RULEMAKING ISSUE
(Notation Vote)

April 28, 2005 SECY-05-0074

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations /RA/

SUBJECT: PROPOSED RULE TO AMEND THE FITNESS-FOR-DUTY REQUIREMENTS IN 10 CFR PART 26

PURPOSE:

To obtain Commission approval to publish the proposed Fitness for Duty (FFD) rule in the *Federal Register* for public comment. The proposed rule would amend FFD requirements in 10 CFR Part 26.

SUMMARY:

Part 26 is being revised in its entirety to improve FFD programs. The staff considered input received from the public and an increased sensitivity to the physical security implications of FFD requirements following the terrorist attacks on September 11, 2001, in preparing the proposed rule. The scope of the proposed rule is being expanded to include Part 52 licensed facilities. Finally, the proposed rule would partially grant two Petitions for Rulemaking (PRM): PRM-26-1

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(submitted by Virginia Electric and Power Company, December 30, 1993) and PRM-26-2 (submitted by Barry Quigley, September 28, 1999).

BACKGROUND:

Drug and Alcohol Testing, and General Fitness for Duty Program Provisions:

In the June 7, 1989, *Federal Register* notice (54 FR 24468), the Commission announced the adoption of a new rule, 10 CFR Part 26, Fitness for Duty Programs. At the time the rule was published, the Commission directed the Nuclear Regulatory Commission (NRC) staff to continue to analyze licensee programs, assess the effectiveness of the rule, and recommend appropriate improvements or changes. The staff completed this assessment and the Commission published proposed amendments to the FFD rule in the *Federal Register* on May 9, 1996, (61 FR 21105). The staff reviewed and considered public comments on the proposed rule, and submitted a final rule to the Commission in SECY-00-0159, dated July 26, 2000.

The Commission affirmed the rule in a Staff Requirements Memorandum (SRM-M001204A) dated December 4, 2000. The affirmed rule was sent to the Office of Management and Budget (OMB) to obtain a clearance under the Paperwork Reduction Act. The request for comments on the clearance was published in the *Federal Register* on February 2, 2001 (66 FR 8812). OMB and NRC received public comments that objected to some aspects of the rule (responses to those comments are included in Section V of the attached *Federal Register* notice). In SECY-01-0134, dated July 23, 2001, the staff recommended withdrawing the request for clearance and preparing a new proposed rule.

In a Staff Requirements Memorandum (SRM-SECY-01-0134) dated October 3, 2001, the Commission approved the staff's recommendation to withdraw the request for clearance and prepare a new proposed rule, and directed staff to conduct stakeholder meetings regarding a combined access authorization and fitness-for-duty guidance document. During the subsequent stakeholder meetings, the staff and stakeholders agreed that a guidance document would be unnecessary if the FFD rule language was clear, detailed, and consistent with access authorization requirements.

Worker Fatigue Provisions:

The NRC's "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors," was first published in the *Federal Register* on February 18, 1982 (47 FR 7352), and later issued to licensees through Generic Letter (GL) 82-12, "Nuclear Power Plant Staff Working Hours," on June 15, 1982. In GL 82-12, the NRC requested that licensees revise the administrative section of their technical specifications to ensure that plant administrative procedures were consistent with the revised work-hours guidelines. The policy was incorporated, directly or by reference, and with variances in wording and detail, into the technical specifications of all but three nuclear power plant sites, which implemented the concept using other administrative controls.

In a letter dated February 25, 1999, Congressmen Dingell, Klink, and Markey expressed concerns to former NRC Chairman Shirley Ann Jackson that low staffing levels and excessive overtime may present a serious safety hazard at some commercial nuclear power plants. The

Union of Concerned Scientists (UCS) expressed similar concerns on March 18, 1999, in a letter from David Lochbaum to Chairman Jackson, and in the UCS report "Overtime and Staffing Problems in the Commercial Nuclear Power Industry," dated March 1999. In a letter dated May 18, 1999, to the Congressmen, the Chairman stated that the staff would assess the need to revise the policy.

Soon thereafter, the Commission received a petition for rulemaking (PRM-26-2), dated September 28, 1999, from Barry Quigley. The petition requested that the NRC amend 10 CFR Parts 26 and 55 to establish clear and enforceable work hour limits to mitigate the effects of fatigue for nuclear power plant personnel performing safety-related work.

The Union of Concerned Scientists petitioned the NRC on April 24, 2001, pursuant to 10 CFR 2.206, to issue a Demand for Information (DFI) to specified licensees. The petition asserted that Wackenhut Corporation has the contractual right to fire security guards who refuse to report for mandatory overtime and that this contractual right conflicts with 10 CFR Part 26. The NRC denied the DFI but addressed the concerns of the petition through the NRC's generic communication process. On May 10, 2002, the staff issued NRC Regulatory Issue Summary (RIS) 2002-07: "Clarification of NRC Requirements Applicable to Worker Fatigue and Self-Declarations of Fitness for Duty." The RIS addressed the applicability of 10 CFR Part 26 to worker fatigue, the potential for sanctions related to worker FFD concerns to have adverse implications for maintaining a work environment conducive to reporting FFD concerns, and the protections afforded workers by 10 CFR 50.7, "Employee protection."

On January 10, 2002, the Commission approved a rulemaking plan for worker fatigue at nuclear power plants (SRM-SECY-01-0113). In accordance with the approved plan, the staff initiated a rulemaking to incorporate fatigue management into 10 CFR Part 26 in order to strengthen the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management of worker fatigue.

During the development of proposed fatigue management requirements, the NRC observed an increase in concerns (e.g., allegations, media and public stakeholder reports) related to the workload and fatigue of security personnel following the terrorists attacks of September 11, 2001. Following an NRC review of the control of work hours for security force personnel, and public interactions with stakeholders, the Commission issued order EA-03-038 on April 29, 2003, requiring compensatory measures related to fitness-for-duty enhancements for security personnel at nuclear power plants, including work hour limits.

Combined Part 26 Rulemaking:

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

May 25, 2004, the Commission directed the staff to combine the rulemaking related to nuclear power plant worker fatigue with the ongoing Part 26 rulemaking activity.

Stakeholder Interactions:

The staff held 11 stakeholder meetings on the drug and alcohol testing portions of Part 26 during 2001-2004, and held 13 stakeholder meetings on the fatigue portion of the draft rule during 2002-2003. Subsequent to the Commission's decision to combine the two rulemaking efforts, the staff held one stakeholder meeting on the combined rule in July 2004, and two subsequent meetings on the fatigue provisions of the combined rule in August and September 2004. Throughout this period of time, the staff made the draft proposed rule language available to the public through the agency's internet-based interactive rulemaking website at http://ruleforum.llnl.gov. Consistent with the rulemaking schedule outlined to stakeholders at the public meetings, comments received prior to September 15, 2004, were considered in developing this package.

On December 21, 2004, the NRC received a letter from Marvin Fertel of the Nuclear Energy Institute (NEI) transmitting comments on the draft proposed rule. Although these comments were received after September 15, 2004, the staff has included responses to NEI's concerns in the Attachment 3 *Federal Register* notice, in addition to responses to the major concerns of other stakeholders.

DISCUSSION:

Attachment 3 to this Commission paper provides a *Federal Register* notice to publish the proposed rule for public comment. The goals to be achieved by the rulemaking are to:

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

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

(3) Improve the effectiveness and efficiency of FFD programs.

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

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

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

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

Each of these goals is expected to result in substantial improvements in FFD programs. The many changes that relate to each goal, and the reasons that the specific changes are being proposed, are discussed in detail in Section VI, Section-by-Section Analysis of Substantive Changes, of the *Federal Register* notice provided in Attachment 3. The most significant changes are also listed in Attachment 1.

These substantial improvements to Part 26 would apply to licensees authorized to operate a nuclear power reactor; licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM); corporations that obtain certificates of compliance or approved compliance plans under Part 76 involving formula quantities of SSNM; and construction permit holders with a nuclear power plant under active construction. In addition, the scope of the proposed rule would be updated to reflect the licensing process for new reactors in 10 CFR Part 52. The worker fatigue provisions would only apply to nuclear power plants.

In contrast with the NRC's initiatives towards performance-based regulations, the proposed revisions to 10 CFR Part 26 include a considerable number of detailed requirements. In the public meetings held during the development of this proposed rule, industry representatives indicated that they consider this level of detail necessary to help protect individual privacy and ensure consistency in implementing the requirements. Additionally, industry representatives indicated that this high level of detail can help to avoid unnecessary litigation between licensees and individual personnel regarding worker non-compliance with specific drug and alcohol testing performance steps. Such litigation would be more likely if those specific performance steps were not required by NRC rule. The level of detail and the enhanced clarity in the new language and organization included in proposed Part 26 have also eliminated the need for a guidance document on the drug and alcohol testing provisions. Industry representatives also indicated that a guidance document would not have the same weight as a rule, and that both licensees and individuals should be protected fully with rigor and specificity in a rule. Industry therefore desired the drug and alcohol testing provisions to be more specific and detailed, in lieu of a guidance document.

The proposed rule would partially grant a petition for rulemaking (PRM-26-1) submitted by Virginia Electric and Power Company (now Dominion Virginia Power) on December 30, 1993, by relaxing several required FFD program audit frequencies. The proposed rule would grant portions of the petition by decreasing the audit frequency for licensee and licensee-approved contractor/vendor (C/V) FFD programs from once every 12 months to "no less frequently than every 24 months." However, the proposed rule would deny portions of the petitioner's request by retaining the current 12-month audit frequency for HHS-certified laboratories and C/V FFD programs where the C/V personnel "are off site or are not under the direct daily supervision or observation of licensee personnel...," including but not limited to, contracted MRO [Medical Review Officer], EAP [Employee Assistance Program], and specimen collection services.

The proposed rule would also partially grant PRM-26-2, submitted on September 28, 1999, by Barry Quigley. The PRM was published for public comment on December 1, 1999 (64 FR 67202). As described in Attachment 3 to SECY-01-0113, the petition requested the NRC to:

(1) Add enforceable working hour limits to 10 CFR Part 26;
(2) Add a criterion to 10 CFR 55.33(a)(1) to require evaluation of known sleeping disorders;
(3) Revise the NRC Enforcement Policy to include examples of working hour violations that warrant various NRC sanctions; and
(4) Revise NRC Form 396 to include self-disclosure of sleeping disorders by licensed operators.

The staff evaluated the merits of PRM-26-2, the comments received in response to the PRM, and assessed the NRC's "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors." The staff concluded that the petitioner proposed a comprehensive set of requirements (items 1 and 2) that could reasonably be expected to effectively address fatigue from individual and programmatic causes. However, the staff also believes that it is possible to achieve these objectives through alternative requirements that are more flexible, more directly focused on risk, and more aligned and integrated with current regulatory requirements. The proposed rule would therefore grant, in part, PRM-26-2.

For item 3, the staff has revised and piloted the Physical Protection Significance Determination Process and implemented a new baseline inspection program in February 2003, which includes a procedure for fitness for duty to reflect order EA-03-038, dated April 29, 2003. Order EA-03-038 required compensatory measures related to fitness-for-duty enhancements for security personnel at nuclear power plants, including work-hour limits. The staff plans to similarly revise these same documents during preparation of the final Part 26 rule. Further, following issuance of the final Part 26 rule and confirmation of licensee implementation of the rule, the staff plans to issue an order withdrawing order EA-03-038. The self-disclosure of sleeping disorders by licensed operators (item 4) is being addressed by the staff as a separate effort from this proposed rule through changes to Regulatory Guide 1.134, "Medical Evaluation of Licensed Personnel at Nuclear Power Plants."

Further, SRM-SECY-01-0113 dated January 10, 2002, also directed the staff to "continue to monitor and keep the Commission informed of the other worker fatigue initiatives underway within the Federal Government..." SECY-01-0113 included Attachment 1, which provided tables of work hour limits imposed by other Federal agencies and foreign governments. A general discussion of those other work hour limits, in comparison with the proposed Part 26 requirements, is included in the Attachment 3 *Federal Register* notice, Section IV.D.

Because of the detailed nature of the drug and alcohol testing provisions in the proposed rule, a guidance document is unnecessary. For the worker fatigue provisions, NEI has preliminarily indicated plans to submit an industry guidance document for NRC endorsement during preparation of the final rule. Therefore, the staff has not prepared a draft NRC guidance document to accompany this proposed rule.

Agency Performance Goals

The staff has evaluated the advantages and disadvantages of the proposed rule in terms of the NRC performance goals.

1. Ensure protection of public health and safety and the environment. The proposed rule would ensure protection of public health and safety and the environment through improving the effectiveness of FFD programs. The proposed rule would enhance the

effectiveness of FFD programs based on lessons learned through implementation of the current FFD rule. The proposed rule would further ensure protection of public health and safety through the requirements for comprehensive fatigue management programs.

2. Ensure the secure use and management of radioactive materials. The proposed rule would maintain and improve upon the secure use and management of radioactive materials. The proposed revisions would enhance the capability to detect subversion of the drug testing process. More effective FFD programs would also improve the level of assurance that individuals who have access to nuclear power plant protected areas, SSNM, and certain FFD program personnel are trustworthy and reliable, as demonstrated by the avoidance of substance abuse. The proposed rule would also codify fatigue management requirements for security force personnel at nuclear power plants.

3. Ensure openness in our regulatory process. The proposed rule was developed using an open regulatory process. The staff held a series of public meetings with stakeholders. Many stakeholders commented on the draft provisions, including NEI, UCS, the International Brotherhood of Electrical Workers (IBEW), the Professional Reactor Operator Society (PROS), industry representatives, and Barry Quigley, the petitioner for the proposed fatigue management amendments, among others. Many comments were incorporated into the proposed rule, and are detailed in Section VI of the *Federal Register* notice in Attachment 3. Significant comments that were not incorporated into the proposed rule are discussed in Section V of Attachment 3.

4. Ensure that NRC actions are effective, efficient, realistic, and timely. The proposed changes to the FFD rule would reduce the need to expend staff resources on rule clarifications and on addressing rule and guidance ambiguities that necessitate generic communications and enforcement discretion related to drug and alcohol testing. By requiring comprehensive fatigue management programs at nuclear power plants, the proposed rule would also enable more effective, efficient, and timely regulatory actions concerning licensee management of worker fatigue. Extensive stakeholder interactions during the development of the proposed rule language have contributed to proposed requirements that are realistic, reflecting due consideration of practical implementation issues.

5. Ensure excellence in agency management to carry out the NRC's strategic objective. The proposed rule was developed by a working group that included members from the Office of Nuclear Reactor Regulation (NRR), the Office of Nuclear Security and Incident Response (NSIR), the Office of the General Council (OGC), the Office of Research (RES), the Office of Administration (ADM), and the Office of Nuclear Material Safety and Safeguards (NMSS) to ensure that the proposed provisions would reflect the needs of each office.

CONTENTS OF THE PROPOSED RULEMAKING PACKAGE:

This rulemaking package includes a summary of significant proposed changes to Part 26 (Attachment 1), a listing of the proposed rule provisions that differ from HHS Guidelines (Attachment 2), the *Federal Register* notice for the proposed rule, which includes the proposed

rule language and statements of consideration (Attachment 3), and the regulatory and backfit analyses (Attachment 4). The rule also would amend information collection requirements that must be submitted to the Office of Management and Budget no later than the date the proposed rule is forwarded to the *Federal Register* for publication. The staff is preparing its supporting statement for this rulemaking, which will be finalized upon Commission approval to publish the proposed rule.

REGULATORY AND BACKFIT ANALYSES:

In SRM-01-0134 dated October 3, 2001, the Commission directed the staff to perform an aggregate analysis of the entire rule. Subsequently, by SRM-SECY-04-0045 dated April 21, 2004, the Commission approved revised Regulatory Analysis Guidelines (RA Guidelines) in NUREG/BR-0058, Revision 4, dated September 2004. Consistent with principles underlying the revised guidelines, the staff has prepared the RA and backfitting discussion as follows:

1. The RA contains an aggregation of all costs and benefits, regardless of whether they constitute backfits or not, which responds to the direction in SRM-01-0134 to "conduct an aggregate backfit analysis of the entire rulemaking." Consistent with the revised RA Guidelines, this discussion is contained in Attachment 4, Section 4.1;

2. The backfitting discussion contains an aggregate analysis of all proposed changes that constitute backfits, consistent with Section 4.3.2 of the RA Guidelines, which specifies guidance on aggregation of proposed requirements. The aggregate analysis also responds to the direction in SRM-01-0134 to conduct an aggregate backfit analysis of the entire rulemaking. This discussion is contained in Attachment 4, Section 4.4.1;

3. The RA and backfitting discussions also discuss the screening review for disaggregation performed by the staff. The analysis was performed consistent with Section 4.3.2 of the RA Guidelines to determine if there are provisions whose costs are disproportionate to the benefits and whose inclusion in the aggregate analysis could obscure their impact, but also responds to the direction in SRM-01-0134 that, "If there is a reasonable indication that a proposed change imposes costs disproportionate to the safety benefit attributable to that change, as part of the final rule package the Commission will perform an analysis of that proposed change in addition to the aggregate analysis of the entire rulemaking to determine whether this proposed change should be aggregated with the other proposed change for the purposes of the backfit analysis. That analysis will need to show that the individual change is integral to achieving the purpose of the rule, has costs that are justified in view of the benefits that would be provided or qualifies for one of the exceptions in 10 CFR §50.109(a)(4)." These results are described in Attachment 4, Sections 4.1.4 and 4.4.2.

Also, in a June 10, 2004, letter to Chairman Diaz, NEI strongly urged that fatigue management provisions be a separate rulemaking and the drug and alcohol testing portions be expedited "because, the [drug and alcohol testing] rule is essentially ready, following significant effort by NRC staff members with substantial input from external stakeholders, over the last three years." Further, in a December 21, 2004, letter to Luis Reyes, NEI stated that, "the requirement for a

48-hour break every 14 days has major cost implications, thus warranting a separate backfit analysis." The NRC staff does not believe that separate backfit analyses should be performed for the fatigue management provisions in the aggregate. Fatigue currently is considered to be part of FFD under current §26.10(a) and §26.20(a)(2). Fatigue management is an integral and necessary aspect of FFD, and is a central goal of the overall revision to Part 26 as directed in SRM-COMSECY-04-0014, dated May 25, 2004. However, the NRC staff has analyzed the proposed fatigue management requirements in the aggregate in the RA in Attachment 4, Section 4.1.4.2. Further, the proposed requirement for a 48 hour break every 14 days was evaluated in the screening review for disaggregation, and was determined to be necessary to meet the objectives of the rule. Therefore, the staff did not perform a separate backfit analysis for that individual requirement.

Note that the regulatory and backfit analyses provide a justification for the proposed rule based on a quantitative and qualitative assessment of the costs, savings and benefits. However, the staff has included an additional quantitative evaluation of the benefits from selected fatigue management provisions in Attachment 4, Addendum 1, which is not necessary for full justification of the proposed rule, but provides further support for those specific provisions.

RELATED ACTIVITIES:

In SRM-COMSECY-04-0037, dated September 1, 2004, the Commission determined FFD enhancements related to the fatigue of security force personnel at Independent Spent Fuel Storage Installations, Decommissioning Reactors, Category I Fuel Cycle Facilities, Gaseous Diffusion Plants and the Natural Uranium Conversion Facility should be pursued as a separate rulemaking activity with additional stakeholder interactions. That activity is scheduled to begin in FY 2006. Publication of a proposed rule related to fatigue of security forces for these materials facilities would not occur until the final rule is published for this rulemaking.

By SRM-SECY-04-0229 dated January 10, 2005, the Commission denied IBEW Local 1245's exemption request related to 10 CFR 26.6, "Exemptions," to exempt clerical, warehouse, and maintenance workers at the Diablo Canyon Nuclear Power Plant from random testing.

The proposed rule is consistent with the enforcement policy revision, which the Commission published in the *Federal Register* (67 FR 66311) on October 31, 2002, with the exception of those provisions of the enforcement policy revision that have been superseded by the access authorization orders issued to nuclear power plant licensees dated January 7, 2003. The proposed rule is consistent with current access authorization requirements, including those in the access authorization order. Additionally, in order to further strengthen the effectiveness of FFD programs in ensuring that individuals who are subject to the rule are trustworthy, reliable, and fit for duty, the proposed rule would require random drug and alcohol testing of individuals who are applying for authorization, which is not required in the access authorization order.

RESOURCES:

The FY 2005 budget includes the following resources for the proposed rulemaking: 2.5 FTE and $385K for NRR, 1.5 FTE and $200K for NSIR, 0.5 FTE for RES, 0.2 FTE for NMSS and 0.3 FTE for OGC. The planned FY 2006 budget request for the final rule includes: 2.0 FTE and $400K

for NRR, 1.5 FTE and $200K for NSIR, 0.5 FTE for RES, 0.2 FTE for NMSS and 0.3 FTE for OGC.

RECOMMENDATIONS:

Based on the background and discussion presented above, the staff recommends that the Commission take the following actions with regard to the proposed FFD rule:

(1) Approve publication of the proposed rule as detailed in the *Federal Register* notice provided in Attachment 3 to this Commission paper.

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

(3) Note the following considerations*:*

(a) The NRC staff will transmit the proposed rule for publication in the *Federal Register* with a 120-day public comment period.

(b) This proposed rule would amend information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Consequently, the staff is sending this proposed rule to OMB for review and approval of the paperwork requirements. The *Federal Register* notice for the proposed rule also serves as the notice for public review and comment of the OMB clearance request with a 30-day public comment period. The OMB supporting statement will be finalized by NRC staff by July 21, 2005, in order to support publication of the proposed rule in the *Federal Register*. NRC staff will make any necessary changes to the OMB Paperwork Reduction Act Statement and §26.8 [Information Collection Requirements: OMB Approval] in the *Federal Register* notice in Attachment 3 to conform with the final OMB supporting statement prior to publication in the *Federal Register*.

(c) The NRC staff will inform the Chief Counsel for Advocacy of the Small Business Administration of the certification regarding economic impact on small entities and the basis for it, as required by the Regulatory Flexibility Act.

(d) The NRC staff will furnish copies of this proposed rule to the State Liaison Officers and Homeland Security Advisors for comment.

(e) The NRC staff will issue a public announcement concerning the proposed rule and the related comment period.

(f) The NRC staff will inform the appropriate congressional committees.

COORDINATION:

The Advisory Committee on Reactor Safeguards (ACRS) has indicated that it will review the proposed rule following the public comment period. Consistent with the direction in SRM-COMEXM-04-0002, dated August 26, 2004, and discussions with the Chairman of the Committee to Review Generic Requirements (CRGR), the staff will schedule the CRGR review following Commission approval of the proposed rule, its publication in the *Federal Register* for public comment, and disposition of the received comments.

The Office of the General Counsel reviewed the proposed rule and has no legal objection. The Office of the Chief Financial Officer (OCFO) has reviewed this paper for resource implications and concurs.

/Martin J. Virgilio, Acting For/

Luis A. Reyes
Executive Director
for Operations

Attachments:
1. Summary of Significant Differences Between the Current and Proposed 10 CFR Part 26 Rules
2. Proposed Rule Provisions That Differ From HHS Guidelines
3. *Federal Register* Notice
4. Regulatory Analysis

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Package: ML050970502
Commission Paper & Attachments 1 & 2: ML050970498
W200400084
Attachment 3: ML050970505
Attachment 4: ML050970509

*via email **via memo

OFFICE	DRIP:RPRP	E	DRIP:RPRP		DRIP:RPRP		DRIP:RPRP		DRIP:RPRP:PD		Tech Ed	
NAME	RKaras		BRichter		BThomas		PRay		CHaney		PKleene*	
DATE	12/8/04		12/9/04		12/14/04		12/17/04		12/17/04		2/23/05	

OFFICE	D:PMAS		D:OE		D:DIPM		OCIO		OGC		D:NSIR	
NAME	CCarpenter (JTappert for)		FCongel (CNolan for)*		BBoger		BShelton**		STreby		RZimmerman	
DATE	2/4/05		2/4/05		2/2/05		2/3/05		4/14/05		2/7/05	

OFFICE	ADM		D:NMSS		OCFO		D:RES		D:STP		D:DRIP	
NAME	MLesar**		JStrosnider		LBarnett (DDrucker for)*		CPaperiello (JCraig for)*		PLohaus*		DMatthews (FGillespie for)	
DATE	2/3/05		2/3/05		2/8/05		1/31/05		1/31/05		4 /15/05	

OFFICE	D:NRR		EDO									
NAME	JDyer		LReyes/MJV Acting for									
DATE	04/21/05		04/28/05		/ /		/ /		/ /		/ /	

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SUMMARY OF SIGNIFICANT DIFFERENCES
BETWEEN THE CURRENT AND PROPOSED 10 CFR PART 26 RULES

Significant Changes in Applicability of the Rule

- Clarify that the rule applies to new reactors constructed and licensed under 10 CFR Part 52. (§26.3)

- Continue to apply the rule to all personnel with unescorted access to the protected area of a nuclear power plant, consistent with the NRC's denial of a 10 CFR 26.6 exemption request by the International Brotherhood of Electrical Workers (IBEW) Local 1245. (§26.25)

- Prohibit the granting of temporary unescorted access to the protected areas in almost all circumstances. (§26.53)

- Clarify that there are no distinctions in the FFD requirements between licensee and contractor/vendor (C/V) personnel who are subject to the FFD requirements. (§26.3)

- Provide that persons who are covered by a program regulated by another Federal or State agency that meets the performance objectives of 10 CFR Part 26 need not be subject to duplicate testing and training requirements by a licensee's FFD program. (§26.25)

Significant Changes To Enhance Consistency With HHS and DOT Guidelines and Programs

C Add requirements for validity tests on urine specimens to determine if a specimen has been adulterated, diluted, or substituted. At the request of stakeholders, the rule would permit licensee testing facilities to perform validity screening tests using non-instrumented testing devices, as proposed by HHS on April 13, 2004 (69 FR 19672), but not yet incorporated into final HHS guidelines.

C Add requirements for the use of oral fluids (i.e., saliva) as acceptable specimens for initial alcohol tests.

Significant Changes To Enhance the Effectiveness and Efficiency of FFD Programs

C Substantially reorganize the rule to eliminate redundancies, group related requirements together, and present requirements in the order in which they would apply to licensee FFD processes.

Subpart B —Program Elements

– Emphasize the Commission's intent that the performance objective of FFD programs is to provide "high" rather than "reasonable" assurance that persons subject to Part 26 are trustworthy and reliable as demonstrated by the avoidance of substance abuse and the adverse behaviors that may accompany it. (§26.23)

- Revise the FFD training requirements to require all individuals subject to the rule to receive the same FFD training, including training on behavioral observation, and complete training prior to assignment to duties within the scope of Part 26; add a requirement for a comprehensive examination; allow the use of alternative training media; and allow individuals who pass a comprehensive "challenge" examination to be exempted from annual refresher training. The rule would permit licensees and other entities to accept passing a "challenge" examination that was administered by another Part 26 program to satisfy the annual refresher training requirement. (§26.29)

- Revise drug and alcohol testing program requirements:

  - Allow properly monitored supervisors, co-workers, or relatives of the individual being tested to collect specimens (except for directly observed collections), but continue to restrict them from performing assessment or evaluation procedures. (§26.31(b)(1))

  - Clarify the situations—"pre-access," "for cause," "post-event," "return-to-duty," "follow-up," and "random"—in which testing would be required. (§26.31(c))

  - Add requirements to include urine specimen validity testing. (§§26.131, 26.137, 26.161, and 26.167)

  - Add a requirement that assays used for testing for drugs in addition to those specified in this part, or testing at more stringent cutoff levels than those specified in this part, would be evaluated and certified by an independent forensic toxicologist. (§26.31(d))

  - Add a requirement that cutoff levels would be applied equally to all individuals subject to testing. (§26.31(d))

  - Lower the blood alcohol concentration (BAC) at which a confirmatory test is required from 0.04 percent to 0.02 percent. (§26.31(d))

  - Eliminate blood testing for alcohol. (§26.31(d))

- Clarify that behavioral observation would be a required element of FFD programs. (§26.33)

- Clarify and strengthen the due process rights of individuals undergoing a review for FFD violations. (§§26.37 and 26.39)

Subpart C—Granting and Maintaining Authorization

- Allow licensees to rely on other licensees' and other entities' Part 26 programs to meet requirements for granting and maintaining authorization. (§26.53)

- Clarify the time period during which an individual may be away from a Part 26 program and maintain authorization. (§26.53(b))

- Reduce from 5 to 3 years the period of time to be addressed by the suitable inquiry for initial applicants who do not report any potentially disqualifying FFD information on the self-disclosure. (§26.55)

- Increase the thoroughness of the suitable inquiry. (§26.55)

- Define the steps that licensees would take in granting initial authorization, authorization updates, and authorization reinstatements. The rule would relate requirements to factors such as whether the individual has held authorization before, the time elapsed since the applicant last held authorization, and whether the individual's last period of authorization was terminated favorably. (§§26.55, 26.57, 26.59)

- Specify the questions and define the time period that would be addressed in the self-disclosure. (§26.61)

- Permit licensees to rely on suitable inquiry information gathered by previous licensees and other entities who would be subject to the rule. (§26.63)

- Reduce the period from 60 to 30 days in which a pre-access drug test would be performed prior to assignment to activities. (§26.65(b))

- Clarify and strengthen requirements for re-authorizing an individual who has had a confirmed positive drug or alcohol test result and whose authorization has been terminated unfavorably. (§26.69)

Subpart D—Management Actions and Sanctions

- Make the minimum sanctions for violations of the FFD policy more stringent. (§26.75)

  - Require permanent denial of authorization for refusing to be tested or attempting to subvert the testing process. (§26.75(b))

  - Add a 5-year denial of authorization for resignation to avoid removal for an FFD violation. (§26.75(d))

  - Require unfavorable termination of authorization for 14 days for a first confirmed positive drug or alcohol test result. (§26.75(e))

  - Increase the authorization denial period for a second confirmed positive drug or alcohol test result from 3 to 5 years. (§26.75(e))

  - Add permanent denial of authorization for additional FFD violations following any previous denial for 5 years. (§26.75(g))

- Clarify the requirements with regard to individuals who may be impaired. (§26.77)

Subpart E —Collecting Specimens for Testing

- Reorganize, clarify, and specify in more detail the requirements that are currently in Appendix A. These changes would make drug and alcohol collection practices more consistent with those of other Federal agencies and would increase consistency among Part 26 FFD programs. Increased consistency would allow Part 26 programs to accept and rely on other Part 26 FFD programs for suitable inquiries, determinations of fitness, authorization decisions, and results of drug and alcohol tests. (Subpart E)

- Permit the use of either breath or oral fluids (i.e., saliva) for initial alcohol tests. The rule would allow only breath specimens to be used for confirmatory alcohol testing and eliminate the donor's discretion to use blood as specimen for alcohol testing. (§26.83(a))

- Clarify requirements for actions to be taken if an individual does not appear for testing. (§26.89)

- Establish requirements regarding the alcohol screening devices (ASDs) that may be used, clarify requirements for evidential breath testing (EBT) devices, and permit use of the same EBT for initial and confirmatory alcohol testing. (§26.91)

- Reduce the number of breath specimens required for alcohol testing from two each for initial and confirmatory testing to one each for the initial and confirmatory testing (consistent with DOT procedures for workplace alcohol testing). (§26.95)

- Eliminate the requirement to list medications prior to specimen collection (in compliance with the privacy requirements of the Americans with Disabilities Act). (§26.89)

- Consistent with DOT procedures, add detailed procedures for conducting initial and confirmatory breath alcohol tests with EBTs, and for conducting initial tests for alcohol with ASDs. (§§ 26.93, 26.95, 26.97, 26.99 and 26.101)

- Reduce from 0.04 percent to 0.02 percent the BAC at which a confirmatory alcohol test would be required (§26.99) and provide cutoff levels for confirmed positive alcohol test results that take into account the length of time the donor had been in a work status. (§26.103)

- Clarify requirements for urine specimen collection procedures and make the procedures more consistent with those of other Federal programs. (§26.105)

- Require donors to provide a "predetermined quantity" of at least 30 mL of urine (decreased from 60 mL in current rule) and eliminate requirements to combine successive specimens from a donor to obtain a specimen of sufficient size. (§26.109)

- Clarify requirements for assessing specimen validity at the collection site. (§26.111)

- Specify grounds to conduct a directly observed collection. (§26.115)

– Combine in one section requirements for safeguarding specimens and preparing them for transfer to the licensee testing facility or an HHS-certified laboratory for testing. (§26.117)

– 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. (§25.119)

Subpart F—Licensee Testing Facilities and Subpart G—HHS-Certified Laboratories

– Clarify and combine requirements applicable to licensee drug testing facilities in Subpart F and combine requirements applicable to HHS-certified laboratories in Subpart G. Many requirements in Subpart F parallel requirements in Subpart G. For increased clarity, stakeholders requested that requirements for each type of laboratory be presented separately and that any requirements that apply to both types of laboratories be presented in both subparts.

Licensee Testing Facilities

C Add cutoff levels for initial validity tests of urine specimens at licensee testing facilities and require tests for creatinine, pH, and one or more oxidizing adulterants. The rule would not allow licensees and other entities to establish more stringent cutoff levels for validity testing, and would also specify the criteria for determining that a specimen must be forwarded to an HHS-certified laboratory for further testing. (§26.131)

C Replace and amend cutoff levels for initial tests for drugs and drug metabolites to be consistent with HHS cutoff levels. (Decrease the cutoff level for marijuana metabolites from 100 ng/mL to 50 ng/mL. Increase the cutoff level for opiate metabolites from 300 ng/mL to 2,000 ng/mL.) (§26.133)

C Eliminate the requirement that licensees must inform the Commission and receive written approval from the Commission before specifying more stringent cutoff levels for drugs and drug metabolites and add a requirement for more stringent cutoff levels to be evaluated and approved by an independent forensic toxicologist. (§26.133)

C Clarify requirements concerning donor requests to test the specimen in Bottle B of a split sample. (§26.135)

HHS-Certified Laboratories

C Add cutoff levels for validity testing at HHS-certified laboratories to be consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. (§26.161)

C Replace and amend cutoff levels for initial tests for drugs and drug metabolites to be consistent with HHS cutoff levels. (Decrease the cutoff level for marijuana

metabolites from 100 ng/mL to 50 ng/mL. Increase the cutoff level for opiate metabolites from 300 ng/mL to 2,000 ng/mL.) (§26.163)

Subpart H—Determining Fitness-for-Duty Policy Violations and Determining Fitness

– Clarify and expand the requirements relating to qualifications, relationships, and responsibilities of the Medical Review Officer (MRO).

  C Add a requirement that the MRO pass a certification examination within 2 years of rule implementation. (§26.183)

  C Add specific prohibitions concerning conflicts of interest. (§26.183)

  C Specify MRO programmatic responsibilities. (§26.183)

– Establish the requirements and responsibilities of the MRO Staff.

  C Add a requirement for the MRO to be directly responsible for the activities of individuals who perform MRO staff duties. (§26.183)

  C Add a requirement that MRO staff duties must be independent from any other activity or interest of the licensee or other entity. (§26.183)

  C Prohibit the MRO from delegating his or her responsibilities for directing MRO staff activities to any individual or entity other than another MRO. (§26.183)

  C Specify the job duties that MRO staff may and may not perform. (§26.183)

– Clarify and expand MRO responsibilities for verifying an FFD violation.

  C Make the MRO responsible for assisting the licensee or other entity in determining whether the donor has attempted to subvert the testing process. (§26.185)

  C Provide detailed guidance on circumstances in which the MRO may verify a non-negative test result as an FFD policy violation without prior discussion with the donor. (§26.185)

  C Clarify MRO responsibilities when the HHS-certified laboratory reports that a specimen is invalid. (§26.185)

  C Specify actions the MRO may take if he or she has reason to believe that the donor may have diluted a specimen in a subversion attempt, including confirmatory testing of the specimen at the assay's lowest level of detection for any drugs or drug metabolites. (§26.185)

  C Add requirements for the MRO to determine whether a donor has provided an acceptable medical explanation for a specimen that the HHS-certified laboratory reported as adulterated or substituted. (§26.185)

- C Incorporate HHS recommendations on verifying a positive drug test for opiates. (§26.185)

- C Incorporate Federal policy prohibiting acceptance of an assertion of consumption of a hemp food product or coca leaf tea as a legitimate medical explanation for a prohibited substance or metabolite in a specimen. (§26.185)

- C Provide detailed requirements for evaluation of whether return-to-duty drug test results indicate subsequent drug use. (§26.185)

– Add a new position, substance abuse expert (SAE), to the minimum requirements for FFD programs and specify the qualifications and responsibilities of the SAE. (§26.187)

- C Specify the role of the SAE in making determinations of fitness and the return-to-duty process, including the initial evaluation, referrals for education and/or treatment, the followup evaluation, continuing treatment recommendations, and the followup testing plan. The rule would specify the role of the SAE in determinations of fitness based on the types of professional qualifications possessed by the SAE. (§26.189)

Subpart I—Managing Fatigue

– Establish program requirements for fatigue management at nuclear power plants.

- C Codify a process for workers to self-declare that they are not fit for duty because of fatigue. (§26.197)

- C Require training for workers and supervisors on symptoms of and contributors to fatigue and on fatigue countermeasures. (§26.197)

- C Require licensees to include fatigue management information in the annual FFD program performance report that would be required under §26.217, including the number of waivers of the individual limits and break requirements that were granted, the collective work hours of any job duty group that exceeded the group average limit in any averaging period, and certain details of fatigue assessments conducted. (§26.197)

– Establish work hour controls for certain job functions at nuclear power plants, performed by operations, maintenance, health physics, chemistry, security and some fire brigade personnel.

- C Establish individual work hour limits of no more than 16 hours in a 24 hour period, 26 hours in a 48 hour period, and 72 hours in a week, excluding shift turnovers. (§26.199)

- C Establish individual break requirements of at least 10 hours between shifts, a 24-hour break in any 7 days, and a 48-hour break in any 2 weeks, with some exceptions for outages. (§26.199)

- Allow licensees to waive the individual work hour limits and break requirements only if necessary to mitigate or prevent a condition adverse to safety or to maintain the security of the facility and if a fatigue assessment is performed for the worker with satisfactory results. (§26.199)

- Would not permit licensees to waive the individual work hour limits and break requirements for individuals who self-declare they are unfit due to fatigue; if a fatigue assessment performed for those individuals determined they were fit, the individuals would only be permitted to perform non-risk significant activities under the waiver. (§26.199)

- Establish a group average limit of 48 hours/week over a 13-week calculation period. (§26.199)

  – The first 8 weeks of a plant outage would be exempted from the limit for non-security personnel and would be increased to 60 hours/week for security personnel. (§26.199)

  – Security personnel would be allowed a 60 hour/week limit during the first 8 weeks of any planned security system outages. (§26.199)

  – Security personnel would not be subject to any group average limit during the first 8 weeks of an unplanned security system outage or increased threat condition. (§26.199)

  – Successive plant outages separated by 2 weeks or less would be considered as a single plant outage for purposes of the 8-week exemption. (§26.199)

- Allow the average work hours of any job duty group to exceed the 48 hour/week limit in one averaging period if either:

  - NRC approval is obtained, or

  - The circumstances could not be reasonably controlled, the group average does not exceed 54 hours/week, and the additional hours are worked only to address the circumstances the licensee could not have reasonably controlled. The group average would not be allowed to exceed the 48-hour/week limit in any two consecutive averaging periods without NRC approval. (§26.199)

- Waive the individual and group limits during a declared emergency. (§26.199)

- Waive the individual and group limits for security personnel if the NRC notifies licensees in writing that the limits are waived in order to assure the common defense and security. (§26.199)

- Require licensees to review individual and group hours worked, including reviews for any individuals granted more than one waiver, individuals assessed for fatigue,

individuals with average work hours over 54 hours/week when subject to a 48 hour/week group average, and individuals with over 66 hours/week when subject to a 60 hour/week group average limit. The rule would require licensees to record, trend, and correct, under the corrective action program, problems found with fatigue management. (§26.199)

- Require face-to-face fatigue assessments for specific post-event, for-cause, self-declaration and follow-up conditions. (§26.201)

Subpart J—Recordkeeping and Reporting Requirements

– Reorganize and present together recording and recordkeeping requirements that are currently in separate sections of the rule.

  C Require submission of program performance data to the NRC every 12 months rather than every 6 months, as in the current rule. (§26.217)

  C Require C/Vs with approved drug and alcohol testing programs to submit program performance data to the NRC. (§26.217)

Subpart K—Inspections, Violations, and Penalties

– Reorganize and present together the current requirements. (§§26.221, 26.223)

PROPOSED RULE PROVISIONS THAT DIFFER FROM HHS GUIDELINES

Introduction

The Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines) (1988, as amended in 1994, 1998, and 2004) establish requirements and standards for drug testing by Federal agencies. The purpose of the HHS Guidelines is to ensure that Federal agencies' urine drug test results are accurate, reliable, and legally defensible. The HHS Guidelines address the collection, laboratory analysis, medical review, and reporting of specimens tested under HHS requirements. The HHS Guidelines are generally recognized as the national standard in this area.

Part 26 includes requirements for drug testing as part of a broader set of requirements for fitness-for-duty (FFD) programs. Most NRC licensees are private-sector employers and, therefore, are not subject to the HHS Guidelines. Historically, however, Part 26 has incorporated many of the provisions of the HHS Guidelines. The proposed revisions to Part 26 generally incorporate the requirements in the most recent revision of the HHS Guidelines, which was published in the *Federal Register* on April 13, 2004 (69 FR 19644).

The proposed Part 26 would supplement, adapt, or update the Guidelines in two areas. First, this proposed rule would supplement and adapt some provisions in the HHS Guidelines to address the unique circumstances of the NRC and its licensees. Second, the proposed rule would incorporate a limited set of revisions to HHS-recommended practices for conducting drug testing that have not yet been published by HHS as a final rule. This attachment discusses these differences in more detail.

Adaptations of Provisions in the HHS Guidelines to NRC's and Licensees' Circumstances

To address the unique circumstances of NRC and its licensees, certain drug testing provisions in the HHS Guidelines would be modified for inclusion in proposed Part 26. The most significant differences between the drug-testing provisions of proposed Part 26 and the HHS Guidelines derive from decisions the Commission made when Part 26 was first published. These differences include:

- Permission for NRC licensees to operate licensee testing facilities at which initial drug tests are performed (at §26.24(d)(1) of the current rule and §26.31(d)(3)(ii) of the proposed rule);

- Permission for NRC licensees to test for any illegal drug or any other substances that an individual is suspected of having abused when testing for cause (at Section 2.1(b) of Appendix A to the current Part 26 and §26.31(d)(1)(ii) of the proposed rule);

- Permission for NRC licensees to establish more stringent cutoff levels for drugs and drug metabolites than those required in the HHS Guidelines (at §26.24(b) of the current rule and §26.31(d)(iii) of the proposed rule);

- A requirement for licensees to test for all five of the drugs and drug metabolites for which testing is permitted under the HHS Guidelines (i.e., the HHS panel) (at Section 2.1(a) of Appendix A to the current Part 26 and §26.31(d)(1) of the proposed rule); and

- Requirements related to ensuring the honesty and integrity of FFD program personnel (at Section 2.3 of Appendix A to the current Part 26 and proposed §26.31(b)(1)).

In addition, proposed Part 26 would incorporate different or more detailed procedural requirements in some areas than the HHS Guidelines.

C Proposed Part 26 would define a procedure for assuring that NRC licensees' drug testing is scientifically sound and legally defensible when the licensee tests for drugs or drug metabolites that are not included in the HHS panel. Proposed §26.31(d)(1) would require a qualified forensic toxicologist to review and certify the assays and cutoff levels that a licensee will use when testing for any drugs or drug metabolites not included in the HHS panel. The HHS Guidelines require Federal agencies to submit written petitions to test for additional drugs to the Secretary for review and approval. The alternative procedure in proposed Part 26 is necessary because NRC licensees do not have access to the HHS review process.

C Proposed §26.31(d)(3)(iii)(B) would require NRC licensees to apply the FFD program's cutoff levels uniformly to all types of tests (e.g., pre-access, random, for cause) and equally to all individuals tested. The HHS Guidelines do not include a similar requirement. The proposed requirement would respond to implementation issues that have arisen since Part 26 was first published and would protect the due process rights of individuals who are subject to the rule.

C Proposed §26.31(d)(5) would permit the Medical Review Officer (MRO) to authorize alternative specimen collection and evaluation procedures for rare circumstances in which it would be difficult or hazardous to the donor to collect breath, oral fluids, or urine specimens. These circumstances would include, but would not limited to, required post-event testing when an individual has been seriously injured. The HHS Guidelines do not include a similar provision. This provision would protect the health of individuals who are subject to Part 26 and would be adapted from the Department of Transportation (DOT) Procedures for Transportation Workplace Drug and Alcohol Testing, effective August 1, 2001 (49 CFR Part 40, 65 FR 79462), in response to stakeholder requests.

C In response to stakeholder requests, proposed §26.87(d) would provide more detailed requirements for collection site security than the HHS Guidelines. The HHS Guidelines require a collection site to be secure, but do not specify the implementation details desired by stakeholders. Proposed Part 26 would not permit unauthorized personnel to have access to a collection site and would permit use of locked doors, alarms, or visual monitoring of the collection site when it is not occupied, or other means, as acceptable security physical measures to control access. Proposed Part 26 would also require posting a sign to indicate access is permitted only for authorized personnel when a site is not solely dedicated to collecting specimens.

- In response to stakeholder requests, proposed Part 26 would permit colors other than blue to be used in toilet tanks or any other source of standing water in an area that is used for urine specimen collections. The HHS Guidelines only permit the color blue to be used. Also in response to stakeholder requests, proposed §26.87(e) would provide more detailed instructions to collectors for ensuring that no potential adulterants are available at the collection site. The HHS Guidelines do not provide similarly detailed instructions.

- Proposed §26.87(f) would provide more detailed requirements than the HHS Guidelines for collection of urine specimens in the unusual circumstance when a designated collection site is inaccessible. These provisions would be adapted from DOT's Procedures in response to stakeholder requests.

- Proposed Part 26 would provide more detailed requirements than the HHS Guidelines for the actions a collector would take if an individual selected for testing fails to appear at the appointed time. The HHS Guidelines direct the collector to "contact the appropriate authority to obtain guidance on the action to be taken." Proposed §26.89(a) would direct the collector to contact FFD program management and would define the steps that FFD program management would take in these circumstances.

- Proposed §26.89(b) would provide more detailed requirements than the HHS Guidelines for identifying a donor, and would require that specimens be collected even if the donor does not present the required photo-identification. The proposed requirements would provide greater assurance that the individual who appears for testing is the correct donor, that FFD program management is informed of any donor-identity problems, and that the collection is not unnecessarily delayed or cancelled, if the lack of identification is easily explained and resolved.

- Proposed §26.89(e) would prohibit any delay in medical treatment that could result from collecting specimens for drug and alcohol testing if an individual has been injured and is subject to post-event testing. The HHS Guidelines do not include a similar provision. This provision would protect the health of individuals who are subject to Part 26 and would be added in response to stakeholder requests.

- In response to stakeholder requests, proposed §26.103(b) would require the donor to permit the collector to examine the contents of the donor's pockets prior to urine specimen collection. The HHS Guidelines require the collector to make the examination and imply, but do not clearly state, that the donor must permit the examination to occur. The current Part 26 requirement is consistent with the HHS provision. Stakeholders requested this clarification because some donors have used this loophole in the current Part 26 to disrupt the collection process.

- Proposed §26.105(a)(3) would permit the collector to set a reasonable limit on the time within which a donor must provide a urine specimen. Neither the HHS Guidelines nor the current Part 26 includes a similar provision. Stakeholders requested this clarification because some donors have used this gap in the current Part 26 to disrupt the collection process. This provision would be adapted from the DOT's Procedures.

- Proposed §26.105(b) would provide more detail on the actions a collector would take if a donor exhibits any conduct that clearly indicates an attempt to tamper with a urine specimen. The related provisions in the HHS Guidelines and in the current Section 2.4(g)(9) in Appendix A to Part 26 require the collector to note the unusual behavior on the specimen custody-and-control form and in the permanent record book. In response to stakeholder requests, proposed §26.105(b) would further direct the collector to contact FFD program management to determine whether a directly observed collection should be performed.

- Proposed §26.105(c) would require the collector to inspect the cubicle or stall in which the donor provides a urine specimen for evidence of a subversion attempt, which would increase the likelihood that a subversion attempt will be detected. The HHS Guidelines do not include such a provision.

- Proposed §26.107 would provide more detailed requirements than the HHS Guidelines related to the quantity of urine that donors would provide for drug testing. The additional requirements would support related provisions in the proposed rule, which would permit licensees to perform initial tests at licensee testing facilities and to test for drugs and drug metabolites that are not included in the HHS panel.

- Proposed §26.113 would provide more detailed procedures than the HHS Guidelines for collecting a urine specimen under direct observation. The procedures would be adapted from the DOT Procedures to increase consistency among Part 26 programs in how directly observed collections are performed as well as consistency between how collections are performed under Part 26 and the DOT's Procedures. Proposed Part 26 would permit licensees to accept drug test results from collections that are performed in accordance with DOT Procedures in some cases and would retain the permission in the current rule for licensees to accept drug test results from other licensee FFD programs.

- Proposed §26.167(f) would require licensees to submit blind performance test specimens to HHS-certified laboratories at a lower rate than the HHS Guidelines require for Federal agencies. This difference from the HHS Guidelines would reduce the performance-testing burden on NRC licensees and, because of the very large number of blind performance test specimens that are submitted by Federal agencies, would not adversely affect the effectiveness of the HHS' laboratory performance-testing requirements.

- Proposed §26.169(a) would require HHS-certified laboratories to report drug test results to the licensee's MRO within 5 business days of receiving the specimen. The HHS Guidelines require the laboratories to report drug test results to the Federal agencies' MROs "within an average of 5 working days." The difference is necessary to support related requirements in Subpart C of proposed Part 26.

- Proposed §26.169(k) would decrease the frequency with which HHS-certified laboratories must submit summary reports of drug test results to NRC licensees from monthly (in the current Section 2.7(g) of Appendix A) to annually. The HHS Guidelines require the laboratories to submit these reports to Federal agencies semiannually. FFD program experience indicates that neither a monthly nor a semiannual summary report is necessary. Proposed Part 26 would reduce the required frequency for submitting these reports to a

frequency consistent with the NRC's need for the information but would not prohibit licensees from obtaining the reports more frequently if they wish.

- In response to implementation issues that have arisen since Part 26 was first published, proposed §26.183(d) would specify requirements related to persons who serve as MRO staff. These provisions would be adapted from the DOT's Procedures to assure the independence and confidentiality of the MRO review function, including those tasks that MRO staff are permitted to perform under the proposed rule. The HHS Guidelines require MRO staff to be under the direct personal supervision of the MRO. Because the MRO is required to be independent, the HHS Guidelines do not include specifics to ensure the staff's independence. Stakeholders requested proposed Part 26 not require MRO staff to be under the direct personal supervision of the MRO and permit staff to be employees of the licensee or other entity subject to Part 26. Accordingly, proposed Part 26 would permit MRO staff to be employees of the licensee or other entity, but would incorporate detailed provisions specifying which tasks the MRO staff may perform, require the MRO to direct the MRO staff's duties, and specify many other of the interactions between the MRO and MRO staff to ensure independence of the MRO staff.

- In response to implementation questions and stakeholder requests, proposed Part 26 would provide more detailed requirements than the HHS Guidelines related to the MRO's contact with a donor who has had a non-negative drug test result that was confirmed by an HHS-certified laboratory, at proposed §26.185(c)–(e). The HHS Guidelines require the MRO to contact the donor as part of the drug test review process. Proposed §26.185(c)–(e) would specify procedures for contacting the donor and the actions the MRO would take in several circumstances. The proposed provisions would be adapted from the DOT's Procedures.

- Proposed Part 26 would permit the MRO to request drug testing at the assay's limit of detection for dilute specimens at proposed §26.185(g). Under the HHS Guidelines, a specimen is considered "dilute" if the specimen's creatinine concentration falls between 2–20 milligrams per deciliter. Submitting a dilute specimen would not be a violation of the FFD policy and no sanctions would be imposed on the donor under the proposed rule because there are many legitimate reasons that a donor may provide a dilute specimen. However, some donors who provide dilute specimens may also have consumed large amounts of liquids in order to decrease the concentrations of drugs or drug metabolites in their urine specimen below the FFD program's cutoff levels. Therefore, the proposed rule would authorize the MRO to request the HHS-certified laboratory to test at the assay's limit of detection to determine whether a urine specimen contains drugs or drug metabolites in order to determine whether the individual has violated the FFD policy.

- Proposed §26.185(j) would provide more detailed requirements for the MRO's review of non-negative test results for opiates and over-the-counter and prescription medications than the HHS Guidelines and the current Section 2.9(d) of Appendix A to Part 26. Proposed Part 26 would add requirements for the MRO's review of non-negative test results from the consumption of supplements or preparations containing ingredients such as hemp oil or coca leaf tea, use of another person's prescription medications, and use of a drug that was legally obtained in a foreign country. The more detailed requirements would be added in response to implementation issues that have arisen since Part 26 was first published. The requirements related to supplements or preparations containing ingredients such as hemp

oil or coca leaf tea would incorporate the Federal policy in this matter that was published by the Department of Transportation, with the concurrence of the Departments of Justice and Health and Human Services and the Office of National Drug Control Policy.

- Proposed §26.185(o) would provide requirements for several steps in the MRO's review of return-to-duty drug test results. The HHS Guidelines do not include a similar provision. The proposed requirements respond to implementation issues that have arisen since Part 26 was first published.

- The HHS Guidelines require Federal agencies to use the Federal specimen custody-and-control form to transmit specimens to HHS-certified laboratories for testing. Proposed Part 26 would not require NRC licensees to use this form because the HHS Guidelines prohibit private-sector employers from using the Federal form. NRC licensees would be able to use their own form.

Updated Provisions

At the same time that the HHS published updated requirements for urine specimen validity testing, HHS also published a Notice of Proposed Revisions to the Guidelines (69 FR 19673; April 13, 2004). Among other changes to the Guidelines, the HHS proposed permitting Federal agencies to use non-instrumented validity testing devices to perform validity screening tests of urine specimens. Proposed Part 26 would incorporate the related provisions from these proposed revisions to the HHS Guidelines and permit licensee testing facilities to rely on such devices to conduct validity screening tests, at proposed §26.131(a). This permission would be added in response to stakeholder concerns that instrumented validity screening testing, as currently required in the HHS Guidelines, would be too costly. In addition, proposed Part 26 would require licensee testing facilities to conduct the performance testing of these devices that the HHS Guidelines would require, at proposed §26.137(b), until the proposed HHS Guidelines have been published as a final rule in the Federal Register and the HHS publishes a list of acceptable devices. Such performance testing is necessary to ensure that the devices produce accurate and legally defensible results.

Attachment 3

Attachment 4