POLICY ISSUE
(Notation Vote)

DATE: July 9, 2024 SECY-24-0058

FOR: The Commissioners

FROM: Raymond V. Furstenau
Acting Executive Director for Operations

SUBJECT: RULEMAKING PLAN ON DRUG AND ALCOHOL TESTING: TECHNICAL ISSUES AND EDITORIAL CHANGES (RIN 3150-AJ15; NRC-2012-0079)

PURPOSE:

This paper requests Commission approval to develop a rulemaking that would amend Title 10 of the *Code of Federal Regulations* (10 CFR) Part 26, "Fitness for Duty Programs" (Part 26), to address technical and administrative issues associated with the implementation of drug and alcohol testing program requirements. This rulemaking would also resolve three petitions for rulemaking (PRM): PRM-26-4, "California Association of Marriage and Family Therapists"; PRM-26-7, "Certification of Substance Abuse Experts"; and PRM-26-8, "Additional Synthetic Drug Testing."

SUMMARY:

The U.S. Nuclear Regulatory Commission (NRC) staff is requesting approval to develop a rulemaking to improve the effectiveness and efficiency of Part 26. If approved, the rulemaking would focus on three areas: 1) incorporating lessons learned from implementing Part 26; 2) aligning Part 26 with updates to the U.S. Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines) and the U.S. Department of Transportation (DOT) drug testing requirements; and 3) resolving

CONTACTS: Brian Zaleski, NSIR/DPCP
301-287-0638

Stewart Schneider, NMSS/REFS
301-415-4123

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three petitions for rulemaking professional credentials to serve as a (two pertaining to Substance Abuse Expert (SAE) under Part 26 and a third requesting testing for additional synthetic drugs). A key driver for pursuing this rulemaking at this time is the continuing prevalence of subversion attempts of the urine drug testing process.

BACKGROUND:

In the staff requirements memorandum to SECY-15-0129, "Staff Requirements—SECY-15-0129—Commission Involvement in Early Stages of Rulemaking," dated February 3, 2016 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16034A441), the Commission approved a new requirement for a streamlined rulemaking plan in the form of a SECY paper that would request Commission approval to initiate all rulemakings not already explicitly delegated to the staff.

The regulatory activity discussed in this paper is a follow-on rulemaking to the Part 26 final rule published in the *Federal Register* (FR) on November 22, 2022 (87 FR 71422), hereafter referred to as the "2022 Part 26 final rule." In SECY-21-0082,[1] which transmitted the 2022 Part 26 draft final rule to the Commission, the staff stated its intention to provide the Commission with a rulemaking plan for the next Part 26 rulemaking titled, "Drug and Alcohol Testing: Technical Issues and Editorial Changes," within 1 year of publishing the 2022 Part 26 final rule.

The 2022 Part 26 final rule was narrowly scoped and primarily focused on enhancing urine drug testing capabilities (i.e., substances tested and testing cutoff levels used), which was accomplished by aligning Part 26 with updates made to the HHS Guidelines in 2008 and 2017. The 2022 Part 26 final rule also strengthened and expanded the use of testing methods to identify subversion attempts of the urine drug testing process. The 2022 Part 26 final rule enhanced the ability of fitness for duty (FFD) programs to identify additional individuals using illegal drugs, misusing legal drugs, or attempting to subvert the urine drug testing process.

The staff has developed this Part 26 rulemaking plan to address a variety of lessons learned from implementing the March 31, 2008, Part 26 final rule (73 FR 16966) and to incorporate anticipated technological advancements in specimen testing (e.g., oral fluid testing). From 2010 through 2012, the NRC also received three petitions for rulemaking (PRM-26-4, PRM-26-7, and PRM-26-8), which the NRC docketed and determined to be appropriate for consideration in a Part 26 rulemaking.[2]

HHS and DOT also have continued to update their drug testing program requirements. On October 12, 2023, HHS published final revisions to the HHS Guidelines for the testing of drugs in urine and oral fluid specimens (88 FR 70768 and 88 FR 70814, respectively). DOT published two final rules amending 49 CFR Part 40, "Procedures for Transportation Workplace Drug and Alcohol Testing Programs." One updated DOT's urine drug testing requirements (November 13, 2017; 82 FR 52229), and the other enabled oral fluid drug testing (May 2, 2023;

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1 "Final Rule: Fitness for Duty Drug Testing Requirements (RIN 3150-AI67; NRC-2009-0225)," dated September 17, 2021 (ML21111A018).

2 See "Petition for Rulemaking Submitted by the California Association of Marriage and Family Therapists," (76 FR 46651, August 3, 2011) (Docket No. NRC-2010-0269); "Certification of Substance Abuse Experts" (77 FR 33619, June 7, 2012) (Docket No. NRC-2011-0220); and "Additional Synthetic Drug Testing" (78 FR 22209, April 15, 2013) (Docket No. NRC-2012-0290).

88 FR 27596). This follow-on rulemaking would consider incorporating into Part 26 some of the updates to the HHS Guidelines and DOT drug testing requirements.

The staff held a public meeting on February 7, 2024, to inform stakeholders about key regulatory issues the agency is proposing to include in this rulemaking plan, as well as to solicit initial stakeholder feedback on the scope of this potential rulemaking activity. External stakeholders were largely supportive of the regulatory issues the staff proposes to consider in this rulemaking plan. The meeting summary package can be found at ML24037A122.

DISCUSSION:

Title

Drug and Alcohol Testing: Technical Issues and Editorial Changes (RIN 3150-AJ15; NRC-2012-0079)

Regulation

10 CFR Part 26, "Fitness for Duty Programs"

Regulatory Issues

The regulatory issues considered in this rulemaking plan address three topic areas that focus on effectiveness and efficiency improvements to Part 26.

Topic Area 1: Incorporating lessons learned from implementing Part 26.

This rulemaking would consider incorporating lessons learned from implementing Part 26 since the issuance of the 2008 Part 26 final rule. The NRC staff has gathered lessons learned from a variety of sources such as questions received from regulated entities; site-specific FFD program performance information received under 10 CFR 26.717, "Fitness-for-duty program performance data," and 10 CFR 26.719, "Reporting requirements"; NRC inspections; NRC staff-identified issues; and out-of-scope comments received on the 2019 Part 26 proposed rule, "Fitness for Duty Drug Testing Requirements" (September 16, 2019; 84 FR 48750), that would be addressed here.

- **Oral fluid specimen testing (10 CFR 26.83).** Attempts to subvert the urine drug testing process, which primarily occur at operating power reactor sites and power reactor construction sites, pose a persistent and ongoing challenge to the safe and secure construction and operation of licensed facilities. Most subversion attempts identified occur when an individual tries to cheat the drug testing process by providing a specimen that did not come from their body (e.g., a synthetic urine). This action is only possible because a donor typically provides a urine specimen inside a privacy enclosure. Expanding the option to collect and drug test oral fluid specimens for all collection conditions under 10 CFR 26.31, "Drug and alcohol testing," would offer an effective means to thwart attempts to subvert the drug testing process because all oral fluid specimens are collected under direct observation.[3]

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[3] Based on public comments received on the 2019 Part 26 proposed rule, the NRC included in the 2022 Part 26 final rule the option to collect and drug test a new specimen, oral fluid, for observed collection

Another possible consideration for expanding the collection and testing of oral fluid specimens is when a donor is unable to provide a minimum quantity of urine in a timely manner or at all (i.e., a shy bladder). Currently, if a donor is unable to provide a urine specimen of adequate volume on the initial attempt, 10 CFR 26.109(b) requires that a donor be offered up to 40 ounces of water over 3 hours to hydrate and provide a urine specimen of adequate volume. If a specimen of adequate volume cannot be provided, the collection process is terminated, and a medical evaluation is required to determine if a legitimate medical explanation exists for the donor's inability to provide a specimen for testing. If none exists, a subversion determination is made for a testing refusal. Under 10 CFR 26.119, "Determining 'shy' bladder," a donor must obtain a medical evaluation within 5 business days of the failed attempt. Obtaining an appointment with an appropriately trained medical professional within 5 business days can also be a challenge.

- **Blind performance test samples (BPTSs) (10 CFR 26.168).** Each calendar quarter, every licensee's FFD program submits to the HHS-certified laboratory under contract to perform testing, a minimum of 10 BPTSs formulated to verify the accuracy and reliability of each drug and validity test performed by the HHS-certified laboratory. BPTSs must be submitted for each drug or drug metabolite tested in donor specimens, as well as each validity test performed to identify subversion attempts. Lessons learned demonstrate that the industry's consolidated use of a limited number of HHS-certified laboratories may support a reduction in the number of BPTSs that must be submitted each quarter for testing, while still maintaining the oversight and testing accuracy challenges of the laboratories. Another issue for consideration is the higher number of BPTSs that must be submitted during the initial 90 days of any contract that an FFD program establishes with an HHS-certified laboratory. In this period, a minimum of 30 BPTSs must be submitted for testing. This higher number may serve as a financial barrier for a licensee to contract with another HHS-certified testing laboratory and is likely unnecessary if testing is already being performed by another Part 26 licensee at the laboratory.

- **Alcohol (10 CFR 26.5 definition; 10 CFR 26.719 reportability).** While Part 26 includes a robust defense-in-depth framework on alcohol (e.g., initial and annual refresher training, 5-hour prohibition of consumption before work, time-dependent alcohol positive test results based on time-in-work status, 24-hour reporting to the NRC if alcohol is identified or consumed inside a protected area (PA), 5-year minimum denial of access for possession or consumption of alcohol in a PA), it does not include a definition of the term "alcohol." Operating experience demonstrates the need for a definition of alcohol. For example, products not traditionally considered alcoholic beverages have been identified in the PAs of some licensed facilities. These products have contained very low (non-impairing) concentrations of alcohol (e.g., kombucha tea with less than 0.5 percent alcohol by volume) and high (impairing) concentrations of alcohol comparable to those in a hard liquor drink (e.g., vanilla extract with 35 percent alcohol by volume). Providing a definition for alcohol that is based on the impairing potential of an alcohol-containing product would reduce regulatory ambiguity and ensure that licensees take effective action when appropriate.

- **Determining an FFD policy violation—Medical Review Officer (MRO) test result reviews (10 CFR 26.185).** In the 2008 Part 26 final rule, the NRC established criteria for the

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conditions (i.e., situations where an indication of a possible subversion attempt exists). Before the 2022 Part 26 final rule, only an observed collection of urine was permitted (i.e., a donor removed clothing from the waist to the knees and the specimen collector observed urine exit directly from the donor's body into the specimen collection container).

standardized MRO review of drug and validity test results to make FFD policy violation determinations. These criteria provide accurate, consistent, and timely reviews of test results that protect public health and safety by ensuring that licensees take immediate action when an individual is determined to have violated the FFD policy and is not fit for duty. These criteria also protect a donor from an FFD policy violation when a legitimate medical explanation exists for a positive test result (e.g., use of a legally prescribed medication). Operating experience demonstrates that additional clarity is needed to address three types of MRO test result reviews:

- **MRO test result reviews pertaining to subversion attempts.** Under 10 CFR 26.183(c), an MRO is responsible for identifying "any evidence of subversion of the testing process"; however, the MRO test result review requirements in 10 CFR 26.185, "Determining a fitness-for-duty policy violation," do not articulate specific actions to take when reviewing test results from multiple urine specimens collected from an individual. Operating experience demonstrates that MROs have not consistently reviewed these test results in the context of a subversion attempt. The most common subversion attempt scenario is when a donor's initial unobserved urine specimen is out of the acceptable temperature range (a reason to suspect a subversion attempt) and is drug negative, and the directly observed second specimen is in the acceptable temperature range and is drug positive. The second subversion attempt scenario is when an HHS-certified laboratory reports an invalid test result (a possible sign of a subversion attempt) for the donor's initial unobserved urine specimen, and the directly observed second specimen is drug positive. A third subversion attempt scenario is when a donor's initial unobserved specimen is out of the acceptable temperature range, the second directly observed specimen is in the acceptable temperature range, and both specimens test negative for drugs. In this third scenario, MROs have made subversion determinations based on impossible variations in the physical characteristics of the two specimens collected (e.g., differences in specimen temperature, creatinine concentration, and pH). Additional information on the MRO's collective review of test result information is needed in 10 CFR 26.185 to ensure that MROs make consistent and uniform subversion determinations in these and other scenarios.

- **MRO evaluation of a prescription medication for legitimate medical explanation determinations for a positive drug test result.** Part 26 does not include information on how an MRO is to determine that a legitimate medical explanation exists for the use of a prescription medication. As a donor protection, under 10 CFR 26.183(c)(1), the MRO is to examine if an alternate medical explanation exists for a positive test result, which includes interviewing the donor and reviewing the donor's medical history and medical records to determine whether the test result is based on "responsible use of legally prescribed medication." Part 26 does not define the term "legally prescribed medication." Part 26 does define an "illegal drug" in 10 CFR 26.5, "Definitions," as "any drug that is included in Schedules I to V of section 202 of the Controlled Substances Act [21 U.S.C 812], but not when used pursuant to a valid prescription or when used as otherwise authorized by law." Part 26 also does not define the term "valid prescription." The HHS and DOT drug testing programs have implemented measures for MROs to evaluate prescription medications with respect to legitimate medical use determinations for positive drug test results, such as verifying the authenticity of medical records, contacting the prescribing physician, or contacting the pharmacy that filled a prescription. This rulemaking would consider incorporating HHS and DOT requirements regarding the review of prescription medication use (see Topic Area 2, which discusses updates implemented by HHS and DOT).

- **MRO evaluation of a positive drug test result when a legitimate medical explanation does not exist (i.e., no valid prescription)—performance of a clinical evaluation of signs of abuse.** Under 10 CFR 26.185(j), "Review for opioids and prescription and over-the-counter medications," the MRO is required to perform a clinical evaluation and verify that clinical signs of abuse exist (e.g., needle tracks) before verifying a positive drug test result as an FFD policy violation. Under 10 CFR 26.185(j)(3), if an MRO determines that a donor has used another individual's prescription medication and no clinical evidence of drug abuse is found, the MRO must report that the donor misused a prescription; this is not considered a positive test result. The MRO is to report a positive test result only when clinical evidence of abuse also exists. These Part 26 requirements are inconsistent with other Federal agency drug testing programs, which tailor the clinical evaluation of abuse only to morphine and codeine positives, as these substances can be found in naturally occurring food products such as poppy seeds. All other test results require a valid prescription; otherwise, the test result is verified as positive. This rulemaking would consider aligning with HHS and DOT requirements regarding the review of positive test results when no valid prescription exists.

- **Substance Abuse Experts (SAEs) (10 CFR 26.187).** The 2008 Part 26 final rule established the position of SAE, with responsibilities to evaluate individuals who have violated the substance abuse provisions of the FFD policy and to make recommendations concerning education, treatment, return to duty, follow-up drug and alcohol testing, and aftercare. Before the 2008 Part 26 final rule, MROs performed these functions, but operating experience demonstrated that additional qualifications and training were necessary. Because of the key role an SAE performs for a licensee's FFD program—determining whether an individual is fit to perform assigned duties safely and competently—each SAE is considered as FFD program personnel under 10 CFR 26.4(g) and thus subject to a licensee's FFD program. Operating experience demonstrates that some SAEs perform functions infrequently and at locations other than the NRC-licensed facility, which may present challenges in administering some FFD program elements such as behavioral observation and random drug and alcohol testing. This rulemaking would consider how to address these challenges.

- **Sanctions (10 CFR 26.75).** The 2008 Part 26 final rule instituted a permanent denial of unescorted access authorization for "any act or attempted act to subvert the testing process." A "subversion" is defined in 10 CFR 26.5 as "a willful act to avoid being tested or to bring about an inaccurate drug or alcohol test result for oneself or others at any stage of the testing process." Cases have been identified where subversion paraphernalia has been discovered inside the PA of power reactor sites, but not as part of the testing process. Examples include discovering a subversion product in the backpack of an individual at the entry to the PA or in an employee's desk drawer. This rulemaking would consider expanding the permanent denial criteria in 10 CFR 26.75(b) to include possession of subversion paraphernalia independent of the testing process.

- **Random testing (10 CFR 26.31(d)).** The 2008 Part 26 final rule included requirements to ensure that random testing is conducted in an unpredictable manner (e.g., nominal weekly testing). Operating experience demonstrates that additional clarification may be needed to address three issues. One, establishing a minimum frequency for the 10 CFR 26.31(d)(2)(i)(B) requirement to test on weekends, backshifts, and holidays (e.g., is one Saturday test a year sufficient?). Two, clarifying if the requirement in

10 CFR 26.31(d)(2)(vii) to randomly test a minimum of 50 percent of the worker population subject to testing annually applies to each site (e.g., each reactor location) or can be managed at the fleet level (e.g., workers from all reactor sites in a single fleet are included in one random testing pool and, on occasion, the 50 percent testing rate is not met at a site in the fleet). Three, clarifying 10 CFR 26.31(d)(2)(iii), which requires individuals who are selected for random testing to report to the collection site "as soon as reasonably practicable after notification, within the time period specified in the FFD program policy." Some sites permit an individual to report within the time period specified in the policy (e.g., 1 hour), but do not require reporting as soon as reasonably practicable. Timely reporting for testing upon notification is important for alcohol testing and reduces the ability to subvert a drug test.

- **Licensee testing facilities (Subpart F of Part 26).** Part 26 enables licensees to conduct initial drug and validity testing on urine specimens at a licensee testing facility (LTF), typically located at the power reactor site. Historically, LTF testing was the preferred option for many FFD programs because of the quick turnaround time on negative drug test results, which enabled the timely processing of individuals during outages. Any specimen that did not test negative or had a validity testing issue was forwarded for additional testing at an HHS-certified laboratory. Use of LTFs has steadily declined over time, and no FFD programs currently use an LTF. HHS-certified laboratories have greatly improved the turnaround times for reporting negative test results. Operating experience demonstrates that future use of LTFs is unlikely given their high operating costs, the increasing technical complexity in testing (e.g., drugs tested, cutoff levels used, validity tests performed), and the fact that LTFs can only test urine specimens. The rulemaking would consider whether to eliminate the option to conduct testing at an LTF. Eliminating the option for LTFs may improve regulatory effectiveness and efficiency by aligning with the HHS and DOT testing programs, which require all drug and validity testing of specimens to be performed at HHS-certified laboratories.

- **HHS-certified laboratories (Subpart G of Part 26).** The 2022 Part 26 final rule eliminated 10 CFR 26.155, "Laboratory personnel," and most of 10 CFR 26.157, "Procedures," because these requirements were duplicative with those in the HHS Guidelines and unnecessary to be included in Part 26. Additional requirements in Subpart G, "Laboratories Certified by the Department of Health and Human Services," may be duplicative and should also be considered for removal in this rulemaking. In addition, operating experience demonstrates that the 10 CFR 26.41(g)(4) requirement to maintain a copy of an HHS-certification inspection report may not be possible because the laboratory will not provide a facsimile of the report. This rulemaking would consider alternative approaches to documenting information contained in the inspection reports.

- **FFD information reporting (significant events, annual FFD performance).**
  - Under 10 CFR 26.719, "Reporting requirements," a licensee's FFD program must report information to the NRC Headquarters Operations Center by telephone within 24 hours of discovering a significant FFD policy violation or programmatic failure. However, operating experience demonstrates that the reporting requirement lacks sufficient specificity to facilitate prompt regulatory action. For example, one report stated that a licensed operator had a confirmed positive result for alcohol during a for-cause FFD test, while another report with the same underlying facts stated that a licensed operator violated the station's FFD policy. Establishing a minimum set of clear reporting elements would ensure that sufficiently detailed information is provided to ensure an appropriate NRC response and maintain transparency with the public.

- Under 10 CFR 26.717, "Fitness-for-duty program performance data," each FFD program submits drug and alcohol testing information on an annual basis. Licensees complete NRC reporting forms[4] to meet the 10 CFR 26.717 requirements. Some fields in these NRC forms are optional. As part of the rulemaking, the staff would assess whether some of the optional fields should be required to enable the staff to better assess testing trends. Licensees voluntarily use the NRC reporting forms to meet the reporting requirements in 10 CFR 26.717. This rulemaking would consider whether to require the use of these NRC forms to ensure uniformity of information provided to the NRC.

- **Select out-of-scope comments received on the 2019 Part 26 proposed rule.**

  On September 16, 2019, the NRC published the proposed rule, "Fitness for Duty Drug Testing Requirements." At least 10 comments received on the proposed rule were considered outside the scope of that rulemaking but provided actionable stakeholder feedback for consideration in this rulemaking. The NRC's response to comments (ML22133A052), which was published with the 2022 Part 26 final rule, discusses each out-of-scope comment, and includes a statement indicating that "the commenter's request could inform future considerations by the NRC." Select comments included the following:

  - **Donor gender identity and observed urine collections (10 CFR 26.115(e)).** One comment requested that the same-gender collection requirement be modified to accommodate a donor who identifies as one gender but has the physical anatomy of the opposite gender, or who identifies as gender X. The staff recommends considering updates introduced in the 2017 HHS Guidelines that address a donor's gender identity. The 2017 HHS Guidelines created a new term, "gender identity," and revised the direct observation collection procedure to enable a donor to be observed by an individual whose gender matches the donor's gender identity.

  - **Behavioral observation program (10 CFR 26.33).** The behavioral observation program requirements in 10 CFR 26.33, "Behavioral observation," state that individuals who perform behavioral observation must be trained to "detect behaviors that may indicate possible use, sale, or possession of illegal drugs; use or possession of alcohol on site or while on duty; or impairment from fatigue or any cause that, if left unattended, may constitute a risk to public health and safety or the common defense and security." One comment requested that the behavioral observation program also include detecting behaviors indicative of mental illness, as well the use of any impairing substance (e.g., solvents, computer cleaners, and other substances that are not defined as "illegal drugs"). The staff recommends exploring whether additional clarity is warranted.

  - **Post-event testing criteria (10 CFR 26.31(c)).** One comment stated that the criterion to conduct post-event testing within 4 hours after an event resulting in illness or injury that is reportable to the U.S. Department of Labor under 29 CFR 1904.7, "General recording criteria," can be difficult to implement (e.g., it may take 24 hours or longer to determine that an event is reportable). Another comment suggested that the criterion to conduct post-event testing after a "substantial degradation to the level of safety" be revised to "degradations of plant safety that generally may compromise general safety and

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4 The NRC created electronic NRC Form 890, "Single Positive Test Form" (ML22321A221), and NRC Form 891, "Annual Reporting Form for Drug and Alcohol Tests" (ML22321A193), in collaboration with the industry. The NRC periodically updates the forms to address user feedback and to improve function (e.g., bug fixes, uniformity of information collected). The forms have been available for use since 2009.

security." The staff would assess whether changes should be made to the post-event testing criterion based on these comments.

- **Sanctions (10 CFR 26.75).** The NRC requires a minimum 5-year denial of FFD authorization under 10 CFR 26.75(c) for "the sale, use or possession of illegal drugs or the consumption of alcohol within a protected area." The staff would assess whether to include in the denial criteria the use of other impairing substances (e.g., solvents, computer cleaners) or any prescription drug with the sole intent of producing a high to alter consciousness, based on a comment received.

- **SAE qualifications (10 CFR 26.187).** A comment recommended that a master's degree in addictions be included as an acceptable credential to serve as an SAE. The staff would consider whether to allow that degree (and possibly others) as an acceptable credential for an SAE.

Topic Area 2: Aligning with testing program updates implemented by HHS and DOT.

HHS published final revisions to the HHS Guidelines for the testing of drugs in urine and oral fluid specimens in October 2023. This rulemaking would focus on effectiveness and efficiency improvements in the HHS Guidelines.

- **2023 HHS Guidelines**. A significant change introduced in these guidelines is the option to conduct additional specimen tests to identify subversion attempts. Specifically, these guidelines established the testing for biomarkers (i.e., testing for the presence of biological substances to validate that a specimen came from a human being). HHS will only approve a biomarker test after it has determined the test is scientifically valid and provides forensically defensible results; at this time, HHS has authorized no biomarkers for testing. Enabling licensee FFD programs to test for HHS-approved biomarkers would offer additional defense-in-depth measures to deter and identify subversion attempts. These HHS Guidelines revisions also addressed the MRO evaluation of prescription medication use when determining whether a legitimate medical explanation exists for a positive test result and clarified that passive exposure to any drug (e.g., exposure to marijuana smoke) or the ingestion of food products containing a drug are not acceptable medical explanations for a positive test result. This rulemaking would consider if including these provisions would benefit the MRO review of drug test results when making FFD policy violation determinations.

  The 2023 HHS Guidelines also introduced a new process to annually review and update, if necessary, the drug and validity testing panels to address drug use and subversion trends in a timely manner. This rulemaking would not consider the possibility of more frequent testing panel changes anticipated by HHS. Instead, the staff intends to prepare a separate Commission paper by the end of calendar year 2024 to explore options to expedite targeted Part 26 rulemakings to address drug and validity testing panel changes that may occur on an annual basis.

DOT amended 49 CFR Part 40, "Procedures for Transportation Workplace Drug and Alcohol Testing Programs," in two final rules. This rulemaking would focus on effectiveness and efficiency improvements in the two DOT rules.

- **2017 DOT final rule**, "Addition of Certain Schedule II Drugs to the Department of Transportation's Drug-Testing Panel and Certain Minor Amendments" (82 FR 52229;

November 13, 2017). This final rule strengthened the MRO review of positive test results by creating a definition for a "legally valid prescription medication"; articulated a methodology to verify the authenticity of a prescription medication; and enabled additional specimen tests that an MRO can direct an HHS-certified laboratory to perform to validate a medical explanation provided by a donor for a positive test result (e.g., conducting chirality testing for amphetamine and methamphetamine to assist in determining whether an individual used a pharmaceutical or an illicitly produced drug). This rulemaking would consider if including these provisions would benefit MRO determinations on the legitimate medical use of prescription medications. This 2017 DOT final rule was outside the scope of the 2022 Part 26 rulemaking.

- **2023 DOT final rule**, "Addition of Oral Fluid Specimen Testing for Drugs" (88 FR 27596; May 2, 2023). This final rule stated, "This additional methodology [i.e., oral fluid testing] for drug testing will give employers a choice that will help combat employee cheating on urine drug tests and provide a less intrusive means of achieving the safety goals of the program." Along with the new 2019 HHS Guidelines for oral fluid testing and revisions in 2023, this 2023 DOT final rule offers a regulatory framework that can be considered in this rulemaking for expanding oral fluid drug testing to additional testing conditions under Part 26 (e.g., pre-access testing, shy-bladder situations).

Topic Area 3: Resolving three petitions for rulemaking.

- PRM-26-4, "California Association of Marriage and Family Therapists" (75 FR 51958; August 24, 2010). The petitioner requested that the NRC add marriage and family therapists to the list of acceptable credentials to serve as an SAE under 10 CFR 26.187, "Substance abuse expert."

- PRM-26-7, "Certification of Substance Abuse Experts" (76 FR 61625, October 5, 2011). The petitioner requested that the NRC add the American Academy of Health Care Providers in the Addictive Disorders to the list of organizations authorized to certify SAEs under 10 CFR 26.187(b)(5).

- PRM-26-8, "Additional Synthetic Drug Testing" (78 FR 22209; April 15, 2013). The petitioner requested that the NRC consider including additional synthetic drugs in the required substances for testing in each specimen that is drug tested.

Existing Regulatory Framework

The NRC published a final rule, "Fitness-for-Duty Programs," on June 7, 1989 (54 FR 24468), which created 10 CFR Part 26 that applied to licensees of nuclear power plants. A subsequent Part 26 final rule, published on June 3, 1993 (58 FR 31467), expanded the scope of Part 26 to include licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material (i.e., Category I special nuclear material facilities).

The NRC published the first substantial revision to 10 CFR Part 26 in the 2008 final rule. The 2008 Part 26 final rule updated the NRC's drug testing panel to align more closely with the 2004 HHS Guidelines (69 FR 19644) and the DOT's testing requirements. A number of important changes in the 2008 FFD final rule included: 1) mandated validity testing of urine specimens to address the potential for subversion of the testing process; 2) advancements in drug and alcohol testing technologies and testing cutoff levels, 3) uniform minimum sanctions for FFD

policy violations; 4) improved consistency between the FFD authorization requirements in 10 CFR Part 26 and the access authorization requirements in 10 CFR 73.56, "Personnel access authorization requirements for nuclear power plants," to align with the security orders issued after the terrorist attacks on September 11, 2001; 5) creation of a fatigue management program; and 6) creation of a new optional FFD program for power reactors under construction. The 2008 Part 26 final rule also addressed numerous lessons learned from implementing Part 26 since 1989, such as providing flexibilities like relaxing a licensee's internal FFD program audit frequency from annually to every 24 months and reducing the reporting of FFD program performance information from every 6 months to annually.

In 2022, the NRC revised 10 CFR Part 26 with the primary focus of aligning the drug testing panel (i.e., substances tested and testing cutoff levels used) with updates made to the HHS Guidelines in 2008 and 2017.

Explanation of Why Rulemaking Is the Preferred Solution

The staff evaluated three alternatives, maintaining the status quo, rulemaking, and guidance development.

Alternative 1: No Action (Status quo). The NRC would not pursue rulemaking to amend 10 CFR Part 26.

Pros:

- It requires no agency resources for rulemaking.
- It requires no licensee resources to modify policy and procedures associated with rulemaking.
- It maintains regulatory stability, given the recent publication and implementation of the 2022 Part 26 final rule.

Cons:

- It does not address trends in subversion attempts, which are a significant and persistent challenge to the trustworthiness and reliability of the workforce. This also is an issue of high interest to industry stakeholders.
- It does not incorporate effectiveness and efficiency improvements (lessons learned) from over 15 years of implementing the 2008 Part 26 final rule.
- It does not improve the clarity and consistency of regulatory requirements by addressing specific issues where regulatory ambiguity exists.
- It does not align NRC requirements with updates made to HHS and DOT drug testing programs (e.g., expanded use of oral fluid drug testing conditions, enabling biomarker testing as an additional validity testing measure).
- The staff would still need to reevaluate the merits of the three petitions for rulemaking (PRM-26-4, PRM-26-7, and PRM-26-8) and determine how to disposition each petition.

Alternative 2: Rulemaking. The NRC would pursue rulemaking to amend 10 CFR Part 26.

Pros:

- It addresses trends in subversion attempts, which are a significant and persistent challenge to the trustworthiness and reliability of the workforce.
- It incorporates effectiveness and efficiency improvements from lessons learned from implementing the 2008 Part 26 final rule.
- It resolves regulatory uncertainty where operating experience demonstrates a lack of clarity or consistency in the implementation of existing requirements, and it provides predictable risk-informed updates beneficial to regulatory compliance.
- It aligns NRC requirements with updates made by HHS and DOT drug testing programs (e.g., expanded use of oral fluid drug testing conditions, enabling biomarker testing as an additional validity testing measure).
- It resolves three petitions for rulemaking (PRM-26-4, PRM-26-7, and PRM-26-8).

Cons:

- It takes several years to complete.
- It requires agency resources to conduct rulemaking.
- It requires licensee resources to participate in the rulemaking process and implement rule changes.

Alternative 3: Guidance. The NRC would revise guidance,[5] independent of rulemaking, to address regulatory ambiguity.

Pros:

- It is less resource intensive and can be completed quicker than a rulemaking.
- It provides one method of complying with a subset of existing requirements where regulatory ambiguity exists.

Cons:

- It would not adequately address regulatory issues of high consequence (e.g., MRO subversion determinations, test result reviews related to prescription use, clinical evaluations of abuse) because regulatory changes are needed.

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5 The 2022 Part 26 final rule created a new regulatory guide (RG) 5.89, "Fitness-For-Duty Programs for Commercial Power Reactor and Category I Special Nuclear Material Licensees" (ML20143A034). The guidance in RG 5.89 is limited to three issues in the 2022 Part 26 final rule.

- It does not address subversion attempt trends—a key driver for this rulemaking—because expanding use of oral fluid drug testing, enabling biomarker testing, and instituting a sanction for the possession of subversion paraphernalia independent of the collection process would require regulatory changes.

- It does not incorporate most effectiveness and efficiency improvements from lessons learned (e.g., blind performance testing).

- The staff would still need to reevaluate the merits of the three petitions for rulemaking (PRM-26-4, PRM-26-7, and PRM-26-8) and determine how to disposition each petition.

The staff recommends Alternative 2, Rulemaking. The rulemaking alternative is supported by over 15 years of programmatic experience, would incorporate technical advancements implemented by Federal drug testing partners, HHS and DOT (e.g., oral fluid testing, which offers significant benefits to deterring subversion attempts), and would at the same time provide a single vehicle to resolve three rulemaking petitions that the NRC has accepted.

Description of Rulemaking: Scope

This rulemaking would amend Part 26 to improve effectiveness and efficiency by addressing technical and administrative issues in three topic areas: 1) incorporating lessons learned from implementing Part 26; 2) aligning Part 26 with updates to the HHS Guidelines and the DOT's drug and alcohol testing requirements; and 3) resolving three petitions for rulemaking: PRM-26-4, PRM-26-7, and PRM-26-8.

Description of Rulemaking: Preliminary Backfitting and Issue Finality Assessment

As part of the rulemaking process, the staff would determine if any of the changes described in this rulemaking plan would constitute "backfitting" as that term is defined in 10 CFR 50.109, "Backfitting," and 10 CFR 70.76, "Backfitting," or affect the issue finality of a combined license under 10 CFR 52.98, "Finality of combined licenses; information requests." If any did, then the NRC would need to justify the changes under those provisions and the Commission's policy in Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests." Currently, the topic areas of this rulemaking do not present a safety issue warranting immediate action.

Description of Rulemaking: Estimated Schedule

If the Commission approves this rulemaking plan, then the staff estimates the following schedule for key milestones:

- Publish regulatory basis for comment—12 months after Commission approval to initiate rulemaking.
- Submit proposed rule to the Commission—12 months after regulatory basis publication.
- Submit final rule to the Commission—12 months after proposed rule publication.

Description of Rulemaking: Preliminary Recommendation on Priority

Based on the Common Prioritization of Rulemaking methodology (ML23018A148), the preliminary priority for this rulemaking is high. The high priority determination (37 out of a possible score of 45) is based on the rulemaking being 1) a significant contributor to the safety and security goal objectives in the NRC's Strategic Plan; 2) a moderate contributor to the implementation of the Principles of Good Regulation; 3) a significant contributor to conformance with other Federal regulations, future regulatory benefits, and the staff's commitment in SECY-21-0082; and 4) a significant contributor to stakeholder confidence by reducing regulatory burden and responding to three petitions for rulemaking.

The priority for a rulemaking activity can change over time. Common reasons for a change in priority are new Commission direction or prioritization, or changes in the rulemaking scope.

Description of Rulemaking: Estimate of Resources

This rulemaking is estimated to involve a medium level of costs to final rule publication. The enclosure to this paper estimates the resources needed within the rulemaking product line under the Operating Reactor Business Line to conduct this rulemaking.

Cumulative Effects of Regulation

The staff's preliminary assessment of the cumulative effects of regulation (CER) concludes that no known activities or affected entities would be impacted significantly by implementing this rulemaking's changes. The staff would follow the NRC's CER process by engaging with external stakeholders throughout the rulemaking. To ensure adequate identification of potential effects not currently foreseen, the staff would hold public meetings during the regulatory basis and proposed and final rule phases.

Agreement State Considerations

The staff identified no Agreement State considerations for this rulemaking because the requirements in Part 26 are not subject to regulation by Agreement States.

Guidance

If the Commission approves the recommended rulemaking alternative, the staff will assess the need to develop new guidance, or enhance existing guidance, based on the type and scope of the regulatory changes.

Advisory Committee on Reactor Safeguards Review

The staff does not recommend review by the Advisory Committee on Reactor Safeguards (ACRS) but will contact the Committee to determine any engagement. For the 2019 Part 26 proposed rule, the ACRS determined the rule was outside the scope of its oversight but requested informational copies of the proposed and final rule packages.

Committee to Review Generic Requirements Review

The staff recommends review by the Committee to Review Generic Requirements during the development of the regulatory basis and proposed and final rules should the staff identify any

potential backfits affecting the licensees of nuclear power plants and Category I special nuclear material facilities.

Advisory Committee on the Medical Use of Isotopes Review

The staff does not recommend review by the Advisory Committee on the Medical Use of Isotopes. The topic of this rulemaking, revisions to the drug and alcohol testing requirements in Part 26, is outside the scope of the Committee's responsibilities regarding the regulation of the medical uses of radioactive material.

Analysis of Legal Matters

The Office of the General Counsel has reviewed this rulemaking plan and has not identified any issues necessitating a separate legal analysis at this time.

COMMITMENT:

This rulemaking has been planned and communicated to the public since 2012 through the agency's rulemaking tracking tool and the Federal Unified Agenda of Regulatory and Deregulatory Activities. If the Commission does not approve the rulemaking, in accordance with SECY-16-0042, "Recommended Improvements for Rulemaking Tracking and Reporting," dated April 4, 2016 (ML16075A070), and Note to Commissioners' Assistants, "Update on Plan to Enhance Commission Involvement in the Early Stages of Rulemaking," dated June 16, 2016 (ML16153A354) (nonpublic), the staff will discontinue this rulemaking activity. Staff would hold a public meeting and issue a *Federal Register* notice to inform stakeholders of the Commission's decision. In addition, the staff would reevaluate the merits of the three petitions accepted for rulemaking and seek Commission approval to disposition each accordingly.

RECOMMENDATION:

The NRC staff recommends that the Commission approve initiation of a rulemaking to amend Part 26 to address technical and administrative issues associated with the implementation of the drug and alcohol testing program requirements and to resolve three petitions for rulemaking: PRM-26-4, "California Association of Marriage and Family Therapists"; PRM-26-7, "Certification of Substance Abuse Experts"; and PRM-26-8, "Additional Synthetic Drug Testing."

RESOURCES:

The enclosure includes an estimate of the resources needed to complete this rulemaking.

COORDINATION:

The Office of the General Counsel has no legal objection to this action. The Office of the Chief Financial Officer has reviewed this paper and has no concerns with the estimated resources in the enclosure.

Raymond V. Furstenau
Acting Executive Director for Operations

Enclosure:
Resource Estimates

SUBECT: RULEMAKING PLAN ON DRUG AND ALCOHOL TESTING: TECHNICAL ISSUES AND EDITORIAL CHANGES (RIN 3150-AJ15; NRC-2012-0079)
DATED: July 9, 2024

OEDO-23-00175-NMSS

ADAMS Accession Nos.:
Pkg: ML24060A005,
SECY: ML24060A008,
Enclosure.: ML24060A009

SECY-012

OFFICE	QTE	NMSS/REFS/RRPB/RS	NMSS/REFS/RRPB/BC	NMSS/REFS/RASB/BC
NAME	JDougherty	GLappert	ABilloch-Colon (Acting)	CBladey
DATE	03/07/2024	03/12/2024	03/14/2024	03/20/2024
OFFICE	NSIR/DPCP/RSB/BC	NMSS/REFS/D	NMSS/DFM/D	NRR/DRO/D
NAME	ABowers	MRalph for CRegan	SHelton	RFelts
DATE	03/20/2024	04/02/2024	04/01/2024	03/28/2024
OFFICE	NSIR/DPCP/D	NSIR/D	NMSS/D	OCFO
NAME	GBowman	CErlanger for MGavrilas	RLewis for JLubinski	LYee
DATE	03/28/2024	04/11/2024	04/15/2024	04/12/2024
OFFICE	OCIO/DIME/FLIC/ICT /CO	OGC (NLO)	NMSS/REFS/RRPB/PM	NRR/D
NAME	DCullison	HBenowitz	SSchneider	MKing for AVeil
DATE	04/11/2024	04/29/2024	05/06/2024	05/14/2024
OFFICE	EDO			
NAME	RFurstenau (Acting)			
DATE	07/09/24			

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