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

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Office of Nuclear Reactor Regulation
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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.,

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[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

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[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.

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[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 4-4I
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]

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

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[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:

  $$[NUM_{Auditors\text{-}Base} \times (COST_{Travel} + (COST_{Lodging} \times NUM_{Nights\text{–}Base}) + (HOURS_{Travel} \times WAGE_{Auditor}))] \times PER_{Annualized}$$

- 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:

    $NUM_{Applicants} \; x \; PER_{Qualify} \; x \; COST_{Onsite} \; x \; NUM_{Units}$

  - 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:

    $NUM_{Applicants} \; x \; PER_{Qualify} \; x \; COST_{Offsite} \; x \; NUM_{Units}$

- 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:

    $NUM_{Applicants} \; x \; PER_{Qualify} \; x \; HOURS_{Onsite\ Worker} \; x \; WAGE_{Worker} \; x \; NUM_{Units}$

  - 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:

    $NUM_{Applicants} \; x \; PER_{Qualify} \; x \; HOURS_{Offsite\ Worker} \; x \; WAGE_{Worker} \; x \; NUM_{Units}$

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[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.

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[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:

    $NUM_{Applicants} \; x \; COST_{Onsite} \; x \; NUM_{Units}$

  - Pre-access drug and alcohol tests need not be performed at facilities with offsite testing laboratories. The associated savings are calculated as follows:

    $NUM_{Applicants} \; x \; COST_{Offsite} \; x \; NUM_{Units}$

- 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:

    $NUM_{Applicants} \; x \; HOURS_{Onsite\ Worker} \; x \; WAGE_{Worker} \; x \; NUM_{Units}$

  - 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:

    $NUM_{Applicants} \; x \; HOURS_{Offsite\ Worker} \; x \; WAGE_{Worker} \; x \; NUM_{Units}$

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.

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[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):

  $COST_{EBT} \ x \ NUM_{new\ EBTs} \ x \ PER_{purchase\ EBT} \ x \ NUM_{facilities}$

- Purchase a regulator used in calibrating new EBT equipment[4]:

  $COST_{regulator} \ x \ PER_{purchase\ EBT} \ x \ NUM_{facilities}$

- Breath alcohol collector training on use of new EBTs:

  $[COST_{training\ course} + (NUM_{collectors} \ x \ (HOURS_{collector\ training} \ x \ WAGE_{collector}))] \ x \ NUM_{facilities} \ x \ PER_{purchase\ EBT}$

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.

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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.

- 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.

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[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.

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[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:

$$[(NUM_{drug\ tests\ per\ quarter} \times PER_{blind\ samples,\ initial\ 90\ days,\ former\ rule} \times COST_{blind\ sample\ and\ testing,\ former\ rule} \times NUM_{reactors}) - (NUM_{drug\ tests\ per\ quarter} \times PER_{blind\ samples,\ initial\ 90\ days,\ final\ rule} \times COST_{blind\ sample\ and\ testing,\ final\ rule} \times NUM_{reactors})] \times PER_{change\ HHS\ lab}$$

[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:

$$[(NUM_{specimens\ to\ HHS\ lab\ per\ quarter\ from\ LTF} \times PER_{blind\ samples,\ initial\ 90\ days,\ former\ rule} \times COST_{blind\ sample\ and\ testing,\ former\ rule} \times NUM_{reactors}) - (NUM_{specimens\ to\ HHS\ per\ quarter\ from\ LTF} \times PER_{blind\ samples,\ initial\ 90\ days,\ final\ rule} \times COST_{blind\ sample\ and\ testing,\ final\ rule} \times NUM_{reactors})] \times PER_{change\ HHS\ lab}$$

Parameter	**Description**
$NUM_{drug\ tests\ per\ quarter}$	Number of drug tests per reactor per quarter (as discussed in the assumptions below and in Appendix 2, Exhibit A2-14)
$PER_{blind\ samples,\ initial\ 90\ days,\ former\ rule}$	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)
$COST_{blind\ sample\ and\ testing,\ former\ rule}$	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)
$PER_{blind\ samples,\ initial\ 90\ days,\ final\ rule}$	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)
$COST_{blind\ sample\ and\ testing,\ final\ rule}$	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)
$PER_{change\ HHS\ lab}$	Percentage of years that an FFD program enters a contract with a different HHS-certified laboratory (as discussed in the assumptions below)
$NUM_{specimens\ to\ HHS\ lab\ per\ quarter\ from\ LTF}$	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.

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[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:

$$(NUM_{drug\ tests\ per\ quarter} \times PER_{blind\ specimens,\ former\ rule} \times COST_{blind\ specimen\ testing,\ former\ rule} \times NUM_{reactors} \times NUM_{quarters\ in\ year}) - (NUM_{drug\ tests\ per\ quarter} \times PER_{blind\ specimens,\ final\ rule} \times COST_{blind\ specimen\ testing,\ final\ rule} \times NUM_{reactors} \times NUM_{quarters\ in\ year})$$

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:

$$(NUM_{drug\ tests\ to\ HHS\ lab\ per\ quarter,\ LTF} \times PER_{blind\ specimens,\ former\ rule} \times COST_{blind\ specimen\ testing,\ former\ rule} \times NUM_{reactors} \times NUM_{quarters\ in\ year}) - (NUM_{drug\ tests\ to\ HHS\ lab\ per\ quarter,\ LTF} \times PER_{blind\ specimens,\ final\ rule} \times COST_{blind\ specimen\ testing,\ final\ rule} \times NUM_{reactors} \times NUM_{quarters\ in\ year})$$

Parameter	**Description**
$NUM_{drug\ tests\ per\ quarter}$	Number of drug tests per reactor per quarter (as discussed in the assumptions below)
$PER_{blind\ specimens,\ former\ rule}$	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)
$COST_{blind\ specimen\ testing,\ former\ rule}$	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)
$PER_{blind\ specimens,\ final\ rule}$	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

Exhibit A2-2: Written Policies and Procedures

Exhibit A2-3: Training and Examinations

Exhibit A2-4: Audits, Inspections, Certifications and Corrective Actions

Exhibit A2-5: Authorizations

Exhibit A2-6: Activities Related to Potential Policy Violations

Exhibit A2-7: Urine Specimen Collections

Exhibit A2-8: Alcohol Testing

Exhibit A2-9: Drug and Validity Testing (Licensee Testing Facilities and HHS-Certified Laboratories)

Exhibit A2-10: Reporting Requirements

Exhibit A2-11: Hourly Wage Rates

Exhibit A2-12: Testing and Applicant Information

Exhibit A2-13: Drug and Alcohol Testing Data

Exhibit A2-14: FFD Programs

Exhibit A2-15: Fatigue Inputs

Exhibit A2-16: Fatigue Input Data

Crosswalk Index of Subpart Sections and Exhibits

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 been 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

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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

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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:

$$\text{If waiver addresses one person, then } (1 \text{ hour} \times WAGE_{Manager})$$
$$\text{If waiver addresses multiple people, then } (2 \text{ hours} \times WAGE_{Manager})$$

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:

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:

$$HOURS_{Turnovers} \times HCOST_{Outage}$$

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.