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

Comments Received Between August 26, 2005 and June 23, 2006

Prepared by:
ICF International
December 13, 2006

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List of Acronyms

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

Introduction

This document summarizes and responds to the comments received on the NRC's proposed revisions to 10 CFR Part 26 – Fitness for Duty Programs. The NRC accepted 81 written public comments on the proposed rule from August 25, 2005 to June 23, 2006. The NRC also considered six comments submitted on a previous working draft of the proposed rule that NRC posted on its website on May 19, 2005, but which were received too late to consider at that time.

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

Exhibit 1 identifies the individuals who provided written comments that the NRC received and the organization the individual is affiliated with, if applicable. Exhibit 2 shows the individuals who spoke during the September 21, 2005, public meeting and the organization the individual is affiliated with, if applicable.

Exhibit 1 - Individuals Providing Written Comments	
Robert Althoff	
Andrew Antrassain	UWUA
Jeffrey Archie	SCE&G
Richard Barkely	
Doug Beck	First Energy, Beaver Valley Station
Jim Bradshaw	AEP
Danielle Brian	POGO
Sue Brown	SAMHSA
F.G. Buford	Entergy
Michael Cantor	Waypoint Research Inc
Michael Coyle	NEI
Ethan Darrow	
Jim Davis	NEI
Darrel Drobnich	NSF

Exhibit 1 - Individuals Providing Written Comments	
Marvin Fertel	NEI
Peter Fowler	Duke Energy
C. L. Funderburk	Dominion
Guy Galster	
Ronald W. Gaston	Detroit Edison
Kevin Glidden	
Greg Gorman	First Energy, Beaver Valley Station
Don Grisette	SNC
Gregory Halnon	FENOC
Peter Hammill	PBNP
Daniel Hansen	Exelon
Mark Haywood	First Energy, Beaver Valley Station
Edwin Hill	IBEW
Mike Jolley	
D.M. Jurss	PBNP
Keith R. Jury	Exelon and AmerGen
Deborah Katz	CAN
Kenneth Kolaczyk	
Donald Lenski	Exelon
David Lochbaum	UCS
Charles LoDico	
Brian McCabe	Progress Energy
B.T. McKinney	PPL
Robert M. Meyer	PROS
Glenn W. Morris	TVA
Todd Newkirk	IBEW
Blaine Peters	Exelon

Exhibit 1 - Individuals Providing Written Comments	
Jim Pulley	Clinton Power Station
Barry Quigley	
Brent Rice	
Mark Rosekind	Alertness Solutions
David Sancic	
A. Edward Scherer	SCE
Steven Schildhouse	
Dennis Specha	Dresden Nuclear Power Station
Jim Springfield	IBEW
J A Stall	FPL
Daniel F. Stenger	NRSG
Richard Sweigart	DCS
Anthony Taylor	Exelon
Dan Todhunter	Exelon, Byron Nuclear Power
Ray Wacker	
Jim Waite	Exelon
Edward Weinkam	NMC
Mark J. Wetterhahn	Winston & Strawn
D R Woodlan	STARS
Keith D. Young	AmerenUE

Exhibit 2 - Individuals Providing Comments at the Public Meeting	
Joseph Bower	Exelon
Randy Cleveland	NMC
John P. Cowan	NMC
Jim Davis	NEI
Peter Defillipi	Westinghouse
Nick Depietro	First Energy
John Fee	SCE
Tom Houten	NEI
Dave Lochbaum	UCS
Brian McCabe	Progress Energy
Dana Millar	Entergy
Todd Newkirk	IBEW
Anthony Rizzo	Salem Hope Creek
Pete Stockton	POGO
Susan Techau	Exelon
Getachew Tesfaye	Constellation
Glenn Wilson	Dominion
David Ziebell	EPRI

1. General Issues

1.1 Support

Comments: Several commenters expressed general support for the rulemaking. One commenter stated that NRC, the licensees, and all the stakeholders have a common goal in mind, and the only issue is how to implement the provisions while providing the necessary operational flexibility [Joe Bauer, Exelon].

NRC Response: The comments do not require a response.

1.2 Oppose

No comments generally opposed the rulemaking.

1.3 Legal Basis

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

NRC Response: The NRC disagrees with the commenter that the proposed rule package discussed licensees “violating” the NRC’s Policy on Worker Fatigue. Instead, the rule package addressed a wide variability in how licensees interpreted and implemented the Policy. The NRC found that, in some cases, the use of waivers, in particular, was inconsistent with the Policy, as was discussed in Section IV.D of the proposed rule *Federal Register* notice. The NRC continues to believe that the reporting requirements are justified for the reasons discussed in Sections V and VI of the final rule *Federal Register* notice and Section 11.2.5 of this document.

1.4 Technical and Scientific Basis

<u>Support for Worker-designed Shifts</u>

Comments: One commenter asserted that Subpart I effectively removes rotating 8-hour schedules for most plants, and it presented a scientific paper supporting worker-designed shift

schedules [Todd Newkirk, IBEW].

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

Correlation between Cited Research and Actual Industry Data

Comments: One commenter, supported by many other commenters, raised several issues with the technical basis discussed in the proposed rule package. The commenter disagreed with the "sweeping generalizations" made in Section IV.D (1) and (2) of the proposed rule *Federal Register* notice regarding alertness problems that may occur as a result of fatigue. The commenter stated that the research alluded to in this discussion is not drawn from the nuclear industry, and there is a lack of correlation between the studies and actual nuclear industry data. As a result, the commenter explained that this raises concerns regarding the validity of the NRC's conclusions. The commenter stated that other factors reduce the potential for fatigue (i.e. industry's safety culture, training, work procedures, and attention to details) and these factors make it difficult to apply conclusions from studies conducted outside the nuclear industry [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J.A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG]. Similarly, another commenter expressed concerns about the reasearch included as the basis for the fatigue portion of the proposed rule, as they did not concern workers in the nuclear power industry [Daniel Hansen, Individual].

NRC Response: The NRC agrees with the commenters that Section IV.D (1) of the *Federal Register* notice for the proposed rule provided a general discussion regarding alertness problems that may occur as a result of fatigue as that was the intent of the section. Section IV.D (1) describes the types of impairments that can result from fatigue, specifically impairments of (1) attention, (2) decision-making, (3) problem solving, and (4) communication and teamwork. The discussion includes citations as examples of studies that demonstrate these types of impairments, and the NRC believes that these effects have been well substantiated and broadly accepted by the scientific community. The NRC provided a factual discussion of these effects and related studies and disagrees with the characterization of this discussion as including sweeping generalizations.

Section IV.D (2) of the *Federal Register* notice for the proposed rule provided a discussion of the prevalence of conditions in the nuclear industry that can contribute to worker fatigue. Specifically, the *Federal Register* notice discusses extended work shifts (i.e., 12 or more hours) with five or more consecutive work days, extensive overtime, shiftwork, early start times and extended commutes, and sleep disorders. With regard to the use of more than five consecutive work shifts and extensive use of overtime, the NRC notes that industry and union commenters (further presented and discussed in Section 11.3.4 ("Limited Access to Supplemental Workers" of this document) have asserted that schedules of 6 or more consecutive 12-hour shifts are

necessary to attract supplemental workers and have proposed that the NRC revise the proposed rule requirements to allow such practices. These comments corroborate NRC's assertion of these practices in the U.S. nuclear power industry. Similarly, the NRC considers the proposed rule's *Federal Register* notice discussion of industry use of shiftwork, shift start times beginning at 7 a.m. or earlier, the potential for extended commutes due to the nature of nuclear power plant sites in relationship to major population centers, and the incidence of sleep disorders to be a factual discussion of these conditions and does not overstate their potential to contribute to worker fatigue at nuclear power plants.

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

Accuracy of Data Provided by Industry

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

NRC Response: The NRC disagrees with the commenters that the NRC's conclusions on industry use of overtime are not justified. The basis for the NRC's conclusions is, in part, a survey developed and distributed by NEI to nuclear power plant licensees. The survey provided clear instructions to include only those hours worked and not to include extra hour compensations for working nights, weekends, or holidays. Specifically, the survey stated: "For the purposes of this survey, *Overtime* is defined as those hours worked in excess of a *nominal* 40-hour work-week. Overtime does not include special compensation for working nights, weekends, or holidays unless they are above and beyond the *nominal* 40-hour week-week." The survey also included an example which demonstrated the nominal 40-hour work-week concept for purposes of calculating overtime in response to the survey. If the instructions were followed by the participants of the survey then overtime hours were not based solely on pay records as suggested by the commenters. At the time the NEI submitted a summary of the data by letter, the NEI made no assertion that participants did not follow the survey instructions.

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

Furthermore, the NRC notes that industry commenters [Michael Coyle, NEI #49; Daniel Hansen, Individual; Donald Lenski, Individual; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG] have asserted that it is necessary to offer large amounts of overtime to prevent the loss of supplemental workers to other industries that can offer overtime without restriction (see Section 11.3.4, "Limited Access to Supplemental Workers"). The premise of this comment is that industry has historically allowed individuals to work large amounts of overtime during outages. The NRC also notes that extensive use of overtime and deviations from Technical Specification work-hour limits has also been documented in NRC inspection reports and in Information Notice 91-36, Nuclear Plant Staff Working Hours. The NRC believes its conclusions regarding industry use of overtime are well founded and consistent with those of many other stakeholders [Kenneth Kolaczyk #33; Michael Jolley, #4; Anonymous, #27, Anonymous #26], including the International Brotherhood of Electrical Workers which observed, "Some of our facilities have done an outstanding job of ensuring a well rested workforce, while other facilities have simply ignored the recommended work hour limitations or relied on other mechanisms to exceed 72 hours per work week" [Edwin Hill, IBEW].

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

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

NRC Response: The NRC agrees with the commenters that the conditions following the events of September 11, 2001, were beyond normal bounds and resulted from conditions that were largely beyond the control of licensees. However, the NRC maintains that the fatigue of security personnel during this period demonstrated that individuals at nuclear power plants will experience cumulative fatigue, even when those individuals are working hours that are within the NRC's policy guidelines of working not more than 16 hours in any 24-hour period and not more than 72 hours in any 7-day period. Furthermore, such work hours and cumulative fatigue may result from conditions that are within a licensee's control, as in the case of the extended

outage for the Davis Besse reactor head vessel replacement. As a consequence, these examples indicate an inadequacy of the former regulatory framework for addressing cumulative fatigue because plant technical specifications for the control of work hours generally do not place any clear limit on the period of time individuals can work substantially in excess of a 40-hour workweek (e.g., 60 to 72 hours per week).

Adequacy of Former Rule

Comments: A number of industry commenters questioned a contradiction in the proposed rule *Federal Register* notice language. Specifically, the *Federal Register* notice states that former regulatory requirements, orders and the policy statement are adequate. However, in other parts of the rule package, the NRC claims that new provisions will result in significant improvements in public health and safety. These commenters argued that this contradiction shows that the added layers of requirements are not warranted [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenters that the *Federal Register* notice statements described by the commenter are contradictory. Adequate protection of public health and safety and the common defense and security are ensured through the NRC's Policy on Worker Fatigue, licensee technical specification requirements related to this policy statement, and former regulations. However, opportunities exist to improve the former framework regarding to the enforceability and consistency of the former requirements to ensure that all licensees provide reasonable assurance that workers are able to safely and competently perform their duties.

The NRC's Policy on Worker Fatigue does not prescribe requirements and is therefore enforceable only to the extent that licensees incorporate the guidelines into a license condition or technical specification requirements. Further, for the licensees who have incorporated the NRC's Policy on Worker Fatigue into a license condition or technical specifications, it is difficult for the NRC to enforce the worker fatigue requirements and work hour limits in an effective, efficient and uniform way due to the following factors: the predominantly advisory language in the specifications, the lack of key term definitions, inconsistent levels of detail in the technical specifications from one licensee to another, varying scopes of requirements, inconsistent interpretation of the covered personnel, and inconsistent implementation of the basic measures used to determine whether an individual's work hours are within or above the technical specification limits. The NRC believes that by addressing these and other limitations of the former regulatory framework with respect to managing the effects of fatigue on worker FFD, the rule will provide a substantial enhancement to the protection of public health and safety and common defense and security.

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

Comments: Several commenters from industry argued that the NRC's justification for a 24-hour break every 7 days and a 48-hour break every 14 days in the proposed rule *Federal*

Register notice is flawed because the proposed rule package discussed the effects of cumulative fatigue without first establishing that cumulative fatigue would exist when every other provision in the proposed rule were observed. The commenters also stated that the lack of industry-specific evidence did not provide adequate justification for these break provisions [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenters that the *Federal Register* notice for the proposed rule discussed the effects of cumulative fatigue without first establishing that cumulative fatigue would exist when every other provision in the proposed rule were observed. As discussed with respect to the comment "September 11, 2001 Not Valid Justification for Fatigue Provisions," the NRC cited operational experience that indicated cumulative fatigue of nuclear power plant personnel at levels of work hours that are lower than those that would be allowed by the other work hour controls. Specifically, the *Federal Register* notice noted that following the terrorists attacks of September 11, 2001, the NRC began to receive a large number of concerns from nuclear power plant security personnel regarding the number of hours they were being required to work and their ability to remain alert and fit for duty. The NRC subsequently reviewed the work hours of security personnel at nuclear power plants and found that the work hours typically did not exceed an average of 60 hours per week. Similarly, the NRC reviewed work hours of personnel at the Davis Besse plant during an extended outage for a reactor vessel head replacement. Although workers had expressed concerns regarding excessive work hours and fatigue, the NRC found that the individual work hours typically did not exceed the guidelines of the NRC's Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors. However, for both the security personnel and the Davis Besse plant staff, the NRC noted that the individuals had worked substantially more than a 40-hour work week for many weeks.

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

Federal Motor Carrier Safety Administration Precedent

Comments: Several commenters from industry argued that the NRC's proposed rule package did not indicate the same rigor in review and application of studies conducted outside the power reactor industry as that of the Federal Motor Carrier Safety Administration (FMCSA). According to the commenters, the NRC often extrapolated narrow research findings into overly broad assertions. The commenters recommended that the NRC consider the FMCSA precedent, which is based on sound science and takes an integrated approach to managing both acute and cumulative fatigue. The FMCSA analysis was guarded in its extrapolation of narrow

research findings into broad regulatory findings. For example, in many of the studies, a psychomotor vigilance test is used to monitor for fatigue. However, as pointed by FMCSA, this does not necessarily equate to actual performance of assigned tasks. The commenters also explained that the FMCSA rules do not include long-term quarterly, annual or group work hour limits and research data support this regulatory approach [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

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

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

2. Specific Questions for Public Comment

In the *Federal Register* notice for the proposed rule (70 FR 50616), the NRC sought public comment on several specific issues. These issues are addressed below.

2.1 Proposed Drug and Alcohol Provisions

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

Issue: "Proposed § 26.75 in Subpart D would increase the sanctions for certain testing-related actions by requiring that: 'Any act or attempted act to subvert the testing process, including refusing to provide a specimen and providing or attempting to provide a substituted or

adulterated specimen, for any test required under this part must result in permanent denial of authorization,' and 'for individuals whose authorization was denied for 5 years ... any subsequent violation of the drug and alcohol provisions of an FFD policy must immediately result in permanent denial of authorization.' The NRC requests comments regarding these proposed changes specifically when compared to the 5-year ban available through the agency's enforcement policy for other acts of deliberate misconduct."

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

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

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

Issue: "Proposed § 26.119 [Determining "shy" bladder] would establish a process for determining whether there is a medical reason that a donor is unable to provide a urine specimen of at least 30 mL. The NRC added this proposed section in response to stakeholder requests and adapted the process from the DOT's Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR 40.197). The DOT Procedures also include processes for determining whether there is a medical reason that a donor is unable to provide a specimen of oral fluids (49 CFR 40.263) or a breath specimen (49 CFR 40.265) of sufficient quantity to support alcohol testing. The NRC invites comments on whether the NRC should consider incorporating these processes for insufficient oral fluids and breath specimens in Part 26."

Comments: Several commenters responded to the request for public comments on whether the NRC should consider incorporating these procedures in Part 26. The commenters stated that, based on many years of experience with the former rule requirements, industry sees no need for this provision because there are few, if any, instances where it would apply [Susan Techau, Exelon; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

One commenter suggested that the alcohol collector qualifications in § 26.85(b) are sufficient to address any "shy lung" issues [Susan Techau, Exelon].

NRC Response: Because there is no evidence of a problem requiring a solution in this matter, the NRC has not included these procedures in the final rule.

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

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

No comments addressed this issue. However, one commenter referenced proposed 26.31, and that comment is discussed in Section 4.6.4 of this document.

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

Issue: "Proposed §§ 26.133 and 26.163 would raise the cutoff levels for initial and confirmatory tests for opiates from 300 nanograms (ng) per milliliter (mL) to 2,000 ng/mL. The proposed rule would also require testing for 6-acetylmorphine (6-AM), a metabolite that comes only from heroin, using a 10 ng/mL confirmatory cutoff level for specimens that tested positive on the initial test. The proposed cutoff levels and new test would be consistent with those used by HHS and DOT, and would reduce the number of specimens in Part 26 programs that test positive for opiates at an HHS-certified laboratory but are subsequently determined to be negative by the MRO after consultation with the donor. The NRC invites comment on these proposed changes."

Comments: Several commenters addressed the proposed provision to raise the cut-off levels for initial and confirmatory tests for opiates from 300 nanograms (ng) per mililiter (mL) to 2,000 ng/mL. They stated that industry strongly supports the proposed requirement, as it would increase the efficiency of FFD programs [Pete Defilippi, Westinghouse Electric Company; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA;

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

NRC Response: The NRC has retained the proposed rule cut-off levels and new test (as discussed above) in the final rule.

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

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

Comments: One commenter, supported by many commenters, addressed the proposal to add new requirements for validity testing of urine specimens to detect specimens that may have been adulterated, substituted, or dilute. The commenter stated that validity testing requirements should be consistent with established HHS criteria and should not be more stringent [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

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

No comments were received on Issues 5a and 5b in *Federal Register* Notice.

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

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

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

NRC Response: The NRC received no public comments supporting the need for specific training requirements for the MRO related to this part and the licensee's or other entity's programs for which the MRO provides services. Therefore, the NRC has retained § 26.183(a) as proposed.

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

Issue: "Proposed §§ 26.135(b) and 26.165(a)(4) and (b)(1) would prohibit licensees and other entities, the MRO, and the NRC from initiating testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission. The NRC is considering an alternative approach that would permit a licensee or other entity to initiate testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission only if all of the following conditions are met: (1) the first results from testing the specimen were confirmed as non-negative by the MRO; (2) the donor has requested a review under proposed § 26.39 or initiated legal proceedings; and (3) the testing is conducted in accordance with proposed § 26.165(c)–(e), as applicable. Under either the proposed provisions or the alternative approach, the proposed rule would require the licensee or other entity to administratively withdraw the donor's authorization until the results from Bottle B or the retest results are available and to rely only on those results in determining whether the licensee or other entity would be required to take management actions or impose sanctions on the donor. The NRC is seeking an appropriate balance between protecting donors' rights to privacy and due process under the rule and the protection of public health and safety and the common defense and security, and invites public comment on the proposed and alternative approaches."

Comments: One commenter, supported by many commenters, addressed administrative withdrawal of the donor's authorization until the results from Bottle B or the retest results are available. The commenter recommended that the NRC consider the protection of public health and safety and the common defense and security as the primary goal. The commenter further argued that no provisions in the proposed rule negatively impacted the donor's rights, and it appears that only the donor, the MRO, and one employee of the licensee or other entity know the rationale for the administrative withdrawal of the donor's authorization. Thus, it is difficult for industry to envision a smaller number of people with this knowledge, and the donor's right to privacy is protected as much as possible. Therefore, the commenter supported this aspect of the proposed rule [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

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

2.2 Rulemaking Issues

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

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

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

NRC Response: In the proposed rule, the NRC stated that it would consider any changes to the draft HHS Guidelines for incorporation in the final FFD rule. HHS has not issued a final rule, and no changes to the draft HHS Guidelines have occurred. Therefore, the NRC is not adopting any changes to the draft HHS Guidelines in the final FFD rule.

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

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

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

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

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

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

Comments: One commenter stated that the reporting requirements associated with the drug and alcohol part of the rule are unnecessary for the NRC to regulate the industry or to protect human health and safety. However, the commenter supported the annual reporting requirements for the purpose of assessing the popularity of specific drug sets. Ultimately, however, the commenter supported the reporting requirements [Jim Davis, NEI].

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

2.3 Proposed Fatigue Provisions

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

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

Impact on 8-hour Shifts

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

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

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

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

Waivers do not Effect Prior Hours Worked

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

NRC Response: The NRC disagrees with the commenter's assertion that waivers have no value. It is not the NRC's intention that waivers be granted after the fact to account for any excess hours that have already been worked above the work hour limits. As stated in § 26.207(a)(1)(ii) of the final rule, a waiver can only be granted subsequent to a supervisor performing a fatigue assessment. A waiver may be granted only if it is necessary to mitigate or prevent a condition adverse to safety or to maintain the security of the facility and only to address circumstances that the licensee could not have reasonably controlled. In such cases, a fatigue assessment must be performed before the additional hours are worked in order to verify that there is reasonable assurance the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver may be granted. Therefore, the NRC retains the provisions for waiving work hour controls in § 26.207 of the final rule.

Flexibility of Waivers

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

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

Agreement with Waiver Provision

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

NRC Response: The final rule retains the criteria for authorizing a waiver that was specified in § 26.199(d)(3)(i)(A) of the proposed rule. These criteria are in § 26.207(a)(1) and (a)(2) of the final rule. The final rule also retains the requirement for an annual report summarizing the licensee's use of waivers from the work hour limits. The reporting requirement is in § 26.203(e) of the final rule.

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

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

Removal of Group Work Hour Limits

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

NRC Response: The NRC disagrees with the commenters that the proposed rule adequately addressed cumulative fatigue through other provisions or layers built into the rule. However, the NRC simplified the rule by eliminating the 48-hour break requirement in the proposed § 26.199(d)(2)(iii) and the collective work hour limits in proposed § 26.199(f) and replaced them with requirements for minimum days off per week averaged over a shift in § 26.205(d)(3) and minimum days off in 15 day blocks in § 26.205(d)(4) of the final rule. This issue is further discussed in detail in Section 11.3.6 of this document. Therefore, the NRC has revised the rule and maintains provisions to address cumulative fatigue on an individual basis and will therefore

provide more uniform assurance of worker fatigue.

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

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

Request for Prototype 8-hour Shift Schedule

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

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

Example of Shift Based on 24-hour Basis

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

NRC Response: The NRC agrees with the concepts provided by the commenter, however the NRC considers the comments to be examples of a good practices that licensees can implement consistent with the requirements of § 26.205(c) of the final rule. The NRC intends to consider the commenter's recommendations for incorporation in the implementation guidance for the final rule. Therefore, no additional changes to the final rule are warranted in response to this comment.

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

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

would better meet the stated objectives of the rule."

Definition of an Outage

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

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

Work Hour Exclusions During Outages

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

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

NRC Response: The NRC disagrees with the commenter that the NRC should reconsider all provisions that allow relaxed work hour controls during outages, especially during planned outages. Although it would be advantageous for fatigue management to level load all activities on systems, structures, and components (SSC's) that a risk informed process has shown to be significant to public health and safety or activities that are essential for effective response to a fire, plant emergency, or implementation of the site security plan, the nature of work in the nuclear industry requires that work often must be completed during an outage in order to ensure worker safety and public health and safety. The NRC recognizes that individuals are capable of working with limited rest without degraded performance for short periods of time. In addition, the NRC recognizes that plant outages are unique, relatively short-term, and involve levels of activity that are substantially higher than most non-outage operating periods. Therefore, the NRC considers it appropriate to allow flexibility within the work hour

requirements to accommodate limited periods of more intensive work schedules.

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

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

Therefore, the NRC retains requirements in the final rule which allow for a relaxation from work hour controls for the first 60 days of an outage.

Increase Work Hour Exclusion During Outages to 10 Weeks

Comments: One commenter, supported by many commenters, argued that the outage exclusion should be increased from 8 weeks to 10 weeks. According to the commenter, this change will provide adequate time to complete extended outages involving major equipment replacements. The commenter also claimed that its analysis of human performance data also supports this recommendation because in each outage evaluated, there was a downward trend in human performance errors as the outage progressed [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenter suggesting an increase from 8 weeks to 10 weeks for the plant outage exclusion from work hour controls in § 26.199(f). In

reviewing the frequency of outages, by duration, the NRC found that it would be necessary to increase the exclusion period substantially to address a marginal number of additional outages of longer lengths. This increase in the exclusion period would substantially increase the period of time that individuals would be working extended work hours with reduced recovery time. During the exclusion period, individuals are permitted to work up to 72 hours in a 7-day period and are assured of just 3 days off in each 15-day period. Individuals who work 12-hour shifts, which is common during outages, will average up to 67.2 hours per week, a rate of 160 percent of their normally scheduled hours with less than half of their normally scheduled days off for recovery, for a period of up to 2 months. Extending the outage exclusion period to prolong these conditions would substantively increase the potential for cumulative fatigue and fatigue-related personnel errors.

The NRC also disagrees with the conclusion that the commenters' analysis of human performance data supports the recommendation to increase the outage exclusion to 10 weeks because in each outage evaluated there was a downward trend in human performance errors as the outage progressed. The conclusions from that study were subjective and based on visual inspections of graphs of condition reports (CRs) compiled during the outage. The number of CRs were in at least one case actually higher in week 13 compared to week 1. Therefore, the conclusions of the report do not withstand a rigorous analysis and are not evidence that the proposed rule should revised.

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

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

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

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

NRC Response: The NRC disagrees with the commenters that requirements to address cumulative fatigue are unnecessary or indefensible, as discussed in the NRC's response to comments on "Collective Work Hour Limits" in Section 11.3.6 of this document. However, the NRC agrees with these commenters' opposition to the use of long-term individual work controls to address cumulative fatigue as an alternative to the group work hour controls (i.e., collective

work hour limits) of the proposed rule. Accordingly, the NRC did not replace the collective work hour limits with long term individual limits. Rather, the NRC eliminated the collective work hour limits and the requirement for a minimum 48-hour break in any 14-day period and addressed cumulative fatigue in the final rule through requirements for a minimum number of days off per week, averaged over a shift cycle, in § 26.205(d)(3), and minimum days off in 15 day blocks, in § 26.205(d)(4) and (d)(5).

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

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

Scope is Appropriate

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

NRC Response: The NRC agrees with the commenter that the scope is appropriate. The scope includes those job functions that the NRC considers to have the most potential for fatigue to degrade the protection of public health and safety and common defense and security. Although broader application of the work hour limits to other job functions could provide additional safety and security benefits, it is not clear that the additional benefit that could be achieved would justify the substantial cost of broader application of the work hour limits.

Definition of "Directing"

Comments: Several commenters from industry suggested that the NRC clearly define what is meant by the term "directing" in § 26.199(a). The commenters expressed concern that this phrase, along with the definition of "directing" in § 26.5 will subject engineering personnel to work-hour controls, thus increasing the recordkeeping burden on industry [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees with the commenters that NRC should clarify the definition

of the term “directing.” Individuals who are responsible for the correct performance of activities on SSCs that a risk-informed process has shown to be significant to public health and safety or functions that are essential for an effective response to a fire, plant emergency, or implementation of the site security plan should be subject to work hour controls, including engineering and technical support personnel.

The revised definition of “directing” is presented in § 26.5 of the final rule. The revised definition clarifies NRC’s expectations that a limited scope of personnel providing technical input would be subject to the requirements of § 26.205. The definition explicitly states the criteria that the term directing refers to an individual who is directly involved “in the execution of the work activity, or is ultimately responsible for the correct performance of that work activity” as opposed to, for example, the planning, development or scheduling of the activity, and that the technical input does not receive “subsequent technical review.” The revised definition more clearly focuses on activities that have the potential to substantively and immediately effect safety.

The definition of "directing" in § 26.5 also applies to the MRO's oversight of MRO staff. In the case of an MRO's direction of MRO staff, the NRC contends that this oversight is necessary because the MRO's direction has the potential to substantively and immediately affect the integrity of the FFD program.

Limit Group Hours to Security Personnel

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

NRC Response: In response to the comments stating concerns regarding the burden and potential effectiveness of the group work hour controls (i.e., collective work-hour limits) , discussed in Section 11.3.6 of this document, the NRC has replaced the collective work hour limits with individual work hour controls that are applicable to individuals including those security personnel described by the commenters.

Specify Job Functions Instead of Job Duty Groups

Comments: Commenters also suggested that the NRC develop a clear set of job functions which would warrant the added work hour restrictions. They argued that such performance-based criteria would help industry in deciding which individuals must be subjected to work hour restrictions [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger,

NRSG].

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

Maintenance Personnel

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

NRC Response: The NRC agrees that categorizing maintenance personnel could be difficult. The NRC has decided that maintenance personnel are subject to work hour requirements if they are maintaining, or providing onsite direction of maintenance of systems, structures, and components that a risk informed evaluation process has shown to be significant to public health and safety regardless of the organizational structure of the maintenance personnel.

Supplemental Workers

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

NRC Response: The NRC agrees with this commenter and notes that the final rule does not retain requirements for collective work hour limits. All work hour limits of the final rule are applicable on an individual basis, including § 26.205(d)(4) of the final rule. This requirement ensures that individuals, including transient workers, receive a minimum of 3 days off in each consecutive 15-day period of a unit outage. The minimum day-off requirement of § 26.205(d)(4) will support the final rule's objective of reasonable assurance that transient

workers who perform activities on SSCs that a risk-informed process has shown to be significant to public health and safety or functions that are essential for effective response to a fire, plant emergency, or implementation of the site security plan are not impaired from cumulative fatigue.

Information Sharing

Comment: One commenter agreed with the NRC's proposal as outlined in Subpart C to require licensees and other entities to collect and share greater amounts of information than under the former rule, subject to the protections of individuals' privacy specified in proposed § 26.37. The commenter argued that facilities should be required to share information on the work hours of transient workers at any facility to ensure they that do not exceed the individual work hour control limits [Darrel Drobnich, NSF].

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

3. Subpart A: Administrative Provisions

3.1 Purpose (§ 26.1)

No comments addressed this section.

3.2 Scope (§ 26.3)

Clarification of § 26.3

Comments: Many commenters addressed the scope of the proposed rule. The majority of these comments focused on § 26.3 and the lack of clarity therein. One commenter at the September 21, 2005, public meeting stated that proposed § 26.3 sufficiently defined the scope until § 26.3(e), which addressed requirements for entities performing construction activities, after which the rule describes program elements and requirements. Industry expressed confusion resolving the requirements here (such as in (e)(1)), "comply with § 26.23, 41 and 189") with the performance objectives described elsewhere in the proposed rule. The commenter also mentioned that industry had difficulty navigating to 10 CFR 52.103 and 50.10(e)(3) and several of the other references mentioned in the language of § 26.3(e) [Jim Davis, NEI].

NRC Response: The NRC agrees with the commenters that the rule language in proposed § 26.3 was unclear about the requirements in Part 26 that apply to each licensee and entity who

is subject to the rule. Therefore, the NRC has reorganized and clarified the provisions in § 26.3 of the final rule and added a description of the licensees and other entities to whom particular sections and subparts of the rule apply (e.g., §§ 26.73 and 26.709).

FFD for Construction

Comments: Several commenters from industry argued that proposed § 26.3(e) was not appropriately written for new plant construction sites [Jim Davis, NEI #48; Tom Houten, NEI; Peter Fowler, Duke Energy; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

The commenters stated that it was unclear what type of FFD program the NRC expect for new plant construction sites. The commenters argued that, by referring to specific sections of the rule which must be met by complying with other sections of the rule, the NRC seemingly applied the entire rule to new construction sites. The commenters stated that it would be difficult for industry to ensure compliance with the referenced sections of the rule without applying the entire rule.

They argued that new plant construction sites should be treated in the same manner as other major, non-nuclear construction sites, which have industrial drug and alcohol programs. The commenters argued that, until fuel arrives on site, there is no reason for public health and safety requirements additional to those applied to large commercial construction facilities [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

They also argued that referring to proposed § 26.23, which required FFD programs to meet the performance objectives of that section, for construction sites was inappropriate because it conflicted with proposed § 26.25. The commenters explained that proposed § 26.25 applied to individuals who have unescorted access to nuclear power plant protected areas, but during the construction phase there will be not yet be any protected areas as cited in proposed § 26.3(e).

Commenters also stated that the application of proposed § 23.23(e) regarding fatigue and degraded alertness was also inconsistent with proposed § 26.195, which applied requirements for managing fatigue only to licensees and other entities identified in proposed § 26.3(a) and (d) but not to (e), the construction phase. [Tom Houten, NEI; Peter Fowler, Duke Energy; Jim Davis NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

They also stated that proposed § 26.41 [Audits and corrective action] and § 26.189 [Determination of fitness] required administrative actions beyond those necessary for a commercial construction site at which there are no protected areas and no nuclear fuel [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn;

Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

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

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

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

The NRC also determined that some of the requirements in proposed § 26.3(e) would be difficult to implement. For example, much of the nuclear power plant construction workforce will

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

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

In contrast, the FFD program in Subpart K applies only to persons who will construct, at the location where the nuclear power plant will be constructed and operated, safety- and security-related structures, systems, and components (SSCs) that are required to be described in the COL/CP applicant's or permit holder's site safety analysis report, preliminary or final safety analysis report, or physical security or safeguards contingency plans (under Part 73). These workers' tasks include fabricating, erecting, integrating, and testing safety- and security-related SSCs and installing their foundations, including the placement of concrete. At a minimum, these individuals must be subject to an FFD program that meets the requirements of Subpart K, which emphasizes performance objectives and does not incorporate all of the requirements of Part 26, unless the licensee or other entity chooses to subject them to an FFD program that meets the Part 26 requirements for operating plants, except the fatigue management requirements in Subpart I of the final rule.

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

constructing safety- and security-related SSCs.

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

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

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

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

require a suitable inquiry/employment history check for these workers. In addition, the staff acknowledged the many complex logistical challenges associated with implementing FFD requirements during construction. Therefore, the Subpart K requirements provide applicants for and holders of COLs and CPs greater flexibility in implementing FFD programs for construction than the rule permits for FFD programs at operating plants.

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

FFD Intent for Fuel Fabrication Facilities

Comment: One commenter asserted that under proposed § 26.3 and § 26.195, Subpart I does not apply to fuel fabrication facilities, which is justified due to the lower level of risk at such facilities. The commenter argued that until the NRC authorizes the possession and use of strategic special nuclear material (SSNM) onsite, there is no reason that FFD requirements should be more stringent than those typically applied in non-nuclear large commercial construction facilities [Richard Sweigart, DCS].

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

Correlation with Part 52

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

NRC Response: The NRC agrees with the commenters and is coordinating the Part 26 and Part 52 rulemakings.

Exception for Long-term Shutdowns

Comment: One commenter stated that the proposed rule contained no provisions for exceptions to the requirements of Subpart I for plants in long-term shutdown status. The commenter stated that there is no reasonable or cost-effective method to comply with the proposed requirements due to the number of personnel being utilized. The commenter suggested that the NRC add subparagraph (g) that states: “Subpart I of this regulation does not apply to plants in long-term shutdown status when fuel has been removed from the reactor vessel and NRC approval is required prior to loading fuel. At the time approval to load fuel is

received, the licensee will be in compliance with all applicable portions of § 26.3 prior to commencement of loading fuel into the reactor vessel." To accompany this change, the commenter suggested that the following phrase be added to § 26.195: "Exceptions are identified in Section 26.3(g)" [Glenn Morris, TVA].

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

3.3 Definitions (§ 26.5)

"Non-Negative" vs. "Positive"

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

NRC Response: The NRC agrees with the commenters that the terms "non-negative" and "positive" in the proposed rule needed clarification. Therefore, the NRC has deleted "non-negative" from the final rule and replaced it with the more specific terminology of "positive, adulterated, dilute, substituted, or invalid." The final rule uses the term "positive" to refer to results from drug and alcohol testing indicating the presence of drugs or drug metabolites in a urine specimen or alcohol in a specimen of breath or oral fluids, and the terms "adulterated, dilute, substituted, or invalid" as appropriate to refer to results of validity tests of urine specimens indicating that the specimen may not be normal human urine.

"Validity Screening"

Comments: Several commenters requested that the definition of validity screening allow for the use of instrumented devices, in addition to non-instrumented devices [Jim Davis, NEI #48; Brian McCabe, Progress Energy; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comments relating to the use of instrumented devices for validity

screening are addressed below in Section 8.9.2 regarding § 26.137(b) of the final rule.

"Directing"

Comments: Several commenters stated that the proposed rule package discussion significantly expanded who would be included in the area of directing, and industry expressed concern with the lack of clarity of "directing" in the operations and maintenance functional groups. The commenters stated that, for operations, this term is understood to mean individuals with direct authority, such as the Senior Reactor Operator directing the activity of the Reactor Operator.

In the maintenance functional group, the commenters said the NRC staff stated that it was the individual who was at the job site providing direct supervision of the job, had the ability to detect errors and was ultimately responsible for the successful completion of the job. Although the commenters agreed that the group should include management personnel routinely assigned to a shift, they claimed the proposed addition of other individuals who provide periodic support, such as a special outage manager, is unwarranted. They stated that the licensed operator is directly responsible for the safe operation of the plant. The commenters stated that, in the maintenance area, the application of the term "directing" to engineering personnel who provide technical advice is of particular concern.

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

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

NRC Response: The NRC agrees that the proposed definition of "directing" was unclear as used in Subpart I and the scope of personnel who must be subject to work hour controls. Therefore, the NRC has modified the definition in the final rule. The revised definition clarifies the NRC's expectations that a limited scope of personnel providing technical input is subject to the requirements of § 26.205 [Work hours]. The definition explicitly states that the term "directing" refers to an individual who is directly involved "in the execution of the work activity, or is ultimately responsible for the correct performance of that work activity" as opposed to, for example, the planning, development or scheduling of the activity, and that the technical input does not receive "subsequent technical review." The NRC believes that the revised definition

more clearly focuses on activities that have the potential to substantively and immediately affect safety.

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

In response to the comment that individuals may not go out into the field to provide technical advice, the NRC notes that work hour limits apply to individuals providing "on-site" direction of the functions specified in § 26.4(a)(1) and (a)(2) of the final rule. As a consequence, an individual would not be exempted from the requirements because the direction was provided from a remote on-site location. The NRC defined the requirement in these terms to address the commenters' concern.

"Authorization"

Comments: Another commenter stated that the term "authorization" was used throughout the proposed rule in a number of different contexts, while historically the term has referenced "access authorization." Therefore, the commenter suggested that the NRC clearly define the different uses of the tem "authorization" or utilize unique terms where appropriate [Keith Jury, Exelon].

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

"Non-Instrumented Testing Devices"

Comments: One commenter addressed § 26.5 and requested that NRC provide a definition for and some examples of non-instrumented testing devices permitted to perform validity screening tests. The commenter also requested that the definition include examples of acceptable devices to use for validity screening tests [Charles LoDico, Individual].

NRC Response: The NRC agrees, in part, with the commenter's request and has revised the definition of "validity screening test" in § 26.5 of the final rule to clarify the proposed meaning of non-instrumented testing device.[1] In addition, the definition of "validity screening test" has been amended to include instrumented tests, based on another comment received on proposed § 26.137(b), that explained that some instrumented tests could also meet the performance testing criteria in § 26.137. The NRC has revised the definition of a validity screening test in § 26.5 of the final rule to mean the use of a non-instrumented test where the endpoint result is obtained by visual evaluation (i.e., read by human eye), or an instrumented test (machine-read end points), to determine the need for initial validity testing of a urine specimen. The NRC disagrees with the commenter's request to include examples of a non-instrumented test as unnecessary specificity.

"Dilute Specimens"

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

NRC Response: The NRC disagrees in part with the commenter. The proposed provision in § 26.5 was consistent with the definition for dilute specimens used in the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. The proposed rule presented the specific gravity cutoffs that HHS-certified laboratories must use to determine if a specimen is dilute in § 26.161(d). Subpart F [Licensee Testing Facilities] of the final rule does not contain a provision on specimen specific gravity testing because NRC is not requiring licensee testing facilities to conduct specimen specific gravity testing. Therefore, the NRC has not amended the definition of "dilute specimen" in the final rule.

"Non-Negative Test Result"

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

NRC Response: As a result of other comments received on the use of the term "non-negative test result" the NRC has eliminated the term in the final rule. The NRC has amended § 26.5 in the final rule to include a new term, "questionable validity," to account for validity screening and initial validity test results from testing conducted at a licensee testing facility that indicate that a specimen may be adulterated, substituted, dilute, or invalid.

3.4 Interpretations (§ 26.7)

No comments addressed this section.

[1]The final rule eliminates the use of the term "device" because of the specific connotation associated with the use of the term identified by another commenter.

3.5 Information Collection Requirements: OMB Approval (§ 26.8)

No comments addressed this section.

3.6 Specific Exemptions (§ 26.9)

No comments addressed this section.

3.7 Communications (§ 26.11)

No comments addressed this section.

4. Subpart B: Program Elements

4.1 Fitness for Duty (§ 26.21)

No comments addressed this section.

4.2 Performance Objectives (§ 26.23)

Comments: One commenter stated that the proposed section (*referring to the performance objectives section*) contained no language to provide reasonable assurance that the program will maintain a level of integrity to ensure the privacy of individuals who are subject to testing, and that the individuals who are subject to testing will not be unjustly or inaccurately portrayed as having violated the FFD requirements. Thus, the commenter suggested that the NRC should include such language in the rule [Todd Newkirk, IBEW].

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

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

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

4.4 Written Policy and Procedures (§ 26.27)

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

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

4.4.1 General (§ 26.27(a))

No comments addressed this section.

4.4.2 Policy (§ 26.27(b))

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

NRC Response: The comments do not require a response.

4.4.3 Procedures (§ 26.27(c))

Use of the Term “Due Process”

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

be subject to judicial review relative to the U.S. Constitution. The commenter suggested replacing "due process rights" with "other rights" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: In a subsequent telephone call, the commenter clarified that the comment was not intended to suggest that due process concerns do not apply to FFD programs and indicated that the proposal to substitute "other rights" for "due process rights" was intended to recognize that an individual's protected rights are not limited to due process. As clarified, the Commission agrees with the commenter that in addition to any due process rights, workers may also have other rights granted by federal and state statutes. Therefore, the NRC has modified the final rule in § 26.27(c)(1) and the preamble to the final rule to refer to "privacy and other rights (including due process) of individuals who are subject to Part 26."

Alcohol Consumption During the Pre-Work Abstinence Period

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

NRC Response: The NRC agrees with this clarification because it is consistent with the NRC's intent to prohibit any consumption of alcohol, not only excess consumption, during the pre-work abstinence period or while on duty. Therefore, the NRC has modified the final rule accordingly.

Use of the Term "Emergency"

Comments: Another commenter, supported by many other commenters, stated that the language in proposed § 26.27(c)(3) was confusing. Specifically, the commenter argued that the term "emergency" was too limiting. Thus, the commenter recommended changing the section to replace the term "emergency" with "unscheduled working tour" and stated that this wording is consistent with the wording "unscheduled working tour" in proposed § 26.27(c)(3)(ii)(c). [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees with this comment and maintains that the use of the term "emergency" in the second sentence of proposed § 26.27(c)(3) accurately conveyed the NRC's

intent that, if an individual's knowledge and skills are necessary to respond to an emergency, the consumption of alcohol resulting in a BAC that exceeds the cutoff levels in Part 26 does not preclude the licensee from relying on the individual during an emergency. However, the NRC has reorganized the language in the final rule to further clarify the differences between the controls and conditions that apply only to an emergency and those that apply to an unscheduled working tour.

Procedures for Called-In Individuals

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

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

Sanctions for Called-in Individual

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

NRC Response: The NRC agrees with the commenter. The intent of this provision is not to subject an individual to the sanctions that are otherwise required under this part for a confirmed positive alcohol test result when the individual is called in unexpectedly and has a confirmed positive test result for alcohol. The NRC believes that sanctions for the consumption of alcohol in these circumstances would be inappropriate, given that the individual would have been unaware that he or she would be called in to work. Therefore, the NRC has modified the final rule language accordingly.

4.4.4 Review (§ 26.27(d))

No comments addressed this section.

4.5 Training (§ 26.29)

Comments: The comments that concerned training are addressed in section 4.4 "Written Policies and Procedures" of this document.

4.6 Drug and Alcohol Testing (§ 26.31)

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

NRC Response: The comments do not require a response.

4.6.1 General (§ 26.31(a))

No comments addressed this section.

4.6.2 Assuring the Honesty and Integrity of FFD Program Personnel (§ 26.31(b))

Comments: Regarding proposed § 26.31(b)(1)(i), one commenter suggested that the NRC consider consistency of screening frequency between FFD personnel and non-critical group personnel. Because licensees and other entities are not required to update their psychological evaluations of non-critical group personnel, the commenter suggested that the NRC delete the words "...and psychological assessments..." from the last sentence of this section [C. L. Funderburk, Dominion].

NRC Response: The NRC disagrees with the commenter. The NRC believes that FFD program personnel hold unique responsibilities under the rule, given their critical role in maintaining the integrity of the FFD program. The time period for updates of credit and criminal history checks and psychological assessments do not need to align with the update time periods

for individuals who are granted unescorted access authorization under 10 CFR 73.56. Therefore, the NRC has not modified this provision in the final rule.

4.6.3 Conditions for Testing (§ 26.31(c))

Post-Event Testing

Comment: One commenter referenced proposed § 26.31(c)(3) and disagreed with the elimination of the phrase in former § 26.24(a)(3), "if there is reasonable suspicion that the worker's behavior contributed t o the event," from the proposed rule. The commenter stated that in the section-by-section analysis of the proposed paragraph, the NRC claimed that this phrase has long been subject to misinterpretation and that the location of this phrase at the end of the list of conditions under which post-event testing must be performed has led some licensees to conclude that this phrase applies only to events involving actual or potential substantial degradations of the level of safety of the plant. The commenter argued that the NRC presented an incorrect interpretation of the meaning on the former regulation, and that this phrase clearly modified not only the direct antecedent but other types of incidents potentially requiring for-cause testing.

The commenter also argued that the definition of "human error" in proposed § 26.31(c)(3) was too broad, and that there were no limits in defining human error which "may have caused or contributed to the event." The commenter argued that the proposed language would have the unintended consequence of causing individuals not to report medical conditions or to delay seeking treatment to avoid drug and alcohol testing procedures. Therefore, the commenter argued that the agency should not adopt the rule as proposed, and the rule relating to post-event situations should require at least a suspicion that drugs or alcohol affected the individual's actions.

However, the commenter supported language that would include the phrase "within 4 hours after the event" to describe recordable personal injuries and illnesses that would trigger post-event testing [Mark Wetterhahn, Winston and Strawn].

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

The proposed rule used the term, "human error," rather than the former term, "worker's behavior," to emphasize that post-event testing is required for acts that unintentionally deviated from what was planned or expected in a given task environment (NUREG/CR-6751, "The Human Performance Evaluation Process: A Resource for Reviewing the Identification and Resolution of Human Performance Problems") as well as failures to act (i.e., errors of omission). Therefore, testing is required regardless of whether there was "reasonable suspicion" that the individual was abusing drugs or alcohol for the consequences listed in the section. This

approach ensures that possible impairment because of substance abuse is always investigated following these significant events, and removes subjectivity from the testing decision.

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

Use of the Phrase "Medical Treatment Beyond First Aid"

Comment: Regarding proposed § 26.31(c)(3)(i), one commenter stated that industry believes that the inclusion of the criterion regarding "medical treatment beyond first aid" was an inappropriately low threshold for post-event testing and suggested that this clause be deleted. The commenter expressed concern that setting the for-cause testing threshold this low could have the unintended consequence of increasing the reporting burden associated with industrial safety incidents. The commenter also questioned the benefit of using this threshold because the results of such testing have not identified evidence of substance abuse within the commenter's facilities [F.G. Burford, Entergy].

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

Typographical Error

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

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

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

Lack of Provision for Specimen Dilution

Comments: One commenter, supported by many commenters, suggested a clarification to proposed § 26.31(d)(1)(ii) to properly account for actions that may be taken under § 26.185(g)(2) or (g)(3), when the MRO has reason to believe a donor has diluted a specimen. The commenter suggested that the NRC add a line to the end of the section, stating: "unless the specimen was considered dilute and the licensee or other entity chooses to have the specimen evaluated under § 26.185(g)(2) and (g)(3)" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

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

Random Testing Requirements

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

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

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

However, the NRC notes that § 26.31(d)(2)(i)(A) has been clarified to specify the NRC's intent that licensees should reasonable steps to create the appearance of when specimens are being collecte. The NRC has modified this section to require that the portions of each day and the days of the week on which it appears that specimens are being collected must vary in a manner that cannot be predicted by donors.

Testing of Individuals Off-Site/Not Reasonably Available

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

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

on site and are not reasonably available for testing" to § 26.31(d)(2)(v).

Licensees Using LOD Cutoffs

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

NRC Response: The proposed provision stated that one of the circumstances in which certification by a qualified toxicologist is not required under this provisions is if the licensee or other entity received written approval of the NRC to test for lower cut-off levels before the implementation of the final rule. If certification or written approval is required, and the licensee has not received written approval or certification, then the licensee will need toxicologist certification.

Delay of Medical Treatment to Conduct Post-Event Testing

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

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

Inadequacy of Long-term Random Testing

Comment: One commenter expressed concern that the industry does not adequately test each employee over the long term. The commenter noted that he has not been tested for many years and felt that this trend could compromise the safety of plant operations [Daniel Hansen, Individual].

NRC Response: The NRC disagrees in part with the commenter. If a random drug and alcohol testing program is conducted correctly, each individual who is subject to random testing has an equal probability of being tested each time testing selections are made. However, given the 50% annual testing rate specified in the rule, the NRC acknowledges that it may be possible for an individual not to be tested over a long period of time. The NRC believes that the 50% annual random testing rate is adequate to protect public health and safety because of the continuing low rates of positive test results reported to the NRC in the FFD program performance reports.

4.7 Behavioral Observation (§ 26.33)

No comments addressed this section.

4.8 Employee Assistance Programs (§ 26.35)

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

NRC Response: The NRC agrees with this clarification because it is not NRC's intent that licensees and other entities provide EAP services to C/V employees, even if they work at the licensee's or other entity's facility. Therefore, the NRC has modified the final rule language.

4.9 Protection of Information (§ 26.37)

Comments: One commenter referenced proposed § 26.37(d) and suggested that the donor or representative, with the permission of the donor, should be allowed to access the donor's FFD records at any time and not just in the case of a non-negative test. The commenter expressed that "this is to ensure that no records exist that should not be there," such as records of tests that tested non-negative initially and that the MRO subsequently declared to be negative [Todd Newkirk, IBEW].

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

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

Comments: Several commenters referenced proposed § 26.39(c), which stated that the procedure must ensure that more than one individual conduct the review, and that the individuals who conduct the review are not associated with the administration of the FFD program. One commenter, supported by many commenters, suggested that the review process required by this section should be consistent with that required by 10 CFR 73.56(e) (personnel access authorization) because this would simplify licensee procedures and would improve the consistency between FFD requirements and access authorization requirements. The commenter suggested rewording this paragraph to state, "The procedure must ensure that the

review is conducted by *at least one impartial and independent internal management individual* and that the *individual or* individuals who conduct the review are not associated with the administration of the FFD program (see the description of FFD program personnel in § 26.25(a)(4))" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees in part with the commenters. The NRC believes that allowing one person who is not associated with the administration of the FFD program to conduct reviews of FFD policy violations will not compromise an individual's right to an independent and impartial review. Therefore, the NRC has modified the provision in the final rule to clarify this intent.

4.11 Audits and Corrective Action (§ 26.41)

No comments addressed this section.

5. Subpart C: Granting and Maintaining Authorization

5.1 Purpose (§ 26.51)

No comments addressed this section.

5.2 General Provisions (§ 26.53)

No comments addressed this section.

5.3 Initial Authorization (§ 26.55)

No comments addressed this section.

5.4 Authorization Update (§ 26.57)

No comments addressed this section.

5.5 Authorization Reinstatement (§ 26.59)

No comments addressed this section.

5.6 Self-Disclosure and Employment History (§ 26.61)

No comments addressed this section.

5.7 Suitable Inquiry (§ 26.63)

Clarification of Present Employer in § 26.63(c)

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

NRC Response: The NRC agrees with the commenter. Licensees and other entities must ensure that a suitable inquiry has been conducted only of those employers that are listed in the self disclosure or employment history. Therefore, the NRC has modified the final rule language in this provision, as well as in § 26.61(c).

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

NRC Response: The NRC disagrees with the commenters. The NRC believes that the current employer could have information that is relevant to the suitable inquiry even if the individual's tenure at the current position has been brief. For example, the current employer may have conducted some form of pre-employment drug testing, the results of which would be relevant to the suitable inquiry. Therefore, the NRC has not modified the provision in the final rule

Use of the Term "Presentation" in § 26.63(d)

Comments: Another commenter, supported by many commenters, disagreed with the use of the word "presentation" in proposed § 26.63(d) with regard to an individual's signed release authorizing the disclosure of information. The commenter argued that a licensee should not have to present an individual's signed release authorizing the disclosure of information to another licensee or other entity and should only have to verify that an individual has signed a release authorizing the disclosure of information. Therefore, the commenter suggested changing the first sentence of the paragraph to state: "In response to another licensee's or other entity's inquiry and verification that an individual has signed a release authorizing the disclosure of information" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey

Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy]. Another commenter suggested that the first sentence of § 26.63(d) stating "and presentation of an individual's signed release authorizing" should be changed to "and the individual has signed a release authorizing" [Brian McCabe, Progress Energy].

NRC Response: The NRC agrees with the commenters. Current industry practices allow for verification of a signed release without a licensee "presenting" the actual document. Therefore, the NRC has eliminated the term "presentation" in the final rule and modified the provision to clarify the NRC's intent.

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

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

NRC Response: The comments do not require a response.

5.8.1. Purpose (§ 26.65(a))

No comments addressed this section.

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

No comments addressed this section.

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

Requirements for Pre-Access Test

Comment: One commenter objected to the language in proposed § 26.65(c)(2) and 26.65(d)(2)(ii). The commenter stated that negative test results from drug and alcohol tests conducted within the past 30 days should qualify as a pre-access test regardless of whether the individual is subject to a behavioral observation and arrest reporting program or is subject to random testing [Anonymous, #16].

NRC Response: The NRC disagrees with the commenter. The NRC intends that if the licensee relies on negative results from drug and alcohol tests that were conducted under the requirements of Subpart C and before the individual applied for authorization, the applicant must also be subject to a behavioral observation and arrest reporting program that meets the requirements of this part. This program must begin on the date the specimens for drug and alcohol testing were collected through the date the individual is granted authorization and throughout their employment. The purpose of this requirement is to minimize the potential for any substance abuse following the test. Behavioral observation provides the necessary deterrence and opportunities to detect any substance abuse during the period that falls between

administration of the pre-access test and the granting of authorization. If the individual is not subject to behavioral observation after the previous test was conducted, it is necessary to conduct a pre-access test to verify that the individual had continued to avoid substance abuse. Therefore, the NRC has not changed the provision in response to this comment. The NRC has also added a requirement that the individual must remain subject to a drug and alcohol testing program that includes random testing in order to be exempt from pre-access testing under § 26.65(c)(2). This measure minimizes the potential for any substance abuse following the drug and alcohol test.

Comments: Another commenter, supported by many commenters, stated that proposed § 26.65(c)(2) and 26.65(d)(2)(ii) contradict § 26.65(b) and 26.65(f). In particular, the commenter argued that licensees should be able to rely on drug and alcohol tests that were conducted before the individual applied for authorization if the individual is subject to a behavioral observation and arrest reporting program and random drug and alcohol testing. Therefore, to improve efficiency the commenter suggested changing § 26.65(c)(2) and (d)(2)(ii) to state, "The licensee or other entity relies upon negative results from drug and alcohol tests that were conducted before the individual applied for authorization, and the individual remains subject to *both a drug and alcohol testing program that includes random testing* and a behavioral observation and arrest reporting program which meet the requirements of this part from the date upon which the individual's last authorization was terminated through the date upon which the individual is granted authorization" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters. The language suggested by the commenter removes the reference to § 26.65(b) in § 26.65(c)(2) and 26.65(d)(2)(ii) to allow licensees to rely on drug and alcohol tests that were conducted more than 30 days before the individual applied for authorization, provided that the individual has been subject to a random drug and alcohol testing program and a behavioral observation program that requires arrest reporting that meet the applicable requirements of this part. The NRC agrees that pre-access testing within 30 days before authorization is granted is unnecessary in these circumstances and has revised the final rule accordingly.

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

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

5.8.5. Authorization Reinstatement After an Interruption of 30 days or Fewer (§ 26.65(e))

No comments addressed this section.

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

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

language in proposed § 26.65(f). The commenter stated that licensees currently conduct pre-access drug and alcohol testing within the 30-day period preceding the date the licensee grants authorization. Also, § 26.65(f) only required that licensees collect a sample in this timeframe. The commenter argued that the effort to implement this change exceeds the benefit of the change. Thus, the commenter suggested that the NRC add the 30-day period to conduct testing to § 26.65(c), and delete § 26.65(f) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

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

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

No comments addressed this section.

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

No comments addressed this section.

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

No comments addressed this section

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

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

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

5.10.1. Purpose (§ 26.69(a))

No comments addressed this section.

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

Comments: One commenter stated that industry is already familiar with the role of Substance Abuse Professionals (SAPs) and suggested that the provision in § 26.69(b)(4) allow for use of either an SAE or SAP as it relates to this section. The commenter recommended that the provision be revised to read, "Ensure that SAE *or SAP* conducts a determination of fitness" and that the remaining paragraphs in the section also include the option of using either an SAE or SAP [C.L. Funderburk, Dominion].

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

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

Consistency in Self-Disclosure Requirements

Comments: Several commenters at the public meeting on September 21, 2005, addressed these sections of the proposed rule. One commenter addressed § 26.69(c)(1) that required the licensee to verify self-disclosure and employment history. The commenter stated that the proposed language in § 26.69(c)(1) only referenced the self-disclosure time period identified in § 26.61(b)(3). The commenter suggested that the language also reference the employment history time period identified in § 26.61(c) [Susan Techau, Exelon].

NRC Response: The NRC agrees with the commenter that the time periods that must be addressed by the self-disclosure and employment history should be clarified. The NRC has modified the final rule accordingly.

Suitable Inquiry with Potentially Disqualifying FFD Information

Comments: In addition, several commenters expressed confusion about proposed § 26.69(c)(2). One commenter asked if the industry must cover every employer if potentially disqualifying FFD information is discovered or disclosed during the suitable inquiry process. The commenter explained that page 50513 of the *Federal Register* notice contains a discussion of this intent [Randy Cleveland, NMC]. A second commenter stated that it is confusing to move from one section of the regulation (§ 26.69(c)(2)) to another section of the regulation (§ 26.63(f)) when one is conducting an investigation and potentially disqualifying FFD information is discovered or disclosed [Jim Davis, NEI]. These sections of the rule discuss different timeframes for the suitable inquiry, and both commenters asked for an explanation of the NRC's intent.

A commenter at the September 21, 2005, public meeting asked a followup question about the suitable inquiry process for an individual whose period of interruption is 2.5 years. If potentially disqualifying FFD information is discovered or disclosed during this period of time, the commenter asked if the licensee would have to request the individual to provider an additional 2.5 years of employment history to satisfy the 5-year suitable inquiry requirement [Susan Techau, Exelon].

NRC Response: The NRC intends that if potentially disqualifying FFD information is discovered or disclosed during the suitable inquiry, the licensee must contact every employer from the applicable period in § 26.61(b)(3). In the case of an individual whose authorization had been interrupted for 2.5 years, § 26.69(c)(2) requires the licensee or other entity to complete the suitable inquiry with every employer by whom the individual claims to have been employed during that 2.5-year interruption period, and to obtain and review any records pertaining to potentially disqualifying FFD information about the individual from the licensees or other entities who had granted authorization to the individual during the earlier 2.5 years of the 5-year period required. If an individual had not held authorization during the 5-year period and potentially disqualifying FFD information was discovered or disclosed that a previous licensee had not resolved, then the receiving licensee is required to obtain an employment history from the individual that addressed the entire 5-year period and conduct the suitable inquiry with every claimed employer from those 5 years.

5.10.4. Maintaining Authorization with Other Potentially Disqualifying FFD Information (§ 26.69(d))

No comments addressed this section.

5.10.5. Accepting Follow-up Testing and Treatment Plans from Another Part 26 Program (§ 26.69(e))

Comments: Several commenters from industry disagreed with proposed § 26.69(e)(1), which required the FFD program to which an individual was subject to assume responsibility for overseeing the continuation of treatment and follow-up testing for an employee who had a positive test result under another FFD program administered by the same or different licensee or entity. The commenters argued that the burden of completion, compliance, and follow-up should remain with the individual, not the licensee, to monitor and verify. The commenters asserted that the difficulty and ability to administer such a process would make the requirement ineffective and suggested that § 26.69(e)(1) be deleted from the proposed rule [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees in part with the commenters. The NRC believes that if it is impractical for the individual to comply with a treatment plan that was developed under another FFD program because of circumstances that are outside of the individual's or licensee's or other entity's control (e.g., geographical distance, closure of a treatment facility), then it is appropriate that the granting FFD program develops a comparable treatment plan, with accountability for monitoring the individual's compliance with the plan assumed by the granting licensee or other

entity. Therefore, the NRC has modified the proposed provision accordingly in the final rule.

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

No comments addressed this section.

5.11. Maintaining Authorization (§ 26.71)

No comments addressed this section.

6. Subpart D: Management Actions and Sanctions to Be Imposed

6.1. Sanctions (§ 26.75)

Agreement with § 26.75(a)

Comments: Several commenters from industry stated that the industry agrees with proposed § 26.75(a). Each licensee and other entity should view this proposed rule as a continuum from previous versions of the rule and may impose stricter sanctions than the rule requires [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comments do not require a response.

Questionable Justification for § 26.75(b)

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

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

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

Comment: One commenter disagreed with proposed § 26.75(d), which stated that any individual who resigns or withdraws his or her application for authorization before authorization is terminated or denied for a first violation of FFD policy shall be subject to a harsher penalty than

a person who does not resign or withdraw. The commenter argued that former § 26.27(c) provided that resignation in such circumstances shall be recorded as a removal for cause [Richard Sweigart, DCS].

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

Comment: One commenter referenced proposed § 26.75(d) and suggested that the rule discuss the way the new system of sanctions will handle past violations. The commenter believes that the new system should not consider past violations [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter and believes that an individual's past behavior should not be ignored under the final rule. Therefore, the NRC has not modified this provision in the final rule.

Sanctions for Non-Negative Test Result

Comment: Another commenter asked if the FFD regulations define a required action for positive tests, such as a 1–3 year ban on unescorted access [Brent Rice, Individual].

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

Clarification of § 26.75(g)

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

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

6.2. Management Actions Regarding Possible Impairment (§ 26.77)

No comments addressed this section.

7. Subpart E: Collecting Specimens

7.1 Purpose (§ 26.81)

No comments addressed this section.

7.2 Specimens to Be Collected (§ 26.83)

No comments addressed this section.

7.3 Collector Qualifications and Responsibilities (§ 26.85)

No comments addressed this section.

7.3.1 Urine Collector Qualifications (§ 26.85(a))

No comments addressed this section.

7.3.2 Alcohol Collector Qualifications (§ 26.85(b))

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

NRC Response: The NRC agrees that § 26.85(b) in the proposed rule did not require certification of alcohol collectors. The NRC has not required this certification in the proposed and final rule because it believes that certification under the U.S. DOT's specimen collector requirements is unnecessary in Part 26. Licensees currently use the systems approach to training (SAT) breath alcohol collectors. The NRC believes that industry training of breath alcohol collectors in accordance with the SAT provides an adequate level of training to ensure the proper completion of specimen collections. Therefore, the NRC has decided not to require alcohol collectors to be certified as breath alcohol technicians, as required by U.S. DOT. The NRC also agrees with the commenter's statement that proposed § 26.85(b) did not include training documentation requirements for collectors. Therefore, the NRC has revised proposed § 26.85 in the final rule by including a new provision, § 26.85(e), to establish documentation requirements for collectors. Maintaining records to document collector proficiency is necessary for NRC inspection purposes as well as to ensure that the records are available for any administrative and/or legal proceedings challenging an alcohol test result.

7.3.3 Alternative Collectors (§ 26.85(c))

Comments: One commenter disagreed with proposed § 26.85(c) that permitted alternative

collectors (i.e., medical professionals, technologists, technicians) to serve as urine and/or breath collectors without meeting the collector qualification requirements in § 26.85 (a) and/or (b) [Sue Brown, Individual].

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

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

No comments addressed this section.

7.4 Collection Sites (§ 26.87)

Coloring Agents Cannot Interfere with the Drug and Validity Testing Assays

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

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

Same Gender Collector for Specimen Collections in Restrooms with Enclosed Stalls

Comments: One commenter objected to proposed § 26.87(f)(3) that required, in the exceptional instance when a designated collection site is unavailable (e.g., post-event test at a hospital) and a restroom with multiple stalls is used for the collection, that a same-gender collector accompany the donor into the restroom, but remain outside the stall used by the donor. The commenter stated that the proposed provision was contrary to the "normal collection process" that, in the commenter's view, did not require a same gender collector to conduct a specimen collection when a donor provides a specimen in a stall, as long as visual privacy is maintained. The commenter asserted that the proposed provision would be burdensome to implement because it would require that a male and a female collector be present at a collection

site at all times. The commenter also noted that the proposed provision would be especially burdensome to implement during outage situations when a large number of individuals must be subject to testing [Jim Bradshaw, AEP].

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

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

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

7.5 Preparing to Collect Specimens for Testing (§ 26.89)

Notification of Selection for Testing

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

NRC Response: The NRC disagrees with the commenter's request to require licensees and other entities to notify, in person, an individual selected for required testing. Requiring a face-to-face notification of testing would be unnecessarily burdensome on licensees and other entities and could delay required testing. The NRC further disagrees with the commenter's assertion that a licensee or other entity can arbitrarily determine whether an individual has attempted to subvert the testing process because the individual did not arrive at the collection site within the required time period. In order to determine that an individual has not reported in a timely manner for testing, the licensee or other entity must maintain a record of the time that an

individual was notified to proceed for testing. Therefore, to conclude that an individual has refused to submit to testing, the licensee must implement a defensible method to document the time that the employee was notified for testing. Although one acceptable notification method would be a face-to-face communication between an FFD program supervisor and the individual selected for testing, the licensee or other entity may meet the rule's requirements by employing other secure methods to notify an individual that he or she has been selected for testing. Therefore, the NRC has not modified the proposed provision in the final rule.

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

Time Limit to Appear for Testing at a Collection Site

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

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

FFD Supervisor - Method to Identify a Donor Without Photo Identification

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

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.89(b)(2) in the final rule. For tests other than pre-access tests, this section in the final rule directs FFD management, upon being informed by the specimen collector that the donor did not present acceptable identification, to contact the donor's supervisor to verify the donor's identity. If the donor's supervisor is not available, FFD management must take other steps to establish the donor's identity and determine whether the lack of identification was an attempt to subvert the testing process. This revision is consistent with the former requirement in Section 2.4(g)(2) in Appendix A to Part 26 that permitted a collector to positively identify a donor "through the presentation of a photo identification or identification by the employer's representative."

Pre-access Testing Prohibition Without Valid Photo Identification

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

NRC Response: The NRC disagrees with the commenter's request. The NRC requires that rule text must use the phrase "may not" to describe a prohibited activity. Therefore, the phrase "may not" is used throughout the final rule instead of the phrase "shall not."

Comments: One commenter addressed proposed § 26.89(b)(2) and disagreed with the permission for a specimen collection to proceed even if the donor's identity cannot be confirmed by the collector. The commenter reasoned that the proposed provision is inconsistent with Section 2.2(f)(2) in the HHS Mandatory Guidelines for Federal Workplace Drug Testing which prohibits a collector from proceeding with a specimen collection if a donor's identity cannot be verified [Sue Brown, Individual].

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

Informing a Donor of Refusal to Test Actions

Comments: One commenter addressed proposed § 26.89(c) that required urine collectors to inform each donor, before beginning a specimen collection, that leaving the collection site before the collection is completed or refusing to cooperate with the specimen collection process will be considered a refusal to test. The commenter stated that solely relying on the collector to verbally inform the donor of the actions considered to be a refusal test under the rule is inadequate

because the collector may forget to convey the information. The commenter requested that a description of the refusal to test actions be included on the donor consent-to-test form or be posted in a conspicuous location at the collection site. [Todd Newkirk, IBEW].

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

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

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

No comments addressed this section.

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

No comments addressed this section.

7.6.3 EBT Capabilities (§ 26.91(c))

Comments: Several commenters addressed the provision in proposed § 26.91(c)(2) that specified the criteria that evidential breath testing (EBT) devices must meet to be acceptable for use in confirmatory alcohol testing. The commenters disagreed that these EBTs should have to display a unique number that can be read before each test. The commenters asserted that some EBTs on the NHTSA Conforming Products List (CPL) do not have this capability. The commenters stated that to implement the proposed provision, some licensees would have to purchase new equipment, even though their current equipment is on the NHTSA CPL. Finally, the commenters suggested that the proposed provision would have a significant economic impact on small entities that manufacture EBTs [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

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

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

No comments addressed this section.

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

External Calibration Definition

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

NRC Response: The NRC disagrees with the commenter's request. The term "external calibration check" has a specific meaning for EBT devices and is a commonly used term for describing the quality assurance measures taken by a collection site to evaluate the performance of an EBT. A collection site must ensure the each EBT used for FFD program alcohol testing is functioning within the acceptable tolerance limits specified in the quality assurance plan of the equipment manufacturer by conducting a specific accuracy check on the equipment, which is called an external calibration check.

Frequency of External Calibration Checks on EBTs

Comments: One commenter addressed proposed § 26.91(e)(1) that required, at a minimum, that an external calibration check must be performed on an EBT according to the time interval specified in the manufacturer's quality assurance plan (QAP). The commenter requested that the NRC revise this section to require an external calibration check to be performed more frequently because a donor could be sanctioned for a positive test result that would be later overturned if the EBT was malfunctioning (i.e., fails the next external calibration check). Specifically, the commenter requested that an external calibration be performed on each EBT used for testing at the start and end of each testing day. [Todd Newkirk, IBEW].

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

<u>EBT Calibrations and Cancellation of Positive Test Results</u>

Comments: One commenter, supported by other commenters, disagreed with the provision in proposed § 26.91(e)(3) pertaining to an EBT that fails an external check of calibration. The commenter objected to the proposed requirement to cancel all positive breath alcohol test results from the point the EBT last passed an external calibration check to the point the EBT failed the external calibration check and was taken out of service. The commenter argued that "since fitness for duty has traditionally been considered an aspect of physical plant security, it causes one to make a comparison to those situations when security equipment fails, and that comparison yields contradictory results. For instance, if access screening equipment fails, all personnel in the protected area are not required to be re-searched because there is not an automatic assumption made that the machine was inoperative and everyone in the plant was improperly screened. In the same manner, personnel within a vital area are not required to leave the area when the access device or door alarm fails because there is not an automatic assumption made that they were able to obtain unauthorized or undetected access. In each of these instances, the assumption is that the equipment failed in the testing officer's presence and compensatory measures are implemented, to include an investigation. . . The same line of thinking should be applied across the spectrum of security, including FFD. Unless evidence can

be provided that can demonstrate failure occurred immediately following the last successful test, the assumption should not be that the equipment was not working, it should be that it worked properly until the failing test was performed." The commenter also asserted that having to "negate all positives since the last successful test will probably cause an increase in the frequency of testing to minimize the impact from this occurring. The implied test frequency exceeds the required frequency, adding burden to FFD staff and increased costs not calculated in the regulatory analysis." [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees that a positive confirmed breath alcohol test result should not be overturned when the EBT used during the test fails an external calibration check. Each donor must receive a fair and accurate test result. A donor should not be subject to sanctions based on a test result produced by a malfunctioning EBT. However, the NRC has revised § 26.91(e) in the final rule to provide licensees and other entities with two options to respond to EBT external calibration check failures. This section retains the proposed § 26.91(e)(3) requirement (in § 26.91(e)(4)(i) in the final rule) that any positive confirmatory alcohol test results that were obtained from an EBT that fails an external calibration check must be cancelled and also that the results of any tests that were conducted with that EBT subsequent to its last successful external calibration check must be cancelled. Section 26.91(e)(4)(ii) in the final rule adds a second option. This section permits licensees and other entities to conduct an external calibration check of the EBT after each positive confirmatory alcohol test result. If the EBT fails the check, the collector must cancel the donor's test result and perform another initial and confirmatory alcohol test, if necessary, using a different EBT. The NRC finds no basis for the commenter's conclusion that the proposed provision would cause additional burden and costs. Given that the positive rate for alcohol testing is low, the likelihood that many test results would be required to be overturned by any FFD program is insignificant.

Copy of the External Calibration Records for EBTs

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

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

7.7 Preparing for Alcohol Testing (§ 26.93)

No comments addressed this section.

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

No comments addressed this section.

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

No comments addressed this section.

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

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

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

7.11 Conducting a Confirmatory Test for Alcohol (§ 26.101)

No comments addressed this section.

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

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

NRC Response: The NRC agrees with the commenters that § 26.103 improves FFD program effectiveness and has retained this provision without change in the final rule.

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

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

NRC Response: The NRC disagrees with the commenter. Individual metabolism rates for alcohol may be influenced by an individual's weight, the number of metabolizing enzymes present in an individual's liver (a healthy liver vs. a diseased liver), and other factors, such as food consumption. However, individual differences in metabolism should not impact the procedures for back-extrapolation in § 26.103(a). The final rule requires individuals to abstain from alcohol use for at least 5 hours before reporting for duty. Back-extrapolation would be conducted for the first, second, or third hour after an individual has reported for duty. These procedures provide an alcohol-free period of 6 to 8 hours before an alcohol test, which is more than an adequate period of time for all alcohol consumed by even a moderately heavy drinker (3 to 4 drinks per episode) to have been metabolized from the body under normal conditions. Further, if a heavy drinker (5 or more drinks per episode) consumed significant amounts of alcohol just before the beginning of the pre-work abstinence period and had tested positive under these procedures, removal from duty would be warranted not only for the alcohol remaining in the individual's body, but also for the likely carry-over effects (e.g., hangovers) that could affect concentration and cognitive skills. The cutoff levels and time periods in § 26.103(a)(2) and (a)(3) are based on the average rate at which normal metabolic processes reduce an individual's BAC over time, which is about 0.01 percent BAC per hour. The NRC is confident that use of this average metabolic rate, in conjunction with back-extrapolation, will result in fair and accurate alcohol test determinations. Thus, if a donor's BAC is measured as 0.03 percent after he or she has been at work for 1 hour, he or she would have had a BAC of approximately 0.04 percent when reporting for work an hour before the test. Through the same metabolic processes, a donor whose BAC is measured as 0.02 percent after he or she has been in a work status for 2 hours would also have had a BAC of approximately 0.04 percent when he or she reported for work 2 hours before the test. These requirements ensure that confirmatory alcohol testing will identify workers who may have posed a risk to public health and safety by being impaired from alcohol use while on duty.

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

NRC Response: The NRC disagrees that there is a conflict between the requirements in §§ 26.103(a) and 26.27(c)(3). Section 26.27(c)(3) requires licensees and other entities to maintain procedures "to ensure that individuals who are called in to perform an unscheduled working tour are fit for duty." In cases where an individual indicates that he or she has consumed alcohol within the pre-duty abstinence period, § 26.27(c)(3)(ii)(A) specifies that this procedure must "Require a determination of fitness by breath alcohol analysis or other

means…." The NRC has revised proposed §26.27(c)(3) by adding specific directives in the final rule regarding whether or not the individual may be assigned to Part 26-related duties, including emergency response duties, depending on whether the determination of fitness indicates that the individual is fit to safely and competently perform his or her duties. Section 26.27(c)(3)(ii)(E) in the final rule further stipulates that "…no sanctions may be imposed on an individual who is called in to perform any unscheduled working tour for having consumed alcohol within the pre-duty abstinence period stated in the policy."

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

7.13 Preparing for Urine Collection (§ 26.105)

Comments: One commenter addressed proposed § 26.105(b) that required each urine specimen donor to empty the contents of his or her pockets so that the collector can inspect the items to ensure that the donor does not possess items that could be used to tamper with, adulterate, or substitute a urine specimen. The commenter requested that the proposed provision be revised to require collection sites to post a list of items that a collector could consider to be used to attempt to subvert the testing process. The commenter expressed concern that the proposed provision was ambiguous in that the collector may determine if an "item appears to have been inadvertently brought to the collection site" or may determine if an item was brought by the donor to the collection site "with the intent to adulterate the specimen." The commenter also expressed concern that an employee might bring a harmless substance such as a bottle of eye drops to the collection site and the collector might wrongly accuse the donor of attempting to subvert the testing process. The commenter suggested that an alternative to a posted list would be to require each donor to place all items on his or her person in a locker outside the collection area. The donor would be provided with the key to the locker which he or she would keep during the collection process [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter. The commenter's suggestion regarding a list of items that potentially could be used to subvert alcohol testing is untenable because collection site personnel would have no effective way to identify all possible items. Further, § 26.105 in the final rule provides for urine collection preparation procedures that protect against unjust determinations of subversion attempts. In particular, § 26.105(b) requires that if a collector identifies an item that the collector determines the donor brought to the collection site with the intent of adulterating or substituting a urine specimen, the collector must contact the MRO or FFD program manager to determine if further action must be taken. This review will ensure that a collector makes an accurate determination of whether or not the donor had intended to subvert the testing process. Also, the final rule requires urine collectors to receive training on collection procedures to ensure that correct decisions regarding the contents of a donor's pockets can be made. Finally, if a collector determines that a donor has

inadvertently brought something to the collection site (e.g., eye drops), the collector is required, by proposed and final § 26.105(b), to secure the item(s) outside the stall or enclosure used by the donor to provide a specimen before beginning a specimen collection. The NRC believes that these provisions provide adequate protections for each donor and ensure the integrity of the testing process. Therefore, the NRC has not modified this provision in the final rule.

Refusal to Test Action - Donor Refusal to Display the Contents of their Pockets

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

NRC Response: The NRC agrees, in part, with the commenter's request. Section 26.89(c) in the final rule requires that a collector must inform a donor that having an item that could be used to interfere with providing an actual urine specimen is a refusal to test. Individuals subject to Part 26 drug and alcohol testing are also informed of refusal to test actions in other ways. All individuals subject to the provisions of a licensee's or other entity's FFD program must be informed of the program policies under § 26.27(b) and must receive training on the FFD policy and consequences of violating the policy under § 26.29(a)(1). Section 26.27(b) requires that a written FFD policy statement be readily available to all covered individuals and include "sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy." One of the minimum FFD policy statement elements in § 26.27(b) is to "describe the actions that constitute a refusal to test, the consequences of refusals to provide a specimen for testing, as well as the consequences of subverting or attempting to subvert the testing process." The NRC believes that individuals subject to Part 26 urine testing will receive adequate notice of the actions that are considered a refusal test through this combination of access to FFD policy statements, training, and being informed at the urine collection site that having an item that could be used to interfere with providing an actual urine specimen is a refusal to test.

7.14 Collecting a Urine Specimen (§ 26.107)

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

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

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

7.15 Urine Specimen Quantity (§ 26.109)

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

NRC Response: The NRC agrees with the commenter and has revised § 26.109(b)(1) to permit donors to consume up to 40 ounces of liquid over a 3-hour period if they fail on their initial attempt to provide the minimum quantity of urine. This is consistent with the quantity of fluid that other Federal testing programs (i.e., U.S. DOT) permit a donor in a shy-bladder situation to consume. The NRC believes that this amount will give donors a better chance than under the proposed rule's 24-ounce limit to provide a urine specimen of the required quantity while at the same time ensuring that individuals who may be subject to water intoxication will not be placed at risk.

<u>Specify That a Collector Must Discard a Specimen that is Less Than 30 mL in Quantity</u>

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

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

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

Acceptable Temperature Range of a Urine Specimen

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

NRC Response: The comment does not require a response.

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

NRC Response: Comments received on point of collection testing and specific gravity testing are addressed in Subpart F.

Timing of Measuring a Donor's Temperature

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

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

Comments: One commenter, supported by many others, addressed proposed § 26.111(a) regarding measuring the temperature of a specimen within 4 minutes of the specimen collection. The commenter stated that the temperature difference between a donor's specimen and a donor's body temperature as specified in § 26.115(a)(2)(ii) lacked a scientific basis without a time consideration. The commenter stated that a donor's specimen will begin to cool immediately and will continue to cool until it reaches temperature equilibrium with the surrounding air. Because the cooling rate of a specimen is largely a function of the temperature difference between the specimen and the surrounding air and the temperature difference is typically significant (approximately 25 degrees F), the commenter suggested that a donor's body temperature be taken as soon as possible after the specimen is determined to be outside the acceptable temperature range. [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees in part with this commenter's requests. The NRC has eliminated the provision in proposed § 26.115(a)(2)(ii) that would have authorized comparing the donor's body temperature and specimen temperature as part of a reason for requiring a subsequent collection of a urine specimen under direct observation. Public comments at stakeholder meetings indicated that the U.S. DOT's experience shows that there are often discrepancies when comparing the temperature provided by a specimen container temperature slip and the temperature provided by a device that measures body temperature. Somewhat contrary to the commenter's second suggestion, however, the NRC has decided to eliminate the option for the donor to volunteer to provide a measurement of body temperature that appeared in proposed § 26.111(b). As compared to the former rule, § 26.111 in the final rule creates a wider range of acceptable specimen temperatures. With this increase in acceptable temperature range, measurement of body temperature is less useful to counter a reason to believe that the donor has altered the specimen. This change is consistent with the testing regulations for other Federal agencies (U.S. DOT, and HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs). It should also be noted that § 26.111(c) in the final rule allows the donor to volunteer to submit a second specimen under direct observation. This provides the donor with an opportunity to counter any reason to believe that he or she may have altered or substituted the first specimen.

Comment: One commenter addressed proposed § 26.111(b) that allowed a donor to volunteer to have his or her body temperature measured by the collector in the circumstance when the specimen that a donor provides is outside the acceptable temperature range. The commenter suggested that NRC reconsider permitting the measurement of a donor's body temperature given that a temperature measuring device is a better indicator of body temperature than the temperature strips used on specimen collection containers [Charles LoDico, Individual].

NRC Response: The NRC agrees with the commenter's request. The NRC has eliminated the proposed provision in § 26.111(b) that, in cases when the specimen is out of the acceptable temperature range, would have allowed the donor to volunteer to have his or her body temperature taken to provide evidence to counter a reason to believe that the donor may have altered or substituted the specimen. As compared to the former rule, § 26.111 in the final rule creates a wider range of acceptable specimen temperatures. With this increase in acceptable

temperature range, measurement of body temperature is less useful to counter a reason to believe that the donor has altered the specimen. The elimination of the option to measure a donor's body temperature is also consistent with the testing regulations for other Federal agencies (U.S. DOT, and HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs).

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

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

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

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

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

7.17 Splitting the Urine Specimen (§ 26.113)

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

NRC Response: The NRC agrees with the commenter's reasoning and has eliminated the proposed provision that a donor may urinate into a specimen bottle. The final rule requires the collector to direct the donor to urinate into a specimen container. Once the donor provides a specimen that is within the acceptable temperature range, is at least 30 mL in quantity, and is

free of any apparent contaminants, the collector will split the specimen into Bottle A and Bottle B under § 26.113(b)(2) and (3) of the final rule.

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

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

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

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

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

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

NRC Response: The NRC has eliminated the requirement in proposed § 26.115(a)(2)(ii) because U.S. DOT's experience shows that there are often discrepancies when comparing the temperature provided by a specimen container temperature slip and the temperature provided by

a device that measures body temperature. Also, § 26.111(b) of the final rule no longer permits a body temperature measurement in instances where a donor provides a specimen that is outside of the acceptable temperature range. Therefore, it is unnecessary for the NRC to make the commenters' suggested change.

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

Specimen Chain of Custody

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

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

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

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

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

7.20 Determining "Shy" Bladder (§ 26.119)

Comments: One commenter addressed proposed § 26.119(a) and stated that the proposed 5-business day time limit for a donor to receive a medical evaluation after failing to provide the minimum quantity of urine within the 3-hour time limit for a specimen collection is inadequate. The commenter asserted that obtaining an appointment with a medical doctor, especially if the doctor is a specialist, is highly unlikely within the proposed 5-day time limit [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenters request. The provision was consistent with other federal testing programs (U.S. DOT). It also accounted for the likelihood

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

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

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

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

NRC Response: The NRC agrees, in part, with the commenter's request. Testing alternate specimens may be necessary in shy-bladder situations. However, it is imperative that a valid medical condition is confirmed and that only the MRO has the authority to order alternate testing. The NRC disagrees that using an alternate specimen for testing in these situations should be a standard procedure to be routinely implemented by specimen collectors. The MRO must be involved in making or reviewing the medical diagnosis, determining the specimens that are to be collected and tested based on the most recent information available about the accuracy and sensitivity of testing methods for alternate specimens, and directing how the collection and testing procedures must be performed. The MRO's involvement in this process is necessary to ensure that testing of alternate specimens will provide valid and legally defensible results. Section 26.31(d)(5) addresses circumstances when it may be impossible or inadvisable to perform urine drug testing on an individual and permits alternative specimen collection and evaluation procedures for rare instances when it would be difficult or hazardous to the donor to collect breath, oral fluids, or urine specimens. This subsection makes clear that only the MRO is permitted to authorize an alternative evaluation procedure, which may include, but is not limited to blood testing for alcohol. Therefore, the NRC has not modified the proposed provision in the final rule.

8. Subpart F: Licensee Testing Facilities

8.1 Purpose (§26.121)

No comments addressed this section.

8.2 Testing Facility Capabilities (§ 26.123)

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

NRC Response: The NRC disagrees with the commenter's suggestion. The proposed revisions to the HHS Mandatory Guidelines for Federal Workplace Drug Testing have yet to be finalized to allow for consideration during the completion of this rulemaking effort and may be revised. The NRC will review the provisions regarding Initial Instrumented Testing Facility specifications once the finalized HHS Guidelines have been published and determine if additional revisions to Part 26 may be warranted at that time.

8.3 Licensee Testing Facility Personnel (§ 26.125)

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

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

8.4 Procedures (§ 26.127)

Comments: One commenter, supported by many others, affirmed that the proposed provision in § 26.127(b) would ensure that licensees and other entities take appropriate corrective actions if an issue is identified with the chain-of-custody for any specimen [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comment does not require a response.

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

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

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

Licensee testing facility security

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

NRC Response: The comment does not require a response.

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

NRC Response: The NRC disagrees with the commenter. The NRC believes that the requirements in this provision are adequate to protect the security of a licensee testing facility. Adding greater specificity with respect to personnel and actions would unnecessarily limit licensees' and other entities' flexibility. Testing facility staffing and physical and operational characteristics vary substantially among licensees and other entities. This variability makes it impractical for the NRC to devise specific language that would be appropriate at all testing facilities. Therefore, the NRC is leaving it to each individual licensee and other entity to determine the personnel who must maintain the security of licensee testing facilities and the actions to be taken if facility security is determined to be compromised.

Specimen Integrity

Comments: One commenter, supported by many others, supported the requirements in proposed § 26.129(b) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comment does not require a response.

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

NRC Response: The NRC disagrees with the commenter's request. The NRC requires that rule text use the phrase "may not" to describe a prohibited activity.

Correcting Custody and Control Form Errors

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

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

Other Appropriate Methods to Track Aliquot Custody and Control

Comments: One commenter objected to the provision in proposed § 26.129(c) permitting licensee testing facilities to use "other appropriate methods of tracking aliquot custody and control." The commenter stated that HHS has always required written documentation on a chain-of-custody form to track specimens and aliquots in certified laboratories. The commenter noted that while bar coding is an effective tracking method used in HHS-certified laboratories, a bar code list generated by a tracking device or instrument is always associated with a custody-and-control form that documents the personnel handling each specimen or aliquot. The commenter stated that written documentation ensures the security of each specimen and aliquot during the testing process [Sue Brown, Individual].

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

Bottle B Retention Location

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

NRC Response: The NRC disagrees with the commenters. The NRC is not aware of any instances where the custody and control of a Bottle B specimen has come into question or a Bottle B specimen has been lost in an attempt to maintain the specimen at a licensee testing facility. Licensee testing facilities have successfully maintained Bottle B specimens and industry experience fails to provide evidence that current practices have been unsuccessful in securing and storing specimens. Therefore, the NRC has not modified § 26.129(f) of the final rule.

Emergency Backup Power

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

NRC Response: The NRC agrees with the commenter and has revised § 26.135(c) in the final rule to require that licensee testing facilities electing to retain Bottle B specimens at the testing facility rather than forwarding the specimens to an HHS-certified laboratory with Bottle A, must ensure that proper storage conditions be maintained (i.e., specimens stored at a temperature of -20^{o} Celcius or less) in the event of a prolonged power failure.

Location of Original Custody-and-Control Form

Comments: One commenter stated that the proposed § 26.129(g) requirement that a licensee testing facility must send the original custody-and-control form with the Bottle A specimen to the HHS-certified laboratory leaves the specimen in Bottle B maintained at the licensee testing facility without the original custody-and-control form. The commenter noted that the proposed procedure was not in agreement with the HHS Mandatory Guidelines for Federal Workplace Drug Testing which require the original custody-and-control form to be maintained with the specimen Bottle A, and if the specimen in Bottle B is to be sent to a second HHS-certified laboratory, a copy of the original custody-and-control form is to be sent. The commenter

recommended both Bottle A and Bottle B be sent to the HHS-certified laboratory instead of maintaining Bottle B at the licensee testing facility [Sue Brown, Individual].

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

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

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

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

NRC Response: A licensee or other entity may choose to send all urine specimens to an HHS-certified laboratory for all required testing (i.e., validity and drug testing) under this part.

Conducting Initial Validity and Validity Screening Testing

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

NRC Response: The NRC does not intend to require licensee testing facilities to perform initial validity testing if they the use validity screening tests. Section 26.131(a) of the final rule requires that all validity test results from licensee testing facilities must be based on performing either a validity screening test or an initial validity test, or both, on one or more aliquots of a urine specimen. In other words, a licensee testing facility may conduct either a validity screening test or an initial validity test on each specimen. The NRC is also permitting licensee testing facilities to perform validity screening testing first and then initial validity testing on specimens that yield questionable validity test results from validity screening tests, at their discretion. Either validity screening or initial validity testing will accomplish the NRC's objective of identifying specimens of questionable validity that must be transferred to an HHS-certified laboratory for additional testing. Therefore, the agency is permitting licensees and other entities to choose which of these validity testing procedures, or a combination of procedures, they will implement at a licensee testing facility.

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

Comments: One commenter addressed proposed § 26.131(b) and suggested that specimen validity testing be performed at the collection site as soon as the donor presents a urine specimen to the collector and before the donor leaves the collection site. The commenter stated that immediate validity testing of a specimen would protect the donor from being accused of

attempting to subvert the testing process and would also allow for an immediate observed second collection if the initial specimen did not pass the validity test. [Todd Newkirk, IBEW]

NRC Response: The NRC disagrees with the commenter's suggestion. The NRC believes that licensees or other entities must conduct all specimen testing at a licensee testing facility and/or at an HHS-certified laboratory. Specimen collectors do not have the appropriate level of training to use validity screening tests. In addition, the commenter's suggested revision would permit the individual who tests the specimen to be aware of the identity of the donor. Since Part 26 was first promulgated, the NRC has maintained that the individuals who perform urine testing must not be aware of a donor's identity to protect against any potential biases that knowledge could introduce into the testing process. This policy is consistent with a similar HHS policy which has always prohibited testing facility employees from collecting specimens if they could link the donor's identity to test results. Therefore, the NRC has not modified the proposed provision in the final rule.

Use of the Term "Cutoff Levels"

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

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

Use of the Term "Non-negative"

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

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

addresses the commenter's concern and improves the clarity of the language used in the final rule.

Validity Screening Testing

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

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

Required Tests for Validity Screening Testing

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

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

Specific Gravity Testing at Licensee Testing Facilities

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

NRC Response: In contrast to the HHS Guidelines requirements for initial validity testing, the final rule does not require licensee testing facilities to test specimens' specific gravity. Instead, § 26.131(b) of the final rule requires licensee testing facilities to forward specimens having a creatinine concentration of less than 20 mg/dL to the HHS-certified laboratory which will measure these specimens' specific gravity. The NRC has chosen this course because of the high costs of refractometers, the instruments that the HHS Guidelines require for measuring

specimens' specific gravity. Although some licensee testing facilities are currently measuring specific gravity, the new HHS Guidelines specific gravity cutoff levels require more sensitive measurement than those licensee testing facilities are currently capable of doing. They would have to purchase new equipment to meet these new cutoff levels. Rather than require licensees to incur the resulting expense, the final rule does not require licensee testing facilities to test specimens' specific gravity nor does it include cutoff levels for specific gravity or quality control requirements for measuring specific gravity.

Licensee Testing Facilities Reporting Negative and Dilute Specimen Result

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

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

Specimen pH Testing Levels

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

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

Specimen Validity Testing - pH Range

Comments: One commenter suggested that proposed § 26.131(b)(2) be revised from "Using either a colorimetric pH test or pH meter" to read "Using either a colorimetric pH test with a dynamic range of 2 to 12 or pH meter." The commenter asserted that the change to include the dynamic pH range is necessary to identify invalid specimens (as defined in the HHS Mandatory

Guidelines for Federal Workplace Drug Testing Programs as a specimen with pH greater than or equal to 3 and less than 4.5, or greater than or equal to 9 and less than 11). The commenter stated that the recommended change would be necessary only if NRC did not revise § 26.131(b)(2)(i) to read “pH less than 4.5” [Sue Brown, Individual].

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

Specimen Validity Testing - Nitrite Concentration

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

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

Specimen Validity Testing - Nitrite Concentration General Oxidant Colorimetric Test

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

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

Specimen Validity Testing - Presence of Chromium (VI)

Comments: One commenter addressed proposed § 26.131(b)(4) and suggested that “Presence of chromium (VI) is indicated” should be revised to read “The possible presence of chromium (VI) is determined using . . .” The commenter recommended the change because neither the general oxidant colorimetric test nor the chromium (VI) colorimetric test is the confirmatory test for the presence of chromium (VI). The commenter noted that the recommended change is consistent with the HHS Guidelines [Sue Brown, Individual].

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

Specimen Validity Testing - Halogen Adulterants

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

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

Specimen Validity Testing - Halogen Adulterants, Additional Test

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

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

Validity Testing Criteria for Adulterants, Glutaraldehyde

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

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

Validity Testing Criteria for Adulterants, Oxidants

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

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

Validity Testing Criteria for Adulterants, Surfactants

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

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

Validity Testing Criteria, Specimen Shows Signs of Adulterants

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

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

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

No comments addressed this section.

8.8 Split Specimens (§ 26.135)

Specimen Retention at the Licensee Testing Facility

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

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

Support for the Proposed Provision

Comments: One commenter, supported by many other commenters, stated that the industry supports the requirement in proposed § 26.135(b) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comment does not require a response.

Written Request for Bottle B Specimen

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

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

MRO Instructions to Donor for Bottle B Specimen Testing

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

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

Other Parties Requesting Bottle B Specimen Testing

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

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

testing of the specimen in Bottle B if he or she questions the accuracy and scientific validity of a test result and believes that this additional testing will aid him or her in determining whether the donor has violated the FFD policy. The NRC believes that permitting the MRO to order this testing or retesting is necessary to meet the rule's objective to improve the effectiveness and efficiency of FFD programs. However, permitting testing of the specimen in Bottle B or retesting of a single specimen for other purposes without the donor's permission would conflict with the NRC's intent for permitting split specimen procedures. Therefore, the NRC has not revised the final rule.

Three Business Day Requirement to Request Testing of Bottle B

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

NRC Response: The NRC believes that the 3 business day time limit in proposed § 26.135(b) provides a donor with sufficient time to direct the MRO to request the retesting of single specimen or the testing of the Bottle B specimen. In addition, this 3 business day time limit provides more flexibility than permitted in Section 2.6(e)(2) of the HHS Guidelines which provide a donor with only 72 hours (i.e., 3 calendar days) after being notified by the MRO of a positive, adulterated, or substituted test result to request Bottle B testing. Therefore, the NRC has not modified the proposed provision in the final rule.

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

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

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

8.9 Quality Assurance and Quality Control (§ 26.137)

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

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

8.9.1 Quality Assurance Program (§ 26.137(a))

No comments addressed this section.

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

FDA Cleared Point-of-Collection Testing Device

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

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

Drug and Validity Point of Collection Testing Requirements

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

NRC Response: The NRC was aware of the differences between the proposed Part 26 provisions and those published by the HHS. However, the NRC is also aware that specimen validity tests now commercially available can meet the stringent quality assurance and

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

Non-instrumented Devices for Validity Screening Tests

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

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

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

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

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

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

Test Results for POCT Devices That Include Both Drug and Specimen Validity Tests on the Same Device

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

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

Validity Screening Testing - Specific Gravity

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

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

Personnel Conducting Performance Testing of Specimen Validity Devices

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

NRC Response: The NRC agrees, in part, with the commenters. The NRC has added § 26.137(b)(1)(ii)(E) in the final rule to require that if a validity screening test is not approved by SAMHSA as a point-of-collection test, the licensee testing facility must submit three consecutive sets of performance testing samples to the manufacturer, using performance testing samples that have been formulated to challenge the validity screening test around the applicable cutoffs specified in § 26.137. The NRC believes that the manufacturer of each validity screening test is the most appropriate entity to conduct initial performance testing before a licensee uses the test in a Part 26 testing program. These revised performance testing requirements will reduce the burden on licensees and other entities while ensuring that validity screening tests provide accurate and consistent test results.

SAMHSA Certified List for Validity Screening Devices

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

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

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

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

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

Initial Performance Testing of a Device to Be Used for Specimen Validity Testing

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

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

Performance Testing of Validity Screening Tests - Nitrite

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

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

Performance Testing of Validity Screening Tests - Creatinine

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

NRC Response: The NRC agrees with the commenter that validity screening tests need only measure the concentration of creatinine in a specimen to a cutoff of 20 mg/dL. In addition, because the final rule requires licensee testing facilities to send any specimen with a creatinine concentration less than 20 mg/dL to an HHS-certified laboratory for further testing, creatinine testing specificity beyond the 20 mg/dL cutoff is unnecessary. Therefore, the NRC has revised the proposed provision to require that a validity screening device must be able to distinguish the creatinine concentration of a specimen at a 20 mg/dL cutoff. Because the NRC has reorganized the proposed performance testing and quality control requirements for validity screening tests, this requirement appears in § 26.137(b)(1)(ii)(A) of the final rule,

Reconsider the Use of Non-instrumented Validity Testing Devices

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

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

Licensee Testing Facility Personnel to Perform Quality Control Sample Testing

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

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

Validity Screening Tests, Creatinine Concentration Measure to 1 Decimal Place

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

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

General Oxidizing Test - Nitrite Cutoff Level

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

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

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

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

NRC Response: Based on this and other comments received, the NRC has eliminated the use of the term "non-negative" in the final rule. Instead, the NRC has replaced the term "non-negative" with a new term "questionable validity" to describe the results of validity screening or initial validity testing at a licensee testing facility. A definition for "questionable validity" has been added in § 26.5 of the final rule and states that "questionable validity means the results of validity screening or initial validity tests at a licensee testing facility indicating that a urine specimen may be adulterated, substituted, dilute, or invalid." The NRC has chosen this term, rather than a term that would directly reference adulterated, substituted, dilute or invalid

specimens, because licensee testing facilities will not be conducting specific gravity testing that would determine these specimen characteristics. Using the term "questionable validity" addresses the concern expressed in the comment and improves the clarity of the final rule.

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

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

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

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

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

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

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

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

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

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

POCTs for Validity Testing

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

NRC Response: The NRC disagrees with the commenter's suggestion. The NRC is permitting licensee testing facilities to use validity screening tests that meet the specifications in § 26.137(b) of the final rule. Therefore, the NRC not modified the proposed provision in the final rule.

Donor Information for Negative Urine Specimens Pooled for Internal QC Program

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

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

Performing Multiple Initial Drug Tests on a Specimen

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

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

Quality Control Requirements for Initial Drug Tests, Quality Control Samples

Comments: One commenter stated that the requirements in proposed § 26.137(e)(6) for quality control samples were consistent with the HHS Guidelines except for one excluded provision in Section 2.5(b)(4) of the Guidelines. The commenter recommended revising the proposed rule

by adding the requirement, “A sufficient number of calibrators to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known calibrators, those values will be used to calculate sample data.” [Sue Brown, Individual]

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

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

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

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

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

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

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

Blind Performance Testing Samples

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

NRC Response: Section 26.137(e)(7) proposed requirements for quality control samples for initial specimen drug testing at a licensee testing facility. The NRC is not permitting drug or

validity testing to be performed at the collection site using POCTs. Rather, the NRC is restricting the use of non-instrumented validity screening tests to licensee testing facilities. Because all specimen validity testing would be conducted at a licensee testing facility and/or at an HHS-certified laboratory, a donor would never be present during specimen validity testing and the issue raised by this comment does not apply. Therefore, the NRC has not modified the proposed provision in the final rule.

Blind Performance Testing Samples - Example

Comments: One commenter addressed the section-by-section analysis of substantive changes in proposed § 26.137(e)(7). The commenter suggested that the example incorrectly presented the number of quality control samples that must be included in an analytical run. The section-by-section analysis stated, "For example, if an analytical run tested 50 donor specimens, the licensee testing facility would include 5 quality control samples in the run. At least one of the 5 would be required to be a blind test sample, and it could be either a blank or a sample fortified with a drug or metabolite at either 25 percent above the FFD program's cutoff level or at 75 percent of the cutoff level. The remaining 4 samples could include any combination of blanks and fortified samples." The commenter also suggested clarifying the following section-by-section discussion: "The blind test sample may be either a blank (certified negative urine), or a sample with drug or drug metabolite, usually targeted at 50% or greater above the cutoff." Specifically, the commenter stated that this discussion appeared to imply that the "fortified" quality control samples may have varied concentrations of drugs or drug metabolites, conflicting with the requirements in proposed § 26.137(e)(6)(ii) and (iii). The commenter recommended that the example explaining the quality control samples be revised in the final rule as follows: "For example, if an analytical run tested 45 donor specimens, the licensee testing facility would include 5 additional samples, all of which are quality control samples. The total number of samples in the analytical run would then be 50. At least one of the 5 quality control samples must be a control that appears as a donor sample to the initial testing technician. This blind test sample could be either a certified drug negative sample or a sample with drug or drug metabolite above the cutoff. The other 4 quality control samples must meet the requirements of § 26.137(e)(6)(i)-(iii)" [Sue Brown, Individual].

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

8.9.6 Errors in Testing (§ 26.137(f))

No comments addressed this section.

8.9.7 Accuracy (§ 26.137(g))

No comments addressed this section.

8.9.8 Calibrators and Controls (§ 26.137(h))

No comments addressed this section.

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

No comments addressed this section.

9. Subpart G: Laboratories Certified by the Department of Health and Human Services

9.1 Purpose (§ 26.151)

No comments addressed this section.

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

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

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

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

Laboratory Personnel Appearing for Administrative/Disciplinary Hearings

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

NRC Response: The NRC disagrees with the comment. The licensee or other entity is responsible, through its contract with the HHS-certified laboratory, for ensuring that the

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

Conflict of Interest Between HHS-Certified Laboratory and MRO

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

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

The NRC disagrees with the commenter's request to specifically exempt as a potential conflict of interest the situation where a medical doctor uses an HHS-certified laboratory for services in his or private practice and also serves as the MRO to a licensee or other entity that uses the same HHS-certified laboratory. Under certain circumstances, this relationship could be construed as a potential conflict of interest. For example, an MRO could negotiate lower pricing for specimen testing with the same laboratory a licensee uses by suggesting that he/she could persuade the licensee to take its business elsewhere. This could be considered a possible conflict of interest situation because the MRO could potentially influence a licensee's decision on changing to a

different HHS-certified laboratory and thereby gain leverage in reducing pricing for the MRO's private practice. Therefore, the NRC has not modified the proposed provision in the final rule to include the requested exemption.

Access to Donor Testing Records and Laboratory Records

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

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

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

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

9.3 Laboratory Personnel (§25.155)

No comments addressed this section.

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

Comments: One commenter disagreed with the NRC's decision in proposed § 26.155(a)(4) to eliminate the requirement for an HHS-certified laboratory to maintain laboratory operating procedures in a "procedure manual" as specified in Sections 2.5(a)(5) and 2.7(o)(1) in Appendix

A to Part 26. The commenter stated that no longer requiring laboratories to maintain a procedure manual would be inconsistent with the requirements in Section 2.4(q)(1) of the HHS Guidelines. For consistency with the HHS Guidelines, the commenter suggested including the requirement for laboratory operating procedures to be maintained in a manual [Sue Brown].

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

9.3.2 Certifying Scientist (§ 26.155(b))

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

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

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

No comments address this section.

9.3.4 Other Personnel (§ 26.155(d))

No comments addressed this section.

9.3.5 Training (§ 26.155(e))

No comments addressed this section.

9.3.6 Files (§ 26.155(f))

No comments addressed this section.

9.4 Procedures (§ 26.157)

No comments addressed this section.

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

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

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

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

Pooling of Urine Specimens Used for Laboratory QC Program

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

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

9.6 Cutoff Levels for Validity Testing (§ 26.161)

No comments addressed this section.

9.6.1 Validity Test Results (§ 26.161(a))

No comments addressed this section.

9.6.2 Initial Validity Testing (§ 26.161(b))

Specific Gravity Testing Instrumentation

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

NRC Response: The type of equipment that an HHS-certified laboratory must use to perform specific gravity testing of urine specimens is described in § 26.167(c)(2)(i) in the proposed and final rule. Therefore, the NRC has not modified § 26.161(b) in the final rule in response to this comment.

Redundancy with Subpart F Discussion in 26.131(c)

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

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

Include Invalid Specimens

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

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

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

Quality Controls for Unidentified Adulterants

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

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

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

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

would be consistent with HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.161(c)(3) through (c)(7) in the final rule by adding hyphens before the word “equivalents” to clarify the accuracy of the language in Part 26 and improve consistency with the HHS Guidelines.

Support for Proposed Provision

Comments: Several commenters stated that industry supports the requirements in proposed § 26.161(c)(8) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The comment does not require a response.

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

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

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

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

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

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

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

Specimen Testing Criteria for Invalid Test Result

Comments: One commenter inquired about testing criteria used to determine that a specimen

is invalid. The commenter asked why a substance could not be identified and suggested that the possibility that a laboratory testing problem might also provide an invalid test result [Todd Newkirk, IBEW].

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

General Oxidant Colorimetric Testing

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

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

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

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

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

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

Support for Proposed Provision

Comments: Several commenters stated that the industry supported proposed § 26.161(g) [Jim

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

NRC Response: The comment does not require a response.

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

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

NRC Response: The NRC disagrees with the request to eliminate the required consultation between the HHS-certified laboratory and the licensee's or other entity's MRO to determine if additional testing should be conducted at a second HHS-certified laboratory to try to identify whether an interfering substance/adulterant is present in a donor's specimen. This consultation is important because not all HHS-certified laboratories have the same testing capabilities to identify additional types of interfering substances and "new" adulterants. Therefore, sending a specimen to any second HHS-certified laboratory without first requiring the MRO and laboratory to confer on the test results from the first laboratory and determine whether an appropriate laboratory exists that has the capabilities to conduct additional types of test may not automatically improve the likelihood that the substance will be identified. Specifically, the HHS-certified laboratory must confer with the MRO to determine if additional testing of the specimen might identify the unidentified substance in a donor's urine specimen that is preventing a valid test result. The commenter need not be concerned that a donor would suffer or be accused of attempting to subvert the testing process. These procedures do not result in an employee being accused of subverting the testing process. No sanctions are imposed on anyone for an invalid test result. As required by § 26.185(f), the MRO must contact the donor to determine if an acceptable medical explanation exists that may cause an invalid specimen test result. Depending on the results of this enquiry, the MRO will require the donor to give another specimen, either under direct observation or not. Therefore, the NRC has not modified the proposed provision in the final rule.

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

contact the MRO for every invalid test result and suggested that the proposed provision be eliminated [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request to eliminate the proposed provision in the final rule. Section 26.161(g) in the proposed and final rule is consistent with Section 2.4(h)(12) in the HHS Guidelines. For invalid specimen test results, a discussion between the HHS-certified laboratory and the MRO is critical because of differences between laboratories in their capabilities to identify interfering substances or "new" adulterants. The intent of this requirement is to deter individuals from attempting to subvert the testing process by introducing interfering substances or adulterants to mask the presence of prohibited drugs and to increase the likelihood of detection if they do. Reporting a specimen as invalid, rather than conducting confirmatory testing for a suspected adulterant when a laboratory is available that is capable of confirming the presence of an adulterant, does not achieve the NRC's objectives in requiring specimen validity testing for adulterants. Therefore, the NRC has not modified the proposed provision in the final rule.

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

No comments addressed this section.

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

No comments addressed this section.

9.7.1 Initial Drug Testing (§ 26.163(a))

Dilute Specimen Testing, Limit of Detection (LOD) Testing

Comments: One commenter addressed proposed § 26.163(a)(2) and suggested revising the provision that permitted an MRO to direct an HHS-certified laboratory to test a specimen for drugs and/or drug metabolites "down to the confirmatory assay's limit of detection (LOD)." The commenter stated that HHS Guidelines do not use the term "limit of detection" and suggested replacing the provision with the phrase "using the laboratory's confirmatory assay" [Sue Brown, Individual].

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

Conducting Initial Drug Testing for Dilute Specimens to LOD

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

If the NRC were to decide not to eliminate this proposed § 26.163(a)(2) requirement, the commenter recommended that the laboratory not be required to re-screen the identified dilute specimen and, instead, be permitted to compare the initial drug test immunoassay response for the specimen to the initial drug test immunoassay response for the cutoff calibrator with the initial drug test kit used for testing. If the specimen's response is within 50 percent of the response of the cutoff calibrator, the laboratory would report this to the licensee's or other entity's MRO on the final report. The commenter noted that an additional burden would be imposed on the laboratory to capture the initial test immunoassay response number and report it on the report form. The commenter suggested that the HHS-certified laboratory could accomplish this reporting using the laboratory's information system [Sue Brown, Individual].

NRC Response: The NRC agrees, in part, with the commenter's request and has eliminated from the final rule proposed § 26.163(a)(2) that required HHS-certified laboratories to use an FDA -approved analytical kit with the lowest concentration levels marketed for the technology(ies) being used to conduct initial drug testing of specimens with dilute initial validity test results. The NRC has accepted the commenter's recommended approach to conduct initial drug testing of each dilute specimen and evaluate the immunoassay response for each drug test such that if the quantitative test result is equal to or greater than 50 percent of the cutoff calibrator for the drug tested, the laboratory would consider the result as an initial positive drug test result. The NRC disagrees with the commenter's assertion that further testing is unnecessary. Given the consequences for donors of a positive drug test result, the NRC believes that confirmatory drug testing to the limit of detection is necessary to confirm the initial drug test result.

Dilute Specimen Testing, Eliminate the Word Confirmatory

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

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

9.7.2 Confirmatory Drug Testing (§ 26.163(b))

No comments addressed this section.

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

No comments addressed this section.

9.8.1 Split Specimens (§ 26.165(a))

No Discussion on Disposal of Negative Bottle A Specimens

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

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

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

Comments: Two commenters stated the prohibition in proposed § 26.165(a)(4) on any entity (e.g., licensee, MRO, NRC) ordering the testing of a Bottle B specimen without a donor's written permission conflicted with Section 2.6(e)(4) of the HHS Guidelines. The HHS Guidelines permit a Federal agency to have a single or split (Bottle B) specimen retested "as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result." The commenters recommended that the NRC should include the HHS Guideline provision [Sue Brown, Individual; Charles LoDico, Individual].

NRC Response: The NRC disagrees with the commenters' recommendation. The requirements for testing split specimens in the former, proposed, and now final rule ensure that each donor receives fair and accurate testing under Part 26. The NRC's intent in the original rule, when permitting split specimen testing, was to enhance donors' confidence in the drug testing process imposed by the rule and provide one means for donors to defend against possible administrative and/or methodological errors in testing the specimen in Bottle A.

Because the NRC's intent in permitting split specimen testing has been to protect donors, and because the NRC believes that testing an individual's biological specimen without his or her permission infringes on an individual's privacy, the NRC declines to adopt the commenter's proposed revision.

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

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

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

Sending Bottle B Specimen to Second HHS-Certified Laboratory

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

NRC Response: Section 26.135(b) in the final rule addresses the issue raised by the commenter. If a licensee testing facility maintains a Bottle B specimen, the licensee or other entity must ensure that the donor's specimen is forwarded to a second HHS-certified laboratory if directed to do so by the MRO, at the specific request of the donor. The NRC believes that the one business day time limit for a licensee testing facility to send a Bottle B specimen to a second HHS-certified laboratory is reasonable. It should be noted that the NRC has relaxed this requirement from the "same-day" requirement for these situations in the former rule. The NRC made this revision because logistical difficulties sometimes created obstacles to FFD program compliance with the former rule's same-day requirement. For example, commenters at public meetings with stakeholders cited communication delays among donors, MROs, and FFD program personnel, particularly on weekends and holidays, as one such difficulty. They also noted that the time required to identify a second laboratory with the appropriate capability to test

the split specimen sometimes made compliance difficult. The NRC is confident that allowing one business day will be sufficient to overcome these logistical obstacles. In response to other comments received on proposed § 26.165(a) and (b), the NRC has revised and consolidated the provisions pertaining to donor requests for the retesting of an aliquot of a single specimen and Bottle B split specimen testing.

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

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

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

Providing Quantitative Values of Specimen Retest Results

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

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

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

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

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

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

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

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

Use of the Phrase "Standard Confirmatory Drug Test"

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

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

Limit of Detection (LOD) Testing

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

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

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

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

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

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

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

NRC Response: The NRC agrees with the commenter's recommendations and has eliminated the second sentence of proposed § 26.165(e) in the final rule to improve the clarity of the requirement to meet Goal 6 of the rulemaking, which is to improve the clarity of the rule's language.

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

Donor Compensation While Awaiting Results of Split Specimen Testing

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

NRC Response: The NRC disagrees with the comment. Section 26.75(i)(2) in the final rule prohibits a licensee or other entity from withholding an individual's compensation and benefits during the time period his or her authorization has been administratively withdrawn following a positive initial drug test result for marijuana and/or cocaine metabolites at a licensee testing facility pending an HHS-certified laboratory specimen test result verified by the MRO. However, the NRC does not agree that this prohibition should be applied when a donor is waiting for the results of split specimen testing at a second HHS-certified laboratory. The difference is that, for § 26.75(i)(2), the donor's specimen has not been subject to initial or, if necessary, confirmatory testing at an HHS-certified laboratory and the result has not been confirmed by the MRO. Section 26.75(i)(2) prohibits action stronger than administrative withdrawal of authorization because the initial and confirmatory testing that could show culpability and justify stronger action have not been conducted. In the situation described by the commenter, the donor's specimen has already been subject to an HHS-certified laboratory's sophisticated testing procedures and

the MRO has confirmed the result as positive, adulterated, or substituted. Unlike the first situation, there is ample test result evidence that would indicate an FFD violation that should lead to sanctions, such as withholding of compensation and benefits. Split specimen testing or retesting of an aliquot of a single specimen is a right that a donor may choose to exercise to verify the accuracy of the first HHS-certified laboratory test result. If the second laboratory's testing fails to reconfirm the initial laboratory test result, the MRO, as required by § 26.186(n)(3) and (n)(4) of the final rule, would report that no FFD policy violation had occurred. Because of the significant difference in indicators of culpability in these two situations, the NRC has chosen not to revise proposed § 26.165(f) of the final rule.

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

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

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

Additional Reason Why a Bottle B Specimen Could Not Be Tested

Comments: One commenter addressed proposed § 26.165(f)(2) and noted that an additional reason that a Bottle B specimen could not be tested for split specimen testing is because of insufficient volume to permit testing or no volume at all.

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

Reporting of Test Results from an HHS-Certified Laboratory

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

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

9.9 Quality Assurance and Quality Control (§ 26.167)

Quality Control Testing

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

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

Replace Hyphens in Control Ranges with "to"

Comments: One commenter addressed proposed § 26.167 and suggested that the NRC should replace the hyphens used when identifying control ranges (e.g., 1-1.5 mg/dL creatinine)

with “to.” The suggested change would make the text consistent with the HHS Guidelines [Sue Brown, Individual].

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

9.9.1 Quality Assurance Program (§ 26.167(a))

No comments addressed this section.

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

No comments addressed this section.

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

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

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

Reorganization of Requirements for pH Tests to Match HHS Guidelines

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

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

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

NRC Response: The NRC disagrees with the commenter’s recommendation. The NRC believes that presenting the antecedent conditions for a requirement before presenting the

requirement in a sentence is clearer than presenting the consequents first. Therefore, the NRC has not modified these provisions.

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

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

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

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

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

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

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

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

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

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

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

9.9.6 Blind Performance Testing (§ 26.167(f))

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

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

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

Blind Performance Testing Sample - Dilute

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

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

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

NRC Response: The NRC agrees with the commenter and has revised § 26.168(e) in the final rule to require FFD programs to submit dilute blind performance testing samples to the HHS-certified laboratory for testing each quarter. Because the NRC is permitting licensees and other entities to subject dilute specimens to testing at the LOD under § 26.163(a)(2) in the final rule, the NRC believes that challenging the laboratory's ability to detect dilute specimens is necessary. The blind performance testing provisions in proposed § 26.167(f) were reorganized into a new section in the final rule, § 26.168(g), to improve the clarify of the final rule.

Eliminate Specific Concentrations for Drug and Validity Performance Testing Samples

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

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

Blind Performance Testing Samples

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

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

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

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

Comments: One commenter identified an inconsistency between proposed § 26.167(f)(5)(i)(D) and the related provision in the HHS Guidelines. Specifically, the HHS Guidelines require a negative sample to contain no drug, while the proposed provision stated, "A negative sample

may not contain the target drug analyte at a concentration greater than 10 percent of the confirmatory cutoff" [Sue Brown, Individual].

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

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

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

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

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

9.9.7 Errors in Testing (§ 26.167(g))

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

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

9.9.8 Accuracy (§ 26.167(h))

No comments addressed this section.

9.10 Reporting Results (§ 26.169)

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

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

Invalid Specimens Not Included as a Non-Negative Test Result

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

NRC Response: The NRC agrees with the commenter and has amended proposed § 26.169(c)(1) in the final rule to include an invalid specimen test result as a result that must be reported by HHS-certified laboratories to MROs. This change clarifies the NRC's intent that HHS-certified laboratories must report test results for invalid specimens to the MRO.

Reporting Numerical Values of Specimen Test Results

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

NRC Response: The NRC agrees with the commenter and has revised proposed § 26.169(c)(3) in the final rule to clarify the intent of the provision. This change clarifies the NRC's intent that HHS-certified laboratories must report to the MRO the numerical values for specimens with substituted and adulterated test results.

Reporting of Numerical Values for Dilute Specimens

Comments: One commenter addressed proposed § 26.169(d) and stated that the provision requiring HHS-certified laboratories to report numerical values for substituted, adulterated, and dilute specimen test results "when applicable" made it appear that the laboratory would have to provide numerical values for dilute specimens. Because the HHS Guidelines do not require laboratories to report the numerical values for dilute specimens, the commenter suggested that NRC revise the proposed provision to be consistent with the HHS Guidelines [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter and has revised the reporting requirements for substituted and adulterated specimen test results in § 26.169(c)(3) of the final rule to clarify the intent of the proposed provision. The NRC is requiring HHS-certified laboratories to report the numerical values to the MRO for only adulterated and substituted test results.

Reporting of Creatinine Result, Substituted Specimens

Comments: One commenter stated that the requirement in proposed § 26.169(d), "If numerical values for creatinine are below the LOD, the laboratory shall report to the MRO 'creatinine none detected' (i.e., substituted) along with the numerical values," was inconsistent with the HHS Guidelines. Specifically, the commenter stated that if the creatinine concentration for a specimen is below the LOD, the HHS-certified laboratory will report a result of "creatinine: none detected" along with the numerical value of the specific gravity test [Sue Brown, Individual]

NRC Response: The NRC agrees with the commenter. The NRC has revised § 26.169(c)(3) in the final rule to specify that for a specimen with a creatinine test result below the LOD, the HHS-certified laboratory will report the result as "creatinine: none detected" along with the specific gravity test result for the specimen. The revision improves consistency between the HHS Guidelines and the related Part 26 provisions.

Reporting of Numerical Values for Drug Positive, Adulterated, and Substituted Test Results

Comments: One commenter suggested that proposed § 26.169(f) requiring the HHS-certified laboratories to "provide numerical values for non-negative confirmatory test results when the MRO requests such information" was redundant, given the reporting requirement in proposed § 26.169(d). The commenter suggested that perhaps the intent of the provision was to require the laboratory to provide numerical values for drug positive test results to the MRO [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter. The NRC has revised § 26.169(c)(2) in the final rule to require an HHS-certified laboratory to provide the quantitative test results for positive test result from confirmatory testing when requested by the MRO. This change clarifies the NRC's intent in the proposed provision.

Reporting of Test Results, Number of Rejected Specimens

Comments: One commenter recommended adding two data elements to the reporting requirements in proposed § 26.169(k). To be consistent with the HHS Guidelines, the commenter suggested that HHS-certified laboratories also report the number of specimens reported as rejected for testing because of a fatal flaw and the number of specimens rejected for testing because of an uncorrected flaw [Sue Brown, Individual].

NRC Response: The NRC agrees with the commenter's recommendation and has added a requirement to § 26.169(h) of the final rule for HHS-certified laboratories to report the number of specimens "rejected for testing and the reason for the rejection." The NRC added this reporting requirement to account for specimens where testing has been canceled by the MRO because of circumstances specified in § 26.159(b)(2) of the final rule.

Reporting of Test Results, Number of Specimens Received or Reported

Comments: One commenter stated that the requirement in proposed § 26.169(k)(1) for an HHS-certified laboratory to report the "total number of specimens received" at the laboratory was inconsistent with HHS Guidelines which require the reporting of only the number of "specimen results reported" [Sue Brown, Individual].

NRC Response: The NRC disagrees with the commenter's request. The NRC considers having HHS-certified laboratories report the total number of specimens received to be a necessary component of NRC oversight of licensee testing programs because it permits the NRC to determine how many specimens licensees and other entities send to HHS-certified laboratories for testing. Therefore, the NRC has not modified the proposed provision in the final rule.

10. Subpart H: Determining FFD Policy Violations and Determining Fitness

10.1. Purpose (§ 26.181)

No comments addressed this section.

10.2. Medical Review Officer (§ 26.183)

No comments addressed this section.

10.2.1. Qualifications (§ 26.183(a))

No comments addressed this section.

10.2.2. Relationships (§ 26.183(b))

Comments: One commenter, supported by many comments, stated that additional guidance is needed in proposed § 26.183(b) to clarify conflict-of-interest relationships between MROs and HHS-certified labs. The commenter suggested that the NRC add language from DOT's 49 CFR 40.101(b) which provides examples of MRO conflicts of interest. The commenter noted that this

suggestion is consistent with Goal 1 of the rulemaking [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenter's request to add specific examples of conflict-of-interest relationships between MROs and HHS-certified laboratories. Therefore, the NRC has clarified the final rule to include specific examples of conflict-of-interest relationships between MROs and HHS-certified laboratories. The basis for the examples is 49 CFR 40.101(b) of the U.S. DOT's Procedures for Transportation Workplace Drug and Alcohol Testing Programs.

10.2.3. Responsibilities (§ 26.183(c))

No comments addressed this section.

10.2.4. MRO Staff (§ 26.183(d))

MRO Staff Performing Other Duties

Comments: One commenter, supported by many commenters, requested that the NRC revisit the requirements of proposed § 26.183(d)(1)(i) because they limit the flexibility of MRO staff who are licensee employees. The commenter requested that the licensee staff who perform MRO functions on a part-time basis be allowed to perform other duties for, and take direction from, the licensee while not working to support the MRO. This change would allow licensees to avoid needless increases to staff size. The commenter recommended that licensees and other entities be allowed to continue assigning individuals to the MRO staff on a part-time basis in accordance with current practices. The commenter suggested that the NRC add the following language to the end of the proposed section: "Employees of licensees and other entities may function as MRO staff. When functioning as MRO staff they shall take direction from the MRO only" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

Two commenters in the public meeting requested clarification on how the new rule applies in certain situations. For example, under the former rule, if a site has MRO staff that are licensee employees and an MRO that is a contractor, the licensee maintains authority over performance evaluations, hiring, and firing. The commenters were confused as to how to implement the new rule in such situations. In this case, the commenters stated that the proposed rule would force the licensee to either have an employee that is an MRO, have the MRO staff as employees, or make them all contractors. The commenters argued that in all cases, there will be a cost burden on industry [Nick Depietro, First Energy; Susan Techau, Exelon].

NRC Response: The NRC agrees with the first comment. It is not the NRC's intent to require MRO staff to be employees of an MRO. Rather, the intent of these provisions was to permit licensee staff who perform MRO functions on a part-time basis be allowed to perform other

duties for the licensee while not working to support the MRO. Therefore, the NRC has added a sentence to § 26.183(d) in the final rule to specifically state this intent.

The NRC agrees with the second set of comments that the rule requires MRO staff to be employees of the licensee or other entity, employees of the MRO, or employees of a C/V. The rule also requires an MRO to be directly responsible for the administrative, technical, and professional activities of individuals who perform MRO staff duties subject to the MRO's authority, and that the MRO's direction of staff must be meaningful. Meaningful direction involves, among other things, providing input to an individual's performance evaluation.

MRO Staff Function

Comments: Several commenters from industry addressed proposed § 26.183(d)(2)(iii) and requested that MRO staff, not exclusively the MRO, be allowed to validate prescription medication information as an administrative function. The commenters believed that this change would better allow MRO staff to assist the MRO in obtaining the information necessary to make decisions about specimens [Jim Davis, NEI #48; Brian Mc Cabe, Progress Energy; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees with this comment. The medications that a donor has taken or is taking is personal information that only a professional who meets the requirements to serve as an MRO is qualified to discuss with the donor and evaluate. Therefore, the NRC has retained the prohibition on permitting MRO staff to request information about prescription medications from donors to protect individuals' privacy under the rule.

Restrictions on MRO Staff

Comments: One commenter, supported by many commenters, disagreed with the language in proposed § 26.183(d)(2)(iv) that prohibited MRO staff from discussing test results with licensees and other entities. The commenter stated that clarification is needed to permit the MRO staff to relate confirmed results and to discuss those results with licensee and other entity personnel. The commenter stated that it is ineffective and inefficient to have only the MRO discuss results with the licensee or other entity personnel. The commenter recommended the following revised language for this subparagraph: "Staff may not report nor discuss any non-negative test results received from the HHS-certified laboratory with any individual other than the MRO and *individuals designated by licensees and other entities*" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenters that MRO staff should be permitted to discuss test results with licensee or other entity personnel because it is inefficient to prohibit the staff from doing so. The intent of this provision is to ensure that test results are not revealed to licensee or other entity personnel until the MRO has reviewed and confirmed them. This

prohibition is necessary to ensure that donors' privacy is protected if there is a legitimate medical explanation for a positive, adulterated, substituted, or invalid initial or confirmatory test result from the HHS-certified laboratory. It is also necessary to avoid any questions that could arise about the donor's fitness or trustworthiness and reliability based on test results that have not been confirmed by the MRO. The former, proposed, and final rules have consistently reflected the NRC's intent in this matter. The NRC intends that MRO staff may not communicate or discuss any positive, adulterated, substituted, invalid, or dilute test results received from the HHS-certified laboratory that have not been reviewed and confirmed by the MRO (i.e., unconfirmed test results) with any person other than other MRO staff or the MRO. Furthermore, the NRC does not believe that MRO staff are qualified to answer questions about an individual's medical condition, the bases for an MRO decision either to confirm an adverse confirmatory test result from an HHS-certified laboratory or to declare the test result as negative, or the meaning of any quantitative confirmatory test results reported by the HHS-certified laboratory. Those discussions must be conducted only by the MRO.

Proposed § 26.183(d)(2)(iv) referred to test results "received from the HHS-certified laboratory," which the NRC intended to be interpreted as meaning test results that have not been confirmed through MRO review. The NRC has modified this provision to more fully explain its intent in the final rule.

10.3. Determining a FFD Policy Violation (§ 26.185)

"Referral Physician"

Comments: One commenter also asked for clarification of "referral" physician in proposed § 26.185(h)(1) and (i)(1). The commenter argued that if it means the donor must be referred to him by the MRO, the commenter asked: "Why can't the donor pick his own specialist, especially if he already has the proof from the specialist in his possession?" [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenter that the term "referral" is ambiguous and has deleted it from § 26.185(h)(1) and (i)(1) in the final rule. The NRC intends the MRO to have sole responsibility to determine whether or not the donor has provided legitimate medical evidence and whether the specialist selected and/or the documentation provided meets the criterion of legitimate medical evidence. However, the rule does not prohibit a donor from selecting his or her own specialist or providing any documentation that the donor possesses.

Providing Legitimate Medical Evidence within Five Days

Comments: With regard to proposed § 26.185(h)(1) and (i)(1), one commenter argued that five days is not enough time to get an appointment to see a specialist. The commenter suggested that it may be better to show proof of appointment with a specialist within five days and have the clearance placed on administrative hold, pending the results from the doctor. Further, the commenter suggested that the MRO should contact the specialist to expedite the appointment. The commenter also stated that if the specialist exonerates the donor, the licensee should be liable for the costs of testing. However, the commenter stated that if the specialist cannot confirm that a medical explanation exists, then the costs should be the responsibility of the donor [Todd Newkirk, IBEW].

Several commenters from industry stated that five business days are sufficient for the donor to have medical records sent to the MRO from the donor's physician who is familiar with the donor's medical issues and recommend that the NRC implement this paragraph as proposed [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC disagrees with the commenter who does not support the proposed provision. Five business days is not an onerous time limitation. The DOT reports that individuals who have legitimate medical evidence related to the circumstances addressed in these provisions have not had difficulty in providing their medical records to an MRO within the 5-day time period required under DOT's procedures. Therefore, the NRC has not modified this provision in the final rule.

10.3.1. MRO Review Required (§ 26.185(a))

Comments: Several commenters from industry stated that the proposed rule language calling for the MRO to determine whether the donor has violated the FFD policy was onerous for the MRO, whose expertise is medical. The commenters stated that MROs should not be required to interpret whether the FFD policy has been violated. Rather, MROs should only be responsible for reviewing non-negative test results before reporting the result to licensees. Therefore, the commenters suggested the NRC strike the phrase "to determine whether the donor has violated the FFD policy" from this proposed section [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC does not agree with the commenters. According to § 26.183(a), the MRO must be knowledgeable of the FFD policies of the licensees or other entities for whom the MRO provides services. Also, according to § 26.185(a), the MRO shall have detailed knowledge of alternate medical explanations for a positive, adulterated, substituted, invalid, or dilute test result. Because the MRO has both detailed medical knowledge and knowledge of the licensee's FFD policies, the NRC believes that review by an MRO is a key element in determining FFD policy violations. Therefore, the NRC has not modified the provision in the final rule.

10.3.2. Reporting of Initial Test Results Prohibited (§ 26.185(b))

No comments addressed this section.

10.3.3. Discussion with the Donor (§ 26.185(c))

No comments addressed this section.

10.3.4. Donor Unavailability (§ 26.185(d))

Comments: One commenter addressed donor unavailability (i.e., to talk to the MRO, or MRO staff) and stated that proposed § 26.185(d)(1) through (3) should be re-written to improve the notification requirements. For example, a night shift worker may not have an answering machine or it may be broken. This situation could make notification impossible, unless the contact is made at work. However, if the MRO were to contact the individual at work and the individual was out of the plant, the commenter asked: "what happens if the message gets lost? What happens if the worker is on vacation, in the hospital, or on a long set of weekday ST days, like 12-hour workers get, and what if the MROs can't make contact?"

This commenter suggested that the licensee should be responsible for contacting the individual's supervisor and making arrangements for the worker to contact the licensee, who would then schedule a time for the MRO discussion. Because the supervisor is aware of the employee's schedule and health status, this would avoid the donor being declared as violating the FFD program simply because he was unavailable due to perfectly innocent reasons [Todd Newkirk, IBEW].

NRC Response: The NRC disagrees with the commenter and believes that the three paragraphs in question give adequate opportunity for the donor to be contacted. The first two paragraphs of this section pertain to situations in which contact with the donor has been made and documented, and which are not the subject of this comment. The third subparagraph clarifies that the MRO may confirm a test result as an FFD policy violation if the MRO is unable to make contact with the donor after the MRO makes all "reasonable efforts" to do so. A reasonable effort is described in this paragraph, which also makes clear that the MRO may go beyond the stated efforts to make contact with the donor.

In response to the commenter's specific examples, the MRO is required to attempt to contact the donor at day and evening phone numbers at least three times spaced reasonably over a 24-hour period. The NRC believes that contacting the donor at work is encompassed within "reasonable" efforts. If the donor is on vacation or in the hospital, reasonable efforts by the MRO will likely uncover this information.

The NRC believes that naming the donor's supervisor, instead of the donor, as the point of contact for the MRO, is inefficient and will not address the issues raised by the commenter because the MRO may face the same challenges in contacting the supervisor as in contacting the donor. In addition, MRO contact with the supervisor has the potential to violate the donor's privacy. However, § 26.185(e) provides donors with an opportunity to contact the MRO and request additional discussion of the test result(s) in the event of circumstances such as those described by the commenter.

In the rare event that a donor is unable to either receive or respond to an MRO's call, § 26.185(e) grants the donor an opportunity to re-open the discussion with the MRO by documenting the reason(s) he or she was unable to contact the MRO to discuss the adverse MRO determination. After the donor has been notified that the MRO has determined the donor violated the FFD policy without discussion, the donor has 30 days to present information to the MRO that documents the unavoidable circumstances which prevented the donor from

establishing contact with the MRO or a representative of the licensee or other entity. After evaluating the information provided by the donor, the MRO may modify the initial determination.

The NRC believes that these provisions adequately protect donors' privacy and other rights (including due process) in the circumstances described by the commenter and has not modified the provisions in the final rule.

10.3.5. Additional Opportunity for Discussion (§ 26.185(e))

No comments addressed this section.

10.3.6. Review of Invalid Specimens (§ 26.185(f))

MRO Judgement

Comments: One commenter addressed proposed § 26.185(f)(2), (f)(3), (g)(1), (h)(1) and (i)(1) and asked what constitutes an "acceptable" or "legitimate" explanation for the drug test result. The commenter argued that the provision should specify that if the individual presents testimony or certification from a medical doctor (especially a specialist), the MRO must accept it as a valid reason [Todd Newkirk, IBEW].

Several commenters from industry stated that industry believes MRO judgement is adequate and appropriate when a donor submits medical evidence to the MRO, and thus recommends that the NRC implement § 26.185(f)(2), (f)(3), (g)(1), (h)(1), and (i)(1) as proposed [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters who support the proposed provisions, and believes it is appropriate and adequate to rely on MRO judgement to determine if there is an acceptable medical explanation for drug test results, based upon his or her medical knowledge, the qualifications and training required under § 26.183(a), and any information that the donor provides. Accordingly, the NRC has not modified the proposed provisions in the final rule.

10.3.7. Review of Dilute Specimens (§ 26.185(g))

Grounds Constituting Reason to Suspect Specimen Dilution

Comments: Another commenter, supported by many commenters, objected to the proposed language in § 26.185(g)(2) that included the specific reasons the MRO may use to determine that a donor has attempted to dilute a specimen. The commenter stated that these reasons were too restrictive, did not afford the opportunity for changes in medical knowledge, and may have negatively impacted the effectiveness of the FFD program. The commenter suggested deleting the last sentence in this paragraph as well as the three paragraphs that follow [(g)(2)(i)-(iii)] [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn

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

NRC Response: The NRC agrees with commenter that the words "exclusive grounds" in the proposed provision were too restrictive. Therefore, the NRC has added language to the final rule clarifying that MROs shall consider the circumstances specified in § 26.185(g)(2)(i) through (g)(2)(iii) as applicable in making the determination required under this paragraph.

Typographical Error

Comments: Several commenters from industry identified a typographical error in proposed § 26.185(g)(2) and (g)(3): instead of citing § 26.31(c)(1)(ii), the NRC should cite § 26.31(d)(1)(ii) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC has revised proposed 26.185(g)(2) in the final rule and has eliminated the need for reference to 26.31(d)(1)(ii). However, the NRC agrees with the commenter that proposed § 26.185(g)(3) contained a typographical error and has revised the final rule accordingly.

MRO Judgement

Comments that addressed MRO judgment are documented in Section 10.3.6 of this document.

10.3.8. Review of Substituted Specimens (§ 26.185(h))

MRO Judgement

Comments that referenced this section are addressed in Section 10.3.6 of this document.

10.3.9. Review of Adulterated Specimens (§ 26.185(i))

Typographical Error

Comments: One industry commenter, supported by many commenters, addressed § 26.185(i)(3) and noted that there is a typographical error in the proposed language. To resolve this issue, the commenter suggested the following language: “If the MRO determines that there *is* a legitimate medical explanation for the adulterated test result and no drugs or drug metabolites were detected in the specimen, the MRO shall report to the licensee or other entity the test is negative”[Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with this comment. The error in the proposed rule resulted in an inconsistent provision. The NRC has revised the final rule accordingly.

MRO Judgement

Comments that addressed MRO judgment are documented in Section 10.3.6 of this document.

10.3.10. Review of Opiates, Prescription and Over-the-Counter Medications (§ 26.185(j))

Donor Responsibility to Determine if Medication is Controlled Substance

Comments: One commenter referenced proposed § 26.185(j)(6) and stated that if a doctor prescribes medication legally as treatment for a medical condition, it should not be the employee's responsibility to determine if this medication is on the list in Schedule I of section 202 of the Controlled Substances Act [21 U.S.C. 812]. The commenter stated that although § 26.21(b)(6) references the "use of prescription and over-the-counter medications that could cause impairment," no mention is made requiring the individual to report the use of prescription and OTC medications to a supervisor. This would be an invasion of the individual's privacy and a supervisor wouldn't be qualified to determine whether use of the medication would cause impairment. The commenter also argued that there is also no requirement for the employee to list his or her prescription and OTC medications when taking an FFD test; this is only required when the employee is called in for the MRO interview after a positive test occurs [Todd Newkirk, IBEW].

Several commenters from industry also referenced § 26.185(j)(6) and stated that industry agrees with the proposed paragraph because the use of drugs contained in Schedule I is a fitness-for-duty policy violation [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: NRC agrees with the commenters who support the proposed provision. The drugs on Schedule I, by definition, do not have legitimate medical uses and, except in very rare circumstances, are not prescribed by licensed physicians. Therefore, donors will not be required to determine whether a medication resides on Schedule I.

Also, the NRC agrees that requiring an individual to report the use of prescription medications would be an invasion of the individual's privacy. Therefore, there is no requirement in the rule for a donor to list his or her prescription and OTC medications when taking an FFD test. To be consistent with the privacy requirements of the Americans with Disabilities Act [Pub. L. 101-336, July 26, 1990], the final rule eliminates the requirement in the former rule to list medications before specimen collection and testing. The final rule requires donors to provide medication information to the MRO only in the event of positive, adulterated, substituted, or invalid confirmatory validity or drug test results in order to enhance their rights to privacy under the rule. This revised requirement is also consistent with the procedures of other Federal agencies.

Review for Over-the-Counter (OTC) Medications

Comments: One commenter made three OTC-related arguments:

1) Anyone taking prescription and OTC medications may be doing so legally, but may be impaired nonetheless. Therefore, there should be a point of contact in the licensees testing program, available at all times that coincide with shift workers' starting hours, who can ensure that the medication being taken does not jeopardize the safety of the individual, coworkers, or the plant.

2) If the workers FFD file contained prescription and OTC medication information, it would eliminate the need for the worker to endure the stress of the MRO review if the medication were the cause of the non-negative test.

3) If the employee forgets about his or her OTC or prescription medications, and an FFD test were to identify them, the employee should be designated, "Not fit for duty due to accepted medical reasons," until the MRO deems that the medication is no longer being taken. [Todd Newkirk, IBEW]

NRC Response: The NRC disagrees with the commenter's first argument that there should be an available point of contact for those individuals taking prescriptions and OTC medications because the final rule contains other provisions that address this topic. Language has already been included in the final rule for such provisions. Specifically, licensees and other entities must establish the FFD program requirements for addressing these issues in their policy (§ 26.27(b)(6)) and in their procedures (§ 26.27(c)(4)).

The NRC also disagrees with the second argument that employees' FFD file should contain information about their OTC prescription medications. Requiring employees to include medication information that is linked to the positive, adulterated, substituted, or invalid test result would be an invasion of the individuals' privacy. Also, MRO's require current medication information, and the information contained in a donor's personnel file may be outdated.

The NRC disagrees with the commenter's final argument. Section 26.185(k) already addresses the commenter's concern that an employee may forget about his or her prescription or OTC medication only to have the medications identified in the FFD test. That provision states that the donor has not violated the FFD policy if an MRO determines that there is legitimate medical explanation for a positive drug test result, that the use of a drug identified through testing was in the manner and at the dosage prescribed, and the results do not reflect a lack of reliability or trustworthiness.

10.3.11. Results Consistent with Legitimate Drug Use (§ 26.185(k))

No comments addressed this section.

10.3.12. Retesting Authorized (§ 26.185(l))

No comments addressed this section.

10.3.13. Result Scientifically Insufficient (§ 26.185(m))

No comments addressed this section.

10.3.14. Evaluating Results from a Second Lab (§ 26.185(n))

No comments addressed this section.

10.3.15. Reauthorization after a First Violation for a Drug-Positive Test Result (§ 26.185(o))

No comments addressed this section.

10.3.16. Time to Complete MRO Review (§ 26.185(p))

Comments: One commenter, supported by many commenters, suggested a clarification for proposed § 26.185(p), and stated that in this paragraph, the NRC did not specify "business days." The commenter argued that the proposed language should be revised to say "business days" to conform to proposed § 26.169(a) [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters that modifying the rule to state "business days" would improve consistency with other provisions. Therefore, the NRC has revised the final rule accordingly.

10.4. Substance Abuse Expert (§ 26.187)

No comments addressed this section.

10.4.1. Implementation (§ 26.187(a))

Comments: One commenter, supported by many commenters, stated that proposed § 26.187(a) needed clarification. Specifically, the commenter said the language should be revised to give the MRO, if qualified, the option to function as the SAE. This would avoid any unnecessary financial burden for licensees that have an MRO that can make SAE determinations. The commenter suggested adding a second sentence to § 26.187(a) that stated the following: "One person who qualifies as both an MRO as required in § 26.183 and an SAE as required by this section may perform the functions of both positions" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, EntergyÅ].

NRC Response: The NRC agrees with the commenters that the final rule should specify that an MRO who meets the applicable requirements may serve as both an MRO and as an SAE. Therefore, the NRC has revised this provision in the final rule accordingly.

10.4.2. Credentials (§ 26.187(b))

No comments addressed this section.

10.4.3. Basic Knowledge (§ 26.187(c))

No comments addressed this section.

10.4.4. Qualification Training (§ 26.187(d))

No comments addressed this section.

10.4.5. Continuing Education (§ 26.187(e))

No comments addressed this section.

10.4.6. Documentation (§ 26.187(f))

Comments: One commenter addressed documentation and stated that SAE documentation should be provided to the individual or designated representative upon request [Todd Newkirk, IBEW].

NRC Response: The NRC agrees with the commenter. Documentation of the credentials, knowledge, and training of the SAE should be available upon request to individuals as well as to NRC representatives, licensees, or other entities. The NRC has added a cross-reference to this provision of the final rule to specify that these types of documents shall be made available in accordance with the protection of information requirements in § 26.37.

10.4.7. Responsibilities and Prohibitions (§ 26.187(g))

Comments: One commenter addressed proposed § 26.187(g)(2) and stated that, in order to best prevent a conflict of interest, once the SAE has made the recommendation for the best treatment of the individual, the individual should be allowed to select the entity that will provide the treatment if the entity meets the credential requirements for the course of treatment provided. The commenter argued that, because personality conflicts may interfere with treatments, the individual should be allowed to change treatment providers (with SAE concurrence) during the course of treatment [Todd Newkirk, IBEW].

NRC Response: The NRC does not agree with the commenter. The NRC notes that nothing in this paragraph prohibits an SAE from considering a donor's preferences, among the other considerations specified, in identifying a treatment provider. However, "personality conflicts" with a treatment provider may be clinically meaningful and changing providers may not represent the most effective resolution to the issues. The NRC is confident that an SAE will be qualified to address such circumstances, and, therefore, has not modified this provision in the final rule.

10.5. Determination of Fitness (§ 26.189)

Definition of Determination of Fitness

Comments: One commenter, supported by other commenters, stated that proposed § 26.189(a) was confusing. The commenter suggested rewording the first sentence of the paragraph to clarify what a determination of fitness is: "A determination of fitness is the process entered when there are indications that an individual may be in violation of the licensee's or other entity's FFD policy or is otherwise unable to safely and competently perform his or her duties" [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters. A determination of fitness is conducted after indications that the individual may be in violation of the FFD policy are discovered, not to determine whether there are such indications. Therefore, the NRC has modified the provision in the final rule to clarify this intent.

Language Clarification

Comments: Another commenter, supported by many commenters, stated that the proposed language in § 26.189(b)(3) was confusing and suggested the following minor word change: "Before an individual is granted authorization when potentially disqualifying FFD information is identified *that* has not previously been evaluated by another licensee or entity who is subject to this part..." [Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: The NRC agrees with the commenters that this edit will clarify the intent of the provision. A determination of fitness is intended to be conducted before an individual is granted authorization when potentially disqualifying fitness-for-duty information (PDFFDI) is identified that has not been previously evaluated by another licensee or entity who is subject to this part. Therefore, the NRC has modified the provision in the final rule to address this comment.

Requirement for Face-to-Face For-Cause Determination of Fitness

Comments: One commenter, supported by many commenters, addressed the proposed language in § 26.189(c) and stated that face-to-face interaction is not always required to make a "for cause" determination of fitness. The commenter stated that the determination of the appropriate approach to this determination should be left to the professional making the determination. The commenter argued that, in other parts of the rule, the qualified professional would be expected to make that determination using techniques that are generally acceptable in the professional community and these may not include face-to-face interaction in all circumstances. For example, if the ultimate issue is whether a certain psychoactive medication will prevent an individual from performing assigned duties, the commenter argued that a clinical

psychologist may be able to provide the needed determination of fitness without a face-to-face interaction. Thus, the commenter suggested deleting this paragraph, renumbering (d) as (c), and moving the subparagraphs in the previous (c) under the new (c) [Randy Cleveland, NMC; Jim Davis, NEI #48; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; C.L. Funderburk, Dominion; F.G. Burford, Entergy].

NRC Response: A for-cause determination of fitness shall be conducted in response to an individual's observed behavior or physical condition indicating that they are in violation of the FFD policy or otherwise unable to safely and competently perform his or her duties. The NRC believes that the assessment should include immediate sensory observation (such as the smell of alcohol or the individual's physical appearance or behavior) that can only be available during a face-to-face interaction. However, the NRC has clarified the final rule to reflect NRC's intent that a for-cause determination of fitness is not required if there is an absence of physical or sensory information (i.e. based solely on receiving information that an individual is engaging in substance abuse).

Second Determination of Fitness

Comment: Regarding proposed § 26.189(d), one commenter stated that this provision appeared to eliminate the use of a second MRO to evaluate additional information supplied by an individual after an initial determination of fitness has been made. The commenter argued that this creates the situation where an individual's fitness cannot subsequently be evaluated if the deciding MRO is unavailable because only that MRO can change his or her initial determination. The commenter also stated that this section appeared to conflict with the review process in § 26.39. Therefore, the commenter suggested that this section be removed from the rule [C.L. Funderburk, Dominion].

NRC Response: The NRC disagrees with the commenter that the provision would lead to situation in which an individual's fitness cannot subsequently be evaluated if the deciding professional is unavailable in the long-term, given that the provision specifically states "Unless the professional who made the initial determination of fitness is no longer employed by or under contract to the licensee or other entity, only that professional is authorized to modify the evaluation and recommendations." In the short-term, if the professional is on vacation or sick leave, the professional may evaluate any new or additional information upon his/her return to duty.

The NRC also disagrees with the statement that the provision conflicts with § 26.39, as §§ 26.189 and 26.39 contain provisions for differing types of reviews. Section 26.189 contains provisions for a determination of fitness, which is a method of determining whether an individual has violated the FFD policy or is fit to safely and competently perform his or her duties. The review process in § 26.39 establishes provisions for the review of a determination that an individual has violated the FFD policy. This section specifically states that the reviewers cannot be associated with the administration of the FFD program (i.e., those who make a determination of fitness in 26.189). Therefore, the NRC has not modified the proposed provision in the final rule.

11. Subpart I: Managing Fatigue

Many commenters referenced the fatigue provisions in Subpart I of the proposed rule. There appeared to be an equal amount of support for and disagreement with the proposed rule.

Support for Subpart I

Comments: Many commenters supported Subpart I. For example, several commenters ardently supported the fatigue provisions for various reasons, including the prevention of worker injuries and forced-overtime, as well as increased opportunity for time workers will have to spend with their families [Anonymous #26; Anonymous #27; Anonymous #28; Anonymous #29; Mark Haywood, First Energy; Greg Gorman, First Energy; Richard Barkley, Individual]. Some commenters argued that the new rules will force the owners/operators of power plants to increase staffing levels and reduce overtime [Mike Jolley, Individual; Anonymous #19; Richard Barkley, Individual]. Another commenter stated that the fatigue provisions are also beneficial from a security standpoint, [Anthony Rizzo Jr, Salem Hope Creek]. Two commenters argued that if fatigue is left unchecked, problems will worsen due to regulation, downsizing, and the aging workforce [Anonymous #29, Anonymous #75]. Another argued that this rule may increase the experience level of current personnel while reducing the operating costs of licensees, as fewer resources will need to be dedicated to the training of replacement personnel [Kenneth Kolaczyk, Individual].

Several commenters supported the fatigue provisions in this Subpart by discrediting industry arguments against it. They disagreed with industry's argument that worker fatigue has not yet led to a significant reactor event, hence, there is no problem to be resolved via the rulemaking [David Lochbaum, UCS; Deborah Katz, CAN; Anonymous #75]. Two commenters explained that this argument is "intellectually bankrupt" for at least two reasons. First, past evaluations of plant events do not parse human performance finely enough to dismiss fatigue as either a primary or contributing factor. The commenters argued that there are indeed events where "failure to follow procedure" is identified as a cause, and this could be a result of fatigue. Second, the commenters argued that "it would be imprudent public policy and unwise business judgement to tolerate an unsafe practice until it caused mayhem." The commenters stated that although NEI data showed that excessive working hours was not rampant in the industry and that most plant owners were responsibly managing working hours, the data also revealed that some plant managers worked employees beyond reason. Thus, the commenters argued that this rulemaking is necessary to control those owners who cannot responsibly manage work hours and to provide adequate protection against impairment from fatigued workers [David Lochbaum, UCS; Deborah Katz, CAN].

Another commenter stated that because the safety of nuclear power plants is predicated upon the proper implementation of programs and procedures by qualified personnel, and studies have shown that fatigued personnel are less likely to conduct activities properly, the proposed work hour restrictions would be a "prudent NRC action" [Kenneth Kolaczyk, Individual].

One commenter supports the inclusion of education and fatigue assessment as compliments to the explicit work-hour policies, as this represents a progressive approach that acknowledges the complexity of managing fatigue in the nuclear generating industry. The commenter stated that although a duty-hour approach to controlling fatigue cannot fully address fatigue factors, it is

essential to provide a reasonable assurance that the risk of fatigue-related events are being managed. However, the commenter stated that while federal duty-hour policies provide a critical and central structure for managing fatigue, there should also be consideration of the need to respond to unforseen circumstances and operational flexibility [Mark Rosekind, Alertness Solutions].

NRC Response: The comments do not require a response.

Individuals' Recognition of Fatigue

Comments: Some commenters stated that workers should be able to recognize when they are fatigued and should be able to correct the issue themselves via the former rule provisions, thus the proposed NRC fatigue regulation is burdensome and unnecessary [Jim Waite, Exelon; Blaine Peters, Exelon; Danny Todhunter, Exelon; Donald Lenski, Individual; Robert Althoff, Individual]. Some commenters suggested that the only change to the FFD program should be the prohibition of forced overtime, and voluntary overtime should be allowed [Jim Waite, Exelon; Donald Lenski, Individual; Guy Galster, Individual].

NRC Response: The NRC agrees in part with the commenters concerning the workers ability to recognize when they are fatigued. However, although individuals are able to make relative judgements regarding their level of fatigue, there have been several studies that noted the tendency for individuals to underestimate their level of impairment from fatigue as discussed in the *Federal Register*, Vol. 70, No. 165, on page 50458. More recently, research has suggested that individuals may not take necessary safety precautions despite a recognition that they are impaired by fatigue (Nabi et al., 2006). The NRC has also received allegations from nuclear power plant workers expressing fear of adverse actions from employers for reporting that they are unfit for duty because of fatigue. As a consequence, the NRC does not believe there is reasonable assurance workers can reliably address excessive fatigue solely through their own actions under the former requirements applicable to worker fatigue or that only a prohibition on forced overtime would be adequate. Therefore, the NRC retains the requirements in the final rule concerning fatigue management.

New Provisions Add Cost and Only Facilitate Regulatory Oversight

Comment: Another commenter stated that, unless the NRC is finding frequent excessive work hours, providing "additional layers of bureaucracy" is adding costs and seems to only facilitate regulatory oversight [David Sancic, Individual].

NRC Response: The NRC disagrees that the NRC is only adding costs to facilitate regulatory oversight. The NRC has documented concerns regarding frequent excessive use of work hours in SECY-01-0113, "Fatigue of Workers at Nuclear Power Plants," and SECY 05-0074, "Proposed Rule to Amend the Fitness-For-Duty Requirements in 10 CFR Part 26." Therefore, establishing clear and enforceable requirements for the management of worker fatigue is necessary to ensure against worker fatigue adversely affecting public health and safety and the common defense and security.

Lack of Correlation between Impacts of Fatigue and Performance at Reactors

Comments: One commenter, supported by other commenters, stated that there has been no correlation between the claimed impacts of fatigue and actual human performance at power reactor sites. As a result, the commenter suggested that there is no need to significantly expand fatigue requirements beyond those contained in Generic Letter 82-12. The commenter also explained that after reviewing facilities' human performance measures, the data showed no adverse trend in a performance for longer outages and beyond the sixth day of work. Therefore, the commenter disagreed with the rule package's contention that increased fatigue after long outages and after the sixth day of work affects human performance [Andrew Antrassian, UWUA; Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the conclusions of the report, “Work Hour Rule Data Summary,” submitted by the commenters. The report concludes that human performance does not suffer in longer outages with greater work schedules and that there is not an adverse trend in human performance for work beyond six straight days. The conclusions of the report do not withstand a rigorous analysis and therefore cannot support leaving fatigue requirements as those stated in Generic Letter 81-12.

According to the text of the report the plot of the number of human performance errors and Corrective Action Reports (CRs) which occurred over a 13 week period has a downward trend (in the data) during an outage. However, both human performance errors and CRs, while declining between weeks 4 and 10, are actually increasing for weeks 11 through 13. (There is no data provided after week 13). Moreover, the number of CRs is actually higher after week 13 compared to week 1 (60 versus 40). The later illustrates a problem generally associated with visual inspection of time series data, namely scale values. If only data for weeks 1 and 13 were shown, then the visual inspection of the data would have led to the observation that human performance errors increase over time during an outage, while CRs are roughly constant.

Several plants submitted data for human performance errors by day of work for seven straight days. Again, the report stated that the data demonstrated that there was either a downward or no trend in human performance errors as a function of the day of shift. Again, there was not a rigorous analysis of the data but rather a subjective conclusion drawn out by visual inspection of graphs.

The NRC recognizes that the analysis of the data collected by licensees to evaluate human performance error during periods of normal operating and outages is of anecdotal value. However, the NRC disagrees that the report is evidence that the proposed rule should be revised. In contrast, the overwhelming body of evidence, as discussed in Section IV.D of the preamble to the final rule, supports the need for periodic days off to prevent cumulative fatigue and human error. Therefore, the final rule language retains provisions to address cumulative fatigue. However, in response to comments regarding the proposed rule provisions concerning the minimum break requirements in § 26.199(d)(2) of the proposed rule and the collective work hour limits in § 26.199(f) of the proposed rule, the NRC has revised the provisions to address

cumulative fatigue. These revised provisions are presented in § 26.205 (d)(2) through (a)(6) of the final rule.

Questionable Data

Comment: Another commenter claimed that the justification for the fatigue provisions is based on speculative and politically skewed data, rather than sound scientific data. [Daniel Hansen, Individual].

NRC Response: The NRC disagrees with the commenter and notes that the commenter provided no basis for this assertion. The studies used by the NRC as the basis for the proposed requirements are largely from refereed journals and the findings of those studies were consistent with the broader research literature and widely accepted fatigue management guidelines. Therefore, the NRC retains the Subpart I requirements for the management of fatigue.

Inconsistency with Goals of the Rulemaking

Comments: Some commenters stated that the proposed work hour provisions in Subpart I are inconsistent with some of the stated goals of the rulemaking. They stated that Subpart I introduces new inefficiencies and unnecessary requirements which are contrary to rulemaking Goals 3 and 5, and suggested that broader application of performance-based principles and fewer prescriptive limits would more effectively meet the Commission's intent in Generic Letter 82-12. [Michael Coyle, NEI #49; Gregory Halnon, First Energy; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees in part with the comments on the proposed work hour provisions. Therefore, the NRC has eliminated the collective work hour controls that would have been required by the proposed rule and has restructured the break and day off requirements in the final rule in a manner that will reduce the burden on licensees and place more emphasis on performance-based requirements. The revised break and day off requirements are presented in § 26.205(d)(2) through (d)(6) of the final rule.

Napping Policies

Comment: One commenter noted studies that show that napping at the workplace is especially effective for workers who need to maintain a high degree of alertness, attention to detail, or make quick decisions. Thus, it encouraged the NRC to include a provision regarding the inclusion of sound napping policies in the fatigue management plans developed by licensees. These napping policies should include the designation of quiet, dark and accessible areas (e.g., rooms in EAP or wellness units) to be used as napping facilities. The use of these facilities should be encouraged especially during outages, the use of heavy overtime, and when waivers are granted [Darrel Drobnich, NSF].

NRC Response: The NRC agrees that napping is a particularly effective fatigue management strategy. The rule does not require licensees to use napping, or address napping in their fatigue management policy, so that licensees have the flexibility to use the methods they consider most appropriate and effective in the specific circumstances they are addressing. However, the NRC notes that § 26.205(b)(2) of the final rule will allow licensees to exclude within-shift break times from work hour calculations if the licensee provides reasonable opportunity and accommodations for sleep. Although this provision does not require licensees to use napping as a fatigue mitigation strategy, allowing licensees to exclude time used for napping from work hour calculations removes a potentially significant disincentive for using this strategy. In addition, § 26.203(c) of the final rule requires licensee FFD training programs to address "the effective use of fatigue countermeasures" and verify worker knowledge and abilities through a comprehensive examination as required by § 26.29(b). As a consequence, the NRC expects that licensees who choose to use napping as a fatigue mitigation strategy will have associated training to ensure effective implementation.

11.1. Applicability (§ 26.195)

No comments addressed this section.

11.2. General Provisions (§ 26.197)

Comments: One commenter supported § 26.197(a), (b), and (c) [Brian McCabe, Progress Energy]. Other commenters expressed support for the provisions in § 26.197(a) through (d). These commenters agreed that establishing clear policies, procedures, training and records will be a significant improvement for the management of work hour requirements [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The comments do not require a response.

11.2.1. Policy (§ 26.197(a))

Comments: Several commenters from industry supported this section of the rule and stated that setting clear expectations for individuals to self-declare and establishing a process for dealing with fatigue are key features of the proposed rule [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The comments do not require a response.

11.2.2. Procedures (§ 26.197(b))

Support for Procedures

Comments: Some commenters supported the procedure requirements of Subpart I, specifically proposed § 26.197(b)(1), which requires that the licensee's FFD program explicitly describe the process for making and handling fatigue self-declarations by all workers. The commenters stated that this language is "absolutely vital to the efficacy and integrity of the program." They also stated the proposed language assures that appropriate checks and balances are in place to limit abuses both in the case of management forcing fatigued workers to stay on the job, as well as workers using fatigue self-declaration to supplement their sick/vacation time [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The comments do not require a response.

Rest Break Procedures

Comment: One commenter suggested that the NRC add to proposed § 26.197(b)(1) subparagraph (iv) and (v) a requirement for a licensee procedure that would describe criteria for workers to activate the 24 or 48 hour optional rest period. The commenter suggested the following language for subparagraph (v): "For individuals working a nominal rotation shift cycle containing a majority of 8 hour shifts for 7 work days not to exceed 8 work days of continuous duty with each work shift providing a break period as described in § 26.199(d)(2)(i); describe the process to be followed when an individual requests to observe a 24 Hour and/or a 48 Hour break period prior to the licensee soliciting or assigning further work to an individual exceeding the last scheduled day containing the 7 or 8 continuous work days as allowed by § 26.199(d)(2)(ii), § 26.199(d)(2)(iii) and § 26.199(d)(4)." The commenter also suggested the following language for subparagraph (v): "Describe the process to be followed when an individual requests to observe a 48 Hour break period for individuals working a nominal rotation shift cycle containing a majority of scheduled hours above 8 hours per shift as allowed by § 26.199(d)(2)(iii)(a) and § 26.199(d)(4) [Edwin Hill, IBEW].

NRC Response: The NRC agrees in part with the commenter, however, it did not conclude that it was appropriate to establish a requirement for optional rest periods. The NRC has revised the final rule text by establishing minimum day off requirements in § 26.205(d)(3) through (d)(6) of the final rule that allow increased flexibility in the specific timing of the breaks. This increased flexibility allows licensees and workers to address personal and work schedule needs while continuing to provide reasonable assurance that individuals do not become impaired from fatigue because of excessive work hours. Therefore, the commenter's concerns have been addressed through alternative requirements.

Self-Declaration Procedures

Comment: One commenter expressed concern that § 26.197(b)(1) would mandate prescriptive requirements for the content of licensee procedures with respect to worker self-declarations of fatigue. The commenter stated that the proposed rule appears to intrude unnecessarily into the employer-employee relationship and may have the effect of establishing new responsibilities and procedural rights beyond existing collective bargaining agreements. The commenter argued that

the rule should not rely on self-declarations as the primary means of identifying fatigue, and the training of shift workers that would be required as part of the fatigue management program under proposed § 26.197(c) should be sufficient. Thus, in view of the adequacy of training, the commenter recommended that the NRC eliminate the requirement for a detailed self declaration process procedure [Daniel Stenger, NRSG].

NRC Response: The NRC disagrees that the proposed rule intrudes unnecessarily into the employer-employee relationship and that the NRC should eliminate the requirement for a self-declaration process. Section 26.197(b)(1) of the final rule requires licensees to develop, implement, and maintain a procedure for self-declaration. It further requires that the procedure describe the individual's and licensee's rights and responsibilities related to self-declaration, the controls and conditions under which an individual may be permitted or required to perform work after that individual declares that he or she is not fit because of fatigue, and the process to be followed if the individual disagrees with the results of a fatigue assessment. The rule does not establish the individual's rights and responsibilities, does not prescribe the controls and conditions that must be established, and does not prescribe the process to be followed if an individual disagrees with the results of a fatigue assessment. As a consequence, the NRC does not believe that the requirement for a procedure intrudes unnecessarily into the employer-employee relationship. However, in light of the allegations that the NRC has received concerning self-declaration of fatigue, it appears that there has been a lack of understanding by licensees and workers regarding the applicability of the requirements of Part 26 and 10 CFR 50.7 to these circumstances, and that a procedure that addresses the self-declaration process is necessary to ensure that self-declaration is an effective means for detecting impairment from fatigue. Therefore, the NRC retains the proposed requirements regarding self-declaration in § 26.203(b)(1) of the final rule.

11.2.3. Training and Examinations (§ 26.197(c))

Comments: One commenter fully endorsed this provision because comprehensive education and training on the promotion of good quality sleep and the mitigation of fatigue is essential to the promotion of safety in the nuclear industry. The commenter also suggested that some education and training on sleep, sleep disorders and the consequences of sleep deprivation, although not necessarily examinations, should be required for all personnel, whether or not they are in safety sensitive positions or covered under work hour controls in proposed § 26.199(a). The commenter stated that education of all personnel, including (and perhaps especially) upper management, is key to fostering a culture that embraces alertness and effective fatigue management [Darrel Drobnich, NSF].

With regard to proposed § 26.197(c)(1), the commenter stated that the NRC should provide specific guidance regarding topics that should be covered in fatigue training and education modules and examinations. The commenter suggested that the NRC take the lead in developing uniform curriculum and examination materials in order to ensure the accuracy and uniformity of information provided. The commenter also argued that all MROs should receive education and training regarding the signs and symptoms of sleep disorders as well as effective treatment options, and that information on the prevention of drowsy driving should be included in any materials that are developed [Darrel Drobnich, NSF].

NRC Response: The NRC agrees with the commenter's general support for this provision. The NRC notes that this training requirement is applicable to all licensee personnel subject to the FFD program, not just workers subject to the work hour controls. Consequently, managers and MROs, who have an important role in fostering an effective fatigue management culture, would be subject to the training requirements. With regard to the commenter's suggestion that the NRC should provide specific guidance regarding the specific topics that should be addressed in fatigue management training, the NRC notes that § 26.203(c)(1) of the final rule requires licensees to include specified knowledge and abilities concerning fatigue management in the content of the FFD training program. Establishing training requirements at the knowledge and abilities level allows licensees the flexibility to update their existing FFD training programs, as necessary and in a manner that efficiently achieves the fundamental objective of the training. Although the NRC agrees that a uniform curriculum may help ensure the accuracy of the information provided, and notes the NRC may participate in the development and review of guidance concerning fatigue management training, it is the responsibility of individual licensees to ensure that training materials are technically correct and support trainee attainment of the required knowledge and abilities. Therefore, the NRC retains the proposed training requirements in § 26.203(c) of the final rule.

11.2.4. Recordkeeping (§ 26.197(d))

Support for Recordkeeping Provisions

Comments: One commenter agreed with the recordkeeping requirements of Subpart I, especially the three year record retention requirement because it is consistent with the inspection cycle of the reactor oversight process (ROP) [David Lochbaum, UCS; Deborah Katz, CAN]

Several commenters from industry said the provision that requires licensees to maintain records, combined with proposed § 26.199(j), provide an additional performance-based provision to the rule and provides assurance that performance expectations are met [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The comments do not require a response.

Records of Rest Breaks

Comment: Another commenter suggested that the NRC add § 26.197(d) subparagraph (6) that states: "Documentation of individual requested rest breaks and final licensee disposition of the requested break in accordance with § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii)" [Edwin Hill, IBEW].

NRC Response: The NRC disagrees with the comment that individual requested rest breaks should be documented. Optional rest breaks alone do not provide reasonable assurance that nuclear power plant workers will obtain an adequate amount of rest. Consequently, the NRC does not believe that recordkeeping of such requests is warranted. However, the NRC has

modified the final rule to include rest break requirements that largely meet the commenter's objective of providing workers increased flexibility in the distribution of their rest breaks. Therefore, the commenters concerns have been addressed. The revised break and day off requirements are presented in § 26.205(d)(2) through (d)(6) of the final rule.

11.2.5. Reporting (§ 26.197(e))

NRC's Justification of Reporting Requirements is Flawed

Comments: Many commenters addressed the reporting requirements for the fatigue provisions. Several commenters from industry argued that the reporting requirements in § 26.197(e) should be deleted from the rule because they will not provide new or unique information to the NRC, are unnecessary to protect public health and safety, are unnecessary to facilitate NRC oversight of the revised rule, and are unduly burdensome for the NRC power reactor licensees [Marvin Fertel, NEI]. A similar comment stated that (e)(1) and (e)(3) should be deleted for these reasons, and § 26.199(e)(2) should be revised to apply only to the job duty group comprised of security personnel as defined in § 26.199(a)(5) [Michael Coyle, NEI #49;, Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

One commenter expanded upon the argument that the requested information is not required for the NRC to ensure public health and safety. The commenter argued that the NRC's FFD rule package does not demonstrate that the industry would fail to comply with the requirements of the revised rule without the imposition of these reporting requirements. Additionally, the commenter stated that the NRC has an effective oversight process that does not depend on extensive data collection from licensees. Thus, the commenter argued that the existing regulatory process is adequate to ensure compliance with regulatory requirements with the reporting provisions in question. The commenter also argued that the NRC's claim that reporting requirements are needed to "focus the NRC inspection resources" is flawed. The commenter stated that the NRC staff will be able to gauge the adequacy of reactor licensees' fatigue management programs without this information collection. With the NRC's baseline inspection program and resident inspectors assigned to each site, the commenter argued that there is adequate attention to a broad range of performance indicators that would indicate any degradation in performance well in advance of a public health and safety issue. Also, the commenter stated this claim is inconsistent with the NRC staff's approach in other areas, such as the corrective action program [Marvin Fertel, NEI].

Some commenters argued that the reporting requirement ignores the significant duplication in licensee efforts that the proposed language creates. For example, § 26.197(d) requires that licensees retain adequate records of waivers and assessments, and § 26.197(j) requires periodic reviews by licensees to assess the effectiveness of the work hour controls, including waivers and fatigue assessments. These reviews are documented and trended under the licensee's corrective action program, and the corrective action program is periodically inspected by the NRC. Thus, industry commenters argued that reporting this data to the NRC under fatigue management on an annual basis is an unnecessary duplication of these requirements

with no attendant increase in protection of public health and safety [Marvin Fertel, NEI; F.G. Burford, Entergy].

NRC Response: The NRC does not agree with comments that the requirements for reporting fatigue management information should be deleted from the rule because they will not provide new or unique information to the NRC, are unnecessary to protect public health and safety, are unnecessary to facilitate NRC oversight of the revised rule, and are unduly burdensome for the NRC power reactor licensees. In choosing to retain reporting requirements regarding the use of waivers the NRC considered several aspects of the work hour requirements in § 26.205 of the final rule: (1) The NRC established the work hour limits in the final rule at levels such that the potential for worker fatigue is substantive for individuals working in excess of those limits; (2) The rule permits licensees to authorize waivers of the limits only for circumstances in which the additional work hours are necessary to prevent or mitigate a condition adverse to safety or security; and (3) the rule only requires a waiver if the individual is operating or maintaining a system, structure, or component (SSC) that a risk-informed evaluation process has shown to be significant to the protection of public health and safety, or if the individual is performing specified functions that are essential for effective response to a fire, plant emergency, or implementation of the site security plan. As a result, information concerning licensee use of waivers provides an indication of: (1) the number of hours worked on risk-significant activities by individuals at increased potential for impairment; and (2) how often a licensee must mitigate or prevent a condition adverse to safety while using individuals at increased potential for impairment. The NRC considers this unique information not otherwise reported to the NRC that is relevant to the NRC's mission.

The NRC similarly considered the need to retain reporting requirements regarding fatigue assessment and any management actions in response to the fatigue assessments. The final rule requires fatigue assessments for 4 conditions: (1) for cause, following an observation indicating impaired alertness, (2) post event, following a plant event or worker injury meeting specified significance criteria, (3) following a self-declaration of being unfit for duty, and (4) when a licensee returns an individual to duty with a break of less than 10 hours after the individual was relieved of duties because of a fatigue assessment conducted for-cause or in response to a self-declaration of fatigue. In regard to fatigue assessments following self-declarations, the NRC notes that individuals are only assessed when a licensee denies a worker request for relief from duty (i.e., a rest break). In all other instances the individual will be allowed time off duty in accordance with the licensee's administrative practices and the rule will not require a fatigue assessment. Given these requirements of the final rule, licensee annual reporting of information pertaining to fatigue assessment will provide an indication of how often: (1) individuals are relieved of duty because of observed impairment from fatigue, (2) fatigue is identified as a causal factor in significant plant events and injuries, (3) individuals are required to remain on duty following their declaration they are unfit, and (4) individuals are returned to duty with less than a 10-hour break following a for-cause assessment for fatigue or a self-declaration of fatigue. The NRC considers this unique information not otherwise reported to the NRC that is relevant to the NRC's mission, particularly when considered in conjunction with information concerning the licensee's use of waivers from the work hour limits.

The NRC also disagrees with the comments that the reporting requirement ignores significant duplication in licensee efforts. The NRC agrees that § 26.205(e) of the final rule requires periodic reviews by licensees to assess the effectiveness of the work hour controls, and that

these reviews will be documented and trended under the licensee's corrective action program, which is periodically inspected by the NRC. However, as noted previously, the NRC considers the burden of the annual report to be limited, and that relative to a review that is limited to evaluation of reports in a licensee's corrective action program, the annual reports will enable the NRC to provide more effective and consistent oversight and achieve other objectives described herein for the effective implementation of the requirements in Subpart I.

The comment recommending that the NRC revise the proposed § 26.197(e)(2) to apply only to security personnel is not applicable to the final rule because collective work hour limits have been removed from the rule and the NRC eliminated the requirement for reporting information pertaining to collective work hours as a conforming change. Therefore the NRC retains the reporting requirements in the final rule with the exception of those related to collective work hour limits.

Intent of Reporting Information

Comments: Some commenters stated that the reports the rule would require do not provide a meaningful indicator of the overall quality of how a licensee manages work hours because there are a number of valid conditions that may warrant waivers of work-hour controls. For example, the series of hurricanes that occurred in 2004 could have resulted in a number of waivers for licensees of nuclear power plants located in Florida and along the Gulf Coast. Thus, the commenter argued that as a result of the way that FFD work-hour waivers are counted and maintained under the NRC regulations, the data requested in these reports would not provide an accurate picture of conditions that may have warranted the waiver [Marvin Fertel, NEI]. To address this issue, another commenter argued that the waivers data should be kept onsite for the NRC inspection so that the data may be accompanied by the plant-specific cause for the waivers [John Cowan, NEI].

Two commenters suggested that the rulemaking should also require licensees to report the number of workers covered under § 26.199(a) to provide appropriate context for the annual reporting of waivers [David Lochbaum, UCS; Deborah Katz, CAN].
A commenter at the public meeting, after acknowledging that the reporting is intended to get management's attention, expressed confusion about the philosophy of the waivers. The commenter asked what the NRC will do with the reports and how many waivers will be considered "too many" [Nick DePietro, First Energy].

NRC Response: The NRC disagrees with the comment that the required reports are not a meaningful indicator of the performance of a FFD program. The NRC agrees in part with the comment that information concerning waivers should be considered in context. The requirements in proposed § 26.197(e)(1) and (e)(3) were revised in response to comments that the required information would not provide a meaningful indicator of licensee performance in managing work hours because there are a number of valid conditions that may warrant waivers of work-hour controls. Through reviews of authorized waivers from the work hour limits in plant technical specifications, the NRC has found that waivers are most frequently associated with outage activities. Accordingly, the NRC has revised the requirements for reporting waivers of the work hour requirements in § 26.205 such that the report shall indicate whether or not the waiver was associated with an outage activity. The requirement for reporting information pertaining to fatigue assessments was also similarly revised such that the report will indicate

whether or not the individual was engaged in an outage related activity at the time of the event or condition that resulted in the need for the licensee to conduct a fatigue assessment.

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

In addition to requiring an indication of whether a waiver was associated with an outage activity, the NRC revised the annual report requirement to require a frequency distribution of waivers for each of the five duty groups described in § 26.4(a) of the final rule. As a result, the annual report would include, for example, a table that shows the number of operators that received just one waiver during the year, the number of operators that received two waivers during the year, etc. The NRC incorporated this requirement in the final rule in response to comments that the rulemaking should also require licensees to report the number of workers covered under § 26.199(a) of the proposed rule to provide appropriate context for the annual reporting of waivers. The NRC understood the intent of this comment was to provide a basis for evaluating the number of waivers from the work hour controls relative to the number of individuals subject to those controls. The NRC chose not to require licensees to report the number of individuals covered under § 26.4(a) of the final rule because that number will vary throughout the course of the reporting period, particularly when the reporting period includes a unit outage. In addition, the NRC believes that the required distribution of waivers more effectively provides context to the waiver use by indicating whether the waivers are concentrated among individuals performing a certain duty and whether the waiver use within a duty group is concentrated within a relatively few individuals or distributed among many.

Reporting Requirements Do Not Satisfy the Paperwork Reduction Act

Comments: The commenters also stated that the NRC has not met its obligation under the Paperwork Reduction Act with respect to the information collection requirements proposed in § 26.197(e). They argued that the NRC has failed to adequately justify the need for these provisions to achieve the objectives of the proposed FFD rule, and has also failed to objectively support its estimate of the burden created on affected licensees.

The commenters note that the NRC rule package estimate for reporting in § 26.197(e)(1) is two hours of clerical and one hour of management time for each facility's annual report. The estimate for § 26.197(e)(2) is two hours management time. The estimate for § 26.197(e)(3) is estimated as 12 hours clerical and two hours management time. The commenters argued that this is a significant understatement of the actual time effort required to prepare, check and review an annual report. The industry estimates that preparing the total report will require at least 30 clerical hours and 20 management hours (and these estimates must be multiplied times the more than sixty nuclear plant sites in the U.S). The commenters argued that the management time required to prepare this report could more effectively be devoted to other activities with a closer nexus to public health and safety.

Accordingly, industry believes that OMB should not approve the data collection proposed in this section of the proposed rule and remand proposed § 26.197(e) to the NRC for its further consideration in light of these inadequacies [Marvin Fertel, NEI; Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with commenters' statement that the NRC has not met its obligation under the Paperwork Reduction Act with respect to the information collection requirements proposed in § 26.197(e). The NRC expects that the information provided by licensees in response to the annual reporting requirements in Subpart I will facilitate NRC oversight of licensee implementation of the requirements through several means:

(1) Consistency, efficiency, and continuity of NRC oversight -- Information provided through the annual FFD program performance reports concerning fatigue management will enable the NRC to achieve a higher level of consistency and efficiency in oversight of the implementation of the requirements in Subpart I and in enforcement of those requirements. Without the reporting requirements, NRC inspection of licensee FFD programs would likely be limited to individual inspectors evaluating licensee fatigue management for a sample of workers at a site for a limited time period. Such assessments would necessarily be conducted without the benefit of broader contextual information of the site and industry normative information that would be available through the annual reports. In contrast, the annual reports will help ensure a common perspective for the individual inspectors conducting the oversight process and maintain consistency in NRC's oversight process. In addition, information in the annual report can enhance the efficiency of NRC inspection by providing a basis for the NRC to focus inspection resources on duty groups (e.g., security or maintenance) or issues (e.g., self-declaration) that the annual report indicates may be areas warranting review. The report will enable NRC to achieve a greater focus during preparation for the inspection, enabling the NRC to reduce the burden of on-site inspection hours and potentially reduce the total number of hours required for the baseline inspection. Furthermore, the annual reporting will help achieve a more complete and continuous assessment of licensee performance given that the NRC intends to conduct the baseline inspection of FFD programs only once every 2 years.

(2) Evaluation of rule implementation for lessons learned – Although the NRC and stakeholders made extensive efforts to ensure clear and enforceable requirements that are effective and practical, by establishing new requirements for the management of worker fatigue the rule introduces the potential for unintended consequences and lessons learned. In addition,

changes in the size and composition of the nuclear industry may have unforeseen implications for site staffing and fatigue management. The NRC expects that the site specific and normative information obtained through the reports can provide important future insights regarding opportunities to amend the rule to improve its effectiveness or reduce unnecessary burden. The NRC notes that such information was the basis for reducing, in this final rule, the random testing rate for drugs and alcohol.

(3) Consistent interpretation of waiver criterion – The final rule provides licensees the discretion to use waivers to exceed the work hour limits and thereby allow levels of work hours that create substantial potential to adversely affect worker fitness for duty. The principal basis for allowing waivers is to reduce the additional staffing burden that licensees would otherwise incur if waivers were not available to address these exigent circumstances. The annual reporting of waiver use, in conjunction with the reporting of information concerning fatigue assessments will enable NRC to ensure that licensees use this discretion consistent with the objectives of the rule, and not as a means to compensate for a lack of adequate staffing. Furthermore, although the use of waivers is limited to conditions in which the work hours are "necessary to prevent or mitigate a condition adverse to safety or security," the NRC recognizes the potential for licensees to develop different interpretations regarding this criterion. Some industry commenters on the proposed rule took exception to the NRC's characterization that the high levels of waiver use at some sites was abuse. These commenters suggested that differences in licensee waiver practices could be attributed to the NRC allowing the policy statement to be subject to a number of interpretations during the many years it has been in effect. Regardless of the cause of the differences in licensee use of work hour control waivers, the NRC considers it prudent to address, through this rulemaking, the lessons learned from past implementation of the policy and provide a level of oversight through the annual reporting requirement that will ensure consistent implementation of the waiver criteria in the future.

In addition to the reasons cited in the preceding paragraphs for why the reporting requirements are necessary for the effective and efficient oversight of the implementation of the rule, the NRC considers the reporting requirements to be justified and beneficial for several additional reasons:

(1) Consistency with Part 26 requirements and performance objectives – The final rule retains the long-standing requirements for the reporting of results of licensee drug and alcohol testing and the performance objective for reasonable assurance that individuals are not impaired from any cause (§§ 26.719 and 26.23(b) of the final rule). In addition, several studies discussed in detail in Section IV.D of the preamble to the final rule have demonstrated that worker fatigue can produce levels of impairment that are comparable to blood alcohol concentrations above levels permitted by this rule. Furthermore, given the frequency of worker concerns regarding fatigue and the work scheduling practices that are common during outages, the incidence of impairment from fatigue is likely greater than the very low incidence of drug and alcohol use that is detected through testing. The NRC therefore considers the reporting of information pertaining to licensee management of worker fatigue consistent with the requirements for reporting information pertaining to drug and alcohol testing, consistent with the performance objective of this rulemaking for licensees to implement a comprehensive FFD program, and consistent with NRC's belief that the management of worker fatigue is no less important to worker fitness for duty than the effective detection and deterrence of drug and alcohol use.

(2) Public confidence -- Public interest stakeholders such as the Union of Concerned Scientists and the Project on Government Oversight have commented at public meetings that much relevant information regarding worker fatigue is withheld to either protect alleger identity or in the case of security personnel, plant security. In addition, several public media articles have been published during the past 2 years reporting instances of guards sleeping and guards

fearing repercussions for refusing forced and excessive overtime. Information submitted by licensees in the annual reports would be publicly available and provide public stakeholders reassurance that the NRC is appropriately cognizant of licensee actions regarding fatigue management and that the NRC's oversight of these activities is transparent to all stakeholders.

(3) The burden is limited and justified – Section 26.203(e) requires the information concerning waiver use and fatigue assessments to be reported as part of the annual FFD program report. As a consequence, the burden associated with this reporting requirement is an incremental change to the reporting requirement for drug and alcohol testing. In addition, the fatigue management information that § 26.203(e) requires licensees to report is largely information that licensees would already have generated in order to comply with other provisions of Subpart I. As a result, the burden associated with the report would largely be associated with compiling the information in a form appropriate for the report and reviewing that compilation. The NRC has reviewed the public comments asserting that the NRC underestimated the number of clerical and management hours associated with this requirement, and have taken these comments into consideration in estimating the burden of the reporting requirements in § 26.203(e) of the final rule. Nevertheless, the NRC considers the burden justified for the reasons described in this and the preceding paragraphs concerning the annual report requirements in § 26.203(e). Therefore, the NRC has retained requirements for an annual report containing information pertaining to fatigue management in § 26.203(e) of the final rule.

11.3. Work Hour Controls (§ 26.199)

Support for Work Hour Controls

Comments: Several commenters generally addressed the work hour control provisions. One commenter stated that the work-hour limits are reasonable, and will ensure that fatigue will be managed at facilities where the heavy use of overtime for extended periods has become routine. It noted that the work-hour limits will only impose a regulatory burden on licensees commensurate with the safety backfit achieved [Richard Barkley, Individual].

NRC Response: The comments do not require a response.

Layers of Requirements are Ineffective and Burdensome

Comments: The commenters argued that short term individual work hour limits address acute and cumulative fatigue, so additional "layers" of prescriptive requirements would be ineffective and burdensome to industry [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the comment that short-term individual work hour limits are adequate to address cumulative fatigue. The short-term individual limits allow up to 72 hours of work per week, excluding turnover time and time worked under waivers, and require only a minimum 10-hour break between successive work periods. The minimum break period of 10 hours does not provide reasonable assurance that individuals will obtain adequate rest when

individuals are working long work days with few days off. Cumulative fatigue will result from the extended work periods combined with reduced sleep periods as individual forego sleep to attend to daily living obligations. Such fatigue effects were reported by security personnel in the months following the terrorists attacks of September 11, 2001. In those instances the NRC found that the security personnel were typically working fewer hours than would be allowed by the short-term individual limits. However, the NRC agrees with the objective of reducing burden and eliminating unnecessary layers of requirements in the rule. In this regard the NRC notes that the NRC eliminated the requirements for a minimum 48-hour break and collective work hour limits that would have been required by § 26.199(d)(2)(iii) and 26.199(f) of the proposed rule and replaced these requirements with the minimum day off requirements of § 26.205(d)(3) of the final rule. The revised provisions will reduce burden and limit the potential for cumulative fatigue by preventing excessive use of the maximum work hours and minimum rest breaks permitted by the individual work hour controls.

11.3.1. Individuals Subject to Work Hour Controls (§ 26.199(a))

Expanding the Scope of Workers Subject to Subpart I

Comments: Some commenters stated that proposed § 26.199(a) limits the scope of the individuals subject to work hour controls to a subset of the work force; thus, those workers outside the scope of this section have no limits on their individual or collective work hours. They suggested that all workers should be subject to work hour controls [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC disagrees, in part, with the comment stating that all workers should be subject to work hour controls. Work hour controls are only a subset of the requirements included in this rule. Individuals who are not covered by the work hour controls in this subpart are still subject to broader fatigue management requirements. Section 26.203 establishes fatigue management requirements for licensees' FFD programs. Section 26.203(a) requires each licensee to have a written policy statement that describes its management's expectations and methods for managing fatigue to ensure that fatigue does not adversely affect any individual's ability to safely and competently perform his or her duties. Section 26.203(b)(1) requires licensees to develop, implement, and maintain procedures that describe the process to be followed any time an individual who is subject to the licensee's FFD program reports to a supervisor that he or she is unfit for duty because of fatigue (i.e., makes a self-declaration). These broad policy and procedure requirements, which apply to all workers, will provide clear expectations for all workers. In addition, § 26.203(c) requires licensees to train all individuals subject to the licensee's FFD program in fatigue management, including shift work strategies for obtaining adequate rest and effective use of fatigue countermeasures.

For the subset of requirements covering work hour controls, subjecting all workers to work hour controls, regardless of job function, would be impractical, burdensome to both individuals and licensees, and would not significantly improve public health and safety or the common defense and security. In determining the scope of personnel who would be subject to the proposed work hour controls, the NRC considered the burdens on individuals and licensees associated with the practical control of work hours in conjunction with the potential for individuals' work activities to affect public health and safety or the common defense and security if their performance is degraded by fatigue. The NRC also considered the nature of these individuals' work activities

and work environments relative to their potential to induce or exacerbate fatigue, the risk significance of the work, and the potential for other controls to prevent or mitigate the consequences of a fatigue-related error. As a result of these deliberations, only the individuals who perform the types of job duties specified in § 26.4(a)(1) through (a)(5) must be subject to the proposed work hour controls.

Therefore, the NRC retains the requirements for the work hour controls for the narrower scope of workers. The NRC also retains in § 26.203 the requirements for management of fatigue, including the policy and procedure and training requirements for all workers. Therefore, no additional changes are warranted in response to this comment.

"On-Site Directing" and the Inclusion of Engineering Personnel

Comments: Another commenter, supported by many commenters, raised concerns regarding the use of "on-site directing" in § 26.199(a)(1) and (a)(2). The commenter stated that the term "directing" has added uncertainty to who should be included in the functional work groups and suggested that the NRC clarify the definition of this term. Also, by using "on-site directing" in these subparagraphs, the commenter argued that this definition could be interpreted to include engineering and technical support personnel, and maintaining records on this group in addition to the job duty groups that are clearly defined could present a burden to utilities. Thus, the commenter recommended changing "on-site" to "job-site" in subparagraphs § 26.199(a)(1) and (a)(2). The commenter argued that this change would make these provisions consistent with the definition of "directing," which clearly focuses on individuals directly involved with the performance of the work activity [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees with the commenter that the definition of the term "directing" should be clarified. Individuals who are responsible for the correct performance of risk-significant work should be subject to work hour controls, including engineering and technical support personnel.

The revised definition of "directing," is presented in § 26.5 of the final rule. The revised definition clarifies NRC's expectations that a limited scope of personnel providing technical input would be subject to the requirements of § 26.205. The definition explicitly states the criteria that the term "directing" refers to an individual who is directly involved "in the execution of the work activity, or is ultimately responsible for the correct performance of that work activity" as opposed to, for example, the planning, development or scheduling of the activity, and that the technical input does not receive "subsequent technical review." The revised definition more clearly focuses on activities that have the potential to substantively and immediately affect safety.

The work hour requirements in § 26.205 also apply to individuals who direct risk-significant operations on site. These individuals include management on shift, such as shift operations management or special outage managers if those individuals provide direction to operators. Individuals to whom the work hour requirements apply also include engineers who provide onsite

technical direction to operations, such as test directors or reactor engineers. These individuals perform tasks that are often highly dependent on cognitive skills (e.g., problem-solving, decision-making, communications) and are susceptible to fatigue-induced errors, as described in Section IV.D of the preamble to the final rule. Incorrect technical direction provided to operators can significantly challenge licensed operators and increase the possibility of errors or events, especially when the direction is provided by an individual who supervises the operators, or an individual who the operator reasonably expects to have specialized technical knowledge of the system or component being operated.

The work hour requirements also apply to those who direct risk-significant maintenance on site. For example, these individuals include maintenance supervisors who provide direction to maintenance technicians, and engineers who provide onsite technical direction to maintenance crews, such as during key outage maintenance activities. These individuals perform tasks that are often highly dependent on cognitive skills (e.g., problem-solving, decision-making, communications) that are susceptible to fatigue, as discussed in Section IV.D of the preamble to the final rule. Incorrect technical direction provided to maintenance technicians can significantly challenge maintenance technicians and increase the possibility of errors or events, especially when that direction is provided by an individual who supervises them, or an individual who the maintenance technician reasonably expects to have specialized technical knowledge of the system or component being maintained.

The NRC disagrees with the comment that the rule language should be revised to change "on-site" to "job-site." Whether the directing is occurring at the job site or in a nearby room by phone is not relevant. Another commenters regarding the definition of "directing" asserted that engineers will not go out into the field to troubleshoot, for fear of being subject to work hour controls, and this is also a reason why work-hour controls should apply to individuals providing "on-site" direction.

In summary, the NRC has revised the definition for "directing" in § 26.5 of the final rule and clarify to whom the requirement should apply.

Expansion of Scope for Work Hour Limits

Comments: Other commenters stated that the proposed work-hour limits should be imposed on all licensee employees and supervisors who perform safety-related work instead of being limited to the work groups listed in the proposed rule. The commenter argued that all workers who perform safety-related work, as well as the individuals who supervise that work, be fit for duty [Barry Quigley, Individual; Anonymous #75]. One commenter stated that if such an expansion of the rule is not possible, then at a minimum, system engineers be included in the scope of this rule, as their job task assignments often require prompt response to the facility and decision-making that can immediately affect the ability to operate safety-related equipment [Richard Barkley, Individual]. Another commenter also addressed this issue and argued that engineering personnel performing or directing safety-related work be included in the scope of the rule [Barry Quigley, Individual].

NRC Response: The NRC disagrees, in part, that the proposed work-hour limits should be imposed on all licensee employees and supervisors who perform safety-related work instead of being limited to the work groups listed in the proposed rule. (See NRC response to comment

"Expanding the Scope of Workers Subject to Subpart I" at the beginning of Section 11.3.1). However, the NRC agrees that engineers directing safety-related work be included in the scope of this rule, as their job task assignments often require prompt response to the facility and decision-making that can immediately affect the ability to operate safety-related equipment.

The NRC revised the definition of "directing," which is presented in § 26.5 of the final rule. The revised definition clarifies NRC's expectations that a limited scope of personnel providing technical input would be subject to the requirements of § 26.205. The definition explicitly states the criteria that the term directing refers to an individual who is directly involved "in the execution of the work activity, or is ultimately responsible for the correct performance of that work activity" as opposed to, for example, the planning, development or scheduling of the activity, and that the technical input does not receive "subsequent technical review."

These individuals include engineers who provide onsite technical direction to operations and maintenance personnel, such as test directors or reactor engineers. These individuals perform tasks that are often highly dependent on cognitive skills (e.g., problem-solving, decision-making, communications) and are susceptible to fatigue-induced errors, as described in Section IV.D of the preamble to the final rule. Incorrect technical direction provided to operators or maintenance personnel can significantly challenge licensed operators and increase the possibility of errors or events, especially when the direction is provided by an individual who the operator reasonably expects to have specialized technical knowledge of the system or component being operated.

Therefore, the NRC retains the requirements for the scope of the working hour controls and the scope of the requirements in § 26.203 for the management of fatigue, including the policy, procedure, and training requirements for all workers. In addition, the NRC has revised the definition for "directing" so that the definition as applied to the direction of operations and maintenance personnel appropriately includes a limited scope of engineering functions that can have an immediate effect on the safe operation of the plant.

Fire Brigade

Comments: Several commenters from industry expressed disagreement with § 26.199(a)(4). Specifically, the commenters stated that the fire brigade member who is responsible for understanding the effects of fire and fire suppressants on safe shutdown capability should not be subject to work hour controls because of the administrative burden. The commenter recommended that § 26.199(a)(4) be deleted from the draft rule [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the comment that fire brigade members should be deleted from the work hour controls because of the administrative burden. In response to other comments, the NRC has eliminated group work hour controls from the final rule. Thus, fire brigade members' work hours are no longer required to be analyzed as a group. The NRC expects this change will eliminate any excess administrative burden. However, fire brigade members remain subject to the individual work hour controls specified in proposed § 26.199(d).

Fire brigade members must retain the cognitive ability to be able to think and determine the best way to suppress a fire to prevent additional damage to safety-related equipment, evaluate equipment affected by a fire to report to control room operators concerning equipment availability, make decisions concerning smoke ventilation to prevent the fire effects from affecting other plant operations, and coordinate all activities with control room operators. Attachment 1 to SECY-99-140, “Recommendation for Reactor Fire Protection Inspections,” dated May 20, 1999, states that "based on IPEEE results, fire events are important contributors to the reported core damage frequency (CDF) for a majority of plants. The reported CDF contribution from fire events can, in some cases, approach (or even exceed) that from internal events."

Fatigue can substantially degrade a worker’s decision-making and communication abilities, cause a worker to take more risks, and cause a worker to maintain faulty diagnoses throughout an event. These abilities are key to the duties of the fire brigade members who are responsible for understanding the effects of fire and fire suppressants on safe shutdown capability for the reactor. Degradations of these abilities could have significant consequences on the outcome of an event involving a fire. For instance, a fatigued worker could incorrectly decide to vent smoke or toxic gas to an area required for alternate shutdown, which could prevent or impair access to equipment needed for safe shutdown of the plant. In addition, a fatigued worker could incorrectly apply the wrong fire suppressant, which could affect additional equipment in the plant. Further, impaired decision-making could lead a worker to improperly control flooding, which could impact other needed equipment, or could incorrectly determine whether an area contains critical equipment and improperly apply a suppressant in that area. Impaired communications could also lead to incomplete disclosure of information to licensed operators in the control room, which could adversely impact the decision-making of those operators. If information known to the impaired worker is not properly communicated, operators may not initiate appropriate actions to mitigate the fire effects, or effects of suppressant activities, on critical equipment.

Ensuring that the ability of fire brigade members to safely and competently assess the effects of a fire and fire suppressants on safe shutdown capability is essential to the overall success of the fire mitigation strategy and the protection of public health and safety. Therefore, because the comment does not present new information or any explanation of unique administrative burden, the NRC will continue to subject fire brigade members to the requirements of Subpart I in the final rule.

11.3.2. Calculating Work Hours (§ 26.199(b))

Support for Exclusion of Turnover Time

Comments: Several commenters from industry supported the exclusion of turnover time as discussed in the rule package [Michael Coyle, NEI #49; Danny Todhunter, Exelon; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The comments do not require a response.

Definition of Shift Turnover

Comments: A commenter stated that the exclusion of shift turnover time from individual work hours was abused in the past, and defining shift turnover time is a step in the right direction. However, the commenter stated that proposed § 26.199(b)(1)(i) would define shift turnover as only those activities that are "necessary to safely transfer information and responsibilities between two or more individuals between shifts." The commenter argued that activities considered to be "necessary" is open to interpretation, and, as a result, there will be continued abuse of shift turnover. Also, the commenter explained that the language appears to allow both on-coming and off-going time to be subtracted; in essence allowing the licensee to "double dip" on how much turnover time can be subtracted. Thus, the commenter felt that the turnover language was not clear and should be revised [Peter Hammill, PBNP].

Another commenter asked why turnover times are not counted as work hours, and argued that turnover is "work" [Anonymous #29].

NRC Response: The NRC agrees in part with these comments. The NRC recognizes that shift turnovers are important for communicating plant status information between work crews. However, the NRC also recognizes that shift turnovers routinely add time to the length of a shift and workweek, and including shift turnovers in work hour calculations may cause indirect pressure on individuals to abbreviate shift turnovers in order to ensure that they do not violate work hour limits. This pressure may compromise the quality of shift turnovers and have unintended adverse safety consequences. Therefore, although the commenter and other stakeholders believe that turnover is part of the workday and should be included in work hour calculations, the NRC believes the benefit of including turnover for managing worker fatigue would be outweighed by the potential adverse consequences on the quality of shift turnovers, if turnovers were subject to time limits.

Section 26.205(b)(1) of the final rule defines shift turnover as only those activities that are necessary to safely transfer information and responsibilities between two or more individuals between shifts. In addition, § 26.205(b) provides specific examples of activities that licensees may and may not exclude as part of turnover to provide clear exceptions regarding NRC's intent. Although questions or differences in opinion may arise regarding what transfer of information is necessary to support safe operations, the rule will limit the potential for individuals and/or licensees to use the proposed shift turnover exclusion to perform other unnecessary work activities and addresses NRC concerns arising from observations that some licensees have occasionally excluded 2 or more hours from calculated work hours on the basis that the individuals were engaged in "turnover."

In order to ensure that turnover is not hurried, the rule does not establish a time limit for an acceptable turnover period. However, by clearly delineating the activities that licensees may consider to be turnover activities, the rule reduces the potential for individuals and/or licensees to use the shift turnover exclusion to perform other work activities.

Post-Turnover Technical Assistance

Comment: One commenter suggested that the NRC add the following sentence after the third sentence in the subparagraph § 26.199(b)(1)(i): "Relieved individuals observing rest break(s)

contained in § 26.199(d)(2) that are contacted by telephone to discuss job continuity and/or technical assistance by the licensee is considered shift turnover and is excluded for work hours accounting purposes." The commenter argued that the need for offsite technical assistance contact needs to be addressed because turnover does not always capture every detail that may cause a question to arise later after the worker has been relieved [Edwin Hill, IBEW].

NRC Response: The NRC agrees in part with the commenter's concern and has modified the final rule to allow short periods of technical assistance to be considered turnover and may be excluded from the work hour calculations. This provision is in § 26.205(b)(5) of the final rule. Licensees may exclude from the calculation of an individual's work hours unscheduled work performed off-site (e.g., technical assistance provided by telephone from an individual's home), provided the duration of the work does not exceed a nominal 30 minutes. For the purposes of compliance with the final rule minimum break requirements of § 26.205(d)(2) and minimum day off requirements of (d)(3), such duties do not constitute work periods or work shifts. This provision provides flexibility in the work hour controls to obtain expert advice or details on recent operating experience that may not have been included in a turnover without the burden that would be imposed by resetting the clock to account for the disruption in a break period. The nominal 30 minute duration of such reduction in the break period is not expected to have a detrimental impact on the individual's overall fatigue level and would be offset by the potential contribution to safety.

The revised requirements on post-turnover technical assistance are in § 26.205(b)(5) of the final rule.

Beginning/Resuming Job Duties in Calculation Period

Comment: With reference to § 26.199(b)(1)(iii), other commenters stated that the first sentence must be revised to read "Licensees *shall not* calculate the work hours of an individual ... [who] has not performed such duties during the applicable calculation period." The commenters argued that, as presently worded, this requirement would allow a licensee to pad the group work hour limit with workers qualified to perform duties but never actually performing said duties [David Lochbaum, UCS; Deborah Katz, CAN].

Another commenter, supported by many commenters, disagreed with the proposed language in § 26.199(b)(1)(iii). Specifically, the commenter stated that the proposed language is overly burdensome and too restrictive because it requires that a licensee include all hours worked by an individual who joins a functional work group at some point during the monitoring period. The commenter suggested that work hour controls should be applied once the individual starts to perform activities within the functional group. The commenter recommended changes to the rule language, striking the phrase "include in the calculation of the individual's work hours all work hours worked, including hours worked performing duties that are not listed in paragraph (a) of this section, and" from § 26.199(b)(1)(iii). [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG]. One other commenter argued that the individual limits of paragraph (d)

will be sufficient to meet the intent of § 26.199(b)(1)(iii) without the additional qualification [Brian McCabe, Progress Energy].

NRC Response: The NRC has not retained the collective work hour limits in the final rule. As a result the comment concerning the need to revise the wording of proposed § 26.199(b)(1)(iii) to prevent padding of collective work hour limit calculations is not applicable to the final rule. The NRC disagrees with the comment that when an individual resumes performing duties subject to the work hour controls, the calculation of work hours should not include all hours worked for the licensee. Section 26.205 of the final rule permits licensees to assign individuals, who are qualified to perform the duties listed in § 26.4(a), to other duties than those listed in proposed § 26.4(a), without controlling their work hours in accordance with the work hour controls contained in proposed § 26.205(d). However, if these individuals are assigned or returned to performing any duties that are listed in § 26.4(a) during the calculation period, the rule requires the licensee to include all of the hours that the individual worked when calculating the individual's work hours and to subject the individuals to the work hour controls in § 26.205(d).

Section 26.205(b)(3) requires licensees to count the hours that the individual worked performing other duties if an individual begins performing the duties listed in § 26.4(a) during the calculation period because the individual's level of fatigue is largely dependent on the total number of hours he or she has worked, regardless of the relationship of the work to maintaining plant safety or security. Therefore, including the hours worked performing other duties provides assurance that fatigue does not compromise that individual's ability to safely and competently perform the duties that are specified in § 26.4(a).

Therefore the NRC retains the requirements of proposed § 26.199(b)(1)(iii) in § 26.205(b)(3) of the final rule.

Calculating Collective Work Hours

Comment: One commenter, supported by many commenters, recommended revisions to § 26.199(b)(2)(ii) and (iii) to replace "individuals" with "security personnel" and "any job duty group" with "the security job duty group." [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC has eliminated the referenced requirements, therefore the comment is not applicable to the requirements of the final rule.

11.3.3 Work Hours Scheduling (§ 26.199(c))

Support for Work Hours Scheduling Provision

Comments: Several commenters addressed work hour scheduling and stated that the work hour guidance in proposed § 26.199(c) is an important feature of the proposed rule. They explained that this section represents a performance-based requirement that allows licensees to

design effective fatigue management programs. In addition, the commenters stated that the importance of this provision is not adequately expressed in the rule package [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees with the commenters' support for this provision and notes that the requirement is retained in the final rule as § 26.205(c). During the development of the proposed rule the NRC had intended this requirement to be limited to the development of work schedules. However, the NRC acknowledges the benefit of implementing this provision as a performance-based requirement applicable to licensee control of the actual hours worked by individuals performing the duties specified § 26.4(a)(1) through (a)(5) and adopts this interpretation for the final rule. As a consequence this provision of the final rule requires the work hours of individuals subject to the requirements of this section to be controlled in a manner that prevents impairment from fatigue because of elements of routine schedules that can significantly affect worker fatigue, such as shift length, the number of consecutive shifts, the duration of breaks between blocks of shifts, and the direction of shift rotation.

Opposition to Work Hours Scheduling Provision

Comments: A commenter argued that § 26.199(c) should be eliminated because it lacks the clarity necessary for consistent implementation and enforcement, and it is unnecessary given the numerous layers of prescriptive work hour limits which accomplish the same objective of preventing impairment from fatigue because of the duration, frequency, or sequencing of successive shifts [Brian McCabe, Progress Energy].

One commenter stated that the proposed rest break provisions and individual work hour controls, if implemented at the upper limits of what would be allowed, could result in work schedules that are not based on the 24-hour biological clock. The commenter argued that if these upper limits of scheduling were allowed in the final rules, there could be facilities that misinterpret these limits as being the established upper boundaries for safe operational performance, and as a result, impose work schedules on employees that actually produce unsafe levels of fatigue – at the plant or when the employee drives home. Therefore, the commenter suggested that the NRC make an additional effort to provide clear guidance regarding the systematic scheduling of 24/7 operations that are consistent with a 24-hour day. Additionally, the commenter suggested that the NRC take steps to add provisions that would encourage licensees to make shift rotations that are not only in keeping with the basics of sleep and human performance research, but are predictable and stable [Darrel Drobnich, NSF].

Two commenters argued that because of the way the proposed rule was written, it is difficult to comply with both proposed § 26.199(c) and § 26.199(d). The commenters stated that there is no mechanism in place in Subpart I for NRC review and approval of routine shift schedules that meet the intent of § 26.199(c). Thus, licensees will have to default back to the guidance of § 26.199(d) and develop schedules that would meet the requirements of this section even though the NRC stated that they are not intended as guidelines or limits for routine work scheduling [D.M. Jurss and Peter Hammill, PBNP].

NRC Response: The NRC agrees in part that § 26.199(c), retained as § 26.205(c) in the final rule, establishes a high level objective for scheduling without providing prescriptive requirements. The maximum work hour and minimum break and day off requirements that are specified in § 26.205(d) are intended for infrequent, temporary circumstances, and not as guidelines or limits for routine work scheduling. In addition, the work hour controls in proposed § 26.205(d) would not address several elements of routine schedules that can significantly affect worker fatigue, such as shift length, the number of consecutive shifts, the duration of breaks between blocks of shifts, and the direction of shift rotation. Therefore, § 26.205(c) requires licensees to schedule personnel consistent with preventing impairment from fatigue from these scheduling factors.

The rule requires licensees to address scheduling factors because human alertness and the propensity to sleep vary markedly through the course of a 24-hour period. These circadian rhythms are the result of changes in physiology outside the control of the individual. Work may be scheduled, and the consequent timing of periods of sleep and wakefulness, in a manner that either facilitates an individual's adaptation to the work schedule or challenges the individual's ability to get adequate rest. Therefore, the duration, frequency, and sequencing of shifts, particularly for personnel who work rotating shifts, are critical elements of fatigue management. The effect of circadian rhythms on worker fatigue is also discussed in Section IV. D. The importance of these elements for fatigue management is reflected in guidelines for work scheduling, such as, EPRI NP-6748 (Baker, et al., 1990), and in technical reports, such as, NUREG/CR-4248 and the Office of Technology Assessment's report, Biological Rhythms: Implications for the Worker (Liskowsky, 1991). Although research provides clear evidence of the importance of these factors in developing schedules that support effective fatigue management, the NRC also recognizes that the complexity of effectively addressing and integrating each of these factors in work scheduling decisions precludes a prescriptive requirement. Therefore, § 26.205(c) establishes a non-prescriptive, performance-based requirement.

During the development of the proposed rule the NRC had intended this requirement to be limited to the development of work schedules. However, the NRC acknowledges the benefit of implementing this provision as a performance-based requirement applicable to licensee control of the actual hours worked by individuals performing the duties specified in § 26.4(a)(1) through (a)(5) and adopts this interpretation for the final rule. As a consequence this provision of the final rule requires the work hours of individuals subject to the requirements of this section to be controlled in a manner that prevents impairment from fatigue because of elements of routine schedules that can significantly affect worker fatigue, such as shift length, the number of consecutive shifts, the duration of breaks between blocks of shifts, and the direction of shift rotation.

Because there are many ways to construct schedules, the industry and the NRC acknowledge that it would be more appropriate to put details in a guidance document. This guidance would make it clear that meeting maximum work hour limits or minimum break requirements by themselves would not satisfy § 26.205(c). Industry stakeholders have proposed that guidance be developed, which would assist in the interpretation and implementation of § 26.205(c). A letter from J. W. Davis, Nuclear Energy Institute, to D. R. Desaulniers, dated March 8, 2006, suggested the development of such guidance and proposed draft criteria or metrics to use in a guidance document (ADAMS Accession No. ML060680403). Such guidance would also support the implementation of § 26.205(e)(1), which requires licensees to review the work hours

and performance of individuals subject to the work hour requirements for consistency with the requirements of § 26.205(c). The NRC will consider endorsing the proposed guidance.

Site-Specific Schedule Approval

Comment: One commenter at the public meeting asked if the NRC has considered approving schedules on a site-specific basis [Anthony Rizzo, Jr, Salem Hope Creek].

NRC Response: The NRC disagrees with the comment that the NRC should consider approving schedules on a site-specific basis. In developing this rulemaking, the intent was to establish requirements that allow for a variety of approaches at a site-specific level, and still meet the overall requirements of § 26.205(c) and (d). In the draft industry guidance applicable to § 26.205(c), (ADAMS Accession No. ML060680403), some example schedules are included as appendices. The NRC will consider endorsing the proposed guidance, however, because of the complexities associated with establishing schedules, it is unlikely that the NRC will specifically endorse those examples. It will be the responsibility of the licensee to establish a schedule that meets the intent of § 26.205(b) through (d) and adhere to that schedule in accordance with endorsed criteria included in the guidance.

11.3.4. Work Hour Controls for Individuals (§ 26.199(d))

Support for Work Hour Controls

Comments: Several commenters from industry supported the individual work hour limits in proposed § 26.199(d)(1) because they are effective in preventing both acute and cumulative fatigue [Michael Coyle, NEI #49; John Cowan; NEI; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees with the comments that support these provisions. However, the NRC does not agree with the assertion that the individual work hour controls in § 26.205(d)(1) are adequate to address cumulative fatigue caused by excessive overtime. To address cumulative fatigue, the final rule includes requirements for rest breaks in § 26.205(d)(2) and the minimum number of days off averaged over a shift cycle in § 26.205(d)(3) and the minimum days off per 15-day block in § 26.205(d)(4) and (5). These provisions will prevent excessive use of the maximum work hours and minimum rest breaks that would be permitted under the proposed individual work hour controls and ensure that the potential for cumulative fatigue, which would otherwise adversely affect the abilities of individuals to perform functions that are important to maintaining the safety and security of the plant, is managed.

Switching between Day and Night Shifts

Comment: One commenter referenced the changing of shifts between night and day and asked: “Do the new rules specify switching between nights, days, nights and then back to days all in one week?” The commenter also suggested that the rule should include language about

changing between shifts to prevent fatigue. Specifically, the commenter suggested "only one switch between nights and days ... in a seven day period when a worker is working 12-hour [shifts]" [Ethan Darrow, Individual].

NRC Response: NRC agrees that some shift schedules can exacerbate fatigue. Section 26.205(c) in the final rule addresses the sequencing of work shifts to prevent impairment from fatigue. Consistent with that provision and anticipated guidance, the NRC expects licensees to develop shift schedules that prevent impairment from fatigue associated with switching between day and night shifts. The final rule also includes additional flexibility in the break and day-off requirements such that licensees will be better able to develop shift schedules that minimize the circadian cycle disruption caused by rotating shifts. Specifically, licensees are not required to provide two consecutive days off, which reduces the potential for adversely affecting circadian adjustment to night shifts.

Negative Impact on Nuclear Power Workers

Comment: Several commenters stated that the proposed rule work-hour limits will have a significant negative financial impact on nuclear power workers by limiting the hours they are allowed to work. One commenter also argued that the proposed rule would produce an out-flow of experienced workers from nuclear facilities to other industries where work hours are not limited, and this loss of experienced workforce will result in the reduction of public health and safety and common defense and security. Further, the commenter argued that this rule language will result in increased contract work to outside entities, which constitutes "union busting" at its most basic level and will contribute to the creation of a hostile work environment at nuclear power facilities [Andrew Antrassian, UWUA]. Another commenter stated that he is re-evaluating his retirement plan because it was based on his previous work during outages. The commenter argued that the work hour provisions will limit the amount of time he will be able to work on outages, thus decreasing his income [Daniel Hansen, Individual].

NRC Response: The NRC disagrees with these comments. The NRC has documented concerns regarding frequent excessive use of work hours in SECY-01-0113, Fatigue of Workers at Nuclear Power Plants," and SECY 05-0074, Proposed Rule to Amend the Fitness-For-Duty Requirements in 10 CFR Part 26. Therefore, establishing clear and enforceable requirements for the management of worker fatigue is indeed necessary to ensure against worker fatigue adversely affecting public health and safety and the common defense and security. Further, the requirements provide a significant amount of flexibility when establishing schedules and they do not dictate or endorse any specific schedule. Therefore, the requirements should not unduly restrain collective bargaining agreements. The NRC also notes that the work hour limits allow for substantial amounts of overtime, allowing approximately a 20% overtime rate when a plant is operating and approximately a more than 50% overtime rate when a plant is in an outage. Furthermore, these limits are only applicable to individuals who are performing duties on systems, structures, or components that a risk-informed evaluation process has shown to be significant to public health and safety, or are performing critical emergency or fire response duties, or are members of the site security force performing duties necessary for execution of the site security plan. The rule does not limit the hours of individuals who are not performing these specified functions.

Limited Access to Supplemental Workers

Comments: Other commenters stated that the work hour restrictions would limit industry's access to supplemental workers. The commenters explained that the break requirements would encourage supplemental workers to seek out jobs in other industries that offer more overtime. Therefore, the commenters stated that this unintended consequence of the break requirements would harm licensees' ability to attract qualified workers. Without a consistent supply of experienced workers, the commenters warned that jobs would be delayed and turnovers would increase. In addition, the commenters predicted that more workers would seek second jobs to supplement their hours. As a result, total hours worked would not necessarily decrease [Michael Coyle, NEI #49; Daniel Hansen, Individual; Donald Lenski, Individual; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the comments and notes that the work hour requirements in Subpart I require the licensee to manage fatigue by limiting work hours, not compensation, as well as ensuring periodic breaks to enhance safety without unduly limiting overtime. The requirements allow for substantial amounts of overtime, up to 32 hours in a week, in excess of 400 hours per year for years without outages, and substantially more hours of overtime in years with outages. Also, in contrast to the commenters' concerns, the NRC believes that limiting work hours may attract and retain workers who perceive former work hours practices as excessive. Furthermore, the limits of the final rule are not substantially different from the limits in Generic Letter 82-12 and most licensees' Technical Specifications. In addition the work hour limits of Subpart I only apply to individuals who are performing duties on systems, structures, or components that a risk-informed evaluation process has shown to be significant to public health and safety, or are performing critical emergency or fire response duties, or are members of the site security force performing duties necessary for execution of the site security plan. The rule does not limit the hours of individuals who are not performing these specified functions.

Generic Letter 82-12

Comments: Commenters also stated that the individual work hour limits of proposed § 26.199(d)(1) are similar to the work-hour limits that are outlined in Generic Letter 82-12, and industry appreciates the minor change that was made to these limits, as it should eliminate inconsistency in the application of these limits [F.G. Burford, Entergy; Brian McCabe, Progress Energy; Jim Davis, NEI].

NRC Response: The comments do not require a response.

Impact on 8-hour Shifts

Comments: Many commenters opposed certain work hour controls because they decrease scheduling flexibility for the 8-hour shifts and will encourage 12-hour shifts [D.M. Jurss, PBNP; Peter Hammil; PBNP; John Cowan, NEI, Kevin Glidden, Individual; Jim Davis, NEI; Todd

Newkirk, IBEW; James Springfield, IBEW; Dennis Specha, Individual; Anonymous #34; Brian McCabe, Progress Energy; Gregory Halnon, First Energy; Anonymous #75; Ray Wacker, Individual]. Other commenters argued that 8-hour shifts allow adequate amounts of sleep between shifts, so the move to 12-hour shifts would be detrimental to nuclear plant workers in terms of preventing fatigue. [D.M. Jurss; PBNP; John Cowan, NEI; Doug Beck, First Energy]. One commenter argued that working 10 or 12 hour shifts would decrease the amount of time workers will be able to spend with their families [Doug Beck, First Energy].

To address this issue, one commenter suggested that the language of § 26.199(d)(2)(iii) be changed to: "A 48-hour break in any 14-day period, except during the first 14 days of any plant outage if the individual is performing the job duties listed in paragraph (a)(1) through (a)(4) of this section." The commenter also recommended adding subparagraph (iv) that states "A 24-hour break in any 8-day period if work hours scheduled under § 26.199(c) is based on an 8-hour shift schedule" [D.M. Jurss, PBNP].

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

Limit Consecutive Hours Worked to Ten

Comments: Another commenter stated that the proposed changes only address the "tail end" of the fatigue cycle, and the commenter suggested that the language limit the number of consecutive hours worked to ten [Jim Pulley, Clinton Power Station].

NRC Response: The NRC disagrees with the comment that the number of consecutive hours worked should be limited to ten hours. Limiting consecutive hours worked to 10 hours would effectively limit schedules providing 24-hour coverage to 8-hour shift lengths. A 10-hour shift length would not be practical and would not be based on a 24-hour clock and therefore would cause significant disruption of worker circadian shift cycles and worker fatigue. Although studies of worker fatigue in other industries have demonstrated deteriorating performance after 9 hours of duty, 12-hour shifts allow more tasks to be completed without a turnover, reduce the number of turnovers between shifts, and frequently allow individuals to turnover to the individuals that they relieved. As a result, 12-hour shifts improve job continuity and reduce the potential for error that can be introduced through the turnover process. The NRC considers these factors to mitigate, to some extent, the degradation in performance that may occur as a result of shift lengths in excess of 8 hours. In addition, many licensees have implemented 12-hour shifts for years and the NRC does not have information to indicate that the performance of individuals at sites with 12-hour shifts is substantively different from the performance of individuals at sites with using 8-hour shifts. As a consequence the NRC concluded that the information available at this time regarding the potential fatigue management benefit of limiting consecutive hours worked to 10 hours does not justify the substantial burden that would result from eliminating 12-hour shifts as a schedule option.

16 Work Hours in any 24 Hour Period – § 26.199(d)(1)

Comment: One commenter expressed concern about the individual work hour control in (d)(1)(i) that would allow 16 hours of work in any 24-hour period. The commenter acknowledged that 12 hour shifts have become increasingly common at U.S. nuclear power plants and that the NRC has proposed provisions (§ 26.199(d)(1)(ii), § 26.199(d)(2)(i)) that would restrict or dissuade the use of 16-hour days. However, the commenter stated that allowing the possibility of 16-hour days for personnel in safety-sensitive positions is counterproductive and potentially hazardous. The commenter stated that the proposed 16-hour value appears to imply that (1) fewer than 8 hours of sleep will be acquired between work shifts, which is insufficient as the NRC itself has noted, or (2) the report time will slip from day to day causing circadian instability, which should not be acceptable. Therefore, the commenter suggested that the maximum number of work hours should be 10 hours per 24 hours for people on 8-hour shifts and 14 hours per 24 hours for people on 12-hour shifts [Darrel Drobnich, NSF]. Another comment stated that workers should not be working more than 8 hours per day [Anonymous #76].

NRC Response: The NRC agrees in part with the commenterers in that the routine use of 16 hour shifts is inappropriate for fatigue management. Attachment 1 to SECY-01-0113 provides the basis for this proposed limit, which is summarized as follows: Studies have shown that task performance declines after 12 hours on a task (Folkard, 1997; Dawson and Reid, 1997; Rosa, 1991). Other studies have shown that the relative risk of having an accident increases dramatically after 9 consecutive hours on the job (Hanecke, et al.,1998; Colquhoun, et al.,1996; U.S. DOT, 49 CFR Parts 350, et al., Proposed Rule, May 2, 2000, 65 FR 25544). Further, a maximum of 12 work hours per day was the limit recommended by nine experts who met in 1984 to develop recommendations for NUREG/CR-4248. Therefore, in originally developing the NRC's Policy on Worker Fatigue, the NRC had planned a 12-hour maximum limit, but revised it to 16 hours in response to practical concerns from industry that the 12-hour limit required personnel who worked 8-hour shifts to split shifts when they work overtime. Those practical concerns remain valid, and the final rule retains a 16-hour limit in § 26.205(d)(1)(i).

Although the rule permits 16-hour shifts, other work hour limits in the rule would effectively limit the number of 16-hour shifts that licensees could assign. Because of this the final rule has requirements that will substantially limit their use. Specifically, the 10-hour break requirement in § 26.205(d)(2)(i) will be applicable to all individuals subject to work hour controls. As a consequence, an individual would not be eligible to return for the beginning of the next normally-scheduled shift without a 10-hour break, and therefore would likely have a day off following a 16-hour shift.

Support for Ten Hour Between-Shift Rest Break – § 26.199(d)(2)(i)

Comments: Many commenters supported the mandatory rest break provision in § 26.199(d)(2)(i) that increases minimum break time from eight hours to ten hours because it will effectively remove the potential for cumulative fatigue by improving operator alertness levels and providing an opportunity to meet an individual's sleep requirement and minimize any acute sleep loss [Kevin Glidden; Individual; Mike Jolley, Individual; Mark Rosekind, Altertness Solutions; Michael Coyle, NEI #49; Ethan Darrow, Individual; D.M. Jurss, PBNP; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory

Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG]. One commenter suggested that the rule package understates the importance of this provision [Michael Coyle, NEI #49].

NRC Response: The NRC agrees with the commenters' support for this provision, but does not agree that the 10-hour break is adequate for preventing impairment from cumulative fatigue. Inadequate rest breaks between shifts not only contribute to a long work day but also cause increased pressure for individuals to reduce their sleep time in order to meet the demands of both work and daily life, resulting in an increased potential for cumulative fatigue. Therefore, the NRC has included other rest break and day off requirements in the final rule to effectively manage the effects of cumulative fatigue. The provision in proposed § 26.199(d)(2)(i) has been retained as § 26.205(d)(2)(i) of the final rule.

Opposition to Ten Hour Between-Shift Rest Break

Comments: One commenter stated the issue of off-duty time is one of the most important issues considered by the NRC. It said that ten hours off between shifts is the very minimum that should be allowed to provide employees the opportunity to get adequate sleep. The commenter encouraged the NRC to consider raising this provision to at least 12 hours off between shifts [Darrel Drobnich, NSF].

One commenter suggested that the 10-hour break requirement has little value. The commenter explained that the few times when workers are applicable to the minimum 8-hour breaks are during "call-outs" or shift changes, but the new 10-hour requirement makes an exception for shift changes [Anonymous #75].

NRC Response: The NRC agrees that a 10 hour rest break is the minimum that should be allowed between work periods. The NRC disagrees that the minimum break period should be increased to 12-hours. In most cases at nuclear power plants, workers are allowed at least a twelve hour break, exclusive of turnover. Therefore, the NRC acknowledges that this provision is applied infrequently. However, in instances of extended shifts (holdovers) or unscheduled shifts ("call-outs"), the 10-hour between-shift break requirement is very important to protect against the effects of acute fatigue. Also, the NRC notes that the 10-hour break exception for shift changes is intended for entire crews when they change shift schedules or shift durations, and is not to be used on an individual or frequent basis. Such transitions may occur at the beginning or end of an outage or when new shift schedules are adopted. As a result, the NRC expects that these instances will be infrequent.

Although a longer minimum rest break requirement would provide greater assurance that individuals have adequate opportunities for sleep, the 10-hour break requirement provides adequate opportunity for rest when used infrequently, as is expected given other requirements in this rule. For example, § 26.205(d)(1)(ii) in the final rule limits individuals to working 26 hours in any 48-hour period. Although licensees could use routine 10-hour breaks in conjunction with atypical shift durations (e.g., alternating 12- and 14-hour shifts), the practical implications of these schedules, such as varied start times, make their use improbable. As a consequence, the 10-hour break requirement is sufficient to assure adequate rest during infrequent circumstances

in which individuals work extended hours (e.g., more hours than their typical 8-,10-, or 12-hour shift) and that rest opportunities will typically vary between 12 and 16 hours in duration.

The minimum 10-hour break duration also accommodates most scheduling circumstances for the common shift durations that are currently in use in the industry. A notable exception is that the 10-hour break requirement could potentially prevent an individual who has worked 16 hours straight (e.g., two consecutive 8-hour shifts) from returning to duty at the start of his or her next regularly scheduled shift. However, the 10-hour break requirement appropriately prevents the individual from working in this circumstance because the potential for degraded job performance resulting from fatigue would be substantial given the individual's continuous hours of work and limited opportunity to sleep. Accordingly the NRC retains the proposed rule provision for a minimum 10-hour break between work shifts in § 26.205(d)(2)(i) of the final rule.

Opposition to 24/7 and 48/14 Breaks – § 26.199(d)(2)(ii) and (iii)

Comments: Many commenters disagreed with some aspects of the rest break provisions in § 26.199(d)(2)(ii) and (iii). They stated that the 24-hour and the 48-hour rest breaks are unnecessary, duplicative of requirements in § 26.199(c), do not address practical implementation issues, will be disruptive of normal shifts, and would negatively impact industry [Michael Coyle, NEI #49; James Springfiled, IBEW; Keith Young, Ameren UE; D.M. Jurss, PBNP; Mark Rosekind, Alertness Solutions; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG; Ray Wacker, Individual].

One commenter, supported by many commenters, stated that fixed break requirements and collective work hour restrictions will lead to significant safety implications and could affect a licensee's ability to restore inoperable equipment in a timely manner. For example, the commenters stated that the break requirements would make it difficult to assign teams to provide 24-hour coverage to complete critical maintenance activities, or to restore inoperable safety equipment, which would result in longer outage times. The commenter also explained that the break requirements will make emergency plan and security drills more difficult to schedule and carry-out. If an individual has to participate on a required day off, there would be limitations on who could participate and there would be an increased need for waivers. According to the commenter, this would add another layer of complexity to planning drills [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

One commenter stated that while the rest breaks of § 26.199(d)(2) are intended to provide opportunities to recover from any cumulative sleep debt from preceding consecutive work periods, the ten-hour break provision would be adequate to obtain sufficient sleep and eliminate or minimize any potential acute sleep loss. Therefore, artificially requiring a 24 hour break every

7 days or a 48 hour break every 14 days is arbitrary and there is no scientific justification to support these specific numbers. [Mark Rosekind, Alertness Solutions].

Several commenters from industry stated that the "recovery concept" is scientifically supported, but the approach used to prevent cumulative fatigue should take into consideration existing work schedules and scheduling practices. The commenter explains that there is a problem with focusing on days off when facilities use 12-hour and 8-hour rotation schedules. Further, the commenter stated that there is no scientific basis for linking recovery breaks to any number of days less than 14 consecutive days. The commenter finds fault with focusing on days off without considering the number of hours worked in a particular day and the breaks between work periods. The commenter illustrates this point in a series of work-hour rotation schedule examples [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

A commenter, supported by many commenters, suggested that § 26.199(d)(2)(ii) should be revised to provide more equitable breaks during periods of normal operations. The commenter argued that a single set of break limits cannot be applied without undermining the viability of eight hour shift rotations, which industry supports. The commenter recommended deleting proposed § 26.199(d)(2)(ii) and replacing it with the following language:

(ii) During periods of normal operations:

(A) For a crew in a predominately 12-hour work schedule, an average of two 24-hour breaks per week over the nominal rotation cycle.

(B) For a crew in a predominately 8-hour or 10-hour work schedule, an average of one 24-hour break per week over the nominal rotation cycle.

(C) The nominal rotation cycle shall be between 4 and 6 weeks.

(D) Individuals are exempt from this requirement for the first 10 weeks of an outage in which the requirements of paragraph (d)(2)(iii) are applied.

[Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

Many commenters raised the issue of work schedule disruption as a result of the 48-hour break requirement in § 26.199(d)(2)(iii). They argued that, for workers on the night shift, having one day off provides an additional rest period and allows the worker to maintain a consistent pattern of work and sleep habits, which reduces the risk of accidents on the job. Two days off, however, may interfere with his or her sleep cycle, and as a result, the individual would have to readjust to the night shift after the two-day break. According to the commenters, some workers have stated that having two days off is worse than having no days off. They also argued that a 1-day break in any 7-day period is more than adequate when combined with other rule provisions to address cumulative fatigue. Thus, they requested that the 48-hour break requirement during outage periods be deleted. One commenter, supported by many other commenters, suggested that NRC replace this provisions with the following language: "During outage periods, in which the requirements of (d)(2)(ii) above are not applied [see above text for commenter suggestion for (d)(2)(ii) language], a 24-hour break in any 7-day period." [Dennis Specha, Individual; Danny

Todhunter, Exelon; Jim Waite, Exelon; Daniel Hansen, Individual; Jim Davis, NEI #48; Michael Coyle, NEI #49; Andrew Antrassain, UWUA; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG; C.L. Funderburk, Dominion].

NRC Response: The NRC agrees that alternative requirements can prevent and mitigate cumulative fatigue while providing licensees increased scheduling flexibility. A significant amount of research has shown that adequate rest breaks are necessary to ensure that licensees provide individuals with sufficient time off between work periods to permit the individuals to recuperate from fatigue and provide reasonable assurance that acute and cumulative fatigue do not compromise the abilities of these individuals to safely and competently perform their duties. However, the NRC has conducted further analysis of the proposed provisions and has concluded that alternative break and day off requirements can effectively support fatigue management while providing greater scheduling flexibility. Therefore, the NRC has modified the work hour controls applicable to periods of normal operations in the final rule.

In response to comments on the break requirement in § 26.199(d)(2)(ii) of the proposed rule, the NRC has revised the maximum number of days between the breaks. The revised requirement is in § 26.205(d)(2)(ii) of the final rule and requires a minimum 34-hour break in any 9-day period. In revising the requirement the NRC considered that although the final rule allows more consecutive work shifts for 8-hour and 10-hour shift schedules, the additional flexibility allowed by the final rule allows licensees to more readily optimize 8-hour shift schedules to minimize transitions between day, evening, and night shifts that can lead to worker fatigue. Although this relaxation also allows more consecutive shifts for individuals on 10-hour shifts, individuals on 10-hour shifts typically do not work a rotating schedule and therefore do not experience the disruption of their circadian cycle that exacerbates the cumulative fatigue effects of consecutive work shifts. The scheduling of 12-hour shifts is unaffected by this requirement because § 26.205(d)(1)(iii) effectively limits the scheduling of 12-hour shifts to not more than 6 consecutive days. The final rule requirement also provides flexibility to accommodate other practical considerations such as scheduling training on a Monday thru Friday basis and allows a contingency day for 8-hour shift schedules that include a series of 7 consecutive 8-hour shifts.

The final rule also revises the minimum duration of the break period from 24 hours, as specified in § 26.199(d)(ii) of the proposed rule, to a minimum 34-hour break in § 26.205(d)(2)(ii) of the final rule. The revision more clearly states NRC's intent to require a periodic "day off" in which individuals have the opportunity for 2 consecutive sleep periods without an intervening work period. The 34-hour break duration provides opportunity for 2 consecutive sleep periods without an intervening work period, supports use of forward rotating and fixed shifts, and allows for the possibility that individuals may work 26 hours in a 48-hour period contiguous to the break.

In response to comments on the proposed 48-hour break requirement (§ 26.199(d)(2)(iii)) and the collective work hour limit (§ 26.199(d)(2)(iii)) of the proposed rule, the NRC has not retained these requirements in the final rule. Rather, the NRC has replaced these requirements with alternative provisions in § 26.205(d)(3) for normal operations and § 26.205(d)(4)-(5) for unit outages, planned security system outages or increased threat conditions.

To address cumulative fatigue during periods when a plant is operating, § 26.205(d)(3) requires each individual subject to the work hour requirements to have a minimum average number of days off per week. This rule provision addresses comments on the 48-hour break requirement and collective work hour limits by addressing cumulative fatigue on an individual basis; by tailoring the breaks to the duration of the shift; by establishing a limit that allows the flexibility of distributing the minimum days off over a shift cycle of up to 6 weeks; and by establishing requirements that are practical and should impose less administrative burden on licensees than would have been required by the collective work hour limits.

These final rule provisions also address those comments on the 48-hour break that were applicable to outage periods, as follows:

(1) The minimum day off requirements of § 26.205(d)(4) and (d)(5) do not require licensees to schedule 2 consecutive days off as would have been required by the 48-hour break requirement. As a consequence licensees are better able to establish schedules that minimize the potential for circadian disruption for individuals on fixed night shifts.

(2) The minimum day off requirements of § 26.205(d)(4) and (d)(5) allow licensees substantial flexibility in scheduling the required days off within the 15 day outage period. As a consequence, licensees are able to implement a range of scheduling options to meet known outage schedule demands and have the flexibility to revise schedules as may be necessary to address emergent needs.

(3) The minimum day off requirements of § 26.205(d)(4) allow licensees to use a predictable repeating schedule. The requirement permits a schedule of 4 consecutive 12 hour shifts followed by 1 day off. This 5 day sequence can repeat 3 times in each 15-day period creating a schedule that is predictable and repeating, characteristics desired by workers and schedulers. It also limits the number of consecutive work shifts to prevent cumulative fatigue and includes sufficient periodic days off to mitigate fatigue.

(4) The minimum day off requirements of § 26.205(d)(4), in conjunction with the other requirements in § 26.205, allow a maximum work week of 72 hours and an average work week of 67.2 hours for a period up to 60 days. As a consequence, the requirement allows licensees to offer, within these limits, substantial amounts of overtime to attract supplemental workers for outage activities, while ensuring that schedules remain consistent with the management of worker fatigue. The NRC acknowledges that some individuals may want to work more than 72 hours, or even more than 84 hours, per week. However, the work hour limits of § 26.205 are applicable to only those duties that have the most direct impact on the protection of public health and safety and common defense and security. As a consequence, the requirements do not prevent individuals from working more than 72 hours per week unless those individuals are performing duties on systems, structures, or components that a risk-informed evaluation process has shown to be significant to public health and safety, or are performing critical emergency or fire response duties, or are members of the site security force performing duties necessary for execution of the site security plan. Accordingly the NRC has replaced the requirements in proposed § 26.199(d)(2)(ii) and (d)(2)(iii) with the requirements in § 26.205(d)(3) of the final rule. The NRC also notes that the final rule includes provisions to accommodate licensees performing unannounced emergency preparedness drills and security drills in response to comments that the break requirements would have made it difficult for licensees to schedule these activities. These provisions are in §§ 26.205(b)(4) and 26.207(b) of the rule, respectively.

Suggested Change to Rest Breaks

Comment: The commenter suggests that, rather than mandatory breaks, individuals should have the discretion to decline or exercise their right to a minimum break period. Specifically, the commenter suggested that NRC modify § 26.199(d)(2)(ii) to state: "A 24-hour break in any 7-day period; *or*" and § 26.199(d)(2)(ii)(A) to state: “During licensee normal operations for individuals identified in § 26.199(d)(4), a 24-hour break after completing 7 or 8 consecutive days of scheduled 8-hour shifts in any 14-day period activated as an individual option requiring reasonable notice by individuals to the licensee to observe the break period. Individuals who do not exercise this option do not require the licensee to adhere to individual waiver requirements in § 26.199(c)(3) unless subject to § 26.199(d). During plant outages § 26.199(d)(2)(ii)(A) is not applicable and § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii) is applicable to § 26.199(d)(4) individuals” [Edwin Hill, IBEW].

Similarly, the commenter suggested that NRC modify § 26.199(d)(2)(iii) to state: “A 48-hour break in any 14-day period activated as an individual option requiring reasonable notice by individuals to the licensee to observe the break period. Individuals who do not exercise this option do not require the licensee to adhere to individual waiver requirements in § 26.199(c)(3) unless subject to § 26.199(d), or” and § 26.199(d)(2)(iii)(A) should state: “During licensee normal operations for individuals identified in § 26.199(d)(4), a 48-hour break in any 14-day period during licensee normal operations. During plant outages § 26.199(d)(2)(iii)(A) is not applicable and § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii) is applicable to § 26.199(d)(4) individuals” [Edwin Hill, IBEW].

NRC Response: The NRC agrees in part with these comments. The break and day off provisions of the final rule in § 26.199(d)(2) through (d)(5) largely meet the commenter’s objective of providing workers and licensees increased flexibility in the distribution of breaks and days off, while allowing the licensee to retain scheduling authority.

Clarification of Rest Breaks

Comment: Another commenter stated that in the proposed rule, it is unclear whether the 24 and 48 hours off could be additive in 14-day period. The commenter asked: “would an individual get 24 hours off in a 7-day period and 48 hours off in a 14-day period, for a total of 72 hours off in the 14-day period?” The commenter suggested that the intent be clarified in the explicit language [Mark Rosekind, Alertness Solutions].

NRC Response: It was not NRC’s intent that the rest break provisions be additive in a 14 day period. Clarification of the NRC’s intent regarding these provisions is unnecessary, as the requirements for a minimum 24-hour break and a minimum 48-hour break have been modified in the final rule in § 26.205(d)(2)(ii) and § 26.205(d)(3) for normal operations and § 26.205(d)(4) through (5) for various outage conditions and these provisions provide a clearer set of requirements.

Exception During Outage

Comments: Other commenters expressed concern about the lack of work hour regulation during outage periods [Ethan Darrow, Individual; Anonymous #75]. In contrast, another

commenter argued the need for an exception from § 26.199(d)(2)(ii) to allow individuals to work for 14 consecutive days during the first two weeks of an outage or during other periods of high work activity [Daniel Stenger, NRSG].

NRC Response: The NRC does not agree that the work hour requirements applicable during outage periods should be made any more or less stringent as recommended by the commenters. Outages are unique, relatively short-term, and involve levels of activity that are substantially higher than most non-outage operating periods. Section 26.205(d)(4) and (d)(5) of the final rule establishes minimum day off requirements applicable to outages that accommodate the increased level activity of outages, but generally limits this more intensive scheduling to a period of 60 days to limit cumulative fatigue. Section 26.205(d)(6) allows an extension of the 60 day periods, but only for individuals who have had periods of less intensive scheduling during the outage. Although more restrictive requirements could perhaps provide greater assurance of worker fitness for duty, the NRC believes the burden on licensees would be excessive relative to the additional fatigue mitigation or prevention that would be gained. Regarding the recommendation to allow 14 consecutive days of work during outages or periods of high work activity, such a provision would allow work schedules with substantial potential for impairment of individuals from fatigue. Accordingly the NRC has not adopted the commenter's recommendation for the final rule.

Outage Length

Comment: One commenter stated that the former regulations allowed personnel to work hours over the guidelines with only a waiver and the ample use of turnover time. The commenter also argued that if the NRC is going to attempt to further limit work hours, then the NRC should mandate the length of an outage, and the commenter suggested a mandated 35 day outage. The commenter argued that if the NRC limits the hours of qualified in-house personnel but does not set a standard outage length, then companies will further rely on non-qualified contractor personnel to do critical work [Anonymous #dpr25].

NRC Response: The NRC does not agree with the comment that the NRC should mandate the length of an outage. The fatigue management provisions of § 26.207 establish criteria for the use of waivers that should substantially limit their use to conditions where warranted by safety or security considerations. Use of turnover time is limited by § 26.205(b)(1) so as to prevent abuse of the exclusion of turnover time from the work hour limits. The suggestion that the NRC limit outage length to prevent excessive work hours could effectively prevent licensees from completing maintenance necessary for the continued safe operation of the facility or create undue pressure to complete such activities within the allowed outage period. The NRC does not agree that the proposed limits will cause increased reliance on contractors, since the limits will also apply to contract personnel.

Conditions for Granting Waivers

Comment: One commenter argued that the process of extending work hours should be difficult for the utility, such that it will only occur under very unusual circumstances [Ethan Darrow, Individual].

NRC Response: The NRC agrees that waivers should only be granted in very unusual circumstances as originally stated in the NRC's Policy on Worker Fatigue. The potential for worker fatigue in conditions that require a waiver is substantial (Baker, et al., 1994; Dawson and Reid, 1997; Stephens, 1995; Strohl, 1999). Therefore, the provision in proposed § 26.199(d)(3) and as retained in § 26.207(a)(1)(i) of the final rule, clearly articulate that licensees must limit the granting of waivers to circumstances in which it is necessary to prevent or mitigate a condition adverse to safety or to maintain the security of the plant.

Also, as stated in § 26.207(a)(2) of the final rule, waivers can be granted only when such circumstances could not reasonably have been controlled. This requirement is necessary because conditions for meeting the waiver criteria that are specified in § 26.207(a)(1) could routinely result from inadequate staffing or work planning. Therefore, § 26.207(a)(2) prohibits the use of waivers in lieu of adequate staffing or proper work planning, for example, but would permit the use of waivers for circumstances that the licensee could not have reasonably controlled, which may include, but would not be limited to, equipment failures or a sudden increase in the personnel attrition rate.

Waiver in Lieu of Adequate Staffing

Comment: A commenter stated that § 26.199(d)(3)(ii) would prohibit the use of a waiver in lieu of adequate staffing, but then gives licensees an "out" by citing a sudden increase in personnel attrition rate as an example of a circumstance that the licensee could not have reasonably controlled, providing further justification for a licensee to stay at inadequate staffing levels [Peter Hammill, PBNP].

NRC Response: The NRC agrees that the waiver provisions allow licensees to use waivers to address a sudden decrease in plant staffing, if the conditions meet the waiver requirements. Specifically, the work to be conducted under the waiver must be necessary to prevent or mitigate a condition adverse to plant safety or security (as required by § 26.207(a)(1)(i) of the final rule), the individual to work under the waiver must be assessed face-to-face, and found fit to perform his or her duties during the additional work period (as required by § 26.207(a)(1)(ii) of the final rule), and, in this example, the sudden decrease in staffing could not have been reasonably controlled (as required by § 26.207(a)(2) of the final rule).

A licensee can reasonably assert that filling a position required by minimum staffing requirements is necessary to prevent or mitigate a condition adverse to safety or security. However, it is not the NRC's intent to allow waivers to compensate for deficiencies in staffing levels or other conditions that a licensee can reasonably control. Nevertheless, the NRC believes that it is reasonable to expect waivers to be used on a temporary basis to meet minimum staffing requirements if the loss of personnel could not have been reasonably controlled by the licensee. The rule would not allow the use of waivers for such conditions for an unlimited period of time because the licensee would eventually have time to respond to the condition and the NRC would consider the condition to be within reasonable control of the licensee. Given these considerations the NRC believes that the rule provision provides appropriate flexibility for conditions beyond the reasonable control of the licensee without providing licensees a blanket exception to use waivers to compensate for inadequate staffing. Accordingly the NRC has retained the provision in § 26.199(d)(3)(ii), which is presented in § 26.207(a)(2) of the final rule.

Insufficient Flexibility of Waivers

Comments: Several commenters from industry suggested that the waiver requirements in proposed § 26.199(d)(3) do not provide sufficient flexibility to grant a waiver to specific workers based on operational needs. They explained that there will be cases where a waiver would allow the completion of important work in a timely manner and would not result in any safety or security impact, and urged that management should have the flexibility to approve waivers in these cases. With the inclusion of the fatigue assessment and allowance for the individual to make a fatigue self-declaration, the commenters stated that this limitation is excessive and may represent a financial burden to the facilities. As a result, one commenter, supported by many commenters recommended adding "or a determination that the waiver is necessary for plant operations" to the end of § 26.199(d)(3)(i)(A) [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

Another commenter recommended that proposed § 26.199(d)(3)(i)(A) be modified to say: "An operations shift manager determines that the waiver is necessary to mitigate or prevent a condition adverse to safety or to support plant operational needs..." [Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenters' concern that the criterion that must be met in order to grant a waiver in proposed § 26.199(d)(3)(i)(A) may be overly-restrictive because it would prohibit the granting of waivers for conditions that could be cost-beneficial to the licensee without a substantive decrease in safety. The potential for worker fatigue in conditions that would require a waiver is substantial. Therefore, the NRC cannot conclude that licensees can reasonably justify the performance of risk-significant activities by individuals who have worked hours in excess of the work hour limits on the basis that granting the waiver would not have an adverse impact on safety or security. This would be inconsistent with the NRC's goal of providing reasonable assurance that an individual will be able to safely and competently perform his or her duties, and therefore this provision has not been substantially modified and is retained as § 26.207(a)(1)(i) in the final rule.

Approval Authority for Waivers

Comment: One commenter stated that the language in the rule implies that the operations manager is the approval authority. The commenter stated that the operations manager should be evaluating the situation and individual, however, the plant manager should be the authority "signing off" on the waiver because of the impact of work hours on fatigue [Ethan Darrow, Individual].

NRC Response: The NRC disagrees with the commenter. The final rule states in § 26.207(a)(1)(i) that the operations shift manager would make the determination of whether the waiver is necessary to mitigate or prevent a condition adverse to safety and the security shift manager would make the determination if the waiver is necessary to maintain the security of the plant. Operations shift managers and security shift managers have the requisite knowledge and qualifications to make the respective safety or security determinations, and making such

determinations is consistent with the scope of duties currently performed by individuals in these positions.

Before the waiver is granted, a face-to-face assessment by a supervisor who is qualified to direct the work to be performed is also required by the final rule in § 26.207(a)(1)(ii) to determine that there is reasonable assurance that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver will be granted. These determinations require knowledge of the specific skills that are necessary to perform the work and the conditions under which the work will be performed in order to assess the potential for fatigue to adversely affect the ability of an individual to safely and competently perform the work. This knowledge is generally limited to individuals who are qualified to direct the work.

In addition, § 26.207(a)(3) of the final rule requires that the waiver assessment be performed no more than four hours before the individual begins performing any work under that waiver, which will ensure that the individual will be fit-for-duty at the time the waiver is needed. Using the plant manager as the approval authority may increase the time that it takes for the waiver to get approved. Thus, using the operations or security shift manager, instead of the plant manager, as the approval authority will ensure that the appropriate personnel make the important waiver approval decisions and that the waiver process will not be abused.

Counting of Waivers

Comment: Another commenter stated that in many cases, waivers include a whole department or crew, so the counting of waivers does not give an accurate indication of how many workers are exceeding the work hour limits [Anonymous #75].

NRC Response: The NRC disagrees with the comment because the proposed rule required that a waiver may be granted to a particular individual under the circumstances outlined in proposed § 26.199(d)(3) only after that individual has undergone a face-to-face assessment to determine whether or not the individual will be able to safely and competently perform his or her duties during the additional period for which the waiver will be granted. As noted in SECY-01-0113, it has never been the NRC's intent in its Policy on Worker Fatigue or in the proposed rule that blanket waivers be granted for a large group of individuals. In addition, proposed § 26.199(d)(3)(iii) establishes a maximum period of four hours before the individual begins working under the waiver as the period within which the supervisory assessment must be performed. Finally, the reporting requirements in proposed § 26.197(e)(1) state that licensees must report waivers of work hour controls for individuals, not groups of individuals. Accordingly the final rule retains these reporting requirements in § 26.203(e)(1), and the waiver requirements in § 26.207(a)(1), (a)(3), and (a)(4).

Qualification of Supervisor Performing Face-to-Face Assessment

Comment: Referencing § 26.199(d)(3)(i)(B), one commenter stated that the phrase "qualified to direct the work to be performed" could inappropriately be linked to the definition of directing included in paragraph § 26.5, Definitions. The commenter further noted: "If, for example, an instrumentation calibration is required during the night and the Shift Manager determines that the adjustment is needed to prevent or mitigate a condition adverse to safety, an I&C supervisor would be notified to request at least one, probably two task qualified individuals to report to the

plant. The individual will report to the control room supervisor, who assumes oversight responsibilities during the performance of the task. The control room supervisor, although trained on the system and system interactions, may not be able to provide technical input for the calibration function that is being performed. As such, if the phrase "qualified to direct the work to be performed" is linked to the definition of directing, the I&C supervisor would also have to report to the site just to perform the fatigue assessment. This would result in an unnecessary prolonged interruption in the sleep cycle of more individuals than seems appropriate." Therefore, the commenter suggested that the wording "A supervisor, who is qualified to direct the work to be performed" be changed to "A supervisor, who is qualified to provide oversight of the work to be performed..." [F.G. Burford, Entergy]

NRC Response: The NRC agrees that requiring a supervisor to report to the site in the middle of the night for the purpose of conducting a fatigue assessment would be a significant burden and would be counterproductive for managing the fatigue of the supervisor. The proposed rule would have required that a supervisor, who is qualified to direct the work to be performed, assess the individual face-to-face to determine that there is reasonable assurance that the individual will be able to safely and competently perform the tasks during the period covered by the waiver. The purpose of the proposed requirement was to ensure that these determinations are made by individuals with knowledge of the specific skills that are necessary to perform the work and the conditions under which the work will be performed in order to effectively assess the potential for fatigue to adversely affect the ability of an individual to safely and competently perform the work. This knowledge is generally limited to individuals who are qualified to direct the work. In response to this comment the NRC revised the requirement to accommodate situations in which there is no supervisor on site who is qualified to direct the work. Accordingly, § 26.207(a)(1)(ii) of the final rule states that the assessment can be performed by a supervisor who is qualified to provide oversight of the work to be performed by the individual. Although this individual may be less familiar with the details of how the work is to be performed, the exception prevents the substantial burden of a licensee requiring a supervisor that is qualified to direct the work to report to the site to perform the assessment as well as preventing the potential fatigue of the supervisor if called in during the night. The NRC also notes that in all instances, the supervisor performing the assessment shall have the training required by §§ 26.29 and 26.203(c), which provide knowledge and abilities that are essential for a supervisor to make valid assessments in this regard. Among other FFD topics, the training addresses the contributors to worker fatigue and decreased alertness in the workplace, the potential adverse effects of fatigue on job performance, and the effective use of fatigue countermeasures.

The final rule retains the requirements in proposed § 26.199(d)(3)(i)(B), with the changes recommended by the commenter, in § 26.207(a)(1)(ii) of the final rule.

Face-to-Face Assessments for Waivers

Comment: One commenter stated that performing face-to-face fatigue assessments as proposed in the rule will be very difficult, no matter how well trained supervisors may become. The commenter noted that even sleep professionals would not rely on observation to determine how fatigued a person may be, and research demonstrates that most people experience cognitive decrements long before they start to exhibit physical manifestations of fatigue that may be observed by a supervisor or co-workers. The commenter argued that without some objective instrument or measure of fatigue, the system as proposed would be vulnerable to error and/or

abuse. The commenter suggested that NRC develop appropriate guidance for the implementation of training programs in relation to performing fatigue assessments [Darrel Drobnich, NSF].

NRC Response: The NRC agrees in part with the comments but notes that current technology for assessing fatigue has not matured to the state where it has been validated for regulatory use and has its own set of limitations in its ability to reliably detect impairment from fatigue. In lieu of such objective measure, the proposed rule would have required that the supervisor who will be conducting the face-to-face assessment to be trained in accordance with the requirements of § 26.29 and § 26.203(c), and must meet other minimum criteria necessary to effectively assess the potential for acute or cumulative fatigue. These requirements have been retained in § 26.29 and § 26.203(c) of the final rule. The required training will provide the knowledge and abilities that are essential for a supervisor to make valid assessments in this regard. Among other FFD topics, the training addresses the contributors to worker fatigue and decreased alertness in the workplace, the potential adverse effects of fatigue on job performance, and the effective use of fatigue countermeasures.

Section 26.207(a)(1)(ii) of the final rule requires that supervisors must perform the assessment face to face with the individual that he or she is assessing for the waiver. This requirement ensures that the supervisor who is performing the assessment has the opportunity to observe the individual's appearance and behavior to note indications of fatigue (e.g., decreased facial tone, rubbing of eyes, slowed speech) and interact with the individual to assess the individual's ability to continue to safely and competently perform his or her duties during the period for which the waiver will be granted.

Section 26.207(a)(1)(ii) of the final rule also requires that the supervisory assessment must address, at a minimum, the potential for acute and cumulative fatigue, considering the individual's work history for at least the past 14 days and the potential for circadian degradations in alertness and performance, considering the time of day for which the waiver will be granted. The potential for acute fatigue can be practically assessed by estimating the total number of continuous hours the individual will have worked by the end of the work period for which the waiver is being considered. The potential for cumulative fatigue can be practically assessed by reviewing the individual's work schedule during the past 14 days to determine (1) whether the individual had adequate opportunity to obtain sufficient rest, considering the length and sequencing of break periods; (2) whether the available sleep periods occurred during the night or at other times when sleep quality may be degraded; and (3) the potential for transitions between shifts (e.g., from days to nights) to have interfered with the individual's ability to obtain adequate rest. The potential for circadian degradations in alertness and performance can be practically assessed by considering the time of day or night during which the work would be performed, as well as the times of day of the individual's recent shift schedules.
Section 26.207(a)(1)(ii) in effect requires supervisors to address the three work schedule factors (i.e., shift timing, shift duration, and speed of rotation) that are generally considered to be the largest determinants of worker fatigue (Akerstedt, 2004; McCallum, et al., 2003; Mallis, et al., 2002; Folkard and Monk, 1980; Rosa, 1995; Rosa, et al., 1996). In determining the scope of the assessment, the NRC also recognizes the need for licensees to be able to focus the assessment on information that is readily available and could be verified.

Section 26.207(a)(1)(ii) further requires that the supervisory assessment for granting a waiver must address the potential for fatigue-related degradations in alertness and performance to affect risk-significant functions, and whether it is necessary to establish controls and conditions under which the individual is permitted to perform work. This requirement is consistent with the NRC's Policy on Worker Fatigue, which states that "the paramount consideration in such authorizations shall be that significant reductions in the effectiveness of operating personnel would be highly unlikely." However, § 26.207(a)(1)(ii) requires the supervisor to identify any risk-significant functions that may be compromised by worker fatigue, thereby focusing the assessment on worker activities that have the greatest impact on the protection of the public, considering the types of skills and abilities that are most sensitive to fatigue-related degradations.

The NRC also notes that the NEI has initiated development of an implementation guide for the rule, including a checklist that addresses the criteria for authorizing a waiver. Therefore it is anticipated that this will be the subject of further development. The NRC notes that these are minimum criteria, and the requirements do not prevent a licensee from developing a tool that may more effectively make this determination.

Comment: Referring to the last sentence in § 26.199(d)(3)(i)(B)(iii), one commenter expressed uncertainty about how this requirement would apply to a case where the face-to-face supervisory assessment allows an individual to cover a work period in excess of four hours. The commenter presented the example of the case where an individual is called in to cover an 8-hour shift because of sickness of another individual. The commenter asked: "Does the face-to-face supervisory assessment conducted immediately prior to the individual assuming the shift cover the entire 8-hour shift or only the first four hours of it?" The commenter argued that a strict reading of the requirement as presently written might preclude that individual from beginning to perform any work under the waiver more than four hours after the face-to-face supervisory assessment [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC disagrees with the commenter's description of the intent of the subparagraph. Proposed § 26.199(d)(3)(iii) requires that a face-to-face supervisory assessment must be conducted sufficiently close in time (four hours) to the period during which the individual "begins performing any work under the waiver" to ensure that the individual's condition will not substantively change before work is performed under the waiver. This provision is not intended to address the length of the extended work period that the waiver would "cover," and only requires that the assessment is conducted within four hours of the start of the extended work period.

<u>Proposal to Amend Break Requirements</u>

Comment: One commenter argued that work groups/crews who want to work rotating 8-hour shifts should be afforded the opportunity to do so without § 26.199(d)(2)(ii) vetoing existing 8-hour shifts at facilities. The commenter suggested that the NRC add § 26.199(d)(4) that states: "During licensee normal operations for individuals working 7 or 8 days of consecutive work periods scheduled for 8 hours each contained in a nominal shift rotation cycle of 14 days or more § 26.199(d)(2)(ii)(A) and § 26.199(d)(2)(iii)(A) is applicable for rest periods with § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii) being inapplicable for normal operations rest periods. For plant outages § 26.199(d)(2)(ii) and § 26.199(d)(2)(iii) are applicable to individuals scheduled

for 8 hour shift rotations for rest periods with § 26.199(d)(2)(ii)(A) and § 26.199(d)(2)(iii)(A) being inapplicable for plant outage rest breaks." In this case, the commenter suggested that § 26.199(d)(1) should state the following: "Except as permitted under paragraph (d)(3) *and/or (d)(4)* of this section, licensees shall ensure that any individual's work hours do not exceed the following limits" because (d)(4) allows consideration of licensees who work 8-hour shift rotations for 7 or 8 days consecutively for a nominal rotation cycle of 14 days or more [Edwin Hill, IBEW].

NRC Response: The NRC agrees in part with this comment and has revised the final rule to eliminate the requirements for a minimum 24-hour break in any 7 days and a 48-hour break in any 14 days. The new requirements in the final rule are for a 34-hour break in any 9 days and a minimum number of days off per week averaged over a shift cycle. These requirements, which accommodate 8-hour shift schedules, are in § 26.205(d)(2)(ii) and § 26.205(d)(3), respectively, of the final rule.

Impact on Rate of Pay

Comment: One commenter suggested that the NRC review the impact on those workers who have negotiated a rate of pay on their second day off as a double-time day instead of a time-and-a-half day. The commenter argued that this provision negatively affects worker morale not only because workers have less control of their weekly schedule, but also because their rate of pay would be reduced when working overtime [James Springfield, IBEW].

NRC Response: The NRC disagrees with this comment since § 26.205(d)(3)-(6) of the final rule provides break and day off requirements that largely meet the commenter's objective of providing increased flexibility in the distribution of breaks and control of weekly schedules. The intent of Subpart I is to limit fatigue not compensation. The increased flexibility of the final rule allows for negotiation between workers and the licensee while providing the necessary controls to reduce the likelihood of fatigue-related errors adversely affecting public health and safety or the common defense and security.

TVA Overtime Agreement

Comment: One commenter referenced the 1991 Overtime Agreement utilized at all nuclear facilities of the Tennessee Valley Authority (TVA). The commenter stated that this agreement addressed the idea that the "16/24, 24/48, and 72/7 had little if any real safety basis when coupled with the volunteering of overtime." The commenter argued that the NRC, TVA and IBEW were satisfied by the results of this agreement, and this agreement has been successfully utilized without challenge for fifteen years. Hence, the commenter questioned the NRC's attempt to override this settlement and formally requested the settlement to be reopened if the NRC disregards it [James Springfield, IBEW].

NRC Response: The NRC disagrees with the comment that individual work hour limits have little safety basis when individuals volunteer for overtime. Although individuals may be able to make relative judgements regarding their level of fatigue, there have been several studies that have noted the tendency for individuals to underestimate their level of impairment from fatigue (Nabi et al, 2006; Wylie, et al., 1996; Dinges, 1995; Rosekind and Schwartz, 1988). The NRC has also received allegations from nuclear power plant workers expressing fear of adverse actions from employers for reporting that they are unfit for duty because of fatigue. As a

consequence, the NRC does not believe there is reasonable assurance workers can reliably address excessive fatigue through their own actions under the former requirements applicable to worker fatigue.

The NRC also notes that limiting hours and fatigue of employees engaged in licensed activities is an exercise of NRC statutory authority to regulate nuclear safety. Such regulation may affect labor agreements between a licensee and a union. If the parties to a labor contract believe that the contract has been made obsolete by subsequent events, e.g., this final rule, the parties to the contract are responsible for renegotiating their contract. The NRC has no authority to compel parties to a labor contract to renegotiate the contract.

11.3.5. Self-Declarations During Extended Work Hours (§ 26.199(e))

Support for Self-Declarations

Comments: Two commenters supported the self-declaration provision in proposed § 26.199(e) [Jim Davis, NEI; Todd Newkirk, IBEW].

NRC Response: The comments do not require a response.

Suggestion for Increased Implementation Guidance

Comment: One commenter commended the NRC for proposing this self declaration provision to provide employees with a process to declare when they might be too fatigued, for whatever reason, to conduct certain tasks. However, while the concept of self declaration is a worthy one in theory, the commenter argued that its use may be impractical since (a) employees may fear reprisal, directly or indirectly; and (b) chronically sleep deprived individuals and individuals with certain sleep disorders are not capable of accurately self-assessing their level of alertness and capacity to perform. The commenter therefore encouraged the NRC to put forward very clear guidance regarding the implementation of this rule to make sure that the potential for abuse for both self-declaration and face-to face assessments is minimized. The commenter also encouraged the NRC and the nuclear industry to support the development and utilization of objective assessment tools and predictive software models currently being tested [Darrel Drobnich, NSF].

NRC Response: The NRC agrees with the comment for implementation guidance. The NRC's past experience with worker fatigue, such as that documented in NRC Regulatory Issue Summary (RIS) 2002-007, Clarification of NRC Requirements Applicable to Worker Fatigue and Self-declarations of Fitness-For-Duty, dated May 10, 2002, indicates that there is a need for individuals to clearly understand their fatigue management responsibilities and those of the licensee.

The Nuclear Energy Institute has agreed to develop implementation guidance for the rule. The NRC will review the guidance and, as appropriate, recommend changes or endorse the guidance in an NRC Regulatory Guide. Through this process implementation guidance will be made available to licensees. Regarding the comment that the NRC and industry should encourage the development of objective assessment tools and predictive software models, the

NRC would support industry development of tools and methods that would facilitate effective implementation of the requirements of this rule.

Oversight of the Self-Declaration Process

Comments: Other commenters argued that the NRC should closely oversee the self-declaration process. They cited examples of self-declaring workers who are afraid to self-declare and forced to work under duress due to the threat of being fired, sent to psychiatrists, and given undesirable schedules. The commenters argued that if there is evidence of retaliation for self-declaration, then the NRC should take enforcement action and levy significant fines against the utilities [Pete Stockton and Danielle Brian, POGO].

NRC Response: The NRC agrees that oversight of the self-declaration process should be part of the NRC's oversight of licensee implementation of the requirements in Subpart I. The NRC will revise the baseline inspection procedure for fitness for duty programs, IP71130.08, as part of the NRC's implementation activities for this rule. The revision will include requirements for the inspection of licensee fatigue management, including the implementation of the self-declaration requirements. In addition, § 26.203(e) of the final rule requires licensees to report information pertaining to fatigue assessments, including self-declarations. This will enable the NRC to monitor licensee use of the self-declaration process. Furthermore, the NRC notes that the NRC's allegation program is available to all licensee employees. Individuals who believe that they are being forced to work when they are unfit for duty because of fatigue may report these concerns through the NRC's allegation process.

Regarding the commenters' recommendation that NRC should take enforcement action against utilities that retaliate against individuals for self-declaration, the NRC notes that 10 CFR 50.7 prohibits retaliation for the reporting of nuclear safety concerns. The NRC has addressed the applicability of this requirement with respect to self-declarations in RIS-2002-007, "Clarification of NRC Requirements Applicable to Worker Fatigue and Self-Declarations of Fitness-For-Duty." In summary, the NRC has several mechanisms for the oversight of the self-declaration process and, therefore, the commenters concerns are adequately addressed through this rulemaking and existing NRC regulations and programs.

11.3.6. Collective Work Hour Limits (§ 26.199(f))

Support for Collective Work Hour Limits

Comment: One commenter stated that cumulative limits are important controls for the long-term mitigation of fatigue, and thus supports their inclusion in the final rule [Barry Quigley, Individual]

NRC Response: The NRC agrees with the commenter's statement supporting provisions that address cumulative fatigue. Although the NRC has eliminated collective work hour limits from the final rule, those limits have been replaced with requirements for minimum number of days off per week averaged over a shift cycle in § 26.205(d)(3) and minimum days off in 15 day blocks in § 26.205(d)(4) that have the same objective of preventing cumulative fatigue. Therefore, the NRC has revised the final rule and maintains provisions to address cumulative fatigue.

Opposition to Collective Work Hour Limits

Comments: Many commenters addressed collective work hour limits, with the majority of them opposing some portion of the provisions. Some commenters stated that the collective work hour limit approach is inconsistent with the rest of the FFD rule and dangerous when coupled with the provision limiting the scope of work hour limits to only those workers with hands-on responsibilities [David Lochbaum, UCS; Deborah Katz, CAN]. Another commenter recommended that the NRC eliminate the specific policies regarding collective work hour limits, because they are not an effective means to address the known physiological fatigue risks contributed by individual operators [Mark Rosekind, Alertness Solutions]. One commenter stated that the group hours should not be adopted for the further reason that the NRC's backfitting analysis does not adequately justify imposing this new requirement (See Section 14.2) [Daniel Stenger, NRSG]. Another one disputed the validity of surveys referenced by the NRC staff to imply that the limits are consistent with worker desires regarding overtime. To the contrary, the commenter believes that the predominant opinion of workers in the nuclear industry is overwhelming opposition to the work-hour limits [Andrew Antrassian, UWUA].

Many commenters from industry stated that the proposed collective work hour limits are unnecessary to mitigate the effects of cumulative fatigue and limit the flexibility to increase work hours in a job-duty group based on operational needs. They expressed that cumulative fatigue is adequately addressed by other rule provisions, such as the work schedule, individual work hour limits, individual break requirements, the fatigue assessment and the self-declaration process. Therefore, the commenters asserted that the inclusion of cumulative work hour controls is unnecessary and should be eliminated for any functional group except security [Michael Coyle, NEI #49; John Cowan, NEI; Jim Davis, NEI, Richard Sweigart, DCS, Keith Jury, Exelon; Keith Young, Ameren UE; Richard Sweigart, DCS; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG; Pete Stockton, POGO]. One commenter suggested that the NRC adopt a more performance-based rulemaking approach that better recognizes the complexity of work scheduling practices at nuclear power plants and allows for more flexibility [Daniel Stenger, NRSG].

Some commenters expressed concern that the utility companies will be able to "fudge" how many armed security officers they have on shift by including the unarmed officers, trainers, and in some cases clerical and managerial staff into the group with the armed responders. Therefore, these commenters suggest that the group hour limits are irresponsible and should be deleted from the rule [Danielle Brian, POGO; Anthony Rizzo Jr, Salem Hope Creek]. One commenter also asserted that the only way to ensure that the collective work hour limit will achieve adequate shift coverage without routine heavy use of overtime is to remove leave hours from the averaging process [Peter Hammill, PBNP].

One commenter stated that collective work hours will allow licensees to force workers to work overtime [Dennis Specha, Individual]. To address this, one commenter suggested that the NRC require that a licensee cannot force someone to work over 48 hours, but an individual may volunteer to work up the 72 hours in a week if it relieves another individual from a forced overtime situation [Guy Galster, Individual]. Another commenter stated that the 48-hour

collective work hour limit will not prevent individuals from working up to the limits of § 26.199(d) on a frequent basis. The commenter argued that the time frame between outages is the time frame when § 26.199(f) will apply, and it is also the period of highest vacation usage. The commenter argued that since overtime is used to cover for vacation or illness, it is possible that during these times one could be working up the limits of § 26.199(d) repeatedly to cover for absences [Peter Hammill, PBNP].

A commenter also noted that the maximum limits for group work hour averages may not be consistent with existing collective bargaining agreements (CBA's), and may result in variations among work groups at a site [Daniel Stenger, NRSG].

Several commenters from industry stated that one of the challenges surrounding the collective work hour limits is the recruitment of supplemental workers past the eight-week point in an outage when the work hours are limited. The commenters argued that, for many individuals, the availability of overtime is a key factor in where they decide to work, and attracting the same individuals to work subsequent outages and retaining them for the duration of the outage significantly improves the quality of the work process. Thus, the commenters suggested that the 8 week outage exemption be increased to 10 weeks because licensees will face the unintended consequence of the loss of supplemental workers in the final stages of an outage [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees in part with the statements made by many commenters concerning collective work hour limits. In response to these comments the NRC has replaced proposed rule requirements for collective work hour limits with the minimum day off requirements in § 26.205(d)(3) of the final rule. The NRC expects that the minimum day off requirements in the final rule will be equally effective in addressing cumulative fatigue, while addressing the commenters' concerns. The requirements of the final rule address cumulative fatigue on an individual basis and therefore provide more uniform assurance against worker fatigue while eliminating the burden of defining and tracking individual membership in job duty groups. The final rule requirements also eliminate the potential that the calculation of collective work hours would not be representative of the hours worked by all individuals in a group or are in some other way biased.

Clarification of Individuals Subject to Collective Work Hours

Comment: Another commenter at the public meeting expressed confusion over which workers were considered to be in the "group" [Pete Stockton and Danielle Brian, POGO]. Others stated that the provision must explicitly state that only those individuals who meet one or more of the criteria in § 26.199(a) shall be included in the group hour calculations [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC agrees that the rule requirements should be clear regarding the individuals to whom they are applicable and the NRC's intent for the collective work hour limits was that these limits would be applicable to only those individuals who met at least one of the

criteria specified in § 26.199(a) of the proposed rule. However, the final rule does not retain the requirements for collective work hour limits. The NRC replaced the collective work hour limits with individual work hour limits and the calculation of work hours for purposes of compliance with the final rule requirements does not depend upon group membership.

Collective Work Hours for Security Personnel

Comments: One commenter, supported by many commenters, recommended revisions to § 26.199(f) to replace "individuals" with "security personnel" or "any job duty group" to "the security job duty group." [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

One commenter suggested that the language in § 26.199(f)(1) and (f)(3) should reference (a)(1) and (a)(5) instead of only "(a)" because collective group hour management will not be the best fatigue management for groups (a)(2), (a)(3) and (a)(4) due to the burdensome tracking of average collective work hours for these groups that have a high occurrence of mobility within the industry. The commenter argued that the recommended provision language focuses on security and operations. [Edwin Hill, IBEW].

NRC Response: The NRC agrees with the comment that licensees could experience a greater burden implementing the collective work hour limits for groups that have a high occurrence of mobility within the industry. The NRC eliminated the requirements for collective work hour limits from the final rule. As a consequence, all fatigue management provisions are applicable on an individual, rather than group, basis. The final rule therefore eliminates the burden associated with tracking group membership for individuals in jobs that are highly mobile in the nuclear power industry.

Exclusions During Plant Outages

Comments: Regarding § 26.199(f)(1), one commenter, supported by many commenters, also recommended that the 8 week exclusion for outages be increased to 10 weeks throughout the rule package to accommodate anticipated upcoming outages of longer duration. The commenter argued that review of recent outages shows an increase in the number of outages that exceed 8 weeks. The commenter also argued that equipment replacements show a number of outages that exceed 8 weeks that could be managed with a 10 week outage [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

Some commenters strongly opposed the relaxation of collective work hour limits during the first eight weeks of a plant outage [David Lochbaum, UCS; Deborah Katz, CAN]. However, another commenter stated that industry is supportive of this exemption [John Cowan, NEI]. Another

commenter argued that this exemption should continue for longer than the first eight weeks of an outage [Todd Newkirk, IBEW].

NRC Response: The NRC does not agree with the commenters' recommendations that the exemption period from the collective work hour limits for unit outages should be either extended or eliminated. Although the NRC has replaced the collective work hour limits of the proposed rule with the minimum day off requirements in § 26.205(d)(3) of the final rule, the requirements of the final rule that are applicable to unit outages are comparable to those of the proposed rule. As a consequence the NRC has retained a comparable exemption period, limiting the exemption from the requirements of § 26.205(d)(3) to the first 60 days of a unit outage or planned security system outage. The relaxation of individual work hours during these specific times accommodates the short-term demand for increased work hours associated with these outages while limiting cumulative fatigue. The NRC considers the burden on licensees of eliminating the exemption period for these conditions to be excessive for the additional assurance that could be gained in worker fitness for duty relative to that achieved by the limited exemption period of the proposed rule.

In setting the maximum duration of the exclusion period, the NRC not only considered the duration of typical and longer term outages, but also considered that, by the end of 60 days of work at the limits permitted by § 26.205(d)(1) and (d)(2), individuals who are performing the duties specified in § 26.4(a)(1)–(a)(4) will have (1) worked 576 hours, including more than 200 hours of overtime, and (2) missed as many as 17 normally scheduled days off. The loss of the 17 normally scheduled days off would be a reduction of 60 percent in the time available to recover and prevent cumulative fatigue. Further, with each passing week of increased work hours and decreased time off, deferring daily living obligations becomes increasingly difficult, causing increased pressure on individuals to reduce their sleep time in order to meet the demands of both work and daily life, resulting in an increased potential for cumulative fatigue. As a result the NRC did not consider it appropriate to extend the exception period without assurance individuals obtained sufficient rest to prevent cumulative fatigue. However, the NRC has included a provision in the final rule (§ 26.205(d)(6)) that permits licensees to extend the outage exception period by 7 days for each 7-day period during the outage an individual works not more than 48 hours. This provision accommodates longer outages when it is justified by the work history of the individual containing adequate recovery periods.

13-Week Averaging Period

Comments: Other commenters stated that the proposed rule is not clear in how the 8-week outage suspension of the collective work hour limits per § 26.199(f)(1) gets reconciled with the 13-week averaging period specified per § 26.199(b)(2) [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC did not retain the proposed collective work hour limits in the final rule. This change to the requirements eliminates the 13-week averaging period. Therefore, the final rule renders moot comments concerning the 13-week averaging period.

Fatigued Individuals

Comments: Commenters stated that the rule must not allow an individual who is already chronically fatigued from entering the collective work hour limit pool, especially when that entry coincides with the 8-week outage "free pass." They suggested that the NRC revise § 26.199(b)(1)(iii) to require a formal, documented check before an individual begins or resumes performing any of the job duties listed in paragraph (a). The commenters stated that the licensee should assess the person's work hour history over at least the prior 13 weeks to verify that the individual is not already likely to be chronically fatigued [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC agrees that chronically fatigued individuals should not be allowed to perform duties covered in proposed § 26.199(a). The NRC does not agree that the rule should be revised to include a formal documented check of a worker's work hour history over at least the prior 13 weeks. The NRC considered methods for licensees to track the work hours of individuals that work for other licensees and other employers and determined that the burden of tracking work hours was substantial and that the ability to verify work hours from other employers was limited. However, the NRC determined that the potential for cumulative fatigue was substantial for individuals who work outages in close succession and that licensees can reasonably track and verify the hours of individuals that may move from outage to outage among their own power plant sites. Accordingly, the NRC revised § 26.199(g) of the proposed rule to provide more effective controls to prevent cumulative fatigue of individuals that work successive outages for the same licensee. The revised requirement is in § 26.205(d)(7) of the final rule. In addition, the NRC notes in the event an individual becomes chronically fatigued, § 26.211(a)(1) of the final rule requires licensees to conduct fatigue assessments for-cause when individuals appear not to be fit for duty because of fatigue and § 26.203(b)(1) requires licensees to establish procedures for the self-declaration of fatigue. The NRC considers that collectively these requirements provide reasonable assurance that individuals will not perform duties that are subject to the work hour controls when they are chronically fatigued or otherwise are not fit to safely and competently perform those duties.

Ensuring Adequate Staffing Levels

Comment: One commenter argued that § 26.199(f)(3)(i) provides an "out" to licensees, in effect telling them that they do not need to maintain adequate staffing when it is not reasonably controllable. Thus, if the intent is to ensure adequate staffing levels, the commenter urges the NRC to define adequate staffing levels [Peter Hammill, PBNP].

NRC Response: The NRC agrees that proposed § 26.199(f)(3)(i) permitted a limited exception from the collective work hour limits for conditions that the licensee could not have reasonably controlled. However, the NRC has not retained the collective work hour requirements for the final rule and has eliminated the provision in proposed § 26.199(f)(3)(i) as part of the elimination of the collective work hour limits.

Collective Work Hour Limits for Security Personnel During Outages

Comments: Regarding § 26.199(f)(2)(i), one commenter expressed concern that security personnel would be allowed to work more hours during outages. The commenter stated that, for

the reasons stated by the NRC in its reasoning in relation to § 26.199(a)(5), work controls should be in place for security personnel, especially during times of increased activity such as planned security system outages or under threat conditions. Thus, the commenter stated that security personnel must be under more stringent work hour controls and should not be included in any provisions that allow waivers during outages or other circumstances other than, possibly, during attack or emergency situations [Darrel Drobnich, NSF].

Other commenters argued that armed security officers should be limited to 48 hours a week, and the only instances in which hours should reach 60 are refueling and heightened security [Pete Stockton and Danielle Brian, POGO].

NRC Response: The NRC agrees, in part, with the commenters. The NRC agrees that the work hour controls for nuclear power plant security personnel should be stringent for the reasons described in the section-by-section analysis of this rule with respect to § 26.205(a) of the final rule. The NRC also agrees that the work hours of armed security guards should not routinely exceed 48 hours per week. However, the NRC does not agree that the rule should not permit limited periods of increased work hours for security personnel during outages or increased threat conditions. The collective work hour requirements in proposed § 26.199(f)(2)(i) have been eliminated from the final rule. However, the alternative requirements in the final rule for individual work hours in § 26.205(d)(5) prescribe less stringent day off requirements than those required by § 26.205(d)(3) during the first 60 days of a plant outage, security system outage, or increased threat condition.

Outages and increased threat conditions are unique, relatively short-term, and involve levels of activity that are substantially higher than most non-outage operating periods. It is not practical to expect licensees to maintain sufficient supplemental security staff to maintain 48-hour weeks under all conditions. A rule that imposed such a requirement would place an exceptionally high burden on licensees and result in a security staff that would not be fully employed under most circumstances. The relaxation of individual work hours for security personnel accommodates the short-term demand for increased work hours associated with these outages and increased security threat conditions. The minimum day off requirements in § 26.205(d)(5) of the final rule, in conjunction with the other provisions in Subpart I, ensure individuals have sufficient days off during these periods of more intensive work schedules to provide reasonable assurance that security personnel are not impaired by fatigue. However, the NRC agrees that such increased periods of work hours create the increased potential for cumulative fatigue. As a result, § 26.205(d)(5) limits the exception period to generally not more than 60 days.

<u>"Hard Cap" on Collective Work Hours</u>

Comments: A couple of commenters noted that § 26.199 (f)(3)(ii) imposes a cap of 54 hours per person per week under certain circumstances and § 26.199 (f)(2)(i) and other sections impose a cap of 60 hours per person per week for security personnel under other circumstances. To rectify this, the commenters suggested that the NRC provide a "hard cap" on collective work hours [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC has revised the rule such that collective work hour limits are eliminated from the final rule, including the provision in § 26.199 (f)(2)(i) of the proposed rule. The comment is therefore not applicable to the requirements of the final rule.

Approval to Exceed Collective Work Hour Limits

Comment: One commenter stated that the requirement in § 26.199(f)(5) for prior NRC approval of a written request by a licensee to exceed any collective work hour limits for any job group is overly restrictive and could have unintended consequences, such as delayed site response and corrective actions to emerging issues [Daniel Stenger, NRSG].

NRC Response: The NRC has revised the rule such that collective work hour limits are eliminated from the final rule, including the requirement in § 26.199(f)(5). As a result of these changes the comment is not applicable to the requirements in the final rule.

11.3.7. Successive Plant Outages (§ 26.199(g))

Multi-Site Licensees

Comments: A couple of commenters stated that the proposed rule is written under the implicit assumption that there are unique licensees for each reactor site, and that assumption is false. They explained that several companies own and operate reactors at multiple sites, and it is not uncommon for these companies to develop specialty work groups and deploy these work groups to all of their sites. The commenters included an example of when the sustained outage provision of § 26.199(g) does not apply, and argued that the rule must not permit this [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC agrees in part with the comment that certain individuals work successive outages and, therefore, the NRC revised § 26.199(g) of the proposed rule to apply to individuals who work successive outages, separated by less than 2 weeks, for a licensee. The proposed rule provision was limited to successive outages at a licensee's site. The commenter noted that several companies own and operate reactors at multiple sites, and it is not uncommon for these companies to develop specialty work groups and deploy these work groups to all of their sites. Section 26.205(d)(7) of the final rule addresses this comment and is applicable to individuals who work in outages in close succession for a licensee, regardless of whether the outages occurred at a single site or more than one site. The final rule provision is applicable to a larger proportion of the individuals that work successive unit outages and thereby provides greater assurance that these individuals are subject to work hour controls that are appropriate for sustained and successive periods of extended work hours associated with outage work schedules. The NRC notes that like the proposed rule provision, § 26.205(d)(7) of the final rule is not applicable to individuals who may work outages in close succession if those outages are for different licensees. The NRC acknowledges that the potential for cumulative fatigue is likely no different for these individuals than for those individuals working successive outages for the same licensee. However, as described with respect to § 26.205(d)(4), the NRC considered the substantial burden of tracking work hours from one licensee to another and determined the burden was not warranted given the expected benefit. The revised requirements applicable to individuals who work in outages in close succession are in § 26.205(d)(7) of the final rule.

Successive Outage Calculations

Comments: Several commenters also stated that § 26.199(g) "tosses out" the collective work hour limits when outages are separated by at least two weeks but less than 13 weeks. They

argued that § 26.199(b)(2) requires collective work hours to be calculated "within an averaging period that may not exceed 13 weeks." Thus, if the licensee specifies 13 weeks as the averaging period and the end of an outage resets the clock for starting an averaging period, then the collective work hour calculation does not become meaningful until 13 weeks after the end of an outage. The commenters argued that, in the interim, the only real limits on working hours are the individual limits in § 26.199(d), and this allows a licensee to use the collective work hour limits “free pass” for an eight week outage as often as possible during a year, as long as the outages are separated by at least two weeks [David Lochbaum, UCS; Deborah Katz, CAN].

NRC Response: The NRC agrees that § 26.199(g) of the proposed rule allows licensees to use the outage exception multiple times in a year if outages are separated by at least 2 weeks. The NRC does not agree that this provision has the effect of “tossing out” the work hour controls generally applicable to routine plant operations. At the conclusion of an outage, individuals are likely to be fatigued from working extended hours and the increased workload associated with the outage and plant restart preparations. Accordingly, § 26.199(g) of the proposed rule ensures that individuals have at least a 2 week period during which their work hours are subject to the requirements applicable to routine plant operations before the individuals are eligible for control of their work hours in accordance with an outage exception. A minimum of 2 weeks under normal workloads provides reasonable assurance that individuals have the opportunity for successive days of rest to reduce the potential for cumulative fatigue. Although consecutive outages separated by more than 2 weeks may create some potential for cumulative fatigue, particularly if individuals are working more than 2 consecutive outages, the NRC considers the 2 week minimum to be adequate to substantively reduce the potential for cumulative fatigue. In addition, the NRC expects that the likelihood of individuals working more than 2 consecutive extended duration outages separated by just 2 weeks is low given that the time period that licensees conduct unit outages is typically limited to periods of low demand for electricity. In this regard the NRC also notes that it also revised this requirement in the final rule to be applicable to individuals who work in outages in close succession for a licensee, regardless of whether the outages occurred at a single site or more than one site. As a result the final rule provision is applicable to a larger proportion of the individuals that work successive unit outages and thereby provides greater assurance that these individuals are subject to work hour controls that are appropriate for sustained and successive periods of extended work hours associated with outage work schedules. Accordingly, § 26.205(d)(7) retains, with limited changes, the requirements in § 26.199(g) of the proposed rule.

Work Schedules During Extended Outages

Comments: One commenter, supported by many commenters, argued that during an extended outage, if a functional work group returned to normal operations for a period in excess of two weeks, the elapsed outage period should be recalculated based on when the functional work group returned to an outage work schedule. Therefore, the commenter said the criteria for successive plant outages could be applied to these situations. It recommended revising proposed § 26.199(g) by adding the following to the end of the proposed paragraph: "If an outage is scheduled such that a functional group returns to a normal operational schedule for at least two weeks, the number of days may be restarted from the date outage manning is resumed" [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey

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

NRC Response: The NRC does not agree with the recommendation to revise the requirement in proposed § 26.199(g). The proposed revision would allow licensees to schedule individuals in accordance with the requirements applicable to outages, which the NRC intends for temporary use, for more than 40 weeks of a year. Although a 2 week period of routine scheduling would substantively reduce cumulative fatigue, a repeated sequence of outage scheduling with only 2 weeks of routine scheduling intervening would not provide reasonable assurance that personnel do not become impaired by cumulative fatigue. However, the NRC has revised the proposed rule to include a provision that allows a 7-day extension of the relaxed outage work hour controls for each independent 7-day period during which the individual has worked not more than 48 hours during the plant or security system outage or increased threat condition. Instead of re-calculating the outage period as the commenters suggested, this provision will essentially give "credit" to an individual for every week that the individual works not more than 48 hours per week, thus allowing the outage to be extended. This provision limits the total duration an individual is scheduled at the relaxed limits applicable to outages but provides licensees flexibility in scheduling the periods of high and low levels of work hours and does not require that the 2 weeks of "normal operational scheduling" be consecutive. The provision allowing 7-day extensions of the outage exception is contained in § 26.205(d)(6) of the final rule. The requirements in § 26.199(g) are retained, with limited changes, as § 26.205(d)(7) of the final rule.

11.3.8. Common Defense and Security (§ 26.199(h))

Comments: One commenter recommended that the wording in proposed § 26.199(h) be changed from "..when informed in writing by the NRC..." to "...when informed verbally and followed up in writing by the NRC..." or some similar wording that would allow the NRC to verbally state that the licensee does not have to meet the requirements of this section and at a later date the NRC could provide written confirmation of that verbal statement. This is similar to the approval of exemptions from code requirements [F.G. Burford, Entergy].

NRC Response: The NRC does not agree that verbal approval is needed to facilitate exemption of requirements in § 26.205 of the final rule. If there is a security emergency in which the licensee must immediately react to assure the common defense and security, the licensee need not meet the requirements of § 26.205 (c) and (d) as stated in § 26.207(d). In all other cases that do not meet the condition of § 26.207(d), the NRC considers timely written consent to be adequate. The final rule retains the requirements of proposed § 26.199(h), without change, in § 26.207(c) of the final rule.

11.3.9. Plant Emergencies (§ 26.199(i))

Comments: One commenter praised the clarity contained in proposed § 26.199(i) [F.G. Burford, Entergy].

NRC Response: The comment does not require a response.

11.3.10. Reviews (§ 26.199(j))

Comments: One commenter argued that the periodic reviews are not consistent with the desired information for the annual report described in § 26.197(e). As previously stated, industry suggested the deletion of § 26.197(e). However, if the data requested in § 26.197(e) is valuable to the NRC, then the commenter suggested that the information be moved to § 26.199(j). The documentation of the periodic review would be available to the NRC resident inspector upon request, and there remains no need to provide an annual submittal to the NRC [F.G. Burford, Entergy].

Analysis: The NRC disagrees with the commenter that the periodic reviews required by proposed § 26.199(j) are inconsistent with the reporting requirements of proposed § 26.197. The requirements of proposed § 26.199(j) are now contained in § 26.205(e) of the final rule and the requirements of proposed § 26.197 are contained in § 26.203 of the final rule. The NRC acknowledges that both the reviews and reports required by the final rule focus on the use of waivers and fatigue assessments. However, the NRC considers the differences in the review and reporting requirements to be consistent with the licensee's responsibility for fatigue management and the NRC's oversight of the licensee's performance in this regard. Therefore the NRC has not revised the final rule to eliminate or move the requirements in proposed § 26.197(e).

11.4. Fatigue Assessments (§ 26.201)

Further Development of Fatigue Assessment Requirements

Comment: One commenter stated that an effective practice of fatigue assessments will add a significant dimension to overall fatigue management activities and further extend efforts beyond just a work hour limits policy. The commenter stated that some aspects are already well defined, such as situations where fatigue assessments would be used and some of the procedures (e.g., done by properly trained personnel, free of bias, and with privacy protections). However, the specific details of what will be assessed, how the information is summarized and analyzed, and the interpretation of findings require further development. The commenter suggested that one approach to explore is how fatigue factors are examined in accident investigations. This provides a structured approach to examining the known physiological factors that underlie fatigue and could be extrapolated and tailored for use in the context of the NRC proposed fatigue assessments [Mark Rosekind, Alertness Solutions].

NRC Response: The NRC agrees that implementation guidance for the fatigue assessments requirements for Subpart I would be beneficial. The Nuclear Energy Institute has agreed to develop implementation guidance for Subpart I. The NRC intends to review the implementation guidance and ensure that the guidance addresses fatigue assessments and supports valid assessments that can be practically implemented by supervisors trained in accordance with § 26.29 and § 26.203(c) of the final rule.

Clarification of "Impaired Alertness"

Comment: One commenter also stated that the rule language should provide a clear definition of "impaired alertness" within the meaning of proposed § 26.201(a)(1) to bound the conditions

that trigger the need for initiating a fatigue assessment. The commenter recommended that the following point should be clarified in the final rule: if a covered employee is found to be in a state of impaired alertness, including unintentionally falling asleep on duty (e.g., nodding off), a fatigue assessment should be performed to identify the root cause before management actions are taken such as disciplinary action [Daniel Stenger, NRSG].

NRC Response: The NRC does not agree that the rule language should be revised to further define “impaired alertness” as used in § 26.201(a) of the final rule. Proposed § 26.201(a)(1) would have required a fatigue assessment to be conducted in response to an observed condition of impaired alertness “creating a reasonable suspicion that an individual is not fit to safely and competently perform his or her duties.” This threshold for action is consistent with the requirements for management action in response to possible impairment as described in § 26.77(b)(1) of the final rule. The NRC also notes that the nature of the duties (for example, whether a job is monotonous), and the sensitivity of the job from impairment from fatigue (e.g., whether lapses in attention or degraded cognitive function affect the individual’s ability to perform safely and competently) will affect the criteria for this determination. As a consequence, the NRC believes that the criteria of “reasonable suspicion that an individual is not fit to safely and competently perform his or her duties” adequately defines the conditions that trigger the need for initiating a fatigue assessment. Furthermore, an example such as “unintentionally falling asleep on the job,” may be interpreted as the threshold for performing assessments. Although the NRC agrees that fatigue assessments should be performed in such cases, the onset of impairment from fatigue begins prior to an individual falling asleep and reasonable suspicion of fatigue can occur through observation of other behavioral and cognitive impairments, before sleep onset. Accordingly, the NRC has retained the requirements in proposed § 26.201(a)(1) as § 26.211(a)(1) of the final rule.

Affects of Fatigue Assessment on Rule Implementation

Comment: After recognizing that the fatigue assessment is a valuable element of the rule package, one commenter stated that the time needed to develop and establish a fatigue assessment program, which includes training, may be the most time consuming aspect of implementing this rule. Therefore, industry requested a one year implementation period from the date of approval of the rule [F.G. Burford, Entergy].

NRC Response: The NRC agrees that training of personnel to conduct fatigue assessments may require a one-year period for all personnel to receive the training in the course of their normal training cycle for the FFD program. Accordingly, the NRC intends to establish a one-year implementation period for this provision.

Personnel Authorized to Conduct Fatigue Assessment

Comment: Referencing proposed § 26.201(b), one commenter recommended that the words "Either a supervisor or a staff member of the FFD program, who is...” should be revised to "Either a supervisor or a FFD program staff member, who is ... " to clarify that the supervisor need not be a member of the FFD program to conduct the fatigue assessment [Brian McCabe, Progress Energy].

NRC Response: The NRC agrees that the recommended wording provision more clearly states the individuals authorized to conduct fatigue assessments and has revised § 26.201(b) accordingly. The revised rule provision is contained in § 26.211(b) of the final rule.

12. Subpart J: Recordkeeping and Reporting Requirements

12.1. General Provisions (§ 26.211)

Comments: One commenter stated that the proposed rule contained various new or amended information collection requirements, most of which industry supports [Marvin Fertel, NEI].

NRC Response: These comments do not require a response.

12.2. Recordkeeping Requirements for Licensees and Other Entities (§ 26.213)

No comments addressed this section.

12.3. Recordkeeping Requirements for Collection Sites, Licensee Testing Facilities, and Laboratories Certified by the Department of Health and Human Services (§ 26.215)

No comments addressed this section.

12.4. Fitness-for-Duty Program Performance Data (§ 26.217)

Comments: One commenter stated that industry supports the need for reporting to the NRC certain drug and alcohol-related information as proposed here [Jim Davis, NEI].

NRC Response: These comments do not require a response.

12.5. Reporting Requirements (§ 26.219)

No comments addressed this section.

13. Subpart K: Inspections, Violations, and Penalties

No comments addressed this subpart.

14. Other Comments

14.1. Regulatory Analysis

Requirements are Too Prescriptive

Comment: One commenter, supported by many commenters, stated that the new requirements are needlessly prescriptive and the regulatory analysis fails to justify the rigid approach. According to the commenters, the NRC's Regulatory Analysis Guidelines (§ 4.2, NUREG/BR-0058, Rev. 4) state that requirements should be performance based unless there is good cause for highly prescriptive rules. Therefore, the commenters suggested that the

regulatory analysis should better justify the prescriptive approach. [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: Although the comment was not specific with regard to which particular provisions might be needlessly prescriptive, the NRC did consider this issue during the development of the rule. The NRC agrees that the rule's drug and alcohol testing provisions are prescriptive when compared to some other NRC regulations. This approach was intentional, however, as discussed in the preamble to the proposed rule (e.g., see 70 FR 50451-50452). As discussed there, the prescriptive approach is intended to improve clarity and enhance effectiveness and, in part, is a response to the requests of industry stakeholders. Therefore, the NRC believes there is good cause for the prescriptive approach and that the basis for the approach is adequately justified. The regulatory analysis accounted for the cost of each provision, and also discussed the effects of improved clarity in Section 4.1.2.2.

With respect to the rule's fatigue management provisions, the NRC agrees that it adopted a prescriptive approach for certain work hour limits. This approach addressed stakeholder concerns, as discussed in SECY-01-0113, Fatigue of Workers at Nuclear Power Plants, related to the clarity and enforceability of NRC's regulatory framework concerning worker fatigue. However, the NRC notes that although certain requirements may be prescriptive, the requirements provide licensees substantial flexibility. As discussed in greater detail with respect to other, more specific comments addressing the relevant provisions, the final rule adopts an approach that is more flexible and considerably less prescriptive. The NRC has revised the regulatory analysis to address the more flexible approach.

Regulatory Analysis Does Not Account for Interaction of Requirements

Comment: One commenter, supported by many commenters, stated that the Regulatory Analysis looks at each provision in isolation and does not allow for a comparison of various portions of the draft rule and the interaction of the various requirements. According to the commenters, the Regulatory Analysis was performed on a section-by-section basis, which makes it difficult to compare the incremental impact of each section given the existence of other proposed requirements. Therefore, the commenters stated that the analysis is deficient because it fails to justify that each section included is essential to the rule and multiple layers were not accounted for properly. [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC agrees that the regulatory analysis was conducted on a section-by-section basis but does not agree that the provisions were considered in isolation. In fact, the cost analysis specifically accounted for the effects of interacting provisions as appropriate, both with respect to drug and alcohol provisions and to fatigue management

provisions. Although it is considerably more difficult to analyze the benefits associated with individual provisions that interact with other provisions, the regulatory benefits analysis of the proposed rule's fatigue management provisions (at which the NRC believes this comment was targeted) was informed by a side-analysis (presented as an addendum to the regulatory analysis), which sought to consider the interaction between key provisions. Nevertheless, the NRC has modified the fatigue management provisions that appear in the final rule in response to other public comments. In light of those rule changes, the NRC believes that this comment is not likely to remain a concern to stakeholders.

Justification for Subpart I Costs

Comment: One commenter, supported by many commenters, claimed that the work hour limits and break requirements in the proposed rule had a disproportionately higher cost than the training, self-declaration, and fatigue assessment provisions. Further, the commenters stated that the Regulatory Analysis did not provide a convincing cost justification for these work hour controls. Also, the commenters stated that the Regulatory Analysis included an extensive analysis of the cost of implementing Subpart I, but the justification for the implementation burden was deficient. [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC disagrees with the commenters. The NRC has modified the fatigue management provisions that appear in the final rule in response to other public comments. In addition, based on insights provided in public comments, the NRC believes that if the proposed fatigue management provisions were not being modified by the final rule then it would be necessary to revise the regulatory analysis to reflect a higher implementation burden associated with certain fatigue management provisions. In light of the rule changes, however, the NRC believes that this comment is not likely to remain a significant concern to stakeholders. In addition, the regulatory analysis has been revised in accordance with the final rule. With respect to the findings of the regulatory analysis for the final rule, the NRC believes there is not a disproportionately higher cost for work hour limits and break requirements than for training, self-declaration, and fatigue assessment provisions.

Disagreement with Safety Goal Evaluation

Comment: One commenter, supported by many commenters, also argued with the Safety Goal Evaluation in section 4.5 of the Regulatory Analysis. According to the commenter, the Safety Goal Evaluation did not fully satisfy the standards set forth in the NRC's Regulatory Analysis Guidelines. Specifically, the commenters stated that in situations where it is not possible to develop adequate quantitative supporting information, "qualitative analysis and perspective" should be provided for the proposed new requirement, and these insights should be "related to the safety goal screening criteria." The commenters argued that the Regulatory Analysis did not address any such criteria. In this regard, the commenter stated that the staff's finding that the proposed changes "may qualify ... as generic safety enhancements because they may affect the likelihood of core damage," and its statement that the rule will reduce the probability of accidents and damages, was cursory and unsubstantiated.

The commenters stated that the Safety Goal Evaluation highlighted the overall lack of rigor and precesion in the entire Regulatory Analysis. The commenter felt that the staff's acknowledgement that its evaluation failed to quantify the "magnitude" of the claimed change in liklihood of core damage, or the claimed added assurance provided by the rule, is significant. Further, the commenter claimed that the generality of the staff's findings undermined the NRC's assertions in the rule package the implementation of Subpart I will "result in substantial non-quantified benefits related to safety and security." [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC's evaluation followed agency guidance in the Regulatory Analysis Guidelines and in Appendix D of the CRGR Charter. Therefore, the NRC disagrees with the comments on the Safety Goal Evaluation and believes that the analysis presented in Section 4.5 of the regulatory analysis was appropriate for this rule. As discussed there, the NRC believes the action is a generic safety enhancement which does not lend itself to a Safety Goal Analysis. The rulemaking provides added assurance that individuals working at nuclear facilities are fit for duty and, consequently, the rule reduces safety and security risks ranging from workplace safety incidents up to radiological damage to the reactor core. A safety goal evaluation generally focuses on the change in likelihood of core damage. However, the magnitude of the change for this rule is not readily quantifiable due to uncertainties regarding the types, frequencies, and results of damage that occurred pre-rule and will occur post-rule. A more dominant effect of the rule will be to reduce the probability of other types of accidents and damages associated with a wide array of acts related to drug and alcohol abuse and fatigue, although this effect is equally difficult to quantify. Because the change in safety associated with the rulemaking cannot be quantified, the rule provisions cannot be compared to the NRC's safety goals. The NRC also disagrees that there was a lack of rigor and precision in the entire regulatory analysis. Nevertheless, in response to other public comments, the NRC has replaced several of the proposed fatigue management provisions (at which the NRC believes this comment was targeted) in the final rule. In light of those rule changes, the NRC believes that this comment is not likely to remain a concern to stakeholders.

14.1.1. Addendum

Comments: In the public meeting, one commenter addressed the Addendum 1 to the Regulatory Analysis, which quantified some of the benefits associated with selected fatigue management provisions in the proposed rule. Industry was confused about the purpose of this addendum and whether the quantitative analysis is considered in the backfit justification of the rule. The commenter did not believe that it should be included in the rule package [Jim Davis, NEI].

One commenter, supported by other commenters, also addressed this issue, expressing disagreement with Addendum 1 to the Regulatory Analysis. Specifically, the commenters stated that the analysis failed to show any correlation between its findings and actual performance and conditions in the commercial nuclear power reactor industry. According to the commenters, this made the "seemingly precise calculations meaningless." The commenters also disagreed with

Addendum 1's conclusions regarding reduced rework. The commenters stated that this conclusion was incorrect because it ignored the many measures in place in the industry, such as use of detailed procedures, supervision and quality assurance measures. [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: It is not the NRC's intent that the quantitative analysis in the addendum be considered in the backfit analysis determination. The addendum was provided only as information related to the rulemaking, as the NRC determined in the regulatory analysis and the backfit analysis that the rulemaking would result in substantial additional benefits beyond those captured in the addendum. The addendum has not been revised to address the final rule and has not been included in the final rulemaking package.

14.2. Backfit Analysis

Comments: Several commenters from industry stated that the backfit analysis for the proposed rule was deficient. The commenters suggested that the backfit analysis did not include a meaningful discussion of the proposed rule's actual improvements in public health and safety. Specifically, the commenters explained that the qualitative statement that each element examined will provide substantial improvement to public health and safety was not supported by facts, and did not consider the diminished impact when other rule provisions are considered. The commenters argued that, considering the rule as whole, the protection of public health and safety will not be diminished if cumulative work hour limits are only applied to security personnel and a flexible approach is used for break requirements. Therefore, The commenters argued that the backfit analysis did not meet the intent of § 50.109 [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

Other commenters supplemented this argument, specifically arguing that the collective work hour limits of the proposed rule should have been subjected to a separate backfitting analysis to assess whether this aspect of the rule would produce a cost-justified substantial increase in safety as required by the NRC's Backfit Rule. The commenters noted that § 50.109(c) requires a backfitting analysis to consider the potential impact of new requirements on plant "operational complexity" and the cost of facility downtime. The commenter argued that because of the "aggregate" backfitting analysis performed for the entire rule, it was not clear that the full impact of the collective work hour limits was considered [Daniel Stenger, NRSG; Brian McCabe, Progress Energy].

NRC Response: The NRC disagrees with the commenters. Although the NRC believes that neither the proposed rule's backfit analysis nor its underlying approach was deficient based on available information, the NRC has gained additional insights from public comments suggesting that the backfit analysis would need to be revised to account for additional operational

complexity if the fatigue management provisions were to be finalized as proposed. However, the NRC has replaced several of the proposed fatigue management provisions at which the NRC believes that comment was targeted in the final rule in response to other public comments. Therefore, the backfit analysis has been revised as appropriate based on the final rule. In light of the rule changes, the NRC believes that it has resolved the concern.

14.3. Paperwork Burden Analysis

Support for Drug and Alcohol Reporting Requirements

Comments: Several commenters from industry found the reporting requirements associated with the drug and alcohol portion of the rule to be appropriate [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: These comments do not require a response.

Paperwork Reduction Act Obligation

Comments: Several commenters argued that the NRC has not met its obligation under the Paperwork Reduction Act with respect to the information collection requirements proposed in § 26.197(e). They claimed that the NRC has failed to adequately justify the need for these provisions to provide useful information for making a determination on the adequacy of a facility's fatigue management program and help the NRC assign inspection resources, and has also failed to objectively support its estimate of the burden created on affected licensees. Therefore, the commenters urged OMB to remand proposed § 26.197(e) to the NRC for its further consideration in light of these inadequacies [Marvin Fertel, NEI; Michael Coyle, NEI #49; F.G. Burford; Brian McCabe, Progress Energy; Gregory Halnon, First Energy; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: The NRC has reviewed its Paperwork Burden Analysis in light of the comments, and has revised certain burden estimates based on information provided by the commenters as well as additional analysis conducted by the staff. The NRC remains convinced, however, that the information collection requirements in the proposed rule are necessary to ensure that the NRC has the information necessary to effectively implement and enforce the FFD program, including its fatigue management requirements, increase consistency of rule enforcement, increase public confidence, and facilitate rule improvement. Section 11.2.5 of this document provides a detailed discussion of the NRC's justification for including these reporting requirements. (Note that the reporting requirements of proposed § 26.197(e) are now contained in § 26.203(e) of the final rule.)

Clarification of OMB Process

Comment: One commenter also asked the question of how the OMB process and the NRC rulemaking process come together with respect to the reporting provisions [Brian McCabe, Progress Energy].

NRC Response: As described in Section XIII of the Supplementary Information for the Proposed Rule (70 FR 50618-50619), under the Paperwork Reduction Act of 1995, the Office of Management and Budget (OMB) must review and approve all new or amended information collection requirements included in the proposed rule. No information collection may be conducted without OMB approval. Thus, the OMB paperwork burden approval process is a key component of the rulemaking process.

14.4. Regulatory Flexibility Analysis

No comments addressed this analysis.

14.5. Implementation

Implementation Process

Comments: Two commenters requested information about the process if the NRC concurred with alternative means of meeting the rule and changed a significant portion of the rule [Brian McCabe, Progress Energy; David Lochbaum, UCS].

NRC Response: Throughout the rulemaking process, the NRC has made efforts to inform stakeholders of significant changes to the proposed rule that resulted from the NRC's consideration of public comment. For example, the NRC held public meetings in March 2006 to discuss changes to the proposed fatigue management provisions and FFD provisions relating to the construction of power reactors. These meetings provided opportunities for the NRC and stakeholders to exchange their views on the proposed provisions. The NRC also published revised rule text on its website in August and October 2006 for public review and to apprise stakeholders of the status of the rulemaking process. In general, changes to the proposed rule that appear in the final rule are clarifications or extensions of the relevant provisions in the proposed rule and were made in response to public comments on the proposed rule.

Implementation Period

Comments: Commenters stated that a significant amount of work will be required to train workers on the provisions of this rule, and asked how long industry will have to implement the final rule. Several commenters from industry argued that, given the significant changes involved in this rulemaking, 12 months will be required for implementation of a majority of the new requirements once the final rule is published [Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

One commenter argued that there is an urgency to push this rulemaking without a thought of the impact on industry. The commenter argued that the implementation of any changes needs to be phased in gradually to give the workforce time to adjust [Daniel Hansen, Individual].

Another commenter asked if the NRC would consider giving the fatigue subpart a different implementation date than the rest of the rule [Dana Millar, Entergy].

NRC Response: The NRC agrees that implementation of the final rule will require time. Therefore, the agency has determined that licensees and other applicable entities may defer implementation of this rule, except for Subparts I and K, until 365 days from the publication of the final rule in the *Federal Register*. Subpart I must be implemented by licensees and other applicable entities no later than 18 months from the publication of the final rule in the *Federal Register*. Additionally, licensees and other applicable entities shall comply with the requirements of Subpart K as of 30 days from the publication of the final rule in the *Federal Register*.

Topics for the Final Rule Package

Comments: One commenter, supported by many commenters, argued that the final rule package must address several issues regarding the implementation process. These issues include:

- Addressing licensees that have work hour limits in their Technical Specifications
- Addressing the process to cancel the security work hour order
- Addressing portions of the Access Authorization Order that may conflict with 10 CFR Part 26

[Michael Coyle, NEI #49; Richard Sweigart, DCS; Keith Jury, Exelon; Mark Wetterhahn, Winston Strawn; Edward Weinkam, NMC; Don Grissette, SNC; Keith D. Young, Ameren; Glenn Morris, TVA; Ronald Gaston, Detroit Edison; Gregory Halnon, FENOC; Jeffrey Archie, SCE&G; Brian McCabe, Progress Energy; A. Edward Scherer, SCE; D.R. Woodlan, STARS; J. A. Stall, FPL; B.T. McKinney, PPL; F.G. Burford, Entergy; Daniel Stenger, NRSG].

NRC Response: With regard to the first bullet, as stated in the *Federal Register* notice for the final rule, the implementation period for the rule is 365 days from the date of publication in the *Federal Register*. The NRC considers this period sufficient to support an orderly transition from control of work hours in accordance with order EA-03-038, which requires compensatory measures for the control of work hours for security personnel, and unit technical specification requirements for the administrative control of work hours for personnel performing safety-related functions. The NRC expects that, during this period, licensees will submit applications to amend unit technical specifications to remove requirements pertaining to the administrative control of work hours for personnel performing safety-related functions.

With regard to the 2nd and 3rd bullets, the NRC intends, on verification that licensees have met requirements set forth in the final rule, to rescind the portions of the orders that are superceded by the final rule.

14.6. Other Miscellaneous Comments

Comment: One commenter recommended that the NRC conduct a formal study of this rulemaking [Jim Davis, NEI].

NRC Response: The NRC does not believe that a formal study of this rulemaking is warranted. However, the staff acknowledges that there were numerous lessons learned that will be beneficial for future NRC rulemaking efforts.

Comment: Another commenter proposed a third-party FFD assessment tool to assist the NRC with this rulemaking [Michael Cantor, WayPoint].

NRC Response: The NRC does not endorse third-party products and will continue to follow formal rulemaking processes.

Comment: One commenter fully supported the NRC's efforts to address the self-disclosure of sleep disorders by operators through other regulatory documents such as the Regulatory Guide 1.134, (Medical Evaluation of Licensed Personnel at Nuclear Power Plants) (see 70 FR 50445). The commenter argued that no employee should be afraid to seek treatment for a sleep disorder that can be effectively diagnosed and treated and the NRC should take appropriate steps to ensure that all MROs receive proper training regarding the signs and symptoms of sleep disorders as well as effective treatments. The commenter stated that the NRC should take appropriate steps to see that uniform education and training materials for MROs are developed to ensure that appropriate topics are covered accurately [Darrel Drobnich, NSF].

NRC Response: The NRC agrees that the assessment of sleep disorders for licensed operators should be addressed through Regulatory Guide 1.134, Medical Evaluation of Licensed Personnel at Nuclear Power Plants, and is revising that guidance through a separate effort. The NRC intends to revise the guidance to communicate its expectations that the evaluation considers sleep disorders among the potential factors that can affect the ability of an operator to remain alert. Regarding the commenters recommendation for uniform education and training materials, the final rule establishes training and examination requirements applicable to all individuals subject to the licensees FFD program, and specifically requires licensees to add "knowledge of . . . indications and risk factors for common sleep disorders, shiftwork strategies for obtaining adequate rest, and the effective use of fatigue countermeasures" to the content of their FFD training and examinations. Although it is common for industry groups such as the Nuclear Energy Institute or the Institute for Nuclear Power Operations to voluntarily develop generic guidance documents for common use by licensees, the final rule does not require uniform training materials. The NRC notes that it the licensee's responsibility to develop and ensure the accuracy of training materials to meet these requirements.

14.7. Comments Outside the Scope of the Rulemaking

No comments addressed this issue.