensee, following discussion with donor, of FFD violation	33 programs	2.2	72
26.185(d)(1): Documentation that donor declined to discuss test results	33 programs	2.2	72
26.185(e): Documentation that donor was unavoidably prevented from discussing test results and request to reopen proceeding	33 programs	0.3	11
26.185(f)(1): MRO consultation with HHS lab to determine whether additional testing needed	33 programs	0.5	17
26.185(f)(2): MRO contact with donor regarding medical explanation for test result	33 programs	0.5	17
26.185(h)(1): MRO contact with donor to offer opportunity to provide medical evidence regarding substituted specimen	33 programs	1.0	33
26.185(h)(1): Donor presents medical explanation for substituted result	33 programs	1.0	33
26.185(h)(2): MRO notification to licensee that no valid medical explanation presented	33 programs	2.0	66
26.185(h)(3): MRO notification to licensee that valid medical explanation presented	33 programs	1.0	33
26.185(i)(1): MRO contact with donor to offer opportunity to provide medical evidence regarding adulterated specimen	33 programs	1.0	33
26.185(i)(1): Donor presents medical explanation for adulterated result	33 programs	1.0	33
26.185(i)(2): MRO notification to licensee that no valid medical explanation presented	33 programs	2.0	66
26.185(i)(3): MRO notification to licensee that valid medical explanation presented	33 programs	1.0	33
26.185(j)(3): MRO notification to licensee where evidence of drug abuse	33 programs	1.0	33
26.185(j)(3): MRO report to licensee that donor has violated FFD policy by use of another individual’s prescription medication	33 programs	0.5	17

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.185(k): MRO report to licensee that no FFD policy violation has occurred	33 programs	1.0	33
26.185(m): MRO review of inspection and audit reports, quality control data, multiple specimens, and other data to determine if positive, adulterated, substituted, or invalid result is scientifically insufficient for determination of FFD policy violation	33 programs	1.0	33
26.185(n): MRO report to licensee on result of analysis by second laboratory	33 programs	2.0	66
26.185(o): MRO request for quantitation of test results	33 programs	0.5	17
26.185(o): Lab provides quantitation of test results	33 programs	1.0	33
26.185(p): MRO notice to licensee of determination of FFD policy violation	33 programs	8.7	288
26.187(d): SAE training requirements	33 programs	20.0	660
26.187(f): Documentation of SAE credentials and training	33 programs	1.0	33
26.189(a): Written record of determination of fitness	33 programs	74.2	2,448
26.189(c): Written record of “for cause” determination of fitness	33 programs	13.1	432
26.189(d): Modification of an initial determination of fitness	33 programs	1.0	33
26.205(e)(1) and (2): Review of control of work hours twice per calendar year	30 programs	40.0	1,200
26.205(e)(3): Document methods for reviews	30 programs	20.0	600
26.205(e)(4): Record and trend problems in regarding work hours	30 programs	20.0	600
26.207(a)(4): Document bases for waiver	3 programs	6.0	18
26.211(f): Document results of fatigue assessments	30 programs	50.0	1,500

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.405(a) Random drug and alcohol testing	12 programs	875.0	10,500[29]
26.405(c)(1): Document pre-assignment testing	19 programs	1,750.0	33,250[30]
26.405(c)(2) and (c)(3): Document for-cause and post accident testing	19 programs	38.0	722
26.405(c)(4): Document follow up testing	19 programs	190.0	3,610
26.405(f): Ensure testing conducted at an HHS-certified laboratory	19 programs	40.0	760
26.405(g): MRO review of positive, adulterated, substituted, and invalid drug and validity test results	19 programs	50.0	950
26.406(c): Maintain fitness monitoring procedures	7 programs	80.0	560
26.411(a): Maintain a system of files and procedures to protect personal information	19 programs	4.0	76
26.411(a): Collect personal information	19 programs	1,750.0	33,250[31]
26.411(b): Obtain signed consent form	19 programs	1.5	29
26.413: Document results of review process	19 programs	80.0	1,520
26.415: Document and report audit results	19 programs	40.0	760
26.821(b): Written agreement between C/Vs and licensees to permit authorized NRC representatives to inspect, copy, or take away copies of C/Vs documents, records, and reports	5 C/Vs	4.0	20
Table 4 Total			**507,795**

[29]Value based on estimate of six construction programs choosing to conduct random testing (rather than fitness monitoring), 1,750 workers per construction site subject to the FFD program, a 50% test rate, and one hour of burden per test. This one hour burden per random test is larger than the 0.5 hours per random test for operating reactor sites, due to the large area of a construction site.

[30]Estimate based on one hour to document pre-assignment testing for 1,750 workers at the construction site subject to the FFD program.

[31]Estimate based on one hour to collect personal information for 1,750 workers at the construction site subject to the FFD program.

Table 5
Annualized NRC Burden

NRC ACTION	No. Actions/Year	Burden Hours/Action	Total Hours
Review exemptions requests under §26.9	1	16 hours per review.	16
Review written FFD policies and procedures under §26.27(d)	12	8 hours. Reviews performed during periodic inspections.	96
Review records under §26.75(h) to ensure no inappropriate records are maintained	1	4 hours/review	4
Review reports under §26.77(c) that NRC employee or contractor is unfit for duty	0	No reports anticipated.	--
Review waiver requests submitted under §26.203(e)(1)	2	8 hours/request	16
Review and approve FFD program plans under §26.401	1	80 hours (one-time) x 19 applicants	506
Review reports under 26.417(b)(1) of significant FFD program failures	1	2 hours/review	2
Review annual reports submitted under 26.417(b)(2)	19	40 hours per report	760
Review annual reports submitted under §26.717(e) and (f)	33	92 hours per report for 28 programs; 44 hours per report for 5 programs that do not include fatigue-related information	2,796
Review reports under §26.719(a) of significant violations of FFD policy, FFD program failures, and errors in testing	24	3 hours per report	72
Table 5 Total			**4,268**