RULEMAKING ISSUE
(Notation Vote)

February 22, 2017 SECY-17-0027

FOR: The Commissioners

FROM: Victor M. McCree
Executive Director for Operations

SUBJECT: PROPOSED RULEMAKING: FITNESS-FOR-DUTY DRUG TESTING REQUIREMENTS (RIN 3150-AI67)

PURPOSE:

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

SUMMARY:

The proposed rule would ensure that 10 CFR Part 26 drug testing programs are effective, strengthen the defense-in-depth regulatory framework associated with access authorization (AA), and increase the overall level of protection of public health and safety and the common defense and security. The staff has prepared the proposed rule for publication in the *Federal Register* (Enclosure 1). The specific objectives of the rulemaking are to: (1) maintain reasonable assurance of a drug-free workplace through the enhanced detection of individuals who are not fit for duty because of illegal drug use, legal drug misuse, or an attempt to subvert

CONTACTS: Stewart Schneider, NRR/DPR
301-415-4123

Brian Zaleski, NSIR/DSP
301-287-0638

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 (3) enhance donor protection and due process requirements for individuals subject to drug testing. In support of these objectives, the proposed rule would also improve the clarity, organization, and flexibility of 10 CFR Part 26.

BACKGROUND:

The general performance objective of 10 CFR Part 26, as described in the statement of considerations in the original final rule (54 FR 24468; June 7, 1989), "is to provide reasonable assurance that nuclear power plant personnel are reliable, trustworthy, and not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties." The NRC also stated in the statement of considerations that a fitness-for-duty (FFD) program "developed under the requirements of this rule is intended to create an environment which is free of drugs and the effects of such substances" (54 FR 24468).

The NRC has relied on the HHS Guidelines as the technical basis to establish and update the requirements in 10 CFR Part 26 for urine specimen collection, laboratory testing of specimens, and test result evaluations and, in general, has only deviated from the HHS Guidelines for considerations specific to the nuclear industry. Periodic updating of 10 CFR Part 26 to align it with the HHS Guidelines ensures that the FFD drug testing program continues to maintain reasonable assurance that the workplace is free of drugs and the effects of such substances.

The HHS Guidelines govern the Federal employee workplace drug testing programs[1] (used by over 100 agencies) and all comparable Federal agency drug testing programs that test civilians in safety- and security-sensitive positions similar to those tested under 10 CFR Part 26, most notably the 6 million individuals (e.g., airline pilots, bus and truck drivers, armed security guards) tested each year by the U.S. Department of Transportation (DOT). The HHS Guidelines also establish the certification requirements that each laboratory must meet to test specimens for Federal employee workplace drug testing programs. Under the National Laboratory Certification Program (NLCP), each laboratory is inspected every 6 months to verify compliance with the HHS Guidelines. The NLCP also verifies laboratory testing accuracy every 3 months. The NRC leverages the rigor of the NLCP by requiring licensees subject to 10 CFR Part 26 to use HHS-certified drug-testing laboratories.

The NRC issued the first substantial revision to the original 10 CFR Part 26 in a 2008 final rule (73 FR 16966, March 31, 2008) that, in part, updated the drug-testing requirements and improved consistency with other relevant Federal rules and guidelines, including the then-latest HHS Guidelines, which were issued on April 13, 2004 (69 FR 19644). The 2008 FFD final rule: (1) required validity testing of each specimen to address the potential for subversion of the testing process, (2) incorporated advancements in drug- and alcohol-testing technologies, (3) changed drug- and alcohol-testing cutoff levels, and (4) incorporated lessons learned from implementation of the 1989 final 10 CFR Part 26 rule (e.g., minimum sanctions for positive alcohol test results and subversion attempts). The NRC made these changes to maintain reasonable assurance that individuals subject to 10 CFR Part 26 are fit for duty and are trustworthy and reliable, as demonstrated by those individuals not using illegal drugs or misusing legal substances (e.g., alcohol and prescription medication) and not being mentally or physically impaired in any way that could adversely affect their ability to safely and competently perform their assigned duties. As a result, FFD programs under 10 CFR Part 26 continued to

[1] Through Executive Order 12564, "Drug-Free Federal Workplace" (51 FR 32889; September 17, 1986), the President of the United States designated the HHS as the Federal agency responsible for establishing and maintaining the requirements and guidance for conducting Federal employee workplace drug testing.

contribute to public health and safety and the common defense and security by requiring licensee implementation of procedures that, in part, result in the early detection of individuals (e.g., through pre-access drug and alcohol testing, AA, and behavioral observation) who may not be fit to perform their assigned duties.[2]

On November 25, 2008, approximately 8 months after publication of the 2008 FFD final rule, HHS issued updated Guidelines (73 FR 71858). The 2008 HHS Guidelines primarily expand the panel of drugs to be tested, lower the drug testing cutoff levels for some substances, and enhance specimen validity testing.[3] Thus, the 2008 FFD final rule (i.e., the current FFD rule) that references the 2004 HHS Guidelines does not reflect the 2008 updates to the HHS Guidelines.

Following issuance of the 2008 HHS Guidelines, the NRC staff held two public meetings in 2009 to review the changes to the 2004 Guidelines and to assess their potential impacts on the drug testing requirements in 10 CFR Part 26. The meeting summaries are available in the NRC's Agencywide Documents Access and Management System (ADAMS) under Accession Nos. ML090771060 and ML091910511, respectively. At that time, the NRC staff elected to forego another FFD rulemaking so soon after the publication of the 2008 FFD final rule. The staff made this decision for two reasons: (1) to give licensees and other entities time to implement the 2008 FFD final rule, and (2) to afford the staff time to evaluate the effectiveness of the 2008 FFD final rule by analyzing FFD program performance testing data and evaluating lessons learned from rule implementation.

A key aspect of assessing the effectiveness of the 2008 FFD final rule was the NRC development, in collaboration with entities regulated under 10 CFR Part 26, of a voluntary electronic reporting (e-reporting) system[4] to facilitate improved reporting of annual FFD performance information required under 10 CFR 26.717, "Fitness-for-duty program performance data." The NRC now receives a detailed report of each FFD testing violation (i.e., positive drug and/or alcohol test and each subversion attempt). This e-reported information has provided the NRC with an increased level of detail on site-specific FFD performance. Based on the analysis of the annual FFD program performance data for all licenses and other entities, the workplace is not free of drugs and the effects of such substances. From 2009 through 2014, 993 to 1,133 individuals each year tested positive for alcohol or drug(s) or were identified attempting to subvert a drug test. This represents a positive test rate of 0.59 to 0.68 percent per year of the tested population.[5] For the majority of facilities covered by 10 CFR Part 26 (i.e., operating reactors), between 3 and 29 positive results per site were reported per year, with the number of

---

[2] These duties are described in 10 CFR 26.4, "FFD program applicability to categories of individuals," and can be summarized, in part, as those associated with safety- or security-significant operations, maintenance, and surveillance; authorization determinations; the Emergency Operations Facility and Technical Support Center; reactor construction; and strategic special nuclear material or sensitive information access and control.

[3] Note, a new revision to the HHS Guidelines was issued on January 23, 2017 (82 FR 7920). This revision will go into effect for Federal workplace drug testing programs on October 1, 2017. The primary focus of this revision is the expansion of the testing panel to include four prescription opiate painkillers (hydromorphone, hydrocodone, oxymorphone, and oxycodone). While the staff has continued to follow these developments, the staff is not proposing to incorporate the 2017 Guidelines in this rulemaking, given that no Federal programs are yet using these protocols, so there is not yet a technical basis to justify their imposition on licensees.

[4] See http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/submit-ffd-reports.html.

[5] For a historical perspective on the Part 26 testing program (1990 through 2014), the positive rate for all tests conducted in a given year has ranged from a low of 0.59 percent in 2010 to a high of 1.09 percent in 2000. These positive rates are generally lower than those for other populations (e.g., the Department of Transportation), based on the staff's comparison of available data, considering differences in random testing rates and testing panels. Further information is provided in Enclosure 2.

positive results generally related to the number of units at the site and whether the site was in outage.

The 2008 HHS Guidelines went into effect in October 2010. The staff then began to evaluate the effectiveness of the drug testing changes by reviewing the test results from the Federal workplace drug-testing programs and DOT. The staff also held two additional public meetings on this topic in 2011 and 2013 (ADAMS Accession Nos. ML112980110 and ML13290A236, respectively). The FFD performance data, combined with drug testing information obtained from other sources, such as HHS and DOT, and lessons learned from implementing the 2008 FFD final rule informed the staff's regulatory basis (ADAMS Accession No. ML13094A179) for the current proposed rule. On July 1, 2013, the NRC published a notice in the *Federal Register* to inform the public of the availability of the regulatory basis that documents the reasoning by which the NRC determined that rulemaking was the appropriate course of action (78 FR 39190).

DISCUSSION:

The proposed rule would enable licensees to enhance their ability to maintain reasonable assurance that the workplace is free of drugs and the effects of such substances. The NRC would enhance the FFD program effectiveness by aligning the drug-testing panel under 10 CFR Part 26 with the 2008 HHS Guidelines and incorporating lessons learned from implementation of the 2008 FFD final rule. Thus, the rulemaking would specifically achieve three objectives: (1) enhance detection of individuals who are not fit for duty 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; and (3) enhance donor protection and due process requirements for individuals subject to drug testing. In support of these objectives, the proposed rule would also improve the clarity, organization, and flexibility of 10 CFR Part 26.

Drug testing program effectiveness may weaken over time if the workforce uses impairing substances that are not included in the testing panel, if products and techniques are used to successfully subvert the drug testing process, or if technological advancements that enhance drug-testing sensitivity are not used. Use of the current national drug-testing standard established by the HHS Guidelines and existing defense-in-depth methods (e.g., behavioral observation, background checks, collection site security, and specimen collections) would enhance licensees' ability to maintain reasonable assurance of a drug-free work environment.

The proposed rule would improve licensees' ability to identify additional individuals that use illegal drugs, misuse legal drugs, or attempt to subvert the testing process to conceal drug use and, as a result, would be determined not to be fit for duty or not to be trustworthy and reliable, or both. Such a determination would result in a denial of unescorted access to the protected areas of NRC-licensed facilities[6] and other locations, access to special strategic nuclear material, or access to sensitive information. The identification of these individuals enhances the existing regulatory framework to prevent drug-induced impairment (acute intoxication and the consequences of recent drug use, such as withdrawal effects) from causing or contributing to human performance errors that may result in unplanned occupational exposure; personal safety issues (e.g., injuries); unplanned radiological releases; or improper operation, maintenance, or surveillance of safety-related structures, systems, or components.

The enhanced testing capabilities resulting from aligning with the 2008 HHS Guidelines and applying lessons learned from implementing the 2008 FFD final rule would address directly the following FFD drug testing program results and trends:

---

[6] The subject of NRC-licensed facilities is described in 10 CFR 26.3, "Scope," and includes, but is not limited to, operating power reactors and Category I fuel cycle facilities.

- The positive test rate for amphetamines increased by approximately 100 percent from calendar year (CY) 2010 through CY 2014 (i.e., 54 to 112 individuals tested positive for amphetamine, methamphetamine, or both, annually).
- Subversion attempts accounted for 17 to 21 percent of drug-testing positives each year from CY 2011 through CY 2014 (i.e., annually 143 to 187 individuals were identified subverting a test).
- Cocaine continued to be the third most detected substance, and use was identified in the critical group (i.e., nuclear power reactor operators and supervisors). From CY 2010 through CY 2014, 106 to 124 individuals each year tested positive for cocaine.
- Approximately 83 to 93 percent of individuals that test positive for multi-substances positive) test positive for amphetamine, methamphetamine, and/or cocaine. From CY 2011 through 2014, 34 to 48 individuals each year tested positive for more than one substance.
- Test results on potential impairment in the workplace (positive drug test results on for-cause and post-event testing[7]) demonstrate that 15 to 22 individuals each year tested positive for amphetamine, cocaine, heroin, and/or methamphetamine in CY 2011 through CY 2014.

Provisions of the proposed rule that would address these FFD drug testing program results and trends include:

- Lowering the initial and confirmatory testing cutoffs for amphetamines (amphetamine and methamphetamine) and cocaine to increase the time period after use that these substances can be detected in a donor's urine specimen.
- Enhancing the testing method for identifying heroin use by adding initial testing for 6-acetylmorphine (6-AM), a metabolite of this illegal drug,[8] and by updating confirmatory testing for 6-AM.
- Expanding the drug testing panel to include three illegal amphetamine-based Ecstasy-type drugs[9].
- Strengthening the testing method to identify subversion attempts by enhancing the testing for drugs and drug metabolites in urine specimens with dilute validity test results and in specimens collected under direct observation.

The regulatory analysis (Enclosure 2) presents detailed information on the projected enhancements in drug detection from each testing program change. These enhancements are

---

7 For-cause testing, as described in 10 CFR 26.31(c)(2), is required when observed behavior, physical condition, or credible information indicates the potential for substance use. Post-event testing is required following the occurrence of certain workplace safety events, as described in 10 CFR 26.31(c)(3), which include, but are not limited to, events that cause death, days away from work, medical treatment beyond first aid, radiation exposure or release in excess of regulatory limits, or an actual or potential substantial degradation of the level of safety of the plant.

8 Section 202 of the Controlled Substances Act (21 U.S.C. 812) defines a Schedule I drug as having a high potential for abuse, with no currently accepted medical use in treatment in the United States (i.e., use of the drug is illegal) and with a lack of accepted safety for use under medical supervision.

9 These three Schedule I drugs are methylenedioxymethamphetamine (MDMA), methylenedioxyamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA).

based on the staff's evaluation of: (1) the DOT drug testing results in CY 2010 through CY 2014 and (2) the FFD program performance data reported to the NRC, on an annual basis, by licensees and other entities under 10 CFR 26.417(b)(2) or 26.717.

Expanding licensees' drug testing capabilities would enhance the effectiveness of their drug-testing programs under 10 CFR Part 26. Historically, approximately 68 percent of drug and alcohol positive test results, on an annual basis, occur at pre-access testing (i.e., before granting unescorted access to NRC-licensed facilities). Therefore, an enhanced testing program supports a proactive regulatory strategy of identifying individuals that use illegal drugs and misuse legal substances before these individuals can perform covered duties and supplements the Commission's AA requirements.[10] However, because pre-access testing is a scheduled event, an individual has time to prepare to subvert the test. The FFD program performance data demonstrate that approximately 75 percent of subversion events since 2011 have occurred at pre-access testing. These data also indicate that approximately 95 percent of those attempting to subvert the testing process are contractors/vendors.

The proposed rule would strengthen the methods for detecting subversion attempts in two ways. First, the proposed rule would require the use of special analyses testing of dilute specimens, which requires the laboratory to use the lowest cutoff level possible that can identify and quantify the substance. This addresses subversion by individuals who may choose to consume large quantities of fluid just before providing a specimen to lower the level of drug(s) in their specimen below the testing cutoff levels (i.e., a dilute specimen). As of 2014, 92 percent of licensees and other entities voluntarily conduct special analyses testing of dilute specimens, as permitted by 10 CFR 26.163(a)(2). Second, the rule would address a far more prevalent subversion method in which a donor attempts to provide a specimen that is not from their own body (i.e., a substituted specimen). These donor attempts to subvert the testing process are often identified by unusually low or high specimen temperatures. In these instances, a second specimen would be collected from the donor under direct observation of the collector by 10 CFR 26.115, "Collecting a urine specimen under direct observation." The proposed rule would require special analyses testing of specimens collected under direct observation.

The proposed rule would improve regulatory efficiency in two ways. First, it would address Enforcement Guidance Memorandum (EGM)-09-003, "Dispositioning Violations of NRC Requirements for Initial Validity and Drug Tests at Licensee Testing Facilities," dated March 31, 2009 (ADAMS Accession No. ML090760728). The EGM-09-003 describes inconsistencies in the current rule's terminology associated with quality control samples used at licensee testing facilities. The proposed rule would correct the current regulations to make the terminology consistent with the intent of the 2008 FFD final rule. Second, the proposed rule would improve the clarity, consistency, and organization of the rule by: (1) adding and updating select 10 CFR Part 26 definitions to be consistent with those described in the 2008 HHS Guidelines, (2) applying lessons learned during implementation of the 2008 FFD final rule (e.g., clarifying ambiguous or imprecise regulatory language), (3) increasing flexibility (e.g., personnel who may monitor a hydrating donor who was unable to provide a urine specimen of adequate volume on the initial attempt), and (4) eliminating two portions of 10 CFR Part 26 (10 CFR 26.155, "Laboratory personnel," and most of 10 CFR 26.157, "Procedures") to address dual regulation of HHS-certified laboratories. As addressed above,

---

[10] See Subpart C, "Granting and Maintaining Authorization," of 10 CFR Part 26; 10 CFR Part 11, "Criteria and Procedures for Determining Eligibility for Access to or Control Over Special Nuclear Material"; and 10 CFR Part 73, "Physical Protection of Plants and Materials," for commercial power reactors (10 CFR 73.56, "Personnel Access Authorization Requirements for Nuclear Power Plants") and Category I fuel cycle facilities (10 CFR 73.46, "Fixed Site Physical Protection Systems, Subsystems, Components, and Procedures").

each provision is included in the HHS Guidelines and is evaluated every 6 months through the NLCP inspection process.

The proposed rule would also enhance donor protection and due process requirements by: (1) adding instructions for same-gender observers who perform an observed collection when a trained collector of the same gender as the donor is not available, (2) requiring the limit of quantitation for special analyses testing of drugs and testing for adulterants (an added measure of testing accuracy), (3) adding a medical review officer (MRO) review of invalid test results of high pH (9.0 to 9.5), and (4) requiring the MRO to document the date and time an oral request was received from a donor to initiate the retesting of a specimen.

Regulatory Analysis

The staff prepared a regulatory analysis to estimate the expected costs and benefits of the proposed rule, both qualitatively and quantitatively. Implementation and operation costs for the proposed rule were based on data obtained from the industry, annual FFD program performance reports required by 10 CFR 26.417(b)(2) and 26.717, and staff expert opinion. Best available information was used to quantify costs, in part, for laboratory specimen testing, MRO reviews, personnel training, and changes to policies and procedures. The staff was able to quantify savings associated with identifying individuals during pre-access testing (averted training costs). Lastly, the staff conducted an uncertainty analysis on key inputs.

Estimated Benefits

The staff estimates that the proposed rule would result in a 10 to 12 percent increase per year in the detection of individuals using drugs, as compared to the 10 CFR Part 26 drug test results for CY 2013 and CY 2014. The estimated increase in detection per site depends on factors such as drug use in the local workforce, the number of individuals tested in a given year, the facility type (e.g., operating reactor, fuel cycle facility), and site conditions (operating or outage). For example, from CY 2009 through CY 2014, a single unit reactor site reported 2 to 7 positive test results per year when in operation (tested approximately 1,200 to 1,500 individuals per year) and 23 to 32 positive test results per year during outage (tested approximately 2,100 to 3,800 individuals per year). During that same time period, a fuel cycle facility reported between 1 and 4 positive test results per year in a tested population of approximately 750 to 875 individuals per year. As a result, for sites such as fuel cycle facilities with historically low positive test results, it is unlikely that the proposed rule would result in a measurable improvement in detection.

The test results for the sites under construction are variable, and appear to be based on phase of construction. For Vogtle Electric Generating Plant, Units 3 and 4, the number of individuals testing positive per year has ranged from 0 (tested 47 individuals) in the first year of construction in 2009 to 168 (tested 9,055 individuals) in the sixth year of construction in 2014. For Virgil C. Summer Nuclear Station, Units 2 and 3, the number of individuals testing positive per year has ranged from 4 (tested 252 individuals) in the first year of construction in 2011 to 127 (tested 5,484 individuals) in the fourth year of construction in 2014. In terms of the number of individuals tested, in the first 3 years of construction, the number of tested individuals was either below or in line with a two-unit operating reactor. For the fourth year and beyond, the number of individuals tested at the construction sites exceeded a typical two unit operating reactor.

The regulatory analysis quantified benefits associated with three affected attributes:

(1) industry implementation
(2) industry operation

(3) NRC implementation

However, the staff had difficulties with monetizing the benefits of seven affected attributes:

(1) public health (accident)
(2) occupational health (accident)
(3) offsite property
(4) onsite property
(5) regulatory efficiency
(6) safeguards and security considerations
(7) other considerations

The attribute of "other considerations" includes public perception, workplace productivity, workplace safety, and improved protection of individual rights. The staff performed a qualitative assessment of these attributes that is consistent with the Commission's direction in the staff requirements memorandum (SRM) for SECY-14-0087, "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," dated March 4, 2015 (ADAMS Accession No. ML15063A568). Because the benefits could not be rigorously quantified and monetized, a quantified comparison of costs and benefits was not possible. Based on the regulatory analysis, the staff finds that the increase in the detection of additional drug users and the qualitative benefits, considered together, continue to maintain reasonable assurance of a drug-free workplace and outweigh the low costs of the proposed rule, as described below.

Estimated Costs

The proposed rule is expected to result in a total one-time cost to industry of approximately $337,100, followed by total annual costs of approximately $168,600. The net present value of these costs is approximately $2.4 million using a 7-percent discount rate and approximately $3.4 million using a 3-percent discount rate over the average remaining reactor license period of 25 years. These costs include industry training costs averted as a result of pre-access testing (i.e., before access is granted and training is conducted—an industry operations saving) of approximately $87,800 annually, which reduces the cost of the proposed rule by between $1.1 million (using a 7-percent discount rate) and $1.6 million (using a 3-percent discount rate). The majority of one-time costs to licensees and affected entities is associated with training personnel subject to 10 CFR Part 26 on changes to the FFD program policy. The annual costs to licensees and other entities are associated with testing each specimen for additional drugs (i.e., Ecstasy-type drugs and 6-AM*)*, MRO reviews of the additional positive test results due to the testing panel and cutoff level changes, and personnel actions that result from each additional individual that tests positive or is identified as having attempted to subvert the drug-testing process.

Backfitting and Issue Finality

The proposed rule would constitute 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 in 10 CFR 70.76, "Backfitting," for applicable current licensees under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." It would also violate the issue finality provisions of 10 CFR 52.98, "Finality of Combined Licenses; Information Requests." The proposed rule would constitute backfitting because it would result in modifications of or additions to the procedures or organization required to operate a facility resulting from new or amended regulations.

The backfit and issue finality analysis can be found in Appendix F of the regulatory analysis. The NRC has determined that backfitting is justified because: (1) the overall level of protection of the public health and safety or the common defense and security would increase substantially and (2) the proposed rule's costs of implementation and the annual costs would be justified in view of this increase.

Cumulative Effects of Regulation

Consistent with the discussion in SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," dated March 2, 2011 (ADAMS Accession No. ML110190027), and the resulting SRM, dated October 11, 2011 (ADAMS Accession No. ML112840466), the staff has applied the cumulative effects of regulation process enhancements to this rulemaking. The staff obtained early, effective, and periodic feedback from affected stakeholders during the previously mentioned four public meetings, International Brotherhood of Electrical Workers annual conventions, and quarterly Nuclear Energy Institute-sponsored FFD and AA working group meetings attended by approximately a dozen AA/FFD managers. During all outreach activities, the staff presented the status of the proposed rule and discussed technical considerations. At the Nuclear Energy Institute meetings, the staff also discussed costs and the use of other regulatory instruments such as voluntary implementation, guidance, and orders. In general, licensee representatives supported the proposed rule option because it would enhance FFD program effectiveness. National and local members of the International Brotherhood of Electrical Workers did not voice concern about the proposed rule; however, some members were concerned about inconsistent implementation of drug and alcohol treatment plans and AA determinations. However, these concerns are outside the scope of the proposed rule.

The proposed rule would require licensees and other entities to update FFD program policies and procedures, update contracts with HHS-certified laboratories and blind performance specimen suppliers, and train existing personnel. There are currently no other NRC-related actions affecting these personnel now or in the near future.

AGREEMENT STATE ISSUES:

The proposed amendments are not a matter of compatibility between the NRC and the Agreement States. The proposed rule provisions are classified as Compatibility Category NRC.

RECOMMENDATIONS:

The staff recommends that the Commission approve the enclosed proposed rule notice for publication in the *Federal Register*.

The Commission should note the following:

- The staff has prepared a regulatory analysis for this rulemaking.
- The staff will publish a draft regulatory guide (ADAMS Accession No. ML16120A435) for comment, concurrent with the publication of the proposed rule.
- The staff will inform the appropriate congressional committees.
- The Office of Public Affairs will issue a press release when the NRC publishes the proposed rule in the *Federal Register*.

- The staff did not create a rulemaking plan because the proposed rulemaking predated the recommendation to prepare such a plan in SECY-15-0129, "Commission Involvement in the Early Stages of Rulemaking," dated October 19, 2015 (ADAMS Accession No. ML15267A715). This recommendation was approved by the Commission in an SRM dated February 3, 2016 (ADAMS Accession No. ML16063A522). The NRC published the regulatory basis for this proposed rule in the *Federal Register* (78 FR 39190; July 1, 2013).

RESOURCES:

The resources for incorporating the 2008 HHS Guidelines into the 10 CFR Part 26 drug-testing provisions are budgeted in the Operating Reactors Business Line. Enclosure 3 (non-public) provides detailed resource information.

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed rule. The Office of the Chief Financial Officer has reviewed this paper and has no objections. The staff met with the Advisory Committee on Reactor Safeguards (ACRS) on April 10, 2015. The ACRS determined that this rulemaking is outside the scope of its oversight but requested to be kept informed. The staff provided ACRS and the Committee to Review Generic Requirements with an informational copy of the proposed rule package.

/RA/

Victor M. McCree
Executive Director
for Operations

Enclosures:
1. *Federal Register* notice
2. Regulatory Analysis and Backfitting and Issue Finality
3. Resource Information (OUO – SII non-public)

PROPOSED RULEMAKING: FITNESS-FOR-DUTY DRUG TESTING REQUIREMENTS
(RIN 3150-AI67) dated January [xx], 2017

ADAMS Accession No: PKG: ML16123A004; SECY: ML16123A005; FRN: ML16123A007; Regulatory Analysis: ML16123A006; Resources: ML16133A207
***via email**

OFFICE	NSIR/DSP/FCTSB/PM*	NRR/DPR/PRMB/PM	NRR/DPR/PRMB/RS	NRR/DPR/PRMB/BC
NAME	BZaleski	SSchneider	GLappert	MKhanna
DATE	5/25/2016	5/27/2016	5/31/2016	6/21/2016
OFFICE	NRR/DPR/D	NRO/D*	NMSS/D*	RES/D*
NAME	LLund	JUhle, MCheok for	SMoore, MLombard for	MWeber, RCorreia for
DATE	6/28/2016	7/12/2016	7/12/2016	7/8/2016
OFFICE	OE/D*	OCFO/D*	ADM/DAS/RADB/BC*	NSIR/D*
NAME	PHolahan, DFurst for	MWylie, VPortillo for	CBladey, CGallagher for	BHolian, CJohnson for
DATE	7/11/2016	7/11/2016	8/8/2016	8/15/2016
OFFICE	QTE*	OCIO/CSD/FPIB/CO	OGC (NLO)*	NRR/D
NAME	JDougherty	DCullison	HBenowitz	WDean
DATE	9/2/2016	10/27/2016	10/11/2016	12/1/2016
OFFICE	EDO			
NAME	VMcCree			
DATE	2/22/2017			

OFFICIAL RECORD COPY