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

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

ABSTRACT

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

CONTENTS

CONTENTS (continued)

EXHIBITS

EXHIBITS (continued)

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 $21.9 million. The total present value of these costs is estimated at $310.1 million (using a 7-percent discount rate) and $481 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 $824,000. The total present value of these costs is estimated at $9,602,000 (using a 7-percent discount rate) and $15,202,000 (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 $438.9 million (present value using a 7-percent discount rate) and $684.8 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 savings on the order of $3.9 million. The total present value of these savings is estimated at $36.2 million (using a 7-percent discount rate) and $68.5 million (using a 3-percent discount rate) over the next 49 years. For the average power reactor licensee's FFD program, which may include multiple

[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.

plants and units, this equates to a one-time cost of approximately $671,200, followed by annual costs of approximately $22,000.[3]

[3] "Per Program" results shown above are presented only for power reactor licensee programs, which are the only licensees subject to Subpart I. For these licensees, the costs of the rule (one-time, annual, and NPV) slightly exceed the savings. The results for industry as a whole, however, include both power reactor licensees and non-reactor licensees. Considering all licensees, including non-reactor licensees, which are not subject to Subpart I, the rule's Pre-Order Baseline savings exceed its costs (annual and NPV). Summing costs and savings for all licensees results in a net savings (annual and NPV).

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,[4] 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.

[4] 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.[5] 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).[6] 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.

(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.

---

[5] 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.

[6] 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.

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."[7] 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.

· *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

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

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.[8]

· *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., 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

[8] 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.

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.[9] 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.[10] (The current regulations, as included in the baseline, take into account the enforcement discretion issued in October 2002.[11]) 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

[9] 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."

[10] 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.

[11] 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.

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 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.[12] 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. The NRC expects an estimated 19 new FFD programs involving individuals constructing new nuclear power 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.

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 2008. 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.)

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

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), Office of Nuclear Material Safety and Safeguards (NMSS), and Office of Federal and State Materials and Environmental Management Programs (FSME). 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 of the sensitivity analysis addressing 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 $311 million (total present value), assuming a 7-percent discount rate, or approximately $482 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: ($310.1 million) using a 7% discount rate ($481.0 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)

	Average Per FFD Program			Total - All FFD Programs		
Sub-part	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)	($1,125,200)	($13,604,000)	($11,808,000)	($31,507,000)	($438,868,000)
J	-	-	-	-	-	-
K	-	-	-	-	-	-
L	-	-	-	-	-	-
M	-	-	-	-	-	-
N	-	$600	$8,700	-	$19,000	$273,000
O	-	-	-	-	-	-
Total	**($481,600)**	**($824,400)**	**($9,601,900)**	**($13,726,000)**	**($21,878,000)**	**($310,062,000)**

* 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.
*** For each subpart, the annual saving (cost) per program is approximately (i.e., excluding the effects of rounding) 1/32 times the annual saving (cost) for all licensee/CV programs because, in the first year the rule is effective, the analysis estimates there will be 32 affected FFD programs (see Section 3.2.2). Subpart I's annual saving (cost) per program is approximately 1/28 times the annual saving (cost) for all licensee/CV programs because Subpart I only applies to the 28 power reactor licensee programs. The analysis calculates NPV per program for every subpart, however, based on a total of 32 FFD programs. Because the NPV per program for Subpart I should be calculated based on fewer FFD programs (the 28 power reactor licensees affected by Subpart I), the resulting NPV per program for Subpart I and the total NPV per program are slightly understated.

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.[13] 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

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

3 percent. As shown, industry costs under the 3-percent discount rate increase to approximately $481 million.

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)	($1,125,200)	($21,739,300)	($11,808,000)	($31,507,000)	($684,777,000)
J	-	-	-	-	-	-
K	-	-	-	-	-	-
L	-	-	-	-	-	-
M	-	-	-	-	-	-
N	-	$600	$15,200	-	$19,000	$445,000
O	-	-	-	-	-	-
Total	**($481,600)**	**($824,400)**	**($15,202,300)**	**($13,726,000)**	**($21,878,000)**	**($480,973,000)**

* 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.
*** For each subpart, the annual saving (cost) per program is approximately (i.e., excluding the effects of rounding) 1/32 times the annual saving (cost) for all licensee/CV programs because, in the first year the rule is effective, the analysis estimates there will be 32 affected FFD programs (see Section 3.2.2). Subpart I's annual saving (cost) per program is approximately 1/28 times the annual saving (cost) for all licensee/CV programs because Subpart I only applies to the 28 power reactor licensee programs. The analysis calculates NPV per program for every subpart, however, based on a total of 32 FFD programs. Because the NPV per program for Subpart I should be calculated based on fewer FFD programs (the 28 power reactor licensees affected by Subpart I), the resulting NPV per program for Subpart I and the total NPV per program are slightly understated.

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)	-

	Average Per FFD Program		Total - All FFD Programs	
26.29(a) Revise and Implement Training, Including Behavioral Observation	Security Activity	($1,251)	-	($40,039)	-
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)
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)
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

	Average Per FFD Program		Total - All FFD Programs	
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, holders of a combined license under 10 CFR part 52 after the Commission has made the finding under 10 CFR 52.103(g), 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 $31,507,000, or approximately $1,125,200 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. The annual cost of this provision is estimated at $254,500 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 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	-	($3,081)	-	($86,277)
26.203(e)(2) Summarize Corrective Actions	-	($402)	-	($11,251)
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	-	($254,548)	-	($7,127,356)
26.205(e) Work Hour Control Reviews	-	($991)	-	($27,747)

Section/ Activity	Average Per FFD Program		Total - All FFD Programs	
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)
26.211(g) Summarize Fatigue Assessment Data	-	($1,639)	-	($45,899)
Total	($421,723)	($1,125,242)	($11,808,235)	($31,506,772)

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,[14] 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 in American society and is an ongoing occupational and safety concern in American industry.[15] 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.[16]

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.[17] 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.

---

[14] 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).

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

[16] 54 FR 24470, “Fitness-For-Duty Programs; Final Rule and Statement of Policy,” June 7, 1989.

[17] 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.

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. 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.[18] 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

[18] 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.

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.

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.[19] 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

[19]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.

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.

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.[20] 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	($421,700)	($1,125,200)	($13,604,000)	($11,808,000)	($31,507,000)	($438,868,000)

[20] 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.

	Average Per FFD Program			Total for All FFD Programs		
(Subpart I)						
Rest of Final Rule	(59,900)	$300,800	$4,002,100	($1,918,000)	$9,628,000	$128,807,000
Total	**($481,600)**	**($824,400)**	**($9,601,900)**	**($13,726,000)**	**($21,878,000)**	**($310,062,000)**

* 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 $21,739,300 per program, or a cost of $684,777,000 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 $15,202,300 per program, or a cost of $480,973,000 to industry as a whole.

** A licensee's FFD program may include more than one facility.

*** For each subpart, the annual saving (cost) per program is approximately (i.e., excluding the effects of rounding) 1/32 times the annual saving (cost) for all licensee/CV programs because, in the first year the rule is effective, the analysis estimates there will be 32 affected FFD programs (see Section 3.2.2). Subpart I's annual saving (cost) per program is approximately 1/28 times the annual saving (cost) for all licensee/CV programs because Subpart I only applies to the 28 power reactor licensee programs. The analysis calculates NPV per program for every subpart, however, based on a total of 32 FFD programs. Because the NPV per program for Subpart I should be calculated based on fewer FFD programs (the 28 power reactor licensees affected by Subpart I), the resulting NPV per program for Subpart I and the total NPV per program are slightly understated.

4.2 Sensitivity Analysis — 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 relevant impacts of the orders in addition to those that are incremental to the final rule.[21] 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 saving of the final rule at $36,227,000 (or $1,192,000 for the average FFD program) using a 7-percent discount rate and $68,505,000 (or $2,612,300 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 saving estimated at $3,924,000 (or a cost of $22,300 for the average program).[22]

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

	Average Per FFD Program			Total - All FFD Programs		
Subpart	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

[21] 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.

[22] "Per Program" results are presented only for power reactor licensee programs, which are subject to Subpart I. For these licensees, the costs of the rule slightly exceed the savings. The results for industry as a whole, however, include not only power reactor licensees, but also non-reactor licensees. For these non-reactor licensees, which are not subject to Subpart I, the rule's savings exceed its costs by a somewhat larger margin. Summing the rule's costs and savings for all licensees results in a relatively small net savings.

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)	($1,158,500)	($13,996,800)	($11,808,000)	($32,439,000)	($451,530,000)
J	-	-	-	-	-	-
K	-	-	-	-	-	-
L	-	-	-	-	-	-
M	-	-	-	-	-	-
N	-	$600	$8,700	-	$19,000	$273,000
O	-	-	-	-	-	-
Total	**($671,200)**	**($22,300)**	**$1,192,000**	**($19,792,000)**	**$3,924,000**	**$36,227,000**

* 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.

*** "Per Program" results are presented only for power reactor licensee programs, which are the only licensees subject to Subpart I. For these licensees, the costs of the rule (one-time, annual, and NPV) slightly exceed the savings, as shown. The results for industry as a whole, however, include both power reactor licensees and non-reactor licensees. For non-reactor licensees, which are not subject to Subpart I, the rule's savings exceed its costs (annual and NPV). Summing costs and savings for all licensees results in a relatively small net savings (annual and NPV), as shown.

**** For each subpart, the annual saving (cost) per program is approximately (i.e., excluding the effects of rounding) 1/32 times the annual saving (cost) for all licensee/CV programs because, in the first year the rule is effective, the analysis estimates there will be 32 affected FFD programs (see Section 3.2.2). Subpart I's annual saving (cost) per program is approximately 1/28 times the annual saving (cost) for all licensee/CV programs because Subpart I only applies to the 28 power reactor licensee programs. The analysis calculates NPV per program for every subpart, however, based on a total of 32 FFD programs. Because the NPV per program for Subpart I should be calculated based on fewer FFD programs (the 28 power reactor licensees affected by Subpart I), the resulting NPV per program for Subpart I and the total NPV per program are slightly understated.

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

	Average Per FFD Program			Total - All FFD Programs		
Subpart	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)	($1,158,500)	($22,376,400)	($11,808,000)	($32,439,000)	($704,786,000)
J	-	-	-	-	-	-
K	-	-	-	-	-	-
L	-	-	-	-	-	-

M	-	-	-	-	-	-
N	-	$600	$15,200	-	$19,000	$445,000
O	-	-	-	-	-	-
Total	**($671,200)**	**($22,300)**	**$2,612,300**	**($19,792,000)**	**$3,924,000**	**$68,505,000**

* 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.

*** "Per Program" results are presented only for power reactor licensee programs, which are the only licensees subject to Subpart I. For these licensees, the costs of the rule (one-time, annual, and NPV) slightly exceed the savings, as shown. The results for industry as a whole, however, include both power reactor licensees and non-reactor licensees. For non-reactor licensees, which are not subject to Subpart I, the rule's savings exceed its costs (annual and NPV). Summing costs and savings for all licensees results in a relatively small net savings (annual and NPV), as shown.

**** For each subpart, the annual saving (cost) per program is approximately (i.e., excluding the effects of rounding) 1/32 times the annual saving (cost) for all licensee/CV programs because, in the first year the rule is effective, the analysis estimates there will be 32 affected FFD programs (see Section 3.2.2). Subpart I's annual saving (cost) per program is approximately 1/28 times the annual saving (cost) for all licensee/CV programs because Subpart I only applies to the 28 power reactor licensee programs. The analysis calculates NPV per program for every subpart, however, based on a total of 32 FFD programs. Because the NPV per program for Subpart I should be calculated based on fewer FFD programs (the 28 power reactor licensees affected by Subpart I), the resulting NPV per program for Subpart I and the total NPV per program are slightly understated.

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 $25,802,000 ($802,100 for the average program), all of which relates to requirements in Subparts B, C, and I.

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

	Average Per FFD Program		Total - All FFD Programs	
Subpart	One-Time Saving (Cost)	Annual Saving (Cost)	One-Time Saving (Cost)	Annual Saving (Cost)
A	-	-	-	-
B	($189,600)	($34,600)	($6,066,000)	($1,105,000)
C	-	$869,900	-	$27,839,000
D	-	-	-	-
E	-	-	-	-
F	-	-	-	-
G	-	-	-	-
H	-	-	-	-
I	-	($33,300)	-	($932,000)
J	-	-	-	-
K	-	-	-	-
L	-	-	-	-
M	-	-	-	-
N	-	-	-	-
O	-	-	-	-
Total	($189,600)	$802,100	($6,066,000)	$25,802,000

* 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, C, and I 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.

A total of over $900,000 in annual costs (over $33,000 per program) results from outage days-off requirements for security officers under Subpart I. As a result of this requirement, licensee will be required to hire additional contract security officers to provide baseline security officers with 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.

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

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
26.205(d)(4)-(6) Outage Days-off Requirements	-	($33,286)	-	($932,000)
Total	($189,567)	$802,156	($6,066,139)	$25,802,124

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 $74,271,000, or $2,251,000 for the average program, assuming a 7-percent discount rate. Assuming a 3-percent discount rate, the costs are estimated to be $105,734,000, or $3,027,000 for the average program.

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

	Average Per FFD Program			Total - All FFD Programs		
Subpart	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)	($1,158,500)	($13,996,800)	($11,808,000)	($32,439,000)	($451,530,000)
J	-	-	-	-	-	-
K	-	-	-	-	-	-
L	-	-	-	-	-	-
M	-	-	-	-	-	-
N	-	$600	$8,700	($0,000)	$19,000	$273,000
O	-	-	-	-	-	-
Total	**($672,000)**	**($275,000)**	**($2,251,000)**	**($19,807,000)**	**($4,169,000)**	**($74,271,000)**

* 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.

*** For each subpart, the annual saving (cost) per program is approximately (i.e., excluding the effects of rounding) 1/32 times the annual saving (cost) for all licensee/CV programs because, in the first year the rule is effective, the analysis estimates there will be 32 affected FFD programs (see Section 3.2.2). Subpart I's annual saving (cost) per program is approximately 1/28 times the annual saving (cost) for all licensee/CV programs because Subpart I only applies to the 28 power reactor licensee programs. The analysis calculates NPV per program for every subpart, however, based on a total of 32 FFD programs. Because the NPV per program for Subpart I should be calculated based on fewer FFD programs (the 28 power reactor licensees affected by Subpart I), the resulting NPV per program for Subpart I and the total NPV per program are slightly understated.

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

	Average Per FFD Program			Total - All FFD Programs		
Subpart	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)	($1,158,500)	($22,376,400)	($11,808,000)	($32,439,000)	($704,786,000)

J	-	-	-	-	-	-
K	-	-	-	-	-	-
L	-	-	-	-	-	-
M	-	-	-	-	-	-
N	-	$600	$15,200	($0,000)	$19,000	$445,000
O	-	-	-	-	-	-
Total	**($672,000)**	**($275,000)**	**($3,027,000)**	**($19,807,000)**	**($4,169,000)**	**($105,734,000)**

* 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.

*** For each subpart, the annual saving (cost) per program is approximately (i.e., excluding the effects of rounding) 1/32 times the annual saving (cost) for all licensee/CV programs because, in the first year the rule is effective, the analysis estimates there will be 32 affected FFD programs (see Section 3.2.2). Subpart I's annual saving (cost) per program is approximately 1/28 times the annual saving (cost) for all licensee/CV programs because Subpart I only applies to the 28 power reactor licensee programs. The analysis calculates NPV per program for every subpart, however, based on a total of 32 FFD programs. Because the NPV per program for Subpart I should be calculated based on fewer FFD programs (the 28 power reactor licensees affected by Subpart I), the resulting NPV per program for Subpart I and the total NPV per program are slightly understated.

Exhibit 4-13 details the specific provisions for which costs are higher under the industry practices baseline than under the pre-order baseline.[23] 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 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)

[23] 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.

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
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	-	($568)	-	($18,176)

Section/ Activity	Average per Program		Total - All Licensee/CV Programs	
Reinstatement Applicants with 31-365 Day Interruption				
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)
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 -	-	($3,992)	-	($127,758)

Section/ Activity	Average per Program		Total - All Licensee/CV Programs	
Onsite Testing Facilities				
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	-	($254,548)	-	($7,127,356)
26.205(e) Work Hour Control Reviews	-	($991)	-	($27,747)
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)	($1,133,806)	($13,726,119)	($31,819,036)

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.
§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

Requirement	Reason
	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.
§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.

Requirement	Reason
§§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.
§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

Requirement	Reason
	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.
§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.

Requirement	Reason
§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.
§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.

Requirement	Reason
§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.
§26.211(g)	This revision does not constitute a backfit because it is an information collection and reporting requirement.
Subpart J	
None.	
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.

Requirement	Reason
§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.
§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 $445 million to industry over the next 49 years (present value), assuming a 7-percent discount rate, or approximately $694 million assuming a 3-percent discount rate.[24] The present value of these costs to the average program is calculated to be approximately $16,204,500 assuming a 7-percent discount rate, and approximately $26,296,300 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 $1,133,800 per year. For industry as a whole, NRC estimates that the backfits result in approximately $13.7 million in one-time costs, and about $31.8 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.*

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

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 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 $21.9 million (or $0.8 million for the average program). Combining these initial and annual costs, this analysis estimates that the final Part 26 rule will cost industry approximately $310.1 million (present value, assuming a 7-percent discount rate) to $481 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	$3,499,475	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
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 than 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.[25] 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 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

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

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).[26] 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.

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	Regulatory Analysis, Section

[26] 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).

CRGR Charter Citation	Information Item to be Included in a Regulatory Analysis Prepared for CRGR Review	Where Item is Discussed
	increase requirements or staff positions, implement existing requirements or staff positions, or relax or reduce existing requirements or staff positions.	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 $310.7 million (total present value over a 49-year period), assuming a 7-percent discount rate, or approximately $482 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 ($482,000 for the average program), and then generates annual costs of about $21.9 million ($0.8 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 $445 million (present value) assuming a 7-percent discount rate, or $694 million assuming a 3-percent discount rate. The provisions cost industry about $13.7 million in initial costs and generate about $31.8 million in annual costs. For the average program, this equates to about $481,700 in one-time costs, and about $1.1 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

APPENDIX 2: DATA USED IN THE ANALYSIS

APPENDIX 3: WAIVER COST METHODOLOGY

[DELETE THIS AND SUBSTITUTE APPENDIX]