RULEMAKING ISSUE
(Affirmation)

September 17, 2021 SECY-21-0082

FOR: The Commissioners

FROM: Margaret M. Doane
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SUBJECT: FINAL RULE: FITNESS FOR DUTY DRUG TESTING REQUIREMENTS (RIN 3150-AI67; NRC-2009-0225)

PURPOSE:

The purpose of this paper is to obtain Commission approval to publish a final rule that would align the U.S. Nuclear Regulatory Commission's (NRC) drug testing requirements in Part 26 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Fitness for Duty Programs," more closely to those specified in the 2008 and 2017 U.S. Department of Health and Human Services' (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (HHS Guidelines). The final rule also addresses lessons learned from implementing 10 CFR Part 26. This paper does not propose any new commitments.

SUMMARY:

The staff has prepared a draft final rule for publication in the *Federal Register* (Enclosure 1). The rule would ensure that 10 CFR Part 26 drug testing programs are effective, strengthen the defense-in-depth regulatory framework associated with access authorization, and increase the overall level of protection of public health and safety or the common defense and security. The

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specific objectives of the rule are to (1) maintain reasonable assurance of a drug-free workplace through the enhanced detection of individuals who are not fit for duty and not trustworthy and reliable because of illegal drug use, legal drug misuse, or an attempt to subvert the drug testing process; (2) harmonize select drug-testing requirements under 10 CFR Part 26 with the 2008 HHS Guidelines (73 FR 71858; November 25, 2008), and the 2017 HHS Guidelines (81 FR 7920; January 23, 2017); and (3) enhance donor protection and due process requirements for individuals subject to drug testing. In support of these objectives, the draft final rule also contains amendments to improve the clarity, organization, and flexibility of 10 CFR Part 26.

The draft final rule constitutes backfitting largely because of mandated changes to the drug testing panel that must be used by licensees and other entities performing testing of individuals under 10 CFR Part 26. The NRC staff addressed the backfitting criteria while conducting this rulemaking and determined that the changes in the draft final rule would substantially increase public health and safety or the common defense and security and are cost-justified.

BACKGROUND:

On June 3, 2019, the Commission issued staff requirements memorandum (SRM)-SECY-17-0027 approving issuance of a proposed rule, "Fitness for Duty Drug Testing Requirements." The proposed rule and draft implementation guidance were published in the *Federal Register* (84 FR 48750; September 16, 2019). The NRC proposed amendments to align the drug testing requirements in 10 CFR Part 26 more closely with the 2008 HHS Guidelines and to enhance the ability of NRC licensees and other entities to identify individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. The proposed rule incorporated lessons learned from implementing the NRC's current fitness for duty (FFD) regulations, provided additional protections to individuals subject to drug testing, and improved the clarity, organization, and flexibility of the FFD regulations.

In the proposed rule, the NRC requested public feedback on seven topics: alignment with the HHS Guidelines, special analyses testing, providing flexibility to conduct additional specimen validity tests, the effective date of the final rule, direct observation of specimen collection, the 2017 HHS Guidelines—New Test Analytes, and methylenedioxyethylamphetamine (MDEA). The NRC received 26 comment submissions on the proposed rule and draft implementation guidance that the staff reviewed and considered in the development of the enclosed draft final rule, as described in Enclosure 2.

DISCUSSION:

The major provisions of the draft final rule are:

- Add initial and confirmatory drug testing for two illegal amphetamine-based controlled substances—MDMA and methylenedioxyamphetamine—referred to as "Ecstasy-type" drugs in the draft final rule.

- Add initial and confirmatory drug testing for four opioid drugs: hydrocodone, hydromorphone, oxycodone, and oxymorphone.

- Add initial drug testing for 6-acetylmorphine (6-AM), a metabolite of the illegal drug heroin, and update the confirmatory drug testing method for 6-AM.

- Lower the initial and confirmatory drug testing cutoff levels for amphetamine, cocaine metabolite, and methamphetamine.

- Enhance the detection of subversion attempts by strengthening the testing methods used to identify drugs and drug metabolites in urine specimens with dilute validity test results and in specimens collected under direct observation.

- Permit the collection and drug testing of an oral fluid specimen as an alternative to the collection and testing of a directly observed urine specimen.

- Require Medical Review Officers (MROs) to evaluate the elapsed time from specimen collection to testing and exposure to high temperature as possible causes of some invalid test results due to high solvated hydrogen ion concentration (i.e., pH).

- Improve the clarity, consistency, and organization of 10 CFR Part 26 by adding and updating definitions; increase flexibility in the personnel who may monitor a donor that is hydrating during a shy-bladder situation; and enhance donor protections by providing additional instruction to same-gender observers used in observed collections and affording due process by requiring MROs to document the date and time that an oral request is received from a donor to initiate the retesting of a specimen.

In addition, the draft final rule addresses two issues in the licensee testing facility quality control sample requirements for initial validity testing and for initial drug testing that were described in a March 31, 2009, "NRC Enforcement Guidance Memorandum – Dispositioning Violations of NRC Requirements for Initial Validity and Drug Tests at Licensee Testing Facilities" (EGM 09-003) (Agencywide Documents Access and Management System (ADAMS) Accession No. ML090760728). The NRC Office of Enforcement will withdraw EGM 09-003 upon the effective date of the final rule.

Changes from the Proposed Rule to the Final Rule

In response to public comments provided on the proposed rule and in developing the draft final rule, the staff made changes to:

- Expand the drug testing panel to include four opioids (hydrocodone, hydromorphone, oxycodone, oxymorphone) listed in the 2017 HHS Guidelines.

- Provide the option to collect an oral fluid specimen as an alternative to the collection and testing of a directly-observed urine specimen.

- Extend the compliance deadline for the final rule from 60 days to 1 year.

- Remove the proposed requirement that hydration monitors be FFD program personnel.

Regulatory Analysis

The staff prepared a regulatory analysis to quantify the costs and benefits of the draft final rule and to examine the qualitative factors to be considered in the NRC's rulemaking decision (Enclosure 3). Relative to the regulatory baseline (status quo), the draft final rule would result in a net benefit to industry of between $418,356, based on a 7-percent net present value, and $692,799, based on a 3-percent net present value. The draft final rule would result in an

estimated total one-time industry cost of $136,936, followed by a total annual industry savings of $47,650. On a per licensee or other entity site basis, the draft final rule would result in an average one-time cost of $2,321 and annual savings of $808. The regulatory analysis includes a discussion of 13 qualitative factors, including public health (accident), occupational health (accident), and regulatory efficiency.

The results of the regulatory analysis show that this rulemaking is cost-justified because the total estimated quantified benefits exceed the estimated costs of the rule. The analysis concludes that adopting the draft final rule would result in an estimated increase of between 16 and 29 percent per year in the detection of individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. Based on the average number of individuals with a positive test result or identified as attempting to subvert a test from calendar years 2009 through 2019, the estimated increase in detection each year is equivalent to identifying approximately 180 additional individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process.

Backfitting and Issue Finality

The draft final rule constitutes backfitting as defined in 10 CFR 50.109, "Backfitting," for current holders of operating licenses and construction permits under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and renewed licenses under 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants," and as defined in 10 CFR 70.76, "Backfitting," for applicable current licensees under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." In addition, the draft final rule affects the issue finality accorded to combined license holders under 10 CFR 52.98, "Finality of combined licenses; information requests."

The revised amendments require nuclear power plant licensees, Category I special nuclear material licensees, and contractors/vendors subject to the requirements of 10 CFR Part 26 to update existing FFD program policies and procedures, conduct training, revise contracts with HHS-certified laboratories and blind performance test sample providers, perform mandatory special analyses testing on some specimens, and modify the drug testing panel. The direct benefits include improved detection of individuals using illegal drugs, misusing legal drugs, or attempting to subvert the testing process; savings to the industry through averted training costs; and efficiencies, flexibilities, and increased donor protections. In light of these benefits, the NRC finds that the backfits contained in the draft final rule, when considered in the aggregate, constitute a cost-justified, substantial increase in the overall protection of the public health and safety or the common defense and security under 10 CFR 50.109 and 10 CFR 70.76. The backfitting and issue finality assessment (Enclosure 4) presents the bases for this determination and addresses the criteria in 10 CFR 52.98 that allow imposition of the final rule on holders of combined licenses.

Cumulative Effects of Regulation

The amendments to 10 CFR Part 26 in the draft final rule would add regulatory burden for applicable NRC licensees and other entities. To mitigate this burden, the NRC has established a compliance deadline of 1 year from the date of publication of the final rule in the *Federal Register*. The 1-year timeframe is the result of public comment on the proposed rule and feedback received at the Cumulative Effects of Regulation public meeting held on April 13, 2021. A public meeting summary is available in the ADAMS under Accession No. ML21096A015.

Implementing Guidance

The NRC would issue new guidance, Regulatory Guide 5.89, "Fitness-For-Duty Programs for Commercial Power Reactor and Category I Special Nuclear Material Licensees" (ADAMS Accession No. ML20143A034), to implement the requirements of the final rule. Draft regulatory guidance was issued for public comment with the proposed rule. Enclosure 2 includes the NRC's responses to public comments received on the draft regulatory guidance.

Timing of the Next Part 26 Rulemaking

In SRM-SECY-17-0027, the Commission directed that the paper accompanying the draft final rule should inform the Commission of the staff's forecast for the necessary timing of the next update to 10 CFR Part 26 drug testing requirements. Future changes to the NRC's requirements are dependent on changes to the HHS Guidelines, which typically address drug use trends and scientific advancements in testing technologies. Although the draft final rule incorporates elements of a new mandatory HHS Guidelines issued in 2019 (84 FR 57554; October 25, 2019), for the drug testing of oral fluid specimens, this option to test oral fluid specimens is limited to direct observation collection conditions due to risk-informed logical outgrowth considerations. The staff expects to consider utilizing oral fluid testing under additional testing conditions in the future due to its potential to deter subversion attempts. In addition, on September 10, 2020, the HHS issued a notice in the *Federal Register* (85 FR 56108) proposing new mandatory Guidelines for the testing of hair for the Federal workplace drug testing program. The staff is not aware of a date for the issuance of final HHS Guidelines for hair testing and would have to evaluate the testing approach and make a recommendation to the Commission on whether to amend 10 CFR Part 26. Any further updates to align 10 CFR Part 26 with HHS Guidelines changes are not anticipated until at least 2026.

With respect to the timing of future 10 CFR Part 26 updates, the staff notes that 10 CFR Part 26 could be revised as part of the 10 CFR Part 53 rulemaking, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (NRC-2019-0062; RIN 3150-AK31)." In addition, the staff expects to provide a rulemaking plan for the long-planned rule, 10 CFR Part 26, "Drug and Alcohol Testing: Technical Issues and Editorial Changes" rulemaking (NRC-2012-0079; RIN 3150-AJ15), within 1 year after the publication of this draft final rule. The rulemaking would address other administrative and technical issues associated with 10 CFR Part 26 rule implementation. If the staff decides a rulemaking plan is not needed in this timeframe, then the staff would provide a CA Note on its rationale and a path forward.

COMMITMENT:

The staff will publish the final rule and notice of associated guidance in the *Federal Register* upon Commission approval.

RECOMMENDATION:

The staff recommends that the Commission take the following actions:

(1) Approve the enclosed draft final rule (Enclosure 1) for publication in the *Federal Register*.

(2) Certify that this rule, if adopted, will not have a significant impact on a substantial number of small entities, to satisfy the requirement of the Regulatory Flexibility Act (5 U.S.C. 605(b)).

(3) Note:

a. The final rule contains amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The staff will submit information collection requirements to the Office of Management and Budget for its review and approval prior to the publication of the final rule in the *Federal Register*.

b. The rulemaking package includes the NRC's response to public comments on the proposed rule (Enclosure 2), a final regulatory analysis (Enclosure 3), and a backfitting and issue finality assessment for the final rule (Enclosure 4).

c. Regulatory Guide 5.89, "Fitness-For-Duty Programs for Commercial Power Reactor and Category I Special Nuclear Material Licensees," will be issued concurrent with the publication of the final rule.

d. The Office of Congressional Affairs will inform the appropriate congressional committees of this action.

e. The Office of Public Affairs will notify the public when the final rule is published in the *Federal Register*.

RESOURCES:

Resources for conducting rulemaking to incorporate the 2008 and 2017 HHS Guidelines into the 10 CFR Part 26 drug-testing provisions are budgeted in the Operating Reactors Business Line. Enclosure 5 includes an estimate of the NRC resources needed to complete this rulemaking.

COORDINATION:

The Office of the General Counsel reviewed the rulemaking package and has no legal objection. The Office of the Chief Financial Officer reviewed the rulemaking package and determined that it has no significant financial impact. The Advisory Committee on Reactor Safeguards (ACRS) discussed the draft final rule as Item 5 of the Planning and Procedures session of the 683rd ACRS Full Committee, March 3–5, 2021, and determined that the ACRS did not need to review

the draft final rule. The staff met with the Committee to Review Generic Requirements (CRGR) on August 24, 2021. The CRGR endorsed the staff's backfitting and issue finality assessment on September 3, 2021, with no changes to the content of the draft final rule.

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Enclosures:
1. Draft Final Rule
2. NRC Responses to Public Comment
3. Regulatory Analysis
4. Backfitting and Issue Finality Assessment
5. Resources

SUBJECT: FINAL RULE: FITNESS FOR DUTY DRUG TESTING REQUIREMENTS (RIN 3150-AI67; NRC-2009-0225) DATED: September 17, 2021

SRM-S17-0027-2

ADAMS Accession No: PKG: ML21111A017; SECY: ML21111A018; FRN: ML21111A024; Regulatory Analysis: ML21111A026; Backfit: ML21111A030; Public Comment Response ML21111A032; Resource Information ML21166A005 ***via email** **SECY-012**

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