

RULEMAKING ISSUE AFFIRMATION

December 22, 2006

SECY-06-0244

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: FINAL RULEMAKING—10 CFR PART 26—FITNESS-FOR-DUTY PROGRAMS

PURPOSE:

To obtain Commission approval to publish the final rule for Fitness-for-Duty Programs.

SUMMARY:

The final rule amends the regulations of the U.S. Nuclear Regulatory Commission (NRC) governing the domestic licensing of production and utilization facilities. The final rule does not apply to reactor manufacturing facilities, spent fuel storage facility licensees, or non-power reactor licensees who possess, use, or transport formula quantities of irradiated Strategic Special Nuclear Materials (SSNM). The rule updates the NRC's current requirements under Title 10, Part 26, "Fitness for Duty Programs," of the *Code of Federal Regulations*, for drug and alcohol testing and enhances consistency of Part 26 with advances in 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 that impose similar requirements on the private sector. The

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final rule also reorganizes and clarifies Part 26, notably Subparts I and K. Subpart I establishes requirements for managing worker fatigue at operating nuclear power plants. Subpart K clarifies fitness-for-duty (FFD) requirements for new plant construction. Licensees and applicants for light-water reactors and applicants for and holders of combined construction and operating licenses (COLs) or construction permits (CPs) for new reactors must adhere to the requirements of this final rule, as applicable. In addition, the final rule grants, in part, a petition for rulemaking (PRM-26-1) submitted by Virginia Electric and Power Company (now Dominion Virginia Power) on December 30, 1993, by relaxing certain FFD program audit frequency requirements. The final rule also partially grants a petition for rulemaking (PRM-26-2) submitted by Barry Quigley on December 28, 1999, by establishing requirements for the management of worker fatigue.

BACKGROUND:

In SECY-05-0074, "Proposed Rule To Amend The Fitness-for-Duty Requirements in 10 CFR Part 26," dated April 28, 2005, the staff presented its proposal to amend the FFD program requirements for licensees authorized to operate or construct a nuclear power reactor, or possess, use, or transport formula quantities of SSNM. Subsequently, the proposed rule was published in the *Federal Register* on August 26, 2005 (70 FR 50442), with a four-month public comment period that ended on December 27, 2005. The NRC also conducted public meetings during the proposed rule comment period at locations near plants to encourage participation from workers who would be affected by changes to the FFD program requirements. Meetings were conducted in Morris, Illinois, and Charlotte, North Carolina (Agencywide Documents Access and Management Systems (ADAMS) Accession No. ML052930058). These meetings provided stakeholders opportunities to ask questions to clarify their understanding of the proposed requirements.

In March 2006, the NRC held a public meeting to discuss the staff's concepts for resolving some of the public comments. The staff presented concepts for alternative fatigue management provisions and certain requirements for FFD programs during new plant construction, and received public input. Subsequently, the staff received comments on the proposed rule and responses to the staff's concepts. Following consideration of public comments, the staff posted for viewing only, the draft final rule text for fatigue management (Subpart I) and FFD programs for new plant construction (Subpart K) in August 2006, and the entire draft final rule text of 10 CFR Part 26 in October 2006, on the NRC's interactive rulemaking Web site http://ruleforum.llnl.gov/cgi-bin/rulemake?source=Part26_risk&st=prule

On November 7, 2006, the NRC held a public meeting with stakeholders to present the technical basis for Subpart K, "FFD Programs for Construction," of the draft final rule and to describe the fitness monitoring option that Subpart K permits in lieu of random testing of certain construction workers. Enclosure 1 of this SECY paper describes that meeting.

DISCUSSION:

Enclosure 3 to this Commission paper is a *Federal Register* notice that would publish the final rule. The staff expects that the final rule will result in substantial enhancement to the public health and safety and the common defense and security. Part 26 will apply to licensees

authorized to operate a nuclear power reactor; licensees authorized to possess, use, or transport formula quantities of SSNM; corporations that obtain certificates of compliance or approved compliance plans under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants," involving formula quantities of SSNM; and CP or COL applicants or holders with a nuclear power plant under construction. The worker fatigue provisions will apply only to personnel at operating nuclear power plants.

The final rule partially grants 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. However, the final rule denies portions of the petitioner's request by retaining the current 12-month audit frequency for HHS-certified laboratories and licensee contractor or vendor (C/V) FFD programs in which 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 medical review officers (MROs), employee assistance programs (EAPs), and specimen collection services.

The final rule also partially grants PRM-26-2, submitted on September 28, 1999, by Barry Quigley. The petition requested that the NRC: (1) add enforceable working hour limits to Part 26, (2) add a criterion to § 55.33(a)(1) to require evaluation of known sleeping disorders, (3) revise the NRC enforcement policy to include examples of work hour violations that warrant various NRC sanctions, and (4) revise NRC Form 396 to include self-disclosure of sleeping disorders by licensed operators. The final rule adds requirements to Part 26 that address item 1 of the petition through requirements that are more flexible and focused on risk than those proposed by the petitioner. The staff is addressing items 2 and 4 concerning sleeping disorders of licensed operators through changes to Regulatory Guide 1.134, Revision 3, "Medical Evaluation of Licensed Personnel at Nuclear Power Plants," issued March 1998. For item 3 of PRM-26-2, the staff revised and piloted the Physical Protection Significance Determination Process and implemented a new baseline inspection program in February 2003, which includes a procedure for inspecting FFD programs and reflects order EA-03-038, dated April 29, 2003, and will similarly revise the significance determination process and the inspection procedure to be consistent with the final Part 26 rule. In addition, following issuance of the final Part 26 rule and confirmation of licensee implementation of the rule, the staff plans to revoke order EA-03-038.

The final rule includes changes to the proposed rule requirements of Subpart I to address substantive comments regarding certain individual break requirements, the collective work hour limits, and the annual reporting requirements. A summary of the public comments on these matters and how the staff resolved the comments is included in enclosure 1 of this SECY paper. In particular, industry and union representatives opposed the proposed operating work hour controls which would have required a minimum 24-hour break in any 7-day period and a minimum 48-hour break in any 14-day period. The NRC also received comments from the Professional Reactor Operator Society and other public stakeholders supporting these requirements. Following consideration of public comment, the staff replaced the requirements for a 24-hour break in any 7-day period with a requirement for a 34-hour break in any 9-day period to provide additional scheduling flexibility for 8-hour shifts. The staff eliminated the proposed rule requirements for a 48-hour break in any 14-day period and the collective work

hour limits. The staff replaced these requirements with more flexible minimum day off requirements. For periods when a reactor unit is operating, the minimum day off requirements are specific to shift duration (i.e., 8, 10, or 12 hours) and require a minimum number of days off over the duration of the shift cycle.

For periods when a reactor is shutdown for an outage, the final rule requires a minimum of 3 days off in each non-overlapping 15-day period. The staff considered alternatives to this outage requirement as discussed in the statement of considerations (SOC) for the rule. An alternative not discussed in the SOC, but also considered by the staff involved reducing the requirements for obtaining a waiver for work being done only on the non-operating unit. Under this alternative, the requirement that work performed under the waiver be necessary to prevent or mitigate a condition adverse to safety or security would be eliminated. However, the staff would have retained the requirement that, prior to authorizing a waiver of the work hour controls, a supervisor shall assess the individual face-to-face and determine that there is reasonable assurance that the individual will be able to safely and competently perform his or her duties. These alternatives would provide licensees additional flexibility in scheduling and accomplishing work on the non-operating unit. In developing these alternatives, the staff considered that although current licensee scheduling practices exceed the recommended scheduling guidelines for preventing fatigue, few events have been attributed to fatigue. However, for the reasons cited in SECY 01-0113, any estimates of events caused by fatigue should be interpreted with caution. Given these considerations, the staff determined that the technical basis for preventing and mitigating cumulative fatigue is best supported by the minimum day off requirements for outages stated in the draft final rule.

The final rule also establishes a Subpart K, which clarifies the former and proposed rule requirements for FFD programs applicable to the construction of new nuclear power plants. A summary of the public comments on these matters and how staff resolved the comments is included in enclosure 1 of this Commission paper. Enclosure 2 to this Commission paper summarizes the staff views of the impact of various requirements in Subpart K. The Executive Director for Operations (EDO) resolved these different staff positions by: (1) requiring individuals performing construction activities for security- or safety-related structures, systems, and components that occur at a location on licensee- or applicant-owned property where the nuclear power plant will be operated to be subject to an NRC-mandated FFD program; (2) allowing COL and CP holders and applicants to implement either a fitness monitoring program or the combination of a random drug and alcohol testing program and behavioral observation program; (3) allowing COL and CP holders and applicants to appropriately designate individuals who serve as monitors and determine the number of monitors and the frequency with which monitoring will occur, rather than requiring all first-line supervisors to be subject to a "full" FFD program (i.e., the same FFD requirements that apply to operating reactors); (4) removing from the final rule the requirement that the NRC review and approve each applicant's FFD program plan for construction; and (5) limiting FFD requirements for security personnel to cover only those security officers who are required by the NRC to be on site.

The supporting documents to this Commission paper (e.g., the *Federal Register* notice) do not yet reflect the EDO's resolutions of the staff positions. The staff will make conforming changes to the final rule text and the supporting documents to reflect the Commission's directions.

IMPLEMENTATION SCHEDULE:

The staff proposes to have the final rule effective 30 days after the date the rule is issued in the Federal Register and require full implementation of the final rule, except for Subparts I and K, within 365 days of the issuance date. Subpart I would need to be implemented no later than 18 months after the issuance date. No enforcement actions will be considered during these implementation periods. Implementation of Subpart K would be required upon the final rule's effective date. The staff anticipates that licensees and other entities will begin to implement the final rule when it is published in the Federal Register and develop internal guidance documents, revise procedures, and train personnel as necessary to meet these implementation schedules.

IMPLEMENTATION GUIDANCE:

By intent, the detailed nature of the drug and alcohol testing provisions in the final rule obviates the need for a guidance document for those provisions applicable to operating plants. However, the NEI published, and the staff has endorsed, NEI 03-01, Rev. 1 (April 2004), "Nuclear Power Plant Access Authorization Program," to provide guidance for implementing the inter-related access authorization and fitness-for-duty requirements contained in the access authorization orders issued to nuclear power plant licensees on January 7, 2003 (EA-02-261, "Access Authorization Order," (January 13, 2003; 68 FR 1643)). Minor revisions to this document will be necessary when Subpart C, "Granting and Maintaining Authorization," of Part 26 is published in the final rule and the 10 CFR 73.56, "Personnel Access Authorization Requirements for Nuclear Power Plants," rulemaking (71 FR 62664, October 26, 2006) is completed. The staff intends to work with stakeholders to update and endorse this guidance document.

Guidance for implementing Subpart K, "FFD Programs for Construction," of Part 26 is warranted because, by contrast to the prescriptive requirements in Part 26 for FFD programs at operating plants, the requirements for FFD programs for new plant construction provide certain holders of and applicants for combined operating licenses under 10 CFR Part 52 and construction permits under 10 CFR Part 50 with greater flexibility in implementing FFD programs for construction. By letter dated August 4, 2006, the NEI submitted a draft industry guidance document, Revision 0 to NEI 06-06, "Fitness for Duty Program for New Plant Construction Sites," for NRC review and endorsement. The staff has commented on NEI 06-06 by letter dated August 10, 2006, and subsequently conducted a public meeting on August 29, 2006, to clarify staff comments. The staff expects to continue working with stakeholders to publish a Regulatory Guide for Subpart K.

Some of the provisions of Subpart I require guidance prior to final implementation. The NEI has agreed to develop an NEI guidance document, by working with the industry and other stakeholders, and submit it to the NRC for endorsement via a Regulatory Guide. Although the NEI submitted draft guidance, NEI-06-11, "Managing Fatigue at Power Reactor Sites" in October 2006 and subsequently met with the staff in November and December, 2006, to discuss the approach, the guidance cannot be completed until the final rule is available. The NEI intends to have a final industry document available soon after the Commission approves

the final rule. Therefore, the staff has not prepared draft NRC guidance documents to accompany this final rule.

CONTENTS OF THE RULEMAKING PACKAGE:

This rulemaking package includes the *Federal Register* notice for the final rule, which contains the rule language and Statements of Consideration (enclosure 3), Regulatory and Backfit Analyses of the Final Rule to Amend the Fitness-for-Duty Programs (enclosure 4), Summary and Analysis of Public Comments Received on Proposed Revision to 10 CFR Part 26 – Fitness-for-Duty Programs (enclosure 5), and OMB Supporting Statement for 10 CFR Part 26, Fitness-for-Duty Programs (enclosure 6).

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, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," dated September 2004. Consistent with the principles underlying the revised guidelines and SRM-01-0134, the staff has prepared the regulatory analysis and backfitting discussion. Sections 4.1.4 and 4.4.2 of enclosure 4 describe the results of the analyses. The results of the regulatory and backfit analyses support issuance of this final rule.

RELATED ACTIVITIES:

In SRM-COMSECY-04-0037, dated September 1, 2004, the Commission determined that 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 rulemaking activity separate from the FFD final rule with additional stakeholder interactions. The staff anticipates that this rulemaking will begin after publication of Part 26 as a final rule in the Federal Register.

RESOURCES:

The FY 2007 budget includes the following resources for the final rulemaking: 0.7 FTE for NRR, 0.4 FTE for NSIR, 0.3 FTE for OGC, and 0.4 FTE and \$100K for RES. These resources are for the development of guidance for fatigue management and FFD programs for construction activities, the review of license amendment submittals associated with work hour controls in Technical Specifications, and the development of guidance for the inspection of licensees' implementation of Part 26.

RECOMMENDATIONS:

That the Commission:

1. Approve the notice of final rulemaking for publication in the *Federal Register* (enclosure 3) with an effective date 30 days after the date of issuance and a phased

implementation of the final rule that includes (1) full implementation of FFD programs applicable to operating nuclear reactor plants within 365 days of the issuance date and (2) full implementation of fatigue management provisions within 18 months of the issuance date, and (3) full implementation of FFD programs applicable to new reactors under construction within 30 days of the issuance date.

2. Certify that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities. The certification is needed to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).
3. Note:
 - a. The final rule (enclosure 3) will be published in the *Federal Register*.
 - b. A final regulatory backfit analysis has been prepared for this rulemaking.
 - c. A final environmental assessment has been prepared for this rulemaking.
 - d. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the basis for it, as required by the Regulatory Flexibility Act.
 - e. The NRC has determined that this action is not a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 and has confirmed this determination with the Office of Management and Budget.
 - f. Copies of the final rule will be distributed to all affected Commission licensees. The document will be sent to other interested parties upon request. Copies of the document are also available in ADAMS, in the NRC Public Document Room, and on the NRC rulemaking Web site.
 - g. The Office of Public Affairs will issue a press release when the final rule is filed with the Office of the Federal Register.
 - h. The appropriate congressional committees will be informed.
 - i. The NRC will publish separately the implementation guidance for this rulemaking with regard to fatigue management and FFD programs for applicants and holders of COLs and CPs during construction in the form of regulatory guides.
 - j. The information collections contained in the final rule (enclosure 6) will be sent to the Office of Management and Budget (OMB) for review and approval as required by the Paperwork Reduction Act of 1995 (44 U.S.C. § 3501 *et seq.*).

COORDINATION:

The Office of General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections. The ACRS considered this final rule discussion and decided to decline the formal review. The CRGR reviewed the proposed rule and elected to waive a briefing on the final rule.

The Commissioners

-8-

The ACRS and CRGR have no objection to issuing this final rule. The Office of the Chief Information Officer has reviewed the final rule for information technology and information management implications and concurs in it.

/RA/

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for Operations

Enclosures:

1. Summary of Discussion of Staff's Resolution (ML062850130)
2. Differences in Staff Positions on FFD Programs for Construction (Subpart K) (ML063540420)
3. Final Rule - Fitness for Duty (ML062550285)
4. Regulatory Analysis (ML062780211)
5. Summary of Analysis of Public Comments (ML062620089)
6. OMB Supporting Statement (ML062850194)

The ACRS and CRGR have no objection to issuing this final rule. The Office of the Chief Information Officer has reviewed the final rule for information technology and information management implications and concurs in it.

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 Executive Director
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1. Summary of Discussion of Staff's Resolution (ML062850130)
2. Differences in Staff Positions on FFD Programs for Construction (Subpart K) (ML063540420)
3. Final Rule - Fitness for Duty (ML062550285)
4. Regulatory Analysis (ML062780211)
5. Summary of Analysis of Public Comments (ML062620089)
6. OMB Supporting Statement (ML062850194)

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ADAMS Accession No.: ML062550268

ADAMS Package No.: ML062550263

*via email (9/18/06) **via email (9/25/06)

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