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United States Nuclear Regulatory Commission

Protecting People and the Environment

NUREG-1912

Summary and Analysis of Public Comments Received on Proposed Revisions to 10 CFR Part 26 – Fitness for Duty Programs

Comments received between August 26, 2005 and May 10, 2007

Office of Nuclear Regulatory Research

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ABSTRACT

On August 26, 2005, the U.S. Nuclear Regulatory Commission (NRC) published proposed amendments to the NRC's regulations for Fitness for Duty (FFD) programs in the *Federal Register* for public comment. The proposed amendments would have revised and updated the FFD regulations that the NRC established in 1989, and would, among other things, have required nuclear power plant licensees and other entities to strengthen the effectiveness of their FFD programs in controlling the use of substances that may affect the trustworthiness, reliability, and performance of workers and to limit worker fatigue by establishing clear and enforceable fatigue management requirements. They also would have increased consistency with other Federal rules and guidelines and with the NRC's access authorization requirements. This report provides a detailed summary of the public comments on the proposed amendments received by the NRC and provides the NRC's resolution of the issues raised by those comments.

FOREWORD

This report provides a detailed summary of each of the public comments received by the U.S. Nuclear Regulatory Commission (NRC) on the proposed revisions to 10 CFR Part 26 – Fitness for Duty Programs that were published in the *Federal Register* on August 26, 2005 (70 FR 50442) and draft final rule text that the staff made available to the public on its website before publication of the final rule. It also provides the NRC's analysis and resolution of the issues raised by each of those comments. The comments are organized by topic area. The document includes a table that links the comments to specific commenters.

The NRC developed this report for agency staff who may evaluate licensees' fitness-for-duty programs and those who may be involved in future NRC rulemakings on topics related to fitness-for-duty. Agency staff should use this report to gain a greater understanding of the bases for the provisions of the rule and the public's perception of some of those provisions.

Christiana Lui, Director
Division of Risk Analysis
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission

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ACKNOWLEDGEMENTS

Initial preparation of this document was conducted by Georgia Schuh, Elizabeth Gormsen, Brian Zaleski, and John Collier of ICF International. ICF International supported the NRC staff in categorizing and summarizing the public comments, and in providing analyses to support the staff's responses to particular issues.

Revision and final compilation of NRC responses to comments was conducted by Kristi M. Branch and Antoinette L. Slavich of Pacific Northwest National Laboratory and Thomas F. Grant of Nancy E. Durbin Consulting. This work included updating the comment database, updating and revising the comment summaries and responses, and preparing an index of commenters to aid in locating the staff's responses to their comments within the document.

LIST OF ACRONYMS

AEP	American Electric Power
AFL-CIO	American Federation of Labor and Congress of Industrial Organizations
CAN	Citizens Awareness Network
CPL	Conforming Products List
DCS	Duke Cogema Stone & Webster
DOT	U.S. Department of Transportation
EAP	Employee Assistance Program-
EBT	Evidential Breath Testing Device
EPRI	Electric Power Research Institute
EGC	Exelon Generation Company
FENOC	FirstEnergy Nuclear Operating Company
FFD	Fitness for Duty
FMCSA	Federal Motor Carrier Safety Administration
FPL	Florida Power and Light
HHS	U.S. Department of Health and Human Services
IBEW	International Brotherhood of Electrical Workers
LOD	Limit of Detection
MRO	Medical Review Officer
NEI	Nuclear Energy Institute
NHTSA	National Highway Traffic Safety Administration
NMC	Nuclear Management Company
NRC	U.S. Nuclear Regulatory Commission
NRSG	Nuclear Regulatory Services Group
NSF	National Sleep Foundation
OMB	Office of Management and Budget
OTC	Over-the-Counter
PDFFDI	Potentially Disqualifying Fitness-for-duty Information
POCT	Point-of-Collection Test
POGO	Project on Government Oversight
PPL	PPL Corporation - Susquehanna
PROS	Professional Reactor Operator Society
QA/QC	Quality Assurance/Quality Control
SAE	Substance Abuse Expert
SAT	Systems Approach to Training
SAMHSA	Substance Abuse and Mental Health Services Administration
SCE	Southern California Edison
SCE&G	South Carolina Electric and Gas Company
SNC	Southern Nuclear Operating Company
STARS	Strategic Teaming and Resource Sharing
TVA	Tennessee Valley Authority
TXU	TXU Energy
UCS	Union of Concerned Scientists
UAJA	United Association of Journeymen and Apprentices
UWUA	Utility Workers Union of America
VEP	Virginia Electric and Power
WGI	Washington Group International

INTRODUCTION

The NRC published the original 10 CFR Part 26 – Fitness for Duty Programs on June 7, 1989 (54 FR 24468). The rule required licensees authorized to operate or construct a nuclear power reactor to implement a fitness-for-duty (FFD) program for all personnel having unescorted access to protected and vital areas at the site. The NRC subsequently expanded the scope of Part 26 to include licensees authorized to possess, use, or transport formula quantities of Strategic Special Nuclear Materials (June 3, 1993; 58 FR 31467). When it published the original rule, the Commission directed the staff to continue to analyze licensee programs, assess the effectiveness of the rule, and recommend appropriate improvements or changes. Over the succeeding years, the staff reviewed information from several sources, including inspections, licensee FFD program performance reports, industry-sponsored meetings, and current research. The staff also considered initiatives by the nuclear power industry, the Substance Abuse and Mental Health Services Administration (SAMHSA, formerly the National Institute on Drug Abuse) of the U.S. Department of Health and Human Services (HHS), and the U.S. Department of Transportation (DOT), which, like the NRC, requires alcohol as well as drug testing. As a result, the NRC published proposed amendments to the FFD rule on May 9, 1996 (61 FR 21105). In response to public comments that objected to some aspects of the proposed amendments, the Commission withdrew those proposed amendments and directed the staff to prepare a new proposed rule.

After continuing to review and analyze additional information, consulting with SAMHSA and DOT, and working constructively with industry and other interested organizations, the NRC published proposed revisions to the FFD rule on August 26, 2005 (70 FR 50442). These proposed revisions were intended to update Part 26 requirements and increase their consistency with other relevant Federal rules and guidelines, including the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. They were also intended to require nuclear power plant licensees and other entities who are subject to Part 26 to strengthen the effectiveness of their FFD programs, including measures to address worker fatigue and the potential for subversion of the drug and alcohol testing processes. On October 24, 2006, the NRC published on its website a draft final version of the rule. In general, the proposed revisions' purpose was to increase assurance that individuals subject to Part 26 requirements are trustworthy and reliable, as demonstrated by avoiding substance abuse; are not under the influence of drugs and alcohol while performing their duties; and are not mentally or physically impaired from any other cause that would in any way adversely affect their ability to perform their duties safely and competently.

This document summarizes and responds to public comments the NRC received on those proposed revisions to Part 26. The NRC accepted 82 written public comments from August 26, 2005 to September 25, 2006. This document also summarizes and responds to 15 additional written public comments received between October 24, 2006, the date on which the Commission published a draft final version of the rule on its website, and May 10, 2007. The NRC also considered and has included in this document six comments submitted on a previous working draft of the proposed rule that the NRC posted on its website on May 19, 2005.

This document also includes the NRC's consideration of comments contained in the transcript of a public meeting held on September 21, 2005 (ADAMS Accession No. ML052420363), at which 18 individuals, excluding NRC staff, spoke, as well as comments, although not written, from several other public meetings: November 7 and 9, 2005 (ADAMS Accession No. ML052990048) that provided clarification on the proposed rule; and December 15, 2005 (ADAMS Accession No. ML053400002) regarding the Nuclear Energy Institute's (NEI's) proposed alternative approach to the work hour portions of the proposed rule.

Exhibit 1 - Individuals Providing Written Comments	
Robert Althoff	
Andrew Antrassain	UWUA
Jeffrey Archie	SCE&G
Richard Barkley	
Dave Barry	Shaw Stone & Webster
Doug Beck	
Jim Bradshaw	AEP
Danielle Brian	POGO
Sue Brown	
F. G. Burford	Entergy
Michael Cantor	Waypoint Research, Inc.
Michael Coyle	NEI
Ethan Darrow	
James Davis	NEI
Darrel Drobnich	NSF
Marvin Fertel	NEI
Douglas Foster	PROS
Peter Fowler	Duke Energy
C. L. Funderburk	Dominion
Guy Galster	
Ronald Gaston	Detroit Edison

Exhibit 1 - Individuals Providing Written Comments	
Kevin Glidden	
Greg Gorman	
Don Grissette	SNC
Gregory Halnon	FENOC
Peter Hammill	
Daniel Hansen	
Mark Haywood	
Edwin Hill	IBEW
William Hite	UAJA
Mike Jolley	
D. M. Jurss	
Keith Jury	EGC/AmerGen
Deborah Katz	CAN
Kenneth Kolaczyk	
Donald Lenski	
David Lochbaum	UCS
Charles LoDico	
Brian McCabe	Progress Energy
B. T. McKinney	PPL
Robert Meyer	PROS
Glenn Morris	TVA
Todd Newkirk	IBEW
Louis Pardi	WGI
Blaine Peters	Exelon
Jim Pulley	
Barry Quigley	

Exhibit 1 - Individuals Providing Written Comments	
T. J. Reddington	Day & Zimmermann and Associated Maintenance Contractors
Brent Rice	
Mark Rosekind	Alertness Solutions
Robert Rutkowski	
David Sancic	
A. Edward Scherer	SCE
Steven Schildhouse	
Dennis Specha	
James Springfield	IBEW
J. A. Stall	FPL
Daniel Stenger	NRSG
Edward Sullivan	AFL-CIO
Richard Sweigart	DCS
Anthony Taylor	
Dan Todhunter	
Ray Wacker	
Jim Waite	
Edward Weinkam	NMC
Mark Wetterhahn	Winston & Strawn
D. R. Woodlan	STARS
Keith Young	Ameren

Exhibit 2 - Individuals Providing Comments at the Public Meeting	
Joseph Bauer	Exelon
David Bouthron	FPL
Randy Cleveland	NMC
John Cowan	NEI
James Davis	NEI
Peter Defilippi	Westinghouse Electric Company
Nick DiPietro	First Energy
John Fee	SCE
Jim Gorman	TXU
Tom Houten	NEI
David Lochbaum	UCS
Brian McCabe	Progress Energy
Dana Millar	Entergy
Todd Newkirk	IBEW
Anthony Rizzo	Salem Hope Creek
Pete Stockton	POGO
Susan Techau	Exelon
David Ziebell	EPRI

Following this introduction, Chapter 1 contains the NRC's responses to public comments on general issues pertaining to the Part 26 rulemaking, including support for, opposition to, and the technical and scientific bases of the proposed rule. In the August 26, 2005 *Federal Register* notice publishing the proposed rule (70 FR 50442), the NRC asked for public comment on seven specific issues. Chapter 2 presents the Commission's responses to public comments received on those issues. The proposed rule was divided into 11 subparts. This document's Chapters 3 through 13 contain the NRC's responses to public comments on those 11 proposed subparts. Chapter 14 presents NRC responses to public comments on other significant issues, including the backfit, paperwork burden, and regulatory flexibility analyses conducted for the rulemaking and comments regarding implementation of the rule as proposed. Each of these 14 chapters is divided into subsections corresponding to major issues and significant sub-issues

raised in the comments following the numerical order of the proposed rule's sections and subsections. Chapter 14 is followed by a references section. This document's last section contains a comments tracking table that identifies the chapter or section where each commenter's comments appear.

1. GENERAL ISSUES

This section provides the NRC's responses to certain issues raised by public comments that apply generally to the Part 26 rulemaking, including support or opposition to the rule making. It also provides responses to comments regarding the technical and scientific basis and policy justification for particular proposed amendments to the rule.

1.1 Support

Comments: Several commenters expressed general support for the rulemaking. One commenter stated that the NRC, the licensees, and all the stakeholders have a common goal in mind, and the only issue is how to implement the provisions while providing the necessary operational flexibility [Joseph Bauer, Exelon; John Cowan, NEI; Robert Meyer, PROS, Marvin Fertel, NEI; Anonymous #19].

NRC Response: The comments do not require a response.

1.2 Oppose

No comments generally opposed the rulemaking.

1.3 Legal Basis

Comments: A number of commenters addressed the legal basis of a statement made in the *Federal Register* notice for the proposed rule. The commenters claimed that the proposed rule package repeatedly stated that licensees have violated NRC requirements in the Policy on Worker Fatigue. Concurrently, the proposed rule package noted that the Policy or guidance documents do not prescribe requirements and are enforceable only when included in licensees' technical specifications. Because the NRC Policy on Worker Fatigue was not enforceable by the NRC, the commenters thought that the claimed violation of policy was not an appropriate basis for the reporting requirements contained in proposed Subpart I [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees that the proposed rule package claimed that licensees had violated the NRC's Policy on Worker Fatigue. As the commenters acknowledge, the NRC's statements in the rule package regarding licensees' implementation of the Policy on Worker Fatigue were made with the implicit recognition that Commission policies do not prescribe requirements that can be "violated" and are enforceable only to the extent that licensees incorporate the policies in their Technical Specifications. Instead, the rule package addressed a wide variability in how licensees interpreted and implemented the Policy. The NRC found that, in some cases, the use of waivers, in particular, was inconsistent with the Policy. This was discussed in Section IV.D of the *Federal Register* notice for the proposed rule. The NRC continues to believe that the reporting requirements are justified for the reasons discussed in

Sections V and VI of the *Federal Register* notice for the final rule and Section 11.2.5 of this document.

1.4 Technical and Scientific Basis

Support for Worker-Designed Shifts

Comments: One commenter asserted that proposed Subpart I effectively removed rotating 8-hour schedules for most plants. The commenter presented a scientific paper supporting worker-designed shift schedules [Todd Newkirk, IBEW].

NRC Response: The NRC understands the commenter's concern to be related to the proposed requirement for a 24-hour break in 7 days. In response to this comment, and related comments, the NRC has revised the rest break provisions to provide substantial additional flexibility in the final rule. For further information, see discussion of comments regarding § 26.199(d)(2) in Section 11.3.4 ("Impact on 8-Hour Shifts") of this document.

Correlation between Cited Research and Actual Industry Data

Comments: One commenter, supported by many other commenters, raised several issues with the technical basis for proposed requirements regarding worker fatigue discussed in the rule package for the proposed rule. The commenter disagreed with what he characterized as the "sweeping generalizations" made in Section IV.D (1) and (2) of the proposed rule's *Federal Register* notice regarding alertness problems that may occur as a result of fatigue. The commenter stated that the research alluded to there was not drawn from the nuclear industry, and that there was a lack of correlation between the studies and actual nuclear industry data that raised concerns regarding the validity of the NRC's conclusions. The commenter stated that other factors reduce the potential for fatigue (i.e., the industry's safety culture, training, work procedures, and attention to details) and these factors make it difficult to apply conclusions from studies conducted outside the nuclear industry. In contrast, two commenters stated that the industry's claim of a lack of correlation between impacts of fatigue and actual human performance at reactor sites is refuted by the fact that many security officers have contacted the commenter's organization to raise safety and security concerns because of fatigue since September 11, 2001 [Michael Coyle, NEI #49; Marvin Fertel, NEI; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J.A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG; Daniel Hansen, Individual; Louis Pardi, WGI; Danielle Brian, POGO; Robert Rutkowski, Individual].

NRC Response: The NRC agrees that Section IV.D (1) of the *Federal Register* notice for the proposed rule provided a general discussion regarding alertness problems that may occur as a result of fatigue. That was the section's intent. Section IV.D (1) described the types of impairment that can result from fatigue, specifically impairment of attention, decision-making, problem solving, and communication and teamwork. The discussion included citations as examples of studies that demonstrate these types of impairment. The NRC believes that these effects have been well substantiated and broadly accepted by the scientific community. The

NRC provided a factual discussion of these effects and related studies and disagrees with the characterization of this discussion as including sweeping generalizations.

Section IV.D (2) of that *Federal Register* notice provided a discussion of the prevalence of conditions in the nuclear industry that can contribute to worker fatigue. Specifically, it discussed extended work shifts (i.e., 12 or more hours) with 5 or more consecutive work days, extensive overtime, shiftwork, early start times and extended commutes, and sleep disorders. With regard to the use of more than 5 consecutive work shifts and extensive use of overtime, the NRC notes that industry and union commenters (further presented and discussed in Section 11.3.4 "Limited Access to Supplemental Workers" of this document) have asserted that schedules of 6 or more consecutive 12-hour shifts are necessary to attract supplemental workers and have proposed that the NRC revise the proposed rule requirements to allow such practices. These comments corroborate the NRC's belief that these practices occur in the U.S. nuclear power industry. Similarly, the NRC considers the proposed rule's *Federal Register* notice discussion of industry use of shiftwork, shift start times beginning at 7 a.m. or earlier, the potential for extended commutes due to some nuclear power plants' locations in relationship to major population centers, and the incidence of sleep disorders to be a factual and accurate discussion of these conditions that does not overstate their potential to contribute to worker fatigue at nuclear power plants.

Regarding the comment that the NRC cited studies that were based on observations of worker performance outside the nuclear industry, the NRC agrees that it reviewed research from a broad spectrum of industries, in addition to studies of worker performance in the nuclear industry. As a result, the NRC believes that it relied upon findings that were demonstrated in multiple settings and that substantiated general principles regarding the relationship between work hours, circadian variations in alertness, and worker performance. In addition, the NRC focused on findings from industries or settings with similar work environments and job demands. Furthermore, in establishing the specific requirements of the final rule, the NRC gave significant consideration to those factors (e.g., level of monitoring and vigilance activities, use of detailed procedures, automated safety systems) and work practices (e.g., use of three-way communications and task verification) that are characteristic of the nuclear power plant setting.

Accuracy of Data Provided by Industry

Comments: Many commenters thought that the NRC misinterpreted data from an industry survey covering 1997-1999 and that, as a result, the NRC's conclusions regarding the abuse of overtime were not justified. These commenters stated that the NRC overstated overtime hours because the survey was based on pay records, which do not accurately reflect the actual hours worked [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees that its conclusions on industry use of overtime were not justified. The basis for those conclusions was in part a survey the NEI developed and distributed to nuclear power plant licensees. The survey provided clear instructions to include only those hours worked and not to include extra hour compensations for working nights, weekends, or holidays. Specifically, the survey stated: "For the purposes of this survey,

Overtime is defined as those hours worked in excess of a *nominal* 40-hour work-week. Overtime does not include special compensation for working nights, weekends, or holidays unless they are above and beyond the *nominal* 40-hour work week." The survey also included an example that demonstrated the nominal 40-hour workweek concept for purposes of calculating overtime in response to the survey. If the survey participants followed these instructions, overtime hours shown in the survey results were not based solely on pay records as suggested by the commenters. At the time it submitted a summary of the data by letter, the NEI made no assertion that participants did not follow the survey instructions.

The NRC also notes that the large number of waivers reported in the survey data could have occurred only with excessive amounts of overtime. If overtime is not being worked, waivers are not necessary. Therefore, if actual overtime was much less than pay reports, the number of waivers would have been over-reported.

Furthermore, the NRC notes that several industry commenters (Michael Coyle, NEI #49; Daniel Hansen, Individual; Donald Lenski, Individual; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG) have asserted that it is necessary to offer large amounts of overtime to prevent the loss of supplemental workers to other industries that can offer overtime without restriction (see Section 11.3.4, "Limited Access to Supplemental Workers"). The premise of this comment is that industry has historically allowed individuals to work large amounts of overtime during outages. The NRC also notes that extensive use of overtime and deviations from technical specification work hour limits have also been documented in NRC inspection reports and in Information Notice 91-36, Nuclear Plant Staff Working Hours. The NRC believes its conclusions regarding industry use of overtime are well founded and consistent with those of many other stakeholders (Kenneth Kolaczyk, Individual; Mike Jolley, Individual; Anonymous, Anonymous), including the International Brotherhood of Electrical Workers which observed, "Some of our facilities have done an outstanding job of ensuring a well rested workforce, while other facilities have simply ignored the recommended work hour limitations or relied on other mechanisms to exceed 72 hours per work week" [Edwin Hill, IBEW].

<u>September 11, 2001 Not Valid Justification for Fatigue Provisions</u>

Comments: One commenter, supported by many other commenters, was concerned with the following proposed rule package statement: "The inadequacy of the current regulatory framework for addressing cumulative fatigue became particularly apparent in the months following the terrorist attacks of September 11, 2001." The commenters asserted: "Any condition that unexpectedly requires security posture at the highest level of alert is beyond the normal bounds." The commenters claimed that the stress on security officers following the events of September 11, 2001 was not a valid justification for many of the proposed fatigue rule provisions [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees that the conditions following the events of September 11, 2001, were beyond normal bounds and resulted from conditions that were largely beyond the control of licensees. However, the NRC maintains that the fatigue of security personnel during this period demonstrated that individuals at nuclear power plants will experience cumulative fatigue, even when those individuals are working hours that are within the NRC's policy guidelines of working not more than 16 hours in any 24-hour period and not more than 72 hours in any 7-day period. Furthermore, such work hours and cumulative fatigue may result from conditions that are within a licensee's control, as in the case of the extended outage for the Davis Besse reactor head vessel replacement. As a consequence, these examples indicate that the former regulatory framework for addressing cumulative fatigue was inadequate because plant technical specifications for the control of work hours generally do not place any clear limit on the period of time individuals can work substantially in excess of a 40-hour workweek (e.g., 60 to 72 hours per week).

Adequacy of Former Rule

Comments: A number of commenters questioned what they considered to be a contradiction in the proposed rule's *Federal Register* notice. Specifically, they read the notice to state that the former regulatory requirements, orders, and the policy statement on fatigue were adequate. However, in other parts of the rule package, the commenters noted that the NRC claimed that new provisions would result in significant improvements in public health and safety. These commenters thought these two statements created a contradiction that showed that added requirements were not warranted [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees that the *Federal Register* notice statements described by the commenters were contradictory. Adequate protection of public health and safety and the common defense and security are ensured through the NRC's Policy on Worker Fatigue, licensee technical specification requirements related to this policy statement, and the former regulation. However, there were opportunities to improve this framework, particularly regarding the enforceability and consistency of the former requirements.

The NRC's Policy on Worker Fatigue does not prescribe requirements and is therefore enforceable only to the extent that licensees incorporate the guidelines into a license condition or technical specification requirements. Further, even when licensees have incorporated the Policy on Worker Fatigue into a license condition or technical specifications, the NRC has found it difficult to enforce the worker fatigue requirements and work hour limits in an effective, efficient, and uniform way because of the following factors: the predominantly advisory language in the specifications, the lack of key term definitions, inconsistent levels of detail in the technical specifications among licensees, varying scopes of requirements, inconsistent interpretation of the covered personnel, and inconsistent implementation of the basic measures used to determine whether an individual's work hours are within or above the technical specification limits. The NRC believes that it has addressed these and other limitations of the former regulatory framework with respect to managing the effects of fatigue on worker fitness and that

the final rule will substantially enhance the protection of public health and safety and common defense and security.

24/7 and 48/14 Rest Break Provisions Not Justified

Comments: Several commenters thought that the NRC's justification in the proposed rule's *Federal Register* notice for a 24-hour break every 7 days and a 48-hour break every 14 days was flawed. They concluded this because it discussed the effects of cumulative fatigue without first establishing that cumulative fatigue would exist when every other provision in the proposed rule was observed. The commenters also stated that the lack of industry-specific evidence provided inadequate justification for these break provisions [Michael Coyle, NEI #49; Marvin Fertel, NEI; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenters. As discussed with respect to the comment "September 11, 2001 Not Valid Justification for Fatigue Provisions," the NRC cited operational experience that indicated cumulative fatigue of nuclear power plant personnel at levels of work hours lower than those that would be allowed by the other work hour controls. Specifically, the *Federal Register* notice noted that, following the terrorists attacks of September 11, 2001, the NRC began to receive a large number of expressions of concern from nuclear power plant security personnel regarding the number of hours they were being required to work and their ability to remain alert and fit for duty. The NRC subsequently reviewed the work hours of security personnel at nuclear power plants and found that they typically did not exceed an average of 60 hours per week. Similarly, the NRC reviewed work hours of personnel at the Davis Besse plant during an extended outage for a reactor vessel head replacement. Although workers had expressed concerns regarding excessive work hours and fatigue, the NRC found that the individual work hours at the Davis Besse plant typically did not exceed the guidelines of the NRC's Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors. However, for both the security personnel and the Davis Besse plant staff, the NRC noted that the individuals had worked substantially more than a 40-hour work week for many weeks.

After reviewing this industry experience and related studies concerning cumulative fatigue, the NRC concluded that it was necessary to include controls in the final rule to provide reasonable assurance that cumulative fatigue does not impair individuals' fitness. The NRC revised the proposed requirements to address cumulative fatigue also in response to comments concerning the impact of these requirements on scheduling flexibility and ability to meet exigent operational demands. For further information on changes to the proposed rule, see Section 11.3.4, "Opposition to 24/7 and 48/14 Breaks - § 26.199(d)(2)(ii) and (d)(2)(iii)," of this document.

Federal Motor Carrier Safety Administration Precedent

Comments: Several commenters thought that the NRC's proposed rule package did not indicate the same rigor in review and application of studies conducted outside the power reactor industry as that of the Federal Motor Carrier Safety Administration (FMCSA) when it developed its Hours of Service for Drivers. According to the commenters, the NRC often extrapolated narrow research findings into overly broad assertions. The commenters recommended that the

NRC consider the FMCSA precedent, which was based on sound science and took an integrated approach to managing both acute and cumulative fatigue. The commenters found the FMCSA analysis to be guarded in its extrapolation of narrow research findings into broad regulatory findings. For example, in many of the studies, a psychomotor vigilance test was used to monitor for fatigue. However, as the FMCSA pointed out, this did not necessarily equate to actual performance of assigned tasks. The commenters also explained that the FMCSA rules do not include long-term quarterly, annual, or group work hour limits and that research data support this regulatory approach [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC believes that it did not extrapolate narrow research findings into overly broad assertions. Although many scientific studies of fatigue cited by the NRC may have considered a limited range of operational conditions, the NRC did not rely on the results of single studies to draw its conclusions. Rather, the NRC relied on findings that were demonstrated in multiple settings that substantiated general, widely accepted principles regarding the relationship between work hours, circadian variations in alertness, and worker performance. In addition, the NRC focused on findings from industries or settings with similar work environments and job demands. Furthermore, in establishing the specific requirements of the final rule, the NRC gave significant consideration to those factors that are unique to the nuclear power plant setting (e.g., use of detailed procedures, automated safety systems) and work practices (e.g., self-checking, peer verification of tasks), which in some cases justified less stringent work hour controls than would have otherwise been indicated for work environments with greater sensitivity to fatigue-induced errors and lapses in attention.

The NRC acknowledges that the FMCSA rules for commercial vehicle operators do not include long-term quarterly, annual, or group limits and agrees that there is a stronger technical basis for requirements that focus on individual work hours over shorter periods of time. Accordingly, the NRC revised the proposed requirements to have all work hour limits applicable to individuals' work hours. In addition, the NRC revised the proposed rule to require an average number of days off per week, for periods when the plant is operating, or a minimum number of days off in a 15-day period, when the plant is shut down. These requirements focus the control of work hours on shorter time periods than the proposed group work hour controls, which established controls for periods up to 13 weeks.

2. SPECIFIC QUESTIONS FOR PUBLIC COMMENT

In the *Federal Register* notice for the proposed rule (70 FR 50616), the NRC sought public comment on several specific issues. This section presents the Commission's responses to public comments received on those issues.

2.1 Proposed Drug and Alcohol Provisions

2.1.1 Proposed Sanction for Attempted Subversion of Testing Process (Issue 1 in *Federal Register* notice)

Issue: "Proposed § 26.75 in Subpart D would increase the sanctions for certain testing-related actions by requiring that: 'Any act or attempted act to subvert the testing process, including refusing to provide a specimen and providing or attempting to provide a substituted or adulterated specimen, for any test required under this part must result in permanent denial of authorization,' and 'for individuals whose authorization was denied for 5 years ... any subsequent violation of the drug and alcohol provisions of an FFD policy must immediately result in permanent denial of authorization.' The NRC requests comments regarding these proposed changes specifically when compared to the 5-year ban available through the agency's enforcement policy for other acts of deliberate misconduct."

Comments: Several commenters agreed with the proposed requirement. They stated that many licensees permanently deny authorization to deter subversion of the testing process. One commenter, supported by several other commenters, noted that attempted subversion must also be considered by the reviewing official during the trustworthiness and reliability decision required in 10 CFR 73.56(b) [Randy Cleveland, NMC; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC has adopted the proposed requirement in the final rule. Section 26.75(b) of the final rule states that any act or attempted act to subvert the testing process, including, but not limited to, refusing to provide a specimen and providing or attempting to provide a substituted or adulterated specimen, for any test required under § 26.31(c) must result in the immediate unfavorable termination of the individual's authorization and permanent denial of authorization thereafter. Also, § 26.75(g) of the final rule states that, for individuals whose authorization was denied for 5 years, any subsequent violation of the drug and alcohol provisions of an FFD policy must immediately result in permanent denial of authorization. The NRC believes that these sanctions are appropriate in light of the importance of protecting the integrity, consistency, and accuracy of the testing process and for deterring individuals who might consider attempting to subvert that process.

2.1.2 Need for "Shy Lung" Procedure (Issue 2 in *Federal Register* notice)

Issue: "Proposed § 26.119 [Determining "shy" bladder] would establish a process for determining whether there is a medical reason that a donor is unable to provide a urine specimen of at least 30 mL. The NRC added this proposed section in response to stakeholder

requests and adapted the process from the U.S. DOT's Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR 40.197). The U.S. DOT Procedures also include processes for determining whether there is a medical reason that a donor is unable to provide a specimen of oral fluids (49 CFR 40.263) or a breath specimen (49 CFR 40.265) of sufficient quantity to support alcohol testing. The NRC invites comments on whether the NRC should consider incorporating these processes for insufficient oral fluids and breath specimens in Part 26."

Comments: Several commenters responded to this request for public comments. They stated that the industry's many years of experience with the former rule requirements indicate no need for this provision because there are few, if any, instances where it would apply. One of these commenters suggested that the alcohol collector qualifications in proposed § 26.85(b) would be sufficient to address any "shy lung" issues [Susan Techau, Exelon; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: Because there was no evidence of a problem requiring a solution in this matter, the NRC did not include these procedures in the final rule.

2.1.3 Forensic Toxicologist (Issue 3 in *Federal Register* notice)

Issue: "Proposed § 26.31(d)(3)(iii)(C) would permit licensees and other entities to specify more stringent cutoff levels for the panel of drugs for which testing is required under this part without informing the NRC within 60 days and without obtaining the written approval of the NRC. Proposed § 26.31(d)(1)(i)(D) and (d)(1)(ii) would also permit licensees and other entities to test for drugs and drug metabolites in addition to those specified in proposed § 26.31(d)(1) without informing or obtaining the written approval of the NRC. However, the proposed paragraphs would require that the scientific and technical suitability of the more stringent cutoff levels and of the assays and cutoff levels used to test for additional drugs or drug metabolites must be evaluated and certified, in writing, by a qualified, independent forensic toxicologist. Certification by a forensic toxicologist would not be required in three circumstances: (1) if the HHS issues more stringent cutoff levels in the HHS Guidelines and the licensee or other entity adopts the revised HHS cutoffs; (2) if the HHS Guidelines are revised to authorize use of the assay in testing for the additional drug or drug metabolites and the licensee or other entity uses the cutoff levels established in the HHS Guidelines for the drug or drug metabolites; and (3) if the licensee or other entity received written approval from the NRC for the lower cutoff levels and/or for testing for the additional drugs or drug metabolites, under former Section 1.1(2) in Appendix A to Part 26. The proposed paragraphs differ from the former requirement in Section 1.1(2) of Appendix A to Part 26. The NRC requests comments regarding these proposed changes."

Comments: No comments addressed this issue. However, one commenter submitted a comment on proposed § 26.31. That comment is discussed in Section 4.6.4 of this document.

2.1.4 Changes to Opiate Testing (Issue 4 in *Federal Register* notice)

Issue: "Proposed §§ 26.133 and 26.163 would raise the cutoff levels for initial and confirmatory tests for opiates from 300 nanograms (ng) per milliliter (mL) to 2,000 ng/mL. The proposed rule

would also require testing for 6-acetylmorphine (6-AM), a metabolite that comes only from heroin, using a 10 ng/mL confirmatory cutoff level for specimens that tested positive on the initial test. The proposed cutoff levels and new test would be consistent with those used by HHS and DOT, and would reduce the number of specimens in Part 26 programs that test positive for opiates at an HHS-certified laboratory but are subsequently determined to be negative by the MRO after consultation with the donor. The NRC invites comment on these proposed changes."

Comments: Several commenters addressed the proposed provision to raise the cutoff levels for initial and confirmatory tests for opiates from 300 to 2,000 ng/mL. They stated that industry strongly supports the proposed requirement, as it would increase the efficiency of FFD programs [Pete Defilippi, Westinghouse Electric Company; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC has retained the proposed higher cutoff levels and new test (as discussed above) in the final rule. These revisions should substantially reduce the opiate test results that HHS-certified laboratories report to Medical Review Officers (MROs) as positive but that MROs ultimately declare as negative, resulting in program efficiencies.

2.1.5 Specimen Validity Testing (Issue 5 in *Federal Register* notice)

Issue: "In proposed §§ 26.131, 26.137, 26.161, and 26.167, the NRC would add new requirements for validity testing of urine specimens to detect specimens that may have been adulterated, substituted, or diluted. The new requirements are adapted from practices the HHS published in the *Federal Register* on April 13, 2004 (69 FR 19643) as a final rule. The NRC invites public comment on the following issues related to the proposed validity testing requirements.

a. Proposed § 26.137 would establish quality assurance and quality control requirements for conducting validity and drug tests of urine specimens. The NRC seeks input regarding any technical or methodological barriers to implementing these requirements at licensee testing facilities.
b. Proposed §§ 26.161(d) and 26.185(h) would establish criteria and procedures for determining whether a specimen has been substituted. A specimen would be reported by the HHS-certified laboratory to the MRO as substituted if it has a creatinine concentration of less than 2 mg/dL and specific gravity of less than or equal to 1.0010, or equal to or greater than 1.0200. For the HHS-certified laboratory to report a specimen as substituted, results in these ranges would be necessary on both the initial and confirmatory creatinine and specific gravity tests on two separate aliquots of the specimen. The NRC invites comments on the proposed revisions."

Comments: One commenter, supported by many other commenters, addressed the proposed new requirements for validity testing of urine specimens to detect those that may have been adulterated, substituted, or dilute. The commenter stated that validity testing requirements should be consistent with established HHS criteria and should not be more stringent [Jim Davis,

NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy]. No comments were directed specifically at Issues 5a and 5b above.

NRC Response: Comments received on validity testing are addressed in Sections 8 and 9 of this document regarding Subparts F and G, respectively.

2.1.6 MRO Training (Issue 6 in *Federal Register* notice)

Issue: "Proposed § 26.183(a) requires that 'The MRO shall be knowledgeable of this part and of the FFD policies of the licensees and other entities for whom the MRO provides services.' The NRC invites comments on whether Part 26 should establish specific training requirements for the MRO related to this part and the licensee's or other entity's programs for which the MRO provides services."

Comments: Several commenters addressed the issue of whether Part 26 should establish specific training requirements for the MRO related to Part 26 and to the licensee's or other entity's programs for which the MRO provides services. The commenters recommended that the NRC not regulate MRO training because MROs are licensed by the states and will be certified, as required under the proposed rule. Therefore, the commenters believed that additional regulation was not required to ensure that MROs understand licensee policies and procedures [Randy Cleveland, NMC; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC disagrees in part with the commenters' recommendation regarding specific training requirements for MROs. Although § 26.183(a) of the final rule does not mandate specific training requirements for MROs, it does make explicit that an MRO must be knowledgeable of Part 26 as well as the FFD policies of the licensees or other entities for whom he or she provides services. This provision is necessary because the Part 26 requirements and the policies and procedures of Part 26 FFD programs may differ from other workplace drug and alcohol testing programs for which the MRO provides services. In addition, § 26.183(a) of the final rule also adds the requirement that the MRO must be certified by a nationally-recognized MRO certification board or sub-specialty board for medical practitioners in the field of medical review of Federally mandated drug tests. This requirement should increase consistency in the MRO function across Part 26 FFD programs. For these reasons, the NRC has retained the MRO qualification requirements of proposed § 26.183(a) in the final rule.

2.1.7 Single or Split Specimen (Bottle B) Retesting (Issue 14 in *Federal Register* notice)

Issue: "Proposed §§ 26.135(b) and 26.165(a)(4) and (b)(1) would prohibit licensees and other entities, the MRO, and the NRC from initiating testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission. The NRC is considering

an alternative approach that would permit a licensee or other entity to initiate testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission only if all of the following conditions are met: (1) the first results from testing the specimen were confirmed as non-negative by the MRO; (2) the donor has requested a review under proposed § 26.39 or initiated legal proceedings; and (3) the testing is conducted in accordance with proposed § 26.165(c) through (e), as applicable. Under either the proposed provisions or the alternative approach, the proposed rule would require the licensee or other entity to administratively withdraw the donor's authorization until the results from Bottle B or the retest results are available and to rely only on those results in determining whether the licensee or other entity would be required to take management actions or impose sanctions on the donor. The NRC is seeking an appropriate balance between protecting donors' rights to privacy and due process under the rule and the protection of public health and safety and the common defense and security, and invites public comment on the proposed and alternative approaches."

Comments: One commenter, supported by many other commenters, addressed administrative withdrawal of the donor's authorization until the results from Bottle B or the retest results are available. The commenter recommended that the NRC consider the protection of public health and safety and the common defense and security as the primary goal. The commenter thought that, because only the donor, the MRO, and one employee of the licensee or other entity would know the rationale for the administrative authorization withdrawal, these proposed provisions would not create unduly negative impacts on the donor's rights. Therefore, the commenter supported this aspect of the proposed rule [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC has chosen to include the proposed approach to single or split specimen testing mentioned above in the final rule. That is, § 26.165(b)(3) of the final rule prohibits licensees and other entities, the MRO, and the NRC from initiating testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission except if the MRO questions the accuracy or scientific validity of a positive, adulterated, substituted, or invalid test result. In such instances, the final rule's § 26.185(l) authorizes the MRO (and only the MRO) to order the retesting of an aliquot of the original specimen or the analysis of any split specimen (Bottle B), without the donor's request, to determine whether the FFD policy has been violated. As noted in the statement of the issue above, § 26.165(f) requires the licensee or other entity to administratively withdraw the donor's authorization until the results of testing Bottle B or retesting an aliquot of the single specimen are available and have been reviewed by the MRO. Consistent with the commenters' views, the NRC believes these requirements, taken together, strike an appropriate balance between protecting donors' privacy and due process rights and the protection of public health and safety and the common defense and security.

The NRC addresses related comments received on the alternative of allowing testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission in Section 8.8 of this document, with respect to comments regarding proposed § 26.135(b), and in Section 9.8.1 of this document, with respect to comments regarding proposed § 26.165(a)(4).

2.2 Rulemaking Issues

2.2.1 Validity Screening Tests (Issue 7 in *Federal Register* notice)

Issue: "The NRC is considering incorporating future changes to the draft HHS Guidelines that were published as a proposed rule for public comment in the *Federal Register* on April 13, 2004 (69 FR 19672) relating to the permission in this proposed Part 26 rule for licensees and other entities to use non-instrumented validity tests to determine whether a urine specimen appears to be adulterated, diluted, or substituted and requires further testing at an HHS-certified laboratory. Proposed Part 26 would permit licensees and other entities to use these devices for validity screening tests, in lieu of the instrumented validity testing required in the April 13, 2004, final version of the HHS Guidelines. Should any changes be made to those draft HHS Guidelines between issuing this proposed rule and issuing the final 10 CFR Part 26 rule, those changes would be considered for incorporation. Any comments related to the potential incorporation of those changes are of interest."

Comments: Several commenters addressed the incorporation of future changes to the draft HHS validity testing guidelines. The comments related to the permission in the proposed rule for licensees and other entities to use non-instrumented validity tests to determine whether a urine specimen appears to be adulterated, dilute, or substituted and requires further testing at an HHS laboratory. The commenters stated that the NRC offered no justification for bypassing its own processes in the brief discussion of this issue. Thus, they stated that changes to the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines) should not be incorporated into the NRC regulations without going through a complete rulemaking process, including opportunity for public comment on, and backfit analysis of, proposed rule changes [Randy Cleveland, NMC; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC stated early in this rulemaking that it would consider incorporating any changes to the draft HHS Guidelines in the final FFD rule. HHS has not issued a final rule and made no changes to the draft HHS Guidelines. Therefore, the NRC has not adopted any changes to the draft HHS Guidelines in this rulemaking.

2.2.2 Adopting Future Changes to the HHS Guidelines without Backfit (Issue 13 in *Federal Register* notice)

Issue: "The NRC is considering amending 10 CFR 50.109, 70.76, and 76.76 to exclude certain future changes to Part 26 from current backfit requirements. The scope of the exclusions would be limited to only those changes to Part 26 that would be necessary to incorporate relevant revisions to the HHS Guidelines when they are published by HHS as final rules. Examples of changes to the HHS Guidelines that may be incorporated into Part 26 in future rulemakings may include, but would not be limited to (1) adopting changes to the cutoff levels established in the Guidelines; (2) the addition or deletion of drugs and adulterants for which testing would be required; and (3) changes in the specimens, instruments, or assays used in drug and validity

testing. The NRC requests comment on excluding such future changes to Part 26 from backfit analysis requirements."

Comments: Several commenters addressed the proposal to amend 10 CFR 50.109, 70.76 and 76.76 to exclude certain future changes to Part 26 from backfit requirements. The commenters did not support this proposal and advocated making no changes to §§ 50.109, 70.76, and 76.76. One commenter, supported by many other commenters, stated that examples of the changes the NRC would like to make without backfit analyses, given in the comment solicitation, did not appear to provide "... a substantial increase in the overall protection of the public health and safety or the common defense and security ..." described in §§ 50.109, 70.76 and 76.76. Therefore, lacking the "substantial increase," the commenter recommended that the NRC should not change these subsections to allow revision of regulations without determining whether the direct and indirect cost of the suggested changes are actually cost beneficial. The commenter also read proposed § 26.31(d)(1)(i) to allow licensees and other entities to add other drugs to the panel of substances for testing, such as those popular in their local geographical areas, and to establish appropriate cutoff levels for any additional substances for which testing will be conducted. Thus, the commenter stated that there was no need to revise §§ 50.109, 70.76 and 76.76, given what the proposed rule would allow in this regard. Finally, the commenter stated that the NRC had offered no justification for bypassing its own processes and, because the example rule changes were not inclusive, the scope of possible changes would be boundless [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; Nick DiPietro, First Energy; F. G. Burford, Entergy].

NRC Response: Based on the commenters' objections and the lack of support to amend 10 CFR 50.109, 70.76 and 76.76 to exclude certain future changes to Part 26 from backfit requirements, the NRC has decided not to pursue modification of the applicability of current backfit requirements relative to Part 26 in this rulemaking.

2.2.3 Reporting Burden (Issue 15 in *Federal Register* notice)

Issue: "The NRC is seeking comment regarding the administrative reporting burden that the proposed rule provisions would create. Provide any comments as described in Section XIII, Paperwork Reduction Act Statement, of this notice."

Comments: One commenter stated that the proposed reporting requirements associated with the drug and alcohol part of the rule would be unnecessary for the NRC to regulate the industry or to protect human health and safety. However, the commenter thought those annual reporting requirements would be useful for assessing the popularity of specific drug sets. In sum, the commenter supported the proposed reporting requirements [Jim Davis, NEI].

NRC Response: The NRC considered this comment and concluded that the reporting requirements associated with the drug and alcohol testing elements of the rule are necessary to provide information from which the NRC can monitor the effectiveness of the drug and alcohol testing activities.

2.3 Proposed Fatigue Provisions

2.3.1 Rest Break Provisions (Issue 8a in *Federal Register* notice)

Issue: "Proposed Subpart I, Managing Fatigue, includes many requirements related to worker fatigue at nuclear power plants. The NRC is especially interested in comments on the following provision: Proposed § 26.199(d)(2)(ii) and (d)(2)(iii) would require licensees to provide individuals who are subject to the proposed work hour limits with at least one 24-hour rest break in any 7-day period and at least one 48-hour rest break in any 14-day period, except during the first 14 days of any outage, as well as certain other circumstances for security force personnel."

Impact on 8-hour Shifts

Comments: Several commenters were concerned about the potential for disruption in operations, such as the provision's potential impact on 8-hour shifts and consecutive working days, due to the rest breaks called for by proposed § 26.199(d)(2)(ii) and (d)(2)(iii). They thought that these rest break provisions would not provide the necessary flexibility and that it would be impossible to build a proper 8-hour shift rotation without violating the regulations as proposed. Commenters predicted that, in response to the inflexible break requirements, licensees with 8-hour shift rotations will adopt 12-hour shift rotations [John Fee, SCE ; Anthony Rizzo, Salem-Hope Creek; Michael Coyle, NEI #49; Marvin Fertel, NEI; Todd Newkirk, IBEW; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: In response to these and related comments, the NRC has conducted further analysis of the proposed rule provisions and agrees that the proposed rest break provisions could have significantly disrupted current shift scheduling practices for 8-hour shifts. The NRC has modified the rest break provisions in the final rule to provide additional flexibility. The requirements of the final rule allow licensees greater flexibility in the number of days between days off and whether the days off are provided consecutively or distributed. This flexibility enables licensees to more readily design schedules that meet operational demands while ensuring an amount of time off comparable to that which would have been required by the proposed rule. Accordingly the final rule provides comparable assurance that cumulative fatigue from inadequate rest does not impair the ability of workers to safely and competently perform their duties. The revised break and day off provisions are in § 26.205(d)(2) through (5) of the final rule.

2.3.2 Waivers of Work Hour Controls (Issue 8b in *Federal Register* notice)

Issue: "Proposed Subpart I, Managing Fatigue, includes many requirements related to worker fatigue at nuclear power plants. The NRC is especially interested in comments on the following provision: Proposed § 26.199(d)(3) would permit licensees to waive individual work hour limits and rest break requirements only in circumstances in which it is necessary to mitigate or prevent a condition adverse to safety, or to maintain the security of the facility. Proposed § 26.197(e)(1) would require licensees to report the number of waivers granted in a year."

Waivers Do Not Affect Prior Hours Worked

Comments: One commenter at the September 21, 2005, public meeting disagreed with the provision, stating that waivers have no value when received after the extra hours have been worked. Likewise they do not prevent utilities from forcing workers to work above the limits [Anthony Rizzo, Salem Hope Creek].

NRC Response: The NRC agrees with the essence of the comment. It is not the NRC's intent that licensees grant waivers after the fact to account for any excess hours that have already been worked above the work hour limits. Instead, § 26.207(a)(1) of the final rule provides that a licensee may grant a waiver only subsequent to a supervisor performing a fatigue assessment, and then only if the waiver is necessary to mitigate or prevent a condition adverse to safety or to maintain the security of the facility. Section 26.207(a)(2) further stipulates that, to the extent practicable, a licensee should issue waivers only to address circumstances that it could not have reasonably controlled. In such cases, a fatigue assessment must be performed before the additional hours are worked in order to verify that there is reasonable assurance the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver may be granted. The NRC believes that these § 26.207 limitations on waiving work hour controls make clear its intent that licensees shall not issue such waivers after the extra hours have been worked.

Flexibility of Waivers

Comments: Several commenters recommended that management should have the ability to grant waivers in situations where it believes a waiver is appropriate, even though safety is not challenged [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees that granting a waiver is appropriate in situations where safety is not challenged. By definition, there is a substantial potential for worker fatigue in conditions that would require a waiver. The NRC cannot conclude that, under such conditions, licensees can reasonably justify that workers should be allowed to perform activities on systems, structures, or components (SSC's) that a risk-informed evaluation process has shown to be significant to public health and safety. Likewise, the NRC cannot conclude that individuals who have worked hours in excess of the work hour limits should be allowed to perform functions that are essential for effective response to a fire, plant emergency, or implementation of the site security plan on the basis that granting the waiver would not have an adverse impact on safety or security. If the NRC revised the rule for situations such as the example provided above, it would be inconsistent with the NRC's goal of providing reasonable assurance that an individual will be able to safely and competently perform his or her duties. It would also increase the likelihood of fatigue-related errors which could adversely affect public health and safety or the common defense and security. Therefore, the NRC has retained this provision as § 26.207(a)(1)(i) of the final rule.

Agreement with Waiver Provision

Comments: One commenter agreed with the NRC's intent that waivers would be granted only "to address circumstances that the licensee could not have reasonably controlled." The commenter stated that the two circumstances in which proposed § 26.199(d)(3)(i)(A) would allow a waiver to be granted – to mitigate or prevent a condition adverse to safety or to maintain the security of the facility – appeared to be reasonable and appropriate. The commenter agreed that all use of waivers should be reported to and tracked by the NRC for analysis of unsafe or inappropriate patterns and should be made available to the public where deemed appropriate [Darrel Drobnich, NSF].

NRC Response: The final rule retains the criteria for authorizing a waiver that were specified in proposed § 26.199(d)(3)(i)(A). These criteria are in the final rule's § 26.207(a)(1) and (a)(2). The final rule also retains the requirement for an annual report summarizing the licensee's use of waivers from the work hour limits. This reporting requirement is in § 26.203(e) of the final rule. The NRC will make available summary information regarding the use of waivers as part of the annual FFD program performance information notice.

2.3.3 48-Hour/Week Collective Work Hour Limits (Issue 8c in *Federal Register* notice)

Issue: "Proposed Subpart I, Managing Fatigue, includes many requirements related to worker fatigue at nuclear power plants. The NRC is especially interested in comments on the following provision: Proposed § 26.199(f) would prohibit job duty groups that are subject to work hour controls from working more than a maximum collective average of 48 hours per person per week, except during the first 8 weeks of any outage, as well as certain other circumstances for security force personnel."

Removal of Group Work Hour Limits

Comments: One commenter, supported by many other commenters, suggested removing the group work hour limits completely for individuals other than security personnel. This commenter thought that cumulative fatigue was adequately addressed through many other proposed provisions such as: inherent alertness abilities that individuals must exhibit, supervisory overviews, individual work hour limits, and rest break provisions [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG; Anthony Rizzo, Salem Hope Creek; Joseph Bauer, Exelon; Jim Davis, NEI].

NRC Response: The NRC disagrees that, in the absence of group work hour limits, the proposed rule adequately addressed cumulative fatigue through other provisions. However, the NRC has simplified requirements in this area by eliminating the proposed § 26.199(d)(2)(iii) 48-hour break requirement and the proposed § 26.199(f) collective work hour limits. The NRC has replaced these provisions with requirements for minimum days off per week averaged over a shift cycle, not to exceed six weeks, during normal operations, in § 26.205(d)(3), and minimum

days off in 15-day blocks during outages, in § 26.205(d)(4) and (d)(5) of the final rule. Section 11.3.6 of this document discusses this issue in more detail.

2.3.4 Alternate Work-Scheduling Examples (Issue 9 in *Federal Register* notice)

Issue: "As a means of determining the flexibility of the proposed rule work hour controls in § 26.199, the NRC is seeking public comment on work-scheduling examples that meet the requirements of the proposed rule and whether such schedules afford a reasonable degree of flexibility to licensee management."

Request for Prototype 8-Hour Shift Schedule

Comments: One commenter requested that the NRC provide a prototype 8-hour rotation because industry could not resolve an alternative shift to fit all the provisions [Todd Newkirk, IBEW].

NRC Response: In response to this and related comments, the NRC conducted further analysis of the proposed rule provisions and agreed that the proposed rest break provisions could significantly disrupt current shift scheduling practices for 8-hour shifts. The NRC has modified the rest break provisions in the final rule to provide substantial additional flexibility in this regard, while providing comparable assurance that cumulative fatigue from inadequate rest does not impair the ability of workers to safely and competently perform their duties. The revised break and day off provisions are in § 26.205(d)(2) through (d)(5) of the final rule.

Example of Shift Based on 24-hour Basis

Comments: One commenter offered an alternative work-scheduling example in response to the NRC's request for examples that would meet the requirements of the work hour controls in proposed § 26.199 and afford a reasonable degree of flexibility to licensee management. The commenter believed that all schedules and shift lengths need to be based firmly on a 24-hour period. The commenter also specified additional limits for shift overlap (or turn-over), for currency training and administration, and for overtime. The commenter suggested requirements for the use of fixed (non-rotating) shifts and rapid rotation (no more than 3 contiguous work days on the same shift) or slow rotation (no fewer than 28 contiguous work and free days on the same shift) for 8- and 12-hour shifts [Darrel Drobnich, NSF].

NRC Response: The NRC agrees with the concepts provided by the commenter and considers them to be examples of good practices that licensees can implement consistent with the requirements of § 26.205(c) of the final rule. The NRC intends to consider the commenter's recommendations for incorporation in the implementation guidance for the final rule.

2.3.5 Outage Work Scheduling (Issue 10 in *Federal Register* notice)

Issue: "The NRC is seeking comment on the exclusions from certain work hour controls that would be allowed by proposed § 26.199(d)(2)(iii), (f)(1), and (f)(2) during maintenance and refueling outages, and how these exclusions could affect human error. The NRC is specifically interested in whether a more precisely defined rule scope with more limited outage exclusions would better meet the stated objectives of the rule."

Definition of an Outage

Comments: One commenter suggested that the rule explicitly define the term "outage" and asked if "package walk-downs and package preps" are to be considered part of an outage. The commenter also stated that, because outages are planned in advance and workers have a chance to prepare for them, it is unreasonable that workers should be expected to work extra hours during an outage [Todd Newkirk, IBEW].

NRC Response: The NRC agrees that the term "outage" should be defined. For purposes of Part 26, the final rule defines the term "unit outage" to mean that the reactor unit is disconnected from the electrical grid. In response to the commenter's question as to whether "package walk-downs and package preps" are considered part of a unit outage, these activities would be considered part of an outage only if they are performed on a unit that is disconnected from the electrical grid.

Regarding the reasonableness of expecting workers to work extra hours during outages, the NRC disagrees with the commenter. Nuclear industry conditions require that work often must be completed during an outage in order to ensure worker safety and public health and safety. The NRC recognizes that individuals are capable of working with limited rest without degraded performance for short periods of time. It also recognizes that plant outages are unique, relatively short-term, and involve levels of activity that are substantially higher than most non-outage operating periods. Therefore, the NRC considers it reasonable that workers can be expected to work extra hours during outages as long as those work hours are governed by Part 26 fatigue management requirements.

Work Hour Relaxations during Outages

Comments: One commenter expressed confusion about the rationale for waiving group work hour controls for the first 8 weeks of outages. The commenter did not agree that employees should be encouraged to work more hours during times when significant maintenance and operational functions such as refueling, testing of systems, repair of failed components and structures, plant modifications, and regulatory inspections are undertaken. Therefore, the commenter requested that the NRC reconsider all provisions that would allow relaxed work hour controls during outages, especially during planned outages [Darrel Drobnich, NSF].

Another commenter stated that intensely focused outage periods are a very effective means of assuring and improving overall safety. The commenter further explained that scientific evidence and plant experience show that "super crews" working six 12-hour shifts have been effective during outage periods up to 10 weeks leading to increased plant safety and no increase in performance errors. The commenter also stated that the proposed rule would have had an impact on 15 percent of the plant outages in 2004, and it would directly impact outages that support major plant improvements in the future. Therefore, the commenter recommended that the proposed rule should not be more restrictive than the former rule [David Ziebel, EPRI].

NRC Response: The NRC disagrees that it should have reconsidered all provisions that allow relaxed work hour controls during outages, especially during planned outages. The NRC agrees that it would be advantageous for fatigue management to avoid peaks of high activity on SSCs that a risk-informed process has shown to be significant to public health and safety or activities that are essential for effective response to a fire, plant emergency, or implementation

of the site security plan. However, nuclear industry conditions require that work often must be completed during an outage in order to ensure worker safety and public health and safety. The NRC recognizes that individuals are capable of working with limited rest without degraded performance for short periods of time. It also recognizes that plant outages are unique, relatively short-term, and involve levels of activity that are substantially higher than most non-outage operating periods. Therefore, the NRC considers it appropriate to allow flexibility within the work hour requirements to accommodate limited periods of more intensive work schedules.

In developing the minimum day off requirements for the final rule, the NRC also considered scheduling practices during outages and determined it could not practically extend the same approach used in § 26.205(d)(3) of the final rule because those requirements are based on shift cycles that provide a defined period for implementing the average day off requirement. The lengths of outages and increased threat conditions are variable and therefore do not provide a consistent averaging period. The NRC further considered establishing the requirement as a minimum 3 days off in any 14-day period for individuals specified in § 26.4(a)(1) through (a)(3) of the final rule because that requirement would have been similar to the requirements it would have replaced. However, the NRC ultimately determined that the requirement for 3 days off in 15-day periods provides licensees the flexibility of establishing a schedule comprising a repeating series of 4 work shifts followed by 1 day off. As a consequence, the final rule allows licensees the option to establish a schedule that is predictable, a characteristic desired by schedulers and workers, and that both mitigates and prevents cumulative fatigue by including periodic rest breaks without an excessive number of consecutive 12-hour shifts. Working 72 hours per week for extended periods is inconsistent with the research cited with respect to the requirements in § 26.205(d)(2)(i) and (d)(2)(ii). Nor is it consistent with providing reasonable assurance that individuals are fit to perform their duties. The minimum day off requirement of the final rule's § 26.205(d)(4) provides an important protection against cumulative fatigue for individuals who work during unit outages, particularly those working extended periods.

The NRC also disagrees that the final rule does not need to be more restrictive than former requirements with regard to a "super crew" working six consecutive 12-hour shifts for up to 10 weeks. Although individuals are capable of working with limited rest without degraded performance for short periods of time, research has shown that the ability to sustain performance without adequate rest is clearly limited. Extending the outage relaxation period to prolong these conditions would substantively increase the potential for cumulative fatigue and fatigue-related personnel errors.

Therefore, the NRC has retained requirements in the final rule that allow for a relaxation from work hour controls for the first 60 days of a unit outage.

Increase Work Hour Relaxation during Outages to 10 Weeks

Comments: One commenter, supported by many other commenters, recommended that the proposed outage relaxation should be increased from 8 to 10 weeks. According to the commenter, this change would provide adequate time to complete extended outages involving major equipment replacements. The commenter also cited an analysis of human performance data that, in his view, supported this recommendation because, in each outage the analysis evaluated, there was a downward trend in human performance errors as the outage progressed [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn

Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC has decided not to increase from 8 weeks to 10 weeks the plant outage relaxation from the work hour controls in proposed § 26.199(f). In reviewing the frequency of outages, by duration, the NRC found that it would be necessary to increase the exclusion period substantially to address a marginal number of additional outages of longer lengths. This increase in the relaxation period would substantially increase the period of time that individuals would be working extended work hours with reduced recovery time. During the relaxation period, individuals are permitted to work up to 72 hours in a 7-day period and are assured of just 3 days off in each 15-day period. Individuals who work 12-hour shifts, which are common during outages, will average up to 67.2 hours per week, a rate of 160 percent of their normally scheduled hours, with less than half of their normally scheduled days off for recovery, for a period of up to 2 months. Extending the outage relaxation period to prolong these conditions would substantially increase the potential for cumulative fatigue and fatigue-related personnel errors.

The NRC also disagrees that the analysis of human performance data cited by the commenter supports the recommendation to increase the outage relaxation to 10 weeks because in each outage evaluated there was a downward trend in human performance errors as the outage progressed. That study's conclusions were subjective and based on visual inspections of graphs of condition reports (CRs) compiled during the outage. The number of CRs was in at least one case actually higher in week 13 compared to week 1. Therefore, those conclusions do not withstand a rigorous analysis and are not evidence that the proposed plant outage relaxation from work hour controls should have been revised.

However, the NRC has included a provision in § 26.205(d)(6) of the final rule that permits licensees to extend the outage relaxation period by 7 days for each 7-day period during the outage that an individual works not more than 48 hours. This provision accommodates longer outage hours when it is justified by the work history of the individual containing adequate recovery periods. Therefore, the NRC has responded to the commenters' concern in a manner that should not increase cumulative fatigue.

2.3.6 Alternatives for Addressing Cumulative Fatigue (Issue 11 in *Federal Register* notice)

Issue: "The NRC is seeking public comment on alternatives to the group work hour controls that could also address cumulative fatigue, such as individual work hour limits based on a longer term (e.g., monthly or quarterly)."

Comments: Several commenters opposed using long-term individual work hour limits as an alternative to group work hour controls to address cumulative fatigue. They thought that these limits would create an unnecessary and indefensible layer of regulatory requirements [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: As discussed in the response to comments on "Collective Work Hour Limits" in Section 11.3.6 of this document, the NRC disagrees that requirements to address cumulative fatigue are unnecessary or indefensible. However, the NRC agrees with these commenters' opposition to the proposed rule's use of long-term individual work hour controls to address cumulative fatigue as an alternative to the group work hour controls (i.e., collective work hour limits) . Accordingly, the NRC did not replace the collective work hour limits with long-term individual limits in the final rule. Rather, the NRC eliminated the collective work hour limits and the requirement for a minimum 48-hour break in any 14-day period and addressed cumulative fatigue in the final rule through requirements for a minimum number of days off per week, averaged over a shift cycle, in § 26.205(d)(3), and minimum days off in 15-day blocks, in § 26.205(d)(4) and (d)(5) for outages and increased threat conditions.

2.3.7 Defining Job Duty Groups (Issue 12 in *Federal Register* notice)

Issue: "Proposed § 26.199(a) would require any individual who performs duties within specified job duty groups to be subject to the work hour control provisions in § 26.199. Other individuals, beyond those specified within the scope of § 26.199(a), might substantially impact the outcome of risk-significant work, such as certain engineers (e.g., Shift Technical Advisors). The NRC requests comment on the inclusion of other individuals in the scope of § 26.199(a). The NRC is also seeking comments on an alternative approach for identifying the specific job functions that would be subject to these requirements. Specifically, the NRC is interested in whether, as an alternative, the scope should instead be structured to define attributes of the job functions (e.g., time-critical nature of decisions needed to ensure public health and safety, operational control of risk-important equipment) that would fall within the scope of the proposed work hour control provisions in § 26.199. Under such an alternative, the licensee would then be required to identify the specific job functions that fit the defined attributes."

<u>Scope is Appropriate</u>

Comments: One commenter stated that there was not necessarily a need to broaden the scope of individuals subject to work hour controls; the groups that were already defined are the critical groups [Dana Millar, Entergy].

NRC Response: The NRC agrees with the commenter that the proposed scope was appropriate. The scope of individuals subject to work hour controls specified in the final rule includes those job functions that the NRC believes have the most potential for fatigue to degrade the protection of public health and safety and common defense and security. Although broader application of the work hour limits to other job functions could provide additional safety and security benefits, it is not clear at this time that those additional benefits would justify the substantial cost of broader work hour limit application.

<u>Definition of "Directing"</u>

Comments: Several commenters asked that the term "directing" in proposed § 26.199(a) be clearly defined. The commenters were concerned that this phrase, along with the definition of "directing" in proposed § 26.5 would subject engineering personnel to work hour controls, thus increasing the record keeping burden on industry [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit

Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees that the definition of the term "directing" in the proposed rule required clarification. The revised definition of "directing," which appears in § 26.5 of the final rule, clarifies the NRC's expectation that a limited scope of personnel exercising technical control over work activities are to be subject to § 26.205 requirements. For an individual to be considered as "directing" a work activity under this revised definition, that individual must be directly involved in, and exercise control over, the activity. Also, the individual must be making technical decisions for the activity without subsequent technical review by another party or be ultimately responsible for the correct performance of the work activity. The revised definition more clearly focuses on activities that have the potential to substantively and immediately affect safety.

This § 26.5 definition of "directing" also applies to the MRO's oversight of MRO staff; to first-line supervisors who direct the construction of safety- and security-related structures, systems, and components; and to individuals who direct access authorization programs which may be instituted during facility construction. In the case of an MRO's direction of MRO staff, the NRC believes this oversight to be necessary because the MRO's direction has the potential to substantively and immediately affect the integrity of the FFD program. The responsibilities associated with the direction of significant construction activities and access authorization programs present similar needs for FFD program coverage.

Limit Group Hours to Security Personnel

Comments: Several commenters agreed that armed security officers, anyone carrying a weapon, armed responders, watch persons, and central alarm station (CAS) and secondary alarm station (SAS) operators should be included in the critical group subject to these provisions [Michael Coyle, NEI #49; Marvin Fertel, NEI; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG]

NRC Response: The NRC agrees that the individuals mentioned by the commenters should be covered by fatigue management requirements. In response to the comments stating concerns regarding the burden and potential effectiveness of the group work hour controls (i.e., collective work hour limits), discussed in Section 11.3.6 of this document, the NRC has replaced the proposed collective work hour limits with work hour controls that are applicable to individuals. These controls apply to the security personnel described by the commenters.

Specify Job Functions Instead of Job Duty Groups

Comments: Several commenters suggested that the NRC develop a clear set of job functions that would warrant the added work hour restrictions. They thought that such performance-based criteria would help industry in deciding which individuals must be subject to work hour restrictions [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark

Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees that performance-based criteria for determining the scope of individuals subject to the work hour controls is an appropriate objective and has attempted to establish the requirements accordingly. In this regard the NRC notes that it did not define the scope of individuals subject to the work hour limits in terms of job titles but rather in terms of functions important to the protection of public health and safety and the common defense and security. As an example, the work hour controls do not apply to all operators or maintenance personnel, but rather only to those who operate or maintain SSCs that a risk-informed evaluation process has shown to be significant to public health and safety. Although the NRC acknowledges that the scope could be defined using more elemental criteria, it notes that one of the commenters further stated that "based on the years of discussions involved in the development of the proposed rule, there appears to be little chance of achieving agreement on this type of performance-based criteria" (Michael Coyle, NEI, #49). Defining the scope in terms of more elemental performance-based criteria presents substantive challenges and may not markedly improve the effectiveness of the rule. It may in fact contribute to additional challenges to clear and consistent interpretation of the scope of individuals subject to the work hour controls. Accordingly the final rule retains the approach developed with substantive stakeholder interaction for defining the scope of individuals subject to the work hour controls.

Maintenance Personnel

Comments: One commenter at the September 21, 2005, public meeting stated that the industry is struggling with identifying and categorizing maintenance personnel. It has found that some maintenance organizations are a single multi-tasked organization and others are cross-functional organizations that perform both safety and non-safety related tasks. Therefore, the industry is finding it difficult to identify maintenance individuals as either safety or non-safety personnel and accordingly categorize them into job duty groups [Jim Davis, NEI].

NRC Response: Recognizing that categorizing maintenance personnel could have been difficult, the NRC has added a definition of "maintenance" in the final rule. This definition is intended, among other things, to clarify the scope of duties described as maintenance in the final rule's § 26.4(a)(4). The definition also distinguishes duties performed by individuals covered by that paragraph from duties performed by individuals who are subject to different work hour limits, such as the duties described in § 26.4(a)(1) through (a)(5). Specifically, the definition clarifies that § 26.205(a) requires that individuals identified in § 26.4(a)(4) (i.e., individuals who are maintaining or providing onsite direction for the maintenance of systems and components that "a risk informed evaluation process has shown to be significant to public health and safety") must be subject to the work hour requirements. These requirements apply to those individuals who perform the following onsite maintenance activities: modification, surveillance, post-maintenance testing, and corrective and preventative maintenance.

Supplemental Workers

Comments: One commenter stated that transient workers should be included under individual work hour controls, but that it would be impractical to include such workers in collective work hour controls [Darrel Drobnich, NSF].

NRC Response: The NRC agrees with this commenter and notes that the final rule does not retain requirements for collective work hour limits. All work hour limits in the final rule are applicable on an individual basis to any individuals who are performing the job duties specified in 26.4(a), including transient workers. In addition, § 26.205(d)(4) ensures that individuals, including transient outage workers, receive a minimum of 3 days off in each consecutive 15-day period of the unit outage. Section 26.205(d)(4) also requires that licensees provide individuals who perform maintenance duties specified in § 26.4(a)(4) at least one day off in any 7-day period. The § 26.205(d)(4) minimum day off requirement will support the final rule's objective of reasonable assurance that transient outage workers who perform activities on SSCs that a risk-informed process has shown to be significant to public health and safety or functions that are essential for effective response to a fire, plant emergency, or implementation of the site security plan are not impaired from cumulative fatigue.

Information Sharing

Comments: One commenter agreed with the NRC's proposal in Subpart C to require licensees and other entities to collect and share greater amounts of information than under the former rule, subject to the protections of individuals' privacy specified in proposed § 26.37. The commenter thought this information collection and sharing is necessary because of the nuclear power industry's increasing use of transient workers. However, the commenter recommended that facilities be required to share information on the work hours of transient workers at any facility to ensure they that do not exceed the individual work hour control limits [Darrel Drobnich, NSF].

NRC Response: The NRC disagrees that licensees should be required to share information on the work hours of transient workers. Although sharing of work hour information among licensees would provide them more complete information concerning the work hours of transient workers, such information would not include the hours that these individuals may work for other employers outside the nuclear power industry. As a result, such sharing would not necessarily produce accurate information with respect to an individual's total work hours though licensees' administrative burden and associated costs could be substantial. Consequently, the NRC does not believe that the potential benefit to management of worker fatigue resulting from sharing this information justifies the significant costs licensees could incur.

3. SUBPART A: ADMINISTRATIVE PROVISIONS

This section provides the NRC's responses to public comments on the proposed rule's Subpart A. That subpart addressed the purpose and scope of the rule, provided definitions of important terms used in the proposed rule, and updated other administrative provisions of the former rule.

3.1 Purpose (§ 26.1)

No comments addressed this section.

3.2 Scope (§ 26.3)

Clarification of § 26.3

Comments: Many commenters addressed the scope of the proposed rule. The majority of their comments focused on what they considered to be a lack of clarity in proposed § 26.3. For example, one commenter at the September 21, 2005, public meeting expressed confusion with respect to proposed § 26.3(e), which the commenter thought was intended to allow licensees to apply a limited scope of FFD requirements during plant construction. In his view, proposed § 26.3(e)(1) appeared contradictory because it seemed to require construction-phase FFD programs to achieve Part 26 performance objectives which, in turn, would likely require licensees to maintain a complete, rather than a more limited, FFD program during construction [Jim Davis, NEI].

NRC Response: The NRC agrees that proposed § 26.3 was unclear. Therefore, the NRC has reorganized and clarified § 26.3 of the final rule and added a description of the licensees and other entities to whom particular sections and subparts of the rule apply (e.g., §§ 26.73 and 26.709).

FFD for Construction

Comments: Several commenters thought that proposed § 26.3(e) was not appropriately written for new plant construction sites. They stated that it was unclear what type of FFD program the NRC expected for new plant construction. The commenters said that, by referring to specific sections of the rule that must be met by complying with other sections of the rule, the NRC seemingly applied the entire rule to new plant construction. The commenters stated that it would be difficult for industry to ensure compliance with the referenced sections of the rule without applying the entire rule. They recommended that new plant construction should be treated in the same manner as other major, non-nuclear construction sites, which have industrial drug and alcohol programs. The commenters stated that, until fuel arrives on site, there is no reason for public health and safety requirements additional to those applied to large commercial construction projects. They also thought that referring to proposed § 26.23, which required FFD programs for construction to meet the performance objectives of that section, was inappropriate because it conflicted with proposed § 26.25. The commenters understood proposed § 26.25 to apply to individuals who have unescorted access to nuclear power plant protected areas, but pointed out that there will be not yet be any protected areas as cited in proposed § 26.3(e) during the construction phase .

These commenters also stated that the application of proposed § 26.23(e) regarding fatigue and degraded alertness was also inconsistent with proposed § 26.195, which applied requirements for managing fatigue only to licensees and other entities identified in proposed § 26.3(a) and (d) but not to (e), the construction phase. They also stated that proposed § 26.41 [Audits and corrective action] and § 26.189 [Determination of fitness] required administrative actions beyond those necessary for a commercial construction site at which there are no protected areas and no nuclear fuel.

To respond to these comments, one industry commenter, supported by many other industry commenters, suggested that the NRC eliminate reference to proposed §§ 26.23, 26.41 and 26.189 in proposed § 26.3(e)(1). Instead, they recommended that § 26.3(e) should state: "1) establish a drug-and-alcohol-free workplace policy, including sanctions to be imposed, 2) implement a pre-employment drug and alcohol testing program and a for-cause testing program, and 3) make provisions for the objective and impartial review of sanctions decisions, protection of information and recordkeeping" [Jim Davis, NEI #48; Tom Houten, NEI; Peter Fowler, Duke Energy; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: In response to these comments and industry efforts to develop guidance on the subject, the NRC has added Subpart K [FFD Programs for Construction] to the final rule to replace proposed § 26.3(e), which contained requirements for combined license holders, combined license applicants, construction permit holders, construction permit applicants, as well as manufacturing license holders under Part 52. Subpart K's FFD program is intended to provide reasonable assurance that individuals involved in the construction of a nuclear power plant who perform specified duties are fit for duty, trustworthy, and reliable, commensurate with the potential risks to public health and safety and the common defense and security that their activities and access to certain information would pose.

The final rule's § 26.3(c) requires that, no later than when they receive special nuclear material in the form of fuel assemblies, the following licensees and other entities must comply with Part 26 requirements, except for those in Subpart I: combined license (COL) applicants, construction permit (CP) applicants, and early site permit holders who have been issued a limited work authorization, if the limited work authorization authorizes the applicant or permit holder to install foundations for safety- and security-related structures, systems, and components; COL holders before the Commission has made the finding under 10 CFR 52.103(g); and CP holders. Section 26.401(a) in Subpart K provides these licensees and other entities the discretion to either establish, implement, and maintain an FFD program that meets Subpart K requirements, to be applicable to individuals specified in § 26.4(f), or to make those individuals subject to an FFD program that meets the requirements of subparts A through H, N, and O.

NRC benchmarking activities indicated that, as a result of the higher incidence of substance abuse problems among construction workers than other occupational groups, pre-employment, for-cause, and post-accident drug and alcohol testing are increasingly common at large, commercial construction projects. Some labor union coalitions have implemented drug and alcohol testing and substance abuse treatment-referral programs for their members who work at such construction projects. In addition, NRC staff also identified several private-sector entities in the petrochemical and steel manufacturing industries that require drug and alcohol testing,

including random testing, employment history evaluations and other background checks for construction workers on large projects. Where safety and/or security during construction are critical, large construction projects initiated by some Federal agencies (e.g., the Department of Energy) require drug and alcohol testing, including random testing, extensive background checks, and continuous behavioral observation for the most sensitive construction tasks. Based on this information, the NRC concluded that (1) implementing FFD requirements for new nuclear power plant construction activities is consistent with the practices of other industries, and (2) taking a graded approach to FFD requirements, by imposing requirements that are commensurate with the potential risks to public health and safety and the common defense and security that the results of construction activities may pose when a plant begins operations, is consistent with the approach implemented by other government agencies when constructing facilities that have the potential to affect public health and safety or the common defense and security.

The NRC also determined that some of the requirements in proposed § 26.3(e) would be difficult to implement. For example, much of the nuclear power plant construction workforce will likely be transient and rapidly changing. As a result, it may be challenging to conduct random drug and alcohol testing in a manner that would meet all Part 26 random testing requirements for operating plants. In addition, some new reactors will be constructed near an operating plant that has readily accessible FFD program resources, such as a specimen collection and alcohol testing site, a licensee testing facility, an FFD training program, and expert staff (e.g., a substance abuse expert, MRO, or EAP representative). However, other new reactors may be constructed at locations that are distant from the FFD program resources of an operating plant. Therefore, the NRC concluded that applying some of the requirements in the proposed rule would be overly burdensome. These include requiring random testing of all construction workers, the requirement for all nuclear power plant construction workers to have access to an employee assistance program (EAP), and the requirement for a determination of fitness process under § 26.189 of the proposed rule.

To streamline administration of the FFD program for construction, add flexibility, and implement an approach that is commensurate with the potential risks resulting from new plant construction, the final rule requires two different levels of FFD requirements for workers in different construction-related job roles. Section 26.4(e) creates the first of these two levels of FFD requirements. It applies to individuals performing six specified types of activities once construction work begins at the location where the nuclear power plant will be constructed and operated. The first of these activity types is that of security personnel required by the NRC, until the licensees or other entities employing these individuals receive special nuclear material in the form of fuel assemblies. At that time, these security personnel must meet the requirements applicable to security personnel in § 26.4(a)(5). The remaining five activity types are performing quality assurance, quality control, or quality verification activities; monitoring the fitness of individuals constructing or directing the construction of safety- or security-related SSCs; witnessing or determining inspections, tests, and analyses certification required under Part 52; supervising or managing the construction of safety- or security-related SSCs; and directing or implementing a licensee's or other entity's access authorization program. Because of their important responsibilities, these individuals must be subject to a full FFD program that meets the same requirements as FFD programs for operating plants (including random drug and alcohol testing at the 50 percent annual rate, behavioral observation training, and a suitable inquiry/employment history check) when they are performing duties at the location where the nuclear power plant is being constructed and will operate, but not Subpart I's fatigue

management requirements. These same requirements apply to the FFD program personnel described in § 26.4(g) who are involved in the day-to-day operation of the FFD program during construction.

A new definition of "supervises or manages" in § 26.5 explains that these terms mean the exercise of control over work activity by an individual who is not directly involved in the execution of the work activity, but who either makes technical decisions for that activity without subsequent technical review, or is ultimately responsible for the correct performance of that work activity. The reference to security personnel is modified by the addition of the words "required by the NRC" to clarify that the FFD requirements are meant to apply to security personnel who perform duties specified by NRC regulations and orders, while other security officers, if any, are not covered by the requirements. And, as noted above, § 26.4(e)(1) in the final rule requires that, once the licensee or other entity has received special nuclear fuel in the form of fuel assemblies, these security personnel must be subject to a FFD program that meets all Part 26 requirements, excepting those of Subpart K but including those of Subpart I.

In contrast to the requirements for those individuals listed in § 26.4(e), § 26.4(f) creates the second of the two levels of FFD requirements for workers in different construction-related job roles. It provides that, at a minimum, individuals who are constructing or directing the construction of safety- or security-related SSCs must be subject to an FFD program that meets the requirements of Subpart K, unless the licensee or other entity chooses to subject them to an FFD program that meets the Part 26 requirements for operating plants, except the fatigue management requirements in Subpart I of the final rule. Subpart K emphasizes performance objectives and does not incorporate all of the requirements of Part 26. Section 26.5 explains that "construction or construction activities" means the tasks involved in building a nuclear power plant that are performed at the location where the nuclear power plant will be constructed and operated, and that these tasks include fabricating, erecting, integrating, and testing safety- and security-related SSCs and the installation of their foundations, including the placement of concrete. The final rule also contains new definitions of "safety-related SSCs" and "security-related SSCs" that clarify the intended scope of § 26.4(f).

If a licensee or other entity specified in § 26.3(c) of the final rule chooses to implement an FFD program for construction under Subpart K, the final rule's § 26.401(b) requires the entity to submit to the NRC a description of the FFD program and its implementation as part of its license, permit, or limited work authorization application. The description must include the FFD policy and procedures prepared by the licensee or other entity, including, but not limited to, procedures for implementing either random testing or fitness monitoring and for identifying the personnel who will be covered by the FFD program. The procedures must also provide for pre-assignment, for-cause, post-accident, and followup drug and alcohol testing. Subpart K also requires an FFD program for construction to include sanctions for FFD policy violations, a system of files and procedures to protect personal information, and procedures for reviewing determinations that an individual has violated the FFD policy. The entity who elects to implement a program under Subpart K must provide individuals who are subject to the FFD program with a clear, concise written FFD policy statement. It must also conduct periodic audits, maintain records, provide reports to the NRC, and develop and apply procedures for suitability and fitness evaluations to determine whether to assign individuals to construct safety- and security-related SSCs. The NRC will evaluate the program description as a part of the application for the license, permit, or limited work authorization and the NRC's finding on the application will include a finding on the FFD program description. The entity will be required to

implement the FFD program that it has described in its application before work begins on the foundations, including placement of concrete, for the safety- or security-related SSCs under the license, permit, or limited work authorization.

To detect and deter substance abuse by individuals who are constructing safety- and security-related SSCs, Subpart K of the final rule permits a licensee or other entity listed in § 26.3(c) of the final rule to subject these individuals either to random testing for drugs and alcohol or a fitness monitoring program. Subpart K also permits FFD programs for construction to—

(1) Collect specimens other than urine for drug testing and/or rely on collection sites at local hospitals or clinics that conduct testing under U.S. DOT procedures, rather than those specified in Subpart E, "Collecting Specimens for Testing," of Part 26;
(2) Rely on healthcare professionals other than a substance abuse expert to evaluate an individual's fitness;
(3) Designate the persons who will perform fitness monitoring, if the entity elects this option, and adjust the number of fitness monitors performing monitoring and the frequency of monitoring to accommodate the stage of construction and local conditions; and
(4) Establish the random testing rate and limit the selection of individuals for testing to only those who are present and constructing safety- or security-related SSCs on a given day, if the entity elects this option.

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

The NRC acknowledges in part that the full defense-in-depth approach of the FFD program for operating plants is not appropriate for all construction workers because many construction activities do not have the potential to impact subsequent plant operations and, before fuel arrives on site, do not impose immediate radiological risks. Therefore, the final rule's requirements for construction require a full FFD program for only a limited number of personnel who have critical oversight responsibilities for verifying that safety- and security-related SSCs

are constructed properly. For workers who will construct the safety- and security-related SSCs, the FFD program requirements in Subpart K are less stringent. For example, Subpart K does not require a suitable inquiry/employment history check for these workers. In addition, the staff acknowledges the many complex logistical challenges associated with implementing FFD requirements during construction. Therefore, the Subpart K requirements provide certain applicants for, and holders of, COLs and CPs and early site permit holders greater flexibility in implementing FFD programs for construction than the rule permits for FFD programs at operating plants.

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

FFD Intent for Fuel Fabrication Facilities

Comments: One commenter noted that, under proposed §§ 26.3 and 26.195, Subpart I would not apply to fuel fabrication facilities. The commenter thought this was justified because of the lower level of risk at such facilities. The commenter also stated that, until the NRC authorizes the possession and use of strategic special nuclear material (SSNM) onsite, there is no reason that FFD requirements should be more stringent than those typically applied during the construction of large commercial non-nuclear facilities [Richard Sweigart, DCS].

NRC Response: The NRC agrees that fuel fabrication facilities will not be subject to the requirements in Subpart I. Section 26.201(a) in the final rule states that the requirements in Subpart I apply only to licensees and other entities identified in § 26.3(a), and, if applicable, § 26.3(c) and (d). These provisions do not include fuel fabrication facilities within their scope.

Consistency with Part 52

Comments: Two commenters at the public meeting noted that there were discrepancies between the proposed rule language and the draft language for Part 52. The commenters suggested that there be coordination between those efforts [Tom Houten, NEI; Peter Fowler, Duke Energy].

NRC Response: The NRC agrees with the commenters and has coordinated the Part 26 and Part 52 final rulemakings.

Exception for Long-Term Shutdowns

Comments: One commenter stated that the proposed rule made no exceptions to the application of proposed Subpart I requirements at plants in long-term shutdown status. The commenter recommended the NRC incorporate such an exception into the rule. His rationale was that there is no reasonable or cost-effective method to comply with the proposed requirements at his organization's nuclear power plant because of the large number of people

being utilized during the recovery effort at that plant. The commenter suggested that the NRC add a new subparagraph (g) to proposed § 26.3 that would state: "Subpart I of this regulation does not apply to plants in long-term shutdown status when fuel has been removed from the reactor vessel and NRC approval is required prior to loading fuel. At the time approval to load fuel is received, the licensee will be in compliance with all applicable portions of § 26.3 prior to commencement of loading fuel into the reactor vessel." To accompany this change, the commenter suggested that the following phrase be added to proposed § 26.195: "Exceptions are identified in Section 26.3(g)" [Glenn Morris, TVA].

NRC Response: The NRC has decided not to include a specific exception for plants in long-term shutdown. The NRC notes that § 26.9 of the final rule allows parties to seek exemptions from Part 26 and considers this provision to be the more appropriate means for addressing such infrequent and unique circumstances.

3.3 Definitions (§ 26.5)

"Non-Negative" vs. "Positive"

Comments: Several commenters requested clarification of whether the terms "non-negative" and "positive" had the same meaning in the proposed rule. They suggested use of a consistent term if usage is interchangeable. One commenter, supported by several other commenters, suggested that, if these terms were synonymous in the proposed rule, the industry preferred the term "positive." The commenter also recommended that, if the NRC did not intend these terms to be synonymous, it should define the term "positive" as 1) "the same as the HHS Mandatory Guidelines defines it," or 2) "the result of a confirmatory test that has established the presence of adulterants, drugs, drug metabolites, or alcohol in a specimen at or above cutoff level and that has been deemed positive by the MRO after evaluation" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees that use of the terms "non-negative" and "positive" in the proposed rule should be clarified. Therefore, the NRC has deleted "non-negative" from the final rule and replaced it with the following more specific terms: "positive," "adulterated," "dilute," "substitute," and "invalid." The final rule uses the term "positive" to refer to results from drug and alcohol testing indicating the presence of drugs or drug metabolites in a urine specimen or alcohol in a specimen of breath or oral fluids equal to or greater than the cutoff concentration. The terms "adulterated," "dilute," "substitute," and "invalid" are used, as appropriate, to refer to results of validity tests of urine specimens indicating that the specimen may have characteristics not normal to human urine.

"Validity Screening"

Comments: Several commenters requested that the NRC allow for the use of instrumented devices, in addition to non-instrumented devices, in validity screening tests [Jim Davis, NEI #48; Brian McCabe, Progress Energy; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young,

Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The comments relating to the use of instrumented devices for validity screening are addressed below in Section 8.9.2 regarding § 26.137(b) of the final rule.

"Directing"

Comments: Several commenters thought the proposed rule significantly expanded the types of people, activities, and responsibilities that would be included within the meaning of the term "directing." They were concerned with what they considered to be a lack of clarity in the definition of "directing," particularly in the operations and maintenance functional groups. The commenters stated that, for operations, this term is understood to mean individuals with direct authority, such as the Senior Reactor Operator directing the activity of the Reactor Operator. Concerning "directing" in relation to the maintenance functional group, the commenters noted that NRC staff had stated that the person who would be considered as "directing" maintenance activities would be the individual who was at the job site providing direct supervision of the job, had the ability to detect errors and was ultimately responsible for the successful completion of the job. Although the commenters agreed that the group should include management personnel routinely assigned to a shift, they claimed the proposed addition of other individuals who provide periodic support, such as a special outage manager, was unwarranted. They stated that the licensed operator is directly responsible for the safe operation of the plant. The commenters also stated that, for maintenance activities, the application of the term "directing" to engineering personnel who provide technical advice was of particular concern.

The commenters stated that the criteria for these two groups should be well-defined and that the proposed definition of the term "directing" created significant uncertainty as to who should be included in each applicable functional group. The commenters stated that, without a better definition of expectations in this area, there will be additional disagreement regarding implementation requirements.

The commenters also mentioned that the distancing of engineering staff from the maintenance and operations staff would be a potential unintended consequence of the proposed definition of "directing." Specifically, whenever possible, licensees would define an engineer as an advisor, not a director, of the operations or maintenance groups. In some cases an engineer may not go into the field to give technical advice or participate in troubleshooting for fear that someone will decide he or she is part of a functional group and thus subject to work hour controls [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees that the proposed definition of "directing" was unclear as used in Subpart I and applied to the scope of personnel who must be subject to work hour controls. Therefore, the NRC has modified the definition in the final rule. The revised definition clarifies the NRC's expectations that a limited scope of personnel providing technical input is subject to the requirements of § 26.205 [Work hours]. The definition in the final rule explicitly

states that the term "directing" refers to an individual "who is directly involved in the execution of the work activity, and either makes technical decisions for that activity without subsequent review, or is ultimately responsible for the correct performance of that work activity" as opposed to, for example, the planning, development or scheduling of the activity. The NRC believes that the revised definition more clearly focuses on activities that have the potential to substantively and immediately affect safety.

In response to the comment that a licensee may define an engineer as an advisor, the NRC notes that the work hour controls are applicable to individuals who perform the functions specified in the final rule's § 26.4(a)(1) through (a)(5), regardless of their position titles.

In response to the comment that individuals may not go out into the field to provide technical advice, the NRC notes that work hour limits apply to individuals providing "onsite" direction of the functions specified in § 26.4(a)(1) or performing the "onsite" emergency response-related duties specified in § 26.4(a)(2) of the final rule. As a consequence, an individual would not be exempted from the work hour limits because he or she directs activities from a remote onsite location. However, he or she would not be subject to the work hour limits if that direction occurs offsite. The NRC defined the requirement in these terms to address the commenters' concern.

"Authorization"

Comments: One commenter stated that the proposed rule used the term "authorization" in a number of different contexts, while historically the term has been synonymous with "access authorization." Therefore, the commenter suggested that the NRC clearly define the different uses of the term "authorization" or use different terms where appropriate [Keith Jury, EGC/AmerGen].

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

"Non-Instrumented Testing Devices"

Comments: One commenter requested that NRC specify what non-instrumented testing devices are permitted for performing validity screening tests. The commenter also requested that the NRC provide examples of acceptable devices [Charles LoDico, Individual].

NRC Response: The NRC agrees in part with the commenter's request and has revised the definition of "validity screening test" in § 26.5 of the final rule. The revised definition specifies that acceptable non-instrumented tests[1] are those in which the endpoint result is obtained by visual evaluation. In addition, the final rule definition authorizes the use of instrumented tests for validity screening, to the extent that results from those tests are machine-read. The NRC made this second revision to respond to another comment that explained that some instrumented tests could also meet the performance testing criteria in § 26.137. The NRC has revised the definition of a validity screening test in § 26.5 of the final rule to mean the use of a non-instrumented test where the endpoint result is obtained by visual evaluation (i.e., read by human eye), or an instrumented test (machine-read end points), to determine the need for initial validity testing of a urine specimen.

The NRC has declined to satisfy the commenter's request to include examples of a non-instrumented test because, at the time the final rule was published, the NRC was not aware of any tests that had either been approved by SAMSHA or met the performance testing criteria included in the final rule. The final rule retains permission for the use of non-instrumented tests for validity screening in the expectation that such tests will become available.

"Dilute Specimens"

Comments: One commenter stated that the proposed § 26.5 definition of "dilute specimen" did not include the specific gravity cutoff level which is necessary to determine if a specimen is dilute or substituted [Charles LoDico, Individual].

NRC Response: The NRC disagrees in part with the commenter. The definition in proposed § 26.5 was consistent with the definition for dilute specimens used in the HHS Guidelines. Proposed § 26.161(d) presented a specific gravity range that HHS-certified laboratories must use to determine if a specimen is dilute. Therefore, the NRC has not amended the definition of "dilute specimen" in the final rule.

"Non-Negative Test Result"

Comments: One commenter stated that the proposed definition of a "non-negative test result" did not include the analytical reporting cutoff for specific gravity to determine whether a specimen is substituted [Charles LoDico, Individual].

NRC Response: As a result of comments received on the proposed term "non-negative test result," the NRC has eliminated the term in the final rule. The NRC has revised § 26.5 in the final rule to include a new term, "questionable validity," to account for validity screening and

[1]The final rule eliminates the use of the term "non-instrumented testing device" in this definition because of the specific connotation associated with the use of the term identified by another commenter.

initial validity test results from testing conducted at a licensee testing facility that indicate that a specimen may be adulterated, substitute, dilute, or invalid.

3.4 Interpretations (§ 26.7)

No comments addressed this section.

3.5 Information Collection Requirements: Office of Management and Budget (OMB) Approval (§ 26.8)

No comments addressed this section.

3.6 Specific Exemptions (§ 26.9)

No comments addressed this section.

3.7 Communications (§ 26.11)

No comments addressed this section.

4. SUBPART B: PROGRAM ELEMENTS

This section provides the NRC's responses to public comments on the proposed rule's Subpart B. That subpart specified the performance objectives that FFD programs would be required to meet and the FFD program elements that licensees and other entities would be required to implement to meet the performance objectives.

4.1 Fitness-for-Duty Program (§ 26.21)

No comments addressed this section.

4.2 Performance Objectives (§ 26.23)

Comments: One commenter recommended that proposed § 26.23 be revised to include an FFD program performance objective of providing reasonable assurance that the program will maintain a level of integrity to ensure the privacy of individuals who are subject to testing, and that the individuals who are subject to testing will not be unjustly or inaccurately portrayed as having violated the FFD requirements. Another commenter noted that declaring an individual as not trustworthy or reliable results in removal of unescorted access. The commenter stated that although such a designation can be devastating for a worker's livelihood, the proposed rule provided no guidance to regulatory processes for workers to appeal designations of being not trustworthy or reliable. This commenter asked the NRC to direct workers to any regulatory procedures and practices for workers to use when seeking appeal to dispute removal of unescorted access [Todd Newkirk, IBEW; Edwin Hill, IBEW].

NRC Response: The NRC agrees that the FFD program performance objectives in proposed § 26.23 did not explicitly address worker protections. Rather, the performance objectives required in proposed § 26.23 focused on protecting public health and safety and the common defense and security, consistent with the NRC's mission. The final rule retains these performance objectives without change. However, the NRC is concerned that FFD programs maintain an appropriate balance between the needs of the public and those of the individuals who are subject to the rule. Therefore, the final rule contains a variety of provisions that are intended to ensure worker privacy and protection, such as § 26.27 [Written policy and procedures], § 26.29 [Training], § 26.37 [Protection of information], § 26.39 [Review process for fitness-for-duty policy violations], § 26.75 [Sanctions], and § 28.185 [Determining a fitness-for-duty policy violation]. In addition, in response to this comment, the NRC has added or modified several requirements (including §§ 26.37(d), 26.53(h) and (i), and 26.711(c) and (d)) to strengthen the final rule's requirements that the privacy of individuals who are subject to the rule must be protected and to ensure that individuals are not unjustly or inaccurately portrayed as having violated FFD requirements.

4.3 Individuals Subject to the Fitness-for-Duty Program (§ 26.25)

No comments addressed this section. However, the NRC has revised and moved this section's proposed requirements to § 26.4 [FFD program applicability to categories of individuals] in the final rule for organizational clarity.

4.4 Written Policy and Procedures (§ 26.27)

Comments: With reference to both proposed §§ 26.27 and 26.29, one commenter stated that the licensee should not screen for drugs in addition to those listed in the proposed rule without identifying them in advance. The commenter said that, if prevention is the true goal, the best way to prevent drug use is to forewarn those subject to testing [Todd Newkirk, IBEW].

NRC Response: The NRC agrees that informing individuals of the substances for which testing will routinely occur and the cutoff levels to be applied may deter abuse of those substances to some extent. Information about the drugs for which testing will occur, and their potential effects on job performance, is also an important part of the FFD training that individuals must receive under § 26.29 of the final rule. Therefore, the NRC has added a new provision in § 26.31(d)(1)(iii) of the final rule to specify that licensees and other entities must document the additional drugs for which testing will be performed in the written policies and procedures. However, the NRC does not agree that a licensee should be prohibited from testing for drugs or drug metabolites in addition to those listed in the rule without identifying them to donors in advance. Although deterring substance abuse is an important goal of the rule, detecting substance abuse is also very important. Therefore, both the former and final rules permit licensees to add drugs to the panel of substances for which they routinely test, as well as to conduct followup, post-event, and for-cause testing to detect any drugs listed on Schedules I-IV of the Controlled Substance Act that the individual is suspected of abusing without identifying them in advance.

4.4.1 General (§ 26.27(a))

No comments addressed this section.

4.4.2 Policy (§ 26.27(b))

Comments: One commenter commended the NRC for considering the impact that untreated sleep disorders have on the health and safety of the workforce at nuclear plants in proposed § 26.27(b)(7). The commenter stated that the NRC had clearly and accurately cited existing information regarding the prevalence of sleep disorders in the United States. The commenter agreed with the NRC that, given the demographics of workers in the nuclear industry, sleep disorders (e.g., sleep apnea) are likely to be prevalent in the workforce and should be diagnosed and treated. The commenter stated that no matter how much time for sleep individuals are afforded, those who suffer from sleep disorders do not accrue the full recuperative benefits from sleep, resulting in an inability to sustain normal levels of alertness and performance throughout the subsequent hours of wakefulness [Darrel Drobnich, NSF].

NRC Response: The comments do not require a response.

4.4.3 Procedures (§ 26.27(c))

<u>Use of the Term "Due Process"</u>

Comments: One commenter, supported by many other commenters, stated that the term "due process" used in proposed § 26.27(c)(1) implied that licensee activities under this rule will be

subject to judicial review relative to the U.S. Constitution. The commenter suggested replacing "due process rights" with "other rights" to recognize that an individual's protected rights are not limited to the right to due process [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees that, in addition to any due process rights, individuals subject to Part 26 may also have other rights granted by Federal and state statutes. These include privacy rights associated with the protection of personal information collected under Part 26 and individual privacy during specimen collection. The right to an impartial review of determinations of FFD policy violations is another example of a right protected under the rule. Therefore, the NRC has modified § 26.27(c)(1) in the final rule to refer to "privacy and other rights (including due process)" as the rights of individuals who are subject to Part 26 to be protected.

Alcohol Consumption during the Pre-Work Abstinence Period

Comments: One commenter, supported by many other commenters, stated that the wording in proposed § 26.27(c)(2)(ii) could be interpreted as prohibiting only excess alcohol consumption during the pre-work abstinence period. The commenter suggested that the wording should more clearly express the prohibition against any alcohol consumption during relevant periods [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC intends to prohibit any consumption of alcohol, not only excess consumption, during the pre-work abstinence period or while workers are on duty. Section 26.27(c)(2)(ii) in the final rule has been modified accordingly.

Use of the Term "Emergency"

Comments: One commenter, supported by many other commenters, thought the term "emergency" in proposed § 26.27(c)(3) was too limiting. The commenter recommended replacing the term "emergency" with "unscheduled working tour" because this wording would be consistent with the use of the term "unscheduled working tour" in proposed § 26.27(c)(3)(ii)(c) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The term "emergency" in the second sentence of proposed § 26.27(c)(3) accurately conveyed the NRC's intent that, if an individual's knowledge and skills are necessary to respond to an emergency, the consumption of alcohol resulting in a BAC that exceeds the cutoff levels in Part 26 should not preclude the licensee from relying on the individual during an emergency. However, the NRC has reorganized the language in § 26.27(c)(3) in the final rule

to further clarify the differences between the controls and conditions that apply only to an emergency and those that apply to an unscheduled working tour.

Procedures for Called-In Individuals

Comments: One commenter, supported by many other commenters, stated that the wording in proposed § 26.27(c)(3)(i) that required individuals who are called in to perform an unscheduled working tour to report whether they consider themselves fit for duty could result in unintended audit requirements and would require excess documentation. The commenter stated that this section's intent can be met by having individuals report if they are not fit for duty or have consumed alcohol within the pre-duty abstinence period. Thus, the commenter suggested revising proposed § 26.27(c)(3)(i) to state: "The procedure must require individuals called in to report by exception. The procedure must require individuals called in to declare, as stated in licensee program when they consider themselves unfit for duty or have consumed alcohol within the pre-duty abstinence period stated in the policy" [Randy Cleveland, NMC; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenters. Proposed § 26.27(c)(3)(i), which required each individual who is called in to state whether he or she considers himself or herself fit for duty or has consumed alcohol within the pre-duty abstinence period stated in the policy, could create a need for the licensee to document the individual's statement. The NRC acknowledges that such documentation could be the subject of auditing. However, the NRC believes that the commenters' suggested alternative of having individuals report only if they believe they are not fit for duty or have consumed alcohol within the pre-duty period would be less protective of public health and safety. An affirmative obligation to provide a statement may dissuade individuals who would be tempted to remain silent. It will also provide a clearer record. Therefore, the NRC has not modified § 26.27(c)(3)(i) in the final rule.

Sanctions for Called-In Individual

Comments: One commenter, supported by many other commenters, stated that proposed § 26.27(c)(3)(ii)(C) could be interpreted to mean that an employee who is called in may not be subjected to sanctions not only for having consumed alcohol within the pre-duty abstinence period but for any misconduct whatsoever. The commenter suggested the following wording change to the subparagraph: "State that no sanctions may be imposed on an individual who is called in to perform an unscheduled working tour for having consumed alcohol within the pre-duty abstinence period stated in the policy" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees with the commenter. The intent of this provision is to assure that an individual called in for unscheduled work is not subject to sanction if he or she has consumed alcohol within the pre-duty abstinence period stated in the licensee's FFD policy. Sanctions for the consumption of alcohol in these circumstances would be inappropriate

because the individual would have been unaware that he or she would be called in to work. However, the NRC does not intend that called-in individuals be shielded from sanctions if the licensee detects another type of misconduct prohibited by the licensee's FFD or other policies. Therefore, the NRC has modified this provision in the final rule, which appears in § 26.27(c)(3)(ii)(E), to clarify this intent.

4.4.4 Review (§ 26.27(d))

No comments addressed this section.

4.5 Training (§ 26.29)

Comments: Comments regarding training are addressed above in section 4.4 "Written Policies and Procedures" of this document.

4.6 Drug and Alcohol Testing (§ 26.31)

Comments: Several commenters supported the majority of the proposed rule's provisions on drug and alcohol testing. One commenter explicitly supported those provisions that incorporate HHS Guidelines requirements, reduce unnecessary regulatory burden, and encourage consistency in implementation with the access authorization program. Another commenter stated that the industry supported most of the proposed drug and alcohol testing provisions because the NRC developed them over a period of many years with due consideration for many improvements recommended by industry groups. The commenter expected that these changes will make FFD programs more efficient and effective [Richard Sweigart, DCS; Brian McCabe, Progress Energy].

NRC Response: These comments do not require a response.

4.6.1 General (§ 26.31(a))

No comments addressed this section.

4.6.2 Assuring the Honesty and Integrity of Fitness-for-Duty Program Personnel (§ 26.31(b))

Comments: For purposes of determining whether FFD program personnel should be subject to periodic psychological assessments as required by proposed § 26.31(b)(1)(i), one commenter suggested that FFD program personnel should be considered to be equivalent to non-critical licensee personnel. Because licensees and other entities do not update the psychological evaluations of non-critical group personnel, the commenter suggested that FFD program personnel should also not be subject to periodic psychological assessments [C. L. Funderburk, Dominion].

NRC Response: The NRC disagrees with the commenter. FFD program personnel hold important and unique responsibilities and play a critical role in maintaining the integrity of the FFD program. Given these responsibilities, the NRC continues to believe that requiring that FFD program personnel be subject to periodic psychological assessments is one means of

assuring their continuing honesty and integrity. Therefore, the NRC has not modified § 26.31(b)(1)(i) in the final rule.

4.6.3 Conditions for Testing (§ 26.31(c))

Post-Event Testing

Comments: One commenter thought that the proposed § 26.31(c)(3) requirement that post-event drug and alcohol testing be conducted after "an event involving a human error... where the human error may have caused or contributed to the event" would be too broad and lead to many implementation questions. The commenter thought the proposed requirement would have the unintended consequence of causing individuals not to report medical conditions or to delay seeking treatment to avoid being tested. Instead, the commenter recommended that, in post-event situations caused by an individual's actions, the individual be subject to testing when there is at least a reasonable suspicion that drugs or alcohol affected the individual's actions. The commenter also stated that he supported the proposed § 26.31(c)(3) provision that required post-event testing if, "within 4 hours after the event," there were determined to be personal injuries and illnesses recordable under certain enumerated circumstances [Mark Wetterhahn, Winston and Strawn].

NRC Response: The NRC disagrees with the commenter and has concluded that it is preferable to determine the need for post-event testing using an objective standard based on the severity of the underlying event. The experience of the DOT with post-accident testing, for example, is that it is more effective to completely separate "for cause" concepts (such as "reasonable suspicion" of substance abuse) from post-event testing. Under the proposed and final rules' approach, if one of the events that the regulations define as requiring post-event testing occurs, then that testing should be carried out irrespective of the presence or absence of any "reasonable suspicion" of substance abuse.

The proposed rule used the term "human error" rather than "worker's behavior," the former rule's term, to emphasize that post-event testing is required for acts that unintentionally deviate from what was planned or expected in a given task environment (NUREG/CR-6751, "The Human Performance Evaluation Process: A Resource for Reviewing the Identification and Resolution of Human Performance Problems") as well as failures to act (i.e., errors of omission). Therefore, testing is required regardless of whether there was "reasonable suspicion" that the individual was abusing drugs or alcohol for the consequences listed in the section. This approach ensures that possible impairment because of substance abuse is investigated following these significant events. It also removes subjectivity associated with someone's suspicion from the testing decision.

Furthermore, the NRC believes that the detailed listing in § 26.31(c)(3)(i) through (c)(3)(iii) of situations when post-event testing should be carried out following an accident resulting in injury substantially eliminates the risk of unnecessary testing after trivial events. In addition, § 26.31(c)(2) continues to allow "for-cause" testing when its preconditions are met. Section 26.31(c)(3)(i) also limits post-event testing to situations in which the licensee or other entity determine that an injury or illness caused by the event meets a specific enumerated threshold within 4 hours after the event has occurred. For all these reasons, the NRC has not modified §26.31(c)(3) in the final rule.

Use of the Phrase "Medical Treatment beyond First Aid"

Comments: One commenter took issue with proposed § 26.31(c)(3)(i) which mandated that an individual whose human error causes an event would be subject to post-event testing if that or another individual suffered an injury or illness that required "medical treatment beyond first aid." He thought this threshold would be too low and inclusive in that it would include too many minor medical incidents. It could also have a chilling effect on the reporting of industrial safety incidents because those suffering minor injuries might not report them to avoid the inconvenience of testing. He also reported that testing at such a low threshold at his company's facilities had not detected substance abuse.

NRC Response: The NRC disagrees with the commenter. The phrase "medical treatment beyond first aid" is based on the general criteria contained in 29 CFR 1904.7 of the regulations of the Occupational Safety and Health Administration (OSHA) for recording occupational injuries and illnesses. To clarify, the NRC does not intend that the phrase "medical treatment beyond first aid" should increase the burden of accident reporting by requiring post-event testing in all situations where a personal injury has occurred (i.e., a paper cut or twisted ankle). On the contrary, the NRC intends that this phrase, in addition to the phrase "where the human error may have caused or contributed to the event" in § 26.31(c)(3), should rarely result in testing after such trivial events. It should instead cause post-event testing to be undertaken for more significant events caused by human error to determine whether the error was caused by impairment from drugs or alcohol. Therefore, the NRC has not modified § 26.31(c)(3)(i) in the final rule.

Typographical Error

Comments: Many commenters identified a typographical error in proposed § 26.31(c)(3)(i). They stated that the citation of OSHA regulations should refer to 29 CFR 1904.7, not 29 CFR 1907.4 [Jim Davis, NEI #48; F. G. Burford, Entergy; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees that proposed § 26.31(c)(3)(i) contained a typographical error and has modified this section in the final rule accordingly.

4.6.4 General Requirements for Drug and Alcohol Testing (§ 26.31(d))

Lack of Provision for Specimen Dilution

Comments: One commenter, supported by many other commenters, suggested that proposed § 26.31(d)(1)(ii) be revised to properly account for actions that may be taken under § 26.185(g)(2) or (g)(3), when the MRO has reason to believe a donor has diluted a specimen. The commenter suggested adding a line to the end of the section, stating: "unless the specimen was considered dilute and the licensee or other entity chooses to have the specimen evaluated under § 26.185(g)(2) and (g)(3)" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory

Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees with this comment. Proposed § 26.185(g)(2) and (g)(3) specified that, if an MRO has reason to believe that the donor may have diluted a specimen in a subversion attempt, the MRO may require the laboratory to conduct confirmatory testing of the specimen at the LOD for any drugs as long as they are evaluated under § 26.31(d)(1)(ii) (typographical error in reference corrected in the final rule). As defined in the rule, the LOD is the lowest concentration of an analyte that an analytical procedure can reliably detect. This concentration could be significantly lower than the established cutoff level. However, proposed § 26.31(d)(1)(ii) specified that test results that fall below the established cutoff levels may not be considered when making sanction decisions. Therefore, the NRC has added language to § 26.31(d)(1)(ii) in the final rule to provide consistency with the provisions in the final rule's § 26.185(g)(3).

Random Testing Requirements

Comments: One commenter, supported by many other commenters, stated that proposed § 26.31(d)(2)(i)(A) limited the unpredictability of specimen collections because it prescriptively required collections on at least 4 days in a calendar week. The commenter thought that this would enable members of the workforce to predict when specimens must be collected during the later days of the week to be in compliance with the regulation [Jim Davis, NEI #48; Marvin Fertel, NEI; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenters. Section 26.31(d)(2)(i)(A) in both the proposed and final rules states that the FFD program, at a minimum, shall "take reasonable steps to either conceal from the workforce that collections will be performed during a scheduled collection period or create the appearance that specimens are being collected during a portion of each day on at least 4 days in each calendar week at each site." This subsection does not require licensees and other entities to actually perform collections on those four days per week, but only to create an appearance that specimens are being collected. It is § 26.31(d)(2)(ii) in both the proposed and final rules that specifies the actual requirement for specimen collection frequency, which is at a minimum nominal weekly frequency.

The NRC believes that the provisions in § 26.31(d)(2)(i) and (d)(2)(i)(B), which specify that random testing must be administered "in a manner that provides reasonable assurance that individuals are unable to predict the time periods during which specimens will be collected" and that licensees shall collect specimens on an "unpredictable schedule," respectively, are adequate to ensure that licensees will schedule random testing appropriately. The NRC notes that, if a licensee is consistently conducting testing on four consecutive days, or on any predictable schedule, the licensee would not be in compliance with these two provisions.

The NRC has also revised § 26.31(d)(2)(i)(A) in the final rule to clarify the NRC's intent that licensees should take reasonable steps to create the appearance that specimens are being collected. This section in the final rule requires that the portions of each day and the days of the week on which it appears that specimens are being collected must vary in a manner that cannot

be predicted by donors.

Testing of Individuals Off-Site/Not Reasonably Available

Comments: One commenter, supported by many other commenters, stated that proposed § 26.31(d)(2)(iv) could be interpreted as requiring individuals who are on site but not reasonably available for testing to be tested immediately. The commenter gave the example of an individual who is suited up for work in a radiologically controlled area from which he or she could not exit to be tested in a reasonable period of time. The commenter stated that requiring testing in this situation would be inconsistent with NRC-endorsed industry practices and NEI 03-01 [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters. Proposed § 26.31(d)(2)(iii) and (d)(2)(iv) addressed several circumstances related to selection, notification, and reporting for random testing. These provisions recognized that there will be delays between the time at which an individual is selected for random testing, is notified that he or she has been selected, and reports to the collection site for testing. For example, an FFD program may implement its process for selecting individuals for random testing at the beginning of a day shift, but some of the individuals who are selected do not report for work until the mid- or night shift. The NRC expects that FFD program personnel would not notify an individual on the mid- or night shift or his or her supervisor that the individual has been selected for testing until the individual reports for duty to avoid forewarning the individual that testing will occur. Similarly, if an individual has been selected for testing, but the FFD program cannot contact the individual because he or she is on vacation or the individual's supervisor indicates that the individual is suited up and performing work in a radiologically controlled area, the NRC expects that neither FFD program personnel nor the individual's supervisor will notify the individual that he or she must report for testing until the individual has returned to the site or has completed his or her work in the radiologically controlled area. However, the NRC also expects that, once an individual has been notified that he or she must be tested, the individual will report to the collection site within the time period specified in the FFD program procedures. The NRC intended proposed § 26.31(d)(2)(iii) to convey these expectations. However, the NRC agrees with the commenters that further clarification was necessary. Therefore, the NRC has added the phrase "or who are on site and are not reasonably available for testing" to § 26.31(d)(2)(v) in the final rule.

Licensees Using LOD Cutoffs

Comments: One commenter asked whether proposed § 26.31(d)(3)(iii)(C) would require licensees already using LOD cutoffs and/or additional substances for testing to submit certification by a forensic scientist or whether they would be grandfathered [Anonymous #18].

NRC Response: The proposed provision stated that certification by a qualified toxicologist is not required if the licensee or other entity has received the NRC's written approval to test for lower cutoff levels before the implementation of the final rule. If certification or written approval is required, and the licensee has not received written approval or certification by that date, the final rule's § 26.31(d)(3)(iii)(C) requires the licensee to obtain a toxicologist's certification.

Delay of Medical Treatment to Conduct Post-Event Testing

Comments: Two commenters agreed that required medical treatment should not be delayed to conduct post-event testing as provided by proposed § 26.31(d)(5)(ii). However, one of them suggested that this paragraph should state that "treatment *must not* be delayed to conduct drug and alcohol testing" [Todd Newkirk, IBEW; Jim Davis, NEI #48].

NRC Response: The NRC agrees that medical treatment must not be delayed to conduct drug and alcohol testing. The term "may not" in this provision (and wherever it appears in the rule) indicates a prohibition. Therefore, the NRC has not modified § 26.31(d)(5)(ii) in the final rule.

Inadequacy of Long-Term Random Testing

Comments: One commenter expressed concern that the industry does not adequately test each employee over the long term. The commenter noted that he has not been tested for many years and thought that such lack of testing of certain individuals could compromise the safety of plant operations [Daniel Hansen, Individual].

NRC Response: The NRC disagrees in part with the commenter. If a random drug and alcohol testing program is conducted correctly, each individual who is subject to random testing has an equal probability of being tested each time testing selections are made. However, given the rule's required 50% annual testing rate, it is possible for an individual not to be tested over a long period of time. The NRC believes that this potential does not reduce random testing's deterrence effect. Instead, the NRC continues to believe that the 50% annual random testing rate adequately protects public health and safety as evidenced by the continuing low rates of positive test results reported in the FFD program performance reports.

4.7 Behavioral Observation (§ 26.33)

No comments addressed this section.

4.8 Employee Assistance Programs (§ 26.35)

Comments: One commenter, supported by many other commenters, found proposed § 26.35(b) confusing. In the commenter's view, this section did not adequately explain who must be provided EAP services. He suggested rewording the paragraph to state: "Licensees and other entities need not provide EAP services to C/V employees *who are working at a licensee's or other entity's facility and are subject to this part. Licensees and other entities need not provide EAP services* to individuals who have applied for, but have not yet been granted, authorization" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees with this clarification. The NRC does not intend that licensees and other entities provide EAP services to C/V employees if they work at the licensee's or other entity's facility. The NRC has modified the final rule language to make this intent clear. Instead, as under the former rule, the final rule requires that C/V employees

subject to Part 26 must have access to an EAP, and that licensees and other entities who rely on a C/V FFD program continue to ensure that the C/V FFD program meets Part 26 requirements.

4.9 Protection of Information (§ 26.37)

Comments: One commenter suggested that proposed § 26.37(d) be modified to allow the donor, or his or her representative with the donor's permission, to gain access to the donor's FFD records at any time and not just when there is a non-negative test. The commenter thought that allowing such access would enable the donor to ensure that no inappropriate records exist such as records of tests that tested non-negative initially but were subsequently declared to be negative by the MRO [Todd Newkirk, IBEW].

NRC Response: The NRC agrees that individuals shall have the right to review FFD information to ensure its accuracy. Therefore, the NRC has added § 26.711(c) in the final rule to require licensees and other entities to inform the individual of his or her right to review information collected under Part 26 to assure its accuracy. It also requires that individuals be provided with an opportunity to correct any inaccurate or incomplete information that licensees and other entities develop about the individual. Section 26.711(d) in the final rule also requires licensees and other entities to ensure that the information they share with other licensees and entities is correct and complete. These additions are consistent with requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003, and are necessary to protect individuals' rights under the rule (including due process).

4.10 Review Process for Fitness-for-Duty Policy Violations (§ 26.39)

Comments: In contrast to the proposed § 26.39(c) requirement that more than one individual conduct the review of an FFD policy violation, one commenter, supported by many other commenters, recommended that the rule allow the reviews to be conducted by at least one impartial and independent internal management individual and that the individual or individuals who conduct the review are not associated with the FFD program administration. The commenter noted that this revision would make this requirement consistent with a similar requirement in 10 CFR 73.56(e) (personnel access authorization) and that it would simplify licensee procedures and improve the consistency between FFD requirements and access authorization requirements [Jim Davis, NEI #48; Marvin Fertel, NEI; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees in part with the commenters. Section 26.39(c) in the final rule requires that only one representative of the licensee's or other entity's management shall conduct the review. This reviewer may not be anyone associated with the administration of the FFD program, including anyone who made the initial decision to impose a sanction under the licensee's or other entity's FFD policy. This revision ensures the consistency of Part 26 with access authorization requirements.

4.11 Audits and Corrective Action (§ 26.41)

No comments addressed this section.

5. SUBPART C: GRANTING AND MAINTAINING AUTHORIZATION

This section provides the NRC's responses to public comments on the proposed rule's Subpart C. That subpart specified requirements related to the process that licensees and other entities would be required to follow, in part, to determine whether an individual is trustworthy and reliable and can be expected to perform his or her job safely and competently. These requirements applied to both granting and maintaining individuals' authorization under Part 26 to have access to certain types of information or protected areas and to perform certain safety- and security-related duties.

5.1 Purpose (§ 26.51)

No comments addressed this section.

5.2 General Provisions (§ 26.53)

No comments addressed this section.

5.3 Initial Authorization (§ 26.55)

No comments addressed this section.

5.4 Authorization Update (§ 26.57)

No comments addressed this section.

5.5 Authorization Reinstatement (§ 26.59)

No comments addressed this section.

5.6 Self-Disclosure and Employment History (§ 26.61)

No comments addressed this section.

5.7 Suitable Inquiry (§ 26.63)

Clarification of Present Employer in § 26.63(c)

Comments: One commenter suggested that the NRC revise proposed § 26.63(c) to state that the licensee or other entity shall conduct the suitable inquiry on a best effort basis by questioning "both the individual's present employer *prior to the day the individual completed the self-disclosure*, and former employers." The commenter stated that this revision would provide more specificity in cases when an individual's current employer changes after the self-disclosure is submitted [Susan Techau, Exelon].

NRC Response: The NRC agrees with the commenter. Licensees and other entities must

ensure that the suitable inquiry includes former employers, and the individual's employer on the day before he or she completes the employment history, if the individual has such an employer. Therefore, the NRC has modified § 26.63(c) in the final rule, as well as making an identical revision in § 26.61(c), to make this requirement explicit.

Comments: One commenter, supported by many other commenters, stated that the present employer may be unable in some cases to answer questions about an individual because of lack of a sufficiently close relationship with the individual. For example, when a C/V hires the individual on the same day or just a few days before a licensee or other entity processes the individual, the C/V may not be able to provide informed and useful information about the individual. Therefore, the commenter suggested that the NRC add a sentence to the end of proposed § 26.63(c) to state: "If the individual is hired within 3 business days from completion of the self-disclosure, the present employer need not be queried" [Jim Davis, NEI #48; Marvin Fertel, NEI; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenters. The NRC believes that, despite having only a brief employment relationship with the individual, the current employer could have information that is relevant to the suitable inquiry. For example, the current employer may have conducted some form of pre-employment drug testing, the results of which would be relevant to the suitable inquiry. Adopting the commenter's proposal might preclude the licensee or other entity from gaining this important information. Therefore, the NRC has not modified § 26.63(c) in the final rule and continues to expect licensees and other entities to include in the suitable inquiry an employer with whom the individual has had only a brief tenure.

<u>Use of the Term "Presentation" in § 26.63(d)</u>

Comments: One commenter, supported by many other commenters, disagreed with the use of the word "presentation" in proposed § 26.63(d) with regard to an individual's signed release authorizing the disclosure of information. The commenter stated that a licensee seeking suitable inquiry information should not have to "present" an individual's signed release authorizing the disclosure of information to another licensee or other entity and should only have to verify that an individual has signed a release authorizing the disclosure of information [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy; Brian McCabe, Progress Energy].

NRC Response: The NRC agrees with the commenters. Current industry practice allows for licensees or other entities seeking suitable inquiry information from another licensee or entity to verify that the individual has signed a release without "presenting" the actual release document. The NRC supports this practice. Therefore, the NRC has eliminated the term "presentation" in § 26.63(d) of the final rule to clarify this intent.

5.8 Pre-Access Drug and Alcohol Testing (§ 26.65)

Comments: Several commenters stated that proposed § 26.65 was generally aligned with current industry practice and recommended that the NRC implement this provision [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The comment does not require a response.

5.8.1 Purpose (§ 26.65(a))

No comments addressed this section.

5.8.2 Accepting Tests Conducted within the Past 30 Days (§ 26.65(b))

No comments addressed this section.

5.8.3 Initial Authorization and Authorization Update (§ 26.65(c))

Requirements for Pre-Access Testing

Comments: One commenter agreed that, when an individual applies for initial or updated authorization, licensees and other entities should be able to rely on negative results from drug and alcohol tests that were conducted within 30 days before the date authorization is granted in lieu of pre-access testing, as provided in both proposed § 26.65(c)(2) and (d)(2)(ii). The commenter objected, however, to these paragraphs' additional requirement that these test results could be relied on only if the individual had been subject to a behavioral observation program meeting Part 26 requirements between the date of the drug and alcohol tests and the granting of authorization [Anonymous, #16].

NRC Response: The NRC disagrees with the commenter. The NRC intends that, if a licensee or other entity relies on negative results from drug and alcohol tests that were conducted under the requirements of Subpart C and before the individual applied for authorization, the applicant must also be subject to a behavioral observation that includes arrest reporting which meets Part 26 requirements. The individual must be subject to this program on the date the specimens for drug and alcohol testing were collected through the date the individual is granted authorization and throughout his or her employment. The purpose of this requirement is to assure that any substance abuse or other indication of lack of trustworthiness or reliability following the test will be detected. Behavioral observation provides the necessary deterrence and opportunities to detect these indicators between administration of the previous drug and alcohol test and the granting of authorization. If the individual were not subject to behavioral observation after the previous test was conducted, it would be necessary to conduct a pre-access test to verify the individual's lack of substance abuse.

In recognition that pre-access testing is not needed if the licensee or other entity relies on previous negative results from drug and alcohol tests conducted under Subpart C requirements

and the applicant has been subject to behavioral observation since the date the specimens for drug and alcohol testing were collected, the NRC has removed reference to the § 26.65(b) pre-access testing provision from both § 26.65(c)(2) and (d)(2)(ii) in the final rule. These paragraphs allow licensees and other entities to rely on drug and alcohol tests that were conducted at any time, rather than within 30 days before the individual applied for authorization, as long as the individual has been subject to a behavioral observation program that requires arrest reporting and meets applicable Part 26 requirements. The NRC has also added to both these paragraphs a requirement that the individual must also have been subject to a drug and alcohol testing program that includes random testing from the time of the drug and alcohol test to the time of granting authorization in order to be exempt from pre-access testing. Like the behavioral observation program requirement, this measure is intended to assure that any substance abuse following the drug and alcohol test is detected.

Comments: One commenter, supported by many other commenters, thought that proposed §§ 26.65(c)(2) and 26.65(d)(2)(ii) contradicted proposed § 26.65(b) and (f). To eliminate this contradiction, the commenter recommended that proposed §§ 26.65(c)(2) and 26.65(d)(2)(ii) be revised to authorize licensees, in lieu of pre-access tests, to rely on drug and alcohol tests that were conducted at any time before the individual applied for authorization, rather than within 30 days before the individual is granted authorization as proposed § 26.65(b) provided, as long as the individual is subject to a behavioral observation and arrest reporting program and random drug and alcohol testing from the date on which the individual's last authorization was terminated through the date on which the individual is granted authorization. The commenter thought these revisions would produce efficiency for companies whose employees visit a number of licensee sites, frequently on short notice [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees in part with the commenters. The NRC agrees that pre-access testing within 30 days before authorization is granted is unnecessary in certain circumstances. Therefore, the NRC has adopted the commenters' recommendation that reference to § 26.65(b) in § 26.65(c)(2) and (d)(2)(ii) in the final rule be removed. This permits licensees to rely on drug and alcohol tests that were conducted more than 30 days before the individual applied for authorization. As the commenters suggested, this revision increases flexibility and improves efficiency. The NRC has also added to both these paragraphs a requirement that the individual must also have been subject to a drug and alcohol testing program that includes random testing, as well as to a behavioral observation program, as the commenters recommended. This revision makes these requirements consistent with industry practice and will increase deterrence and detection of potential substance abuse before authorization is granted. However, the NRC has not revised these paragraphs to permit reliance on previous test results as long as the individual is subject to these programs from the date on which the individual's last termination was terminated through the date on which the individual is granted authorization, as recommended by the commenters. Paragraphs 26.65(c)(2) and (d)(2)(ii) in the final rule continue to require that the individual be subject to these programs from the date the relied-upon drug and alcohol testing was conducted through the date the individual is granted authorization. The NRC expects this requirement to provide the necessary assurance that the individual is qualified to be granted authorization.

5.8.4 Authorization Reinstatement after an Interruption of More than 30 Days (§ 26.65(d))

The preceding section addresses the comments that related to this section.

5.8.5 Authorization Reinstatement after an Interruption of 30 Days or Fewer (§ 26.65(e))

No comments addressed this section.

5.8.6 Time Period for Testing (§ 26.65(f))

Comments: One commenter, supported by many other commenters, disagreed with the proposed § 26.65(f) requirement that specimens to be used for pre-access testing must be collected within the 30-day period that precedes the date upon which the licensee or other entity grants authorization to an individual. The commenter stated that licensees currently conduct pre-access drug and alcohol testing, rather than just collecting the specimen as proposed § 26.65(f) provided, within the 30-day period preceding the date the licensee grants authorization. The commenter thought that the effort to implement this change would exceed its benefit. Thus, the commenter suggested deleting proposed § 26.65(f) and adding the 30-day period to conduct testing to § 26.65(c) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters. The NRC has deleted proposed § 26.65(f) from the final rule to eliminate the unnecessary requirements that were contained therein. However, to accommodate this change, the NRC has revised both § 26.65(c)(1) and (d)(1)(i) to make it clear that, in these circumstances, the licensee may rely only on pre-access tests that were conducted within the 30-day period preceding the granting of authorization by the licensee, consistent with the intent of these provisions of the rule.

5.8.7 Administrative Withdrawal of Authorization (§ 26.65(g))

No comments addressed this section.

5.8.8 Sanctions for a Confirmed Positive, Adulterated, or Substituted Pre-Access Test Result (§ 26.65(h))

No comments addressed this section.

5.9 Random Drug and Alcohol Testing of Individuals Who Have Applied for Authorization (§ 26.67)

No comments addressed this section

5.10 Authorization with Potentially Disqualifying Fitness-for-Duty Information (§ 26.69)

Comments: Two commenters thought that proposed § 26.69 did not provide reviewing officials with sufficient flexibility to make rational FFD decisions when there is a single event that is considered potentially disqualifying information (for example, a citation for driving under the influence or an open container violation). These commenters suggested that licensees need more latitude so they may conduct an appropriate level and type of investigation on the individual, depending on the extent of the potentially disqualifying FFD information disclosed [Jim Davis, NEI; Randy Cleveland, NMC].

NRC Response: The NRC disagrees with the commenters and believes that § 26.69(d) in the final rule provides appropriate flexibility to the reviewing official by permitting him or her to decide whether a determination of fitness is required under the circumstances described by the commenters.

5.10.1 Purpose (§ 26.69(a))

No comments addressed this section.

5.10.2 Authorization after a First Confirmed Positive Drug or Alcohol Test Result or a 5-Year Denial of Authorization (§ 26.69(b))

Comments: One commenter stated that the industry is familiar with the role of Substance Abuse Professionals (SAPs) and suggested that proposed § 26.69(b)(4) be revised to allow for use of either a Substance Abuse Expert or an SAP to perform the functions covered in this paragraph [C. L. Funderburk, Dominion].

NRC Response: The NRC disagrees with the commenter's suggestion. The NRC notes that the SAP training and credentialing process emphasizes knowledge about the SAP role in 10 CFR Part 40 programs. However, although an SAP under Part 40 meets many of the criteria established in Part 26, thorough knowledge of Part 26 requirements is also necessary. Therefore, the NRC has not modified this provision in the final rule.

5.10.3 Granting Authorization with Other Potentially Disqualifying FFD Information (§ 26.69(c))

<u>Consistency in Self-Disclosure Requirements</u>

Comments: One commenter noted that the proposed § 26.69(c)(1) requirement that licensees verify the self-disclosure and employment history of an applicant for authorization referenced only the self-disclosure time period identified in proposed § 26.61(b)(3). The commenter suggested that the provision should also reference the employment history time period identified in proposed § 26.61(c) [Susan Techau, Exelon].

NRC Response: The NRC agrees with the commenter that the time periods that must be addressed by the self-disclosure and employment history should be completely described in the rule. Therefore, the NRC has revised § 26.69(c)(1) in the final rule to require the self-

disclosures and employment histories required by that paragraph to address the shortest of the following periods: the past 5 years, since the individual's eighteenth birthday, or since the individual's last period of authorization was terminated.

Suitable Inquiry with Potentially Disqualifying FFD Information

Comments: Several commenters expressed confusion about proposed § 26.69(c)(2). One commenter asked if the industry must cover every employer if potentially disqualifying FFD information is discovered or disclosed during the suitable inquiry process. A second commenter thought it would be confusing to move from one section of the regulation (§ 26.69(c)(2)) to another (§ 26.63(f)) when conducting an investigation and potentially disqualifying FFD information is discovered or disclosed. These proposed paragraphs discussed different time frames for the suitable inquiry, and both commenters asked the NRC to explain its intent. Another commenter asked if the licensee would have to request the individual whose period of authorization interruption is 2.5 years to provide an additional 2.5 years of employment history to satisfy the 5-year suitable inquiry requirement if potentially disqualifying FFD information is discovered or disclosed during the 2.5-year period [Randy Cleveland, NMC; Jim Davis, NEI; Susan Techau, Exelon; David Bouthron, FPL].

NRC Response: The NRC intends that, if potentially disqualifying FFD information is discovered or disclosed during the suitable inquiry, the licensee must contact every employer from the applicable period in § 26.61(b)(3). In the case of an individual whose authorization had been interrupted for 2.5 years, § 26.69(c)(2) requires the licensee or other entity to complete the suitable inquiry with every employer by whom the individual claims to have been employed during that 2.5-year interruption period, and to obtain and review any records pertaining to potentially disqualifying FFD information about the individual from the licensees or other entities who had granted authorization to the individual during the earlier 2.5 years of the 5-year period required. If an individual had not held authorization during the 5-year period and potentially disqualifying FFD information was discovered or disclosed that a previous licensee had not resolved, then the receiving licensee is required to obtain an employment history from the individual that addresses the entire 5-year period and conduct the suitable inquiry with every claimed employer from those 5 years. In response to the comments, the NRC has clarified this intent by consolidating these requirements in the final rule's § 26.69(c)(2). When an applicant for authorization has held authorization within the past 5 years, this section requires the licensee or other entity to obtain and review pertinent information for the last 5 years, including employment history and records that other licensees or entities who are subject to this part may have developed with regard to potentially disqualifying FFD information about the individual from the past 5 years.

5.10.4 Maintaining Authorization with Other Potentially Disqualifying Fitness-for-Duty Information (§ 26.69(d))

No comments addressed this section.

5.10.5 Accepting Follow-Up Testing and Treatment Plans from another Part 26 Program (§ 26.69(e))

Comments: Several commenters disagreed with proposed § 26.69(e)(1), which required the

FFD program to which an individual was subject to assume responsibility for overseeing the continuation of treatment and follow-up testing for an individual who had a positive test result under another FFD program administered by the same or a different licensee or entity. The commenters thought that the burden of completion, compliance, and follow-up should remain with the individual, not the licensee, to monitor and verify. The commenters asserted that the difficulty of administering such a process would make the requirement ineffective. They suggested either that proposed § 26.69(e)(1) be deleted or that it be revised to place the responsibility for ensuring that the follow-up testing requirements are met on the licensee granting authorization to the individual [Jim Davis, NEI #48; Marvin Fertel, NEI; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees in part with the commenters. The NRC believes that, if it is impractical for the individual to comply with a treatment plan that was developed under another FFD program because of circumstances that are outside the individual's or licensee's or other entity's control (e.g., geographical distance, closure of a treatment facility), then it is appropriate that the granting FFD program develop a comparable treatment plan and be accountable for monitoring the individual's compliance with the plan. The NRC does not agree, as the commenters suggest, that the individual should be responsible for monitoring and verifying completion, compliance, and follow-up of the treatment plan. Although the individual is responsible for complying with a treatment plan, the NRC believes it would be unreasonable to require the individual to be responsible for administering unannounced follow-up testing and to monitor and verify his or her compliance with a treatment plan. As noted above, these are the responsibilities of the licensee or other entity choosing to grant authorization to the individual. The NRC has modified § 26.69(e)(1) in the final rule to reflect this allocation of responsibilities.

5.10.6 Sanctions for Confirmed Non-Negative Drug and Alcohol Test Results (§ 26.69(f))

No comments addressed this section.

5.11 Maintaining Authorization (§ 26.71)

No comments addressed this section.

6. SUBPART D: MANAGEMENT ACTIONS AND SANCTIONS TO BE IMPOSED

This section provides the NRC's responses to public comments on the proposed rule's Subpart D. That subpart specified the minimum sanctions that licensees and other entities would be required to impose when an individual has violated the drug and alcohol provisions of an FFD policy. It also specified required responses to indications of impairment.

6.1 Sanctions (§ 26.75)

Agreement with § 26.75(a)

Comments: Several commenters stated that the industry agreed with proposed § 26.75(a), which authorized licensees and other entities to impose more stringent sanctions for FFD policy violations than the minimum sanctions defined elsewhere in § 26.75. In their view, each licensee and other entity should view the proposed rule as a continuum from previous versions of the rule and may impose stricter sanctions than the rule requires [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The comments do not require a response.

Questionable Justification for § 26.75(b)

Comments: One commenter questioned whether there was adequate justification for the proposed § 26.75(b) requirement that refusal to provide a specimen for testing should be considered an act of subversion. The commenter thought that this provision was a significant change from § 26.27(c) in the former rule, which stated that refusal to provide a specimen for testing must be recorded as a removal for cause [Richard Sweigart, DCS].

NRC Response: The NRC disagrees with the commenter. Refusals to test reflect a sufficient lack of trustworthiness and reliability to be considered an act of subversion. They warrant permanent denial of authorization because a refusal to provide a specimen for testing thwarts the testing process, as there is no specimen to test. The NRC believes that those who refuse to provide a specimen for testing may also be willing to disregard other rules and regulations, such as safeguards requirements, which ensure the protection of public health and safety and the common defense and security. Therefore, the NRC has not modified § 26.75(b) in the final rule.

Sanctions for Withdrawal/Reassignment of Application for Authorization – § 26.75(d)

Comments: One commenter disagreed with proposed § 26.75(d), which stated that any individual who resigns or withdraws his or her application for authorization before authorization is terminated or denied for a first violation of an FFD policy shall be subject to a harsher penalty than a person who does not resign or withdraw. The commenter noted that § 26.27(c) in the former rule provided that resignation in such circumstances shall be recorded as a removal for cause [Richard Sweigart, DCS].

NRC Response: The NRC disagrees with the commenter and notes that proposed § 26.75(d) amended the portion of former § 26.27(c) that required licensees to record as a removal for cause an individual's resignation that occurred before the licensee removed the individual for violating the FFD policy. Because the former provision raised many implementation questions from licensees about the appropriate actions to take in this case, the proposed provision clarified the NRC's intent and provided a more appropriate sanction than the former provision. Therefore, the NRC has not modified § 26.75(d) in the final rule.

Comments: One commenter suggested that proposed § 26.75(d) be revised to address the way the new system of sanctions will handle past violations. The commenter thought the new system should not consider past violations [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter and believes that an individual's past behavior should not be ignored. Past behavior associated with FFD policy violations is relevant because it sheds light on the individual's current trustworthiness to be granted authorization. The NRC believes that any licensee or other entity who may consider granting an individual authorization should be aware of the individual's past resignation or withdrawal of an application before his or her authorization was terminated or denied for a FFD policy violation. That information would be germane to the current authorization application because, for example, it would allow the licensee or other entity to determine what, if anything, the individual has done to address and overcome the problem that led to the past resignation or application withdrawal. The licensee or other entity will then be able to ensure that the minimum requirements for granting authorization are met. Therefore, the NRC has not modified § 26.75(d) in the final rule.

Sanctions for Non-Negative Test Result

Comments: One commenter asked if the FFD regulations define a required action for positive test results, such as a 1- to 3-year ban on unescorted access [Brent Rice, Individual].

NRC Response: The final rule contains several provisions that address the minimum sanctions to be imposed for positive test results, as well as for adulterated, substitute, and invalid results from specimen validity testing. For example, § 26.65(g) describes the minimum sanctions for a confirmed positive, adulterated, or substitute pre-access test result; § 26.67(c) describes the minimum sanctions for confirmed positive, adulterated, or substitute random testing results (not a positive test result); and § 26.75(e) describes the minimum sanctions for a confirmed positive drug or alcohol test result as an indication of off-site drug or alcohol abuse.

Clarification of § 26.75(g)

Comments: One commenter, supported by many other commenters, stated that proposed § 26.75(g) applied to § 26.75(e)(2) and not to § 26.75(e)(1). Therefore, the commenter suggested that the NRC change the reference in § 26.75(g) from "(e)" to "(e)(2)" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees that proposed § 26.75(g) contained a typographical error and has modified the provision in the final rule to correct the error.

6.2 Management Actions Regarding Possible Impairment (§ 26.77)

No comments addressed this section.

7. SUBPART E: COLLECTING SPECIMENS FOR TESTING

This section provides the NRC's responses to public comments on the proposed rule's Subpart E. That subpart contained requirements for collecting specimens for drug testing and for conducting alcohol tests. In particular, it specified qualifications for collectors and collection sites and detailed steps to prepare for collection. It laid out the steps for alcohol testing, both initial testing and confirmatory testing, and for collecting, splitting, handling, and verifying the acceptability of urine specimens.

7.1 Purpose (§ 26.81)

No comments addressed this section.

7.2 Specimens to Be Collected (§ 26.83)

No comments addressed this section.

7.3 Collector Qualifications and Responsibilities (§ 26.85)

No comments addressed this section.

7.3.1 Urine Collector Qualifications (§ 26.85(a))

No comments addressed this section.

7.3.2 Alcohol Collector Qualifications (§ 26.85(b))

Comments: One commenter noted that proposed § 26.85(b) did not require alcohol collectors to be certified, as required for breath alcohol technicians in the U.S. DOT's specimen collector requirements in 49 CFR Part 40. The commenter also stated that the proposed provision did not include documentation requirements for training nor continuing competency training [Sue Brown, Individual].

NRC Response: The NRC agrees that proposed § 26.85(b) did not require certification of alcohol collectors. The NRC has not required this certification in the proposed and final rules because it believes that certification under the U.S. DOT's specimen collector requirements is unnecessary in Part 26. Licensees currently apply the systems approach to training (SAT) for training breath alcohol collectors. The NRC believes that industry training of breath alcohol collectors in accordance with the SAT provides an adequate level of training to ensure the proper completion of specimen collections. The NRC also notes that it is not aware of problems with alcohol collections that would have warranted the additional regulatory burden of requiring breath alcohol collection certification. Therefore, the NRC has decided not to require alcohol collectors to be certified as breath alcohol technicians, as required by the U.S. DOT. The NRC also agrees with the commenter's statement that proposed § 26.85(b) did not include training documentation requirements for collectors. Therefore, the NRC has revised proposed § 26.85 in the final rule by including a new provision, § 26.85(e), to establish documentation requirements for collectors. Maintaining records to document collector proficiency is necessary

for NRC inspection purposes as well as to ensure that the records are available for any administrative and/or legal proceedings challenging an alcohol test result.

7.3.3 Alternative Collectors (§ 26.85(c))

Comments: One commenter disagreed with proposed § 26.85(c) that permitted alternative collectors (i.e., medical professionals, technologists, technicians) to serve as urine and/or breath collectors without meeting the collector qualification requirements in § 26.85 (a) and/or (b) [Sue Brown, Individual].

NRC Response: The NRC agrees that the intent of the provision as proposed was unclear. The NRC intends that alternative collectors be allowed to conduct specimen collections only in those circumstances, such as post-event testing in a hospital setting, when there is a time period within which a specimen must be collected and a collector who is trained under the requirements of Part 26 cannot reasonably be made available by the licensee or other entity to perform the collection. Therefore, the NRC has reorganized and revised proposed § 26.85(c) in the final rule to clarify this intended meaning.

7.3.4 Personnel Available to Testify at Proceedings (§ 26.85(d))

No comments addressed this section.

7.4 Collection Sites (§ 26.87)

<u>Coloring Agents Cannot Interfere with the Drug and Validity Testing Assays</u>

Comments: One commenter objected to the proposed § 26.87(e)(1) requirement that a coloring agent that is added to any source of standing water in the stall or room in which a donor provides a specimen cannot interfere with drug and validity testing assays. The commenter stated the proposed provision did not make sense and requested that it be eliminated [Charles LoDico, Individual].

NRC Response: The NRC agrees with the commenter's request and has eliminated the proposed provision that the coloring agent added to standing water in a stall or room to deter specimen tampering must not interfere with drug and validity testing assays. The NRC eliminated the provision because the requirement cannot be effectively implemented. For example, some validity tests use an assay that produces a color result. If a specimen were to contain a coloring agent that an individual had added in an attempt to subvert the testing process, the assay could not function correctly and would produce an invalid test result. Therefore, the proposed requirement that a coloring agent added to water may not interfere with the drug and validity testing assays is not possible for all validity and drug testing assays used by licensee testing facilities and HHS-certified laboratories.

<u>Same Gender Collector for Specimen Collections in Restrooms with Enclosed Stalls</u>

Comments: One commenter objected to the proposed § 26.87(f)(3) requirement that, in the exceptional instance when a designated collection site is unavailable (e.g., a post-event test at a hospital) and a restroom with multiple stalls is used for the collection, a same-gender collector

must accompany the donor into the restroom, but remain outside the stall used by the donor. The commenter stated that the proposed provision was contrary to the "normal collection process" that, in the commenter's view, did not require a same-gender collector to conduct a specimen collection when a donor provides a specimen in a stall, as long as visual privacy is maintained. The commenter asserted that the proposed provision would be burdensome to implement because it would require that a male and a female collector be present at a collection site at all times. The commenter also noted that the proposed provision would be especially burdensome to implement during outage situations when a large number of individuals must be subject to testing [Jim Bradshaw, AEP].

NRC Response: The NRC disagrees with the commenter and has retained the proposed requirement in the final rule. This requirement applies only in the exceptional event that a designated collection site is not available (e.g., a post-event test in a hospital setting). Because these circumstances are rare, the NRC does not believe that the requirement imposes an undue burden and that it is necessary to protect donors' privacy rights under the rule. The NRC does not intend to require collectors to be of the same gender as the donor under the "normal collection process."

Comments: One commenter objected to the proposed § 26.87(f)(3) requirement that a same-gender collector accompany a donor into a non-dedicated collection site (e.g., a public restroom with multiple stalls) but remain outside the stall used by the donor to provide a specimen. The commenter stated that the proposed provision was inconsistent with the proposed observed specimen collection requirements that did not require a same-gender collector [Charles LoDico, Individual].

NRC Response: The NRC disagrees with the commenter. The circumstance addressed in the final rule's § 26.87(f)(3) is not an observed collection situation. This provision addresses an exceptional circumstance in which a designated site is not available for specimen collection. In addition, § 26.87(f)(3) is consistent with the same requirement in Section 2.4(g)(10) in Appendix A to Part 26 of the former rule. Therefore, the NRC has not modified the proposed provision in the final rule.

7.5 Preparing to Collect Specimens for Testing (§ 26.89)

Notification of Selection for Testing

Comments: One commenter stated that, because a licensee or other entity can "arbitrarily determine" that an employee has attempted to subvert the testing process by failing to appear for testing at a collection site in a timely manner, proposed § 26.89(a) should have required that each employee receive a "positive contact" of their selection for testing. The commenter suggested that an employee's FFD supervisor be required to notify the employee via face-to-face communication because it is impossible to verify the notifier's identity over the telephone. The commenter also suggested that any FFD supervisor who notifies an employee to appear for testing should be subject to the same subversion of testing provisions as those applicable to donors [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter's request to require licensees and other entities to notify, in person, an individual selected for required testing. Requiring a face-to-

face notification of testing would be unnecessarily burdensome on licensees and other entities and could delay required testing. The NRC also disagrees with the commenter's assertion that a licensee or other entity can arbitrarily determine that an individual has attempted to subvert the testing process because the individual did not arrive at the collection site within the required time period. In order to determine that an individual has not reported in a timely manner for testing, the licensee or other entity must maintain a record of the time that an individual was notified to proceed for testing. Therefore, to conclude that an individual has refused to submit to testing, the licensee must implement a defensible method to document the time that the individual was notified for testing. Although one acceptable notification method would be a face-to-face communication between an FFD program supervisor and the individual selected for testing, the licensee or other entity may meet the rule's requirements by employing other secure methods to notify an individual that he or she has been selected for testing. Therefore, the NRC has not modified proposed § 26.89(a) in the final rule.

The NRC agrees with the commenter that individuals who notify donors that they have been selected for testing must be subject to sanctions for any attempt or act to subvert the testing process, as required under § 26.75(b) of the final rule. To clarify the applicability of this sanction to FFD program personnel, § 26.73 of the final rule specifically states that the sanctions in Subpart D [Management Actions and Sanctions To Be Imposed] apply to the individuals listed in the final rule's § 26.4(g).

Time Limit to Appear for Testing at a Collection Site

Comments: One commenter requested that proposed § 26.89(a) specify the acceptable time period within which a donor must appear at the designated collection site for testing [Charles LoDico, Individual].

NRC Response: The NRC disagrees with the commenter's request. The types and physical circumstances of licensees and other entities subject to Part 26 vary widely. Accordingly, acceptable time limits for donors to appear for testing at collection sites also vary widely among licensees and other entities. A time limit appropriate in one licensee's circumstances may be infeasible for another licensee. Therefore, the NRC has chosen to continue to allow each licensee's or other entity's FFD program to establish the acceptable time limit within which a donor must appear at the designated collection site for testing.

FFD Supervisor - Method to Identify a Donor without Photo Identification

Comments: One commenter suggested that proposed § 26.89(b)(2) be revised to allow an additional method to confirm the identity of a donor. The commenter recommended that FFD supervisors be permitted, except for pre-access testing, to positively identify employees that arrive at a collection site without acceptable photo identification. The commenter reasoned that, if an FFD supervisor is trusted to observe a donor, the FFD supervisor should be considered sufficiently trustworthy to verify the donor's identity [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.89(b)(2) in the final rule. For tests other than pre-access tests, this section directs FFD management, upon being informed by the specimen collector that the donor did not present acceptable identification, to contact the donor's supervisor to verify the donor's identity. If the donor's supervisor is not available, FFD management must take other steps to establish the donor's

identity and determine whether the lack of identification was an attempt to subvert the testing process. This revision is consistent with the former requirement in Section 2.4(g)(2) in Appendix A to Part 26 that permitted a collector to positively identify a donor "through the presentation of a photo identification or identification by the employer's representative."

Pre-access Testing Prohibition without Valid Photo Identification

Comments: One commenter addressed proposed § 26.89(b)(2) and requested clarification on the intent of words "may not" in the sentence, "If the donor is scheduled for pre-access testing and cannot produce acceptable identification, the collector may not proceed with the collection." (This wording appears in § 26.89(b)(3) of the final rule.) The commenter stated that by using the words "may not" it appeared that a licensee or other entity has a choice of whether or not to permit testing. The commenter suggested replacing "may not" with "shall not" to emphasize that no collection is permitted [C. L. Funderburk, Virginia Electric and Power].

NRC Response: The NRC disagrees with the commenter's request. The term "may not" in this provision (and wherever it appears in the rule) indicates a prohibition. Therefore, the NRC has not modified § 26.89(b)(3) in the final rule.

Comments: One commenter disagreed with the permission granted in proposed § 26.89(b)(2) for a specimen collection to proceed if the collector cannot confirm the donor's identity. The commenter reasoned that the proposed provision was inconsistent with Section 2.2(f)(2) in the HHS Guidelines which prohibits a collector from proceeding with a specimen collection if a donor's identity cannot be verified [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. The final rule permits a specimen collection for any testing that is required under Part 26 other than pre-access testing to proceed when a donor does not have acceptable identification. Individuals subject to FFD program requirements must have identification with them at all times while at a licensed facility. Therefore, cases in which a donor does not have an acceptable form of identification will be infrequent. However, the NRC has revised proposed § 26.89(b)(2) in the final rule to explicitly require FFD management to take steps to verify the individual's identity or take other necessary actions. In instances where the donor does not present acceptable identification, final § 26.89(b)(2) requires FFD management to contact the donor's supervisor to verify in person the donor's identity. If the supervisor is unavailable, FFD management must take other steps to investigate the reason the donor was unable to present acceptable identification to ensure that the donor was not attempting to subvert the testing process by having another individual provide a specimen for him or her. Steps that FFD program management may take to investigate the reason an individual did not present acceptable identification at the collection site include assigning a security officer to accompany the individual to his or her car or locker to obtain identification that verifies the individual's claim while ensuring that the individual does not have the opportunity to bring an adulterant or substitute urine back to the collection site. FFD program management could also request collection site personnel to photograph any individual who is unable to present acceptable identification for the FFD manager's use in the investigation.

Informing a Donor of Refusal to Test Actions

Comments: One commenter addressed proposed § 26.89(c) that required urine collectors to

inform each donor, before beginning a specimen collection, that leaving the collection site before the collection is completed or refusing to cooperate with the specimen collection process will be considered a refusal to test. The commenter stated that relying solely on the collector to verbally inform the donor of the actions considered to be a refusal to test would be inadequate because the collector may forget to convey the information. The commenter requested that a description of the refusal to test actions be included on the donor consent-to-test form or be posted in a conspicuous location at the collection site [Todd Newkirk, IBEW].

NRC Response: The NRC has declined to grant the commenter's request. The beginning of the testing process is not the first or only time when the rule requires licensees and other entities to inform donors of the actions that will be considered a refusal to test and the consequences of a refusal to test. The final rule's § 26.27(b) requires licensees and other entities to inform all individuals who are subject to an FFD program of the program policies. It also requires licensees and other entities to ensure that a written FFD policy statement is readily available to all covered individuals. That policy statement must include sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy. Among these details are "the consequences of subverting or attempting to subvert the testing process" in proposed and final § 26.27(b)(3). Likewise, § 26.29(a)(1) of the final rule requires licensees and other entities to provide training that addresses the FFD policy and the consequences of violating the policy. With regard specifically to a donor's refusal to test, the NRC has revised proposed § 26.27(b)(3) in the final rule to explicitly require that the FFD policy statement describe donor actions considered to be a refusal to test, and the consequences of refusals to test. These various requirements, considered together, ensure that individuals subject to FFD program drug and alcohol testing are adequately informed of the licensee's or other entity's policy regarding refusals to test.

7.6 Acceptable Devices for Conducting Initial and Confirmatory Tests for Alcohol and Methods of Use (§ 26.91)

7.6.1 Acceptable Alcohol Screening Devices (§ 26.91(a))

No comments addressed this section.

7.6.2 Acceptable Evidential Breath Testing Devices (§ 26.91(b))

No comments addressed this section.

7.6.3 EBT Capabilities (§ 26.91(c))

Comments: Several commenters addressed the requirement in proposed § 26.91(c)(2) that specified the criteria that evidential breath testing (EBT) devices must meet to be acceptable for use in confirmatory alcohol testing. The commenters disagreed that these EBTs should have to display a unique number that can be read before each test. They asserted that some EBTs on the National Highway Traffic Safety Administration (NHTSA) Conforming Products List (CPL) do not have this capability. The commenters stated that some licensees would have to purchase new equipment, even though their current equipment is on the NHTSA CPL. Finally, the commenters suggested that the proposed provision would have a significant economic impact

on small entities that manufacture EBTs [Jim Davis, NEI #48; Marvin Fertel, NEI; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenters' request. Section 26.91(c)(2) in the proposed and final rules specifically applies to EBTs that must be used to conduct confirmatory alcohol tests and may be used to conduct initial tests (designated on the NHTSA CPL without an asterisk). It does not apply to EBT models identified on the NHTSA CPL that may be used only to conduct initial alcohol tests but not confirmatory tests (designated with an asterisk on the NHTSA CPL). The majority of EBT models appearing on the NHTSA CPL without an asterisk have the capability to display a unique test number before each test and print the same unique test number with the alcohol test result once the test is completed. Requiring an EBT that is used for confirmatory testing to display and print a unique test number establishes the chain of custody for the test result and ensures that the result is legally defensible. For example, if the same EBT is used to conduct both initial and confirmatory testing, a unique test number for each test provides the documentation necessary to establish that the individual has actually been tested two different times. Therefore, if the EBTs used by the commenters do not meet the functional requirements specified in § 26.91(c)(2), test results from these EBTs may not be legally defensible if challenged. The final rule permits a licensee or other entity to continue to use any approved EBT model on the most current NHTSA CPL to perform initial alcohol tests. However, confirmatory alcohol tests must be conducted using an EBT meeting the specifications in § 26.91(c). In addition, the industry affirmed that the cost estimate in the regulatory analysis of the proposed rule provision is consistent with projected new equipment purchases by some FFD programs. The NRC also considers it unlikely that this requirement will have any significant impact on EBT manufacturers. Because other Federal agencies have similar EBT requirements, most notably the U.S. DOT, this NRC requirement should have no appreciable impact on the EBT market.

7.6.4 Quality Assurance and Quality Control of ASDs (§ 26.91(d))

No comments addressed this section.

7.6.5 Quality Assurance and Quality Control of EBTs (§ 26.91(e))

<u>External Calibration Check Definition</u>

Comments: One commenter, supported by many other commenters, noted that proposed § 26.91(e) did not define the term "external calibration check." The commenter suggested eliminating "external" from the term "external calibration check" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenter's request. The term "external calibration check" has a specific meaning for EBT devices and is a commonly used term for describing the quality assurance measures taken by a collection site to evaluate the

performance of an EBT. A collection site must ensure that each EBT used for Part 26 alcohol testing is functioning within the acceptable tolerance limits specified in the equipment manufacturer's quality assurance plan by conducting a specific accuracy check on the equipment. This external calibration check simulates delivering a breath sample with a known alcohol concentration to the EBT to verify that it is reading within acceptable limits. The external standards used for calibration checks are typically either wet bath (i.e., a solution of ethanol in water) or a dry gas (i.e., a mixture of pressurized gas, usually ethanol in nitrogen). They are delivered to the EBT through a regulator or other device that simulates a human breath exhalation. Calibrating devices may be included in an EBT "kit" or sold separately.

Frequency of External Calibration Checks on EBTs

Comments: One commenter addressed the proposed § 26.91(e)(1) requirement that, at a minimum, an external calibration check must be performed on an EBT according to the time interval specified in the manufacturer's quality assurance plan (QAP). The commenter requested that the NRC revise this section to require an external calibration check to be performed more frequently because a donor could be sanctioned for a positive test result that would be later overturned if the EBT was malfunctioning (i.e., fails the next external calibration check). Specifically, the commenter requested that an external calibration be performed on each EBT used for testing at the start and end of each testing day. [Todd Newkirk, IBEW]. Another commenter recommended that proposed § 26.91(e) be revised to require calibration as described in the EBT manufacturer's instructions. He also recommended that the optional means of ensuring that confirmed positive alcohol test results are derived from an EBT that is calibrated be eliminated from proposed § 26.91(e)(4)(I) [Marvin Fertel, NEI].

NRC Response: The NRC agrees in part with these commenters' requests. The QAPs for many EBTs require only monthly external calibration checks and/or external calibration checks more frequently if a specific number of tests have been performed. The NRC considered requiring more frequent external calibration checks, but could find no reasonable basis for establishing schedules that would be more appropriate for every EBT on the NHTSA list than those recommended by EBT manufacturers. To address this concern, § 26.91(e)(4) in the final rule provides two optional procedures that licensees or other entities must choose from for reacting to an EBT's failure of an external calibration check. The first option directs that, if an EBT fails an external calibration check, the licensee or other entity is to cancel every confirmed positive test result that was obtained using the EBT from any tests that were conducted after the EBT passed its last external calibration test. Alternatively, collection sites are directed to conduct an external calibration check on the EBT in the presence of the donor after every confirmed positive test result using that EBT. If the EBT fails the external calibration check, the rule requires the collector to cancel the donor's test result and immediately conduct a second specimen collection (initial and, if necessary, confirmatory test) using another EBT. Performing the external calibration check while the donor is still present ensures that, if an EBT is malfunctioning, another EBT that meets § 26.91(c) requirements can be used to perform additional alcohol testing in a timely manner. Under either of these options, performing external calibration checks at the start and end of each testing day would be unnecessary and both options ensure that donors will not be subject to sanctions based on erroneous test results.

EBT Calibrations and Cancellation of Positive Test Results

Comments: One commenter, supported by many other commenters, disagreed with the

provision in proposed § 26.91(e)(3) pertaining to an EBT that fails an external check of calibration. The commenter objected to the proposed requirement to cancel all positive breath alcohol test results from the point the EBT last passed an external calibration check to the point the EBT failed the external calibration check and was taken out of service. The commenter stated that, "since fitness for duty has traditionally been considered an aspect of physical plant security, it causes one to make a comparison to those situations when security equipment fails, and that comparison yields contradictory results. For instance, if access screening equipment fails, all personnel in the protected area are not required to be re-searched because there is not an automatic assumption made that the machine was inoperative and everyone in the plant was improperly screened. In the same manner, personnel within a vital area are not required to leave the area when the access device or door alarm fails because there is not an automatic assumption made that they were able to obtain unauthorized or undetected access. In each of these instances, the assumption is that the equipment failed in the testing officer's presence and compensatory measures are implemented, to include an investigation. The same line of thinking should be applied across the spectrum of security, including FFD. Unless evidence can be provided that can demonstrate failure occurred immediately following the last successful test, the assumption should not be that the equipment was not working, it should be that it worked properly until the failing test was performed." The commenter also asserted that having to "negate all positives since the last successful test will probably cause an increase in the frequency of testing to minimize the impact from this occurring. The implied test frequency exceeds the required frequency, adding burden to FFD staff and increased costs not calculated in the regulatory analysis" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC disagrees that a positive confirmed breath alcohol test result should not be overturned when the EBT used during the test fails an external calibration check. Each donor must receive a fair and accurate test result. A donor should not be subject to sanctions based on a test result produced by a malfunctioning EBT. However, the NRC has revised § 26.91(e) in the final rule to provide licensees and other entities with two options to respond to EBT external calibration check failures. This section retains the proposed § 26.91(e)(3) requirement (in § 26.91(e)(4)(i) in the final rule) that any positive confirmatory alcohol test results that were obtained from an EBT that fails an external calibration check must be cancelled and also that the results of any tests that were conducted with that EBT subsequent to its last successful external calibration check must be cancelled. Section 26.91(e)(4)(ii) in the final rule adds a second option. This section permits licensees and other entities to conduct an external calibration check of the EBT after each positive confirmatory alcohol test result. If the EBT fails the check, the collector must cancel the donor's test result and perform another initial and confirmatory alcohol test, if necessary, using a different EBT. The NRC finds no basis for the commenter's conclusion that the proposed provision would cause additional burden and costs. Given that the positive rate for alcohol testing is low, the likelihood that many test results would be required to be overturned by any FFD program is minimal. In addition, the NRC notes that nothing in the final rule prohibits licensees and other entities from conducting external calibration checks more frequently than required by the manufacturer's QAP to minimize the potential number of test results that would be cancelled if the EBT fails an external calibration check.

Copy of the External Calibration Records for EBTs

Comments: One commenter addressed the quality assurance and quality control provisions contained in proposed § 26.91(e)(3) and requested that a provision be added to permit a donor or donor representative to receive a copy of the external calibration check record performed on the EBT used to test the donor [Todd Newkirk, IBEW].

NRC Response: The NRC's expansion of donors' right to obtain their FFD-related records in § 26.37(d) of the final rule addresses this comment. This section stipulates that individuals subject to Part 26 requirements, or their designated representatives, have the right to request and receive "...all FFD records pertaining to the individual, including, but not limited to,...drug and alcohol test results...." This information includes records of external calibration checks on EBTs from a collection site. The NRC believes that access to this information is necessary to protect donors' rights, including due process, under the rule.

7.7 Preparing for Alcohol Testing (§ 26.93)

No comments addressed this section.

7.8 Conducting an Initial Test for Alcohol Using a Breath Specimen (§ 26.95)

No comments addressed this section.

7.9 Conducting an Initial Test for Alcohol Using a Specimen of Oral Fluids (§ 26.97)

No comments addressed this section.

7.10 Determining the Need for a Confirmatory Test for Alcohol (§ 26.99)

Comments: One commenter requested that proposed § 26.99 be revised to specifically prohibit any further licensee actions or sanctions against a donor with a breath alcohol concentration result of less than 0.02 percent BAC [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter's request. Section 26.23(b) in the final rule stipulates that FFD programs must "provide reasonable assurance that individuals are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties...." Moreover, when an individual appears to be impaired or the individual's fitness appears to be questionable, § 26.77(b) in the final rule requires a licensee or other entity to take immediate action to prevent the person from performing activities that would make him or her subject to Part 26 requirements. Although an individual may have an initial alcohol test result of less than 0.02 percent BAC, other indicators may suggest possible impairment. In these cases, the licensee or other entity must take action consistent with § 26.77(b) to assure the individual's ability to safely and competently perform duties covered by Part 26.

7.11 Conducting a Confirmatory Test for Alcohol (§ 26.101)

No comments addressed this section.

7.12 Determining a Confirmed Positive Test Result for Alcohol (§ 26.103)

Comments: One commenter, supported by many other commenters, stated that proposed § 26.103 would improve the effectiveness of FFD programs in detecting alcohol misuse by ensuring that confirmatory alcohol testing identifies employees who have either consumed alcohol while on duty or before duty and may pose a risk to public health and safety [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: This comment does not require a response.

Scientific Basis for Assigning a Positive Alcohol Test Result for 0.02 and 0.03 BAC Levels

Comments: One commenter addressed proposed § 26.103(a)(2) and (a)(3) by questioning the scientific validity of assigning a positive test result for an individual with a BAC of 0.03 percent and work status of at least 1 hour, or a BAC of 0.02 percent and work status of at least 2 hours. The commenter asked, "Due to differences in metabolism how can a straight line cutoff be established?" The commenter suggested that several breath specimens should be collected to calculate the decay ratio for the individual being tested [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter. Individual metabolism rates for alcohol may be influenced by an individual's weight, the number of metabolizing enzymes present in an individual's liver (a healthy liver vs. a diseased liver), and other factors, such as food consumption. However, individual differences in metabolism should not impact the procedures for back-extrapolation in § 26.103(a) of the final rule. The final rule requires individuals to abstain from alcohol use for at least 5 hours before reporting for duty. Back-extrapolation would be conducted for the first, second, or third hour after an individual has reported for duty. These procedures provide an alcohol-free period of 6 to 8 hours before an alcohol test, which is more than an adequate period of time for all alcohol consumed by even a moderately heavy drinker (3 to 4 drinks per episode) to have been metabolized from the body under normal conditions. Further, if a heavy drinker (5 or more drinks per episode) consumed significant amounts of alcohol just before the beginning of the pre-work abstinence period and had tested positive under these procedures, removal from duty would be warranted not only for the alcohol remaining in the individual's body, but also for the likely carry-over effects (e.g., hangovers) that could affect concentration and cognitive skills. The cutoff levels and time periods in the final rule's § 26.103(a)(2) and (a)(3) are based on the average rate at which normal metabolic processes reduce an individual's BAC over time, which is about 0.01 percent BAC per hour. The NRC is confident that use of this average metabolic rate, in conjunction with back-extrapolation, will result in fair and accurate alcohol test determinations. Thus, if a donor's BAC is measured as 0.03 percent after he or she has been at work for 1 hour, he or she would

have had a BAC of approximately 0.04 percent when reporting for work an hour before the test. Through the same metabolic processes, a donor whose BAC is measured as 0.02 percent after he or she has been in a work status for 2 hours would also have had a BAC of approximately 0.04 percent when he or she reported for work 2 hours before the test. These requirements ensure that confirmatory alcohol testing will identify workers who may have posed a risk to public health and safety by being impaired from alcohol use while on duty.

Comments: One commenter stated that proposed § 26.103(a) conflicted with the FFD policy requirement in proposed § 26.27(c)(3) that pertained to unscheduled working tours. Specifically, § 26.27(c)(3) stated that "no sanctions may be imposed on an individual called in to perform an unscheduled working tour and has consumed alcohol within the pre-duty abstinence period stated in the policy." [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees that there was a conflict between the requirements in proposed §§ 26.103(a) and 26.27(c)(3). Section 26.27(c)(3) in the final rule requires licensees and other entities to maintain procedures "to ensure that individuals who are called in to perform an unscheduled working tour are fit for duty." In cases where an individual indicates that he or she has consumed alcohol within the pre-duty abstinence period, § 26.27(c)(3)(ii)(A) specifies that this procedure must "Require a determination of fitness by breath alcohol analysis or other means...." The NRC has revised proposed § 26.27(c)(3) by adding specific directives in the final rule regarding whether or not the individual may be assigned to Part 26-related duties, including emergency response duties, depending on whether the determination of fitness indicates that the individual is fit to safely and competently perform his or her duties. Section 26.27(c)(3)(ii)(E) in the final rule further stipulates that "...no sanctions may be imposed on an individual who is called in to perform any unscheduled working tour for having consumed alcohol within the pre-duty abstinence period stated in the policy."

Section 26.103(a) in the final rule, on the other hand, establishes the cutoff levels for confirmatory alcohol test results that licensees and other entities must declare as positive test results. These requirements are to be used in the "...determination of fitness by breath alcohol analysis or other means..." required in § 26.27(c)(3)(ii)(A) as in any other Part 26 alcohol testing. Section 26.103(a) does not, however, contain any requirements related to sanctions because a positive alcohol test result under these circumstances does not violate the pre-duty abstinence period requirement. Thus, there is no conflict between the § 26.103(a) test result requirements and the § 26.27(c)(3)(ii)(E) stipulation that no sanctions may be imposed on an individual who is called in to perform any unscheduled working tour for having consumed alcohol within the pre-duty abstinence period. Therefore, the NRC has not modified these provisions in the final rule.

7.13 Preparing for Urine Collection (§ 26.105)

Comments: One commenter addressed the proposed § 26.105(b) requirement that each urine specimen donor empty the contents of his or her pockets so that the collector can inspect the items to ensure that the donor does not possess items that could be used to tamper with, adulterate, or substitute a urine specimen. The commenter requested that the proposed provision be revised to require collection sites to post a list of items that a collector could consider to be used to attempt to subvert the testing process. The commenter expressed concern that the proposed provision was ambiguous in that the collector may subjectively

determine if an "item appears to have been inadvertently brought to the collection site" or may determine if an item was brought by the donor to the collection site "with the intent to adulterate the specimen." The commenter also expressed concern that an employee might bring a harmless substance such as a bottle of eye drops to the collection site and the collector might wrongly accuse the donor of attempting to subvert the testing process. The commenter suggested that an alternative to a posted list would be to require each donor to place all items on his or her person in a locker outside the collection area. The donor would be provided with the key to the locker which he or she would keep during the collection process [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees in part with the commenter. The commenter's suggestion regarding a list of items that potentially could be used to subvert testing is untenable because there is no effective way to identify all possible items. Further, § 26.105 in the final rule provides for urine collection preparation procedures that protect against unjust determinations of subversion attempts. In particular, § 26.105(b) requires that, if a collector identifies an item that the collector determines the donor brought to the collection site with the intent of adulterating or substituting a urine specimen, the collector must contact the MRO or FFD program manager to determine if further action must be taken. This review will ensure that a collector makes an accurate determination of whether or not the donor had intended to subvert the testing process. Also, the final rule requires urine collectors to receive training on collection procedures to ensure that correct decisions regarding the contents of a donor's pockets can be made. Finally, if a collector determines that a donor has inadvertently brought something to the collection site (e.g., eye drops), the collector is required, by proposed and final § 26.105(b), to secure the item(s) outside the stall or enclosure used by the donor to provide a specimen before beginning a specimen collection. The NRC believes that these provisions provide adequate protections for each donor and ensure the integrity of the testing process. Therefore, the NRC has not modified this provision in the final rule. However, the NRC views as a good practice the commenter's suggestion for each donor to place all items on his or her person in a locker outside the collection area, retaining the key to the locker during the collection process.

Refusal to Test Action - Donor Refusal to Display the Contents of his/her Pockets

Comments: One commenter addressed the proposed § 26.105(b) statement that a donor's refusal to show the collector the items in his or her pockets is an action considered to be a refusal to test. The commenter stated that solely relying on a collector to verbally inform the donor of the actions considered a refusal test is inadequate because the collector may forget to convey the information. The commenter requested that a description of the refusal to test actions be included on the donor consent-to-test form or be posted in a conspicuous location at the collection site [Todd Newkirk, IBEW].

NRC Response: The NRC agrees in part with the commenter's request. Section 26.89(c) in the final rule requires that a collector must inform a donor that having an item that could be used to interfere with providing an actual urine specimen is a refusal to test. Individuals subject to Part 26 drug and alcohol testing are also informed of refusal to test actions in other ways. All individuals subject to the provisions of a licensee's or other entity's FFD program must be informed of the program policies under § 26.27(b) and must receive training on the FFD policy and consequences of violating the policy under § 26.29(a)(1). Section 26.27(b) requires that a written FFD policy statement be readily available to all covered individuals and include "sufficient detail to provide affected individuals with information on what is expected of them and

what consequences may result from a lack of adherence to the policy." One of the minimum FFD policy statement elements in § 26.27(b) is to "describe the actions that constitute a refusal to test, the consequences of refusals to provide a specimen for testing, as well as the consequences of subverting or attempting to subvert the testing process." The NRC believes that individuals subject to Part 26 urine testing will receive adequate notice of the actions that are considered a refusal test through this combination of access to FFD policy statements, training, and being informed at the urine collection site that having an item that could be used to interfere with providing an actual urine specimen is a refusal to test.

7.14 Collecting a Urine Specimen (§ 26.107)

Comments: Two commenters addressed proposed § 26.107(a)(3). One commenter, supported by many others, agreed with the proposed provision that permitted a collector to use professional judgment to determine an acceptable time limit for a donor to void. The commenter stated that the provision provided flexibility for a collector to accommodate a donor who needs additional time, when appropriate, but also ensured that the collector can prevent a donor from disrupting the testing process by attempting to delay the testing process [Jim Davis, NEI].

Another commenter requested that the proposed provision be revised to specify the time limit that is considered a "reasonable time limit for voiding." The commenter requested that a time limit be specified to remove possible subjectivity as to what a collector may deem as a reasonable time limit for voiding [Todd Newkirk, IBEW].

NRC Response: The first comment does not require a response. The NRC disagrees with the second commenter's request to establish a specific time limit that is acceptable for a donor to void. Collectors need flexibility to allow some donors additional time to provide a specimen (e.g., an individual with a disability). However, during public meetings some stakeholders reported incidents in which some donors delayed the testing process and challenged the collector's authority to set a time limit on voiding. The intent of § 26.107(a)(3) in the final rule is to provide collectors with the necessary authority to set a reasonable time limit for voiding while preventing a donor from disrupting the testing process. The collector should rely on his or her professional judgment in setting this time limit. Section 26.85(a) specifies new training and qualification requirements for collectors to ensure that they are able to exercise this professional judgment appropriately. Section 26.107(a)(3) is also consistent with other Federal agency requirements (e.g., U.S. DOT). Therefore, the NRC has not modified the proposed provision in the final rule.

7.15 Urine Specimen Quantity (§ 26.109)

Comments: One commenter addressed proposed § 26.109(b)(1) that permitted a donor to consume up to 24 ounces of fluid in situations where the donor fails on an initial attempt to provide the minimum quantity of urine. The commenter stated that the proposed provision was consistent with the HHS Guidelines, but not the U.S. DOT's provision to permit a donor up to 40 ounces of fluid [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.109(b)(1) to permit donors to consume up to 40 ounces of liquid over a 3-hour period if they fail on their initial attempt to provide the minimum quantity of urine. This is consistent with

the quantity of fluid that other Federal testing programs (e.g., U.S. DOT) permit a donor to consume in a "shy bladder" situation. The NRC believes that this amount will better protect donors' rights to a fair and equitable testing process while at the same time ensuring that individuals who may be vulnerable to water intoxication will not be placed at risk.

Specify that a Collector Must Discard a Specimen that is less than 30 mL in Quantity

Comments: One commenter stated that proposed § 26.109(b) did not clearly state that if the quantity of urine collected from a donor is less than 30 mL the collector must discard the specimen and collect another. The commenter suggested that the NRC revise proposed § 26.109(b)(1) to state: "The collector shall discard the specimen and a second specimen shall be collected" and delete the second sentence under proposed § 26.109(b)(1) [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request. Section 26.109(b)(4) in the final rule addresses the commenter's concern. It states that "The collector shall discard specimens of less than 30 mL, except if there is reason to believe that the donor has diluted, adulterated, substituted or otherwise tampered with the specimen...." Therefore, the NRC has not modified the proposed provision in the final rule.

7.16 Checking the Validity of the Urine Specimen (§ 26.111)

Acceptable Temperature Range of a Urine Specimen

Comments: One commenter, supported by many other commenters, agreed with the proposed § 26.111 expansion of the acceptable temperature range of a urine specimen [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The comment does not require a response.

Comments: One commenter requested the NRC to clarify proposed § 26.111 by specifying whether validity screening (including specific gravity testing) is to be performed at the point of collection or at the point of testing [Anonymous #17].

NRC Response: Comments received on point-of-collection testing and specific gravity testing are addressed in Section 8 of this document.

Timing of Measuring a Donor's Temperature

Comments: One commenter addressed the proposed § 26.111(a) requirement that a collector must measure the temperature of a specimen sooner than the 4-minute limit from the time the specimen is provided to the collector, if the ambient temperature was low or the specimen quantity was small. The commenter stated that the proposed provision would be difficult to monitor and subject to legal challenge and recommended that it be eliminated from the final rule [Charles LoDico, Individual].

NRC Response: The NRC agrees with the commenter and has eliminated the wording in proposed § 26.111(a) to which the commenter objected. The normal collection process is that the collector immediately measures the temperature of the specimen once the donor presents the specimen to the collector. The intent of the proposed provision was to serve as guidance to collectors, directing them to take special care to quickly measure the temperature of a specimen under the specified circumstances. However, the NRC recognizes that obtaining an accurate temperature reading on specimens smaller than 15 mL can be difficult. Thus, § 26.109(b)(4) in the final rule requires collectors to discard these small specimens. This section also directs collectors to discard specimens of 15 mL or more, but less than 30 mL, unless they have a reason to believe that these specimens have been diluted, adulterated, substituted, or otherwise altered. In these cases, § 26.109(b)(4) directs collectors to transfer the suspect specimens to an HHS-certified laboratory and contact FFD program management to determine whether a directly observed collection is required. It should also be noted, however, that, when a small specimen's temperature falls outside the temperature range specified in § 26.111(b), § 26.111 gives MROs and FFD program managers the authority to decide that the low temperature is not a reason to believe that attempted subversion has occurred and they are not required to order a directly observed collection in every instance.

Comments: One commenter, supported by many others, addressed proposed § 26.111(a) regarding measuring the temperature of a specimen within 4 minutes of the specimen collection. The commenter stated that the temperature difference between a donor's specimen and a donor's body temperature as specified in § 26.115(a)(2)(ii) lacked a scientific basis without a time consideration. The commenter stated that a donor's specimen will begin to cool immediately and will continue to cool until it reaches temperature equilibrium with the surrounding air. Because the cooling rate of a specimen is largely a function of the temperature difference between the specimen and the surrounding air and the temperature difference is typically significant (approximately 25 degrees F), the commenter suggested that a donor's body temperature be taken as soon as possible after the specimen is determined to be outside the acceptable temperature range [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy]. Addressing proposed § 26.111(b) that allowed a donor to volunteer to have his or her body temperature measured by the collector in the circumstance when the specimen that a donor provides is outside the acceptable temperature range, another commenter suggested that the NRC reconsider permitting the measurement of a donor's body temperature given that a temperature measuring device is a better indicator of body temperature than the temperature strips used on specimen collection containers [Charles LoDico, Individual].

NRC Response: The NRC agrees in part with these commenters' requests. The NRC has eliminated proposed § 26.115(a)(2)(ii) that would have authorized comparing the donor's body temperature and specimen temperature as a basis for requiring a subsequent collection of a urine specimen under direct observation. Public comments at stakeholder meetings indicated that the U.S. DOT's experience shows that there are often discrepancies when comparing the temperature provided by a specimen container temperature slip and the temperature provided by a device that measures body temperature. The NRC has also decided to eliminate the option for the donor to volunteer to provide a measurement of body temperature that appeared

in proposed § 26.111(b). As compared to the former rule, § 26.111 in the final rule creates a wider range of acceptable specimen temperatures. With this increase in acceptable temperature range, measurement of body temperature is less useful to counter a reason to believe that the donor has altered the specimen. This change is consistent with other Federal agencies' testing regulations (i.e., U.S. DOT, and HHS Guidelines). However, to ensure that a donor has an opportunity to counter any reason to believe that he or she may have altered or substituted the first specimen, § 26.111(c) in the final rule allows the donor to volunteer to submit a second specimen under direct observation.

Comments: One commenter addressed proposed § 26.111(b) and stated that, if the temperature of a specimen is outside the acceptable range, the collector should use a form to record the donor's actual temperature or the donor should be allowed to sign the form to acknowledge refusing to permit his or her body temperature to be measured [Todd Newkirk, IBEW.]

NRC Response: The NRC has addressed this commenter's concern by eliminating this provision in the final rule, as discussed with respect to the preceding comments.

Use of the Word "Validity" in the Title for § 26.111

Comments: One commenter, supported by many other commenters, requested that the word "validity" in the heading for proposed § 26.111, "Checking the validity of the urine specimen," be changed to "acceptability." The commenter recommended this change to reduce possible confusion that may arise given that three definitions in proposed § 26.5 (initial validity testing, screening validity testing, confirmatory validity testing) already included the word "validity." The commenter suggested using the word "acceptability" given its use in proposed § 26.111(g), which stated that an acceptable specimen is within the acceptable temperature range, is at least 30 mL in quantity, and is free of any apparent contaminants [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees with this request and has revised the heading of § 26.111 in the final rule to improve the clarity of the language used to describe the provisions in this section.

7.17 Splitting the Urine Specimen (§ 26.113)

Comments: One commenter disagreed with the proposed § 26.113(b)(1) requirement that a donor urinate into either a specimen bottle or a specimen container. The commenter asserted that the proposed process might produce conflicting results for Bottle A and Bottle B, especially if a donor successfully adulterates one bottle and the laboratory identifies the adulterant. The donor could challenge the laboratory result by requesting that the Bottle B specimen be tested, which would produce a different test result (if no adulterant were added to the Bottle B specimen), resulting in the cancellation of the test result. The commenter recommended that for all specimen collections, the rule require that a urine specimen be collected in a collection cup and that the collector transfer the urine specimen into the A and B bottles [Charles LoDico,

Individual].

NRC Response: The NRC agrees with the commenter's reasoning and has eliminated the proposed provision that a donor may urinate into a specimen bottle. Section 26.113(b)(2) and (b)(3) of the final rule require the collector to direct the donor to urinate into a specimen container. Once the donor provides a specimen that is within the acceptable temperature range, is at least 30 mL in quantity, and is free of any apparent contaminants, the collector will split the specimen into Bottle A and Bottle B.

Comments: One commenter addressed proposed § 26.113(b)(2) and suggested that the phrase "a minimum of" be added to the requirement that "Bottle B must contain 15 mL" [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's request and has revised § 26.113(b)(2) in the final rule. This provision requires the collector to pour a minimum of 15 mL of urine into Bottle B or all urine that remains after pouring 30 mL into Bottle A. As revised, this section more clearly specifies that the specimen in Bottle A must be used for drug and validity testing even if there is less than 15 mL of urine available for Bottle B. The NRC made this clarification because, in the experience of other Federal agencies, some collection sites have discarded any specimen of less than 45 mL and conducted another collection to obtain a sufficient amount of urine to fill both Bottles A and B. The NRC intends that licensees and other entities subject to Part 26 do not adopt this burdensome practice.

Comments: One commenter stated that proposed § 26.113(b)(2) appeared to suggest that a collector would not send Bottle B to either the HHS-certified laboratory or to a licensee testing facility if the quantity of the specimen in Bottle B is less than 15 mL. The commenter suggested that the provision be revised to read: "If there is less than 15 mL of urine available for Bottle B, all remaining urine must be poured into Bottle B. Bottle A and Bottle B must be sent to the HHS-certified laboratory." [Sue Brown, Individual]

NRC Response: The NRC agrees with the commenter's suggestion and has revised § 26.113(b)(2) in the final rule to require the collector to send both Bottles A and B to the HHS-certified laboratory in circumstances where there is less than 15 mL of urine available for Bottle B. In this circumstance, forwarding the Bottle B specimen to a licensee testing facility is unnecessary, because there is insufficient urine for conducting any testing. This requirement is also consistent with other provisions of the final rule that require collectors to forward specimens with other unusual characteristics to the HHS-certified laboratory.

7.18 Collecting a Urine Specimen under Direct Observation (§ 26.115)

Comments: One commenter asked the NRC to define the terms "EC" and "EF" in proposed § 26.115(a)(2)(ii) that stated: "The donor's measured body temperature varies by more than 1EC/1.8EF from the temperature of the specimen." [Charles LoDico, Individual]. Another commenter, supported by many others, recommended that NRC replace the letter "E" in the terms "EC" and "EF" with the word "degrees" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L.

Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC has eliminated the requirement in proposed § 26.115(a)(2)(ii) because the U.S. DOT's experience shows that there are often discrepancies when comparing the temperature provided by a specimen container temperature slip and the temperature provided by a device that measures body temperature. Also, § 26.111(b) of the final rule no longer permits a body temperature measurement in instances where a donor provides a specimen that is outside of the acceptable temperature range. Therefore, it is unnecessary for the NRC to make the commenters' suggested changes.

7.19 Preparing Urine Specimens for Storage and Shipping (§ 26.117)

Specimen Chain of Custody

Comments: One commenter requested that proposed § 26.117(g) be revised to more precisely describe what a break in the chain of custody is and what specific actions must be taken [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenter's request. The final rule's § 26.129(b) in Subpart F and § 26.159(b) in Subpart G identify the circumstances that require the MRO to cancel the testing of a specimen as a result of conditions that demonstrate the specimen's chain of custody is unverifiable (e.g., the identification numbers on the specimen bottle seal(s) do not match the identification numbers on the custody-and-control form). These requirements are consistent with the U.S. DOT's related drug testing provisions and are necessary to protect the integrity of the testing process.

Specimen Storage Requirements - Cooling to Not More than 6 Degrees Celsius:

Comments: One commenter addressed the proposed § 26.117(j) requirement that a specimen be stored at not more than 6 degrees Celsius if the specimen is not shipped to an HHS-certified laboratory or licensee testing facility within 24 hours of the specimen collection or if a specimen is suspected of being tampered with, adulterated, or substituted. The commenter stated that the HHS Guidelines do not contain these proposed specimen storage requirements [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter and has chosen to maintain the former rule's refrigerated specimen storage requirement. This requirement improves FFD programs' ability to reduce the likelihood of specimen degradation that can lead to erroneous test results and improves the ability of the FFD program to detect and deter prohibited drug use. Therefore, the NRC has not modified the proposed provision in the final rule.

7.20 Determining "Shy" Bladder (§ 26.119)

Comments: One commenter stated that the proposed § 26.119(a) 5-business-day time limit for a donor to receive a medical evaluation after failing to provide the minimum quantity of urine within the 3-hour time limit for a specimen collection is inadequate. The commenter thought that it would be highly unlikely for a donor to be able to make an appointment with a medical doctor

within the proposed 5-day time limit, especially if the doctor is a specialist [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter's request. This provision was consistent with the U.S. DOT's testing programs. It also accounted for the likelihood that most doctors' offices do not offer appointments during weekends or holidays. The NRC established the time limit of 5 business days as a trade-off between the need to provide the donor with sufficient time to locate a qualified physician and obtain an appointment, and for the physician to complete the evaluation (i.e., the donor's right to due process), and the public's interest in a rapid determination of whether the donor had attempted to subvert the testing process by refusing to provide a sufficient specimen. The U.S. DOT's experience indicates that 5 days is sufficient to complete the evaluation. Therefore, the NRC has not modified the proposed provision in the final rule.

Comments: One commenter addressed § 26.119(a) and asked why a medical doctor who conducts the "shy bladder" evaluation on a donor must be acceptable to the MRO [Todd Newkirk, IBEW].

NRC Response: The NRC has retained the requirement that a licensed physician who evaluates the donor must be acceptable to the MRO in the final rule's § 26.119(a). This is necessary to ensure that the physician is qualified because not all physicians may have the requisite expertise specific to this particular medical condition. MROs will be qualified to assess the expertise of other physicians as a result of the training required to obtain certification under § 26.183(a) of the final rule.

Comments: One commenter addressed proposed § 26.119 and stated that the NRC should consider the use of alternate specimen testing in situations where a donor fails to provide the minimum quantity of urine necessary for specimen testing within the permitted 3-hour time limit. The commenter suggested that alternate specimen testing be considered an option for "shy bladder" situations, given that proposed § 26.31(d)(5) allowed for alternate specimen testing if an MRO determines that a donor has a medical condition that precludes urine drug testing [Todd Newkirk, IBEW].

NRC Response: The NRC agrees in part with the commenter's request. Testing alternate specimens may be necessary in "shy bladder" situations. However, it is imperative that a valid medical condition is confirmed and that only the MRO has the authority to order alternate testing. The NRC disagrees that using an alternate specimen for testing in these situations should be a standard procedure to be routinely implemented by specimen collectors. The MRO must be involved in making or reviewing the medical diagnosis, determining the specimens that are to be collected and tested based on the most recent information available about the accuracy and sensitivity of testing methods for alternate specimens, and directing how the collection and testing procedures must be performed. The MRO's involvement in this process is necessary to ensure that testing of alternate specimens will provide valid and legally defensible results. Section 26.31(d)(5) of the final rule addresses circumstances when it may be impossible or inadvisable to perform urine drug testing on an individual and permits alternative specimen collection and evaluation procedures for rare instances when it would be difficult or hazardous to the donor to collect breath, oral fluids, or urine specimens. This paragraph makes clear that only the MRO is permitted to authorize an alternative evaluation procedure, which

may include, but is not limited to, blood testing for alcohol. Therefore, the NRC has not modified the proposed provision in the final rule.

8. SUBPART F: LICENSEE TESTING FACILITIES

This section provides the NRC's responses to public comments on the proposed rule's Subpart F. That subpart contained the requirements licensee and other entity testing facilities would have to meet in conducting initial validity and drug testing. In particular, it specified proposed requirements for the facility and facility personnel and detailed the general procedures such facilities would be required to follow during specimen receipt, testing, storage, and shipping or disposal to ensure security and preservation. It also listed specific cutoff levels for both initial specimen validity tests and for drug tests and provided detailed requirements for quality assurance of testing technologies and the testing process.

8.1 Purpose (§26.121)

No comments addressed this section.

8.2 Testing Facility Capabilities (§ 26.123)

Comments: One commenter suggested that each licensee testing facility be required to meet the Initial Instrumented Testing Facility (IITF) specifications described in the proposed revisions to the HHS Guidelines (69 FR 19672) [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's suggestion. The proposed revisions to the HHS Guidelines had not been finalized to allow for consideration during the completion of this rulemaking effort and may be revised. The NRC will review the provisions regarding Initial Instrumented Testing Facility specifications once the finalized HHS Guidelines have been published and determine if additional revisions to Part 26 may be warranted at that time.

8.3 Licensee Testing Facility Personnel (§ 26.125)

Comments: Two commenters objected to the proposed elimination of the requirement that licensee testing facilities retain records on color blindness testing of their laboratory personnel. The commenters stated that because some non-instrumented validity tests require testing personnel to evaluate the color of the assay to determine the result, color blindness testing is necessary to ensure laboratory technician competency [Sue Brown, Individual; Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenters and has revised § 26.125(c) in the final rule to require that licensee testing facilities retain color blindness test results for laboratory testing personnel conducting specimen validity testing. The ability of laboratory personnel to identify the color of test results is a necessary job requirement.

8.4 Procedures (§ 26.127)

Comments: One commenter, supported by many others, affirmed that proposed § 26.127(b), which specified what chain-of-custody procedures must describe, would ensure that licensees and other entities take appropriate corrective actions if an issue is identified with the chain of

custody for any specimen [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The comment does not require a response.

Comments: One commenter requested that proposed § 26.127(b) be revised to specify the required actions that must be taken if the chain of custody for a specimen is "broken" [Todd Newkirk, IBEW]

NRC Response: The NRC has revised proposed § 26.129(b) in the final rule to include a description of the required actions to be taken by a licensee testing facility if testing facility personnel believe the integrity or identity of a specimen is in question (as a result of tampering or discrepancies between the information on the specimen bottle and on the accompanying custody-and-control forms that cannot be resolved). The provisions also describe procedures to address instances where either the Bottle A or Bottle B specimen leaks in transport from the collection site to the testing facility. Further, the revisions to § 26.129(b) include specific circumstances that would require the cancellation of the testing of a donor's urine specimen. These revisions are consistent with the U.S. DOT's requirements.

8.5 Assuring Specimen Security, Chain of Custody, and Preservation (§ 26.129)

Licensee Testing Facility Security

Comments: One commenter, supported by many others, affirmed the adequacy of the proposed security requirements for licensee testing facilities [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The comment does not require a response.

Comments: One commenter requested that proposed § 26.129(a) be revised to specify the personnel who must maintain the security of licensee testing facilities and what actions must be taken if facility security is determined to be compromised [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the request. The NRC believes that the § 26.129(a) requirements are adequate to protect the security of a licensee testing facility. Adding greater specificity with respect to personnel and actions would unnecessarily limit licensees' and other entities' flexibility. Testing facility staffing and physical and operational characteristics vary substantially among licensees and other entities. This variability makes it impractical for the NRC to devise specific language that would be appropriate at all testing facilities. Therefore, the NRC is permitting each licensee and other entity to determine the personnel who must

maintain the security of licensee testing facilities and the actions to be taken if facility security is determined to be compromised.

Specimen Integrity

Comments: One commenter, supported by many others, supported the proposed § 26.129(b) requirements for licensee testing facility inspection of urine sample packages for tampering and comparison of information on specimen containers with information on custody-and-control forms [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The comment does not require a response.

Comments: One commenter suggested that proposed § 26.129(b) be revised to state that a specimen "must not be tested if the integrity or identity" is in question, instead of the proposed wording that a specimen "may not be tested if the integrity or identity" of a specimen is in question [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter's request. The term "may not" in this provision (and wherever it appears in the rule) indicates a prohibition. Therefore, the NRC has not modified § 26.129(b) in the final rule.

Correcting Custody-and-Control Form Errors

Comments: One commenter suggested that proposed § 26.129(b) be revised to stipulate that, when attempting to resolve any discrepancies with information entered on the specimen custody-and-control form, licensee testing facility personnel should attempt to obtain a "memorandum for the record" from the specimen collector instead of making any corrections to the original custody-and-control form. The commenter stated that obtaining a memorandum for the record is a forensically acceptable means to correct discrepancies found on a custody-and-control form while permitting a collector to modify the original custody-and-control form is not [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter. Corrections to the original custody-and-control form should be made only by the collector during the specimen collection process and in the presence of the donor. Once the donor leaves the collection site, any errors identified on the custody-and-control form must be corrected using a memorandum for the record and not on the original custody-and-control form. Therefore, the NRC has revised proposed § 26.129(b) in the final rule to include a description of the process for obtaining a memorandum for the record from the collector to correct any custody-and-control form errors identified after the specimen collection process has been completed and the donor has departed from the collection site.

Other Appropriate Methods to Track Aliquot Custody and Control

Comments: One commenter objected to the provision in proposed § 26.129(c) permitting

licensee testing facilities to use "other appropriate methods of tracking aliquot custody and control." The commenter stated that HHS has always required written documentation on a chain-of-custody form to track specimens and aliquots in certified laboratories. The commenter noted that although bar coding is an effective tracking method used in HHS-certified laboratories, a bar code list generated by a tracking device or instrument is always associated with a custody-and-control form that documents the personnel handling each specimen or aliquot. The commenter stated that written documentation ensures the security of each specimen and aliquot during the testing process [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. The NRC is not aware of any instances where the custody and control of a specimen has been jeopardized or called into question as a result of the specimen tracking methods used by a licensee testing facility. Therefore, the NRC has not modified the proposed provision in the final rule.

Bottle B Retention Location

Comments: One commenter addressed proposed § 26.129(f) and recommended that for split specimen collections both Bottles A and B should be maintained together at all times and that both bottles should be sent to the HHS-certified laboratory if Bottle A has any non-negative test result. The commenter suggested that keeping both bottles together would reduce the possibility that a specimen could be lost and would improve the timeliness in testing Bottle B [Charles LoDico, Individual]. Another commenter noted that the proposed provision would create a cumbersome requirement because the licensee testing facility must maintain proper custody and control for Bottle A and Bottle B separately. In addition, the licensee testing facility must ensure that Bottle B is moved from refrigeration to frozen storage, or discarded. The commenter suggested that the probability that an error could occur with the custody-and-control documentation would increase given the number of times Bottle B could be moved at the licensee testing facility [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenters. The NRC is not aware of any instances where the custody and control of a Bottle B specimen has come into question or a Bottle B specimen has been lost in an attempt to maintain the specimen at a licensee testing facility. Licensee testing facilities have successfully maintained Bottle B specimens and industry experience fails to provide evidence that current practices have been unsuccessful in securing and storing specimens. Therefore, the NRC has not modified § 26.129(f) in the final rule. However, nothing in the rule prohibits licesees and other entities from forwarding the Bottle B specimen to the HHS-certified laboratory for retention.

Emergency Backup Power

Comments: One commenter addressed proposed § 26.129(f) and disagreed with the NRC's decision not to require each licensee testing facility to have emergency power equipment available in case of a prolonged power failure. The commenter stated that emergency power equipment is necessary to maintain specimens in long-term frozen storage if a licensee testing facility is permitted to retain specimens rather than transferring them to an HHS-certified laboratory [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.135(c) in the final rule to require that licensee testing facilities electing to retain Bottle B specimens at the testing

facility rather than forwarding the specimens to an HHS-certified laboratory with Bottle A must ensure that proper storage conditions are maintained (i.e., specimens stored at a temperature of -20° Celcius or less) in the event of a prolonged power failure.

Location of Original Custody-and-Control Form

Comments: One commenter stated that the proposed § 26.129(g) requirement that a licensee testing facility must send the original custody-and-control form with the Bottle A specimen to the HHS-certified laboratory leaves the specimen in Bottle B maintained at the licensee testing facility without the original custody-and-control form. The commenter noted that the proposed procedure was not consistent with the HHS Guidelines which require the original custody-and-control form to be maintained with the specimen Bottle A, and if the specimen in Bottle B is to be sent to a second HHS-certified laboratory, a copy of the original custody-and-control form is to be sent. The commenter recommended both Bottle A and Bottle B be sent to the HHS-certified laboratory instead of maintaining Bottle B at the licensee testing facility [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. The NRC is not aware of any instances where the custody and control of a specimen has been jeopardized or called into question as a result of the specimen tracking procedures currently used by licensee testing facilities. Therefore, the NRC has not modified the proposed provision in the final rule.

8.6 Cutoff Levels for Validity Screening and Initial Validity Tests (§ 26.131)

Validity Testing at Licensee Testing Facility if Sending All Specimens to HHS-certified Laboratory?

Comments: One commenter asked if proposed § 26.131 required validity testing to be conducted at a licensee testing facility even if the licensee does not conduct immunoassay drug screening onsite at a licensee testing facility (i.e., the FFD program sends all specimens to an HHS-certified laboratory for testing) [Anonymous #15].

NRC Response: A licensee or other entity may choose to send all urine specimens to an HHS-certified laboratory for all required testing (i.e., validity and drug testing) under Part 26 rather than operate a licensee testing facility. If a licensee or other entity does not operate a licensee testing facility, then onsite validity testing in not required.

Conducting Initial Validity and Validity Screening Testing

Comments: One commenter addressed proposed § 26.131(a) and requested the NRC to clarify whether initial validity testing must be conducted if a licensee testing facility conducts validity screening tests [Susan Techau, Exelon].

NRC Response: The NRC does not intend to require licensee testing facilities to perform initial validity testing if they the use validity screening tests. Section 26.131(a) of the final rule requires that all validity test results from licensee testing facilities must be based on performing either a validity screening test or an initial validity test, or both, on one or more aliquots of a

urine specimen. In other words, a licensee testing facility may conduct either a validity screening test or an initial validity test on each specimen. The NRC is also permitting licensee testing facilities to perform validity screening testing first and then initial validity testing on specimens that yield questionable validity test results from validity screening tests, at their discretion. Either validity screening or initial validity testing will accomplish the NRC's objective of identifying specimens of questionable validity that must be transferred to an HHS-certified laboratory for additional testing. Therefore, the agency is permitting licensees and other entities to choose which of these validity testing procedures, or a combination of procedures, they will implement at a licensee testing facility.

Conduct Validity Testing at Collection Site as Soon a Specimen is Received

Comments: One commenter suggested that proposed § 26.131(b) be revised to require that specimen validity testing be performed at the collection site as soon as the donor presents a urine specimen to the collector and before the donor leaves the collection site. The commenter stated that immediate validity testing of a specimen would protect the donor from being accused of attempting to subvert the testing process and would also allow for an immediate observed second collection if the initial specimen did not pass the validity test [Todd Newkirk, IBEW]

NRC Response: The NRC disagrees with the commenter's suggestion. The NRC believes that licensees or other entities must conduct all specimen testing at a licensee testing facility and/or at an HHS-certified laboratory. Specimen collectors do not have the appropriate level of training to use validity screening tests. Therefore, the NRC has not modified the proposed provision in the final rule.

Use of the Term "Cutoff Levels"

Comments: One commenter suggested revising proposed § 26.131 by replacing the term "cutoff levels" with "decision points" for validity screening and initial validity testing because validity testing is based on decision points and not cutoff levels [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's specific request. The term "cutoff levels" is consistent with testing terminology familiar to licensees and other entities subject to Part 26. To maintain consistency with terminology used by its stakeholders, the NRC has decided not to modify the proposed provision in the final rule. However, the NRC has revised the definition of "cutoff level" in § 26.5 in the final rule to address the commenter's concern. The definition of "cutoff level" has been revised to mean "the concentration or decision criteria established for designating and reporting a test result as positive, of questionable validity (referring to validity screening or initial validity test results from a licensee testing facility), or adulterated, substitute, dilute, or invalid (referring to initial or confirmatory test results from an HHS-certified laboratory)."

Use of the Term "Non-Negative"

Comments: One commenter stated that use of the term "non-negative" in proposed § 26.131(a) to describe some validity screening and initial validity test results was inaccurate. Instead of "non-negative," the commenter recommended using "presumptive adulterated, substituted, or invalid" for validity screening and initial validity test result reporting [Sue Brown, Individual].

NRC Response: The NRC agrees in part with the commenter's request. Throughout the final rule, the NRC has replaced the term "non-negative test result" with a new term to address validity screening and initial validity test results from a licensee testing facility that indicate that a specimen may be adulterated, substitute, dilute, or invalid. The new term is "questionable validity." (The NRC has chosen this term, rather than a term that would directly reference possible adulteration, substitution, dilution, or an invalid specimen, because licensee testing facilities will not be conducting the specific gravity testing that is required to establish these specimen characteristics.) The NRC has defined "questionable validity" in § 26.5 of the final rule. Adding the term "questionable validity" addresses the commenter's concern and improves the clarity of the language used in the final rule.

Validity Screening Testing

Comments: One commenter addressed proposed § 26.131(a) and stated that licensee testing facilities are capable of performing only validity screening testing. The commenter asserted that validity screening tests usually do not have the same sensitivity as initial validity tests and therefore could not meet the cutoff levels listed in proposed § 26.131(b). The same commenter also stated that validity screening tests, at a minimum, should meet the cutoff criteria for an "invalid" specimen in the HHS Guidelines. [Sue Brown, Individual]

NRC Response: The NRC disagrees that licensee testing facilities should be authorized to perform only validity screening tests and is continuing to permit initial validity testing at licensee testing facilities. However, the NRC agrees that validity screening tests must be able to meet the invalid specimen criteria in the HHS Guidelines. The NRC has revised the specimen criteria for pH and nitrite concentration in the final rule to identify potentially invalid specimens, consistent with the HHS Guidelines, as specimens with a pH less than 4.5 or a nitrite concentration equal to or greater than 200 mcg/mL. The provisions accounting for invalid specimens have been included in § 26.131(b)(2) and (b)(3) of the final rule.

Required Tests for Validity Screening Testing

Comments: One commenter addressed proposed § 26.131(b) and asked if a licensee testing facility could meet the validity screening testing requirements by only conducting instrumented specimen testing for pH and creatinine [Anonymous #15].

NRC Response: A licensee testing facility will not meet the validity screening testing requirements if each urine specimen is tested only for pH and creatinine. Section 26.131(b) of the final rule requires licensee testing facilities to test each urine specimen for creatinine, pH, and one or more oxidizing adulterants.

Specific Gravity Testing at Licensee Testing Facilities

Comments: One commenter noted that proposed § 26.131(b) did not include requirements for specific gravity testing at a licensee testing facility. The commenter stated that the HHS Guidelines require specific gravity testing for any specimen with a creatinine concentration less that 20 mg/dL. The commenter further added that, because specific gravity testing is not currently permitted at licensee testing facilities, the NRC has not properly defined specimen dilution and substitution criteria, which both require specific gravity test results [Charles LoDico, Individual].

NRC Response: In contrast to the HHS Guidelines requirements for initial validity testing, the final rule does not require licensee testing facilities to test specimens' specific gravity. Instead, § 26.131(b) of the final rule requires licensee testing facilities to forward specimens having a creatinine concentration of less than 20 mg/dL to the HHS-certified laboratory which will measure these specimens' specific gravity. The NRC has chosen this course because of the high costs of refractometers, the instruments that the HHS Guidelines require for measuring specimens' specific gravity. Although some licensee testing facilities are currently measuring specific gravity, the new HHS Guidelines specific gravity cutoff levels require more sensitive measurement than those licensee testing facilities are currently capable of doing. They would have to purchase new equipment to meet these new cutoff levels. Rather than require licensees to incur the resulting expense, the final rule does not require licensee testing facilities to test specimens' specific gravity nor does it include cutoff levels for specific gravity or quality control requirements for measuring specific gravity.

Licensee Testing Facilities Reporting Negative and Dilute Specimen Result

Comments: One commenter addressed proposed § 26.131(b)(1) and asked if a licensee testing facility would be permitted to report a specimen as negative and dilute. The commenter noted that, if a licensee testing facility were permitted to report a specimen as negative and dilute, the facility would have to perform an initial creatinine test with a calibrator at 2.0 mg/dL, and perform a specific gravity test, using a 3-place refractometer. The licensee testing facility would then forward any specimen with a creatinine less than 5.0 mg/dL to an HHS-certified laboratory for additional testing. The commenter also noted that for a licensee testing facility that performs only validity screening testing for creatinine, all specimens with a creatinine concentration less than 20 mg/dL must be forwarded to an HHS-certified laboratory for further testing [Sue Brown, Individual].

NRC Response: Section 26.131(b) in the final rule does not require licensee testing facilities to conduct specific gravity testing. Therefore, licensee testing facilities are not permitted to report a specimen as negative and dilute. The NRC agrees that any specimen that is determined by a licensee testing facility to have a creatinine concentration less than 20 mg/dL as a result of either validity screening testing and/or initial validity testing must be forwarded to an HHS-certified laboratory for further testing under the final rule.

Specimen pH Testing Levels

Comments: One commenter addressed proposed § 26.131(b)(2)(i) and stated that the proposed specimen pH criteria did not account for specimens meeting the "invalid" criteria specified in the HHS Guidelines. The commenter recommended revising the provision to account for invalid specimen criteria from "pH less than 3" to "pH less than 4.5." This change would provide decision points for both presumptive invalid and adulterated specimens that would require additional specimen testing at an HHS-certified laboratory [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.131(b)(2) in the final rule to read "pH less than 4.5" to be consistent with Section 2.4(h)(7)(ii) in the HHS Guidelines.

Specimen Validity Testing - pH Range

Comments: One commenter suggested that proposed § 26.131(b)(2) be revised by changing "Using either a colorimetric pH test or pH meter" to read "Using either a colorimetric pH test with a dynamic range of 2 to 12 or pH meter." The commenter asserted that the change to include the dynamic pH range is necessary to identify invalid specimens (as defined in the HHS Guidelines as a specimen with pH greater than or equal to 3 and less than 4.5, or greater than or equal to 9 and less than 11). The commenter stated that the recommended change would be necessary only if NRC did not revise § 26.131(b)(2)(i) to read "pH less than 4.5" [Sue Brown, Individual].

NRC Response: Because the NRC has revised § 26.131(b)(2) in the final rule to read "pH less than 4.5," the comment does not require a response.

Specimen Validity Testing - Nitrite Concentration

Comments: One commenter stated that the proposed nitrite concentration of "equal to or greater than 500 mcg/mL" in proposed § 26.131(b)(3) would not identify invalid specimens. Specifically, the commenter referenced the criteria in the HHS Guidelines that identify a specimen as possibly invalid when the specimen has a nitrite concentration "greater than or equal to 200 mcg/mL but less than 500 mcg/mL." The commenter suggested revising the proposed nitrite concentration to be equal to or greater than 200 mcg/mL so that invalid specimens would be detected [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised the nitrite concentration in § 26.131(b)(3) in the final rule to read "nitrite or other oxidant concentration equal to or greater than 200 mcg/mL." This change incorporates the invalid specimen criteria in Section 2.4(h)(7)(iii) of the HHS Guidelines to ensure that potentially invalid specimens are detected through validity screening tests and/or initial validity testing at a licensee testing facility.

Specimen Validity Testing - Nitrite Concentration General Oxidant Colorimetric Test

Comments: One commenter suggested that the reference to the "general oxidant colorimetric test" in proposed § 26.131(b)(3) be revised to include an additional reference that the test must have a "cutoff equal to or greater than 200 mcg/mL nitrite-equivalents." The commenter thought that the additional information would emphasize that the general oxidant test must be calibrated with a 200 mcg/mL nitrite solution in order to ensure that the test could identify invalid specimens [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.131(b)(3) in the final rule to state that the general oxidant colorimetric test must have a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents. The revision improves consistency with the HHS Guidelines to ensure that potentially invalid specimens are detected through validity screening tests and/or initial validity at a licensee testing facility.

Specimen Validity Testing - Presence of Chromium (VI)

Comments: One commenter suggested that "Presence of chromium (VI) is indicated" in proposed § 26.131(b)(4) be revised to read "The possible presence of chromium (VI) is

determined using...." The commenter recommended the change because neither the general oxidant colorimetric test nor the chromium (VI) colorimetric test is the confirmatory test for the presence of chromium (VI). The commenter also noted that the recommended change would be consistent with the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.131(b)(4) in the final rule to improve the accuracy of the language used in the final rule and its consistency with the HHS Guidelines.

Specimen Validity Testing - Halogen Adulterants

Comments: One commenter suggested that "Presence of halogen...indicated" in proposed § 26.131(b)(5) be revised to read "The possible presence of halogen (e.g., bleach, iodide, fluoride) is determined using . . ." The commenter recommended the change because neither the general oxidant colorimetric test nor the halogen colorimetric test is the confirmatory test for the presence of halogen. The commenter noted that the suggested change is consistent with the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.131(b)(5) in the final rule to improve the accuracy of the language used in the final rule and its consistency with the HHS Guidelines.

Specimen Validity Testing - Halogen Adulterants, Additional Test

Comments: One commenter suggested that NRC consider adding the odor of the specimen as an additional criterion to evaluate a specimen for the possible presence of halogen. The commenter noted that the suggested revision would be consistent with criteria used in the HHS Guidelines to detect the possible presence of halogen [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and revised § 26.131(b)(5) in the final rule to add the suggested method to evaluate the possible presence of halogen. The final rule's § 26.131(b)(5) now includes a statement that the possible presence of halogen can be determined using the "odor of the specimen as the initial test." Including specimen odor as a method to detect the possible presence of halogen is consistent with Section 2.4(h)(7)(v) of the HHS Guidelines.

Validity Testing Criteria for Adulterants, Glutaraldehyde

Comments: One commenter suggested replacing "Presence of glutaraldehyde is indicated" in proposed § 26.131(b)(6) with the phrase "The possible presence of glutaraldehyde is determined using...." The commenter noted that neither the aldehyde test nor the characteristic immunoassay response is the confirmatory test for the presence of glutaraldehyde. The commented noted that the suggested change would be consistent with wording in the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.131(b)(6) in the final rule to improve the accuracy of the language used in the final rule and its consistency with the HHS Guidelines.

Validity Testing Criteria for Adulterants, Oxidants

Comments: One commenter suggested revising proposed § 26.131(b)(7) to be consistent with the related provision in the HHS Guidelines. Specifically, the commenter stated that the general oxidant colorimetric test and the chromium (VI) colorimetric test can detect only the possible presence of an oxidizing adulterant and cannot specifically identify pyridine as suggested by the proposed requirement [Sue Brown, Individual].

NRC Response: The NRC agrees in part with the commenter's request. The NRC has consolidated proposed § 26.131(b)(4) and (b)(7) in § 26.131(b)(4) of the final rule, given that both provisions in the proposed rule use the same general oxidant colorimetric test and chromium (VI) colorimetric test to detect the possible presence of an oxidizing adulterant.

Validity Testing Criteria for Adulterants, Surfactants

Comments: One commenter stated that proposed § 26.131(b)(8) incorrectly identified the surfactant colorimetric test as the confirmatory test for surfactant. The commenter also asserted that using the wording "presence of surfactant is indicated" in the proposed rule text implied that the colorimetric test can identify surfactant, which it cannot. The commenter requested that this proposed paragraph be revised to state the "possible presence of surfactant is determined...." In addition, the commenter requested that the final rule be revised to include a "foam/shake test" as an additional method to identify the possible presence of surfactant and noted that the HHS Guidelines permit a "foam/shake test" to identify possible invalid specimens that result from surfactant [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's requests. Section 26.131(b)(7) in the final rule states, "The possible presence of surfactant is determined by using. . ." It also includes the "foam/shake test" as an additional method to identify the possible presence of surfactant. Including this additional test is consistent with Section 2.5(h)(7)(viii) of the HHS Guidelines.

Validity Testing Criteria, Specimen Shows Signs of Adulterants

Comments: One commenter suggested that the phrase "on separate aliquots" in proposed § 26.131(b)(9)(iii) be revised to read "on two separate aliquots." The commenter noted that the suggested change would be consistent with the HHS Guidelines which require testing of two separate aliquots to demonstrate the inability to obtain a valid immunoassay drug test result and for a specimen to be considered possibly an invalid specimen [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.131(b)(9)(iii) (§ 26.131(b)(9) in the final rule) to clarify the intent of the provision and improve the consistency of the final rule with the HHS Guidelines.

8.7 Cutoff Levels for Drugs and Drug Metabolites (§ 26.133)

No comments addressed this section.

8.8 Split Specimens (§ 26.135)

Specimen Retention at the Licensee Testing Facility

Comments: One commenter addressed proposed § 26.135(a) and suggested that the licensee testing facility should be required to forward both Bottle A and Bottle B from split specimen collections to an HHS-certified laboratory for any specimen that yields a non-negative test result from testing at a licensee testing facility. The commenter stated that the proposed system appeared cumbersome and open to possible errors at the licensee testing facility that might affect the security and integrity of a specimen in Bottle B. The commenter suggested that HHS-certified laboratories currently have processes in place to ensure the security and integrity of specimens in Bottles A and B [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. The NRC is unaware of instances that demonstrate that the security and integrity of a specimen has been affected by licensee testing facilities maintaining Bottle B onsite, while Bottle A is sent to an HHS-certified laboratory for further testing. Therefore, the NRC has not modified the proposed provision in the final rule.

Support for the Proposed Provision

Comments: One commenter, supported by many other commenters, stated that the industry supported the provision in proposed § 26.135(b) giving the donor the opportunity to request that the split specimen in Bottle B be tested by another HHS-certified laboratory after the first HHS-certified laboratory has reported that the donor's specimen yielded a non-negative test [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The comment does not require a response.

Written Request for Bottle B Specimen

Comments: One commenter stated that the proposed § 26.135(b) requirement that a donor must submit a written request to the MRO to direct Bottle B specimen testing at a second HHS-certified laboratory was inconsistent with the HHS Guidelines. Specifically, the commenter noted that the HHS Guidelines do not prescribe any specific method of notification for the donor to direct the MRO to contact the HHS-certified laboratory to request that the donor's Bottle B specimen be sent for testing at another HHS-certified laboratory [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has eliminated the proposed requirement that a donor must provide a written request to the MRO to direct the retesting of an aliquot of a single specimen or the testing of the Bottle B specimen at a second HHS-certified laboratory. Section 26.165(b) in the final rule provides a donor with more flexibility in communicating with the MRO. The NRC modeled the revised provisions on the U.S. DOT's requirements in 49 CFR 40.171(a) and related provisions in the HHS Guidelines to increase the consistency of Part 26 with other Federally mandated workplace drug testing programs.

MRO Instructions to Donor for Bottle B Specimen Testing

Comments: One commenter suggested that proposed § 26.135(b) be revised to require the MRO to provide each donor with an instruction form to use to request Bottle B specimen testing. The same commenter also requested that the rule specify whether the 3 business day limit could be met with a postmark date or if the written request must be received by the MRO within 3 business days [Todd Newkirk, IBEW].

NRC Response: The NRC agrees in part with the commenter's requests and has revised proposed § 26.165(b)(2) in the final rule to require the MRO to provide the donor with specific instructions for requesting a retest of an aliquot of a single specimen or the testing of the Bottle B specimen. It also stipulates that the request, whether written or oral, must be received by the MRO within 3 business days. The revised provision is based on the U.S. DOT's drug testing regulations in 49 CFR 40.171 and therefore enhances the consistency of Part 26 with advances in other relevant Federal rules and guidelines. However, the NRC has not revised proposed § 26.165(b)(2) in the final rule to address postmarking or receipt of a written request by the MRO because the final rule no longer requires a written request, as discussed with respect to the previous comment on this section.

Other Parties Requesting Bottle B Specimen Testing

Comments: One commenter stated that the proposed § 26.135(b) requirement to prohibit any entity (e.g., licensee, MRO, NRC) from ordering the testing of a Bottle B specimen without a donor's written permission conflicted with Section 2.6(e)(4) of the HHS Guidelines. The HHS Guidelines permit a Federal agency to have a single or split (Bottle B) specimen retested "as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result." The commenter recommended that NRC should include the HHS Guideline provision [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's recommendation. The NRC intentionally diverged from the HHS Guidelines when former Part 26 was first published by permitting split specimen procedures, which the HHS Guidelines did not permit at the time. The NRC's intent when permitting, but not requiring, split specimen procedures was to enhance donors' confidence in the drug testing process imposed by the rule and provide one means for donors to defend against possible administrative and/or methodological errors in testing the specimen in Bottle A, if a licensee or other entity chose to implement split specimen procedures. The NRC's experience has been that its objectives of detecting and deterring substance abuse can be met with testing a single specimen, but it has permitted split specimen procedures solely for the potential benefits to donors, who are private citizens under Part 26 by contrast to the Federal employees who are subject to testing under the HHS Guidelines and may have a reduced expectation of privacy. The NRC is concerned that permitting testing of the specimen in Bottle B of a split specimen or retesting of a single specimen without the donor's permission in order to defend against a donor's legal or administrative challenge to a drug test result would decrease donors' confidence in the FFD program. In addition, this testing or retesting would also conflict with the principle embodied in § 26.31(d)(6) of the final rule that the donor must retain control over his or her biological specimens for privacy reasons. Section 26.185(l) of the final rule continues to permit an MRO to order retesting an aliquot of a single specimen or testing of the specimen in Bottle B if he or she questions the accuracy and scientific validity of a test result and believes that this additional testing will aid him or her in determining whether the

donor has violated the FFD policy. The NRC believes that permitting the MRO to order this testing or retesting is necessary to meet the rule's objective to improve the effectiveness and efficiency of FFD programs. However, permitting testing of the specimen in Bottle B or retesting of a single specimen for other purposes without the donor's permission would conflict with the NRC's intent for permitting split specimen procedures. Therefore, the NRC has not made these revisions in the final rule.

Three-Business-Day Requirement to Request Testing of Bottle B

Comments: One commenter, supported by many others, stated that industry experience suggests that the 3-business-day time limit for a donor to request Bottle B testing in proposed § 26.135(b) was adequate, given that donors typically request Bottle B specimen testing on the same day as the MRO notification of a positive test result [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy]. However, another commenter disagreed with the 3-business-day time limit and suggested 10 business days instead. The commenter stated that some shift workers may have difficulty meeting the 3-business-day time limit [Todd Newkirk, IBEW].

NRC Response: The NRC believes that the 3-business-day time limit provides a donor with sufficient time to direct the MRO to request the retesting of single specimen or the testing of the Bottle B specimen. In addition, this time limit provides more flexibility than permitted in Section 2.6(e)(2) of the HHS Guidelines which provides a donor with only 72 hours (i.e., 3 calendar days) to request Bottle B testing after being notified by the MRO of a positive, adulterated, or substitute test result. Therefore, the NRC has not modified the proposed provision in the final rule.

Emergency Backup Power for Long-Term, Frozen Storage of Specimens

Comments: One commenter recommended that proposed § 26.135(c) be revised to require that licensee testing facilities maintain emergency backup power to ensure that specimens in long-term, frozen storage remain at the required temperature during power outages [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and added this requirement to § 26.135(c) in the final rule. Licensee testing facilities must provide emergency backup power to ensure that Bottle B specimens that have been retained by the licensee testing facility and placed in long-term frozen storage remain at the required temperature during power outages. This provision is consistent with former Section 2.7(c) in Appendix A to 10 CFR Part 26 which required a licensee testing facility to have emergency power equipment available in case of a prolonged power failure.

8.9 Quality Assurance and Quality Control (§ 26.137)

Comments: One commenter noted that proposed § 26.137 did not require a licensee testing facility to conduct quality assurance testing on performance testing samples [Sue Brown, Individual].

NRC Response: The NRC is not aware of any problems related to the quality control and performance testing samples used by licensee testing facilities and, at this time, does not believe there is a need to require quality assurance testing of performance testing samples by licensee testing facilities. The quality control provisions included in § 26.137 of the final rule will effectively identify any testing issues related to performance testing samples.

8.9.1 Quality Assurance Program (§ 26.137(a))

No comments addressed this section.

8.9.2 Performance Testing and Quality Control Requirements for Specimen Validity Testing (§ 26.137(b))

FDA Cleared Point-of-Collection Tests

Comments: One commenter addressed proposed § 26.137(b)(1)(i) and stated that a drug point-of-collection tests (POCT) is a "device" in FDA terminology and approved by the FDA while a specimen validity POCT is not required to be cleared by the FDA and should not be referred to as a "device." The commenter suggested that NRC delete this proposed requirement [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has eliminated the requirement for FDA approval of a specimen validity POCT from § 26.137(b)(1)(i) in the final rule. The NRC also agrees with the commenter's request to eliminate the use of the term "device" with respect to validity screening tests given the specific connotation of the use of the term with FDA approval of tests.

Drug and Validity Point-of-Collection Testing Requirements

Comments: One commenter addressed proposed § 26.137(b) and stated that proposed amendments to the HHS Guidelines (April 13, 2004, FR19673-19732) included a new category of specimen drug and validity tests called point-of-collection tests (POCT) that differed from those proposed for validity testing by the NRC. Unlike proposed § 26.137(b), the proposed amendments to the HHS Guidelines did not separate the drug and specimen validity testing requirements. The proposed HHS Guidelines included quality assurance, device validation, annual validation, training and re-training of testers, provision for performance testing, provision for failures of the POCTs, and reporting of results. The commenter stated that it would be difficult to permit only the use of validity POCTs, as proposed by the NRC [Sue Brown, Individual].

NRC Response: The NRC was aware of the differences between the proposed Part 26 provisions and those published by HHS. However, the NRC is also aware that some specimen

validity tests now commercially available may meet the stringent quality assurance and performance testing requirements established in the final rule. Furthermore, the NRC is satisfied that licensees' and other entities' processes for ensuring that testing facility personnel are properly trained to conduct drug testing will be adequate when applied to training personnel to conduct validity screening tests. In response to this comment, the NRC has reviewed the provisions that addressed quality assurance, POCT validation, re-validation, training, performance testing, provisions for testing failures, and reporting results in the proposed amendments to the HHS Guidelines. On the basis of this review, the NRC has made several changes in the final rule to further strengthen the requirements related to validity screening tests in Part 26. The specific changes and their bases are discussed in Section VI of the *Federal Register* notice publishing the final rule.

Non-Instrumented Devices for Validity Screening Tests

Comments: One commenter addressed proposed § 26.137(b) and suggested that permitting licensee testing facilities to use only non-instrumented testing devices to perform validity screening tests would be unduly restrictive. The commenter stated that some instrumented tests can successfully meet the performance testing requirements for validity screening tests as described in proposed § 26.137(b). The commenter provided two examples of instrumented tests. The proposed § 26.137(b)(5) requirement for colorimetric pH tests that have a narrow dynamic range and do not support the 2-12 pH cutoffs can be met using an instrumented test (as most HHS-certified laboratories use for pH screening). The commenter also stated that the proposed requirement in § 26.137(b)(6) for a general oxidizing adulterant test or one or more specific oxidizing adulterant tests for validity screening can be performed using an instrumented test (as HHS-certified laboratories use for initial validity testing) [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter that some instrumented tests can meet the performance testing requirements for validity screening tests. Therefore, the NRC has revised the definition of "validity screening test" in § 26.5 of the final rule to include "a test that is instrumented to the extent that results are machine-read." The NRC has also eliminated the term "non-instrumented" from the discussion in § 26.137(b) of the final rule and instead simply references validity screening tests.

Eliminate Provision to Permit Licensee Testing Facilities to Use Specimen Validity POCTs

Comments: One commenter addressed proposed § 26.137(b) and suggested that the NRC reconsider permitting licensee testing facilities to use POCTs to conduct validity screening tests. Instead, the commenter suggested the NRC permit screening validity tests currently permitted in the HHS Guidelines. The commenter stated that licensee testing facilities would most likely follow the current HHS-certified laboratory practice for specimen validity testing (e.g., use of pH paper, dipstick tests for pH, dipstick tests for oxidants, dipstick tests for nitrite, and instrumented colorimetric pH tests with a narrow dynamic range) [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request. The NRC is permitting licensee testing facilities to use POCTs to conduct validity screening and/or initial validity testing. This provides licensee testing facilities with flexibility in conducting validity testing. However, the NRC has revised proposed § 26.137(b)(1)(i) and (b)(1)(ii) to require that licensee testing facilities use only validity screening tests that either have been placed on the SAMHSA

list of POCTs that are certified for use in the Federal Workplace Drug Testing Program as published in the *Federal Register*, or that meet § 26.137(b)(1)(ii) performance testing criteria.

Test Results for POCTs that Include Both Drug and Specimen Validity Tests on the Same Device

Comments: One commenter addressed proposed § 26.137(b) and identified a possible concern related to permitting licensee testing facilities to use POCTs to perform validity screening testing. Because many of the current POCTs available include both drug and specimen validity tests, the commenter asked what the licensee testing facility would do with drug tests results [Sue Brown, Individual].

NRC Response: Section 26.137(e) in the final rule prohibits licensees and other entities from taking management actions on the basis of any drug test results obtained from non-instrumented devices that may be used for validity screening tests. The NRC is aware that several non-instrumented devices are currently available that combine tests for the presence of drugs and drug metabolites in a urine specimen with tests for other attributes of a urine specimen, such as creatinine concentration. The final rule permits the use of such combination tests for validity screening. However, the drug testing capabilities of these tests are not yet sufficiently accurate and sensitive for Part 26 drug testing purposes. In the future the NRC may consider accepting the use of initial drug test results from non-instrumented tests if and when the HHS publishes a final revision to its Guidelines that establishes requirements for their use in Federal workplace drug testing programs. At this time, however, the final rule retains the former prohibition on licensee testing facilities using these tests for drug testing.

Validity Screening Testing - Specific Gravity

Comments: One commenter addressed proposed § 26.137(b) and suggested that NRC consider adding specific gravity testing using a three-place refractometer so that licensee testing facilities could report dilute specimens [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. The NRC is not requiring licensee testing facilities to conduct specific gravity testing on urine specimens for the reasons discussed in Section 8.6 of this document in response to a comment received on proposed § 26.131(b). Therefore, the NRC has not revised the proposed provision in the final rule.

Personnel Conducting Performance Testing of Specimen Validity Tests

Comments: One commenter suggested that proposed § 26.137(b)(1)(ii)(A) be revised to require that licensee testing facility personnel who use specimen validity devices be the ones to conduct performance testing of those devices. The commenter stated that HHS-certified laboratory personnel will not be using these types of devices and would therefore not be trained in the performance testing procedures [Sue Brown, Individual]. Another commenter stated that HHS-certified laboratories do not perform performance testing on non-instrumented validity testing devices [Charles LoDico, Individual].

NRC Response: The NRC agrees in part with the commenters. The NRC has added § 26.137(b)(1)(ii)(E) to the final rule to require that, if a validity screening test is not approved by the SAMHSA as a POCT, the licensee testing facility must submit three consecutive sets of

performance testing samples to the manufacturer, using performance testing samples that have been formulated to challenge the validity screening test around the applicable cutoffs specified in § 26.137. The NRC believes that the manufacturer of each validity screening test is the most appropriate entity to conduct initial performance testing before a licensee uses the test in a Part 26 testing program. These revised performance testing requirements will reduce the burden on licensees and other entities while ensuring that validity screening tests provide accurate and consistent test results.

SAMHSA Certified List for Validity Screening Devices

Comments: Two commenters addressed proposed § 26.137(b)(1)(i) and stated that the SAMHSA does not currently have a list of certified POCTs acceptable for validity screening testing for use in the Federal Workplace Drug Testing Program [Sue Brown, Individual; Charles LoDico, Individual]. One of the two commenters noted that although HHS has proposed guidelines (April 13, 2004, FR19673-19732) for the use of POCTs, the rule has yet to be finalized [Sue Brown, Individual].

NRC Response: The NRC is aware that the SAMHSA has yet to publish a list of approved POCTs and that the proposed HHS Guidelines are not yet finalized. The final rule's § 26.137(b)(i) references a SAMHSA list of certified POCTs so that licensee testing facilities may rely on that list when it becomes available. To enable licensee testing facilities to begin using validity screening tests before the SAMHSA publishes its list, the NRC has added § 26.137(b)(1)(ii) to the final rule which creates stringent validity screening test performance testing requirements. These requirements will both protect donors' interests in having accurate test results and provide licensee testing facilities with flexibility in conducing validity testing.

Clarify the Meaning of pH Tests that Have a Narrow Dynamic Range

Comments: One commenter requested that the NRC clarify the phrase in proposed § 26.137(b)(5) that stated "pH tests that have a narrow dynamic range and do not support the 2-12 pH cutoffs" [Charles LoDico, Individual].

NRC Response: The NRC agrees with this comment and has eliminated the proposed provision from the final rule. Instead, § 26.137(b)(1)(ii)(B) in the final rule clarifies that a pH specimen validity screening test must be able to determine if pH is less than 4.5 and if pH is equal to or greater than 9.

Initial Performance Testing of a POCT to Be Used for Specimen Validity Screening

Comments: One commenter stated that the proposed § 26.137(b)(1)(ii) requirement that a licensee or other entity ensure, before using a validity screening device for specimen testing, that the device effectively determines the validity of the specimen would be overly burdensome [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenters and has revised the performance testing provisions in § 26.137(b)(1)(ii) of the final rule to reduce the burden that the proposed rule would have imposed on licensees and other entities. This section as revised requires validity screening test manufacturers to demonstrate the performance characteristics of their tests. The NRC believes that the manufacturer is best qualified to demonstrate the

effectiveness of each test because the manufacturer, rather than a person with limited training at an HHS-certified laboratory, has the greatest knowledge of correct testing procedures. The final rule continues to require licensee testing facilities to challenge the validity screening tests they intend to use. It requires licensee testing facilities to submit three consecutive sets of performance test samples (6 samples in each round) to the manufacturer for performance testing rather than submitting to an HHS-certified laboratory at least one out of every 10 specimens that test negative using the non-instrumented validity screening device, as proposed § 26.137(b)(1) required. The revised requirement reduces the number of performance test samples that an FFD program must submit to meet the minimum performance testing requirements for creatinine, pH, and one oxidizing adulterant, while at the same time ensuring that the accuracy and sensitivity of the each validity screening test has been successfully evaluated. The revised requirements in the final rule will continue to ensure that validity screening tests used in Part 26 programs meet the NRC's objective of detecting specimens of questionable validity that require further testing at an HHS-certified laboratory.

Performance Testing of Validity Screening Tests - Nitrite

Comments: One commenter addressed proposed § 26.137(b)(1)(ii)(B) and asserted that a validity POCT for nitrite should be able to identify invalid specimens that have a nitrite concentration equal to or greater than 200 mcg/dL. In the commenter's view, the proposed requirement to validate a device with samples with nitrite concentrations in the range of 650 to 800 mcg/mL or 250 mcg/mL to 400 mcg/mL would not evaluate a device at the 200 mcg/mL cutoff [Sue Brown, Individual].

NRC Response: The NRC agrees that the nitrite concentrations specified in the proposed rule would not evaluate a validity screening device at the nitrite concentration that meets the HHS Guidelines criteria for an invalid specimen. Therefore, the proposed nitrite concentrations were contrary to the NRC's intent. Because the NRC has reorganized the performance testing and quality control requirements for validity screening tests in the final rule, § 26.137(b)(1)(ii)(E) in the final rule establishes requirements for nitrite performance testing samples and incorporates the commenter's suggestion. This provision of the final rule states that "The performance testing samples for oxidizing adulterants must contain nitrite and other oxidizing adulterant concentrations in a range of less than or equal to a 200 mcg/mL nitrite-equivalent cutoff to a 500 mcg/mL nitrite-equivalent cutoff..."

Performance Testing of Validity Screening Tests - Creatinine

Comments: One commenter addressed proposed § 26.137(b)(1)(ii)(B) and stated that validity screening POCTs will not be able to distinguish creatinine concentrations in the proposed ranges of 5-20 and 1-5 mg/dL. The commenter noted that a validity screening POCT, at best, would have a creatinine concentration cutoff of 20 mg/dL and should be able to distinguish between a sample with a creatinine concentration of 15 mg/dL from a sample with a creatinine concentration of 25 mg/dL [Sue Brown, Individual].

NRC Response: The NRC agrees that validity screening tests need only measure the concentration of creatinine in a specimen to a cutoff of 20 mg/dL. In addition, because the final rule requires licensee testing facilities to send any specimen with a creatinine concentration less than 20 mg/dL to an HHS-certified laboratory for further testing, creatinine testing specificity beyond the 20 mg/dL cutoff is unnecessary. Therefore, the NRC has revised the proposed

provision to require that a validity screening test must be able to distinguish the creatinine concentration of a specimen at a 20 mg/dL cutoff. Because the NRC has reorganized the proposed performance testing and quality control requirements for validity screening tests, this requirement appears in § 26.137(b)(1)(ii)(A) of the final rule.

Reconsider the Use of Non-Instrumented Validity Screening Tests

Comments: One commenter referenced proposed § 26.137(b)(1)(iii) and requested that the NRC reconsider permitting the use of non-instrumented validity testing devices given that the current SAMHSA Federal Workplace Drug Testing Program does not have any rules or regulations permitting the use of non-instrumented validity screening tests [Charles LoDico, Individual].

NRC Response: The NRC is aware that the SAMHSA has not yet published a list of certified POCTs. However, when it publishes such a list, the SAMHSA will require that a POCT to meet the same or very similar performance testing requirements as those contained in § 26.137(b)(1)(ii) of the final rule. Incorporating these performance testing requirements in the rule now permits licensee testing facilities to conduct the required performance testing and begin using any devices that meet the criteria before the SAMHSA publishes its list. Therefore, the NRC disagrees with the commenter's request to eliminate the option of using non-instrumented validity screening tests. However, in response to other comments received on the performance testing provisions for validity screening tests, the NRC has revised proposed § 26.137(b) in the final rule, as discussed with respect to previous comments on this topic.

Licensee Testing Facility Personnel to Perform Quality Control Sample Testing

Comments: One commenter addressed proposed § 26.137(b)(2) and suggested that licensee testing facility personnel performing validity screening tests should also be responsible for testing quality control samples. The commenter reasoned that because non-instrumented tests have visually read endpoints, the test result must be interpreted by the tester. Therefore, each tester must be able to interpret the quality control samples correctly before conducting tests on donor specimens [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's reasoning and has amended § 26.137(b)(2)(i) in the final rule to require that licensee testing facility personnel who conduct validity screening tests must also conduct the required quality control testing. This testing, which is essential to ensuring accurate and reliable test results, is intended to verify that the validity screening tests to be used are functioning properly and that licensee testing facility personnel are able to conduct the tests appropriately.

Validity Screening Tests, Creatinine Concentration Measure to 1 Decimal Place

Comments: One commenter addressed proposed § 26.137(b)(4) and stated that validity screening tests must measure specimen creatinine concentration to one (1) decimal place [Charles LoDico, Individual]. Another commenter stated that no validity screening tests can measure to 1 decimal place and that, at best, a dipstick method to measure creatinine has a cutoff of 20 mg/dL. This commenter suggested deleting the requirement to measure creatinine to 1 decimal point [Sue Brown, Individual].

NRC Response: The NRC disagrees with the comment that validity screening tests must measure specimen creatinine concentration to 1 decimal place and agrees with the comment suggesting that validity screening tests can only measure creatinine concentration at the 20 mg/dL cutoff required in the final rule. The final rule does not require licensee testing facilities to conduct validity screening testing for creatinine concentration to 1 decimal place or the specific gravity testing that is necessary for HHS-certified laboratories to report substituted, dilute, or invalid validity test results. Rather, licensee testing facilities are only required to identify specimens of questionable validity under Part 26. Therefore, measuring specificity beyond the 20 mg/dL creatinine cutoff is unnecessary. The NRC has revised the proposed provision accordingly at § 26.137(b)(1)(ii)(A) in the final rule. This change reflects the current capabilities of validity screening tests and supports the NRC's intent that licensee testing facilities need only be able to identify whether a specimen has a creatinine concentration of less than 20 mg/dL.

General Oxidizing Test - Nitrite Cutoff Level

Comments: One commenter stated that the nitrite cutoff level of 500 mcg/mL in proposed § 26.137(b)(6) was for adulterated specimens and did not provide the ability to identify possible "invalid" specimens. The commenter suggested revising the cutoff level to 200 mcg/mL of nitrite [Sue Brown, Individual].

NRC Response: The NRC agrees with the comment. The final rule requires using a nitrite cutoff level of 200 mcg/mL to account for invalid specimens in § 26.137(b)(1)(ii)(C) of the final rule. The 200 mcg/mL nitrite cutoff is consistent with the nitrite decision point for a general oxidizing test in Section 2.4(h)(7)(iii) of the HHS Guidelines.

8.9.3 Non-Negative Validity Screening (§ 26.137(c))

Comments: One commenter noted that the words "may be adulterated, substituted, dilute, or invalid" in proposed § 26.137(c) appeared to be inconsistent with use of the term "non-negative" in other sections of the proposed rule [Sue Brown, Individual].

NRC Response: Based on this and other comments, the NRC has eliminated the term "non-negative" in the final rule. The NRC has replaced that term with a new term, "questionable validity," to describe the results of validity screening or initial validity testing at a licensee testing facility. A definition of "questionable validity" has been added to § 26.5 of the final rule. It states that "questionable validity means the results of validity screening or initial validity tests at a licensee testing facility indicating that a urine specimen may be adulterated, substituted, dilute, or invalid." The NRC has chosen this term, rather than a term that would directly reference adulterated, substituted, dilute or invalid specimens, because licensee testing facilities will not be conducting specific gravity testing that would determine these specimen characteristics. Using the term "questionable validity" addresses the concern expressed in the comment and improves the clarity of the final rule.

Comments: One commenter recommended that proposed § 26.137(c) be revised to refer only to validity screening test results that indicate a specimen may be adulterated (because of pH or an oxidizing adulterant) or substituted (because of creatinine concentration less than 20 mg/dL). The commenter suggested eliminating references to dilute and invalid specimens given that the requirements in proposed § 26.131(b) did not provide for the ability to determine if a specimen is dilute or invalid [Sue Brown, Individual].

NRC Response: The NRC agrees in part with the commenter's request. Instead of using the specific test results that a licensee testing facility may report for an individual specimen, the NRC has created a new term, "questionable validity," to apply to specimens that have a creatinine concentration of less than 20 mg/dL or the specimen exhibits characteristics of adulteration, such as an abnormal pH or the possible presence of an oxidant. In addition, the NRC has revised other sections in the final rule to address the commenter's statement that the proposed rule did not provide licensee testing facilities with the capability to identify a specimen that may be invalid. Specifically, § 26.131(b)(2)(i) and (b)(3) in the final rule provide licensee testing facilities with the ability to identify specimens that may be invalid based on pH less than 4.5 or greater than or equal to 9 or a nitrite concentration equal to or greater than 200 mcg/dL.

8.9.4 Quality Control Requirements for Performing Initial Validity Tests (§ 26.137(d))

Quality Control Requirements for Initial Validity Tests at Licensee Testing Facilities - Creatinine

Comments: One commenter recommended that proposed § 26.137(d)(1) be revised to be consistent with the HHS Guidelines by adding a creatinine calibrator at 2 mg/dL and a control in the range of 1.0 mg/dL to 1.5 mg/dL [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request. The calibrators specified in proposed § 26.137(d)(1) pertain to initial validity testing for creatinine and need to ensure only that the test can determine if a specimen's creatinine concentration is less than 20 mg/dL. Because the final rule does not require licensee testing facilities to conduct specific gravity testing or report substitute specimen test results, calibrators at lower creatinine concentrations are unnecessary. Therefore, the NRC has not modified the proposed provision in the final rule.

Incorrect Reference in Section-by-Section Analysis in Proposed Rule

Comments: One commenter addressed the section-by-section analysis of substantive rule changes in the proposed rule (page 50550 of the *Federal Register* notice). The commenter stated that, although the discussion referred to a proposed § 26.137(d)(7), that section did not exist in the proposed rule [Sue Brown, Individual].

NRC Response: The NRC agrees with the comment and has corrected the section-by-section analysis of substantive rule changes in the *Federal Register* notice publishing the final rule to reference the section on blind performance test samples, § 26.137(e)(6)(v).

8.9.5 Quality Control Requirements for Initial Drug Tests (§ 26.137(e))

POCTs for Validity Testing

Comments: One commenter recommended that the second and third sentences of proposed § 26.137(e)(1) be deleted, because the NRC should not permit licensee testing facilities to use POCTs for validity testing [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's suggestion. The NRC is permitting licensee testing facilities to use validity screening tests that meet the specifications in

§ 26.137(b) of the final rule. Therefore, the NRC has not modified the proposed provision in the final rule.

Donor Information for Negative Urine Specimens Pooled for Internal QC Program

Comments: One commenter recommended that proposed § 26.137(e)(2) be revised to clarify that donor-specific information should be disassociated from samples pooled to be used in the laboratory internal quality control program [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with this comment and has revised § 26.137(e)(2) in the final rule to prohibit licensee testing facilities from retaining any information linking donors to specimens pooled for use in the internal quality control program. No reason exists for a laboratory to retain donor-specific information for negative urine specimens used in the internal quality control program. This change further protects the privacy of individuals who are subject to Part 26. A similar provision has been added to § 26.159(j) that applies to HHS-certified laboratories.

Performing Multiple Initial Drug Tests on a Specimen

Comments: One commenter asked the NRC to clarify the intent of proposed § 26.137(e)(3) that permitted licensee testing facilities to perform multiple initial drug tests on a specimen for the same drug or drug class provided that all tests meet the cutoffs and quality control requirements in Part 26. The commenter asked if the provision permitted multiple analyses of a donor specimen for the same drug class. The commenter also asserted that the NRC was promoting individual licensee testing instead of a standard applying to all licensee testing facilities [Charles LoDico, Individual].

NRC Response: The NRC agrees with this comment and has revised proposed § 26.137(e)(3) in the final rule to include a more precise description of when multiple initial drug tests on a specimen (also known as rescreening) are permitted. A similar revision was made to proposed § 26.167(d)(2) in the final rule to apply to HHS-certified laboratories. These revisions are consistent with the related provision in the HHS Guidelines and limit the potential variability in testing of concern to the commenter.

Quality Control Requirements for Initial Drug Tests, Quality Control Samples

Comments: One commenter stated that the requirements in proposed § 26.137(e)(6) for quality control samples were consistent with the HHS Guidelines except for one excluded provision in Section 2.5(b)(4) of the Guidelines. The commenter recommended revising the proposed rule by adding the requirement, "A sufficient number of calibrators to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known calibrators, those values will be used to calculate sample data." [Sue Brown, Individual]

NRC Response: The NRC agrees with the comment and has added the recommended wording to § 26.137(e)(6)(iv) of the final rule. This change enhances quality control procedures at licensee testing facilities and increases the consistency of Part 26 with related provisions in the HHS Guidelines.

Comments: One commenter suggested deleting "a" in the phrase "...at least one control fortified with a drug or drug metabolite targeted at 25 percent..." in proposed § 26.137(e)(6)(ii) because using "a" would imply that the control may have only one drug or drug metabolite. The commenter stated that a positive control must be positive for all drugs and drug metabolites and that a positive control must be analyzed with each analytical run. [Sue Brown, Individual]

NRC Response: The NRC agrees with the comment and has revised § 26.137(e)(6)(ii) in the final rule to more clearly state the intent of the provision.

Comments: One commenter suggested deleting "a" in the phrase "...at least one control fortified with a drug or drug metabolite targeted at 75 percent..." in proposed § 26.137(e)(6)(iii) because using "a" would imply that the control may have only one drug or drug metabolite. The commenter stated that a control below the cutoff for each drug and drug metabolite must be analyzed with each analytical run [Sue Brown, Individual].

NRC Response: The NRC agrees with the comment and has revised § 26.137(e)(6)(iii) in the final rule to more clearly state the intent of the provision.

Comments: One commenter suggested reorganizing one of the provisions in proposed § 26.137(e)(7). The commenter noted that because the second sentence in proposed § 26.137(e)(7) discussed a quality control sample requirement, the provision should be moved to § 26.137(e)(6) which described the quality control sample requirements for each analytical run [Sue Brown, Individual].

NRC Response: The NRC agrees with this suggestion. The NRC has renumbered the provisions in proposed § 26.137(e)(7) as § 26.137(e)(6) and (e)(6)(v) in the final rule to improve the rule's clarity.

Blind Performance Testing Samples

Comments: One commenter asked how the proposed § 26.137(e)(7) requirement to include blind performance tests samples in each run could be met for non-instrumented testing devices when a donor must be present. The commenter also questioned how a blind performance test sample could be introduced into the batch during this testing process [Charles LoDico, Individual].

NRC Response: Section 26.137(e)(7) proposed requirements for quality control samples for initial specimen drug testing at a licensee testing facility. The NRC is not permitting drug or validity testing to be performed at the collection site using POCTs. Rather, the NRC is restricting the use of non-instrumented validity screening tests to licensee testing facilities. Because all specimen validity testing would be conducted at a licensee testing facility and/or at an HHS-certified laboratory, a donor would never be present during specimen validity testing and the issue raised by this comment does not apply. Therefore, the NRC has not modified the proposed provision in the final rule.

Blind Performance Testing Samples - Example

Comments: One commenter addressed the section-by-section analysis of substantive changes regarding proposed § 26.137(e)(7). The commenter suggested that the example

incorrectly presented the number of quality control samples that must be included in an analytical run. The section-by-section analysis stated, "For example, if an analytical run tested 50 donor specimens, the licensee testing facility would include 5 quality control samples in the run. At least one of the 5 would be required to be a blind test sample, and it could be either a blank or a sample fortified with a drug or metabolite at either 25 percent above the FFD program's cutoff level or at 75 percent of the cutoff level. The remaining 4 samples could include any combination of blanks and fortified samples." The commenter also suggested clarifying the following section-by-section discussion: "The blind test sample may be either a blank (certified negative urine), or a sample with drug or drug metabolite, usually targeted at 50% or greater above the cutoff." Specifically, the commenter stated that this discussion appeared to imply that the "fortified" quality control samples may have varied concentrations of drugs or drug metabolites, conflicting with the requirements in proposed § 26.137(e)(6)(ii) and (e)(6)(iii). The commenter recommended that the example explaining the quality control samples be revised in the final rule as follows: "For example, if an analytical run tested 45 donor specimens, the licensee testing facility would include 5 additional samples, all of which are quality control samples. The total number of samples in the analytical run would then be 50. At least one of the 5 quality control samples must be a control that appears as a donor sample to the initial testing technician. This blind test sample could be either a certified drug negative sample or a sample with drug or drug metabolite above the cutoff. The other 4 quality control samples must meet the requirements of § 26.137(e)(6)(i)-(iii)" [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's suggestion and has revised the example used to explain quality control sample requirements in the section-by-section analysis of substantive rule changes for § 26.137(e)(6), where these requirements appear in the final rule. The example more precisely explains the requirement that 10 percent of all specimens tested in each analytical run must be quality control samples. Although the section-by-section analysis was technically accurate for an analytical run of 50 donor specimens, the discussion should have more clearly stated that 10 percent of the number of donor specimens, or 5 additional specimens, must be quality control samples. The total specimens in the example analytical run would be 55 specimens.

8.9.6 Errors in Testing (§ 26.137(f))

No comments addressed this section.

8.9.7 Accuracy (§ 26.137(g))

No comments addressed this section.

8.9.8 Calibrators and Controls (§ 26.137(h))

No comments addressed this section.

8.10 Reporting Initial Validity and Drug Test Results (§ 26.139)

No comments addressed this section.

9. SUBPART G: LABORATORIES CERTIFIED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

This section provides the NRC's responses to public comments on the proposed rule's Subpart G. That subpart presented requirements related to the HHS-certified laboratories that licensees and other entities are required to use for specimen validity and drug testing. In particular, it set forth proposed requirements for laboratory personnel and procedures that HHS-certified laboratories would be required to follow during specimen receipt, testing, storage, and shipping or disposal to ensure security and preservation. It listed specific cutoff levels for specimen validity tests and for both initial and confirmatory drug tests. It also provided detailed requirements for quality assurance of testing technologies and the testing process.

9.1 Purpose (§ 26.151)

No comments addressed this section.

9.2 Using Certified Laboratories for Testing Urine Specimens (§ 26.153)

More Stringent Cutoff Levels and/or Testing for Other Substances - Oversight

Comments: One commenter addressed proposed § 26.153(d) and requested that, in situations where a licensee or other entity chooses to use more stringent cutoff levels than those specified in Part 26 and/or chooses to test for substance not mandated by Part 26, that the NRC, and not the licensee or other entity, should ensure that the HHS-certified laboratory takes measures consistent with Part 26 to ensure that test results are valid and defensible [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with this comment. The NRC believes that the evaluations of assays and cutoff levels by an independent forensic toxicologist, as required in § 26.31(d)(1)(i)(D) and (d)(1)(ii) of the final rule, and the auditing activities required under § 26.41 of the final rule provide adequate assurance that any testing conducted under this subpart will provide results that are valid and defensible. Therefore, the NRC has not modified the proposed provision in the final rule.

Laboratory Personnel Appearing for Administrative/Disciplinary Hearings

Comments: One commenter suggested revising proposed § 26.153(f)(2) by requiring "more stringent provisions" to compel laboratory personnel to appear to testify at an administrative and disciplinary proceeding against an individual when the proceeding is based on urinalysis results reported by an HHS-certified laboratory. The commenter stated that, if laboratory personnel fail to appear at an administrative or disciplinary proceeding, the case against the donor should be dropped [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the comment. The licensee or other entity is responsible, through its contract with the HHS-certified laboratory, for ensuring that the appropriate personnel from the HHS-certified laboratory are available to testify in an

administrative or disciplinary proceeding when that proceeding is based on urinalysis results reported by the HHS-certified laboratory. If the licensee does not ensure that the appropriate individuals are available, or the HHS-certified laboratory does not make the individuals available, both the licensee and HHS-certified laboratory could be subject to NRC enforcement action. However, the final rule does not require laboratory personnel to appear in person. Therefore, the NRC believes these provisions adequately protect donors' rights to a fair and objective review and are sufficiently stringent. The NRC also does not agree that dropping the case against an individual is acceptable if laboratory personnel are not made available. The NRC requires reviewing officials to make a positive determination that individuals are fit for duty and trustworthy and reliable, as demonstrated by the avoidance of substance abuse, in order for licensees or other entities to grant or maintain an individual's authorization. If test results are received that call into question an individual's fitness for duty, trustworthiness, and reliability, the individual's authorization must be withdrawn to protect public health and safety and the common defense and security until the question can be resolved. The licensee or other entity is responsible for ensuring that sufficient information is available for the reviewing official to make either a positive or negative determination. Therefore, the NRC has not modified the proposed provision in the final rule.

Conflict of Interest between HHS-Certified Laboratory and MRO

Comments: One commenter, supported by many other commenters, addressed proposed § 26.153(f)(5) and requested the NRC to provide specific examples of relationships between HHS-certified laboratories and MROs that the NRC considers to be conflicts of interest. The commenter suggested including the conflict of interest examples specified in the U.S. DOT's drug and alcohol testing regulations in 49 CFR 40.101(b). The commenter also requested that the NRC specifically exempt a potential conflict of interest situation in which a medical doctor uses an HHS-certified laboratory for services in his or her private practice and who also serves as the MRO to a licensee that uses the same HHS-certified laboratory [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees in part with the commenter's request and has revised proposed § 26.183(b) in the final rule, which also addresses such conflicts of interest, to include specific examples of conflict of interest relationships between MROs and HHS-certified laboratories. As requested, the basis for these examples is 49 CFR 40.101(b) of the U.S. DOT's Procedures for Transportation Workplace Drug and Alcohol Testing Programs.

The NRC disagrees with the commenter's request to specifically exempt as a potential conflict of interest the situation where a medical doctor uses an HHS-certified laboratory for services in his or her private practice and also serves as the MRO to a licensee or other entity that uses the same HHS-certified laboratory. Under certain circumstances, this relationship could create the appearance of a potential conflict of interest. For example, although the NRC is unaware of any examples of an MRO exerting inappropriate influence, an MRO may have the ability to influence a licensee's selection of an HHS-certified laboratory and thereby gain leverage to negotiate with laboratories for reduced pricing in the MRO's private practice. Therefore, the NRC has not modified the proposed provision in the final rule to include the requested exemption.

Access to Donor Testing Records and Laboratory Records

Comments: Several commenters supported proposed § 26.153(f)(4) and stated that the industry agreed that access to laboratory records, beyond that required for licensee or other entity FFD program functions, should be restricted to individual donors viewing their own records [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The commenters' apparent interpretation of proposed § 26.153(f)(4) was contrary to the NRC's intended meaning of that section. The NRC intends that an individual who is subject to a drug test under Part 26 shall have the right to designate a representative to review the HHS-certified laboratory's records related to the individual's validity and drug test as well as any records related to the results of any certification, review, or revocation-of-certification proceedings relevant to the individual. This right to designate a representative is consistent with § 26.37(d) of the proposed and final rules which permits an individual, as well as a designated representative, consistent with the former rule requirements in § 26.29(b), to request and receive copies of all records pertaining to a determination that the individual has violated the FFD policy. The NRC has revised proposed § 26.153(f)(4) in the final rule to clarify the ambiguity in the proposed rule.

Comments: One commenter suggested that the NRC revise proposed § 26.153(f)(4) to permit authorized employee representatives to have access to an HHS-certified laboratory's records pertaining to an employee's validity and drug test results, as well as laboratory records of relevant certification, review, and revocation-of certification proceedings [Todd Newkirk, IBEW].

NRC Response: The NRC intended that proposed § 26.153(f)(4) would authorize an individual's designated representatives to have access to the records mentioned by the commenter. The NRC has revised proposed § 26.153(f)(4) in the final rule to clarify the ambiguity in the proposed rule. This revision makes § 26.153(f)(4) consistent with § 26.37(d) in the final rule which permits the donor, and his or her designated representative, to request copies of all records pertaining to the determination of a violation of the FFD policy, including test results, from an HHS-certified laboratory.

9.3 Laboratory Personnel (§26.155)

No comments addressed this section.

9.3.1 Day-to-Day Management of the HHS-Certified Laboratory (§ 26.155(a))

Comments: One commenter disagreed with the NRC's decision in proposed § 26.155(a)(4) to eliminate the requirement for an HHS-certified laboratory to maintain laboratory operating procedures in a "procedure manual" as specified in Sections 2.5(a)(5) and 2.7(o)(1) in Appendix A to Part 26. The commenter stated that no longer requiring laboratories to maintain a procedure manual would be inconsistent with the requirements in Section 2.4(q)(1) of the HHS Guidelines. For consistency with the HHS Guidelines, the commenter suggested

including the requirement for laboratory operating procedures to be maintained in a manual [Sue Brown, Individual].

NRC Response: The NRC agrees with the comment. The NRC has revised proposed § 26.155(a)(4) in the final rule to require an HHS-certified laboratory to maintain laboratory operating procedures in a procedure manual, consistent with the former rule and the related requirement in the HHS Guidelines.

9.3.2 Certifying Scientist (§ 26.155(b))

Comments: One commenter addressed the section-by-section analysis of substantive changes regarding proposed § 26.155(b). The section-by-section analysis stated that "...the proposed rule would provide more detailed requirements with respect to the individual who validates test results at the HHS-certified laboratory." The commenter recommended that the term "validates" should be replaced by the term "certifies" because test results at HHS-certified laboratories are certified and not validated [Sue Brown, Individual].

NRC Response: The NRC agrees with the recommendation and has revised proposed § 26.155(b)(1) in the final rule to state that "HHS-certified laboratories shall have one or more certifying scientists who review all pertinent data and quality control results to certify the laboratory's test results."

9.3.3 Day-to-Day Operations and Supervision of Analysts (§ 26.155(c))

No comments address this section.

9.3.4 Other Personnel (§ 26.155(d))

No comments addressed this section.

9.3.5 Training (§ 26.155(e))

No comments addressed this section.

9.3.6 Files (§ 26.155(f))

No comments addressed this section.

9.4 Procedures (§ 26.157)

No comments addressed this section.

9.5 Assuring Specimen Security, Chain of Custody, and Preservation (§ 26.159)

Comments: One commenter addressed proposed § 26.159(f) that directed an HHS-certified laboratory to include the original custody-and-control form with a specimen that is transferred to

a second HHS-certified laboratory for additional testing. The commenter recommended that the proposed requirement be revised to conform to the chain-of-custody procedures used at HHS-certified laboratories. Specifically, HHS-certified laboratories provide a copy, rather than the original custody-and-control form, with a specimen that is transferred to a second HHS-certified laboratory for additional testing [Sue Brown, Individual].

NRC Response: The NRC agrees with the recommendation. The NRC has revised § 26.159(f) in the final rule to require that a copy of the custody-and-control form is packaged with an aliquot of a single specimen or a Bottle B specimen that is transferred to a second HHS-certified laboratory for testing. This revision makes the final rule consistent with the procedures required in the HHS Guidelines.

Pooling of Urine Specimens Used for Laboratory QC Program

Comments: One commenter stated that proposed § 26.159(j) should be revised to require donor-specific information to be disassociated from valid samples that test negative on initial or confirmatory drug tests and that the laboratory chooses to pool for use in the internal quality control program at the laboratory [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the comment and has revised § 26.159(j) in the final rule to prohibit HHS-certified laboratories from retaining any information linking donors to specimens pooled for use in the internal quality control program. No reason exists for a laboratory to retain donor-specific information for negative urine specimens used in the internal quality control program. This change further enhances the privacy of individuals who are subject to Part 26. A similar provision has been added to § 26.137(e)(2) that applies to licensee testing facilities.

9.6 Cutoff Levels for Validity Testing (§ 26.161)

No comments addressed this section.

9.6.1 Validity Test Results (§ 26.161(a))

No comments addressed this section.

9.6.2 Initial Validity Testing (§ 26.161(b))

Specific Gravity Testing Instrumentation

Comments: One commenter addressed proposed § 26.161(b) and asked that the final rule specify the type of instrument to be used to perform specific gravity testing. The commenter stated that the HHS Guidelines require specific gravity testing to be performed using a four-place refractometer [Charles LoDico, Individual].

NRC Response: Section 26.167(c)(2)(i) in the proposed and final rules addresses the type of instrument that HHS-certified laboratories must use to perform specific gravity testing of urine specimens. The requirement in that section is consistent with the related requirements in the HHS Guidelines. Therefore, the NRC has not modified § 26.161(b) in the final rule in response

to this comment.

Redundancy with Subpart F Discussion in § 26.131(c)

Comments: One commenter noted the redundancy between the initial validity testing requirements in proposed § 26.131(c) through (f) of Subpart F for licensee testing facilities and the requirements in proposed § 26.161(b)(2) for HHS-certified laboratories. The commenter suggested deleting the requirements in proposed § 26.161(b)(2). [Sue Brown, Individual]

NRC Response: The NRC agrees with the suggestion and has deleted the proposed requirements in § 26.161(b)(2) because they are captured in § 26.161(c) through (f) of the final rule.

Include Invalid Specimens

Comments: One commenter suggested revising proposed § 26.161(b)(2) to include invalid specimens in the statement "...there is a reason to believe the donor may have diluted, substituted, or adulterated the specimen..." [Sue Brown, Individual].

NRC Response: The NRC has eliminated proposed § 26.161(b)(2) from the final rule in response to an earlier comment.

9.6.3 Results Indicating an Adulterated Specimen (§ 26.161(c))

Quality Controls for Unidentified Adulterants

Comments: One commenter addressed proposed § 26.161(c)(8) and inquired about what, if any, quality controls exist when testing specimens where "any other adulterant" is reported as the test result. The commenter inquired as to how an HHS-certified laboratory is to identify and quantify the substance. [Todd Newkirk, IBEW]

NRC Response: If a specimen is identified as containing "any other adulterant," the adulterant identified by the HHS-certified laboratory is a substance other than those described in § 26.161(c)(1) through (c)(7) of the final rule. An instance that might warrant a laboratory testing for an adulterant not specified in § 26.161(c)(1) through(c)(7) may arise when a specimen yields an invalid test result (e.g., interference occurs on the immunoassay drug tests on two separate aliquots and a valid immunoassay drug test result cannot be obtained). If an HHS-certified laboratory conducts testing for "any other adulterant," the laboratory must use two types of testing techniques (as specified in § 26.161(c)(8)). Also, in order to validate the accuracy of the adulterant tests used, the laboratory must use standard controls containing known concentrations of the substance (i.e., "the adulterant that the test identifies") for which testing is conducted. Further, both proposed and final § 26.169(d) require the laboratory to report the numerical value of a test result to the MRO for a specimen with an adulterated test result. Therefore, the NRC has not modified the proposed provision in the final rule.

Addition of Hyphens for Chromium (VI), Nitrite, and Sulfonate Equivalents

Comments: One commenter addressed proposed § 26.161(c)(3) through (c)(7) and requested that hyphens be inserted before the word "equivalents' in "chromium (VI) equivalents," "nitrite

equivalents," and "sulfonate equivalents." The commenter stated that the suggested changes would be consistent with HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.161(c)(3) through (c)(7) in the final rule by adding hyphens before the word "equivalents" to make Part 26 wording more accurate and improve its consistency with the HHS Guidelines.

Support for Proposed Provision

Comments: Several commenters stated that industry supported proposed § 26.161(c)(8) which provided that the presence of an adulterant not specified in § 26.161 (c)(3) through (c)(7) is to be verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The comment does not require a response.

9.6.4 Results Indicating a Substitute Specimen (§ 26.161(d))

Comments: One commenter addressed a statement in the section-by-section analysis of substantive changes regarding proposed § 26.161(d). The commenter said that the discussion incorrectly stated that a refractometer must measure to 3 decimal places (e.g., specimen specific gravity levels of 1.001 and 1.020). The commenter asserted that a refractometer must measure to 4 decimal places (e.g., specific gravity levels of 1.0010 and 1.0200) in order to report a specimen as substitute [Sue Brown, Individual].

NRC Response: The NRC agrees with the comment and has revised the section-by-section analysis of § 26.161(d) in the final rule to correct the specific gravity range for a substituted specimen by referencing specimen specific gravity levels of 1.0010 and 1.0200.

9.6.5 Results Indicating a Dilute Specimen (§ 26.161(e))

Comments: One commenter addressed a statement in the section-by-section analysis of substantive changes regarding proposed § 26.161(e). The commenter stated that the discussion incorrectly specified the specific gravity range for a dilute specimen as "less than or equal to 1.001 or equal to or greater than 1.020." The commenter stated that the correct specific gravity range is "greater than 1.0010 but less than 1.0030" [Sue Brown, Individual]

NRC Response: The NRC agrees with the comment and has revised the section-by-section analysis of § 26.161(d) in the final rule to correct the specific gravity range for a dilute specimen to "greater than 1.0010 but less than 1.0030."

9.6.6 Results Indicating an Invalid Specimen (§ 26.161(f))

Specimen Testing Criteria for Invalid Test Result

Comments: One commenter inquired about testing criteria used to determine that a specimen is invalid. The commenter asked why a substance could not be identified and suggested that the possibility that a laboratory testing problem might also provide an invalid test result [Todd Newkirk, IBEW].

NRC Response: The NRC notes that there are at least two types of situations in which a laboratory may not be able to identify a substance and therefore reports that the specimen is invalid. In one case, the physical characteristics of the "specimen" indicate that it is clearly not human urine and cannot be tested by the laboratory without damage to its equipment. Examples include "specimens" consisting of tar or soil. In other cases, a laboratory may not have the ability to test for a certain adulterant beyond those prescribed in the rule. Sections 26.161(g) and 26.185(f) of the proposed and final rules establish procedures for the laboratory and MRO to follow in this instance.

The NRC agrees with the commenter that errors in testing are possible. For this reason, Part 26 includes numerous provisions to ensure the accuracy of testing. Proposed and final § 26.161(f) specify the initial validity testing criteria that HHS-certified laboratories must use to determine whether a specimen is invalid. To ensure that each validity test performed on a specimen functions correctly, § 26.167(b) and (c) require HHS-certified laboratories to evaluate the accuracy of the assays performed using calibrators and controls in each analytical run of specimen testing performed. Each analytical run of specimens must also include blind performance testing samples under § 26.168 of the final rule. Given that sufficient controls exist in the final rule to ensure that initial validity tests function correctly, the NRC has not revised proposed § 26.161(f) in the final rule.

General Oxidant Colorimetric Testing

Comments: One commenter suggested that the requirement "equal to or greater than 200 mcg/mL nitrite equivalents using a general oxidant colorimetric test" in proposed § 26.161(f)(3) was inconsistent with the intended meaning in the HHS Guidelines and should be revised to state "equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test." The commenter stated that the intended meaning of the HHS Guidelines requirement is that the general oxidant test must be positive with an equivalent of 200 mcg/mL of nitrite. The commenter noted that the general oxidant test can be calibrated with a 200 mcg/mL nitrite calibrator or with a 50 mcg/mL chromium (VI) calibrator. If calibrated with the 50 mcg/mL chromium (VI) calibrator, the general oxidant test would produce a positive result for specimens with nitrite concentrations much less than 200 mcg/mL; not the intended cutoff for nitrite in the proposed provision [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.161(f)(3) in the final rule to clarify the intent of the provision. That section now reads "equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test."

Addition of Hyphens for Chromium (VI), Nitrite, and Sulfonate Equivalents

Comments: One commenter requested that proposed § 26.161(f)(7) and (f)(8) be revised by adding hyphens before the word "equivalents" in the terms "nitrite equivalents," "chromium (VI) equivalents," and "sulfonate equivalent." The commenter noted the suggested revisions are consistent with HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.161(f)(7) and (f)(8) in the final rule by adding hyphens before the word "equivalents" to improve consistency between the HHS Guidelines and these Part 26 provisions.

9.6.7 Additional Testing by a Second Lab (§ 26.161(g))

Support for Proposed Provision

Comments: Several commenters stated that the industry supported proposed § 26.161(g) which, in instances of the presence of a suspected interfering substance/adulterant, required HHS-certified laboratory personnel to consult with the licensee's or other entity's MRO and, with the MRO's agreement, to send the specimen to another HHS-certified laboratory that has the capability to identify the suspected substance [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The comment does not require a response.

HHS-Certified Laboratory Contacting MRO, Specimens with Possible Interfering Substances/ Adulterants

Comments: One commenter addressed the proposed § 26.161(g) requirement that HHS-certified laboratories must consult with a licensee's or other entity's MRO to receive approval to send a specimen to a second HHS-certified laboratory for additional testing if the laboratory suspects the presence of an interfering substance/adulterant that could make a specimen test result invalid. The commenter stated that the specimen should be automatically sent to a second HHS-certified laboratory for additional testing. The commenter reasoned that no employee should suffer or be accused of attempting to subvert the testing process because of an unidentified substance [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the request to eliminate the required consultation between the HHS-certified laboratory and the licensee's or other entity's MRO to determine if additional testing should be conducted at a second HHS-certified laboratory to try to identify whether an interfering substance/adulterant is present in a donor's specimen. This consultation is important because not all HHS-certified laboratories have the same testing capabilities to identify additional types of interfering substances and "new" adulterants. Therefore, sending a specimen to any second HHS-certified laboratory without first requiring the MRO and laboratory to confer on the test results from the first laboratory and determine whether an appropriate laboratory exists that has the capabilities to conduct additional types of test may not automatically improve the likelihood that the substance will be identified. Specifically, the HHS-

certified laboratory must confer with the MRO to determine if additional testing of the specimen might identify the unidentified substance in a donor's urine specimen that is preventing a valid test result. The commenter need not be concerned that a donor would suffer or be accused of attempting to subvert the testing process. These procedures do not result in an individual being accused of subverting the testing process. No sanctions are imposed for an invalid test result. As required by the final rule's § 26.185(f), the MRO must contact the donor to determine if an acceptable medical explanation exists that may have caused an invalid specimen test result. Depending on the results of this enquiry, the MRO will require the donor to provide another specimen, either under direct observation or not. Therefore, the NRC has not modified the proposed provision in the final rule.

Comments: One commenter stated that the proposed § 26.161(g) requirement that the HHS-certified laboratory contact a licensee's or other entity's MRO conflicted with Section 2.4(h)(12) in the HHS Guidelines. Specifically, the HHS Guidelines permit HHS-certified laboratories to report an "invalid" specimen test result using the same initial test on two separate aliquots. The commenter stated that most HHS-certified laboratories have eliminated their confirmatory tests for adulterants, and have been reporting more invalid results. The commenter thought that the proposed provision would impose a burden on HHS-certified laboratories to contact the MRO for every invalid test result and suggested that the proposed provision be eliminated [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's suggestion to eliminate the proposed provision in the final rule. For test results indicating an invalid specimen, a discussion between the HHS-certified laboratory and the MRO is critical because of differences between laboratories' capabilities to identify interfering substances or "new" adulterants. The intent of this requirement is to deter individuals from attempting to subvert the testing process by introducing interfering substances or adulterants to mask the presence of prohibited drugs and to increase the likelihood of detection if they do. Reporting a specimen as invalid, rather than conducting confirmatory testing for a suspected adulterant when a laboratory is available that is capable of identifying the presence of an adulterant, would not achieve the NRC's objectives in requiring specimen validity testing for adulterants. Therefore, the NRC has not modified the proposed provision in the final rule.

9.6.8 More Stringent Validity Test Cutoff Levels are Prohibited (§ 26.161(h))

No comments addressed this section.

9.7 Cutoff Levels for Drugs and Drug Metabolites (§ 26.163)

No comments addressed this section.

9.7.1 Initial Drug Testing (§ 26.163(a))

Dilute Specimen Testing, Limit of Detection (LOD) Testing

Comments: One commenter addressed proposed § 26.163(a)(2) and suggested revising the provision that permitted an MRO to direct an HHS-certified laboratory to test a specimen for drugs and/or drug metabolites "down to the confirmatory assay's limit of detection (LOD)." The

commenter stated that HHS Guidelines do not use the term "limit of detection" and suggested replacing the proposed wording with the phrase "using the laboratory's confirmatory assay" [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request because it is contrary to the intent of the proposed provision. The NRC is aware that there are many legitimate reasons for specimens being dilute. However, dilution is also a method some donors use to subvert the testing process. Dilution may decrease the concentration of a drug or drug metabolites sufficiently that applying Part 26 cutoff levels, or a licensee's or other entity's more stringent cutoff levels, would produce false negative drug test results. The special processing of dilute specimens required by § 26.163(a)(2) increases the likelihood that any drugs and drug metabolites in the specimen will be detected. Therefore, the final rule continues to permit licensees and other entities to conduct confirmatory testing to the assay's limit of detection for dilute specimens.

Conducting Initial Drug Testing for Dilute Specimens to LOD

Comments: One commenter stated that the proposed § 26.163(a)(2) requirement "to conduct initial drug testing of dilute specimens using FDA-approved analytical kits that have the lowest concentration levels available for the initial testing technologies" would be overly burdensome to HHS-certified laboratories. The commenter said the requirement would be burdensome because, in her experience, a large Category Five HHS-certified laboratory may have as many as 10 percent of specimens yielding dilute results. The commenter stated that many health-conscious individuals may have dilute specimen test results simply because they consume large quantities of water, not because they are attempting to conceal drug use. The commenter also stated that the proposed provision would be burdensome because an HHS-certified laboratory would need to have more than one FDA-approved analytical kit for a drug or metabolite to fulfill the proposed requirement. For example, the initial drug test cutoff level for marijuana metabolite is 50 ng/mL. The initial drug test kit manufacturers market a kit for use at the 50 ng/mL cutoff and at the 20 ng/mL cutoff. To meet the proposed requirement, a laboratory would need to re-screen the dilute specimen with the 20 ng/mL cutoff kit, using different controls. The commenter noted that some kit manufacturers also offer lower cutoffs for opiate metabolites and amphetamines. By using the lower cutoff levels, the NRC would effectively be lowering the initial test cutoff levels for these drugs and, by doing so, treating donors with dilute specimens differently.

If the NRC were to decide not to eliminate this requirement, the commenter recommended that the laboratory not be required to re-screen the identified dilute specimen and, instead, be permitted to compare the initial drug test immunoassay response for the specimen to the initial drug test immunoassay response for the cutoff calibrator with the initial drug test kit used for testing. If the specimen's response is within 50 percent of the response of the cutoff calibrator, the laboratory would report this to the licensee's or other entity's MRO on the final report. The commenter noted that an additional burden would be imposed on the laboratory to capture the initial test immunoassay response number and report it on the report form. The commenter suggested that the HHS-certified laboratory could accomplish this reporting using the laboratory's information system [Sue Brown, Individual].

NRC Response: The NRC agrees in part with the commenter's request and has eliminated from the final rule proposed § 26.163(a)(2) that required HHS-certified laboratories to use an

FDA-approved analytical kit with the lowest concentration levels marketed for the technology(ies) being used to conduct initial drug testing of specimens with dilute initial validity test results. The NRC has accepted the commenter's recommended approach to conduct initial drug testing of each dilute specimen and evaluate the immunoassay response for each drug test such that if the quantitative test result is equal to or greater than 50 percent of the cutoff calibrator for the drug tested, the laboratory would consider the result as an initial positive drug test result. The NRC disagrees with the commenter's assertion that further testing is unnecessary. Given the consequences for donors of a positive drug test result, the NRC believes that confirmatory drug testing to the limit of detection is necessary to confirm the initial drug test result.

Dilute Specimen Testing, Eliminate the Word Confirmatory

Comments: One commenter suggested eliminating the word "confirmatory" in the sentence "If confirmatory validity testing indicates that a specimen is dilute . . ." in proposed § 26.163(a)(2). The commenter reasoned that a dilute specimen test result may be reported by testing a single aliquot of a specimen [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has eliminated the word "confirmatory" in § 26.163(a)(2)(i) of the final rule. This change increases the consistency of Part 26 with the related provision in the HHS Guidelines.

9.7.2 Confirmatory Drug Testing (§ 26.163(b))

No comments addressed this section.

9.8 Testing Split Specimens and Retesting Single Specimens (§ 26.165)

No comments addressed this section.

9.8.1 Split Specimens (§ 26.165(a))

No Discussion on Disposal of Negative Bottle A Specimens

Comments: One commenter noted that, although proposed § 26.165(a)(3) permitted the HHS-certified laboratory to discard the Bottle B specimen if the Bottle A specimen is determined to be a valid specimen free of any drugs or drug metabolites, it did not also specify that the Bottle A specimen may be discarded [Sue Brown, Individual].

NRC Response: The NRC agrees with the comment and has revised proposed § 26.165(a)(3) in the final rule to specify that an HHS-certified laboratory may also discard the specimen in Bottle A once the specimen is determined to be valid and free of any drugs or drug metabolites.

Written Request to Test Bottle B Specimen or Retest Aliquot of Single Specimen

Comments: Two commenters stated that the proposed § 26.165(a)(4) prohibition of any entity (e.g., licensee, MRO, NRC) ordering the testing of a Bottle B specimen without a donor's written

permission conflicted with Section 2.6(e)(4) of the HHS Guidelines. The HHS Guidelines permit a Federal agency to have a single or split (Bottle B) specimen retested "as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result." The commenters recommended that the NRC include the HHS Guideline provision in the final rule [Sue Brown, Individual; Charles LoDico, Individual].

NRC Response: The NRC disagrees with the commenters' recommendation. The requirements for testing split specimens in the former, proposed, and final rule ensure that each donor receives fair and accurate testing under Part 26. The NRC's intent in the original rule, when permitting split specimen testing, was to enhance donors' confidence in the drug testing process imposed by the rule and provide one means for donors to defend against possible administrative and/or methodological errors in testing the specimen in Bottle A. Because the NRC's intent in permitting split specimen testing has been to protect donors, and because the NRC believes that testing an individual's biological specimen without his or her permission infringes on the individual's privacy, the NRC has declined to adopt the commenters' proposed revision.

Clarity of Requirement for Requesting Bottle B (Split Specimen) Testing

Comments: One commenter suggested that the NRC revise proposed § 26.165(a)(4) that allowed donors the opportunity to request the testing of a Bottle B specimen. The commenter stated that the proposed provision was lengthy, confusing, and did not specify that MROs must first verify that an HHS-certified laboratory test result is drug positive, adulterated, or substituted before informing a donor of the right to request testing of the Bottle B specimen. The commenter recommended that proposed § 26.164(a)(4) be revised to be consistent with proposed § 26.165(b)(1), which allowed a donor to request a retest of a single specimen at a second HHS-certified laboratory. The commenter suggested using Section 2.6(e) in the HHS Guidelines as an example when considering the suggested revisions. The same commenter also recommended that the first sentence in proposed § 26.165(a)(4) be relocated to the results reporting section of the rule, given that the sentence instructed the laboratory to report test results to the MRO [Sue Brown, Individual].

NRC Response: The NRC agrees with the comments. It has revised the provision in proposed § 26.165(a)(4) and moved it to § 26.165(b) in the final rule to improve the rule's organization. In addition, the NRC has consolidated the proposed provisions on retesting of an aliquot of a single specimen and the testing of Bottle B specimens into a single section (§ 26.165(b)(1) through (b)(6)) to improve the organization and clarity of the final rule.

Sending Bottle B Specimen to Second HHS-Certified Laboratory

Comments: One commenter stated that proposed § 26.165(a)(5) did not allow for the possibility that a licensee testing facility, rather than the HHS-certified laboratory, may retain Bottle B specimens as allowed under proposed § 26.135(a) and would have to forward Bottle B specimens to a second HHS-certified laboratory. The commenter also noted that, in situations where a Bottle B specimen is located at a licensee testing facility, the one business day requirement to send the specimen to a second HHS-certified laboratory may not provide sufficient time [Sue Brown, Individual].

NRC Response: Section 26.135(b) in the final rule addresses the issue raised by the

commenter. If a licensee testing facility maintains a Bottle B specimen, the licensee or other entity must ensure that the donor's specimen is forwarded to a second HHS-certified laboratory if directed to do so by the MRO, at the specific request of the donor. The NRC believes that the one business day time limit for a licensee testing facility to send a Bottle B specimen to a second HHS-certified laboratory is reasonable. It should be noted that the NRC has relaxed this requirement from the "same-day" requirement for these situations in the former rule. The NRC made this revision because logistical difficulties sometimes created obstacles to FFD program compliance with the former rule's same-day requirement. For example, commenters at public meetings with stakeholders cited communication delays among donors, MROs, and FFD program personnel, particularly on weekends and holidays, as one such difficulty. They also noted that the time required to identify a second laboratory with the appropriate capability to test the split specimen sometimes made compliance difficult. The NRC is confident that allowing one business day will be sufficient to overcome these logistical obstacles. In response to other comments received on proposed § 26.165(a) and (b), the NRC has revised and consolidated the provisions pertaining to donor requests for the retesting of an aliquot of a single specimen and Bottle B split specimen testing into § 26.165(b) in the final rule to improve the clarity and organization of rule.

Personnel Responsible for Directing a Laboratory to Send a Bottle B Specimen for Testing

Comments: One commenter stated that the phrase "If the donor requests that the specimen in Bottle B be tested..." in proposed § 26.165(a)(5) did not accurately reflect the notification process for split specimen testing. The commenter noted that the MRO, at the request of a donor, directs the HHS-certified laboratory to send the Bottle B specimen to a second HHS-certified laboratory for testing [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.165(b) in the final rule to clarify that, at the request of the donor, it is the MRO who directs the HHS-certified laboratory to send the Bottle B specimen for testing at another HHS-certified laboratory. In response to other comments on proposed § 26.165(a) and (b), the NRC has revised and consolidated the provisions pertaining to donor requests for the retesting of an aliquot of a single specimen and testing of a Bottle B specimen into § 26.165(b) in the final rule to improve the clarity and organization of rule.

Providing Quantitative Values of Specimen Retest Results

Comments: One commenter addressed proposed § 26.165(a)(6) and asked why the NRC was proposing to allow the MRO to provide a donor with the quantitative values of a specimen retest result. The commenter noted that the proposed requirement was inconsistent with Section 2.6(h) in the HHS Guidelines [Sue Brown, Individual].

NRC Response: The proposed provision requiring the MRO to provide a donor with the quantitative values of positive test results was consistent with the former provision in Section 2.7(j) in Appendix A to Part 26. The NRC has retained this provision in the final rule to maintain donors' rights to this information and has intended to differ from the HHS Guidelines on this issue since Part 26 was first published. Therefore, the NRC has not modified the proposed provision in the final rule.

9.8.2 Donor Request to the MRO for Retest of Single Specimen (§ 26.165(b))

Comments: One commenter recommended that proposed § 26.165(b) be combined with proposed § 26.165(a)(4) and the heading of the combined section be titled "Donor request to MRO for a retest." The commenter also suggested that the combined paragraph be modeled after the discussion in Section 2.6(e) of the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has consolidated the proposed provisions on retesting of an aliquot of a single specimen and the testing of Bottle B specimens into a single section (§ 26.165(b)(1) through (b)(6) in the final rule) to clarify the NRC's intent in the final rule.

Comments: One commenter noted that the first sentence in proposed § 26.165(b)(2) prohibited a donor from requesting a retest for an invalid specimen test result and that this was consistent with the HHS Guidelines. The commenter also thought that the second sentence in the proposed provision was confusing and appeared to allow a donor to request a retest of a specimen with an invalid test result [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised and consolidated the provisions in proposed § 26.165(a) and (b) to improve the clarity of the final rule. Section 26.165(b)(1) in the final rule states that a donor is not permitted to request the retesting of an aliquot of a single specimen or a split specimen (Bottle B) that the laboratory's testing had determined to be invalid. The NRC is imposing this prohibition because some invalid specimens create a risk of damaging laboratory equipment and because retesting invalid specimens would not provide useful information.

9.8.3 Retesting a Specimen for Drugs (§ 26.165(c))

<u>Use of the Phrase "Standard Confirmatory Drug Test"</u>

Comments: One commenter stated that the phrase "The second laboratory shall use its standard confirmatory drug test when retesting..." in proposed § 26.165(c)(1) was not an accurate description of the test. The commenter requested that the word "standard" be deleted since no "standard confirmatory drug test" is used by an HHS-certified laboratory [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter that HHS-certified laboratories do not use a standard confirmatory drug test and has eliminated the word "standard" from proposed § 26.165(c)(1) in the final rule.

<u>Limit of Detection (LOD) Testing</u>

Comments: One commenter suggested that the NRC eliminate the requirement in proposed § 26.165(c)(2) that confirmatory drug testing be performed down to the an assay's LOD for the retesting of an aliquot of a single specimen or for Bottle B split specimen testing. The commenter noted that the HHS Guidelines do not contain a similar provision [Sue Brown, Individual].

NRC Response: The NRC disagrees with this request. Section 26.163(a)(2) in the final rule permits licensees and other entities, at their discretion, to require the HHS-certified laboratory to conduct special analyses of dilute specimens, including confirmatory testing down to the LOD, for those drugs and/or drug metabolites for which the response was equal to or greater than 50 percent of the cutoff. The NRC is aware that this provision differs from the HHS Guidelines. However, testing at the LOD may be necessary to confirm the presence of drugs or metabolites in a dilute specimen. Therefore, requiring the second HHS-certified laboratory to test at the LOD is appropriate.

9.8.4 Retesting a Specimen for Adulterants (§ 26.165(d))

Comments: One commenter addressed proposed § 26.165(d) and suggested changing the word "appropriate" in the phrase "A second laboratory shall use the appropriate confirmatory validity test and criteria..." to "required." The suggested change would improve the consistency of the proposed provision with the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter that the word "required" more accurately characterizes the confirmatory validity test and criteria and has revised § 26.165(d) in the final rule accordingly.

9.8.5 Retesting a Specimen for Substitution (§ 26.165(e))

Comments: One commenter recommended deleting the second sentence of proposed § 26.165(e), suggesting that the sentence was confusing and redundant. Specifically, the commenter noted that, if the second HHS-certified laboratory does not find creatinine and specific gravity values that meet the substitute specimen criteria, the laboratory would report the result to the MRO as "failed to reconfirm," not as "non-confirmed" as the proposed provision would have required. The commenter also suggested deleting the sentence because its phrase "exceed the original test cutoff parameters" was redundant with the first sentence of the proposed requirement [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's recommendations and has eliminated the second sentence of proposed § 26.165(e) in the final rule.

9.8.6 Management Actions and Sanctions (§ 26.165(f))

<u>Donor Compensation While Awaiting Results of Split Specimen Testing</u>

Comments: One commenter stated that the NRC should prohibit a licensee or other entity from withholding an employee's compensation and benefits during the time period when an employee is awaiting the test results of split specimen (Bottle B) testing [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the comment. Section 26.75(i)(2) in the final rule prohibits a licensee or other entity from withholding an individual's compensation and benefits during the time period his or her authorization has been administratively withdrawn following a positive initial drug test result for marijuana and/or cocaine metabolites at a licensee testing facility pending an HHS-certified laboratory specimen test result verified by the MRO. However, the NRC does not agree that this prohibition should be applied when a donor is waiting for the

results of split specimen testing at a second HHS-certified laboratory. The difference is that, for § 26.75(i)(2), the donor's specimen has not been subject to initial or, if necessary, confirmatory testing at an HHS-certified laboratory and the result has not been confirmed by the MRO. Section 26.75(i)(2) prohibits action stronger than administrative withdrawal of authorization because the initial and confirmatory testing that could show culpability and justify stronger action have not been conducted. In the situation described by the commenter, the donor's specimen has already been subject to an HHS-certified laboratory's sophisticated testing procedures and the MRO has confirmed the result as positive, adulterated, or substituted. Unlike the first situation, there is ample test result evidence that would indicate an FFD violation that should lead to sanctions, such as withholding of compensation and benefits. Split specimen testing or retesting of an aliquot of a single specimen is a right that a donor may choose to exercise to verify the accuracy of the first HHS-certified laboratory test result. If the second laboratory's testing fails to reconfirm the initial laboratory test result, the MRO, as required by § 26.186(n)(3) and (n)(4) of the final rule, would report that no FFD policy violation had occurred. Because of the significant difference in indicators of culpability in these two situations, the NRC has chosen not to revise proposed § 26.165(f) of the final rule.

Cancel Test Result If Donor Requests Retest and Specimen Is Insufficient for Testing

Comments: One commenter stated that proposed § 26.165(f)(2) conflicted with the HHS Guidelines. The proposed provision required that an MRO cancel an initial confirmed test result if the donor requests a retest and testing by the second laboratory cannot be performed because of circumstances outside of the donor's control (e.g., insufficient quantity of single specimen to permit retesting, or a courier, the HHS-certified laboratory, or a licensee testing facility loses Bottle B). The commenter noted that, in this instance, the HHS Guidelines also require the MRO to direct the donor to submit a second specimen under direct observation [Charles LoDico, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.165(f)(2) in the final rule. That section now requires the MRO to inform the licensee or other entity that a second specimen collection under direct observation must occur if a donor requests the retesting of an aliquot of a single specimen or the testing of the Bottle B specimen after a confirmed positive, adulterated, or substituted test result, but the second HHS-certified laboratory is unable to test the specimen because of circumstances outside of the donor's control. Without this revision, it would have been be possible for a donor to test positive for a drug but, because the single specimen or the specimen in Bottle B of a split specimen could not be retested, the first confirmed positive test result would be cancelled and the licensee or other entity would not be required to take any further action. However, if the same donor did not request a retest of his or her specimen, the first confirmed positive test result would stand and the licensee or other entity would impose the appropriate sanctions on the individual. By requiring a second collection under direct observation, this section as revised ensures that the individual is not using prohibited drugs whether or not he or she requests the first specimen be retested. Including this provision in the final rule also increases the consistency of Part 26 with the drug testing requirements of other Federal agencies.

Additional Reason Why a Bottle B Specimen Could Not Be Tested

Comments: One commenter addressed proposed § 26.165(f)(2) and noted that an additional reason that a Bottle B specimen could not be tested for split specimen testing is because of

insufficient volume to permit testing or no volume at all [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.165(f)(2) in the final rule to include insufficient volume in Bottle B as an additional reason why a split specimen (Bottle B) could not be tested.

Reporting of Test Results from an HHS-Certified Laboratory

Comments: One commenter addressed the section-by-section analysis of substantive changes in proposed § 26.165(f)(1). The commenter stated that the phrase "If the test results from the second laboratory confirm any non-negative test results from the first HHS-certified laboratory, the proposed paragraph would require the licensee..." was inconsistent with the HHS Guidelines. The commenter suggested that the word "confirms" should be revised to "reconfirms" [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's request and has revised proposed §26.165(f)(1) in the final rule accordingly. In addition, in response to other comments received on the use of the term "non-negative test result," the NRC has replaced that term in this provision with "positive, adulterated, substituted, or invalid test result," as applicable.

9.9 Quality Assurance and Quality Control (§ 26.167)

Quality Control Testing

Comments: One commenter addressed proposed § 26.167 and recommended that quality control tests be conducted at the start of the testing period. If a specimen tests positive during the analytical run, the commenter recommended that a quality control test should be performed immediately after the positive test result was obtained to ensure that the testing equipment was functioning properly (i.e., the equipment is not reporting false positive results). A copy of the tests results for quality control testing performed at the start of the testing period along with the test results from the quality control test performed immediately after the positive specimen test should be provided to the MRO for each specimen that has a positive result. The commenter also recommended that, if back-to-back positive test results occur during a batch run, the second of the two samples should be tested again to ensure that carryover did not occur [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter's request. The NRC believes that the quality assurance and quality control provisions in the final rule provide enhanced measures to evaluate the performance of HHS-certified laboratory testing processes when compared to the commenter's suggestion because the rule requires that a variety of quality control samples must be included in every analytical run of specimens. Including quality control samples in each analytical run ensures that they are subject to the same testing conditions as any donor specimens that yield positive results. If quality control samples are tested only before and after each analytical run, it would be more difficult to conclude that any errors in testing identified also affected donor specimens because the conditions under which testing occurred differed. The purpose of including these quality control samples is to verify the accuracy of the testing process while it is occurring. Therefore, the NRC has not modified the proposed provisions in the final rule.

Replace Hyphens in Control Ranges with "to"

Comments: One commenter suggested replacing the hyphens used in proposed § 26.167 when identifying control ranges (e.g., 1-1.5 mg/dL creatinine) with "to." The suggested change would make the text consistent with the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has replaced the hyphens used in the control ranges specified in proposed § 26.167 with the word "to" in the final rule. The NRC also made this change in proposed § 26.137, where applicable.

9.9.1 Quality Assurance Program (§ 26.167(a))

No comments addressed this section.

9.9.2 Calibrators and Controls Required (§ 26.167(b))

No comments addressed this section.

9.9.3 Quality Control Requirements for Performing Initial and Confirmatory Validity Testing (§ 26.167(c))

Comments: One commenter addressed proposed § 26.167(c)(1)(iv) and stated that the creatinine concentration for the lower control should be revised from 1 to 1.0. The commenter indicated that the decimal place is important at the low end of the linear range [Charles LoDico, Individual].

NRC Response: The NRC agrees with the commenter and has revised the creatinine concentration from 1 to 1.0 in § 26.167(c)(1)(iv) of the final rule to improve accuracy in the language of the rule.

Reorganization of Requirements for pH Tests to Match HHS Guidelines

Comments: One commenter recommended that proposed § 26.167(c)(3)(i) through (c)(3)(v) addressing pH testing should be reorganized to be more consistent with the HHS Guidelines. Specifically, the commenter requested that proposed § 26.167(c)(3)(ii) be moved to the end of § 26.167(c)(3) and renumbered as (c)(3)(vi) and that the last sentence in proposed § 26.167(c)(3)(i) be moved to a new provision as § 26.167(c)(3)(ii) [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has reorganized § 26.167(c)(3) accordingly. These changes increase the final rule's consistency with related provisions in the HHS Guidelines.

Comments: One commenter recommended that the sentence structure of proposed § 26.167(c)(3)(iii) through (c)(3)(v) should be revised to be more consistent with the sentence structure used in the HHS Guidelines for the related provisions. The commenter suggested that the NRC should reverse the order of the clauses in the proposed provisions to present the requirements in these provisions before presenting the conditions under which each requirement applies [Sue Brown, Individual]

NRC Response: The NRC disagrees with the commenter's recommendation. The NRC believes that presenting the antecedent conditions for a requirement before presenting the requirement in a sentence is clearer than presenting the consequents first. Further, this practice is familiar to NRC licensees and other entities because it is consistent with the manner in which information is presented in operating, maintenance, and other types of procedures at nuclear facilities. Therefore, the NRC has not modified these provisions.

§ 26.167(c)(4) - Add References to Cutoff Concentration Sections

Comments: One commenter suggested revising proposed § 26.167(c)(4)(i) that stated, "Initial tests for oxidizing adulterants must include a calibrator at the appropriate cutoff concentration for the compound of interest..." to also include a reference to the sections in proposed § 26.161(c) that specified the cutoff concentrations. The commenter suggested that the recommended change would improve consistency with the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.167(c)(4)(i) in the final rule to include references to § 26.161(c) and (f). These provisions specify the cutoff concentrations for initial tests for oxidizing adulterants. The NRC made similar revisions to proposed § 26.167(c)(4)(ii) in the final rule. These changes improve the final rule's clarity.

Comments: One commenter recommended that the phrase, "Each confirmatory analytical run..." in proposed § 26.167(c)(4)(ii) should be replaced with the phrase, "Each confirmatory test batch" to be consistent with Section 2.5(h)(2) of the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request and believes that the proposed language adequately conveyed the testing requirement. Therefore, the NRC has not modified the proposed provision in the final rule.

9.9.4 Quality Control Requirements for Performing Initial Drug Tests (§ 26.167(d))

Comments: One commenter addressed § 26.167(d)(2) and (d)(3) and suggested that the wording in the proposed provisions should be reorganized to be consistent with proposed § 26.137(e)(6) [Sue Brown, Individual].

NRC Response: The NRC agrees in part with the commenter's suggestion. The NRC has revised § 26.167(d)(3) in the final rule to be consistent with the organization of § 26.137(e)(6). The NRC disagrees with the commenter's request to reorganize § 26.167(d)(2) because the proposed provision adequately conveys the intent of the requirement.

9.9.5 Quality Control Requirements for Performing Confirmatory Drug Test (§ 26.167(e))

Comments: One commenter addressed proposed § 26.167(e)(1) and recommended that, because the provision did not describe quality control samples, it should be deleted [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. Section 26.167(e)(1) presents quality control requirements for performing confirmatory drug testing, not only requirements for quality control samples to be included in each analytical run of specimens subject to confirmatory testing, as indicated by the commenter. Therefore, the NRC has not modified the proposed provision in the final rule.

9.9.6 Blind Performance Testing (§ 26.167(f))

Criteria for Positive Samples May Not Result in a Positive Test Result

Comments: One commenter addressed proposed § 26.167(f)(3) and stated that the drug or drug metabolite level for blind performance testing samples at "60-80 percent of the initial cutoff values for the panel of drugs" would not produce a positive result. The commenter also noted that the proposed drug or drug metabolite levels were inconsistent with those proposed for blind performance testing samples for licensee testing facilities in § 26.137(f)(6) [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.167(f)(9)(ii) to require that a drug positive blind performance testing sample must contain a measurable amount of the target drug or analyte between 150 and 200 percent of the initial cutoff value. This requirement appears in § 26.168(g)(2) of the final rule. In addition, the NRC has revised proposed § 26.167(f) to include specific criteria that each blind performance test sample type (i.e., negative, drug positive, adulterated, dilute, substituted, and false negative challenge) must meet. The final rule's § 26.168(g) contains these criteria. The criteria will ensure that each licensee and other entity sufficiently challenges the testing assays of HHS-certified laboratories to ensure accurate and reliable test results, thus improving the effectiveness and efficiency of FFD programs. The blind performance testing provisions in proposed § 26.167(f) were reorganized into a new section in the final rule, § 26.168(g), to improve the organization and clarity of the final rule.

Blind Performance Testing Sample - Dilute

Comments: One commenter addressed the proposed § 26.167(f)(3) requirement that a licensee or other entity submit blind performance testing samples to an HHS-certified laboratory meeting the criteria for a dilute specimen. The commenter stated that the HHS Guidelines contain no such requirement [Sue Brown, Individual].

NRC Response: The NRC has chosen to challenge HHS-certified laboratories with blind performance testing sample types beyond those required by the HHS Guidelines. Because the NRC is permitting licensees and other entities to subject dilute specimens to testing at the LOD under § 26.163(a)(2) in the final rule, the NRC believes that it is necessary to challenge the laboratory's ability to detect dilute specimens. Therefore, the NRC has not modified the proposed provision in the final rule.

Comments: One commenter noted that proposed § 26.167(f)(5) did not include reference to dilute specimens, as required by proposed § 26.167(f)(3) [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.168(e) in the final rule to require FFD programs to submit dilute blind performance testing samples to the HHS-

certified laboratory for testing each quarter. Because the NRC is permitting licensees and other entities to subject dilute specimens to testing at the LOD under § 26.163(a)(2) in the final rule, the NRC believes that challenging the laboratory's ability to detect dilute specimens is necessary. The blind performance testing provisions in proposed § 26.167(f) were reorganized into a new section in the final rule, § 26.168(g), to improve the organization and clarity of the final rule.

Eliminate Specific Concentrations for Drug and Validity Performance Testing Samples

Comments: One commenter addressed proposed § 26.167(f)(5)(i)and (f)(5)(ii) and thought that listing the specific concentrations for drug and validity performance testing samples may be confusing and restrictive. The commenter also noted that because proposed § 26.167(f)(5) listed the criteria for performance testing samples, the requirements in proposed § 26.167(f)(5)(i) and (f)(5)(ii) should be deleted [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's recommendations and has revised proposed § 26.167(f)(5)(i) and (f)(5)(ii) in the final rule. Specifically, the NRC replaced the proposed provisions with revised provisions in § 26.168(g) of the final rule that specify the criteria that each type of blind performance test sample must meet. The sample criteria in the final rule are less restrictive to ensure that FFD programs have the maximal flexibility to challenge the testing capabilities of HHS-certified laboratories. The blind performance testing provisions in proposed § 26.167(f) were reorganized into a new section in the final rule, § 26.168(g), to improve the organization and clarity of the final rule.

Blind Performance Testing Samples

Comments: One commenter addressed the drug performance testing sample provisions in proposed § 26.167(f)(5)(i)(A) and stated that samples at the proposed "20 percent above the designated cutoff for the initial drug test" may produce a negative result. The commenter recommended that the drug or drug metabolite concentration should be between 1.5 and 2 times the initial drug test cutoff concentration to ensure a drug positive on the initial drug test [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter. The NRC has moved proposed § 26.167(f)(5)(i)(A) to § 26.168(g)(2) of the final rule and revised it to require that drug positive blind performance testing samples must contain a measurable amount of the target analyte between 150 and 200 percent of the initial cutoff value for each drug tested. This revision will ensure that the accuracy of drug testing at HHS-certified laboratories is effectively evaluated. Also, the blind performance testing provisions in proposed § 26.167(f) were reorganized into a new section in the final rule, § 26.168(g), to improve the organization and clarity of the final rule.

Comments: One commenter addressed proposed § 26.167(f)(5)(i)(C) and asked why a drug performance testing "routine sample" would need to be below the cutoff for "special purposes." The commenter stated that the initial drug tests performed on a routine sample submitted to an HHS-certified laboratory would produce a negative test result because the drug concentration was below the initial cutoff level. The commenter recommended clarifying the statement or deleting the requirement from the final rule [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's request and has eliminated proposed § 26.167(f)(5)(i)(C) from the final rule.

Comments: One commenter identified an inconsistency between proposed § 26.167(f)(5)(i)(D) and the related provision in the HHS Guidelines. Specifically, the HHS Guidelines require a negative sample to contain no drug, while the proposed provision stated, "A negative sample may not contain the target drug analyte at a concentration greater than 10 percent of the confirmatory cutoff" [Sue Brown, Individual].

NRC Response: The NRC agrees with the comment. The blind performance test sample criteria have been revised in § 26.168(g)(1) of the final rule. That section now requires that a negative blind performance test sample may not contain a measurable amount of a target analyte and must be certified by immunoassay and confirmatory testing. The blind performance testing provisions in proposed § 26.167(f) were reorganized into a new section in the final rule, § 26.168(g), to improve the organization and clarity of the final rule.

Comments: One commenter addressed proposed § 26.167(f)(5)(i)(E) and recommended that the phrase "fortified with" be replaced with the word "contain" [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's request. The NRC has eliminated proposed § 26.167(f)(5)(i)(E) in the final rule in response to another comment. Therefore, no additional action is necessary to respond to this comment. However, the word "fortified" has been eliminated in the final rule in § 26.137(d) and § 26.167(d) and (e) to improve the final rule's clarity.

Comments: One commenter suggested that the NRC combine proposed § 26.167(f)(5)(ii)(D) and (f)(5)(ii)(E) to ensure that blind performance testing samples meet the requirements for substituted or dilute specimens required in proposed § 26.167(f)(3) [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter. To clarify the intent of the proposed provisions in § 26.167(f)(5)(ii)(D) and (f)(5)(ii)(E), the NRC has revised the blind performance test sample criteria for dilute samples in § 26.168(g)(5) of the final rule and for substituted samples in § 26.168(g)(6) in the final rule.

9.9.7 Errors in Testing (§ 26.167(g))

Comments: One commenter stated that proposed § 26.167(g)(3) incorrectly identified the title of the individual at an HHS-certified laboratory who is responsible for overseeing any corrective action required as a result of a false positive error. The commenter stated that position title should be the "responsible person" and not the "certifying scientist" [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised § 26.167(f)(3) in the final rule to refer to the individual at an HHS-certified laboratory who oversees any corrective action required as a result of a false positive error as the "responsible person." This change clarifies the intent of the rule.

9.9.8 Accuracy (§ 26.167(h))

No comments addressed this section.

9.10 Reporting Results (§ 26.169)

Comments: One commenter stated that the proposed § 26.169(a) requirement that HHS-certified laboratories must report for each specimen tested "...any indications of tampering, adulteration, or substitution that may be present..." was redundant given that laboratories will report validity test results as adulterated, substitute, invalid, or dilute. In addition, the commenter noted that any notation made on the custody-and-control form by the specimen collector also will be reported by the HHS-certified laboratory in the test result documentation. The commenter suggested that the NRC delete the proposed provision [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter. Tampering may occur after a specimen has been collected and before it arrives at the HHS-certified laboratory. Such tampering cannot be detected only through testing. For example, there may be physical evidence to suggest that a shipping container containing donor specimens had been opened in transit. If the proposed provision were eliminated from the final rule, the laboratory may not inform the licensee or other entity of the physical evidence and the possibility that tampering had occurred would not then be investigated, as required under § 26.159(b) of the final rule. Therefore, the NRC has not modified the proposed provision in the final rule.

Invalid Specimens Not Included as a Non-Negative Test Result

Comments: One commenter addressed proposed § 26.169(b), which specified the non-negative test results that an HHS-certified laboratory must report to the MRO. The commenter noted that the provision did not include invalid specimen test results [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has amended proposed § 26.169(c)(1) in the final rule to include an invalid specimen test result as a result that must be reported by HHS-certified laboratories to MROs.

Reporting Numerical Values of Specimen Test Results

Comments: One commenter addressed proposed § 26.169(d) and stated that the phrase "when applicable" in the provision for reporting of numerical values for dilute, adulterated, and substitute test results appeared to give HHS-certified laboratories the option of providing this information for specimens with substitute and adulterated test results, as opposed to requiring it. The commenter stated that the HHS Guidelines require laboratories to report to the MRO the numerical values for specimens with substitute and adulterated test results [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.169(c)(3) in the final rule to clarify the NRC's intent that HHS-certified laboratories must report to the MRO the numerical values for specimens with substitute and adulterated test results.

Reporting of Numerical Values for Dilute Specimens

Comments: One commenter addressed proposed § 26.169(d) and stated that the provision requiring HHS-certified laboratories to report numerical values for substitute, adulterated, and

dilute specimen test results "when applicable" made it appear that the laboratory would have to provide numerical values for dilute specimens. Because the HHS Guidelines do not require laboratories to report the numerical values for dilute specimens, the commenter suggested that the NRC revise the proposed provision to be consistent with the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised the reporting requirements for substitute and adulterated specimen test results in § 26.169(c)(3) of the final rule to clarify its intent that HHS-certified laboratories are required to report numerical values to the MRO for only adulterated and substitute test results.

Reporting of Creatinine Result, Substituted Specimens

Comments: One commenter stated that the requirement in proposed § 26.169(d), "If the numerical values for creatinine are below the LOD, the laboratory shall report to the MRO 'creatinine none detected' (i.e., substituted) along with the numerical values," was inconsistent with the HHS Guidelines. Specifically, the commenter stated that, if the creatinine concentration for a specimen is below the LOD, the HHS-certified laboratory will report a result of "creatinine: none detected" along with the numerical value of the specific gravity test [Sue Brown, Individual]

NRC Response: The NRC agrees with the commenter. The NRC has revised § 26.169(c)(3) in the final rule to specify that for a specimen with a creatinine test result below the LOD, the HHS-certified laboratory will report the result as "creatinine: none detected" along with the specific gravity test result for the specimen. The revision improves consistency between Part 26 and related HHS Guidelines provisions.

Reporting of Numerical Values for Drug Positive, Adulterated, and Substituted Test Results

Comments: One commenter suggested that proposed § 26.169(f) requiring the HHS-certified laboratories to "provide numerical values for non-negative confirmatory test results when the MRO requests such information" was redundant, given the reporting requirement in proposed § 26.169(d). The commenter suggested that perhaps the intent of the provision was to require the laboratory to provide numerical values for drug positive test results to the MRO [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter. The NRC has revised § 26.169(c)(2) in the final rule to require an HHS-certified laboratory to provide the quantitative test results for positive test results from confirmatory testing when requested by the MRO.

Reporting of Test Results, Number of Rejected Specimens

Comments: One commenter recommended adding two data elements to the reporting requirements in proposed § 26.169(k). To be consistent with the HHS Guidelines, the commenter suggested that HHS-certified laboratories should also report the number of specimens reported as rejected for testing because of a fatal flaw and the number of specimens rejected for testing because of an uncorrected flaw [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's recommendation and has added a requirement to § 26.169(h) of the final rule for HHS-certified laboratories to report the number of

specimens "rejected for testing and the reason for the rejection." The NRC added this reporting requirement to account for specimens where testing has been canceled by the MRO because of circumstances specified in § 26.159(b)(2) of the final rule.

Reporting of Test Results, Number of Specimens Received or Reported

Comments: One commenter stated that the requirement in proposed § 26.169(k)(1) for an HHS-certified laboratory to report the "total number of specimens received" at the laboratory was inconsistent with the HHS Guidelines which require the reporting of only the number of "specimen results reported" [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request. The NRC considers having HHS-certified laboratories report the total number of specimens received to be a necessary component of NRC oversight of licensees' and other entities' testing programs because it permits the NRC to determine how many specimens licensees and other entities send to HHS-certified laboratories for testing. Therefore, the NRC has not modified the proposed provision in the final rule.

Requirements Too Costly

Comments: One commenter stated that the revisions the NRC made to proposed §§ 26.168 and 26.169 to define blind performance testing and reporting results with more specificity were broad, unjustified, and would add significant costs to implement. He recommended that the NRC adopt in the final rule the requirements that it published in August 2005 in the *Federal Register* [Marvin Fertel, NEI].

NRC Response: The NRC disagrees with the commenter. (Section 26.168 in the final rule, and in the later version of the proposed rule on which this comment was based, appeared as § 26.167(f) through (i) in the proposed rule published on August 26, 2005.) The NRC has carefully considered both the practical means of implementing the revisions to which the commenter refers as well as the expected costs of implementing them. In each case the NRC believes the revisions to be necessary for the reasons stated below. The revisions to proposed §§ 26.168 and 26.169 include the following.

As compared to the proposed rule, the final rule's § 26.168 provides more detailed requirements for the formulation of blind performance test samples that licensees and other entities use to obtain HHS-certified laboratory performance data. It also revises the number, composition, and percentages of blind samples that licensees and other entities must submit to the HHS-certified laboratories. The NRC made these changes in response to detailed public comments that addressed these issues. For example, with respect to the proposed rule, the NRC has substantially changed the requirements in proposed § 26.167(f)(3) in response to extensive comments on the proposed blind performance test sample provisions. The final rule's § 26.168(b) requires that approximately 60 percent of all blind performance test samples that licensees and other entities send to the HHS-certified laboratory must be positive for one or more of the drugs for which the licensee or other entity tests. It also requires that all drugs for which the licensee or other entity tests must be submitted to the HHS-certified laboratory at least once a quarter except as indicated in § 26.168(b)(1) and (b)(2). This requirement will ensure that all licensees, including those who will send only the minimum number of blind samples the rule requires, will submit several samples for each drug being tested. This change

will permit licensees and other entities to better monitor and make more informed decisions regarding their HHS-laboratories' performance.

Section 26.168(c) of the final rule limits the submission of positive blind performance test samples to the HHS-certified laboratory to samples containing only those drugs for which the licensee or other entity tests and requires that the blind samples sent to HHS-certified laboratories must be formulated according to the requirements established in § 26.168(g)(2). With respect to the proposed rule, the final rule replaces the proposed requirement for positive samples to be spiked to between 60 and 80 percent of the initial cutoff levels used by the licensee or other entity with a cross-reference to the more detailed requirements for positive blind performance test samples in § 26.168(g)(2), which requires positive samples to be spiked to between 150 and 200 percent of initial cutoff levels.

The NRC has also added § 26.168(d) to the final rule. This paragraph requires licensees and other entities to submit approximately 10 percent of all blind performance test samples as false negative challenge samples to the HHS-certified laboratory according to the requirements established in § 26.168(g)(3). The NRC has added this provision in response to public comments on proposed § 26.167(f) that blind samples containing drugs or drug metabolites at a concentration 20 percent above the cutoff levels would frequently yield false negative test results and, therefore, unfairly challenge HHS-certified laboratories. False negatives occur when drug levels that are positive but close to the initial drug test cutoff level may actually be reported as negative. Assuming that an initial negative drug test has an error rate of one percent (one percent false negatives) and all HHS-certified laboratories perform equally, then over time, for every 100 people who have recently used drugs and been tested by licensees and other entities, one person will not be identified as having a positive test result for one or more drugs on the basis of the initial test alone. Recent research [Cone et. al., 2003)] strongly suggests that the issue of false negatives may be significantly greater than previously understood. The NRC recognizes that false negatives will occur within its drug testing requirements, but intends to minimize them as much as is reasonably possible within scientific constraints and practical resource limitations. Therefore, the NRC has established the requirements for the characteristics of false negative challenge samples under the final rule to present a fair test to HHS-certified laboratories because they are targeted at specimens clearly above the range of laboratory controls yet below the standard cutoff levels.

The final rule's § 26.168(e) requires licensees and other entities to submit approximately 20 percent of all blind samples as adulterated, dilute, or substituted and formulated according to the requirements established in § 26.168(g)(4) through (g)(6). The NRC added this provision for consistency with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed above with respect to comments on proposed § 26.31(d)(3)(i). This performance testing is necessary to challenge the accuracy of the HHS-certified laboratories' specimen validity testing. With respect to proposed § 26.167(f)(3), the final rule increases the proportion of blind samples that licensees and other entities must submit to challenge the laboratories' specimen validity testing. The NRC made this change in response to public comments on the proposed rule and the NRC's concern that validity test results are accurate.

The final rule also substantially decreases the percentage of negative blind performance test samples that licensees were required to submit to HHS-certified laboratories in former Section 2.8(e)(3) of Appendix A and in proposed § 26.168(f). The former and proposed

provision required 80 percent of blind samples to be negative. The final rule revises this percentage to 10 percent. The NRC made this change in response to public comments on the proposed rule and because the NRC believes that carryover effects (i.e., a positive sample contaminates a negative sample because of improper laboratory equipment cleaning), while a concern during the early years of drug testing, are not an issue in current HHS-certified laboratories based on current specimen testing practices. The NRC also believes that it is more appropriate to challenge the drug and validity testing capabilities of HHS-certified laboratories and therefore, has increased the percentage of positive, adulterated, substituted, dilute, and invalid specimens submitted as blind performance test samples in each quarter of testing.

The NRC has added formulation standards for the blind performance test samples that licensees and other entities must use in § 26.168(g). The final rule revises proposed § 26.167(f)(5)(i) in response to detailed public comments on the scientific and technical suitability of the proposed standards in achieving the NRC's objective of ensuring that the performance testing required under this rule ensures that test results from HHS-certified laboratories are accurate.

In summary, the NRC has made these changes in § 26.168(b) through (g) to increase the ability of licensees and other entities to independently monitor the ability of their HHS-certified laboratories to consistently identify positive, adulterated, dilute, and substituted specimens and hold false negatives to a minimum.

Section 26.169 of the final rule contains requirements for HHS-certified laboratories' reporting of test results to the licensee's or other entity's MRO. In response to public comments on the proposed rule, the NRC has added § 26.169(c)(3) to require the HHS-certified laboratory to report to the MRO numerical values supporting an adulterated or substituted test result. The final rule also adds instructions for the laboratory's report to the MRO if a specimen's numerical values for creatinine are below the LOD. The NRC added this provision for consistency with the HHS Guidelines. With respect to the proposed rule, the NRC has also added requirements for the laboratory to report whether a specimen that has been reported as positive and dilute was subject to the special analyses permitted under § 26.163(a)(2) and the number of specimens reported as rejected for testing. The NRC added these reporting requirements in response to public comment noting that the NRC requires this information to maintain adequate oversight of FFD programs and for consistency with related provisions in the HHS Guidelines.

10. SUBPART H: DETERMINING FITNESS-FOR-DUTY POLICY VIOLATIONS AND DETERMINING FITNESS

This section provides the NRC's responses to public comments on the proposed rule's Subpart H. That subpart contained requirements related to the decisions that MROs and other health care professionals must make when providing input to licensees' and other entities' decisions on whether an individual has violated the FFD policy and when making determinations of fitness.

10.1 Purpose (§ 26.181)

No comments addressed this section.

10.2 Medical Review Officer (§ 26.183)

No comments addressed this section.

10.2.1 Qualifications (§ 26.183(a))

No comments addressed this section.

10.2.2 Conflict of Interest Relationships (§ 26.183(b))

Comments: One commenter, supported by many other commenters, recommended that the NRC provide additional guidance in proposed § 26.183(b) to clarify what kinds of relationships between MROs and HHS-certified labs could potentially be construed as conflicts of interest. The commenter suggested that the NRC add language from U.S. DOT's 49 CFR 40.101(b) which provides examples of MRO conflicts of interest. The commenter noted that this suggestion is consistent with Goal 1 of the rulemaking [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees with the commenter's suggestion and has included in § 26.183(b) of the final rule specific examples of relationships between MROs and HHS-certified laboratories that could potentially be considered conflicts of interest. One such example would be a laboratory employing an MRO who reviews test results produced by the laboratory. The basis for these examples is 49 CFR 40.101(b) of the U.S. DOT's Procedures for Transportation Workplace Drug and Alcohol Testing Programs.

10.2.3 Responsibilities (§ 26.183(c))

No comments addressed this section.

10.2.4 MRO Staff (§ 26.183(d))

MRO Staff Performing Other Duties

Comments: One commenter, supported by many other commenters, thought that proposed § 26.183(d)(1)(i) would unduly limit the flexibility of MRO staff who are licensee employees. The commenter requested that licensee staff who perform MRO functions on a part-time basis be allowed to perform other duties for, and take direction from, the licensee while not working to support the MRO. The commenter thought this change would allow licensees to avoid needless increases to staff size. The commenter also recommended that licensees and other entities be allowed to continue assigning individuals to the MRO staff on a part-time basis in accordance with current practices. The commenter suggested that the NRC add the following language to the end of the proposed section: "Employees of licensees and other entities may function as MRO staff. When functioning as MRO staff they shall take direction from the MRO only" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees with this comment. The NRC does not intend to require that individuals who perform the function of MRO staff be employees of an MRO. Rather, the intent is to permit licensee staff who perform MRO functions on a part-time basis to perform other duties for the licensee while not working to support the MRO. Therefore, the NRC has added a sentence to § 26.183(d) in the final rule to make this intent clear.

Comments: Two commenters requested clarification on how the proposed rule would apply in certain situations. For example, under the former rule, if a site had MRO staff who were licensee employees and an MRO who was a contractor, the licensee would maintain authority over performance evaluations, hiring, and firing. The commenters expressed confusion as to how proposed § 26.183(d) would be implemented in such situations. The commenters stated that they interpreted the proposed rule to require the licensee to have an employee who is an MRO, have the MRO staff as employees, or make them all contractors. The commenters stated that there would be a cost burden on industry in all such cases [Nick DiPietro, First Energy; Susan Techau, Exelon].

NRC Response: Section 26.183(b) in the final rule allows the MRO to be an employee of the licensee or other entity or a contractor. Section 26.183(d) in the final rule stipulates that MRO staff may be employees of a licensee or other entity, employees of the MRO, or employees of an organization with which a licensee or other entity contracts for MRO services. Thus, for example, a licensee's MRO can be a contractor who works with MRO staff who are licensee employees. Whatever the MRO's and MRO staff's employment affiliations are, § 26.183(d)(1) stipulates that the MRO shall be directly responsible for the administrative, technical, and professional activities of MRO staff while they are performing MRO staff functions and that the MRO must direct those staff functions.

MRO Staff Function

Comments: Addressing proposed § 26.183(d)(2)(iii), several commenters requested that MRO staff, not exclusively the MRO, be allowed to validate prescription medication information as an

administrative function. The commenters believed that this change would allow MRO staff to better assist the MRO in obtaining the information necessary to make decisions about specimens [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC disagrees with this comment. The medications that a donor has taken or is taking is personal information that only a professional who meets the requirements to serve as an MRO is qualified to discuss with the donor and evaluate. NRC FFD program experience and that of other Federal programs indicates the necessity of having only MROs conducting these interviews. Therefore, the NRC has retained the prohibition on permitting MRO staff to request information about prescription medications from donors to protect individuals' privacy under the rule.

Restrictions on MRO Staff

Comments: One commenter, supported by many other commenters, disagreed with the language in proposed § 26.183(d)(2)(iv) that prohibited MRO staff from discussing non-negative test results with licensees and other entities. The commenter asked that MRO staff be permitted to relate confirmed results and to discuss those results with licensee and other entity personnel. The commenter stated that it is ineffective and inefficient to have only the MRO discuss results with the licensee or other entity personnel. The commenter recommended the following revised language for this subparagraph: "Staff may not report nor discuss any non-negative test results received from the HHS-certified laboratory with any individual other than the MRO and *individuals designated by licensees and other entities*" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: Allowing MRO staff to discuss non-negative test results with "individuals designated by licensees or other entities" would unduly expand the categories of personnel with whom MRO staff could discuss these results. Section 26.183(d)(2)(iv) in the final rule prohibits MRO staff from reporting or discussing any positive, adulterated, substitute, invalid or dilute test results with anyone other than the MRO or other MRO staff before the MRO has confirmed those results. It also stipulates that, once the MRO has confirmed those results, MRO staff may discuss such results only with other FFD program personnel and that these discussions may not include quantitative test results nor reveal any of the donor's personal medical information. These provisions are necessary to protect donor confidentiality and the integrity of the MRO review process. Only the MRO possesses the qualifications and experience to be able to answer questions from people outside the FFD program as to such sensitive and technical matters as the bases for his or her decisions and the proper interpretation of HHS-certified laboratory test results. Likewise, the NRC does not believe that MRO staff members are qualified to answer questions about an individual's medical condition, the bases for an MRO decision either to confirm an adverse confirmatory test result from an HHS-certified laboratory or to declare the test result as negative, or the meaning of any quantitative confirmatory test

results reported by the HHS-certified laboratory. Only the MRO can be permitted to conduct these discussions as § 26.183(d)(2)(iv) continues to require.

It should also be noted that proposed § 26.183(d)(2)(iv) referred to test results "received from the HHS-certified laboratory," which the NRC intended to be interpreted as meaning test results that have not been confirmed through MRO review. The NRC has modified this provision in the final rule to more fully convey its intent.

10.3 Determining a Fitness-for-Duty Policy Violation (§ 26.185)

"Referral Physician"

Comments: One commenter asked for clarification of the term "referral physician" in proposed § 26.185(h)(1) and (i)(1). The commenter recommended that the donor be allowed to choose his own specialist, especially if he has already obtained from the specialist the medical evidence required by these paragraphs [Todd Newkirk, IBEW].

NRC Response: The NRC agrees that the term "referral physician" was ambiguous and has deleted "referral" from § 26.185(h)(1) and (i)(1) in the final rule. The NRC intends that the MRO have sole responsibility to determine whether or not the donor has provided legitimate medical evidence and whether the specialist selected and/or the documentation provided meet the criterion of legitimate medical evidence. However, the rule does not prohibit a donor from selecting his or her own specialist or providing any documentation that the donor possesses.

Providing Legitimate Medical Evidence within 5 Days

Comments: With regard to proposed § 26.185(h)(1) and (i)(1), one commenter stated that 5 days is not enough time to get an appointment to see a specialist. The commenter suggested that it may be better to show proof of appointment with a specialist within 5 days and have the clearance placed on administrative hold, pending the results from the doctor. Further, the commenter suggested that the MRO should contact the specialist to expedite the appointment. The commenter also stated that, if the specialist exonerates the donor, the licensee should be liable for the costs of testing. However, the commenter stated that, if the specialist cannot confirm that a medical explanation exists, then the costs should be the responsibility of the donor [Todd Newkirk, IBEW].

Several other commenters stated that 5 business days is a sufficient period for the donor to have medical records sent to the MRO because the donor's physician is familiar with the donor's medical issues. They recommend that the NRC adopt this paragraph as proposed [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC believes that 5 business days is a reasonable period within which to expect donors to obtain their medical records. The U.S. DOT reports that people who have legitimate medical evidence related to the circumstances addressed in these provisions have not found it difficult to provide their medical records to an MRO within the 5-day time period

required under U.S. DOT's procedures. Therefore, the NRC has not modified this provision in the final rule.

10.3.1 MRO Review Required (§ 26.185(a))

Comments: Several commenters stated that the proposed § 26.185(a) requirement that MROs determine whether donors have violated FFD policy was onerous for MROs, whose expertise is medical. The commenters stated that MROs should not be required to interpret whether the FFD policy has been violated. Rather, MROs should be responsible only for reviewing non-negative test results before reporting the results to licensees [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC does not agree with the commenters. Section § 26.183(a) requires that MROs be knowledgeable of the FFD policies of the licensees or other entities for whom they provides services. Also, § 26.185(a) requires that MROs have detailed knowledge of alternate medical explanations for positive, adulterated, substitute, invalid, or dilute test results. The NRC believes that the combination of relevant specialized medical knowledge and knowledge of the licensees' or other entities' FFD policies adequately prepare MROs to make determinations of FFD policy violations. Therefore, the NRC has not modified this provision in the final rule.

10.3.2 Reporting of Initial Test Results Prohibited (§ 26.185(b))

No comments addressed this section.

10.3.3 Discussion with the Donor (§ 26.185(c))

No comments addressed this section.

10.3.4 Donor Unavailability (§ 26.185(d))

Comments: One commenter addressed the conditions under which proposed § 26.185(d)(1) through (d)(3) authorized an MRO to declare a non-negative test result or other occurrence to be an FFD policy violation without having first discussed the test result or other occurrence directly with the donor. The commenter recommended that these paragraphs be revised to make the licensee responsible for contacting the donor's supervisor and making arrangements for the donor to contact the licensee, who would then schedule a time for the MRO-donor discussion. Because the supervisor would be aware of the donor's schedule and health status, this would avoid the donor being declared in violation of FFD policy simply because he or she was unavailable due to perfectly innocent reasons [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter and believes that the three paragraphs in question provide adequate opportunity for the donor to be contacted without putting undue administrative or financial burden on the licensee. The first two paragraphs pertain to situations in which contact with the donor has been made and documented, and

which are not the subject of this comment. Section 26.185(d)(3) in the final rule authorizes the MRO to confirm a test result as an FFD policy violation if the MRO is unable to make contact with the donor "after making all reasonable efforts" to do so. This paragraph describes the actions that comprise "reasonable efforts" and also makes clear that the MRO may go beyond the stated efforts to make contact with the donor. It requires that the MRO, at a minimum, attempt to contact the donor at day and evening phone numbers at least three times, spaced reasonably over a 24-hour period. The NRC believes that contacting the donor at work is encompassed within "reasonable efforts." If the donor is on vacation or in the hospital, the MRO's reasonable efforts will likely uncover this information.

The NRC believes that naming the donor's supervisor, instead of the donor, as the point of contact for the MRO would be inefficient and would not address the issues raised by the commenter because the MRO may face the same challenges in contacting the supervisor as in contacting the donor. In addition, MRO contact with the supervisor would have the potential to violate the donor's privacy. However, § 26.185(e) provides donors with an opportunity to contact the MRO and request additional discussion of the test result(s) in circumstances such as those described by the commenter.

In the rare event that a donor is unable to either receive or respond to an MRO's call, § 26.185(e) grants the donor an opportunity to re-open the discussion with the MRO by documenting the reason(s) he or she was unable to contact the MRO. After the donor has been notified that the MRO has determined an FFD policy violation without discussion, the donor has 30 days to give the MRO information that documents the unavoidable circumstances which prevented the donor from establishing contact with the MRO or a representative of the licensee or other entity. After evaluating that information, the MRO may modify the initial determination.

The NRC believes that these provisions adequately protect donors' privacy and other rights (including due process) in the circumstances described by the commenter and has not modified the provisions in the final rule.

10.3.5 Additional Opportunity for Discussion (§ 26.185(e))

No comments addressed this section.

10.3.6 Review of Invalid Specimens (§ 26.185(f))

MRO Judgment

Comments: One commenter addressed proposed § 26.185(f)(2), (f)(3), (g)(1), (h)(1) and (i)(1) and asked what constitutes an "acceptable" or "legitimate" explanation for the drug test result. The commenter recommended that the provision should specify that, if the individual presents testimony or certification from a medical doctor (especially a specialist), the MRO must accept it as a valid reason [Todd Newkirk, IBEW].

Several other commenters stated that the industry believes MRO judgment to be adequate and appropriate when a donor submits medical evidence to the MRO, and thus recommended that the NRC adopt § 26.185(f)(2), (f)(3), (g)(1), (h)(1), and (i)(1) as proposed [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA;

Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters who supported the proposed provisions, and believes it is appropriate and adequate to rely on MRO judgment to determine if there is an acceptable medical explanation for drug test results, based upon his or her specialized medical knowledge, the qualifications and training required by § 26.183(a), and any information that the donor provides. Accordingly, the NRC has not modified the proposed provisions in the final rule.

10.3.7 Review of Dilute Specimens (§ 26.185(g))

Grounds Constituting Reason to Suspect Specimen Dilution

Comments: One commenter, supported by many other commenters, objected to the proposed language in § 26.185(g)(2) that included the specific circumstances that could constitute a reason the MRO may use to determine that a donor has attempted to dilute a specimen. The commenter stated that these circumstances were too restrictive, did not afford the opportunity for changes in medical knowledge, and could negatively impact the effectiveness of FFD programs. The commenter suggested deleting the last sentence in this paragraph as well as the three paragraphs that follow [(g)(2)(i) through (g)(2)(iii)] [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees that the term "exclusive grounds" made proposed § 26.185(g)(2) too restrictive. Therefore, the NRC has added language to the final rule clarifying that MROs shall consider the circumstances specified in § 26.185(g)(2)(i) through (g)(2)(iii) as applicable, but that these particular circumstances should not be considered the exclusive grounds to believe the donor may have diluted a specimen in a subversion attempt.

Typographical Error

Comments: Several commenters identified a typographical error in proposed § 26.185(g)(2) and (g)(3) which incorrectly referred to § 26.31(c)(1)(ii) rather than to § 26.31(d)(1)(ii) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The commenters were correct in identifying this typographical error. Revisions to § 26.185(g)(2) in the final rule have eliminated the need for the reference to § 26.31(d)(1)(ii). The NRC has revised § 26.185(g)(3) in the final rule so that it correctly refers to § 26.31(d)(1)(ii).

10.3.8 Review of Substitute Specimens (§ 26.185(h))

MRO Judgment

Comments that referenced this section are addressed in Section 10.3.6 of this document.

10.3.9 Review of Adulterated Specimens (§ 26.185(i))

Typographical Error

Comments: One commenter, supported by many other commenters, § 26.185(i)(3) noted a typographical error in proposed § 26.185(i)(3). The commenter suggested the following language to correct this error: "If the MRO determines that there *is* a legitimate medical explanation for the adulterated test result and no drugs or drug metabolites were detected in the specimen, the MRO shall report to the licensee or other entity the test is negative" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees that the error in proposed § 26.185(i)(3) resulted in an inconsistent provision and has revised the final rule accordingly.

10.3.10 Review of Opiates, Prescription, and Over-the-Counter Medications (§ 26.185(j))

Donor Responsibility to Determine if Medication Is Controlled Substance

Comments: Referring to proposed § 26.185(j)(6), which provided that the MRO may not consider a prescription for any drug on Schedule I of section 202 of the Controlled Substances Act [21 U.S.C. 812] as a legitimate medical explanation for a positive confirmatory drug test result, one commenter thought that an employee should not be responsible for determining if a medication prescribed for a medical condition is on Schedule I. The commenter also noted that, although proposed § 26.27(b)(6) referenced "the use of prescription and over-the-counter (OTC) medications that could cause impairment" as a factor that FFD policies must address, the proposed rule seemed to be inconsistent in that it did not require the individual to report the use of prescription and OTC medications to a supervisor [Todd Newkirk, IBEW].

Several other commenters stated that the industry agreed with the proposed § 26.185(j)(6) requirements because the use of Schedule I drugs is an FFD policy violation [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters who supported the proposed provision. The drugs on Schedule I, by definition, do not have legitimate medical uses and, except in very unique circumstances, are not prescribed by licensed physicians. Therefore,

donors will be required to communicate with their prescribing physicians to ensure that any medications are not listed on Schedule I.

Also, as noted by one commenter, the proposed rule did not require an individual using a prescription or OTC drug to report that drug use to the licensee or other entity. The NRC believes that requiring an individual to report use of prescription and OTC medications would be an invasion of the individual's privacy. To comply with the privacy requirements of the Americans with Disabilities Act [Pub. L. 101-336, July 26, 1990], the final rule eliminates the former rule's requirement that donors list their prescription and OTC medications before specimen collection and testing. The final rule requires donors to provide medication information to the MRO only in the event of positive, adulterated, substitute, or invalid confirmatory validity or drug test results in order to enhance their rights to privacy under the rule. This revised requirement is also consistent with the procedures of other Federal agencies.

Review for OTC Medications

Comments: After noting that the proposed rule did not require an individual to disclose his or her prescription and OTC medications when taking an FFD test, one commenter made three related points regarding the proposed § 26.185(j) requirement that the MRO review a donor's use of OTC medications. First, the commenter recommended that, because a donor could be taking OTC medications legally but be impaired nonetheless, the rule should require the licensee's testing program to designate a point of contact, available at all times, who could determine whether the medication being taken has the potential to jeopardize the safety of the individual, coworkers, or the plant. Second, the commenter recommended that the rule permit workers to report their use of prescription and OTC medications. In the commenter's view, this would eliminate the need for the worker to endure the stress of the MRO review if a medication were the cause of the non-negative test. Third, the commenter recommended that, if the employee were to forget about his or her OTC or prescription medications, and an FFD test were to identify them, the employee should be designated "Not fit for duty due to accepted medical reasons," until the MRO deems that the medication is no longer being taken. [Todd Newkirk, IBEW]

NRC Response: The NRC has chosen not to require that FFD programs designate a point of contact for individuals taking prescriptions and OTC medications. Section 26.27(b)(6) of the final rule requires that FFD policies address factors that could cause impairment, including the use of prescription and OTC medications. Also, § 26.27(c)(4) of the final rule requires that licensees and other entities must establish FFD program procedures to address this issue. Licensees and other entities have long-standing policies and procedures to address potential impairment from prescription and OTC medications, and the NRC is not aware of a need to improve them.

The NRC disagrees that donors should be allowed to report their OTC or prescription medications before specimen collection and testing. As noted in the NRC's response to the preceding comment, for reasons of individual privacy and consistency with the related requirements of other Federal agencies, the final rule eliminates the former rule's requirement that donors list their prescription and OTC medications before specimen collection and testing.

With respect to the commenter's third point, § 26.185(k) in the final rule addresses the commenter's concern that a donor may forget about his or her prescription or OTC medication

only to have the medications identified in the FFD test. That provision states that, if an MRO determines that there is a legitimate medical explanation for a positive drug test result, that the donor's use of a drug identified through testing was in the manner and at the dosage prescribed, and the test results do not reflect a lack of reliability or trustworthiness, the MRO will not determine that the individual has violated the FFD policy.

10.3.11 Results Consistent with Legitimate Drug Use (§ 26.185(k))

No comments addressed this section.

10.3.12 Retesting Authorized (§ 26.185(l))

No comments addressed this section.

10.3.13 Result Scientifically Insufficient (§ 26.185(m))

No comments addressed this section.

10.3.14 Evaluating Results from a Second Lab (§ 26.185(n))

No comments addressed this section.

10.3.15 Reauthorization after a First Violation for a Drug-Positive Test Result (§ 26.185(o))

No comments addressed this section.

10.3.16 Time to Complete MRO Review (§ 26.185(p))

Comments: One commenter, supported by many other commenters, suggested that proposed § 26.185(p) be revised to make it clear that the time period within which the MRO must complete his or her review of test results should be "business" days. The commenter suggested that this revision would ensure consistency between this paragraph and proposed § 26.169(a) which required that the HHS-certified laboratory report test results within 5 business days after receiving the specimen [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters and has revised § 26.185(p) in the final rule to make it clear that the period within which the MRO must complete his or her review of test results is to be measured in "business days."

10.4 Substance Abuse Expert (§ 26.187)

No comments addressed this section.

10.4.1 Implementation (§ 26.187(a))

Comments: One commenter, supported by many other commenters, recommended that proposed § 26.187(a) be revised to give the MRO, if qualified, the option to function as the substance abuse expert (SAE). This would avoid any unnecessary financial burden for licensees who have MROs qualified to make SAE determinations [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford Entergy].

NRC Response: The NRC agrees with the commenters and has revised § 26.187(a) in the final rule to specify that an MRO who meets the applicable requirements may serve as both an MRO and an SAE.

10.4.2 Credentials (§ 26.187(b))

No comments addressed this section.

10.4.3 Basic Knowledge (§ 26.187(c))

No comments addressed this section.

10.4.4 Qualification Training (§ 26.187(d))

No comments addressed this section.

10.4.5 Continuing Education (§ 26.187(e))

No comments addressed this section.

10.4.6 Documentation (§ 26.187(f))

Comments: One commenter recommended that the SAE documentation requirements in proposed § 26.187(f) be revised to require that such documentation be provided upon request to the individual subject to FFD policy requirements or to his or her designated representative [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenter. Documentation of the credentials, knowledge, and training of the SAE should be available upon request to individuals subject to FFD policy requirements or to their designated representatives as well as to NRC representatives, licensees, or other entities. The NRC has added a cross-reference in § 26.37 to § 26.187(f) in the final rule to specify that SAE documentation shall be made available in accordance with the protection of information requirements.

10.4.7 Responsibilities and Prohibitions (§ 26.187(g))

Comments: One commenter recommended revising proposed § 26.187(g)(2) such that, once the SAE has made the recommendation for the best treatment of the individual, the individual should be allowed to select the entity that will provide the treatment as long as the entity meets the credential requirements for the course of treatment provided. In the commenter's view, this would prevent potential conflicts of interest. The commenter also stated that, because personality conflicts may interfere with treatment, the individual should be allowed to change treatment providers (with SAE concurrence) during the course of treatment [Todd Newkirk, IBEW].

NRC Response: The NRC has declined to make the commenter's recommended revision. The NRC notes that § 26.187(g)(2) in the final rule does not preclude the SAE from considering a donor's preferences, among the other considerations specified, in identifying a treatment provider. However, "personality conflicts" with a treatment provider may be clinically meaningful and changing providers may not represent the most effective resolution to the issues. The NRC is confident that an SAE will be qualified to address such circumstances, and, therefore, has not modified this provision in the final rule.

10.5 Determination of Fitness (§ 26.189)

Definition of Determination of Fitness

Comments: One commenter, supported by other commenters, stated that proposed § 26.189(a) was confusing. The commenter suggested rewording the first sentence of the paragraph to clarify what a determination of fitness is: "A determination of fitness is the process entered when there are indications that an individual may be in violation of the licensee's or other entity's FFD policy or is otherwise unable to safely and competently perform his or her duties" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters. A determination of fitness is conducted when indications are identified that the individual may be in violation of the FFD policy, not to determine whether there are such indications. Therefore, the NRC has modified the provision in the final rule to clarify this intent.

Language Clarification

Comments: Another commenter, supported by many other commenters, stated that proposed § 26.189(b)(3) was confusing and suggested the following minor word change: "Before an individual is granted authorization when potentially disqualifying FFD information is identified *that* has not previously been evaluated by another licensee or entity who is subject to this part..." [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey

Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters. A determination of fitness should be conducted before an individual is granted authorization when potentially disqualifying fitness-for-duty information (PDFFDI) that has not been previously evaluated by another licensee or entity subject to Part 26 is identified. Therefore, the NRC has modified § 26.189(b)(3) in the final rule to clarify this intent.

Requirement for Face-to-Face For-Cause Determination of Fitness

Comments: Addressing proposed § 26.189(c), one commenter, supported by many other commenters, stated that face-to-face interaction is not always required to make a "for cause" determination of fitness. The commenter stated that the determination of the appropriate method of conducting this determination should be left to the professional making the determination. The commenter thought that, in other parts of the rule, the qualified professional would be expected to make a determination of fitness using methods that are generally acceptable in the professional community and these may not include face-to-face interaction in all circumstances. For example, if the ultimate issue is whether a certain psychoactive medication will prevent an individual from performing assigned duties, a clinical psychologist may be able to provide the needed determination of fitness without a face-to-face interaction. Thus, the commenter suggested deleting this paragraph, renumbering (d) as (c), and moving the subparagraphs in the previous (c) under the new (c) [Randy Cleveland, NMC; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C. L. Funderburk, Dominion; F. G. Burford, Entergy].

NRC Response: The NRC has revised § 26.189(c) of the final rule by adding the phrase "because of observed behavior or a physical condition." With respect to the proposed rule, § 26.189(c) of the final rule makes explicit that a qualified professional must make a for-cause determination of fitness only when an individual's observed behavior or physical condition indicates that he or she may be in violation of the FFD policy or otherwise unable to safely and competently perform his or her duties. This paragraph also requires that a for-cause determination of fitness must be conducted through face-to-face interaction between the professional and the individual. The NRC believes that this assessment should be conducted face to face so as to include immediate sensory observation (such as the smell of alcohol or the individual's physical appearance or behavior). The professional can make these observations only during a face-to-face interaction.

The NRC has added the phrase "because of observed behavior or a physical condition" to § 26.189(c) of the final rule also to make explicit that a for-cause determination of fitness is not required if there is an absence of relevant physical or sensory information (e.g., based solely on receiving information that an individual is engaging in substance abuse). If the licensee or other entity chooses to determine an individual's fitness in such circumstances, the final rule does not require that the determination be conducted face to face.

Second Determination of Fitness

Comments: One commenter stated that proposed § 26.189(d) appeared to eliminate the use of a second MRO to evaluate additional information supplied by an individual after an initial determination of fitness has been made. The commenter thought that this would create the situation where an individual's fitness cannot subsequently be evaluated if the deciding MRO is unavailable because only that MRO can change his or her initial determination. The commenter also stated that this section appeared to conflict with the review process in § 26.39. Therefore, the commenter suggested removing this section from the rule [C. L. Funderburk, Dominion].

NRC Response: The NRC disagrees that proposed § 26.189(d) would lead to situation in which an individual's fitness cannot subsequently be evaluated if the deciding professional, including an MRO, is unavailable in the long-term. Section § 26.189(d) prohibits individuals, licensees, and other entities from seeking a second determination of fitness once a qualified professional has made the initial determination of fitness. However, it does allow the professional to "...modify his or her evaluation and recommendations based on new or additional information...." Furthermore, in cases where "...the professional who made the initial determination of fitness is no longer employed by or under contract to the licensee or other entity..." this section also permits a second qualified professional to modify the evaluation and recommendations. In these instances, § 26.189(d) makes the licensee or other entity responsible for arranging a consultation between the two professionals. In the short-term, if the professional who made the original fitness determination is on vacation or sick leave, he or she may evaluate any new or additional information upon returning to duty.

The NRC also disagrees that proposed § 26.189(d) conflicts with § 26.39. Sections 26.189 and 26.39 contain provisions for differing types of reviews. Section 26.189(d) pertains to a determination of fitness, which is the process of determining whether an individual is fit to safely and competently perform his or her duties. Qualified professionals make these determinations under § 26.189(b) of the final rule. The review process required in § 26.39, on the other hand, is intended to determine whether there are facts or circumstances to support a determination that an individual has not violated the FFD policy, after an initial determination that the individual violated the policy has been made. This section specifically states that persons conducting these reviews cannot be associated with the administration of the FFD program (e.g., those who made the original adverse § 26.189(d) determination of fitness). Therefore, the NRC has not modified the proposed provision in the final rule.

11. SUBPART I: MANAGING FATIGUE

This section provides the NRC's responses to public comments on the proposed rule's Subpart I. That subpart was intended to strengthen the effectiveness of FFD programs by establishing clear and enforceable requirements for the management of worker fatigue. Many commenters submitted comments on proposed Subpart I. This section begins by addressing comments expressing general support for those proposed provisions and other comments on significant general technical and policy issues they raised. The remainder of this section addresses comments on specific sections of proposed Subpart I.

Support for Subpart I

Comments: Many commenters supported Subpart I. For example, several commenters strongly supported the fatigue provisions for various reasons, including the prevention of worker injuries and forced overtime, as well as increased opportunity for time workers will have available to spend with their families [Anonymous #26; Anonymous #27; Anonymous #28; Anonymous #29; Mark Haywood, Individual; Greg Gorman, Individual; Richard Barkley, Individual]. Some commenters stated that the new requirements will force the owners/operators of power plants to increase staffing levels and reduce overtime [Mike Jolley, Individual; Anonymous #19; Richard Barkley, Individual]. Another commenter thought that the fatigue provisions will also be beneficial from a security standpoint, [Anthony Rizzo, Salem Hope Creek]. Two commenters stated that, if fatigue is left unchecked, problems will worsen due to regulation, downsizing, and the aging workforce [Anonymous #29, Anonymous #75]. Another predicted that the fatigue provisions may increase the experience level of current personnel while reducing the operating costs of licensees, as fewer resources will need to be dedicated to the training of replacement personnel [Kenneth Kolaczyk, Individual]. Another commenter welcomed the fatigue management requirements because the nuclear industry workforce is aging and nuclear plant operators are slower to recuperate from changing shift rotations and less receptive to disruptions in a daily life schedule. He also said that the industry does not want to accept worker fatigue as an issue because it would mean hiring and training additional nuclear power plant operators [Douglas Foster, PROS]

Several commenters supported the fatigue provisions in Subpart I by challenging industry arguments against the requirements. They disagreed with the industry's argument that, because worker fatigue has not yet led to a significant reactor event, there is apparently no problem to be resolved by regulation [David Lochbaum, UCS; Deborah Katz, CAN; Anonymous #75]. Two commenters thought that this argument is "intellectually bankrupt" for at least two reasons. First, past evaluations of plant events do not parse human performance finely enough to dismiss fatigue as either a primary or contributing factor. The commenters noted that there are indeed events where "failure to follow procedure" is identified as a cause, and this could be a result of fatigue. Second, the commenters thought that "it would be imprudent public policy and unwise business judgment to tolerate an unsafe practice until it caused mayhem." The commenters stated that, although NEI data showed that excessive working hours were not rampant in the industry and that most plant owners were responsibly managing working hours, the data also revealed that some licensees worked employees beyond reason. Thus, the commenters thought that this rulemaking was necessary to control those licensees who cannot responsibly manage work hours and to provide adequate protection against impairment from fatigued workers [David Lochbaum, UCS; Deborah Katz, CAN].

Another commenter stated that, because nuclear power plant safety is predicated upon the proper implementation of programs and procedures by qualified personnel, and studies have shown that fatigued personnel are less likely to conduct activities properly, the proposed work hour restrictions would be a "prudent NRC action" [Kenneth Kolaczyk, Individual].

One commenter supported the inclusion of education and fatigue assessment as complements to the explicit work hour policies, as this would represent a progressive approach that acknowledges the complexity of managing fatigue in the nuclear power industry. The commenter stated that, although a duty-hour approach to controlling fatigue cannot fully address fatigue factors, it is essential to provide reasonable assurance that the risk of fatigue-related events is being managed. However, the commenter stated that, while Federal duty-hour policies provide a critical and central structure for managing fatigue, there should also be consideration of the need to respond to unforeseen circumstances and operational flexibility [Mark Rosekind, Alertness Solutions].

NRC Response: These comments do not require a response.

Individuals' Recognition of Fatigue

Comments: Several commenters stated that workers should be able to recognize when they are fatigued and should be able to correct the issue themselves using the NRC's former regulatory framework that addressed fatigue issues. Thus, these commenters thought that the proposed fatigue requirements would be overly burdensome and unnecessary. Some of these commenters suggested that the only fatigue-related change to the FFD program should be the prohibition of forced overtime. They thought voluntary overtime should be allowed [Jim Waite, Individual; Blaine Peters, Exelon; Dan Todhunter, Individual; Donald Lenski, Individual; Robert Althoff, Individual; Guy Galster, Individual]. Another commenter recommended that the rule provide support to any individual who needs a second day off during an outage to be able to request it without fear of intimidation by licensee management [Edwin Hill, IBEW].

NRC Response: The NRC agrees in part with the commenters concerning workers' ability to recognize when they are fatigued. However, although individuals are able to make relative judgments regarding their level of fatigue, there have been several studies that noted the tendency for individuals to underestimate their level of impairment from fatigue, as discussed in the *Federal Register* on August 26, 2005 (70 FR 50458). More recent research has suggested that individuals may not take necessary safety precautions despite recognizing that they are impaired by fatigue (Nabi et al., 2006). The NRC has also received allegations from nuclear power plant workers expressing fear of adverse actions from employers for reporting that they are unfit for duty because of fatigue. As a consequence, the NRC does not believe there was reasonable assurance workers can reliably address excessive fatigue solely through their own actions under the former policy applicable to worker fatigue or that only a prohibition on forced overtime would be adequate. Therefore, the NRC has retained requirements in the final rule concerning fatigue management.

New Provisions Add Cost and Only Facilitate Regulatory Oversight

Comments: One commenter stated that, unless the NRC was finding frequent excessive work hours being worked by nuclear power plant workers, providing "additional layers of bureaucracy" would add costs while only seeming to facilitate regulatory oversight [David Sancic, Individual].

Another commenter predicted that the industry will require workers to track and record hours they have performed on "covered work" and "non-covered work." Doing this will distract workers and reduce their ability to safely complete their tasks. He also thought that compliance with proposed Subpart I would be excessively burdensome on industry by, for example, requiring licensees to develop or modify existing payroll systems to capture the layered work control limit requirements [Edwin Hill, IBEW].

NRC Response: The NRC disagrees that the final rule's fatigue management requirements will add costs but only seem to facilitate regulatory oversight. The NRC has documented concerns regarding frequent excessive use of work hours in SECY-01-0113, "Fatigue of Workers at Nuclear Power Plants," and SECY 05-0074, "Proposed Rule to Amend the Fitness-For-Duty Requirements in 10 CFR Part 26." For example, the NRC staff reported in SECY-01-0113 that more than 80 percent of the authorizations written by licensees to exceed the technical specification work hour limits during outages were for exceeding 72 hours (e.g., six 12-hour shifts) in a 7-day period. Based on a pattern of similar findings over several years, the NRC strongly believes that establishing clear and enforceable requirements for the management of worker fatigue is necessary to ensure that worker fatigue does not adversely affect public health and safety and the common defense and security. The NRC is confident that the industry's costs to comply with these requirements will be no more than is reasonable to achieve these important goals.

Lack of Correlation between Impacts of Fatigue and Performance at Reactors

Comments: One commenter, supported by several other commenters, stated that no correlation has been found between the claimed impacts of fatigue and actual human performance at power reactor sites. Thus, the commenter thought that there was no need to significantly expand fatigue requirements beyond those contained in Generic Letter 82-12. The commenter also stated that facilities' human performance data showed no adverse trend in performance for longer outages and beyond the sixth day of work. Therefore, the commenter disagreed with the staff's contention that increased fatigue after long outages and after the sixth day of work affects human performance [Andrew Antrassian, UWUA; Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG; T. J. Reddington, Associated Maintenance Contractors; Edward Sullivan, AFL-CIO; William Hite, UAJA; Dave Barry, Shaw Stone & Webster; Edwin Hill, IBEW].

NRC Response: The NRC disagrees with the conclusions of the report, "Work Hour Rule Data Summary," submitted by the commenters. The report concludes that human performance does not suffer in longer outages with longer work hours and that there is no adverse trend in human performance for work beyond six straight days. The report's conclusions do not withstand a rigorous analysis and therefore cannot support retaining only the fatigue management practices described in Generic Letter 82-12.

According to the report the plot of the number of human performance errors and corrective action reports (CRs) that occurred over a 13-week period has a downward trend (in the data) during an outage. However, both human performance errors and CRs, while declining between

weeks 4 and 10, are actually increasing for weeks 11 through 13. (There are no data provided after week 13.) Moreover, the number of CRs is actually higher in week 13 as compared to week 1 (60 versus 40). These numbers illustrate a problem generally associated with visual inspection of time series data, namely scale values. If only data for weeks 1 and 13 were shown, visual inspection of the data would have led to the observation that human performance errors increase over time during an outage, while CRs are roughly constant.

Several plants submitted data for human performance errors by day of work for 7 straight days. Again, the report stated that the data demonstrated that there was either a downward or no trend in human performance errors as a function of the number of days worked. As with the previous plot, this conclusion was not the result of a rigorous analysis of the data but rather a subjective conclusion based on visual inspection of graphs.

The NRC recognizes that the analysis of the data collected by licensees to evaluate human performance errors during periods of normal operations and outages is of anecdotal value. However, the NRC disagrees that the report is evidence that the proposed rule should have been revised to eliminate the fatigue management requirements. In contrast, the overwhelming body of evidence, as discussed in Section IV.D of the preamble to the final rule, supports the need for periodic days off to prevent cumulative fatigue and human error. Therefore, the final rule language retains provisions to address cumulative fatigue. However, in response to comments regarding the proposed § 26.199(d)(2) provisions concerning the minimum break requirements and the collective work hour limits in proposed § 26.199(f), the NRC has revised the provisions to address cumulative fatigue. The final rule's § 26.205(d)(2) through (d)(6) contains the revised minimum break and day off requirements; the NRC has eliminated the collective work hour requirements in the final rule.

Questionable Data

Comments: One commenter claimed that the justification for the proposed fatigue provisions was based on speculative and politically skewed information rather than on sound scientific data [Daniel Hansen, Individual].

NRC Response: The NRC disagrees with the commenter and notes that the commenter provided no basis for this assertion. The studies relied on by the NRC as the basis for the proposed requirements are largely from refereed journals. The findings of those studies were consistent with the broader research literature and widely accepted fatigue management guidelines. Therefore, the NRC has retained the Subpart I requirements for the management of fatigue in the final rule.

Inconsistency with Goals of the Rulemaking

Comments: Several commenters stated that the proposed Subpart I work hour provisions were inconsistent with some of the stated goals of the rulemaking. They thought that Subpart I would introduce new inefficiencies and unnecessary requirements which would be contrary to the rulemaking's Goals 3 and 5. They suggested that broader application of performance-based principles and fewer prescriptive limits would more effectively meet the Commission's intent in Generic Letter 82-12 [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory

Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees in part with the comments on the proposed work hour provisions. Therefore, the NRC has eliminated the collective work hour controls that would have been required by the proposed rule and has restructured the rest break and day off requirements in the final rule in a manner that will reduce the burden on licensees and place more emphasis on performance-based requirements. The revised break and day off requirements are presented in § 26.205(d)(2) through (d)(6) of the final rule.

Napping Policies

Comments: One commenter noted studies that show that napping at the workplace is especially effective for workers who need to maintain a high degree of alertness, attention to detail, or make quick decisions. Based on this information, the commenter encouraged the NRC to include a requirement for sound napping policies in licensees' fatigue management plans. The commenter recommended that these napping policies include the designation of quiet, dark and accessible areas (e.g., rooms in EAP or wellness units) to be used as napping facilities. The commenter also recommended that use of these facilities should be encouraged, especially during outages, the use of heavy overtime, and when waivers are granted [Darrel Drobnich, NSF].

NRC Response: The NRC agrees that napping is a particularly effective fatigue management strategy. The final rule does not require licensees to use napping, or address napping, in their fatigue management policies so that licensees have the flexibility to use the methods they consider most appropriate and effective in the specific circumstances they face. However, the NRC notes that § 26.205(b)(2) of the final rule allows licensees to exclude within-shift break times from work hour calculations if the licensee provides reasonable opportunity and accommodations for sleep and mentions napping as an example means of doing so. Although this provision does not require licensees to use napping as a fatigue mitigation strategy, permitting licensees to exclude time used for napping from work hour calculations removes a potentially significant disincentive for using this strategy. In addition, § 26.203(c) of the final rule requires licensee FFD training programs to address "the effective use of fatigue countermeasures" and verify worker knowledge and abilities through a comprehensive examination as required by § 26.29(b). As a consequence, the NRC expects that licensees who choose to use napping as a fatigue mitigation strategy will have associated training to ensure effective implementation.

11.1 Applicability (§ 26.195)

No comments addressed this section.

11.2 General Provisions (§ 26.197)

Comments: One commenter supported proposed § 26.197(a) through (c) [Brian McCabe, Progress Energy]. Other commenters expressed support for the provisions in proposed § 26.197(a) through (d). These commenters agreed that establishing clear policies, procedures,

training and records will be a significant improvement in work hour management requirements [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: These comments do not require a response. The final rule's § 26.203 establishes fatigue management requirements for licensees' FFD programs, replacing § 26.197 of the proposed rule.

11.2.1 Policy (§ 26.197(a))

Comments: Several commenters supported proposed § 26.197(a) and stated that setting clear expectations for individuals to self-declare and establishing a process for dealing with fatigue were key features of the proposed rule [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: These comments do not require a response. The proposed § 26.197(a) requirement that licensees establish a fatiue management policy has been moved to the final rule's § 26.203(a).

11.2.2 Procedures (§ 26.197(b))

Support for Self-Declaration Procedures

Comments: Some commenters supported the procedure requirements of Subpart I, specifically those in proposed § 26.197(b)(1). This paragraph required licensee FFD programs to explicitly describe a process for making and handling fatigue self-declarations by all workers. The commenters stated that this requirement would be "absolutely vital to the efficacy and integrity of the program." They also stated the proposed language would assure that appropriate checks and balances are in place to limit abuses both in the case of management forcing fatigued workers to stay on the job, as well as workers using fatigue self-declaration to supplement their sick/vacation time [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: These comments do not require a response. The proposed § 26.197(b)(1) requirement that licensees establish procedures to accommodate individuals' self-declarations of fatigue has been moved to the final rule's § 26.203(b).

Rest Break Procedures

Comments: One commenter suggested that the NRC add to proposed § 26.197(b)(1)(iv) and (b)(1)(v) a requirement for a licensee procedure that would describe criteria for workers to use to activate the 24- or 48-hour optional rest period. The commenter suggested the following language for § 26.197(b)(iv): "For individuals working a nominal rotation shift cycle containing a

majority of 8-hour shifts for 7 work days not to exceed 8 work days of continuous duty with each work shift providing a break period as described in § 26.199(d)(2)(i); describe the process to be followed when an individual requests to observe a 24-hour and/or a 48-hour break period prior to the licensee soliciting or assigning further work to an individual exceeding the last scheduled day containing the 7 or 8 continuous work days as allowed by § 26.199(d)(2)(ii), (d)(2)(iii) and (d)(4)." The commenter also suggested the following language for § 26.199(b)(1)(v): "Describe the process to be followed when an individual requests to observe a 48 Hour break period for individuals working a nominal rotation shift cycle containing a majority of scheduled hours above 8 hours per shift as allowed by § 26.199(d)(2)(iii)(a) and § 26.199(d)(4) [Edwin Hill, IBEW].

NRC Response: While agreeing in part with the commenter, the NRC did not conclude that it was appropriate to establish a requirement for optional rest periods. The NRC has, however, revised proposed § 26.197(d)(3) through (d)(6) by establishing minimum day off requirements that allow increased flexibility in the specific timing of the breaks. (These requirements appear in § 26.205(d)(3) through (d)(6) of the final rule.) This increased flexibility permits licensees and workers to address personal and work schedule needs while continuing to provide reasonable assurance that individuals do not become impaired from fatigue because of excessive work hours. Therefore, the commenter's concerns have been addressed through alternative requirements.

Self-Declaration Procedures

Comments: One commenter was concerned that proposed § 26.197(b)(1) would mandate overly prescriptive requirements for the content of licensee procedures with respect to worker self-declarations of fatigue. The commenter stated that the proposed rule appeared to intrude unnecessarily into the employer-employee relationship and would establish new responsibilities and procedural rights beyond existing collective bargaining agreements. The commenter recommended that the rule should not rely on self-declarations as the primary means of identifying fatigue, and that the training of shift workers that would be required as part of the fatigue management program under proposed § 26.197(c) would be sufficient. Thus, in view of the adequacy of training, the commenter recommended that the NRC eliminate the requirement for a detailed self-declaration procedure [Daniel Stenger, NRSG].

NRC Response: The NRC disagrees that the proposed rule intruded unnecessarily into the employer-employee relationship and that the NRC should have eliminated the requirement for a self-declaration process. Section 26.203(b)(1) of the final rule requires licensees to develop, implement, and maintain a procedure for self-declaration. It further requires that the procedure describe the individual's and licensee's rights and responsibilities related to self-declaration, the controls and conditions under which an individual may be permitted or required to perform work after that individual declares that he or she is not fit because of fatigue, and the process to be followed if the individual disagrees with the results of a fatigue assessment. The rule does not establish the individual's rights and responsibilities, does not prescribe the controls and conditions that must be established, and does not prescribe the process to be followed if an individual disagrees with the results of a fatigue assessment. As a consequence, the NRC does not believe that the requirement for a procedure intrudes unnecessarily into the employer-employee relationship. However, in light of the allegations that the NRC has received concerning self-declaration of fatigue, it appears that there has been a lack of understanding by licensees and workers regarding the applicability of the requirements of Part 26 and 10 CFR 50.7 to these circumstances, and that a procedure that addresses the self-declaration

process is necessary to ensure that self-declaration is an effective means for detecting impairment from fatigue. Therefore, the NRC has retained the proposed self-declaration requirements in § 26.203(b)(1) of the final rule.

11.2.3 Training and Examinations (§ 26.197(c))

Comments: One commenter fully endorsed proposed § 26.197(c) because, in his view, comprehensive education and training on the promotion of good quality sleep and the mitigation of fatigue are essential to the promotion of safety in the nuclear industry. The commenter also suggested that some education and training on sleep, sleep disorders and the consequences of sleep deprivation, although not necessarily examinations, should be required for all personnel, whether or not they are in safety sensitive positions or covered under work hour controls in proposed § 26.199(a). The commenter stated that education of all personnel, including (and perhaps especially) upper management, is key to fostering a culture that embraces alertness and effective fatigue management. With regard to proposed § 26.197(c)(1), this commenter recommended that the NRC provide specific guidance regarding topics that should be covered in fatigue training and education modules and examinations. The commenter suggested that the NRC take the lead in developing uniform curriculum and examination materials in order to ensure the accuracy and uniformity of information provided. The commenter also recommended that all MROs should receive education and training regarding the signs and symptoms of sleep disorders as well as effective treatment options, and that information on the prevention of drowsy driving should be included in any materials that are developed [Darrel Drobnich, NSF].

NRC Response: The NRC agrees in part with the commenter's suggestions. The NRC notes that the training requirement, which appears in § 26.203(c) in the final rule, applies to all licensee personnel subject to the FFD program, not only to workers subject to the work hour controls. Consequently, managers and MROs, who have an important role in fostering an effective fatigue management culture, are subject to the training requirements. With regard to the commenter's suggestion that the NRC provide guidance regarding the specific topics that should be addressed in fatigue management training, the NRC notes that § 26.203(c)(1) of the final rule requires licensees to include specified knowledge and abilities concerning fatigue management in the content of the FFD training program. Establishing training requirements at the knowledge and abilities level permits licensees the flexibility to update their existing FFD training programs, as necessary and in a manner that efficiently achieves the fundamental objective of the training. Although the NRC agrees that a uniform curriculum may help ensure the accuracy of the information provided, and notes the NRC may participate in the development and review of guidance concerning fatigue management training, individual licensees are responsible for ensuring that their training materials are technically correct and support trainee attainment of the required knowledge and abilities.

11.2.4 Recordkeeping (§ 26.197(d))

<u>Support for Recordkeeping Provisions</u>

Comments: Two commenters supported the proposed § 26.197(d) recordkeeping requirements, especially the 3-year records retention requirement, because it would be consistent with the inspection cycle of the reactor oversight process. Several other commenters thought this proposed provision, combined with the reviews of control of work hours required in

proposed § 26.199(j), would provide an additional performance-based provision to the rule and would also assure that performance expectations would be met [David Lochbaum, UCS; Deborah Katz, CAN; Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: These comments do not require a response. The recordkeeping requirements in proposed § 26.197(d) now appear, with revisions, in the final rule's § 26.203(d).

Records of Rest Breaks

Comments: One commenter suggested that the NRC add to proposed § 26.197(d) the requirement that licensees retain "Documentation of individual requested rest breaks and final licensee disposition of the requested break in accordance with § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii)" [Edwin Hill, IBEW].

NRC Response: The NRC disagrees that individual requested rest breaks should be documented. Optional rest breaks alone do not provide reasonable assurance that nuclear power plant workers will obtain an adequate amount of rest. Consequently, the NRC does not believe that recording such requests is warranted. However, the NRC has modified the proposed rule to include rest break requirements that largely meet the commenter's objective of providing workers increased flexibility in the distribution of their rest breaks. The revised break and day off requirements, which address the commenter's concerns, are presented in § 26.205(d)(2) through (d)(6) of the final rule.

11.2.5 Reporting (§ 26.197(e))

NRC's Justification of Reporting Requirements

Comments: Several commenters recommended that the proposed § 26.197(e) fatigue management program reporting requirements should be deleted because they would not provide new or unique information to the NRC, protect public health and safety, or facilitate NRC oversight, but would instead be unduly burdensome for NRC power reactor licensees. A similar comment stated that proposed § 26.199(e)(1) and (e)(3) should be deleted for these reasons, and that proposed § 26.199(e)(2) should be revised to apply only to security personnel as defined in proposed § 26.199(a)(5) [Michael Coyle, NEI #49; Marvin Fertel, NEI; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

One commenter expanded upon the argument that the requested information is not required for the NRC to ensure public health and safety. The commenter thought that the NRC's FFD rule package did not demonstrate that the industry would fail to comply with the requirements of the revised rule without the imposition of these reporting requirements. Additionally, the commenter

stated that the NRC has an effective oversight process that does not depend on extensive data collection from licensees. Thus, the commenter stated that the existing regulatory process is adequate to ensure compliance with regulatory requirements without the reporting provisions in question. The commenter also stated that the NRC's claim that reporting requirements are needed to "focus the NRC inspection resources" was flawed. The commenter stated that the NRC staff will be able to gauge the adequacy of reactor licensees' fatigue management programs without this information. With the NRC's baseline inspection program and resident inspectors assigned to each site, the commenter thought that there is adequate attention to a broad range of performance indicators that would indicate any degradation in performance well in advance of a public health and safety issue. Also, the commenter stated this claim is inconsistent with the NRC staff's approach in other areas, such as the corrective action program [Marvin Fertel, NEI].

Some commenters thought that the reporting requirements ignored the significant duplication in licensee efforts that the proposed requirements would create. For example, proposed § 26.197(d) required that licensees retain adequate records of waivers and assessments, and proposed § 26.197(j) required periodic reviews by licensees to assess the effectiveness of the work hour controls, including waivers and fatigue assessments. These reviews are documented and trended under the licensee's corrective action program, and the corrective action program is periodically inspected by the NRC. Thus, these commenters thought that reporting these data to the NRC on an annual basis as part of fatigue management requirements would be an unnecessary duplication of these requirements with no attendant increase in protection of public health and safety [Marvin Fertel, NEI; F. G. Burford, Entergy].

NRC Response: The NRC disagrees that the fatigue management information reporting requirements will not provide new or unique information to the NRC, are unnecessary to protect public health and safety, are unnecessary to facilitate NRC oversight of implementation of the final rule, and will be unduly burdensome for the NRC power reactor licensees. In choosing to retain reporting requirements regarding the use of waivers the NRC considered several aspects of the work hour requirements in § 26.205 of the final rule: (1) the NRC established the work hour limits in the final rule at levels such that the potential for worker fatigue is substantive for individuals working in excess of those limits; (2) the rule permits licensees to authorize waivers of the limits only for circumstances in which the additional work hours are necessary to prevent or mitigate a condition adverse to safety or security; and (3) the rule requires a waiver only if the individual is operating or maintaining an SSC that a risk-informed evaluation process has shown to be significant to the protection of public health and safety, or if the individual is performing specified functions that are essential for effective response to a fire, plant emergency, or implementation of the site security plan. As a result, information concerning licensee use of waivers provides an indication of: (1) the number of hours worked on risk-significant activities by individuals at increased potential for impairment; and (2) how often a licensee must mitigate or prevent a condition adverse to safety while using individuals having increased potential for impairment. The NRC considers this to be unique information not otherwise reported to the NRC that is relevant to the NRC's mission.

The NRC similarly considered the need to retain the proposed fatigue assessment reporting requirements and the requirement to report any management actions in response to fatigue assessments. The NRC concluded that the fatigue assessment information that would have been reported under the proposed requirements is more within the purview of a licensee's corrective action program. It would also have been more detailed than the program

performance data for drug and alcohol testing required under § 26.717(c) of the final rule. Accordingly, § 26.203(e)(2) in the final rule requires licensees to report a summary of corrective actions, if any, resulting from their analyses of waiver and fatigue assessment data. These reports will provide information that will focus more on licensee performance in managing worker fatigue and will enable the NRC to review licensee reporting of waivers in the context of associated corrective actions.

The NRC also disagrees with the comments that the reporting requirements ignore significant duplication in licensee efforts. The NRC agrees that § 26.205(e) of the final rule requires periodic reviews by licensees to assess the effectiveness of the work hour controls, and that these reviews will be documented and trended under the licensee's corrective action program, which is periodically inspected by the NRC. However, as noted previously, the NRC considers the burden of the annual report to be limited, and that, relative to a review that is limited to evaluation of reports in a licensee's corrective action program, the annual reports will enable the NRC to provide more effective and consistent oversight and achieve other objectives for the effective implementation of Subpart I requirements described in the *Federal Register* notice that published the final rule.

The comment recommending that the NRC revise proposed § 26.197(e)(2) to apply only to security personnel is not applicable to the final rule because collective work hour limits have been removed from the rule and the NRC has eliminated the requirement for reporting information pertaining to collective work hours as a conforming change.

Intent of Reporting Information

Comments: Two commenters stated that the proposed § 26.197(e) work hour waiver report requirement would not provide a meaningful indicator of the overall quality of how a licensee manages work hours because there are a number of valid conditions that may warrant waivers of work hour controls. For example, the series of hurricanes that occurred in 2004 could have resulted in a number of valid waivers for licensees of nuclear power plants located in Florida and along the Gulf Coast. Thus, the commenters thought that, as a result of the way that FFD work hour waivers are counted and maintained under the NRC regulations, the data requested in these reports would not provide an accurate picture of conditions that may have warranted the waiver. To address this issue, one of the commenters recommended that the waivers data should be kept onsite for review by NRC inspectors so that the data may be accompanied by information regarding the plant-specific cause for the waivers [Marvin Fertel, NEI; John Cowan, NEI].

Two other commenters suggested that the rule should also require licensees to report the number of workers covered under proposed § 26.199(a). This would provide appropriate context for the annual reporting of waivers [David Lochbaum, UCS; Deborah Katz, CAN]. Another commenter, after acknowledging that the reporting is intended to get management's attention, expressed confusion about the underlying purpose of the waivers. The commenter asked what the NRC will do with the reports and how many waivers will be considered "too many" [Nick DiPietro, First Energy].

NRC Response: The NRC does not agree that the required reports will not provide a meaningful indicator of the performance of an FFD program. The NRC agrees in part with the comment that information concerning waivers should be considered in context. The

requirements in proposed § 26.197(e)(1) and (e)(3) were revised in response to comments that the required information would not provide a meaningful indicator of licensee performance in managing work hours because there are a number of valid conditions that may warrant waivers of work hour controls. Through reviews of authorized waivers from the work hour limits in plant technical specifications, the NRC has found that waivers are most frequently associated with outage activities. Accordingly, the NRC has revised the requirements for reporting waivers of the work hour requirements. Section 26.205 in the final rule requires that the reports shall indicate whether or not the waiver was associated with an outage activity.

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

In addition to requiring an indication of whether a waiver was associated with an outage activity, the NRC has revised the proposed § 26.197(e) annual report requirement to require a frequency distribution of waivers for each of the five duty groups described in § 26.4(a) of the final rule. As a result, the annual report will include, for example, a table that shows the number of operators that received just one waiver during the year, the number of operators that received two waivers during the year, etc. The NRC incorporated this requirement in § 26.201(e)(1)(iii) in the final rule in response to a commenter recommending that the rule require licensees to report the number of workers covered under § 26.199(a) of the proposed rule to provide appropriate context for the annual reporting of waivers. The NRC understood the intent of this comment was to provide a basis for evaluating the number of waivers from the work hour controls relative to the number of individuals subject to those controls. The NRC chose not to require licensees to report the number of individuals covered under § 26.4(a) of the final rule because that number will vary throughout the course of the reporting period, particularly when the reporting period includes a unit outage. In addition, the NRC believes that the required distribution of waivers more effectively provides context to the waiver use data by indicating whether the waivers are concentrated among individuals performing a certain duty and whether the waiver use within a duty group is concentrated within a relatively few individuals or distributed among many.

Reporting Requirements Do Not Satisfy the Paperwork Reduction Act

Comments: Several commenters stated that the NRC had not met its obligation under the Paperwork Reduction Act with respect to the proposed § 26.197(e) information collection requirements. They thought that the NRC had failed to adequately justify the need for these provisions and to objectively support its estimate of the burden created for affected licensees. In particular, the commenters noted that the NRC estimated that the reporting required by proposed § 26.197(e)(1) would take 2 hours of clerical and 1 hour of management time for each facility's annual report. The estimate for the proposed § 26.197(e)(2) reporting was 2 hours of management time. The estimate for § 26.197(e)(3) reporting was 12 hours of clerical and 2 hours of management time. The commenters stated that these burden estimates significantly understated the actual effort that would be required to prepare, check, and review an annual report. In contrast, the industry estimated that preparing the total report required by proposed § 26.197(e) would take at least 30 clerical hours and 20 management hours (and that these estimates must be multiplied by the more than 60 nuclear reactor sites in the U.S). The commenters thought that the management time required to prepare this report could more effectively be devoted to other activities with a closer nexus to public health and safety. Accordingly, they thought the OMB should not approve the NRC's data collection effort associated with proposed § 26.197(e) but should remand it to the NRC for its further consideration [Marvin Fertel, NEI; Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC believes that it has met its Paperwork Reduction Act obligation with respect to the information collection requirements associated with proposed § 26.197(e). The NRC expects that the information provided by licensees in response to the annual reporting requirements in Subpart I will facilitate NRC oversight of licensee implementation of the requirements through several means:

(1) Consistency, efficiency, and continuity of NRC oversight – The NRC will use the fatigue management information provided in the annual FFD program performance reports to achieve a higher level of consistency and efficiency in oversight of the implementation of the requirements in Subpart I and in enforcement of those requirements. Without these reporting requirements, NRC inspection of licensee FFD programs would likely be limited to individual inspectors evaluating licensee fatigue management for a sample of workers at a site for a limited time period. These assessments would necessarily be conducted without the benefit of broader contextual information of the site or industry normative information that would be available through the annual reports. In contrast, the annual reports will help ensure individual inspectors have a common perspective for conducting the oversight process and maintaining consistency in the NRC's oversight process. In addition, information in a particular licensee's annual report will increase NRC inspection efficiency by providing a basis for the inspectors to focus their resources on job duty groups (e.g., security or maintenance) or issues (e.g., self-declaration) that the annual report indicates may be areas warranting review. The report will enable the inspectors to achieve a greater focus during preparation for the inspection, enabling the NRC to reduce the burden of onsite inspection hours and potentially reduce the total number of hours required for the baseline

inspection. Furthermore, the annual reporting will help achieve a more complete and continuous assessment of licensee performance given that the NRC intends to conduct the baseline inspection of FFD programs only once every 2 years.

(2) Evaluation of rule implementation for lessons learned – Although the NRC and stakeholders made extensive efforts to ensure clear and enforceable requirements that are effective and practical, the new fatigue management requirements introduce the potential for unintended consequences and lessons learned. In addition, changes in the size and composition of the nuclear industry may have unforeseen implications for site staffing and fatigue management. The NRC expects that the site-specific and normative information obtained through the reports will likely provide important future insights regarding opportunities to amend the rule to improve its effectiveness or reduce unnecessary burden. The NRC notes that such information was the basis for reducing the random testing rate for drugs and alcohol in a previous amendment to Part 26.

(3) Consistent interpretation of waiver criterion – The final rule provides licensees the discretion to use waivers to exceed the work hour limits and thereby allow levels of work hours that create substantial potential to adversely affect worker fitness for duty. The principal basis for allowing waivers is to reduce the additional staffing burden that licensees would otherwise incur if waivers were not available to address these exigent circumstances. The NRC will use the annual reporting of waiver use to ensure that licensees use this discretion consistent with the objectives of the rule, and not as a means to compensate for a lack of adequate staffing. Furthermore, although the use of waivers is limited to conditions in which the work hours are "necessary to prevent or mitigate a condition adverse to safety or security," the NRC recognizes the potential for licensees to develop different interpretations regarding this criterion. Some industry commenters on the proposed rule took exception to the NRC's characterization that the high levels of waiver use at some sites was abuse. These commenters suggested that differences in licensee waiver practices could be attributed to the NRC allowing the policy statement to be subject to a number of interpretations during the many years it has been in effect. Regardless of the cause of the differences in licensee use of work hour control waivers, the NRC considers it prudent to address, through this rulemaking, the lessons learned from past implementation of the policy and provide a level of oversight through the annual reporting requirement that will ensure consistent implementation of the waiver criterion in the future.

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

(1) Consistency with Part 26 requirements and performance objectives – The final rule retains the long-standing requirements for the reporting of results of licensee drug and alcohol testing and the performance objective for reasonable assurance that individuals are not impaired from any cause (§§ 26.719 and 26.23(b) of the final rule). In addition, several studies discussed in detail in Section IV.D of the preamble to the final rule have demonstrated that worker fatigue can produce levels of impairment that are comparable to blood alcohol concentrations above levels permitted by this rule. Furthermore, given the frequency of worker concerns regarding fatigue and the work scheduling practices that are common during outages, the incidence of impairment from fatigue is likely greater than the

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

(2) Public confidence – Public interest stakeholders such as the Union of Concerned Scientists and the Project on Government Oversight have commented at public meetings that much relevant information regarding worker fatigue is withheld to either protect alleger identity or, in the case of security personnel, plant security. In addition, several public media articles have been published since the terrorist attacks of September 11, 2001 reporting instances of guards sleeping and guards fearing repercussions for refusing forced and excessive overtime. Information submitted by licensees in the annual reports would be publicly available and provide public stakeholders reassurance that the NRC is appropriately cognizant of licensee actions regarding fatigue management and that the NRC's oversight of these activities is transparent to all stakeholders.

(3) The burden is limited and justified – Section 26.203(e) in the final rule requires the information concerning management of worker fatigue to be reported as part of the annual FFD program report. As a consequence, the burden associated with this reporting requirement is an incremental change to the reporting requirement for drug and alcohol testing. In addition, the fatigue management information that § 26.203(e) requires licensees to report is largely information that licensees would already have generated in order to comply with other provisions of Subpart I. Therefore, the burden associated with the report will largely be the result of compiling the information in a form appropriate for the report and reviewing that compilation. The NRC has reviewed the public comments asserting that the NRC underestimated the number of clerical and management hours associated with this requirement, and has taken these comments into consideration in estimating the burden of the reporting requirements in § 26.203(e) of the final rule. The NRC considers the burden justified for the reasons described in this and the preceding paragraphs. Therefore, the NRC has retained requirements for an annual report containing information pertaining to fatigue management in § 26.203(e) of the final rule.

11.3 Work Hour Controls (§ 26.199)

Support for Work Hour Controls

Comments: One commenter stated that the work hour limits were reasonable and would ensure that licensees manage fatigue at facilities where the heavy use of overtime for extended periods has become routine. In the commenter's view, the proposed work hour limits would impose a regulatory burden on licensees commensurate with the safety backfit achieved [Richard Barkley, Individual].

NRC Response: The comment does not require a response.

Layers of Requirements Are Ineffective and Burdensome

Comments: Several commenters stated that, because short-term individual work hour limits address acute and cumulative fatigue, additional "layers" of prescriptive requirements would be ineffective and burdensome to industry [Michael Coyle, NEI #49; Marvin Fertel, NEI; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees that, by themselves, short-term individual work hour limits are adequate to address cumulative fatigue. The final rule's § 26.205(d) short-term individual limits allow up to 72 hours of work per week, excluding turnover time and time worked under waivers, and require only a minimum 10-hour break between successive work periods. The minimum 10-hour break does not provide reasonable assurance that individuals will obtain adequate rest when they are working long work days with few days off. They will experience cumulative fatigue resulting from the extended work periods combined with reduced sleep periods as they forego sleep to attend to daily living obligations. The NRC notes that security personnel reported such fatigue effects in the months following the September 11, 2001 terrorist attacks. In those instances the NRC found that the security personnel were typically working fewer hours than would be permitted by the short-term individual limits. However, the NRC agrees with the objective of reducing burden and eliminating unnecessary layers of requirements in the rule. In this regard the NRC notes that it eliminated the requirements for a minimum 48-hour break and collective work hour limits that would have been required by proposed § 26.199(d)(2)(iii) and (f). The minimum day off requirements of § 26.205(d)(3) of the final rule replace these proposed requirements. These revised provisions will reduce burden that would have been attributed to the provision in the proposed rule and limit the potential for cumulative fatigue by preventing excessive use of the maximum work hours and minimum rest breaks permitted by the individual work hour controls.

11.3.1 Individuals Subject to Work Hour Controls (§ 26.199(a))

Expanding the Scope of Workers Subject to Work Hour Controls

Comments: Two commenters thought that proposed § 26.199(a) would limit the scope of individuals subject to work hour controls to a subset of the work force. Thus, those workers outside this limited scope would have no limits on their individual or collective work hours. They suggested that all workers should be subject to work hour controls [David Lochbaum, UCS; Deborah Katz, CAN]. Another commenter recommended that Subpart I requirements apply to anyone engaging in licensee work within the protected area, with particular focus on those workers who spend the majority of their time engaged in full-time shift rotation assignments. He warned that exempting some of the workers would erode the teamwork skills need to accomplish work [Edwin Hill, IBEW]. A fourth commenter recommended that the Commission not add personnel who perform independent quality control/verification checks to the groups covered by work hour controls without first allowing the public to comment on that proposed requirement [Marivn Fertel, NEI].

NRC Response: The NRC disagrees in part that all workers should be subject to work hour controls. Work hour controls are only a subset of the rule's fatigue management requirements.

Individuals not covered by the work hour controls are still subject to the broader fatigue management requirements of Subpart I. Section 26.203 of the final rule establishes fatigue management requirements for licensees' FFD programs, incorporating revisions to those in proposed § 26.197. Section 26.203(a) requires each licensee to have a written policy statement applicable to all individuals who are subject to the licensee's FFD program. That policy must describe the licensee's expectations and methods for managing fatigue to ensure that fatigue does not adversely affect any individual's ability to safely and competently perform his or her duties. Section 26.203(b)(1) requires licensees to develop, implement, and maintain procedures that describe the process to be followed any time an individual who is subject to the licensee's FFD program reports to a supervisor that he or she is unfit for duty because of fatigue (i.e., makes a self-declaration). In addition, § 26.203(c) requires licensees to train all individuals subject to the licensee's FFD program in fatigue management, including shift work strategies for obtaining adequate rest and effective use of fatigue countermeasures. These broad policy, procedure, and training requirements, which apply to all workers who are subject to a licensee's FFD program, will ensure that all individuals subject to the program will have clear expectations of their opportunities and responsibilities related to fatigue management.

The NRC believes that subjecting all workers to work hour controls, regardless of job function, would be impractical, burdensome to both individuals and licensees, and would not significantly improve public health and safety or the common defense and security. In determining the scope of personnel who would be subject to the proposed work hour controls, the NRC considered the burdens on individuals and licensees associated with the practical control of work hours in conjunction with the potential for individuals' work activities to affect public health and safety or the common defense and security if their performance is degraded by fatigue. The NRC also considered the nature of these individuals' work activities and work environments relative to their potential to induce or exacerbate fatigue, the risk significance of the work, and the potential for other controls to prevent or mitigate the consequences of a fatigue-related error. As a result of these deliberations, the NRC has retained the requirement that only the individuals who perform the types of job duties specified in § 26.4(a)(1) through (a)(5) of the final rule must be subject to work hour controls.

Insofar as personnel who perform independent quality control/verification checks under licensees' NRC-approved Quality Assurance Programs are concerned, the NRC believes such personnel should be subject to the same Subpart I provisions as other personnel who perform activities that may have an impact on public health and safety. However, the NRC has determined that the Administrative Procedure Act would have required re-notice of and comment on a proposed provision subjecting such personnel to those Subpart I provisions in this rulemaking. The NRC has, therefore, decided not to require that these individuals be covered by Subpart I provisions in the final rule. The NRC intends to consider doing so in a future rulemaking, which will provide opportunities for public comment as part of the rulemaking process.

<u>"Onsite Directing" and the Inclusion of Engineering Personnel</u>

Comments: One commenter, supported by many other commenters, questioned the use of the term "onsite directing" in proposed § 26.199(a)(1) and (a)(2). The commenter stated that the term would not make clear who should be included in the functional work groups and suggested that the NRC define this term. Also, the commenter thought that "onsite directing" could be interpreted to include engineering and technical support personnel, and that maintaining records

on this group in addition to the job duty groups that were clearly defined could present a burden to licensees. The commenter recommended changing "onsite" to "job-site" in proposed § 26.199(a)(1) and (a)(2). The commenter thought this change would make these provisions consistent with the proposed definition of "directing," which clearly focused on individuals directly involved with the performance of the work activity [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees that the proposed definition of the term "directing" needed clarification. Individuals responsible for the correct performance of risk-significant work, including engineering and technical support personnel, should be subject to work hour controls. Section 26.5 of the final rule contains a revised definition of "directing." It clarifies the NRC's expectation that a limited scope of personnel providing technical input are subject to § 26.205 requirements. The definition explicitly states that the term "directing" refers to an individual "who is directly involved in the execution of the work activity, and either makes technical decisions for that activity without subsequent review, or is ultimately responsible for the correct performance of that work activity" as opposed to, for example, the planning, development or scheduling of the activity. This revised definition more clearly focuses on activities that have the potential to substantively and immediately affect safety or security.

The § 26.205 work hour requirements also apply to individuals who direct risk-significant operations on site. These individuals include management on shift, such as shift operations management or special outage managers if those individuals provide direction to operators. The work hour requirements also apply to engineers who provide onsite technical direction to operations, such as test directors or reactor engineers. These individuals perform tasks that are often highly dependent on cognitive skills (e.g., problem-solving, decision-making, communication) and that are susceptible to fatigue-induced errors, as described in Section IV.D of the preamble to the final rule. Incorrect technical direction provided to licensed operators can significantly challenge the operators and increase the possibility of errors or events. This is particularly true when the direction is provided by an individual who supervises the operators, or an individual who the operator reasonably expects to have specialized technical knowledge of the system or component being operated.

The work hour requirements also apply to those who direct risk-significant maintenance on site. These individuals include maintenance supervisors who provide direction to maintenance technicians and engineers who provide onsite technical direction to maintenance crews, such as during key outage maintenance activities. Like the people mentioned above, these individuals perform tasks that are often highly dependent on cognitive skills (e.g., problem-solving, decision-making, communication) that are susceptible to fatigue, as discussed in Section IV.D of the preamble to the final rule. Incorrect technical direction provided to maintenance technicians can significantly challenge those technicians and increase the possibility of errors or events. This is especially true when the direction is provided by a maintenance technician's supervisor or an individual who the maintenance technician reasonably expects to have specialized technical knowledge of the system or component being maintained.

The NRC disagrees with the commenter's recommendation that "onsite" should have been changed to "job-site." Whether the directing is occurring at the job site or in a nearby, onsite room by phone is irrelevant. The NRC would also note that another commenter asserted that a definition which limited "directing" to the job-site would result in engineers not going out into the field to troubleshoot, for fear of being subject to work hour controls. To eliminate the possibility that the rule could discourage engineers or other personnel from going "into the field," i.e., elsewhere on site, where their services are needed, work hour controls should apply to individuals providing "onsite," as opposed to "job-site," direction.

In summary, for the reasons stated above, the NRC has revised the definition of "directing" in § 26.5 of the final rule to clarify to whom the term applies.

Expansion of Scope for Work Hour Limits

Comments: Three commenters recommended that the proposed work hour limits be imposed on all licensee employees and supervisors who perform safety-related work instead of being limited to the work groups listed in the proposed rule. The commenters stated that the rule should ensure that all workers who perform safety-related work, as well as the individuals who supervise that work, are fit for duty [Richard Barkley, Individual; Barry Quigley, Individual; Anonymous #75]. One of these commenters also stated that, if such an expansion of the rule is not possible, then at a minimum work hour requirements should be extended to system engineers, as their job task assignments often require prompt response to the facility and decision-making that can immediately safety-related equipment operation [Richard Barkley, Individual]. Another of these commenters also recommended that engineering personnel performing or directing safety-related work should be included within the scope the proposed work hour limits [Barry Quigley, Individual].

NRC Response: The NRC disagrees in part that the proposed work hour limits should be imposed on all licensee employees and supervisors who perform safety-related work instead of being limited to the work groups listed in the proposed rule. (See NRC response to comment "Expanding the Scope of Workers Subject to Work Hour Controls" at the beginning of Section 11.3.1 of this document). However, the NRC agrees that engineers directing safety-related work should be subject to work hour limits, as their job task assignments often require prompt response to the facility and decision-making that can immediately affect the ability to operate safety-related equipment.

Section 26.5 of the final rule contains a revised definition of "directing." It clarifies the NRC's expectation that a limited scope of personnel providing technical input are subject to § 26.205 work hour control requirements. As noted in the previous NRC response, the term "directing" refers to an individual "who is directly involved in the execution of the work activity, and either makes technical decisions for that activity without subsequent review, or is ultimately responsible for the correct performance of that work activity" as opposed to, for example, the planning, development, or scheduling of the activity.

These individuals include engineers who provide onsite technical direction to operations and maintenance personnel, such as test directors or reactor engineers. These individuals perform tasks that are often highly dependent on cognitive skills (e.g., problem-solving, decision-making, communication) and that are susceptible to fatigue-induced errors, as described in Section IV.D of the preamble to the final rule. Incorrect technical direction provided to operators or

maintenance personnel can significantly challenge those workers and increase the possibility of errors or events, especially when, for example, an individual who the operator reasonably expects to have specialized technical knowledge of the system or component being operated provides the direction.

Therefore, the NRC has retained the proposed work hour control requirements in the final rule's § 26.205. These relatively narrowly scoped requirements are complemented by the more general § 26.203 fatigue management requirements regarding policy, procedure, and training requirements applicable to all workers covered by Part 26.

Fire Brigade

Comments: Several commenters disagreed with the proposed § 26.199(a)(4) requirement that fire brigade members responsible for understanding the effects of fire and fire suppressants on safe shutdown capability be subject to work hour controls. They thought this requirement would cause undue administrative burden [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees that fire brigade members responsible for understanding the effects of fire and fire suppressants on safety shutdown capability should not be subject to the work hour controls to reduce administrative burden. In response to other comments, the NRC has eliminated the proposed group work hour controls from the final rule. Thus, under the final rule, licensees need not analyze fire brigade members' work hours as a group. The NRC expects this change will eliminate any excess administrative burden. However, fire brigade members remain subject to the individual work hour controls as specified in § 26.205(a) of the final rule.

Fire brigade members must retain the cognitive ability to be able to determine the best way to suppress a fire to prevent additional damage to safety-related equipment, evaluate equipment affected by a fire to report to control room operators concerning equipment availability, make decisions concerning smoke ventilation to prevent the fire from affecting other plant operations, and coordinate all activities with control room operators. Attachment 1 to SECY-99-140, "Recommendation for Reactor Fire Protection Inspections," dated May 20, 1999, states that "based on IPEEE results, fire events are important contributors to the reported core damage frequency (CDF) for a majority of plants. The reported CDF contribution from fire events can, in some cases, approach (or even exceed) that from internal events."

Fatigue can substantially degrade a worker's decision-making and communication abilities, cause a worker to take more risks, and cause a worker to maintain faulty diagnoses throughout an event. Decision-making and communication abilities are key to fire brigade members' duties as they are responsible for understanding the effects of fire and fire suppressants on safe shutdown capability for the reactor. Degradations of these abilities could have significant adverse consequences on the outcome of an event involving a fire. For instance, a fatigued worker could incorrectly decide to vent smoke or toxic gas to an area required for alternate shutdown, which could prevent or impair access to equipment needed for safe shutdown of the

plant. In addition, a fatigued worker could incorrectly apply the wrong fire suppressant, which could affect additional equipment in the plant. Further, impaired decision-making could lead a worker to improperly control flooding, which could impact other needed equipment, or could incorrectly determine whether an area contains critical equipment and improperly apply a suppressant in that area. Impaired communications could also lead to incomplete disclosure of information to licensed operators in the control room, which could adversely impact the decision-making of those operators. If information known to the impaired worker is not properly communicated, operators may not initiate necessary actions to mitigate the fire effects, or effects of suppressant activities, on critical equipment.

The ability of fire brigade members to safely and competently assess the effects of a fire and fire suppressants on safe shutdown capability is essential to the overall success of the fire mitigation strategy and the protection of public health and safety. Therefore, because the comment did not present new information or any explanation of unique administrative burden, the final rule's §§ 26.4(a)(3) and 26.205(a) continue to subject fire brigade members to the requirements of Subpart I.

11.3.2 Calculating Work Hours (§ 26.199(b))

Support for Exclusion of Turnover Time

Comments: Several commenters supported the exclusion of turnover time as discussed in the *Federal Register* notice for the proposed rule [Michael Coyle, NEI #49; Dan Todhunter, Individual; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The comments do not require a response.

Definition of Shift Turnover

Comments: One commenter stated that, because the exclusion of shift turnover time from individual work hours was abused in the past, defining shift turnover time would be a step in the right direction. However, the commenter stated that the proposed § 26.199(b)(1)(i) definition of shift turnover as "only those activities that are necessary to safely transfer information and responsibilities between two or more individuals between shifts" would leave what activities are considered to be "necessary" too open to interpretation and result in continued abuse of shift turnover. Also, the commenter explained that the language appeared to allow both on-coming and off-going time to be subtracted, allowing the licensee to "double dip" on how much turnover time can be subtracted. Thus, the commenter thought that the turnover language was not clear and should be revised [Peter Hammill, Individual]. Another commenter asked why turnover times are not counted as work hours and stated that turnover is "work" [Anonymous #29].

NRC Response: The NRC agrees in part with these comments. The NRC recognizes that shift turnovers are important for communicating plant status information between work crews. The NRC also recognizes that shift turnovers routinely add time to the length of a shift and workweek. However, including shift turnovers in work hour calculations may cause indirect

pressure on individuals to abbreviate shift turnovers in order to ensure that they do not violate work hour limits. This pressure could compromise the quality of shift turnovers and have unintended adverse safety consequences. Therefore, although the commenter and other stakeholders believe that turnover is part of the workday and should be included in work hour calculations, the NRC believes the benefit of including turnover for managing worker fatigue would be outweighed by the potential adverse consequences on the quality of shift turnovers, if turnovers were to be subject to time limits.

Section 26.205(b)(1) of the final rule defines shift turnover as only those activities that are necessary to safely transfer information and responsibilities between two or more individuals between shifts. In addition, to make the NRC's intent clear, § 26.205(b) provides specific examples of activities that licensees may and may not exclude as part of turnover. Although questions or differences in opinion may arise regarding what transfer of information is necessary to support safe operations, the rule will limit the potential for individuals and/or licensees to use the proposed shift turnover exclusion to perform other work activities. It also addresses NRC concerns arising from observations that some licensees have occasionally excluded 2 or more hours from calculated work hours on the basis that the individuals were engaged in "turnover."

In order to ensure that turnover time is not hurried, the rule does not establish a time limit for an acceptable turnover period. However, by clearly delineating the activities that licensees may consider to be turnover activities, the rule reduces the potential for individuals and/or licensees to use the shift turnover exclusion to perform other work activities.

Post-Turnover Technical Assistance

Comments: One commenter suggested that the NRC revise proposed § 26.199(b)(1)(i) to stipulate that instances in which individuals in rest breaks are contacted by the licensee by telephone to discuss job continuity and/or technical assistance are to be considered shift turnover and excluded from work hours. The commenter thought that the need for such offsite technical assistance contacts should be addressed because turnover does not always capture every detail that may cause a question to arise later after the worker has been relieved [Edwin Hill, IBEW].

NRC Response: The NRC agrees in part with the commenter's concern and has revised § 26.205(b)(5) of the final rule to allow short periods of technical assistance to be considered turnover that may be excluded from the work hour calculations. Licensees may exclude from the calculation of an individual's work hours unscheduled work performed off-site (e.g., technical assistance provided by telephone from an individual's home), provided the duration of the work does not exceed a nominal 30 minutes. For purposes of complying with § 26.205(d)(2) minimum break requirements and § 26.205(d)(3) minimum day off requirements, such duties do not constitute work periods or work shifts. This provision provides flexibility in the work hour controls to obtain expert advice or details on recent operating experience that may not have been included in a turnover without the burden that would be imposed by resetting the clock to account for the disruption in a break period. The nominal 30-minute duration of this reduction in the break period is not expected to have a detrimental impact on the individual's overall fatigue level and would be offset by the potential contribution to safety.

Beginning/Resuming Job Duties in Calculation Period

Comments: Two commenters recommended that proposed § 26.199(b)(1)(iii) be revised to clearly prohibit licensees from calculating the work hours of individuals who, while being qualified to perform the job duties listed in proposed § 26.199(a), have not actually performed such duties during the applicable calculation period. The commenters thought that proposed § 26.199(b)(1)(iii) would have allowed licensees to pad the group work hour limit with workers qualified to perform duties but never actually performing such duties [David Lochbaum, UCS; Deborah Katz, CAN].

Another commenter, supported by many other commenters, stated that proposed § 26.199(b)(1)(iii) would be overly burdensome and too restrictive because it required that a licensee include all hours worked by an individual who joins a functional work group at some point during the monitoring period. The commenter recommended that work hour controls be applied once the individual starts to perform activities within the functional group. To accomplish this goal, the commenter recommended striking the phrase "include in the calculation of the individual's work hours all work hours worked, including hours worked performing duties that are not listed in paragraph (a) of this section, and" from proposed § 26.199(b)(1)(iii) [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG]. Another commenter stated that the individual limits of proposed § 26.199(d) would be sufficient to meet the intent of proposed § 26.199(b)(1)(iii) without stating that, when an individual begins or resumes performing certain job duties, the licensee shall include in the calculation of the individual's work hours all work hours worked for the licensee, including hours worked performing duties other than those particular duties [Brian McCabe, Progress Energy].

NRC Response: The NRC has not retained the collective work hour limits in the final rule. This addresses the comment concerning the need to revise proposed § 26.199(b)(1)(iii) to prevent padding of collective work hour limit calculations. The NRC disagrees with the comment that, when an individual resumes performing duties subject to the work hour controls, the calculation of work hours should not include all hours worked for the licensee. Section 26.205(b) of the final rule permits licensees to assign individuals who are qualified to perform the duties listed in § 26.4(a) to duties other than those listed in that paragraph without controlling their work hours in accordance with the work hour controls contained in the final rule's § 26.205(d). However, if these individuals are assigned or returned to performing any duties listed in § 26.4(a) during the calculation period, § 26.205(b)(3) requires the licensee to include all of the hours that the individual worked for the licensee when calculating the individual's work hours and to subject the individuals to the work hour controls in § 26.205(d). This requirement recognizes that the individual's level of fatigue is substantially dependent on the total number of hours he or she has worked, regardless of the relationship of the work to maintaining plant safety or security. Therefore, including the hours worked performing other duties provides assurance that fatigue does not compromise the individual's ability to safely and competently perform the duties specified in § 26.4(a) of the final rule. Therefore the NRC has retained the requirements of proposed § 26.199(b)(1)(iii) in § 26.205(b)(3) of the final rule.

Calculating Collective Work Hours

Comments: One commenter, supported by many other commenters, recommended replacing "individuals" with "security personnel" and "any job duty group" with "the security job duty group" in proposed § 26.199(b)(2)(ii) and (iii) [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC has eliminated the proposed collective work hour limits to which the commenters referred. Therefore the comment is not applicable to the requirements of the final rule.

11.3.3 Work Hours Scheduling (§ 26.199(c))

Support for Work Hours Scheduling Provision

Comments: Several commenters stated that the work hour scheduling guidance in proposed § 26.199(c) was an important feature of the proposed rule. They thought that this paragraph was a performance-based requirement that would allow licensees to design effective fatigue management programs. In addition, the commenters thought that the importance of this provision was not adequately expressed in the rule package [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC notes that proposed § 26.199(c) is retained in the final rule's § 26.205(c). During the development of the proposed rule the NRC had intended this requirement to be limited to the development of work schedules. However, the NRC acknowledges the benefit of implementing this provision as a performance-based requirement applicable to licensee control of the hours individuals actually work while performing the duties specified § 26.4(a)(1) through (a)(5) and adopts this interpretation for the final rule. As a consequence, § 26.205(c) requires licensees to control the work hours of individuals subject to the requirements of this section in a manner that prevents impairment from fatigue resulting from elements of routine schedules that can significantly affect worker fatigue. These can include elements such as shift length, the number of consecutive shifts, the duration of breaks between blocks of shifts, and the direction of shift rotation.

Opposition to Work Hours Scheduling Provision

Comments: One commenter recommended that proposed § 26.199(c) be eliminated because it lacked the clarity necessary for consistent implementation and enforcement. This commenter also thought the work hours scheduling provision was unnecessary given the numerous layers of prescriptive work hour limits which would accomplish the same objective of preventing

impairment from fatigue because of the duration, frequency, or sequencing of successive shifts [Brian McCabe, Progress Energy].

Another commenter stated that the proposed rest break provisions and individual work hour controls, if implemented at the upper limits of what would be allowed, could result in work schedules that are not based on the 24-hour biological clock. The commenter predicted that, if the final rule allows these upper limits of scheduling, there could be facilities that misinterpret these limits as being the established upper boundaries for safe operational performance. As a result, the commenter warned that licensees could impose work schedules on employees that actually produce unsafe levels of fatigue, either at the plant or when the employee drives home. Therefore, the commenter asked the NRC to provide clear guidance regarding the systematic scheduling of 24/7 operations that are consistent with a 24-hour day. Additionally, the commenter suggested that the NRC take steps to add provisions that would encourage licensees to schedule shift rotations that are not only in keeping with the basics of sleep and human performance research, but are also predictable and stable [Darrel Drobnich, NSF]. Two other commenters made the related point that requiring an employee to take 1 or 2 days off during an outage could actually cause more exhaustion due to change in sleep routine [Anthony Taylor, Individual; Dan Todhunter, Individual].

Two other commenters thought that it would be difficult to comply with both proposed §§ 26.199(c), which established work hour scheduling requirements, and 26.199(d), which required licensees to control individuals' work hours. The commenters stated that there was no mechanism in place in Subpart I for NRC review and approval of routine shift schedules that meet the intent of proposed § 26.199(c). Thus, licensees would have to default back to the guidance of proposed § 26.199(d) and develop schedules that would meet the requirements of this section even though the NRC stated that they are not intended as guidelines or limits for routine work scheduling [D. M. Jurss, Individual; Peter Hammill, Individual].

NRC Response: The NRC agrees in part that proposed § 26.199(c), retained as § 26.205(c) in the final rule, established a high-level objective for work scheduling without providing prescriptive requirements. The NRC intend that the maximum work hour and minimum break and day off requirements that are specified in § 26.205(d) be applied to infrequent, temporary circumstances. They should not be used as guidelines or limits for routine work scheduling. In addition, the § 26.205(d) work hour controls do not address several elements of routine schedules that can significantly affect worker fatigue. These include shift length, the number of consecutive shifts, the duration of breaks between blocks of shifts, and the direction of shift rotation. Therefore, § 26.205(c) requires licensees to schedule personnel consistent with preventing impairment from fatigue from these scheduling factors.

The rule requires licensees to address scheduling factors because human alertness and the propensity to sleep vary markedly through the course of a 24-hour period. These circadian rhythms are the result of changes in physiology outside the control of the individual. Work, with the consequent timing of periods of sleep and wakefulness, may be scheduled in a manner that either facilitates an individual's adaptation to the work schedule or challenges the individual's ability to get adequate rest. Therefore, the duration, frequency, and sequencing of shifts, particularly for personnel who work rotating shifts, are critical elements of fatigue management. The importance of these elements for fatigue management is reflected in guidelines for work scheduling, such as, EPRI NP-6748 (Baker, et al., 1990), and in technical reports, such as, NUREG/CR-4248 and the Office of Technology Assessment's report, Biological Rhythms:

Implications for the Worker (Liskowsky, 1991). Although research provides clear evidence of the importance of these factors in developing schedules that support effective fatigue management, the NRC also recognizes that the complexity of effectively addressing and integrating each of these factors in work scheduling decisions precludes a prescriptive requirement. Therefore, § 26.205(c) establishes a non-prescriptive, performance-based requirement.

As noted in the previous NRC response, as it developed the proposed rule the NRC had intended this requirement to be limited to the development of work schedules. However, the NRC acknowledges the benefit of implementing this provision as a performance-based requirement applicable to licensee control of the hours individuals actually work while performing the duties specified in § 26.4(a)(1) through (a)(5) and adopts this interpretation for the final rule. As a consequence, § 26.205(c) requires licensees to control the work hours of individuals subject to the requirements of this section in a manner that prevents impairment from fatigue because of elements of routine schedules that can significantly affect worker fatigue. These can include elements such as shift length, the number of consecutive shifts, the duration of breaks between blocks of shifts, and the direction of shift rotation.

Because there are many ways to construct schedules, the NRC acknowledges that it would be more appropriate to discuss implementation details in a guidance document. This guidance would make it clear that meeting maximum work hour limits or minimum break requirements by themselves would not satisfy § 26.205(c). Industry stakeholders have proposed that such guidance be developed, which would assist in the interpretation and implementation of § 26.205(c). A letter from J. W. Davis, Nuclear Energy Institute, to D. R. Desaulniers, dated March 8, 2006, suggested the development of such guidance and proposed draft criteria or metrics to use in a guidance document (ADAMS Accession No. ML060680403). The guidance would also support the implementation of § 26.205(e)(1), which requires licensees to review the work hours and performance of individuals subject to the work hour requirements for consistency with the requirements of § 26.205(c). The NRC will consider endorsing the proposed guidance.

Site-Specific Schedule Approval

Comments: One commenter asked if the NRC had considered approving schedules on a site-specific basis [Anthony Rizzo, Salem Hope Creek].

NRC Response: The NRC does not believe it should consider approving work hour schedules on a site-specific basis. In developing this rule, the NRC intended to establish requirements that allow for a variety of approaches at a site-specific level to meet the overall requirements of the final rule's § 26.205(c) and (d). An early outline of draft industry guidance applicable to § 26.205(c) included example work hour schedules as appendices (ADAMS Accession No. ML060680403). The NRC has reviewed that and subsequent drafts and, through Regulatory Guide 5.73, "Fatigue Management for Nuclear Power Plant Personnel" (dated March 2009, ADAMS Accession No. ML0834750028), has endorsed, with certain clarifications, conditions, and exceptions, that industry guidance (ADAMS Accession No. ML090360158). In Its final, endorsed form, the industry guidance does not include example work schedules, reflecting the NRC's intention that nuclear power plant licensees and other entities subject to § 26.205(c) and (d) requirements have the flexibility to meet those requirements on a site-specific basis.

11.3.4 Work Hour Controls for Individuals (§ 26.199(d))

Support for Work Hour Controls

Comments: Several commenters supported the proposed § 26.199(d)(1) individual work hour limits because they would effectively prevent both acute and cumulative fatigue [Michael Coyle, NEI #49; John Cowan; NEI; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC does not agree that the individual work hour controls in the final rule's § 26.205(d)(1) are adequate to address cumulative fatigue caused by excessive overtime. To address cumulative fatigue, the final rule includes requirements for rest breaks in § 26.205(d)(2), the minimum number of days off averaged over a shift cycle in § 26.205(d)(3), and the minimum days off per 15-day block during outages and increased threat conditions in § 26.205(d)(4) and (d)(5). These provisions will prevent excessive use of the maximum work hours and minimum rest breaks that would be permitted under the rule's individual work hour controls. They will also ensure that the potential for cumulative fatigue, which would otherwise adversely affect individuals' ability to perform functions that are important to maintaining the safety and security of the plant, is managed.

Switching between Day and Night Shifts

Comments: Referring to the changing of shifts between night and day, one commenter asked whether the proposed rule would allow licensees to switch workers' shifts between nights, days, nights and then back to days all in one week. The commenter also recommended that the rule include language about changing between shifts to prevent fatigue. Specifically, the commenter suggested that the rule allow only one switch between nights and days in a 7-day period when a worker is working 12-hour shifts [Ethan Darrow, Individual].

NRC Response: The NRC agrees that some shift schedules can exacerbate fatigue. Section 26.205(c) in the final rule addresses the sequencing of work shifts to prevent impairment from fatigue. Consistent with that provision, the NRC expects licensees to develop shift schedules that prevent impairment from fatigue associated with switching between day and night shifts. The final rule also includes additional flexibility in the break and days off requirements such that licensees will be better able to develop shift schedules that minimize the circadian cycle disruption caused by rotating shifts. Specifically, licensees need not provide 2 consecutive days off, as proposed § 26.199(d)(2) would have required. This added flexibility reduces the potential for adversely affecting circadian adjustment to night shifts.

Negative Impact on Nuclear Power Workers

Comments: Several commenters stated that the proposed work hour limits would have a significant negative financial impact on nuclear power workers by limiting the hours they are allowed to work. One commenter also thought that the proposed rule would produce an out-flow of experienced workers from nuclear facilities to other industries where work hours are not limited, resulting in the reduction of public health and safety and common defense and security.

Further, the commenter stated that the proposed work hour limits would result in increased contract work going to outside entities, which would constitute "union busting" at its most basic level. They would also contribute to the creation of a hostile work environment at nuclear power facilities [Andrew Antrassian, UWUA]. Another commenter stated that he is re-evaluating his retirement plan because it was based on his previous work during outages. The commenter thought that the proposed work hour provisions would limit the amount of time he will be able to work on outages, thus decreasing his income [Daniel Hansen, Individual].

NRC Response: The NRC disagrees that work hour limits will create the impacts the commenters predict. The NRC has documented concerns regarding frequent excessive use of work hours in SECY-01-0113, "Fatigue of Workers at Nuclear Power Plants," and SECY 05-0074, "Proposed Rule to Amend the Fitness-For-Duty Requirements in 10 CFR Part 26." Therefore, establishing clear and enforceable requirements for the management of worker fatigue is necessary to ensure against worker fatigue adversely affecting public health and safety and the common defense and security. Further, the work hour controls provide licensees with a significant amount of flexibility when establishing schedules. They do not dictate or endorse any specific schedule. Therefore, the requirements should not unduly restrain collective bargaining agreements. The NRC also notes that the work hour limits allow for substantial amounts of overtime, allowing approximately a 20% overtime rate when a plant is operating and approximately a more than 50% overtime rate when a plant is in an outage. Furthermore, these limits are applicable only to individuals who are performing duties on SSCs that a risk-informed evaluation process has shown to be significant to public health and safety; are performing critical emergency or fire response duties; or are members of the site security force performing duties necessary for execution of the site security plan. The rule does not limit the hours of individuals who are not performing these specified functions.

Limited Access to Supplemental Workers

Comments: Several commenters stated that the proposed work hour restrictions would limit the industry's access to supplemental workers. They predicted that the proposed rest break requirements would encourage supplemental workers to seek jobs in other industries that offer more overtime. Therefore, the commenters stated that this unintended consequence of the break requirements would harm licensees' ability to attract qualified workers. The commenters warned that, without a consistent supply of experienced workers, jobs would be delayed and turnover would increase. In addition, the commenters predicted that more workers would seek second jobs to supplement their hours. As a result, total hours worked would not necessarily decrease [Michael Coyle, NEI #49; Edwin Hill, IBEW; Daniel Hansen, Individual; Donald Lenski, Individual; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG; T. J. Reddington, Day & Zimmermann and Associated Maintenance Contractors; Edward Sullivan, AFL-CIO; William Hite, UAJA; Dave Barry, Shaw Stone & Webster].

NRC Response: The NRC disagrees with the commenters' predictions and notes that the Subpart I work hour requirements require licensees to manage fatigue by limiting work hours, not compensation. They also ensure periodic breaks to enhance safety and security without unduly limiting overtime. The requirements allow for substantial amounts of overtime, up to 32

hours in a week, in excess of 400 hours per year for years without outages, and substantially more overtime hours in years with outages. Also, in contrast to the commenters' concerns, the NRC believes that limiting work hours may attract and retain workers who perceive former work hour practices as excessive. Furthermore, the final rule's Subpart I work hour limits are not substantially different from the limits in Generic Letter 82-12 and most licensees' technical specifications. In addition these limits apply only to individuals who are performing duties on SSCs that a risk-informed evaluation process has shown to be significant to public health and safety; are performing critical emergency or fire response duties; or are members of the site security force performing duties necessary for execution of the site security plan. The rule does not limit the hours of individuals who are not performing these specified functions.

Generic Letter 82-12

Comments: Three commenters stated that the proposed § 26.199(d)(1) individual work hour limits were similar to the work hour limits outlined in Generic Letter 82-12. These commenters expressed the industry's appreciation of the minor change that was made to these limits, as it would eliminate inconsistency in the application of these limits [F. G. Burford, Entergy; Brian McCabe, Progress Energy; Jim Davis, NEI].

NRC Response: The comments do not require a response.

Impact on 8-Hour Shifts

Comments: Many commenters opposed the proposed § 26.199(d)(2) work hour controls because they thought they would decrease scheduling flexibility for 8-hour shifts and encourage 12-hour shifts [D. M. Jurss, Individual; Peter Hammill; Individual; John Cowan, NEI, Kevin Glidden, Individual; Jim Davis, NEI; Todd Newkirk, IBEW; James Springfield, IBEW; Dennis Specha, Individual; Anonymous #34; Brian McCabe, Progress Energy; Gregory Halnon, FENOC; Anonymous #75; Ray Wacker, Individual]. Other commenters stated that 8-hour shifts allow adequate amounts of sleep between shifts, so the proposed move to 12-hour shifts would be detrimental to nuclear plant workers by increasing the prevalence of fatigue [D. M. Jurss; Individual; John Cowan, NEI; Doug Beck, Individual]. One of these commenters predicted that working 10- or 12-hour shifts would decrease the amount of time workers will be able to spend with their families [Doug Beck, Individual]. Another suggested a new subparagraph (iv) be added to proposed § 26.199(d)(2) that would authorize a 24-hour break in any 8-day period if work hours scheduled under proposed § 26.199(c) are based on an 8-hour shift schedule [D. M. Jurss, Individual].

NRC Response: In response to these and related comments, the NRC has further analyzed the proposed § 26.199(d)(2) provisions and agrees that the proposed rest break provisions could have significantly disrupted current shift schedules and rotations. Therefore, the NRC has modified the rest break provisions in the final rule to provide substantial additional flexibility in this regard, while providing comparable assurance that cumulative fatigue from inadequate rest does not impair the ability of workers to safely and competently perform their duties. The revised break and day off provisions are in § 26.205(d)(2) through (d)(5) of the final rule.

Limit Consecutive Hours Worked to 10

Comments: One commenter stated that the proposed rule addressed only the "tail end" of the fatigue cycle. The commenter suggested that the rule limit the number of consecutive hours worked to 10 [Jim Pulley, Individual].

NRC Response: The NRC disagrees that the number of consecutive hours worked should be limited to 10 hours. Limiting consecutive hours worked to 10 hours would effectively limit schedules providing 24-hour coverage to 8-hour shift lengths. A 10-hour shift length would not be practical and would not be based on a 24-hour clock and therefore could cause significant disruption of worker circadian rhythms and worker fatigue. Although studies of worker fatigue in other industries have demonstrated deteriorating performance after 9 hours of duty, 12-hour shifts allow more tasks to be completed without a turnover, reduce the number of turnovers between shifts, and frequently allow individuals to turnover to the individuals that they relieved. As a result, 12-hour shifts improve job continuity and reduce the potential for error that can be introduced through the turnover process. The NRC considers these factors to mitigate, to some extent, the degradation in performance that may occur as a result of shift lengths in excess of 8 hours. In addition, many licensees have implemented 12-hour shifts for years and the NRC does not have information to indicate that the performance of individuals at sites with 12-hour shifts is substantively different from the performance of individuals at sites with using 8-hour shifts. As a consequence the NRC concluded that the information available at this time regarding the potential fatigue management benefit of limiting consecutive hours worked to 10 hours does not justify the substantial burden that would result from eliminating 12-hour shifts as a schedule option.

Sixteen Work Hours in any 24-Hour Period (§ 26.199(d)(1))

Comments: One commenter expressed concern about the individual work hour control in proposed § 26.199(d)(1)(i) that would allow 16 hours of work in any 24-hour period. The commenter acknowledged that 12-hour shifts have become increasingly common at U.S. nuclear power plants and that the NRC has proposed provisions (§ 26.199(d)(1)(ii) and § 26.199(d)(2)(i)) that would restrict or dissuade the use of 16-hour days. However, the commenter stated that allowing the possibility of 16-hour days for personnel in safety-sensitive positions is counterproductive and potentially hazardous. The commenter stated that the proposed 16-hour value appeared to imply that fewer than 8 hours of sleep will be acquired between work shifts, which is insufficient as the NRC itself has noted, or that the report time will slip from day to day causing circadian instability, which should not be acceptable. Therefore, the commenter suggested that the maximum number of work hours should be 10 hours per 24 hours for people on 8-hour shifts and 14 hours per 24 hours for people on 12-hour shifts [Darrel Drobnich, NSF]. Another commenter stated that workers should not be working more than 8 hours per day [Anonymous #76].

NRC Response: The NRC agrees in part with the commenters in that the routine use of 16-hour shifts is inappropriate for fatigue management. Attachment 1 to SECY-01-0113, "Fatigue of Workers at Nuclear Power Plants," provides the basis for this proposed limit, which is summarized as follows: Studies have shown that task performance declines after 12 hours on a task (Folkard, 1997; Dawson and Reid, 1997; Rosa, 1991). Other studies have shown that the relative risk of having an accident increases dramatically after 9 consecutive hours on the job (Hanecke, et al.,1998; Colquhoun, et al.,1996; U.S. DOT, 49 CFR Parts 350, et al., Proposed

Rule, May 2, 2000, 65 FR 25544). Further, a maximum of 12 work hours per day was the limit recommended by nine experts who met in 1984 to develop recommendations for NUREG/CR-4248. Therefore, in originally developing the NRC's Policy on Worker Fatigue, the NRC had planned to set a 12-hour maximum limit. However, in response to practical concerns from industry that the 12-hour limit required personnel who worked 8-hour shifts to split shifts when they work overtime, the NRC revised that limit to 16 hours. Those practical concerns remain valid, and the final rule retains a 16-hour limit in § 26.205(d)(1)(i).

Although the final rule permits 16-hour shifts, it also sets other work hour limits that effectively limit the number of 16-hour shifts that licensees can assign. Specifically, the § 26.205(d)(2)(i) 10-hour break requirement will be applicable to all individuals subject to work hour controls. As a consequence, an individual would not be eligible to return for the beginning of the next normally scheduled shift without a 10-hour break, and therefore would likely have a day off following a 16-hour shift.

Support for 10-Hour, Between-Shift Rest Break (§ 26.199(d)(2)(i))

Comments: Many commenters supported the proposed § 26.199(d)(2)(i) mandatory 10-hour rest break provision. They thought required rest breaks would effectively remove the potential for cumulative fatigue by improving operator alertness levels and providing an opportunity to meet individuals' sleep requirements and minimize any acute sleep loss [Kevin Glidden; Individual; Mike Jolley, Individual; Mark Rosekind, Altertness Solutions; Michael Coyle, NEI #49; Ethan Darrow, Individual; D. M. Jurss, Individual; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG]. One of these commenters suggested that the rule package understated the importance of this provision [Michael Coyle, NEI #49].

NRC Response: The NRC agrees that the requirement for a 10-hour break between work periods will be helpful in preventing fatigue, but does not agree that the 10-hour break is adequate for preventing impairment from cumulative fatigue. Inadequate rest breaks between shifts not only contribute to a long work day but also cause increased pressure for individuals to reduce their sleep time in order to meet the demands of both work and daily life, resulting in an increased potential for cumulative fatigue. Therefore, the NRC has included other rest break and day off requirements in the final rule to reduce the effects of cumulative fatigue. The provision in proposed § 26.199(d)(2)(i) has been retained as § 26.205(d)(2)(i) of the final rule.

Opposition to 10-Hour, Between-Shift Rest Break

Comments: One commenter stated the issue of off-duty time is one of the most important issues considered by the NRC. He said that 10 hours off between shifts is the very minimum that should be allowed to provide employees the opportunity to get adequate sleep. The commenter encouraged the NRC to consider raising the proposed § 26.199(d)(2)(i) requirement of a minimum 10-hour break between work shifts to at least 12 hours off between shifts [Darrel Drobnich, NSF]. Another commenter suggested that the proposed 10-hour break requirement would have little value. The commenter explained that the few times when workers are subject

to the minimum 8-hour breaks are during "call-outs" or shift changes, and the proposed 10-hour requirement would include an exception for such shift changes [Anonymous #75].

NRC Response: The NRC agrees that a 10-hour rest break is the minimum that should be allowed between work periods but disagrees that the minimum break period should be increased to 12 hours. In most cases at nuclear power plants, workers are allowed at least a 12-hour break, exclusive of turnover. However, in instances of extended shifts (holdovers) or unscheduled shifts ("call-outs"), the requirement of a 10-hour break between shifts is very important to protect against the effects of acute fatigue. Also, the NRC notes that the 10-hour break exception for shift changes is intended for entire crews when they change shift schedules or shift durations. It is not to be used on an individual or frequent basis. Such transitions may occur, for example, at the beginning or end of an outage or when new shift schedules are adopted. As a result, the NRC expects that these instances will be infrequent.

Although a longer minimum rest break requirement would provide greater assurance that individuals have adequate opportunities for sleep, the 10-hour break will provide adequate opportunity for rest when used infrequently, as the NRC expects it to be used given other requirements in the rule. For example, § 26.205(d)(1)(ii) in the final rule limits individuals to working 26 hours in any 48-hour period. Although licensees could use routine 10-hour breaks in conjunction with atypical shift durations (e.g., alternating 12- and 14-hour shifts), the practical implications of these schedules, such as varied start times, make their use improbable. As a consequence, the 10-hour break requirement is sufficient to assure that individuals get adequate rest during infrequent circumstances in which they work extended hours (e.g., more hours than their typical 8-,10-, or 12-hour shift) and that rest opportunities will typically vary between 12 and 16 hours in duration.

The minimum 10-hour break duration also accommodates most scheduling circumstances for the common shift durations that are currently in use in the industry. A notable exception is that the 10-hour break requirement could potentially prevent an individual who has worked 16 hours straight (e.g., two consecutive 8-hour shifts) from returning to duty at the start of his or her next regularly scheduled shift. However, the 10-hour break requirement appropriately prevents the individual from working in this circumstance because the potential for degraded job performance resulting from fatigue would be substantial given the individual's continuous hours of work and limited opportunity to sleep. Accordingly the NRC has retained the proposed § 26.199(d)(2)(i) requirement of a minimum 10-hour break between work shifts in § 26.205(d)(2)(i) of the final rule.

<u>Opposition to 24/7 and 48/14 Breaks (§ 26.199(d)(2)(ii) and (iii))</u>

Comments: Many commenters disagreed with some aspects of the rest break provisions in proposed § 26.199(d)(2)(ii) and (d)(2)(iii). They stated that the 24-hour and 48-hour rest breaks were unnecessary, duplicated requirements in proposed § 26.199(c), did not address practical implementation issues, would disrupt normal shifts, and would negatively impact the industry [Michael Coyle, NEI #49; Marvin Fertel, NEI; James Springfield, IBEW; Keith Young, Ameren; D. M. Jurss, Individual; Mark Rosekind, Alertness Solutions; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan,

STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG; Ray Wacker, Individual].

One commenter, supported by many other commenters, stated that fixed break requirements and collective work hour restrictions would lead to significant safety implications and could affect a licensee's ability to restore inoperable equipment in a timely manner. For example, the commenter stated that the proposed break requirements would make it difficult to assign teams to provide 24-hour coverage to complete critical maintenance activities, or to restore inoperable safety equipment which would result in longer outage times. The commenter also explained that the break requirements would make emergency plan and security drills more difficult to schedule and carry out. For example, the commenter thought that, if an individual has to participate on a required day off, there would be limitations on who could participate and there would be an increased need for waivers. According to the commenter, this would add another layer of complexity to planning drills [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

One commenter stated that, although the rest breaks of proposed § 26.199(d)(2) were intended to provide opportunities to recover from any cumulative sleep deficit from preceding consecutive work periods, a 10-hour break would be adequate for the individual to obtain sufficient sleep and eliminate or minimize any potential acute sleep loss. Therefore, the commenter thought that artificially requiring a 24-hour break every 7 days or a 48-hour break every 14 days would be arbitrary and that there is no scientific justification to support these specific numbers [Mark Rosekind, Alertness Solutions]. Four other commenters asserted that the requirement for a minimum number of days off per shift schedule is unnecessary and should be eliminated. They also recommended that the draft final rule requirement that the individuals specified in § 26.4(a)(1) through (a)(3) have at least 3 days off in each successive 15-day period be revised to having a 34-hour break in any 9-day period [Marvin Fertel, NEI; T. J. Reddington, Day & Zimmermann and Associated Maintenance Contractors; Edward Sullivan, AFL-CIO; William Hite, UAJA]. Another commenter took issue with this 34-hour break recommendation, saying that recovery time should allow at least 2 consecutive nights of sleep and be available every 7 days at a minimum [Darrel Drobnich, NSF]. Still another commenter recommended that this requirement be revised to require a minimum number of off-hours per day of work [Edward Sullivan, AFL-CIO].

One commenter, supported by several other commenters, stated that the "recovery concept" is scientifically supported, but the approach used to prevent cumulative fatigue should take into consideration existing work schedules and scheduling practices. The commenter explained that there is a problem with focusing on days off when facilities use 12-hour and 8-hour rotation schedules. Further, the commenter stated that there is no scientific basis for linking recovery breaks to any number of days less than 14 consecutive days. The commenter faulted the proposed rule's focus on days off without considering the number of hours worked in a particular day and the breaks between work periods. The commenter illustrated this point in a series of work hour rotation schedule examples [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison;

Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

A commenter, supported by many other commenters, suggested that proposed § 26.199(d)(2)(ii) should be revised to provide more equitable breaks during periods of normal operations. The commenter stated that a single set of break requirements cannot be applied without undermining the viability of 8-hour shift rotations, which the industry supports. The commenter recommended deleting proposed § 26.199(d)(2)(ii) and replacing it with the following language:

> "(ii) During periods of normal operations:
> (A) For a crew in a predominately 12-hour work schedule, an average of two 24-hour breaks per week over the nominal rotation cycle.
> (B) For a crew in a predominately 8-hour or 10-hour work schedule, an average of one 24-hour break per week over the nominal rotation cycle.
> (C) The nominal rotation cycle shall be between 4 and 6 weeks.
> (D) Individuals are exempt from this requirement for the first 10 weeks of an outage in which the requirements of paragraph (d)(2)(iii) are applied"

[Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

Many commenters raised the issue of work schedule disruption as a result of the 48-hour break requirement in proposed § 26.199(d)(2)(iii). They stated that, for workers on the night shift, having one day off provides an additional rest period and allows the worker to maintain a consistent pattern of work and sleep habits, which reduces the risk of accidents on the job. Two days off, however, may interfere with his or her sleep cycle and, as a result, the individual would have to readjust to the night shift after the two-day break. According to the commenters, some workers have stated that having 2 days off is worse than having no days off. They also thought that a 1-day break in any 7-day period is more than adequate when combined with other rule provisions to address cumulative fatigue. Thus, they requested that the 48-hour break requirement during outage periods be deleted. One commenter, supported by many other commenters, suggested that the NRC replace this provision with the following language: "During outage periods, in which the requirements of (d)(2)(ii) above are not applied [see above text for commenter suggestion for (d)(2)(ii) language], a 24-hour break in any 7-day period" [Dennis Specha, Individual; Dan Todhunter, Individual; Jim Waite, Individual; Daniel Hansen, Individual; Jim Davis, NEI #48; Michael Coyle, NEI #49; Andrew Antrassain, UWUA; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG; C. L. Funderburk, Dominion].

NRC Response: The NRC agrees that alternative requirements can prevent and mitigate cumulative fatigue while providing licensees increased scheduling flexibility. A significant

amount of research has shown that adequate rest breaks are necessary to ensure that individuals have sufficient time off between work periods to permit them to recuperate from fatigue and to provide reasonable assurance that acute and cumulative fatigue do not compromise their abilities to safely and competently perform their duties. However, the NRC has conducted further analysis of the proposed provisions and has concluded that alternative break and day-off requirements can effectively support fatigue management while providing greater scheduling flexibility. Therefore, the NRC has modified the work hour controls applicable to periods of normal operations in the final rule.

In response to comments on the break requirement in proposed § 26.199(d)(2)(ii), the NRC has revised the maximum number of days permitted between the breaks. The revised requirement is in § 26.205(d)(2)(ii) of the final rule and requires a minimum 34-hour break in any 9-day period. In revising this requirement the NRC considered that, although the final rule allows more consecutive work shifts for 8-hour and 10-hour shift schedules, the additional flexibility provided by increasing the period within which the extended break must occur from 7 to 9 days allows licensees to more readily optimize 8-hour shift schedules to minimize transitions between day, evening, and night shifts that can lead to worker fatigue. Although this relaxation also allows more consecutive shifts for individuals on 10-hour shifts, individuals on 10-hour shifts typically do not work a rotating schedule and therefore do not experience the disruption of their circadian cycle that exacerbates the cumulative fatigue effects of consecutive work shifts. The scheduling of 12-hour shifts is unaffected by this requirement because § 26.205(d)(1)(iii) effectively limits the scheduling of 12-hour shifts to not more than 6 consecutive days. The final rule also provides flexibility to accommodate other practical considerations such as scheduling training on a Monday-through-Friday basis and allows a contingency day for 8-hour shift schedules that include a series of 7 consecutive 8-hour shifts.

The final rule also revises the minimum duration of the break period from 24 hours, as specified in proposed § 26.199(d)(ii), to a minimum 34-hour break in § 26.205(d)(2)(ii) of the final rule. The revision more clearly states the NRC's intent to require a periodic "day off" in which individuals have the opportunity for 2 consecutive sleep periods without an intervening work period. The 34-hour break duration provides opportunity for 2 consecutive sleep periods without an intervening work period, supports use of forward rotating and fixed shifts, and allows for the possibility that individuals may work 26 hours in a 48-hour period contiguous to the break.

In response to comments on the proposed 48-hour break requirement (§ 26.199(d)(2)(iii)) and proposed collective work hour limits (§ 26.199(d)(2)(iii)), the NRC has not retained these requirements in the final rule. Rather, the NRC has replaced these requirements with alternative provisions in § 26.205(d)(3) for normal operations and § 26.205(d)(4) and (d)(5) for unit outages, planned security system outages or increased threat conditions.

To address cumulative fatigue during periods when a plant is operating, § 26.205(d)(3) requires each individual subject to the work hour requirements to have a minimum average number of days off per week. This requirement responds to comments on the proposed 48-hour break requirement and collective work hour limits by addressing cumulative fatigue on an individual basis; by tailoring the breaks to the duration of the shift; by establishing a limit that allows the flexibility of distributing the minimum days off over a shift cycle of up to 6 weeks; and by establishing requirements that are practical and should impose less administrative burden on licensees than would have been required by the proposed collective work hour limits.

These final rule provisions also address those comments on the 48-hour break that were applicable to outage periods, as follows:

(1) The minimum day off requirements of § 26.205(d)(4) and (d)(5) do not require licensees to schedule 2 consecutive days off as would have been required by the 48-hour break requirement. As a consequence, licensees are better able to establish schedules that minimize the potential for circadian disruption for individuals on fixed night shifts.

(2) The minimum day off requirements of § 26.205(d)(4) and (d)(5) allow licensees substantial flexibility in scheduling the required days off within the 15-day outage period. As a consequence, licensees are able to implement a range of scheduling options to meet known outage schedule demands and have the flexibility to revise schedules as may be necessary to address emergent needs.

(3) The minimum day off requirements of § 26.205(d)(4) allow licensees to use a predictable repeating schedule. The requirements permit a schedule of 4 consecutive 12-hour shifts followed by 1 day off. This 5-day sequence can repeat 3 times in each 15-day period creating a schedule that is predictable and repeatable, characteristics desired by workers and schedulers. This schedule limits the number of consecutive work shifts to prevent cumulative fatigue and includes sufficient periodic days off to mitigate fatigue. For individuals performing the maintenance duties described in § 26.4(a)(4), these requirements allow a predictable repeating schedule of 6 consecutive work days followed by 1 day off.

(4) The minimum day off requirements of § 26.205(d)(4), in conjunction with the other requirements in § 26.205, allow a maximum work week of 72 hours and an average work week of 67.2 to 72 hours for a period up to 60 days. As a consequence, the requirement allows licensees to offer, within these limits, substantial amounts of overtime to attract supplemental workers for outage activities. The NRC acknowledges that some individuals may want to work more than 72 hours, or even more than 84 hours, per week. However, the § 26.205 work hour limits apply only to those duties that have the most direct impact on the protection of public health and safety and common defense and security. Therefore, the requirements do not prevent individuals from working more than 72 hours per week unless they are performing duties on SSCs that a risk-informed evaluation process has shown to be significant to public health and safety, or are performing critical emergency or fire response duties, or are members of the site security force performing duties necessary for execution of the site security plan. Accordingly the NRC has replaced the requirements in proposed § 26.199(d)(2)(ii) and (d)(2)(iii) with the requirements in § 26.205(d)(3) of the final rule. The NRC also notes that the final rule includes provisions to accommodate licensees performing unannounced emergency preparedness drills and security drills in response to comments that the break requirements would have made it difficult for licensees to schedule these activities. These provisions are in §§ 26.205(b)(4) and 26.207(b) of the rule, respectively.

Suggested Change to Rest Breaks

Comments: One commenter suggested that, rather than mandatory breaks, individuals should have the discretion to decline or exercise their right to a minimum break period. Specifically, the commenter suggested that the NRC modify proposed § 26.199(d)(2)(ii) to state: "A 24-hour break in any 7-day period; *or*" and § 26.199(d)(2)(ii)(A) to state: "During licensee normal operations for individuals identified in § 26.199(d)(4), a 24-hour break after completing 7 or 8

consecutive days of scheduled 8-hour shifts in any 14-day period activated as an individual option requiring reasonable notice by individuals to the licensee to observe the break period. Individuals who do not exercise this option do not require the licensee to adhere to individual waiver requirements in § 26.199(c)(3) unless subject to § 26.199(d). During plant outages § 26.199(d)(2)(ii)(A) is not applicable and § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii) is applicable to § 26.199(d)(4) individuals" [Edwin Hill, IBEW].

Similarly, the commenter suggested that the NRC modify proposed § 26.199(d)(2)(iii) to state: "A 48-hour break in any 14-day period activated as an individual option requiring reasonable notice by individuals to the licensee to observe the break period. Individuals who do not exercise this option do not require the licensee to adhere to individual waiver requirements in § 26.199(c)(3) unless subject to § 26.199(d), or...." The commenter also recommended that § 26.199(d)(2)(iii)(A) should be revised to state: "During licensee normal operations for individuals identified in § 26.199(d)(4), a 48-hour break in any 14-day period during licensee normal operations. During plant outages § 26.199(d)(2)(iii)(A) is not applicable and § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii) is applicable to § 26.199(d)(4) individuals" [Edwin Hill, IBEW].

NRC Response: The NRC agrees in part with these comments. The break and day off provisions in § 26.205(d)(2) through (d)(5) of the final rule largely meet the commenter's objective of providing workers and licensees increased flexibility in the distribution of breaks and days off, while allowing the licensee to retain scheduling authority. However, the NRC does not agree that individuals should have the option to waive the break requirements as the commenter suggests. Research on how fatigue affects individuals' judgment amply demonstrates that fatigue can adversely affect judgment and that fatigued individuals may not be aware of those effects. Therefore, allowing individuals the option to waive required breaks would run the risk of having fatigued individuals misjudge their need for breaks, potentially leading to impaired work performance.

Clarification of Rest Breaks

Comments: One commenter stated that proposed § 26.199(d)(2)(ii) and (iii) were unclear as to whether the required 24- and 48-hour breaks could be additive in a 14-day period. The commenter asked, "Would an individual get 24 hours off in a 7-day period and 48 hours off in a 14-day period, for a total of 72 hours off in the 14-day period?" The commenter suggested that the NRC clarify its intent on this issue [Mark Rosekind, Alertness Solutions].

NRC Response: The NRC did not intend that the proposed § 26.199(d)(2)(ii) and (d)(2)(iii) rest break provisions be additive in a 14-day period. To eliminate this potential ambiguity and further clarify its intent regarding rest breaks, the NRC has revised the minimum duration of the break period. Section 26.205(d)(2)(ii) of the final rule requires licensees to ensure that individuals, at a minimum, have a 34-hour break in any 9-day period. This revision more clearly reflects the NRC's intent to require a periodic "day off" in which individuals have the opportunity for two consecutive sleep periods without an intervening work period. The 34-hour break duration provides this opportunity. It also supports the use of forward rotating and fixed shifts, and allows for the possibility that individuals may work 26 hours in a 48-hour period contiguous to the break.

Exception During Outage

Comments: One commenter expressed concern about the proposed rule's exception to work hour regulation during outage periods [Ethan Darrow, Individual; Anonymous #75]. Another commenter asked whether there was a safety-related rationale for this exception [Darrel Drobnich, NSF]. A third commenter stated that, if the exception during outages was too restrictive, it would limit licensees' ability to have personnel at multi-unit sites alternate between an operating unit and the unit in an outage. He recommended that outage workers be allowed a 34-hour break in any 7-day period [Marvin Fertel, NEI]. In contrast, another commenter saw a need for an exception from proposed § 26.199(d)(2)(ii) that would allow individuals to work for 14 consecutive days during the first two weeks of an outage or during other periods of high work activity [Daniel Stenger, NRSG].

NRC Response: The NRC does not agree that the work hour requirements applicable during outage periods should be made any more or less stringent as recommended by the commenters. Outages are unique, relatively short-term, and involve levels of activity that are substantially higher than most non-outage operating periods. Section 26.205(d)(4) and (d)(5) of the final rule establish minimum day off requirements applicable to outages that accommodate the increased level of activity of outages, but generally limit this more intensive scheduling to a period of 60 days to limit cumulative fatigue. Section 26.205(d)(6) in the final rule allows an extension of the 60-day period, but only for individuals who have had periods of less intensive scheduling during the outage. Although more restrictive requirements could perhaps provide greater assurance of worker fitness for duty, the NRC believes the burden on licensees would be excessive relative to the additional fatigue mitigation or prevention that would be gained. Regarding the recommendation to allow 14 consecutive days of work during outages or periods of high work activity, such a provision would allow work schedules with substantial potential for impairment of individuals from fatigue. Accordingly the NRC has not adopted this commenter's recommendation in the final rule.

Outage Length

Comments: One commenter stated that the former requirements allowed personnel to work hours over the guidelines with only a waiver and the ample use of turnover time. The commenter recommended that, if the NRC is going to attempt to further limit work hours, it should mandate the length of an outage. The commenter suggested a mandated 35-day outage. The commenter also thought that, if the NRC limits the hours of qualified in-house personnel but does not set a standard outage length, licensees will further rely on unqualified contractor personnel to do critical work [Anonymous #dpr25].

NRC Response: The NRC does not agree that it should mandate the length of an outage. The fatigue management provisions of the final rule's § 26.207 establish criteria for the use of waivers that should substantially limit their use to conditions where safety or security are a concern. Use of turnover time is limited by § 26.205(b)(1) to ensure that extended periods of turnover time are subject to the work hour limits. The suggestion that the NRC limit outage length to prevent excessive work hours could have the undesirable effect of preventing licensees from completing maintenance necessary for the continued safe operation of the facility or create undue pressure to complete such activities within the allowed outage period. The NRC does not agree that the proposed limits will cause increased reliance on contractors,

because the limits will also apply to contract personnel who are performing work on SSCs that a risk-informed evaluation has shown to be significant to public health and safety.

Conditions for Granting Waivers

Comments: One commenter stated that the process of extending work hours should be difficult for the utility, such that it will occur only under very unusual circumstances. Another commenter thought the waiver provisions in proposed § 26.199(d)(3) might result in licensees granting more waivers than under the former requirements [Ethan Darrow, Individual, Jim Gorman, TXU].

NRC Response: The NRC agrees that waivers should be granted only in very unusual circumstances, as originally stated in the NRC's Policy on Worker Fatigue. The potential for worker fatigue in conditions that require a waiver is substantial (Baker, et al., 1994; Dawson and Reid, 1997; Stephens, 1995; Strohl, 1999). Therefore, like proposed § 26.199(d)(3)(i)(A), § 26.207(a)(1)(i) of the final rule clearly states that licensees must limit the granting of waivers to circumstances in which it is necessary to prevent or mitigate a condition adverse to safety or to maintain the security of the plant. Also, as stated in proposed § 26.199(d)(3)(ii) and § 26.207(a)(2) of the final rule, licensees can grant waivers only when such circumstances could not reasonably have been controlled. This requirement is necessary because conditions for meeting the waiver criteria that are specified in § 26.207(a)(1) could routinely result from inadequate staffing or work planning. Therefore, § 26.207(a)(2) prohibits the use of waivers in lieu of adequate staffing or proper work planning, for example, but would permit the use of waivers for circumstances that the licensee could not have reasonably foreseen, which may include, but would not be limited to, equipment failures involving safety- or security-related SSCs or a sudden increase in the personnel attrition rate.

Waiver in Lieu of Adequate Staffing

Comments: One commenter stated that proposed § 26.199(d)(3)(ii) would prohibit the use of a waiver in lieu of adequate staffing, but then gave licensees an "out" by citing a sudden increase in personnel attrition rate as an example of a circumstance that the licensee could not have reasonably controlled. In the commenter's view, this would provide justification for a licensee to stay at inadequate staffing levels. Another commenter thought the rule's provision for waivers would result in workers being exempted from fatigue management and experiencing increased excessive work hours disguised as "non-covered work" [Peter Hammill, Individual; Edwin Hill, IBEW].

NRC Response: The NRC agrees that the waiver provisions allow licensees to use waivers to address a sudden decrease in plant staffing, if the conditions meet the waiver requirements. Specifically, the work to be conducted under the waiver must be necessary to prevent or mitigate a condition adverse to plant safety or security (as required by § 26.207(a)(1)(i) of the final rule); the individual who will work under the waiver must be assessed face-to-face and found fit to perform his or her duties during the additional work period (as required by § 26.207(a)(1)(ii) of the final rule); and, in this example, the sudden decrease in staffing could not have been reasonably controlled (as required by § 26.207(a)(2) of the final rule).

A licensee can reasonably assert that filling a position required by minimum staffing requirements is necessary to prevent or mitigate a condition adverse to safety or security. However, it is not the NRC's intent to allow waivers to compensate for deficiencies in staffing

levels or other conditions that a licensee can reasonably control. Nevertheless, the NRC believes that it is reasonable to expect waivers to be used on a temporary basis to meet minimum staffing requirements if the loss of personnel could not have been reasonably controlled by the licensee. The rule does not allow the use of waivers for such conditions for an unlimited period of time because the licensee would eventually have time to respond to the condition and the NRC would consider the condition to be within reasonable control of the licensee. Given these considerations the NRC believes that the final rule provides licensees appropriate flexibility to respond to conditions beyond their reasonable control without providing them blanket permission to use waivers to compensate for inadequate staffing. Accordingly the NRC has retained the provision in proposed § 26.199(d)(3)(ii), which is presented in § 26.207(a)(2) of the final rule.

Insufficient Flexibility of Waivers

Comments: Several commenters suggested that the proposed § 26.199(d)(3) criterion for granting waivers did not provide sufficient flexibility to grant a waiver to specific workers based on operational needs. They explained that there will be cases where a waiver would allow the completion of important work in a timely manner and would not result in any safety or security impact. They urged that management should have the flexibility to approve waivers in these cases. With the inclusion of the fatigue assessment and permission for the individual to make a fatigue self-declaration, the commenters thought that this limitation was excessive and could cause a financial burden to the facilities. As a result, one of these commenters, supported by many other commenters, recommended adding "or a determination that the waiver is necessary for plant operations" to the end of proposed § 26.199(d)(3)(i)(A) [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

Another commenter recommended that proposed § 26.199(d)(3)(i)(A) be modified to say: "An operations shift manager determines that the waiver is necessary to mitigate or prevent a condition adverse to safety or to support plant operational needs..." [Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenters' concern that the proposed § 26.199(d)(3)(i)(A) criterion for granting a waiver was overly-restrictive because it would prohibit the granting of waivers in conditions that could be cost-beneficial to the licensee without a substantive decrease in safety. There is substantial potential for worker fatigue in conditions that would require a waiver. Therefore, the NRC cannot conclude that licensees can reasonably justify the performance of risk-significant activities by individuals who have worked hours in excess of the work hour limits on the basis that granting the waiver would not have an adverse impact on safety or security. This would be inconsistent with the NRC's goal of providing reasonable assurance that individuals must be able to safely and competently perform their duties. Therefore, the NRC has retained this provision, with a minor modification that substituted the term "site" for "facility," as § 26.207(a)(1)(i) of the final rule.

Approval Authority for Waivers

Comments: One commenter stated that the proposed rule implied that the operations manager is the approval authority for the granting of waivers. The commenter stated that, although the operations manager should be evaluating the situation and the individual, the plant manager should be the authority "signing off" on the waiver because of the impact of work hours on fatigue [Ethan Darrow, Individual].

NRC Response: The NRC disagrees with the commenter. Section 26.207(a)(1)(i) of the final rule states that the operations shift manager is to make the determination of whether the waiver is necessary to mitigate or prevent a condition adverse to safety and the security shift manager is to make the determination if the waiver is necessary to maintain the security of the plant. Operations shift managers and security shift managers have the requisite knowledge and qualifications to make the respective safety or security determinations, and making such determinations is consistent with the scope of duties currently performed by individuals in these positions.

Before the waiver is granted, § 26.207(a)(1)(ii) of the final rule requires that a supervisor who is qualified to direct the work to be performed conduct a face-to-face assessment to determine whether there is reasonable assurance that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver will be granted. These determinations require knowledge of the specific skills that are necessary to perform the work and the conditions under which the work will be performed in order to assess the potential for fatigue to adversely affect the ability of an individual to safely and competently perform the work. This knowledge is generally limited to individuals who are qualified to direct the work.

In addition, § 26.207(a)(3) of the final rule requires that the supervisor conduct the fatigue assessment no more than 4 hours before the individual begins performing work under that waiver. This provision ensures that the individual will be fit for duty at the time the waiver is needed. Using the plant manager as the approval authority would likely increase the time that it takes for a waiver to be approved. Thus, relying on the operations and security shift managers as the approval authorities, instead of the plant manager, will ensure that appropriate personnel make the important waiver approval decisions.

Counting of Waivers

Comments: One commenter stated that in many cases waivers cover a whole department or crew, so counting waivers does not accurately indicate how many workers are exceeding the work hour limits [Anonymous #75].

NRC Response: The granting of group waivers would be out of compliance with both the proposed and final rules. The proposed rule permitted a waiver to be granted to a particular individual under the circumstances outlined in proposed § 26.199(d)(3) only after that individual had undergone a face-to-face assessment to determine whether the individual would be able to safely and competently perform his or her duties during the period for which the waiver would be granted. That requirement appears in § 26.207(a)(1)(ii) of the final rule. The NRC has never intended that its Policy on Worker Fatigue authorized the granting of blanket waivers for large groups of individuals. In addition, § 26.207(a)(4) of the final rule requires licensees to document the bases for individual waivers, not for waivers for groups of individuals. These requirements

make clear that the granting of waivers to an entire department or crew, as the commenter reported, would be a violation of the rule.

Qualification of Supervisor Performing Face-to-Face Assessment

Comments: One commenter stated that the phrase "qualified to direct the work to be performed" in proposed § 26.199(d)(3)(i)(B) could inappropriately be linked to the definition of directing included in paragraph § 26.5, Definitions. The commenter further noted: "If, for example, an instrumentation calibration is required during the night and the Shift Manager determines that the adjustment is needed to prevent or mitigate a condition adverse to safety, an I&C supervisor would be notified to request at least one, probably two task-qualified individuals to report to the plant. The individual will report to the control room supervisor, who assumes oversight responsibilities during the performance of the task. The control room supervisor, although trained on the system and system interactions, may not be able to provide technical input for the calibration function that is being performed. As such, if the phrase "qualified to direct the work to be performed" is linked to the definition of directing, the I&C supervisor would also have to report to the site just to perform the fatigue assessment. This would result in an unnecessarily prolonged interruption in the sleep cycle of more individuals than seems appropriate." Therefore, the commenter suggested that the wording "A supervisor, who is qualified to direct the work to be performed" be changed to "A supervisor, who is qualified to provide oversight of the work to be performed..." [F. G. Burford, Entergy]

NRC Response: The NRC agrees that requiring a supervisor to report to the site in the middle of the night for the purpose of conducting a fatigue assessment would be a significant burden and would be counterproductive for managing the supervisor's fatigue. The proposed rule would have required that a supervisor, who is qualified to direct the work to be performed, assess the individual face-to-face to determine that there is reasonable assurance that the individual will be able to safely and competently perform the required tasks during the period covered by the waiver. The proposed requirement's purpose was to ensure that these determinations are made by individuals with knowledge of the specific skills that are necessary to perform the work and the conditions under which the work will be performed in order to assess the potential for fatigue to adversely affect the ability of an individual to safely and competently perform the work. This knowledge is generally limited to individuals who are qualified to direct the work. In response to this comment the NRC has revised the requirement to accommodate situations in which there is no supervisor on site who is qualified to direct the work. Accordingly, § 26.207(a)(1)(ii) of the final rule states that the assessment may be performed by a supervisor who is qualified to provide oversight of the work to be performed by the individual. Although this individual may be less familiar with the details of how the work is to be performed, the revised requirement prevents the substantial burden of a licensee requiring a supervisor who is qualified to direct the work to report to the site to perform the assessment as well as preventing the potential fatigue of the supervisor if called in during the night. The NRC also notes that in all instances the supervisor performing the assessment must have the training required by §§ 26.29 and 26.203(c). This training will provide knowledge and abilities that are essential for a supervisor to make valid assessments in this regard. Among other FFD topics, the training addresses the contributors to worker fatigue and decreased alertness in the workplace, the potential adverse effects of fatigue on job performance, and the effective use of fatigue countermeasures. The final rule retains the requirements in proposed § 26.199(d)(3)(i)(B), with revisions similar to those recommended by the commenter, in § 26.207(a)(1)(ii) of the final rule.

Face-to-Face Assessments for Waivers

Comments: One commenter stated that performing face-to-face fatigue assessments as the proposed rule required would be very difficult, no matter how well trained supervisors may become. The commenter noted that even sleep professionals would not rely on observation to determine how fatigued a person may be, and research demonstrates that most people experience cognitive decrements long before they start to exhibit physical manifestations of fatigue that may be observed by a supervisor or co-workers. The commenter also thought that, without some objective instrument or measure of fatigue, the process as proposed would be vulnerable to error and/or abuse. The commenter suggested that the NRC develop appropriate guidance for the implementation of training programs in relation to performing fatigue assessments [Darrel Drobnich, NSF].

NRC Response: The NRC agrees in part with the comments but notes that current technology for assessing fatigue has not matured to the state where it has been validated for regulatory use. The technology has its own set of limitations in its ability to reliably detect impairment from fatigue. In lieu of such objective measures, the proposed rule would have required that the supervisor who will be conducting the face-to-face assessment be trained in accordance with the requirements of § 26.29 and § 26.203(c), and meet other minimum criteria necessary to assess the potential for acute or cumulative fatigue. These training requirements have been retained in § 26.29 and § 26.203(c) of the final rule. The required training will provide the knowledge and abilities that are essential for a supervisor to make valid assessments in this regard. Among other FFD topics, the training addresses the contributors to worker fatigue and decreased alertness in the workplace, the potential adverse effects of fatigue on job performance, and the effective use of fatigue countermeasures.

Section 26.207(a)(1)(ii) of the final rule requires that supervisors must perform the assessment face to face with the individual who is being assessed for the waiver. This requirement ensures that the supervisor has the opportunity to observe the individual's appearance and behavior to note indications of fatigue (e.g., decreased facial tone, rubbing of eyes, slowed speech). The face-to-face interview will also enable the supervisor to interact with the individual to assess his or her ability to continue to safely and competently work during the period for which the waiver will be granted.

Section 26.207(a)(1)(ii) of the final rule also requires that the supervisory assessment must address, at a minimum, the potential for acute and cumulative fatigue, considering the individual's work history for at least the past 14 days and the potential for circadian degradations in alertness and performance, considering the time of day for which the waiver will be granted. The potential for acute fatigue can be practically assessed by estimating the total number of continuous hours the individual will have worked by the end of the work period for which the waiver is being considered. The potential for cumulative fatigue can be practically assessed by reviewing the individual's work schedule during the past 14 days to determine (1) whether the individual had adequate opportunity to obtain sufficient rest, considering the length and sequencing of break periods; (2) whether the available sleep periods occurred during the night or at other times when sleep quality may be degraded; and (3) the potential for transitions between shifts (e.g., from days to nights) to have interfered with the individual's ability to obtain adequate rest. The potential for circadian degradations in alertness and performance can be practically assessed by considering the time of day or night during which the work would be performed, as well as the times of day of the individual's recent shift schedules. Thus,

§ 26.207(a)(1)(ii) requires supervisors to address the three work schedule factors (i.e., shift timing, shift duration, and speed of rotation) that are generally considered to be the largest determinants of worker fatigue (Akerstedt, 2004; McCallum, et al., 2003; Mallis, et al., 2002; Folkard and Monk, 1980; Rosa, 1995; Rosa, et al., 1996). In determining the scope of the assessment, the NRC also recognizes the need for licensees to be able to focus the assessment on information that is readily available and can be verified.

Section 26.207(a)(1)(ii) of the final rule further requires that the supervisory assessment for granting a waiver must address the potential for fatigue-related degradations in alertness and performance to affect risk-significant functions, and whether it is necessary to establish controls and conditions under which the individual is permitted to perform work. This requirement is consistent with the NRC's Policy on Worker Fatigue, which states that "the paramount consideration in such authorizations shall be that significant reductions in the effectiveness of operating personnel would be highly unlikely." However, § 26.207(a)(1)(ii) requires the supervisor to identify any risk-significant functions that may be compromised by worker fatigue, thereby focusing the assessment on worker activities that have the greatest impact on the protection of the public, considering the types of skills and abilities that are most sensitive to fatigue-related degradations.

The NRC notes that the NEI has developed guidance for industry compliance with the final rule's requirements for managing personnel fatigue at nuclear power plants (ADAMS Accession No. ML090360158). The NRC has reviewed that guidance and, through Regulatory Guide 5.73, "Fatigue Management for Nuclear Power Plant Personnel" (dated March 2009, ADAMS Accession No. ML0834750028), has endorsed it with certain clarifications, conditions, and exceptions. This guidance contains specific directions for conducting fatigue assessments and an acceptable step-by-step approach for granting waivers. The NRC also notes that the rule establishes minimum criteria, and the requirements do not prevent a licensee from developing tools for more effectively making these determinations.

Comments: One commenter expressed uncertainty about how the proposed § 26.199(d)(3)(i)(B)(iii) requirement that the licensee not perform the face-to-face assessment more than 4 hours before the individual begins performing any work under a waiver would apply to a case where the face-to-face supervisory assessment allows an individual to perform work under the waiver for a period in excess of 4 hours. The commenter gave the example of a case where an individual is called in to cover an 8-hour shift because of a co-worker's sickness. The commenter asked whether the face-to-face assessment conducted immediately prior to the individual assuming the shift would cover the entire 8-hour shift or only the shift's first 4 hours. The commenter thought that a strict reading of the proposed requirement might preclude that individual from beginning to perform any work under the waiver more than 4 hours after the face-to-face supervisory assessment [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC disagrees with the commenter's interpretation of the provision. Proposed § 26.199(d)(3)(iii) would have required that a face-to-face supervisory assessment must be conducted sufficiently close in time (no more than 4 hours) to the period during which the individual "begins performing any work under the waiver." This requirement's purpose was to ensure that the individual's condition would not substantively change before work is performed under the waiver. This provision, which appears in § 26.207(a)(3) of the final rule, is not intended to address the length of the extended work period that the waiver would "cover."

Instead, it requires only that the assessment is conducted within 4 hours of the start of the extended work period.

Proposal to Amend Break Requirements

Comments: One commenter recommended that work groups/crews who want to work rotating 8-hour shifts should be allowed to do so without the requirements in proposed § 26.199(d)(2)(ii) vetoing existing 8-hour shifts at facilities. The commenter suggested that the NRC revise these requirements by adding the following wording to proposed § 26.199(d)(4): "During licensee normal operations for individuals working 7 or 8 days of consecutive work periods scheduled for 8 hours each contained in a nominal shift rotation cycle of 14 days or more § 26.199(d)(2)(ii)(A) and § 26.199(d)(2)(iii)(A) is applicable for rest periods with § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii) being inapplicable for normal operations rest periods. For plant outages § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii) are applicable to individuals scheduled for 8 hour shift rotations for rest periods with § 26.199(d)(2)(ii)(A) and § 26.199(d)(2)(iii)(A) being inapplicable for plant outage rest breaks." In this case, the commenter suggested that proposed § 26.199(d)(1) should state the following: "Except as permitted under paragraph (d)(3) *and/or (d)(4)* of this section, licensees shall ensure that any individual's work hours do not exceed the following limits" because (d)(4) allows consideration of licensees who work 8-hour shift rotations for 7 or 8 days consecutively for a nominal rotation cycle of 14 days or more [Edwin Hill, IBEW].

NRC Response: The NRC agrees in part and has revised the final rule to eliminate the requirements for a minimum 24-hour break in any 7 days and a 48-hour break in any 14 days. The final rule requires a 34-hour break in any 9 days and a minimum number of days off per week averaged over a shift cycle. These requirements, which accommodate 8-hour shift schedules, are in § 26.205(d)(2)(ii) and (d)(3), respectively, of the final rule.

Impact on Rate of Pay

Comments: One commenter suggested that the NRC review the impact on those workers who have negotiated a rate of pay on their second day off as a double-time day instead of a time-and-a-half day. The commenter thought that the proposed rule would negatively affect worker morale not only because workers would have less control of their weekly schedule, but also because their rate of pay would be reduced when working overtime [James Springfield, IBEW].

NRC Response: Section 26.205(d)(3) through (d)(6) of the final rule provides break and day off requirements that largely meet the commenter's objective of providing increased flexibility in the distribution of breaks and control of weekly schedules. The NRC's intent for Subpart I is to limit fatigue, not compensation. The increased flexibility granted by the final rule allows for negotiation between workers and the licensee while providing the necessary controls to reduce the likelihood of fatigue-related errors adversely affecting public health and safety or the common defense and security.

TVA Overtime Agreement

Comments: One commenter stated that the 1991 Overtime Agreement used at all Tennessee Valley Authority (TVA) nuclear facilities questions whether 16/24, 24/48, and 72/7 work hour limits have any real safety basis when coupled with volunteering for overtime. The commenter noted that the NRC, TVA, and IBEW were satisfied by the results of this agreement, and this

agreement has been successfully implemented without challenge for 15 years. The commenter questioned what he considered to be the NRC's attempt to override this settlement and formally requested that the settlement be reopened if the NRC disregards it [James Springfield, IBEW].

NRC Response: The NRC disagrees that individual work hour limits have little safety basis when individuals volunteer for overtime. Although individuals may be able to make relative judgments regarding their level of fatigue, there have been several studies that have noted the tendency for individuals to underestimate their level of impairment from fatigue (Nabi et al, 2006; Wylie, et al., 1996; Dinges, 1995; Rosekind and Schwartz, 1988). The NRC has also received allegations from nuclear power plant workers expressing fear of adverse actions from employers for reporting that they are unfit for duty because of fatigue. As a consequence, the NRC does not believe there is reasonable assurance that workers can reliably address excessive fatigue through their own actions under the former requirements applicable to worker fatigue.

The NRC also notes that limiting hours and fatigue of employees engaged in licensed activities is an exercise of NRC statutory authority to regulate nuclear safety. Such regulation may affect labor agreements between a licensee and a union. If the parties to a labor contract believe that the contract has been made obsolete by subsequent events, e.g., this final rule, the parties to the contract are responsible for renegotiating their contract. The NRC has no authority to compel parties to a labor contract to renegotiate the contract.

11.3.5 Self-Declarations during Extended Work Hours (§ 26.199(e))

Support for Self-Declarations

Comments: Three commenters supported the self-declaration provision in proposed § 26.199(e) [Jim Davis, NEI; Todd Newkirk, IBEW; Edwin Hill, IBEW].

NRC Response: These comments do not require a response. The self-declaration provision in proposed § 26.199(e) appears in § 26.209 of the final rule.

Suggestion for Increased Implementation Guidance

Comments: One commenter commended the NRC for proposing the self-declaration provision to provide employees with a process to declare when they might be too fatigued, for whatever reason, to conduct certain tasks. However, although the concept of self declaration is a worthy one in theory, the commenter thought that its use may be impractical since (a) employees may fear reprisal, directly or indirectly; and (b) chronically sleep-deprived individuals and individuals with certain sleep disorders are not capable of accurately self-assessing their level of alertness and capacity to perform. The commenter therefore encouraged the NRC to put forward very clear guidance for implementing the rule to make sure that the potential for abuse for both self-declaration and face-to face assessments is minimized. The commenter also encouraged the NRC and the nuclear industry to support the development and use of objective assessment tools and predictive software models currently being tested [Darrel Drobnich, NSF].

NRC Response: The NRC agrees with the need for implementation guidance. The NRC's past experience with worker fatigue, such as that documented in NRC Regulatory Issue Summary (RIS) 2002-007, "Clarification of NRC Requirements Applicable to Worker Fatigue and Self-declarations of Fitness-For-Duty," dated May 10, 2002, indicates that individuals must

clearly understand their fatigue management responsibilities and those of the licensee. To that end, NEI developed draft industry guidance for managing fatigue at nuclear power reactor sites. The NRC has reviewed that draft guidance and, through Regulatory Guide 5.73, "Fatigue Management for Nuclear Power Plant Personnel" (dated March 2009, ADAMS Accession No. ML0834750028), has endorsed, with certain clarifications, conditions, and exceptions, that industry guidance (ADAMS Accession No. ML090360158). Regarding the comment that the NRC and industry should encourage the development of objective assessment tools and predictive software models, the NRC would support industry development of tools and methods that would facilitate effective implementation of the requirements of this rule.

Oversight of the Self-Declaration Process

Comments: Three commenters urged the NRC to closely oversee the self-declaration process. They cited examples of workers who were afraid to self-declare and forced to work under duress due to the threat of being fired, sent to psychiatrists, and given undesirable schedules. The commenters recommended that, if there is evidence of retaliation for self-declaration, the NRC should take enforcement action and levy significant fines against the utilities [Pete Stockton and Danielle Brian, POGO; Robert Rutkowski, Individual].

NRC Response: The NRC's oversight of the self-declaration process will be part of its general oversight of licensee implementation of Subpart I requirements. The NRC will revise the baseline inspection procedure for fitness for duty programs, IP71130.08, as part of its implementation activities. The revision will include requirements for the inspection of licensee fatigue management, including the implementation of the self-declaration requirements. Furthermore, the NRC notes that the NRC's allegation program is available to all licensee employees. Individuals who believe they are being forced to work when they are unfit for duty because of fatigue may report these concerns through the NRC's allegation process.

Regarding the commenters' recommendation that the NRC should take enforcement action against utilities that retaliate against individuals for self-declaration, the NRC notes that 10 CFR 50.7 prohibits retaliation for the reporting of nuclear safety concerns. The NRC has addressed the applicability of this requirement with respect to self-declarations in RIS-2002-007, "Clarification of NRC Requirements Applicable to Worker Fatigue and Self-Declarations of Fitness-For-Duty."

In summary, the NRC has several mechanisms for the oversight of the self-declaration process and, therefore, the commenters concerns are adequately addressed through this rulemaking and existing NRC regulations and programs.

11.3.6 Collective Work Hour Limits (§ 26.199(f))

Support for Collective Work Hour Limits

Comments: One commenter stated that cumulative limits are important controls for the long-term mitigation of fatigue, and thus supported their inclusion in the final rule [Barry Quigley, Individual]

NRC Response: This comment does not require a response.

Opposition to Collective Work Hour Limits

Comments: Many commenters addressed the proposed collective work hour limits, with the majority of them opposing some portion of the provisions. Some commenters stated that the collective work hour limit approach was inconsistent with the rest of the FFD rule and dangerous when coupled with the provision limiting the scope of work hour limits to only those workers with hands-on responsibilities [David Lochbaum, UCS; Deborah Katz, CAN]. Another commenter recommended that the NRC eliminate the specific policies regarding collective work hour limits, because they would not be an effective means to address the known physiological fatigue risks contributed by individual operators [Mark Rosekind, Alertness Solutions]. One commenter stated that the group hours should not be adopted for the additional reason that the NRC's backfitting analysis did not adequately justify imposing this new requirement [Daniel Stenger, NRSG]. Another commenter disputed the validity of surveys referenced by the NRC staff to imply that the limits would be consistent with worker desires regarding overtime. To the contrary, the commenter thought that the predominant opinion of workers in the nuclear industry is overwhelming opposition to the work hour limits [Andrew Antrassian, UWUA].

Many commenters stated that the proposed collective work hour limits were unnecessary to mitigate the effects of cumulative fatigue and would limit the flexibility to increase work hours in a job-duty group based on operational needs. They thought that cumulative fatigue was adequately addressed by other rule provisions such as the work scheduling requirement, individual work hour limits, individual break requirements, the fatigue assessment and the self-declaration process. Therefore, the commenters asserted that the inclusion of cumulative work hour controls was unnecessary and should be eliminated for any functional group except security [Michael Coyle, NEI #49; John Cowan, NEI; Jim Davis, NEI, Richard Sweigart, DCS, Keith Jury, EGC/AmerGen; Keith Young, Ameren; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG; Pete Stockton, POGO]. One of these commenters suggested that the NRC adopt a more performance-based rulemaking approach that would better recognize the complexity of work scheduling practices at nuclear power plants and allows for more flexibility [Daniel Stenger, NRSG].

Some commenters were concerned that licensees would be able to "fudge" how many armed security officers they have on shift by including unarmed officers, trainers, and in some cases clerical and managerial staff into the group with the armed responders. Therefore, these commenters suggested that the group hour limits were irresponsible and should be deleted from the rule [Danielle Brian, POGO; Anthony Rizzo, Salem Hope Creek; Robert Rutkowski, Individual]. One commenter also asserted that the only way to ensure that collective work hour limits will achieve adequate shift coverage without routine heavy use of overtime is to remove leave hours from the averaging process [Peter Hammill, Individual].

One commenter stated that collective work hours will allow licensees to force workers to work overtime [Dennis Specha, Individual]. To address this potential, one commenter suggested that the NRC prohibit licensees from forcing individuals to work over 48 hours, but allow an individual to volunteer to work up the 72 hours in a week if that would relieve another individual from a forced overtime situation [Guy Galster, Individual]. Another commenter stated that the proposed 48-hour collective work hour limit would not prevent individuals from working up to the

proposed limits in proposed § 26.199(d) on a frequent basis. The commenter thought that the time frame between outages is the time frame when proposed § 26.199(f) would apply, and noted that it is also the period of highest vacation usage. The commenter also stated that, because overtime is used to cover for vacation or illness, it is possible that during these times one could be working up to the limits of § 26.199(d) repeatedly to cover for absences [Peter Hammill, Individual].

A commenter also noted that the maximum limits for group work hour averages may not be consistent with existing collective bargaining agreements (CBAs), and may result in variations among work groups at a site [Daniel Stenger, NRSG].

Several commenters stated that one of the challenges surrounding the proposed collective work hour limits was the recruitment of supplemental workers past the 8-week point in an outage when work hours are limited. The commenters noted that, for many individuals, the availability of overtime is a key factor in where they decide to work, and attracting the same individuals to work subsequent outages and retaining them for the duration of the outage would significantly improve the quality of the work process. Thus, the commenters suggested that the 8-week outage exemption be increased to 10 weeks because licensees will face the unintended consequence of the loss of supplemental workers in the final stages of an outage [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees in part with many of the commenters' statements concerning collective work hour limits. In response to these comments the NRC has replaced the proposed rule requirements for collective work hour limits with the minimum day off requirements in § 26.205(d)(3) of the final rule. The NRC expects that the minimum day off requirements in the final rule will be equally effective in addressing cumulative fatigue, while addressing these commenters' concerns. The requirements of the final rule address cumulative fatigue on an individual basis and therefore provide more uniform assurance against worker fatigue. They also eliminate the burden of defining and tracking individual membership in job duty groups that the proposed collective work hour limits would have created. The final rule requirements also eliminate the potential that the calculation of collective work hours would not be representative of the hours worked by all individuals in a group or would be biased in some other way.

Clarification of Individuals Subject to Collective Work Hours

Comments: Two commenters expressed confusion over which workers were to considered to be in the "group" referred to in proposed § 26.199(f) [Pete Stockton and Danielle Brian, POGO]. Other commenters recommended that the proposed collective work hour limits must explicitly state that only those individuals who meet one or more of the criteria in § 26.199(a) shall be included in the group hour calculations [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC agrees that the rule requirements should be clear regarding to whom they are applicable. The NRC's intent for the collective work hour limits was that those limits would be applicable to only those individuals who met at least one of the criteria specified

in proposed § 26.199(a). However, the final rule does not retain the requirements for collective work hour limits. The NRC replaced the collective work hour limits with individual work hour limits in the final rule. The calculation of work hours for purposes of compliance with those requirements does not depend upon group membership.

Collective Work Hours for Security Personnel

Comments: One commenter, supported by many commenters, recommended that the term "individuals" be replaced with "security personnel" and the term "any job duty group" be replaced with "the security job duty group" in proposed § 26.199(f) [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

Another commenter suggested that proposed § 26.199(f)(1) and (f)(3) should reference only § 26.199(a)(1) and (a)(5) instead of all of § 26.199(a). He thought that collective group hour management would not be the best fatigue management for the groups referenced in § 26.199(a)(2), (a)(3), and (a)(4) due to the burdensome tracking of average collective work hours for the referenced groups that have a high occurrence of mobility within the industry. The commenter believed that his recommended revision would more appropriately focus on security and operations [Edwin Hill, IBEW].

NRC Response: The NRC agrees that licensees could have experienced a greater burden implementing the collective work hour limits for groups that have a high occurrence of mobility within the industry. For that and other reasons, the NRC has eliminated the requirements for collective work hour limits from the final rule. As a consequence, all fatigue management provisions are applicable on an individual, rather than group, basis. The final rule, therefore, has eliminated that potential burden associated with tracking group membership for individuals in jobs that are highly mobile in the nuclear power industry.

Relaxations During Plant Outages

Comments: One commenter, supported by many other commenters, recommended that the 8-week exclusion for outages in proposed § 26.199(f)(1) be increased to 10 weeks to accommodate anticipated upcoming outages of longer duration. To support his recommendation, the commenter noted that review of recent outages shows an increase in the number of outages that exceed 8 weeks. The commenter also stated that equipment replacements show a number of outages that exceed 8 weeks that could be managed with a 10-week outage [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

Some other commenters strongly opposed the relaxation of collective work hour limits during the first 8 weeks of a plant outage [David Lochbaum, UCS; Deborah Katz, CAN]. However,

another commenter stated that the industry supported this exemption [John Cowan, NEI]. Another commenter recommended that this exemption should continue for longer than the first 8 weeks of an outage [Todd Newkirk, IBEW].

NRC Response: The NRC does not agree that the exemption period from the proposed collective work hour limits for unit outages should have been either extended or eliminated. Although the NRC has replaced those proposed collective work hour limits with the minimum day off requirements in § 26.205(d)(3) of the final rule, the requirements of the final rule that are applicable to unit outages are comparable to those of the proposed rule. As a consequence the NRC has retained a comparable exemption period, limiting the exemption from the requirements of § 26.205(d)(3) to the first 60 days of a unit outage, planned security system outage, or increased threat condition. The relaxation of individual work hours during these specific times accommodates the short-term demand for increased work hours associated with these outages and conditions while limiting cumulative fatigue. The NRC considers the burden on licensees of eliminating the exemption period for these conditions to be excessive for the additional assurance that could be gained in worker fitness for duty relative to that achieved by the limited exemption period of the proposed rule.

In setting the maximum duration of the exclusion period, the NRC considered the duration of typical and longer-term outages. It also considered that, by the end of 60 days of work at the limits permitted by § 26.205(d)(1) and (d)(2), individuals who are performing the duties specified in § 26.4(a)(1) through (a)(4) will have (1) worked 576 hours, including more than 200 hours of overtime, and (2) missed as many as 17 normally scheduled days off. The loss of the 17 normally scheduled days off would be a reduction of 60 percent in the time available to recover and prevent cumulative fatigue. Further, with each passing week of increased work hours and decreased time off, deferring daily living obligations becomes increasingly difficult. This, in turn, causes increased pressure on individuals to reduce their sleep time in order to meet the demands of both work and daily life, resulting in an increased potential for cumulative fatigue. As a result the NRC did not consider it appropriate to extend the exception period without assurance that individuals would obtain sufficient rest to prevent cumulative fatigue. However, the NRC has included§ 26.205(d)(6) in the final rule, a provision that permits licensees to extend the outage exception period by 7 days for each 7-day period during the outage that an individual works not more than 48 hours. This provision accommodates longer outages when it is justified by the work history of the individual containing adequate recovery periods.

13-Week Averaging Period

Comments: Two commenters thought that the proposed rule did not clearly indicate how the 8-week outage suspension of collective work hour limits of proposed § 26.199(f)(1) would be reconciled with the 13-week averaging period specified in § 26.199(b)(2) [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC did not retain the proposed collective work hour limits in the final rule, thus eliminating the 13-week averaging period.

Fatigued Individuals

Comments: Two commenters stated that the rule should prohibit an individual who is already chronically fatigued from entering the collective work hour limit pool, especially when that entry

would coincide with the 8-week outage "free pass." They suggested that the NRC revise proposed § 26.199(b)(1)(iii) to require a formal, documented check before an individual begins or resumes performing any of the job duties listed in proposed § 26.199(a). The commenters stated that the licensee should be required to assess the person's work hour history over at least the prior 13 weeks to verify that the individual is not already likely to be chronically fatigued [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC agrees that chronically fatigued individuals should not be allowed to perform duties covered in proposed § 26.199(a) (§ 26.205(a) of the final rule). The NRC does not agree that the means to achieve that objective should be to require licensees to conduct a formal documented check of a worker's work hour history over at least the prior 13 weeks. The NRC considered methods for licensees to track the work hours of individuals that work for other licensees and other employers and determined that the burden of tracking work hours would be substantial and that the ability to verify work hours from other employers was limited.

In addition, the NRC notes that, in the event an individual becomes chronically fatigued, § 26.211(a)(1) of the final rule requires licensees to conduct fatigue assessments for-cause when individuals appear not to be fit for duty because of fatigue and § 26.203(b)(1) requires licensees to establish procedures for the self-declaration of fatigue. The NRC considers that collectively these requirements provide reasonable assurance that individuals will not perform duties that are subject to the work hour controls when they are chronically fatigued or otherwise are not fit to safely and competently perform those duties.

Ensuring Adequate Staffing Levels

Comments: One commenter thought that proposed § 26.199(f)(3)(i) provided an "out" to licensees, in effect telling them that they do not need to maintain adequate staffing when it is not reasonably controllable. Thus, if the intent was to ensure adequate staffing levels, the commenter urged the NRC to define adequate staffing levels [Peter Hammill, Individual].

NRC Response: The NRC agrees that proposed § 26.199(f)(3)(i) permitted a limited exception from the collective work hour limits for conditions that the licensee could not have reasonably controlled. However, the NRC disagrees that this proposed limited exception would have led to the result posited by the commenter. The NRC considers that the proposed rule's collective requirements to address fatigue would have provided reasonable assurance that individuals would not perform duties subject to work hour controls when they are chronically fatigued or otherwise are not fit to safely and competently perform those duties. Further, the NRC has not retained the collective work hour requirements in the final rule, thus eliminating the requirements in proposed § 26.199(f)(3)(i).

Collective Work Hour Limits for Security Personnel during Outages

Comments: One commenter was concerned that proposed § 26.199(f)(2)(i) would allow security personnel to work more hours during outages. The commenter stated that, for the reasons given by the NRC regarding proposed § 26.199(a)(5), work controls should apply to security personnel, especially during times of increased activity such as planned security system outages or under threat conditions. Thus, the commenter stated that security personnel must be under more stringent work hour controls and should not be included in any provisions

that allow waivers during outages or other circumstances other than, possibly, during attack or emergency situations [Darrel Drobnich, NSF].

Other commenters thought that armed security officers should be limited to working 48 hours a week, and the only instances in which hours should reach 60 are during refueling and heightened security [Pete Stockton and Danielle Brian, POGO].

NRC Response: The NRC agrees in part with the commenters. Work hour controls for nuclear power plant security personnel should be stringent for the reasons described in the section-by-section analysis of § 26.205(a) in the *Federal Register* notice promulgating the final rule. The NRC also agrees that armed security guards' work hours should not routinely exceed 48 hours per week. However, the NRC does not agree that the rule should prohibit limited periods of increased work hours for security personnel during outages or increased threat conditions. The collective work hour requirements in proposed § 26.199(f)(2)(i) have been eliminated from the final rule. However, the alternative requirements in the final rule for individual work hours in § 26.205(d)(5) prescribe less stringent day off requirements than those required by § 26.205(d)(3) during the first 60 days of a plant outage, security system outage, or increased threat condition.

Outages and increased threat conditions are unique, relatively short-term, and involve levels of activity that are substantially higher than most non-outage operating periods. It is not practical to expect licensees to maintain sufficient supplemental security staff to maintain 48-hour weeks under all conditions. A rule that imposed such a requirement would place an exceptionally high burden on licensees and result in a security staff that would not be fully employed under most circumstances. The relaxation of individual work hours for security personnel accommodates the short-term demand for increased work hours associated with these outages and increased security threat conditions. The minimum day off requirements in § 26.205(d)(5) of the final rule, in conjunction with the other provisions in Subpart I, ensure individuals have sufficient days off during these periods of more intensive work schedules to provide reasonable assurance that security personnel are not impaired by fatigue. However, the NRC agrees that such increased periods of work hours create the increased potential for cumulative fatigue. As a result, § 26.205(d)(5) limits the exception period to generally not more than 60 days.

<u>"Hard Cap" on Collective Work Hours</u>

Comments: Two commenters noted that proposed § 26.199(f)(3)(ii) imposed a cap of 54 hours per person per week under certain circumstances and proposed § 26.199(f)(2)(i) and other sections imposed a cap of 60 hours per person per week for security personnel under other circumstances. To rectify this, the commenters suggested that the NRC provide a "hard cap" on collective work hours [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC has revised the rule such that collective work hour limits are eliminated from the final rule, including the provision in proposed § 26.199(f)(2)(i). The comment is therefore not applicable to the requirements of the final rule.

<u>Approval to Exceed Collective Work Hour Limits</u>

Comments: One commenter stated that the proposed § 26.199(f)(5) requirement for prior NRC approval of a written request by a licensee to exceed any collective work hour limits for any job

group would be overly restrictive and could have unintended consequences, such as delayed site response and corrective actions to emerging issues [Daniel Stenger, NRSG].

NRC Response: The NRC has eliminated the proposed collective work hour limits from the final rule, including the requirement in proposed § 26.199(f)(5). As a result of these changes, the comment is not applicable to the requirements in the final rule.

11.3.7 Successive Plant Outages (§ 26.199(g))

Multi-Site Licensees

Comments: Two commenters stated that the proposed rule implicitly assumed that there are unique licensees for each reactor site; and that this assumption is false. They explained that several companies own and operate reactors at multiple sites, and it is not uncommon for these companies to develop specialty work groups and deploy these work groups to all of their sites. The commenters included an example of when the sustained outage provision of proposed § 26.199(g) would not apply, and recommended that the rule not permit this [David Lochbaum, UCS; Deborah Katz, CAN]. On a related issue, four commenters recommended eliminating the draft final rule's proposed fatigue management requirements that would have applied to individuals working on two or more successive outages that start less than 2 weeks apart [Marvin Fertel, NEI; T. J. Reddington, Day & Zimmermann and Associated Maintenance Contractors; Edward Sullivan, AFL-CIO; William Hite, UAJA].

NRC Response: Proposed § 26.199(g) would have established control of work hour requirements during unit and security system outages that follow a preceding outage by less than 2 weeks. The proposed requirements' objective would have been to limit the potential for cumulative fatigue that could result from working successive outages in close succession. The NRC has eliminated these proposed requirements from the final rule.

In deciding to eliminate the requirements pertaining to successive plant outages the NRC considered several related factors. Although reduced work hours between successive outages would reduce the potential for cumulative fatigue, transient workers would in many cases be likely to have days off between outages as they travel between nuclear power plant sites or wait for the beginning of the next outage. As a result, the proposed requirement for reduced work hours between successive outages would have provided no or limited additional benefit in these circumstances. The NRC also considered the limited applicability of the proposed requirement. The requirement would have been limited to instances in which individuals worked successive outages for the same licensee. As a result, it would have benefited only a limited scope of individuals in these circumstances. The NRC also considered the increased challenge licensees would face in retaining crews of supplemental workers between outages if these workers were required to take a full 2 weeks off between outages. Licensees could have alternatively complied with the proposed requirement by employing supplemental workers for a 2-week period at the conclusion of an initial outage or the beginning of a successive outage at the levels applicable to an operating plant. The NRC acknowledges that such a practice would likely extend outages and that the reduced work hours could cause some individuals to seek alternative employment. In addition, the NRC considered the potential for the successive outage requirement to adversely affect outage schedules. Specifically, if a planned outage must be extended due to unforeseen complications, the schedule for subsequent outages could be

affected if the outage extension affects the ability of individuals to have 2 weeks of reduced work hours before the subsequent outage.

Given the limited scope of individuals that would have benefited from the requirements in proposed § 26.199(g) and the potential for substantial adverse impacts on licensees' ability to plan and conduct outages, the NRC has eliminated the successive plant outage requirements in the final rule. However, the NRC notes that the final rule includes other provisions that will reduce the potential for cumulative fatigue from successive outages. These include work hour controls more stringent than the work hour controls required by plant technical specifications, requirements for a process through which individuals may self-declare if they believe they are not fit for duty because of fatigue, and requirements for training in fatigue management.

Successive Outage Calculations

Comments: Several commenters stated that proposed § 26.199(g) would have effectively canceled the collective work hour limits when outages are separated by at least 2 weeks but less than 13 weeks. They read proposed § 26.199(b)(2) to require collective work hours to be calculated "within an averaging period that may not exceed 13 weeks." Thus, if the licensee specifies 13 weeks as the averaging period and the end of an outage resets the clock for starting an averaging period, the collective work hour calculation would not become meaningful until 13 weeks after the end of an outage. The commenters thought that, in the interim, the only real limits on working hours would be the individual limits in proposed § 26.199(d), and this would allow a licensee to use the collective work hour limits as a "free pass" for an 8 week outage as often as possible during a year, as long as the outages are separated by at least 2 weeks [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC agrees that the successive plant outage requirements of proposed § 26.199(g) would have allowed licensees to use the outage relaxation multiple times in a year if outages are separated by at least 2 weeks. However, the NRC does not agree that this provision would have had the effect of canceling the work hour controls generally applicable to routine plant operations. At the conclusion of an outage, individuals are likely to be fatigued from working extended hours and the increased workload associated with the outage and plant restart preparations. Accordingly, proposed § 26.199(g) would have ensured that individuals have at least a 2-week period during which their work hours are subject to the requirements applicable to routine plant operations before the individuals are eligible for the outage relaxation. A minimum of 2 weeks under normal workloads provides reasonable assurance that individuals have the opportunity for successive days of increased rest to reduce the potential for cumulative fatigue. In any case, for the reasons described in the NRC response to the previous comments, the NRC has eliminated the proposed § 26.199(g) successive plant outage requirements in the final rule.

Work Schedules during Extended Outages

Comments: One commenter, supported by many other commenters, stated that during an extended outage, if a functional work group returned to normal operations for a period in excess of 2 weeks, the elapsed outage period should be recalculated based on when the functional work group returned to an outage work schedule. Therefore, the commenter said the proposed requirement regarding successive plant outages could be applied to these situations. The commenter recommended revising proposed § 26.199(g) by adding the following to the end of

the proposed paragraph: "If an outage is scheduled such that a functional group returns to a normal operational schedule for at least 2 weeks, the number of days may be restarted from the date outage manning is resumed" [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC does not agree with the recommended revision to proposed § 26.199(g). That revision would have allowed licensees to schedule individuals in accordance with the requirements applicable to outages, which the NRC intends for temporary use, for more than 40 weeks of a year. Although a 2-week period of routine scheduling would substantively reduce cumulative fatigue, a repeated sequence of outage scheduling with only 2 weeks of routine scheduling intervening would not provide reasonable assurance that personnel do not become impaired by cumulative fatigue. Nonetheless, for the reasons extensively stated in a previous related NRC response, the NRC has eliminated the proposed § 26.199(g) successive plant outage requirements in the final rule.

11.3.8 Common Defense and Security (§ 26.199(h))

Comments: One commenter recommended that the wording in proposed § 26.199(h) be changed from "...when informed in writing by the NRC..." to "...when informed verbally and followed up in writing by the NRC..." or similar wording. This revised wording would allow the NRC to verbally state that the licensee does not have to meet the requirements of this section and at a later date the NRC could provide written confirmation of that verbal statement. The commenter stated that this would be similar to the approval of exemptions from code requirements [F. G. Burford, Entergy].

NRC Response: The NRC does not agree that simple verbal approval should be sufficient to facilitate exemption of requirements in § 26.205 of the final rule. Instead, § 26.207(c) provides that, in periods in which security personnel must take action to ensure the common defense and security, licensees need not meet the § 26.205 requirements for the duration of that period only after the NRC has informed the licensee in writing of the waiver of the requirements for that period. The NRC believes that requiring written rather than verbal approval will not postpone in any way the licensee's ability to mobilize its security personnel to take the needed action.

11.3.9 Plant Emergencies (§ 26.199(i))

Comments: One commenter praised the clarity of proposed § 26.199(i) [F. G. Burford, Entergy].

NRC Response: The comment does not require a response.

11.3.10 Reviews (§ 26.199(j))

Comments: One commenter thought that the periodic reviews required by proposed § 26.199(j) would be inconsistent with the information in the annual report required by

§ 26.197(e). However, if the data requested in proposed § 26.197(e) is valuable to the NRC, the commenter suggested that the requirement for submitting that information be moved to § 26.199(j). The documentation of the periodic review would be available to the NRC resident inspector upon request and, in the commenter's view, there would be no need to provide an annual submittal to the NRC [F. G. Burford, Entergy].

NRC Response: The NRC disagrees that the periodic reviews required by proposed § 26.199(j) were inconsistent with the reporting requirements of proposed § 26.197. The requirements of proposed § 26.199(j) are now contained in § 26.205(e) of the final rule and the requirements of proposed § 26.197 are contained in § 26.203 of the final rule. The NRC acknowledges that both the reviews and reports required by the final rule focus on the use of waivers and fatigue assessments. However, the NRC considers the differences in the review and reporting requirements to be consistent with the licensee's responsibility for fatigue management and the NRC's oversight of the licensee's performance in this regard.

11.4 Fatigue Assessments (§ 26.201)

Further Development of Fatigue Assessment Requirements

Comments: One commenter stated that effective fatigue assessments will add a significant dimension to overall fatigue management activities and further extend efforts beyond a simple work hour limits policy. The commenter stated that some aspects are already well defined, such as situations where fatigue assessments would be used and some of the procedures (e.g., performed by properly trained personnel, free of bias, and with privacy protections). However, the specific details of what will be assessed, how the information is summarized and analyzed, and the interpretation of findings require further development. The commenter suggested that one approach to explore is how fatigue factors are examined in accident investigations. This would provide a structured approach to examining the known physiological factors that underlie fatigue and could be extrapolated and tailored for use in the context of the NRC proposed fatigue assessments [Mark Rosekind, Alertness Solutions].

NRC Response: The NRC agrees that implementation guidance for the fatigue assessment requirements for Subpart I would be beneficial. To that end, NEI developed draft industry guidance for managing fatigue at nuclear power reactor sites. The NRC has reviewed that draft guidance and, through Regulatory Guide 5.73, "Fatigue Management for Nuclear Power Plant Personnel" (dated March 2009, ADAMS Accession No. ML0834750028), has endorsed, with certain clarifications, conditions, and exceptions, that industry guidance (ADAMS Accession No. ML090360158). This guidance addresses fatigue assessments and supports valid assessments that can be practically implemented by supervisors trained in accordance with §§ 26.29 and 26.203(c) of the final rule.

Clarification of "Impaired Alertness"

Comments: One commenter stated that the rule should clearly define the term "impaired alertness" within the meaning of proposed § 26.201(a)(1) in order to bound the conditions that trigger the need for initiating a fatigue assessment. The commenter also recommended that the final rule should clarify whether, if a covered employee is found to be in a state of impaired alertness including unintentionally falling asleep on duty (e.g., nodding off), a fatigue

assessment should be performed to identify the root cause before management actions such as disciplinary action are taken [Daniel Stenger, NRSG].

NRC Response: The NRC does not agree that the term "impaired alertness," as now used in § 26.211(a) of the final rule, needed further definition. Proposed § 26.201(a)(1) required a fatigue assessment to be conducted in response to an observed condition of impaired alertness "creating a reasonable suspicion that an individual is not fit to safely and competently perform his or her duties." This threshold for action is consistent with the requirements for management action in response to possible impairment from any cause as described in § 26.77 of the final rule. The NRC also notes that the nature of the duties (for example, whether a job is monotonous), and the sensitivity of the job to impairment from fatigue (e.g., whether lapses in attention or degraded cognitive function affect the individual's ability to perform safely and competently) will affect the criteria for this determination. As a consequence, the NRC believes that the criteria of "reasonable suspicion that an individual is not fit to safely and competently perform his or her duties" adequately defines the conditions that trigger the need for initiating a fatigue assessment. Furthermore, an example such as "unintentionally falling asleep on the job," may be interpreted as the threshold for performing assessments. Although the NRC agrees that fatigue assessments should be performed in such cases, the onset of impairment from fatigue begins prior to an individual falling asleep and reasonable suspicion of fatigue can occur through observation of other behavioral and cognitive impairments, before sleep onset. Accordingly, the NRC has retained the requirements in proposed § 26.201(a)(1) as § 26.211(a)(1) of the final rule.

Effects of Fatigue Assessment on Rule Implementation

Comments: After recognizing that the fatigue assessment is a valuable element of the rule package, one commenter stated that the time needed to develop and establish a fatigue assessment program, which includes training, may be the most time-consuming aspect of implementing the rule. Therefore, the commenter requested a one-year implementation period from the date of approval of the rule [F. G. Burford, Entergy].

NRC Response: The NRC agrees that training of personnel to conduct fatigue assessments may require a 1-year period for all personnel to receive the training in the course of their normal training cycle for the FFD program. Accordingly, the NRC has established an 18-month implementation period for this provision.

Personnel Authorized to Conduct Fatigue Assessments

Comments: One commenter recommended that the phrase "Either a supervisor or a staff member of the FFD program, who is..." in proposed § 26.201(b) should be revised to "Either a supervisor or a FFD program staff member, who is..." to clarify that the supervisor need not be a member of the FFD program to conduct the fatigue assessment [Brian McCabe, Progress Energy].

NRC Response: The NRC agrees that the recommended wording more clearly describes the individuals authorized to conduct fatigue assessments and has revised proposed § 26.201(b) accordingly. The revised rule provision is in § 26.211(b) of the final rule.

12. SUBPART J: RECORDKEEPING AND REPORTING REQUIREMENTS

This section provides the NRC's responses to public comments on the proposed rule's Subpart J. That subpart established proposed requirements for licensees and other entities for maintaining records and submitting reports to the NRC, including program performance reports.

12.1 General Provisions (§ 26.211)

Comments: One commenter stated the industry's support for most of the various new or revised information collection requirements in the proposed rule [Marvin Fertel, NEI].

NRC Response: This comment does not require a response. (The recordkeeping and reporting requirements in proposed § 26.211 have been moved to § 26.711 in the final rule.)

12.2 Recordkeeping Requirements for Licensees and Other Entities (§ 26.213)

No comments addressed this section.

12.3 Recordkeeping Requirements for Collection Sites, Licensee Testing Facilities, and Laboratories Certified by the Department of Health and Human Services (§ 26.215)

No comments addressed this section.

12.4 Fitness-for-Duty Program Performance Data (§ 26.217)

Comments: One commenter stated the industry's support for the proposed § 26.217 requirement that licensees and other entities report FFD program performance data to the NRC [Jim Davis, NEI].

NRC Response: This comment does not require a response. (The FFD program performance data requirements in proposed § 26.217 have been moved to § 26.717 in the final rule.)

12.5 Reporting Requirements (§ 26.219)

No comments addressed this section.

13. SUBPART K: FITNESS-FOR-DUTY PROGRAM FOR CONSTRUCTION

Comments in this section pertain to the requirements in Subpart K Fitness-for-Duty Program for Construction. The NRC published these FFD program requirements that would apply during nuclear power plant construction on its rulemaking website on October 24, 2006, as part of the entire draft final rule text. Several closely related comments on proposed § 26.3 are addressed in Section 3.2 in this document. The proposed rule published in the *Federal Register* on August 26, 2005 included a different proposed Subpart K, which contained requirements for inspections, violations, and penalties. The NRC received no comments on that previous proposed Subpart K, which is Subpart O in the final rule.

Comments: One commenter supported the Subpart K application of certain FFD requirements to nuclear power plant construction. Though he disagreed that protecting sensitive information provided sufficient rationale for applying FFD requirements to construction workers, he did think that ensuring that individuals who receive, inspect, and assemble safety-related plant components are not impaired by drugs and alcohol provides a sufficiently strong rationale for such requirements. He also thought that industry quality assurance programs should not be relied upon to provide this assurance [David Lochbaum, UCS].

NRC Response: The NRC agrees that certain FFD program requirements applicable to individuals who perform specified duties during nuclear power plant construction are appropriate and necessary to provide reasonable assurance that those individuals are fit for duty, trustworthy, and reliable, commensurate with the potential risks to public health and safety and the common defense and security that their activities would pose. However, the NRC disagrees that the protection of sensitive information should not be part of the rationale for these requirements. The NRC considers certain individuals' access to such information as an important concern that Subpart K FFD programs will address.

Comments: One commenter recommended deletion of proposed Subpart K because there is no radiological hazard at construction sites before nuclear fuel is received. In his view, a variety of NRC and licensee activities are sufficient to ensure that a plant is constructed and will function as designed. These activities include licensees' quality assurance/quality control programs and the NRC construction inspection program and construction testing, pre-operation testing, and start-up testing programs. The commenter also noted that licensees will have a drug and alcohol testing regime consistent with standard construction practices. All workers will be subject to this testing. Furthermore, before receipt of nuclear fuel on a construction site, the licensee will perform a "lockdown and secure" procedure, at which time Part 26 requirements will become effective for all personnel within the scope of Part 26 on the site. In summary, the commenter stated that the proposed additional requirements in Subpart K would impose a significant burden on the industry without commensurate safety benefit [Marvin Fertel, NEI].

NRC Response: The NRC response to this comment appears in a response to related comments in the discussion of "FFD for Construction" in Section 3.2 of this document.

Comments: One commenter recommended that personnel who perform quality assurance/quality control activities at nuclear power plant construction sites be made subject to

an FFD program that meets all of the requirements of Part 26 except Subpart I [Marvin Fertel, NEI].

NRC Response: The NRC agrees with the commenter. Because of their important oversight responsibilities, the final rule's § 26.4(e) makes individuals who, when construction activities begin, perform quality assurance, quality control, or quality verification activities (i.e., those activities specified in Appendix B to Part 50, related to safety- or security-related SSCs) subject to a full FFD program that meets the same requirements as FFD programs for operating plants, except Subpart I. Section 26.4(e) of the final rule also subjects the following personnel to the same FFD requirements when construction activities begin: individuals who witness or determine inspections, tests, and analyses certification required under Part 52; individuals who serve as security personnel required by the NRC, until the licensee or other entity receives special nuclear material in the form of fuel assemblies; individuals who monitor the fitness of any individual who is constructing or directing the construction of safety- or security-related SSCs; individuals who supervise or manage the construction of safety- or security-related SSCs; and certain individuals who direct or implement a licensee's or other entity's access authorization program.

14. OTHER COMMENTS

This section provides the NRC's responses to public comments on elements of the Part 26 rulemaking other than the proposed rule text. These elements include the Commission's backfit, paperwork burden, and regulatory flexibility analyses conducted for the rulemaking. This section also addresses comments regarding implementation of the rule as proposed.

14.1 Regulatory Analysis

Requirements Are Too Prescriptive

Comments: One commenter, supported by many other commenters, stated that the proposed new requirements appeared to be needlessly prescriptive and that the regulatory analysis failed to justify this rigid approach. According to the commenters, the NRC's Regulatory Analysis Guidelines (§ 4.2, NUREG/BR-0058, Rev. 4) state that requirements should be performance-based unless there is good cause for highly prescriptive rules. Therefore, the commenters suggested that the regulatory analysis should better justify the prescriptive approach [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: Although the comment was not specific with regard to which particular provisions might be overly prescriptive, the NRC did consider this issue throughout development of the proposed, draft final and final rules. In fact, many of the revisions to the former rule result from the NRC's general intent to reduce the prescriptive nature of that rule's requirements and to provide licensees and other entities the flexibility they need to more effectively implement Part 26. However, the NRC agrees that the rule's drug and alcohol testing provisions are prescriptive when compared to some other NRC regulations. This approach was intentional, however, as discussed in the preamble to the proposed rule (e.g., see 70 FR 50451-50452). As mentioned there, the NRC intends the prescriptive approach to improve clarity and enhance effectiveness. In part, this approach responds to industry stakeholders' requests. Therefore, the NRC believes there is good cause for the prescriptive approach in these particular requirements. The regulatory analysis accounted for the cost of each provision and also discussed the effects of improved clarity in Section 4.1.2.2.

With respect to the rule's fatigue management provisions, the NRC agrees that it adopted a prescriptive approach for certain work hour limits. This approach addressed stakeholder concerns, as discussed in SECY-01-0113, "Fatigue of Workers at Nuclear Power Plants," related to the clarity and enforceability of the NRC's regulatory framework concerning worker fatigue. However, the NRC notes that, although certain requirements may be prescriptive, the requirements provide licensees substantial flexibility. As discussed in greater detail with respect to other, more specific comments addressing the relevant provisions such as the rest break provisions and minimum days off requirements in the final rule's § 26.205(d), the final rule adopts an approach that is more flexible and considerably less prescriptive than that provided by the proposed rule. The NRC has revised the regulatory analysis to address the final rule's more flexible approach to these requirements.

Regulatory Analysis Does Not Account for Interaction of Requirements

Comments: One commenter, supported by many other commenters, stated that the Regulatory Analysis considered each provision in isolation and did not allow for a comparison of various portions of the draft rule and the interaction of the various requirements. According to the commenter, the Regulatory Analysis was prepared on a section-by-section basis, which made it difficult to compare the incremental impact of each section given the existence of other proposed requirements. Therefore, the commenter stated that the analysis was deficient because it failed to justify that each section included was essential to the rule and multiple layers were not accounted for properly [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees that the regulatory analysis was conducted on a section-by-section basis but does not agree that each proposed provision was considered in isolation. In fact, the cost analysis specifically accounted for the effects of interacting provisions as appropriate, both with respect to drug and alcohol provisions and to fatigue management provisions. Although it is considerably more difficult to analyze the benefits associated with individual provisions that interact with other provisions, the regulatory benefits analysis of the proposed rule's fatigue management provisions (at which the NRC believes this comment was targeted) was informed by a side-analysis (presented as an addendum to the regulatory analysis), which sought to consider the interaction between key provisions. Nevertheless, the NRC has modified the fatigue management provisions that appear in the final rule in response to other public comments. In light of those rule changes, the NRC believes that the issues expressed in this comment are not likely to remain a concern to stakeholders.

Justification for Subpart I Costs

Comments: One commenter, supported by many other commenters, claimed that the proposed rule's work hour limits and break requirements had a disproportionately higher cost than its training, self-declaration, and fatigue assessment provisions. Further, the commenter stated that the Regulatory Analysis did not provide a convincing cost justification for these work hour controls. Also, the commenter stated that the Regulatory Analysis included an extensive analysis of the cost of implementing Subpart I, but the justification for the implementation burden was deficient [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenter. The NRC has modified the fatigue management provisions that appeared in the proposed rule in response to other public comments. In addition, based on insights provided in public comments, the NRC believes that, if the proposed fatigue management provisions were not modified by the final rule, it would be necessary to revise the regulatory analysis to reflect a higher implementation burden associated

with certain fatigue management provisions. In light of the revisions incorporated in the final rule, however, the NRC believes that the issues raised in this comment are not likely to remain a significant concern to stakeholders. In addition, the regulatory analysis has been revised in accordance with these revisions in the final rule.

Disagreement with Safety Goal Evaluation

Comments: One commenter, supported by many other commenters, questioned the Safety Goal Evaluation in Section 4.5 of the Regulatory Analysis. According to the commenter, the Safety Goal Evaluation did not fully satisfy the standards set forth in the NRC's Regulatory Analysis Guidelines. Specifically, the commenters stated that, in situations where it was not possible to develop adequate quantitative supporting information, the analysis should have provided "qualitative analysis and perspective" for the proposed new requirement, and these insights should have been "related to the safety goal screening criteria." The commenter thought that the Regulatory Analysis did not address any such criteria. In this regard, the commenter stated that the staff's finding that the proposed changes "may qualify ... as generic safety enhancements because they may affect the likelihood of core damage," and its statement that the rule will reduce the probability of accidents and damages, was cursory and unsubstantiated.

The commenter also stated that the Safety Goal Evaluation highlighted the overall lack of rigor and precision in the entire Regulatory Analysis. The commenter thought it significant that the staff acknowledged that its evaluation failed to quantify the "magnitude" of the claimed change in likelihood of core damage, or the claimed added assurance provided by the rule. Further, the commenter claimed that the generality of the staff's findings undermined the NRC's assertions in the rule package that the implementation of Subpart I will "result in substantial non-quantified benefits related to safety and security" [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC's evaluation followed agency guidance in the Regulatory Analysis Guidelines and in Appendix D of the Committee to Review Generic Requirements (CRGR) Charter. Therefore, the NRC disagrees with the comments on the Safety Goal Evaluation and believes that the analysis presented in Section 4.5 of the Regulatory Analysis was appropriate for this rulemaking. As discussed there, the NRC believes the action is a generic safety enhancement which does not lend itself to a Safety Goal Analysis. The revisions to Part 26 provide added assurance that individuals working at nuclear facilities are fit for duty and, consequently, the rule reduces safety and security risks ranging from workplace safety incidents up to radiological damage to the reactor core. A safety goal evaluation generally focuses on the change in likelihood of core damage. However, the magnitude of the change for this rule is not readily quantifiable due to uncertainties regarding the types, frequencies, and results of damage that occurred pre-rule and will occur post-rule. A more dominant effect of the rule will be to reduce the probability of other types of accidents and damages associated with a wide array of acts related to drug and alcohol abuse and fatigue, although this effect is equally difficult to quantify. Because the change in safety associated with the rulemaking cannot be quantified, the rule provisions cannot be compared to the NRC's safety goals. The NRC also disagrees

that there was a lack of rigor and precision in the entire regulatory analysis. Nevertheless, in response to other public comments, the NRC has revised several of the proposed fatigue management provisions (at which the NRC believes this comment was targeted) in the final rule. In light of those rule changes, the NRC believes that the issues raised in this comment are not likely to remain a concern to stakeholders.

14.1.1 Addendum

Comments: One commenter addressed Addendum 1 to the Regulatory Analysis, which quantified some of the benefits associated with selected proposed fatigue management provisions. The commenter stated that the industry was confused about the addendum's purpose and whether the quantitative analysis was considered in the proposed rule's backfit justification. The commenter thought that it should not be included in the rule package. Other commenters also expressed disagreement with Addendum 1. Specifically, these commenters stated that the analysis failed to show any correlation between its findings and actual performance and conditions in the commercial nuclear power reactor industry. According to the commenters, this made the "seemingly precise calculations meaningless." The commenters also disagreed with Addendum 1's conclusions regarding reduced rework. They stated that this conclusion was incorrect because it ignored the many measures in place in the industry, such as use of detailed procedures, supervision and quality assurance measures [Jim Davis, NEI; Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC does not intend that Addendum 1's quantitative analysis be considered in the backfit analysis determination. The addendum was provided only as information related to the rulemaking, as the NRC determined in the regulatory analysis and the backfit analysis that the rulemaking would result in substantial additional benefits beyond those captured in the addendum. The addendum has not been revised to address the final rule and has not been included in the final rulemaking package.

14.2 Backfit Analysis

Comments: Several commenters found the backfit analysis for the proposed rule to be deficient. The commenters suggested that the backfit analysis did not include a meaningful discussion of the proposed rule's actual improvements in public health and safety. One of these commenters mentioned the proposed Subpart I "days-off' requirements in this regard. The commenters explained that the qualitative statement that each element examined will provide substantial improvement to public health and safety was not supported by facts, and did not consider the diminished impact when other rule provisions are considered. The commenters thought that, considering the proposed rule as a whole, the protection of public health and safety would not be diminished if cumulative work hour limits would be applied only to security personnel and a flexible approach would be used for break requirements. Therefore, the commenters stated that the backfit analysis did not meet the intent of 10 CFR 50.109 [Michael Coyle, NEI #49; Marvin Fertel, NEI; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young,

Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

Other commenters supplemented this argument, stating that the collective work hour limits of the proposed rule should have been subjected to a separate backfit analysis to assess whether this aspect of the rule would produce a cost-justified substantial increase in safety as required by the NRC's Backfit Rule. The commenters noted that 10 CFR 50.109(c) requires a backfit analysis to consider the potential impact of new requirements on plant "operational complexity" and the cost of facility downtime. The commenters stated that, because of the "aggregate" backfit analysis was performed for the entire rule, it was not clear that the full impact of the collective work hour limits was considered [Daniel Stenger, NRSG; Brian McCabe, Progress Energy; Marvin Fertel, NEI].

NRC Response: The NRC disagrees with the commenters. The NRC believes that neither the proposed rule's backfit analysis nor its underlying approach was deficient based on then available information. However, the NRC has gained additional insights from public comments suggesting that the backfit analysis would need to be revised to account for additional operational complexity if the fatigue management provisions were to be finalized as proposed. In response to other public comments, the NRC has revised several of the proposed fatigue management provisions at which the NRC believes this comment was targeted. The NRC believes these rule revisions that appear in the final rule have resolved the commenters' concerns. Furthermore, the NRC has revised the backfit analysis as appropriate based on the final rule.

14.3 Paperwork Burden Analysis

Support for Drug and Alcohol Reporting Requirements

Comments: Several commenters found the reporting requirements associated with the drug and alcohol portion of the rule to be appropriate [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: This comment does not require a response.

Paperwork Reduction Act Obligation

Comments: Several commenters thought that the NRC had not met its obligation under the Paperwork Reduction Act with respect to the information collection requirements in proposed § 26.197(e). They claimed that the NRC had failed to adequately justify the need to provide useful information for making a determination on the adequacy of a facility's fatigue management program and to help the NRC assign inspection resources, and had also failed to objectively support its estimate of the burden created on affected licensees. Therefore, the commenters urged the OMB to remand proposed § 26.197(e) to the NRC for its further

consideration in light of these inadequacies [Marvin Fertel, NEI; Michael Coyle, NEI #49; F. G. Burford; Brian McCabe, Progress Energy; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; Daniel Stenger, NRSG].

NRC Response: After reviewing its Paperwork Burden Analysis, the NRC has revised certain burden estimates based on information provided by the commenters as well as additional analysis conducted by the staff. The NRC remains convinced, however, that the information collection requirements in the final rule are necessary to ensure that the NRC has the information it needs to effectively implement and enforce the FFD program (including its fatigue management requirements), increase consistency of rule enforcement, increase public confidence, and facilitate rule improvement. Section 11.2.5 of this document provides a detailed discussion of the NRC's justification for including these reporting requirements. (Note that the reporting requirements of proposed § 26.197(e) are now in § 26.203(e) of the final rule.)

Clarification of OMB Process

Comments: One commenter asked how the OMB process and the NRC rulemaking process come together with respect to the reporting provisions [Brian McCabe, Progress Energy].

NRC Response: As described in Section XIII of the Supplementary Information for the Proposed Rule (70 FR 50618-50619), the Paperwork Reduction Act of 1995 requires the OMB to review and approve all new or amended information collection requirements included in the final rule. No information collection may be conducted without OMB approval. Thus, the OMB paperwork burden approval process is a key component of the rulemaking process.

14.4 Regulatory Flexibility Analysis

No comments addressed this analysis.

14.5 Implementation

Implementation Process

Comments: Two commenters requested information about the process the NRC would use if it concurred with alternative means of meeting the proposed rule requirements and revised a significant portion of the proposed rule [Brian McCabe, Progress Energy; David Lochbaum, UCS].

NRC Response: Throughout the rulemaking process, the NRC has informed stakeholders of significant changes to the proposed rule that resulted from the NRC's consideration of public comments. For example, the NRC held public meetings in March 2006 to discuss changes to the proposed fatigue management provisions and FFD provisions relating to the construction of power reactors. These meetings provided opportunities for the NRC and stakeholders to exchange views on the proposed provisions. The NRC also published draft final rule text on its website in August and October 2006 to apprise stakeholders of the status of the rulemaking

process. In general, changes to the proposed rule that appear in the final rule are clarifications or extensions of the relevant provisions in the proposed rule made in response to public comments on the proposed rule.

Implementation Period

Comments: Several commenters stated that a significant amount of work will be required to train workers on the provisions of this rule. They asked how long industry will have to implement the final rule. Several commenters stated that, given the significant changes to Part 26, the industry will require 12 months to implement a majority of the new requirements once the final rule is published. One of these commenters asked the NRC to consider giving the Subpart I fatigue management requirements a later implementation date than the rest of the rule [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG; Dana Millar, Entergy; Steven Schildhouse, Individual].

NRC Response: The NRC agrees that implementation of the final rule will require time. Therefore, the agency has determined that licensees and other affected entities may defer implementation of this rule, except for Subparts I and K, until 365 days from the publication of the final rule in the *Federal Register*. Subpart I must be implemented by licensees and other applicable entities no later than 18 months from the publication of the final rule in the *Federal Register*. Additionally, licensees and other affected entities shall comply with the requirements of Subpart K as of 30 days from the publication of the final rule in the *Federal Register*.

Comments: One commenter thought the NRC was proceeding too quickly through the rulemaking process and not giving sufficient thought to the impact on industry. The commenter recommended that the implementation of any changes should be phased in gradually to give the workforce time to adjust [Daniel Hansen, Individual].

NRC Response: The NRC believes this rulemaking has proceeded with due deliberation. Both the NRC staff and the Commission itself have made considerable efforts to ascertain and consider the final rule's impacts on the industry throughout the rulemaking. As noted in the previous NRC response, licensees and other entities will have the opportunity to take a phased approach to implementing the final rule. The NRC believes this phased approach will give the workforce sufficient time to adjust to the new requirements.

Topics for the Final Rule Package

Comments: One commenter, supported by many other commenters, recommended that the final rule package address several issues regarding the implementation process. These issues included:

- Licensees that have work hour limits in their technical specifications;
- The process to cancel the security work hour order, and
- Parts of the Access Authorization Order that may conflict with 10 CFR Part 26

[Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, EGC/AmerGen; Mark Wetterhahn, Winston & Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D. R. Woodlan, STARS; J. A. Stall, FPL; B. T. McKinney, PPL; F. G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: With regard to the first issue, the NRC has established a 365-day implementation period from the date of publication of the final rule in the *Federal Register*. The NRC considers this period sufficient to support an orderly transition from control of work hours in accordance with order EA-03-038. That order requires compensatory measures for the control of work hours for security personnel, and unit technical specification requirements for the administrative control of work hours for personnel performing safety-related functions. The NRC expects that, during this implementation period, licensees will submit applications to amend unit technical specifications to remove requirements pertaining to the administrative control of work hours for personnel performing safety-related functions.

With regard to the other two issues, the NRC intends, on verification that licensees have met requirements set forth in the final rule, to rescind the portions of the orders that the final rule supersedes.

14.6 Other Miscellaneous Comments

Comments: One commenter recommended that the NRC conduct a formal study of this rulemaking [Jim Davis, NEI].

NRC Response: The NRC does not believe that a formal study of this rulemaking is warranted. However, the staff acknowledges that this rulemaking produced numerous lessons learned that will be beneficial for future NRC rulemaking efforts.

Comments: One commenter offered to present an overview of his company's FFD assessment tool [Michael Cantor, WayPoint].

NRC Response: The NRC does not endorse third-party products.

Comments: One commenter fully supported the NRC's efforts to address the self-disclosure of sleep disorders by operators through other regulatory documents such as the Regulatory Guide 1.134, "Medical Evaluation of Licensed Personnel at Nuclear Power Plants" (see 70 FR 50445). The commenter stated that no employee should be afraid to seek treatment for a sleep disorder that can be effectively diagnosed and treated and that the NRC should take appropriate steps to ensure that all MROs receive proper training regarding the signs and symptoms of sleep disorders as well as effective treatments. The commenter also urged the NRC to take appropriate steps to see that uniform education and training materials for MROs are developed to ensure that appropriate topics are covered accurately [Darrel Drobnich, NSF].

NRC Response: The NRC agrees that the assessment of sleep disorders for licensed operators should be addressed through Regulatory Guide 1.134, "Medical Evaluation of Licensed Personnel at Nuclear Power Plants," and is revising that guidance through a separate effort. The NRC intends to revise the guidance to communicate its expectation that the

evaluation consider sleep disorders among the factors that potentially can affect the ability of an operator to remain alert. Regarding the commenter's recommendation for uniform education and training materials, § 26.203(c) in the final rule establishes training and examination requirements applicable to all individuals subject to licensees' FFD programs. It also specifically requires licensees to add "...knowledge of indications and risk factors for common sleep disorders, shiftwork strategies for obtaining adequate rest, and the effective use of fatigue countermeasures..." to the content of their FFD training and examinations. Although it is common for industry groups such as the Nuclear Energy Institute or the Institute for Nuclear Power Operations to voluntarily develop generic guidance documents for common use by licensees, the final rule does not require uniform training materials. The NRC notes that it is the licensee's responsibility to develop and ensure the accuracy of training materials to meet these requirements.

14.7 Comments Outside the Scope of the Rulemaking

No comments addressed this topic.

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APPENDIX

COMMENTS TRACKING

The following table identifies the section of this document where each commenter's comments appear.

Name/Organization	Report Sections
Althoff, Robert A. Individual	11
Anonymous #15	8.6
Anonymous #16	5.8.3
Anonymous #17	7.16
Anonymous #18	4.6.4
Anonymous #19	1.1; 11
Anonymous #26	11
Anonymous #27	11
Anonymous #28	11
Anonymous #29	11; 11.3.2
Anonymous #34	11.3.4
Anonymous #75	11; 11.3.1; 11.3.4
Anonymous #76	11.3.4
Anonymous #dpr25	11.3.4
Antrassian, Andrew UWUA	11; 11.3.4; 11.3.6
Archie, Jeffrey SCE&G	1.3; 1.4; 2.1.1; 2.1.2; 2.1.4; 2.1.5; 2.1.6; 2.1.7; 2.2.1; 2.2.2; 2.3.1; 2.3.2; 2.3.3; 2.3.5; 2.3.6; 2.3.7; 3.2; 3.3; 4.4.3; 4.6.3; 4.6.4; 4.8; 4.10; 5.7; 5.8; 5.8.3; 5.8.6; 5.10.5; 6.1; 7.6.3; 7.6.5; 7.12; 7.16; 7.18; 8.4; 8.5; 8.8; 9.2; 9.6.3; 9.6.7; 10.2.2; 10.2.4; 10.3; 10.3.1; 10.3.6; 10.3.7; 10.3.9; 10.3.10; 10.3.16; 10.4.1; 10.5; 11; 11.2; 11.2.1; 11.2.4; 11.2.5; 11.3; 11.3.1; 11.3.2; 11.3.3; 11.3.4; 11.3.6; 11.3.7; 14.1; 14.1.1; 14.2; 14.3; 14.5
Barkley, Richard Individual	11; 11.3; 11.3.1
Barry, Dave Shaw Stone & Webster	11; 11.3.4
Bauer, Joseph Exelon	1.1; 2.3.3
Beck, Doug Individual	11.3.4
Bouthron, David FPL	5.10.3
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11. ABSTRACT *(200 words or less)*

On August 26, 2005, the U.S. Nuclear Regulatory Commission (NRC) published proposed amendments to the NRC's regulations for Fitness for Duty (FFD) programs in the Federal Register for public comment. The proposed amendments would have revised and updated the FFD regulations that the NRC established in 1989, and would, among other things, have required nuclear power plant licensees and other entities to strengthen the effectiveness of their FFD programs in controlling the use of substances that may affect the trustworthiness, reliability, and performance of workers and to limit worker fatigue management requirements. They also would have increased consistency with other Federal rules and guidelines and with the NRC's access authorization requirements. This report provides a detailed summary of the public comments on the proposed amendments received by the NRC and provides the NRC's resolutions of the issues raised by those comments.

12. KEY WORDS/DESCRIPTORS *(List words or phrases that will assist researchers in locating the report.)*

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