[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 26

[NRC-2009-0225]

RIN 3150-AI67

Fitness for Duty Drug Testing Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule and draft regulatory guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations regarding fitness for duty (FFD) programs for certain NRC licensees and other entities to more closely align the NRC's drug testing requirements with the updates made to the U.S. Department of Health and Human Services "Mandatory Guidelines for Federal Workplace Drug Testing Programs" in 2008, which became effective on October 1, 2010. The proposed rule would also incorporate lessons learned from implementation of the NRC's current FFD regulations. These changes would 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 would also provide additional protections to individuals subject to drug testing and would improve the clarity, organization, and flexibility of the NRC's FFD regulations. The NRC is also requesting comment on draft regulatory guide 5040.

DATES: Submit comments by **[INSERT DATE 75 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].** Comments received after this date will

be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal Rulemaking Web site:** Go to https://www.regulations.gov and search for Docket ID NRC-2009-0225. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this proposed rule.
- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.
- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.
- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Stewart Schneider, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-4123; e-mail:

Stewart.Schneider@nrc.gov; Brian Zaleski, Office of Nuclear Security and Incident Response, telephone: 301-287-0638; email: Brian.Zaleski@nrc.gov; or Paul Harris, Office of Nuclear Security and Incident Response, telephone: 301-287-9294; e-mail: Paul.Harris@nrc.gov; U.S. Nuclear Regulatory Commission, Washington DC 20555-0001.

SUPPLEMENTARY INFORMATION:

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations regarding fitness for duty (FFD) programs for certain NRC licensees and other entities to more closely align the NRC's drug testing requirements with the updates made in 2008 to the U.S. Department of Health and Human Services (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (HHS Guidelines), which were published in the *Federal Register* on November 25, 2008 (73 FR 71858), corrected on December 10, 2008 (73 FR 75122), and became effective on October 1, 2010 (75 FR 22809; April 30, 2010). The HHS Guidelines govern Federal employee workplace drug testing programs at more than 100 Federal agencies and Federal agency drug testing programs (e.g., U.S. Department of Transportation (DOT)) that test civilians in safety- and security-sensitive positions similar to personnel tested under part 26, "Fitness for Duty Programs," in title 10 of the *Code of Federal Regulations* (10 CFR). More closely aligning the drug testing provisions under 10 CFR part 26 with the 2008 HHS Guidelines would enhance the ability of licensees and other entities to identify individuals using illegal drugs and misusing legal drugs. The proposed rule would also incorporate

lessons learned from implementation of the 10 CFR part 26 final rule published in the *Federal Register* on March 31, 2008 (73 FR 16966; hereafter referred to as "2008 FFD final rule"). These lessons include improved methods to identify attempts to subvert the drug testing process and improvements in the clarity, consistency, and flexibility of donor protections under 10 CFR part 26. Historically, the NRC has relied upon the HHS Guidelines to establish the technical requirements for urine specimen collection, drug testing, and results evaluation and has required licensees and other entities to use HHS-certified laboratories to perform drug testing. The last NRC alignment with the HHS Guidelines was completed with the 2008 FFD final rule, which incorporated provisions from the 2004 HHS Guidelines (69 FR 19643; April 13, 2004).

B. Major Provisions

Major provisions of the proposed rule include the following:

- Add initial and confirmatory drug testing for two illegal amphetamine-based controlled substances—methylenedioxymethamphetamine (MDMA) and methylenedioxyamphetamine (MDA)—referred to as Ecstasy-type drugs in this proposed rule.

- 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 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.

- 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 by addressing personnel who may monitor a donor in a shy-bladder situation who is hydrating; and enhance both donor protections by providing additional instructions for same-gender observers used in observed collections and 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.

C. Costs and Benefits

The NRC prepared a draft regulatory analysis to quantify the costs and benefits of the proposed rule, as well as to examine the qualitative factors to be considered in the NRC's rulemaking decision. The analysis concluded that the proposed rule would result in net costs to the industry. The proposed rule, relative to the regulatory baseline, would result in a net cost to industry of between $2.4 million based on a 7 percent net present value and $3.4 million based on a 3 percent net present value. The estimated average net cost per licensee or other entity site would be a one-time cost of $5,031 and an annual cost of $2,516. Thirteen qualitative factors were evaluated in the draft regulatory analysis: public health (accident), occupational health (accident), offsite property, onsite property, regulatory efficiency, safeguards and security considerations, and other considerations (public perception, public trust, worker productivity, improved protection of individual rights, work environment free of drugs and the effects of such substances, safety vulnerability, and security vulnerability). The draft regulatory analysis includes a narrative discussion of each qualitative factor.

If the results of the regulatory analysis were based solely on the costs and the benefits that could be quantified, then the regulatory analysis would show that rulemaking is not justified because the total estimated quantified benefits of the proposed regulatory action do not equal or exceed the estimated costs of the proposed regulatory action. However, when the qualitative benefits are considered, together with the quantified benefits, then the benefits outweigh the identified quantitative and qualitative impacts.

In the draft regulatory analysis, the NRC concluded that the proposed rule should be adopted because it would result in a 10- to 12-percent increase per year in the detection of individuals using drugs or attempting to subvert the drug testing process. In comparison to the test results from calendar years 2013 and 2014, the estimated increase in detection each year is equivalent to identifying approximately 95 additional individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. This improved detection would prevent drug-using individuals from gaining or maintaining unescorted access authorization to NRC-licensed facilities (i.e., operating nuclear power reactors, nuclear power reactors under construction, and Category I fuel cycle facilities) and other locations (e.g., Emergency Operations Facilities, Technical Support Centers). In addition, the enhanced detection would prevent drug-using individuals from gaining or maintaining unescorted access authorization to special strategic nuclear material (SSNM) or sensitive information. An enhanced drug testing program might also deter drug-using individuals from seeking employment in 10 CFR part 26 regulated positions and/or incentivize those already in regulated positions to cease drug use or to seek medical assistance to address an addiction or misuse issue.

For more information, please see the regulatory analysis (Accession No. ML19169A115 in the NRC's Agencywide Documents Access and Management System (ADAMS)).

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2009-0225 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Web site:** Go to https://www.regulations.gov and

search for Docket ID NRC-2009-0225.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at https://www.nrc.gov/reading-rm/adams.html. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.
- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC-2009-0225 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at https://www.regulations.gov as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment

submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

A. The Health and Human Services Guidelines

Through Executive Order 12564 (51 FR 32889; September 17, 1986), the President of the United States designated the Department of Health and Human Services (HHS) as the Federal agency responsible for establishing and maintaining the requirements and guidance for conducting Federal employee workplace drug testing. In execution of this designation, and under the authority of Section 503 of Public Law 100-71, 5 U.S.C. Section 7301 notes, HHS developed the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (HHS Guidelines) that established a robust legal framework to conduct drug testing to provide the following: reasonable assurance of donor privacy; drug testing accuracy and precision; specimen collection, custody, and control; and results review by a Medical Review Officer (MRO).

The HHS Guidelines also established the certification requirements that each laboratory must meet to test specimens for Federal employee workplace drug testing programs. To obtain certification, a laboratory must successfully complete several rounds of performance testing and a National Laboratory Certification Program (NLCP) inspection. The certification requirements include, but are not limited to, laboratory staffing and qualifications, testing procedures, quality assurance and quality control, and results reporting. Once certified, each laboratory is subject to quarterly performance testing and NLCP inspection every 6 months to verify adherence to the HHS Guidelines. The HHS laboratory certification process provides assurance to the NRC, licensees, and

other entities that the testing of specimens, under 10 CFR part 26, is conducted with the highest standards of accuracy, precision, and quality.

Periodically, HHS updates the HHS Guidelines to enhance testing program effectiveness based on advances in drug testing technologies, processes, methodologies, and instrumentation; revise the authorized substances in the testing panel as societal drug-use trends change; and incorporate lessons learned from the NLCP. Each revision of the HHS Guidelines is published following a rigorous process that includes scientific, policy, legal, and technical review by the independent Drug Testing Advisory Board, which advises the Administrator of the HHS Substance Abuse and Mental Health Services Administration (SAMHSA); academic peer reviews; public review and comment; and input from Federal agencies that implement the HHS Guidelines. The HHS also conducts extensive outreach with affected stakeholders and researches societal drug-use trends to promulgate effective drug testing methods.

The HHS Guidelines govern the drug testing programs of over 100 Federal agencies that test Federal employees; are used by many Federal agencies that test civilians in safety- and security-sensitive positions similar to personnel tested under 10 CFR part 26, such as the U.S. Department of Transportation (DOT); and by many private entities. The NRC has historically relied on HHS to establish the technical requirements for urine specimen collection, specimen testing and test result evaluation, and in general only deviates from the HHS Guidelines for considerations specific to the nuclear industry. The NRC relies on the HHS Guidelines as part of its technical basis for the drug testing requirements contained under 10 CFR part 26. Updating 10 CFR part 26 to align with changes in the 2008 HHS Guidelines would help to ensure that the NRC's regulations continue to be scientifically and technically sound.

B. History of the NRC's Fitness for Duty Program

In the 1970s, the NRC and the commercial nuclear power industry began addressing concerns about the potential public health and safety impacts of fitness for duty (FFD) problems at nuclear power plants. Most nuclear utilities voluntarily implemented FFD programs during the 1980s, and the NRC monitored the comprehensiveness and effectiveness of these programs. On August 4, 1986 (51 FR 27921), the NRC published the Commission Policy Statement on Fitness for Duty of Nuclear Power Plant Personnel, which outlined the need for nuclear power plant licensees to implement programs to address FFD problems—including illegal drug use, alcohol abuse, misuse of legal drugs, and any other mental or physical problems that could impair job performance. An evaluation of licensee programs following the implementation of the policy statement identified a wide range in the quality and comprehensiveness of licensee FFD testing programs that ultimately resulted in the NRC's decision to pursue rulemaking.

The NRC published a final rule, entitled "Fitness-for-Duty Programs," in the *Federal Register* on June 7, 1989 (54 FR 24468), adding 10 CFR part 26. The 1989 FFD final rule was based on the 1988 version of the HHS Guidelines (53 FR 11970; April 11, 1988). A subsequent final rule, published in the *Federal Register* on June 3, 1993 (58 FR 31467), expanded the scope of 10 CFR part 26 to include licensees authorized to possess, use, or transport formula quantities of strategic special nuclear materials (SSNM).

The NRC issued the first substantial revision to 10 CFR part 26 in a final rule on March 31, 2008 (73 FR 16966; hereafter referred to as the "2008 FFD final rule"). The 2008 FFD final rule updated the NRC's drug testing requirements to align with the then-latest HHS Guidelines, which were issued in 2004 (69 FR 19644; April 13, 2004). The 10 CFR part 26 updates included the following: 1) required validity testing of each

specimen to address the potential for subversion of the testing process, 2) advancements in drug and alcohol testing technologies, 3) changes to drug and alcohol testing cutoff levels, and 4) lessons learned from the implementation of 10 CFR part 26 since its addition in 1989.

On November 25, 2008, HHS issued the 2008 HHS Guidelines (73 FR 71858), which included the following: 1) an expanded drug testing panel, 2) lower drug testing cutoff levels for some substances, 3) advances in testing technologies, and 4) more detailed requirements for specimen collectors and MROs. The 2008 HHS Guidelines became effective on October 1, 2010. The 2008 Guidelines' updates to the 2004 Guidelines are currently not reflected in 10 CFR part 26.

III. Discussion

A. The Need for Rulemaking

1. Alignment with the 2008 Health and Human Services Guidelines

In the 2008 HHS Guidelines, HHS enhanced the detection of illegal drug use and the misuse of prescription drugs through the following changes: 1) lowering the initial and confirmatory testing cutoff levels for amphetamine, cocaine, and methamphetamine; 2) establishing an initial testing requirement and revising the confirmatory testing cutoff level for the heroin metabolite 6-AM; and 3) establishing testing for Ecstasy-type drugs (which are part of the amphetamine class of drugs).

The effectiveness of the 2008 HHS Guidelines is demonstrated by the enhanced detection evident in the test results reported by HHS, the DOT, and Quest Diagnostics® (Quest), which is an HHS-certified laboratory that conducts testing for both Federal workplace drug testing programs (i.e., Federally-mandated) and private company testing programs (i.e., U.S. general workforce). Quest annually publishes a Drug Testing

Index™ report, which presents Quest laboratory testing results for Federally-mandated drug tests. On March 13, 2012, Quest reported a 33 percent increase from 2010 to 2011 in cocaine positive test results for 1.6 million Federal workplace tests conducted. Quest attributed the increase, in large part, to the lower cocaine testing cutoff levels implemented as a result of the 2008 HHS Guidelines (Quest, 2012). In the same report, Quest also noted that amphetamines positives rose by nearly 26 percent, continuing an existing upward trend, but also were "likely boosted by better detection related to the new, lower Federally-mandated cutoffs." In comparison to the 2010 positive testing rates for Federal workplace drug testing performed by Quest, the results for 2012 indicate a 12.5 percent increase in cocaine positives and a 37 percent increase in amphetamines positives with 2013 continuing the multi-year upward trend (Quest, 2014).

As detailed in the NRC report, "Summary of Fitness for Duty Performance Reports for Calendar Year 2013," an adverse trend in the commercial nuclear industry had been observed over the prior 5 years associated with the year-over-year increases in amphetamines[1] positive test results (see table in this section). While accounting for a relatively small percentage of the total positive drug test results in 2013 at 8.9 percent, amphetamines positives have continued to grow in comparison to previous years. For example, the share of amphetamines positives, as a percentage of all positive drug test results in 2013 (8.9 percent), is 2.3 times higher than the percentage in 2009 (3.9 percent). Viewed another way, the percentage of individuals testing positive for amphetamines has trended upward since 2009. In 2009, 0.023 percent of individuals tested positive for amphetamines; by 2013, the positive rate increased to 0.052 percent. Conversely, cocaine use as a percentage of all positives has declined by 15.9 percent from 1990 (the first year of 10 CFR part 26 drug testing) to 2013. While cocaine use has

[1] Initial drug testing for amphetamines and confirmatory drug testing for amphetamine and methamphetamine is required by 10 CFR part 26.

trended downward, it continues to be the third most detected substance, accounting for 13.2 percent of positive drug test results in 2013.

Trends in Amphetamines and Cocaine Use

Substance	1990	2009	2010	2011	2012	2013	Change (1990 – 2013)
Amphetamines	2.8%	3.9%	5.7%	8.3%	6.2%	8.9%	6.1%
Cocaine	29.0%	16.2%	13.1%	12.4%	12.9%	13.2%	-15.9%

Notes: 1. The positive testing percentages are calculated by taking the total number of positives for the particular substance and dividing that figure by the total number of positive drug test results in the year.

2. Data from 1990, the first year of testing under 10 CFR part 26, are included as the baseline for comparison.

While most of the proposed changes in this rulemaking would be made to better align 10 CFR part 26 with the 2008 HHS Guidelines, some are based on lessons learned during the implementation of the 2008 FFD final rule by licensees and other entities. In particular, the NRC is proposing a number of changes that would enhance the ability of licensees and other entities to identify individuals attempting to subvert the drug testing process.

Beginning in 2009, licensees and other entities had the option to use electronic reporting forms (e-forms) created by the NRC, in collaboration with licensees and other entities, in order to meet the annual FFD drug and alcohol testing program reporting requirements in § 26.717, “Fitness-for-duty program performance data” and § 26.417(b)(2). These e-forms[2] provide a uniform way of reporting detailed information on each drug and alcohol testing violation, and their use by licensees and other entities has continued to grow (from over 80 percent in 2011 to 93 percent in 2013).

[2] The NRC FFD electronic forms are available for review at the following NRC website: https://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/submit-ffd-reports.html.

Analysis of FFD program performance data from 2011 through 2014 identified a significant new trend: the prevalence of subversion attempts of the drug testing process. In 2011, over 13.2 percent of the total testing violations were donor subversion attempts (143 of 1,080 testing violations), with even more subversion attempts in subsequent years: 15.9 percent in 2012 (177 of 1,114 testing violations), 14.7 percent in 2013 (148 of 1,007 violations), and 16.5 percent in 2014 (187 of 1,133 testing violations). If the number of alcohol positive testing violations is removed from the total testing violations each year, the percentage of drug testing violations determined to be subversion attempts increases to 17.5 percent in 2011, 20.6 percent in 2012, 19.2 percent in 2013, and 21.3 percent in 2014. An attempt to subvert the testing process demonstrates a lack of integrity and honesty and a willful act to refuse to comply with an NRC-required drug test (see 10 CFR 26.89(c), 26.825, "Criminal penalties," and 50.5, "Deliberate misconduct"). Consequently, drug-using individuals present a safety vulnerability because of the potential for human performance issues due to drug use. Drug-using individuals could also present a security vulnerability because of their impairment or willful misconduct. As a result, the NRC is proposing a number of changes in this proposed rule to enhance the ability of FFD testing programs to detect individuals attempting to subvert the drug testing process.

Stakeholder outreach on the proposed rule is described in Section III.B of this document. The basis for each proposed change is discussed in Section III.C of this document. The regulatory basis for this proposed rule, issued on May 10, 2013, provides further discussion on the technical merits of this rulemaking.

2. Societal Drug Use

As described in the President's 2014 "National Drug Control Strategy," societal use of legal and illegal drugs and substances continues to evolve and affects every

sector of society. The prevalence of drug use in society is also documented in the "Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health" (NSDUH), an annual survey sponsored by SAMHSA. This survey is the primary source of information on the use of illegal drugs, alcohol, and tobacco in the civilian, non-institutionalized population in the United States, ages 12 and older. The NSDUH survey estimated that in 2014, 10.2 percent of the U.S. population aged 12 or older (approximately 27.0 million Americans) used an illegal drug in the past month. This estimate was based on the number of individuals surveyed that reported using an illegal drug during the month prior to participating in the NSDUH survey interview. Among adults aged 26 or older, those potentially in the U.S. workforce, the rate of illegal drug use was 8.3 percent, representing an upward trend since 2002. Although SAMHSA attributes this increase to marijuana use, it demonstrates the prevalence of illegal drug use in the workforce. Societal drug use presents a continual challenge to the fitness of the workforce relied on by licensees and other entities to perform safety and security significant duties, with the result that potential impairment and the adverse impact on human performance may affect public health and safety.

B. Public Input Regarding Proposed Revisions to 10 CFR Part 26 to Include Aspects of the 2008 Health and Human Services Guidelines

After HHS issued the 2008 HHS Guidelines, the NRC performed a comprehensive review of 10 CFR part 26 and the 2008 HHS Guidelines to identify provisions in the NRC's regulations that may need to be revised. Two public meetings were held in 2009, on February 24 and June 24, with regulated entities, interest groups, and members of the general public to discuss the changes in the 2008 HHS Guidelines. In 2010, the NRC analyzed the DOT's final rule changes to 49 CFR part 40, "Procedures for Transportation Workplace Drug and Alcohol Testing Programs" (75 FR 49850;

August 16, 2010) to understand how another Federal agency that tests civilians implemented the 2008 HHS Guidelines. The NRC also analyzed lessons learned from implementation of the 2008 FFD final rule. Collectively, these efforts resulted in a list of potential changes to 10 CFR part 26 that the NRC presented, for feedback, at a third public meeting held on October 11, 2011. The NRC summarized public comments received at the October 11 meeting, as well as e-mailed comments received subsequent to the meeting, in a document titled "Comments for the October 11, 2011, Public Meeting" (included as Enclosure 3 in package available via ADAMS Accession No. ML112930153). A fourth meeting was held on September 11, 2013, to inform the public of the status of the rulemaking. Public meetings were attended by representatives of nuclear power plant licensees, the Nuclear Energy Institute, the Institute of Nuclear Power Operations, the International Brotherhood of Electrical Workers, and HHS.

Based upon feedback received during the four public meetings, some of the NRC-proposed revisions were removed from consideration because the NRC decided that it was not appropriate to pursue those particular issues in this rulemaking, while others were revised. The NRC-proposed revisions, along with associated issues raised by the public, are discussed in Section III.C of this document.

C. Description of Proposed Changes

This section includes a description of each proposed change, the rationale for each change, and a discussion of public comments that informed the NRC's development of the changes.

Definitions

During the October 11, 2011, public meeting, an industry participant requested that the NRC review the use of certain terms under 10 CFR part 26 for consistency with

the 2008 HHS Guidelines. The NRC performed a review and proposes to add seven new definitions and revise seven existing definitions under § 26.5, "Definitions." The revisions and additions would improve consistency with Section 1.5 of the 2008 HHS Guidelines and would improve the clarity, consistency, and accuracy of the requirements under 10 CFR part 26. Specifically, the following definitions would be added: *cancelled test*, *carryover*, *Certifying Scientist*, *Federal custody and control form*, *lot*, *rejected for testing,* and *Responsible Person*. The following definitions would be revised: *calibrator*, *control*, *dilute specimen*, *HHS-certified laboratory*, *invalid result*, *limit of quantitation*, and *substituted specimen*.

Cancelled test. The MRO will cancel the testing of a donor's urine specimen and report that action to the licensee or other entity after the testing laboratory (i.e., licensee testing facility (LTF) or HHS-certified laboratory) reports that the specimen was rejected for testing or the donor requested additional testing of a specimen at a second HHS-certified laboratory under § 26.165(b) and the specimen was not available for testing due to circumstances outside of the donor's control (e.g., specimen is lost in transit). Sections 26.129(b)(2) and 26.159(b)(2) describe the only circumstances requiring an MRO to "cancel the testing of a donor's urine specimen." However, §§ 26.129(b)(2) and 26.159(b)(2) do not use the term *cancelled test*, nor is the term defined under § 26.5. Adding the definition for *cancelled test* and updating §§ 26.129(b)(2) and 26.159(b)(2) to specifically use that term would clarify the actions taken by an MRO and improve consistency between 10 CFR part 26 and the 2008 HHS Guidelines. The NRC is also proposing to add the term *cancelled test* to § 26.165(f)(1) and (f)(2) to clarify the actions taken by an MRO when a specimen is rejected for testing by the laboratory and the MRO cancels the testing of the specimen. For completeness, a *cancelled test* for alcohol breath testing is also defined. The definition presented by the NRC staff at the October 11, 2011, public meeting only described cancelled test results associated with

urine testing. For alcohol testing only, *cancelled test* means a test result that was not acceptable because testing did not meet the quality assurance and quality control requirements in § 26.91.

Carryover. The proposed rule would add a definition for *carryover* to § 26.5. *Carryover* is the effect that occurs when a test result for a donor's specimen or quality control sample has been affected by a preceding specimen tested on the same analytical instrument. For example, if the concentration of a drug in one donor specimen was not completely eliminated from the analytical instrument before the next donor specimen is tested, the residual drug concentration in the instrument may contribute to a false positive test result for the next donor specimen tested. *Carryover* would also apply to donor specimens containing an adulterant or interfering substance. The term *carryover* is not currently defined under § 26.5. However, the term *carryover* is used in §§ 26.137(e)(7) and 26.167(a), which require LTFs and HHS-certified laboratories to ensure that *carryover* does not contaminate the testing of a donor's specimen or otherwise affect a donor's specimen results. In addition, § 26.91(c)(5) describes the requirement to ensure that *carryover* does not affect alcohol testing results when using evidential breath testing devices. The NRC's proposed definition is similar to the definition in Section 1.5 of the 2008 HHS Guidelines but does not include the phrase "(e.g., drug concentration)" because *carryover* applies also to validity testing (e.g., adulterants, interfering substances) and alcohol testing.

Certifying Scientist. The proposed rule would add a definition for *Certifying Scientist* to § 26.5. The position title is used in § 26.169(a) and (g) but is not currently defined. A *Certifying Scientist* would be defined as the individual at the HHS-certified laboratory responsible for verifying the chain of custody and scientific reliability of any test result reported by the HHS-certified laboratory. Adding this definition would improve consistency between 10 CFR part 26 and the 2008 HHS Guidelines. A conforming

change would be made to § 26.169(a) to capitalize the position title in the phrase "the laboratory's certifying scientist."

Federal custody and control form (Federal CCF). The proposed rule would add a definition for the term *Federal custody and control form (Federal CCF)* to § 26.5. The Federal CCF is defined as any HHS-approved form, which has not expired, that is published in the *Federal Register* and is used to document the collection, custody, transport, and testing of a specimen. Including this definition would align 10 CFR part 26 with Section 1.5 of the 2008 HHS Guidelines and improve the clarity of the rule by defining the term, which is already used in § 26.153(g). The proposed rule would revise the NRC's initial proposed definition of *Federal CCF*, based on feedback received during the October 11, 2011, public meeting. The definition that the NRC proposed at that meeting listed the specific name of the HHS-approved form used for urine drug testing (i.e., Federal Drug Testing Custody and Control Form) and closely paralleled the definition in Section 1.5 of the 2008 HHS Guidelines. However, based on comments received during the meeting, the NRC agrees that referencing the specific name on the form was too prescriptive and could require additional revision to 10 CFR part 26, should HHS revise the form name in the future. Therefore, the NRC is proposing to use the generic title, *Federal CCF,* to avoid the need for future regulatory changes, should the title of the form change. The definition may also provide flexibility in accounting for additional forms that SAMHSA may create for use when conducting drug and validity testing of alternative specimens (e.g., oral fluids, hair). To align with the new definition, "Federal custody-and-control form," which appears in § 26.153(g), would be replaced with the term "*Federal CCF*." In addition, to improve the consistency of terminology used throughout 10 CFR part 26, the NRC is also proposing to replace the term "custody and control form" with the term "*Federal CCF*." The plural versions, "custody and control forms" and "custody and control form(s)," would also be replaced with the terms "Federal

CCFs" and "Federal CCF(s)," respectively. Finally, the proposed rule would correct inconsistencies where "custody-and-control" form or forms were used incorrectly and instead should have referred to "chain of custody" form or forms.

The NRC's regulations under 10 CFR part 26 do not preclude the use of electronic versions of the Federal CCF or the use of licensee or other entity-developed forms, consistent with existing requirements in § 26.153(g). The NRC supports the use of technological advancements to improve the quality of information included on the Federal CCF (e.g., legibility, accuracy, and completeness of information); reduce undue delays and/or the canceling of specimen tests due to paperwork irregularities; facilitate timely transmission of information to and from collectors, laboratories, and responsible licensee representatives (e.g., the MRO); and reduce recordkeeping and reporting costs.

Lot. The proposed rule would add a definition for *lot* to § 26.5, representing units that have the same starting materials, performance characteristics, and expiration date. The term is used in 10 CFR part 26 but is not currently defined. Adding this definition would improve consistency between 10 CFR part 26 and the definition of *lot* in Section 1.5 of the 2008 HHS Guidelines. The proposed rule would use the same definition in the 2008 HHS Guidelines by defining *lot* as a number of units of an item manufactured from the same starting materials within a specified period of time for which the manufacturer states that the items have essentially the same performance characteristics and the same expiration date. The proposed rule also would include in the definition the parenthetical statement from the 2008 HHS Guidelines definition that provides examples of the term "item." The NRC would change one of the examples in the parenthetical statement by replacing "quality control material" with "quality control samples." The term "quality control material" has not been used in 10 CFR part 26.

Rejected for testing. The proposed rule would add to § 26.5 a definition for *rejected for testing* that is similar to the definition in Section 1.5 of the 2008 HHS

Guidelines, referring to a report by a licensee testing facility or HHS-certified laboratory that no tests can be performed on a specimen. The term *rejected for testing* appears in § 26.169(h)(8) but is not currently defined. Including a definition would clarify what information is being reported by the HHS-certified laboratory to the licensee or other entity in the annual quantitative summary of test results. In addition, defining the term would align with two additional proposed changes to §§ 26.129(b)(1)(ii) and 26.159(b)(1)(ii), clarifying the existing step that an LTF or HHS-certified laboratory would take, if a licensee or other entity had reason to question the integrity and identity of a specimen (i.e., reject the specimen for testing). In § 26.129(b)(1)(ii), the phrase "the specimen may not be tested" would be replaced with the phrase "the licensee testing facility shall reject the specimen for testing." In § 26.159(b)(1)(ii), the phrase "the specimens may not be tested" would be replaced with the phrase "the laboratory shall reject the specimens for testing." Improving the consistency of terminology used when a specimen cannot be tested improves the regulatory efficiency of 10 CFR part 26.

Responsible Person. The proposed rule would add a definition for *Responsible Person* to § 26.5. The position title is used in § 26.31(d)(1)(D) but is not currently defined. A *Responsible Person* would be defined as the person at the HHS-certified laboratory who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory. Adding this definition would improve consistency between 10 CFR part 26 and the 2008 HHS Guidelines. A conforming change would be made to § 26.167(f)(3) to capitalize the position title in the phrase "a statement by the laboratory's responsible person."

Calibrator. The proposed rule would revise the definition for *calibrator* in § 26.5 to more closely align with the definition in Section 1.5 of the 2008 HHS Guidelines and to also improve internal consistency of terminology used in 10 CFR part 26. The definition of *calibrator* would be revised to include a clarifying statement that a calibrator is a

solution of known concentration “in the appropriate matrix” that aligns with the definition in the 2008 HHS Guidelines. The phrase “test specimen/sample” would be replaced with the phrase “donor specimen or quality control sample” to improve consistency with the terminology used in 10 CFR part 26. The last sentence of the definition, which states that “calibrators may be used to establish a cutoff concentration and/or a calibration curve over a range of interest,” would be deleted. Although a part of this sentence aligns with the 2008 HHS Guidelines, the sentence is not a definition, but rather a voluntary provision that a laboratory may use a calibrator to establish a calibration curve. The determination of calibration curves is an internal laboratory process that already must be described in standard operating procedures for LTFs in § 26.127, “Procedures,” and is evaluated during NLCP inspection of HHS-certified laboratories.

Control. The proposed rule would revise the definition of *control* in § 26.5 to conform to the definition of the term in Section 1.5 of the 2008 HHS Guidelines. The term *control* in § 26.5 would be revised by replacing the phrase “a sample used to monitor the status of an analysis to maintain its performance within predefined limits” with the phrase “a sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.”

Dilute specimen. The proposed rule would revise the definition of *dilute specimen* in § 26.5 to conform to the definition of the term in Section 1.5 of the 2008 HHS Guidelines. The phrase “concentrations that are lower than expected for human urine” would be revised to read as “values that are lower than expected but are still within the physiologically producible ranges of human urine.” The current definition incorrectly references “concentrations” which does not apply to a specific gravity reading. The current definition also does not clearly state that creatinine and specific

gravity measurements in a dilute specimen are still within the range that could be produced by a human being.

HHS-certified laboratory. The current definition of an *HHS-certified laboratory* in § 26.5 lists the *Federal Register* citations for each final version of the HHS Guidelines (originally published in 1988, and amended in 1994, 1998, and 2004). Under this definition, an HHS-certified laboratory must meet the 2004 HHS Guidelines, which were published on April 13, 2004 (69 FR 19643). No laboratory performing testing for 10 CFR part 26 licensees or other entities currently meets this definition because the definition refers to the superseded 2004 HHS Guidelines; rather, HHS certifies laboratories to the HHS Guidelines that are in effect. The proposed rule would correct this restriction by defining an *HHS-certified laboratory* as a laboratory that is certified to meet the standards of the HHS Guidelines at the time that drug and validity testing of a specimen is performed for a licensee or other entity. Other requirements in 10 CFR part 26 already specify the drug testing panel and testing cutoff levels, validity testing requirements, and quality control requirements. The proposed change to the definition of *HHS-certified laboratory* would eliminate the need to revise 10 CFR part 26, should future versions of the HHS Guidelines be published. Two conforming changes would also be made, based on the revision to the definition of *HHS-certified laboratory*. The first change would revise §§ 26.4(j)(3) and 26.153(a) to reference "HHS-certified laboratories as defined in § 26.5." Section 26.153(a) would also be revised to remove the reference to the physical address of the Division of Workplace Programs as the location to obtain information concerning the certification status of laboratories.

Invalid result. The proposed rule would revise the definition of *invalid result* in § 26.5 to be consistent with the definition of the term in Section 1.5 of the 2008 HHS Guidelines and would also improve the clarity and accuracy of the 10 CFR part 26 rule. The phrase "for a specimen that contains an unidentified adulterant, contains an

unidentified interfering substance, has an abnormal physical characteristic, contains inconsistent physiological constituents, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result" would be replaced with "in accordance with the criteria established in § 26.161(f) when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test." The revised definition would also correct an inaccuracy in the current definition of *invalid result*, which does not include "specimen validity test."

Limit of Quantitation. The proposed rule would revise the definition for *Limit of Quantitation (LOQ)* in § 26.5 to more closely align with Section 1.5 of the 2008 HHS Guidelines. To align with the terminology used in 10 CFR part 26, the proposed definition would use "analyte" instead of the word "measurand."[3]

Substituted specimen. The proposed rule would revise the definition of *substituted specimen* in § 26.5 to align with the definition of the term in Section 1.5 of the 2008 HHS Guidelines. The phrase "specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human physiology" would be replaced with "a specimen that has been submitted in place of the donor's urine, as evidenced by creatinine and specific gravity values that are outside the physiologically producible ranges of human urine."[4] The revision would also improve the clarity of the rule by explaining that a substituted specimen is the result of donor action to subvert the testing process by stating that the specimen "has been submitted in place of the donor's urine."

[3] "Analyte" means the drug or drug metabolite measured by an initial or confirmatory drug test.
[4] "Creatinine" means a substance that is created in a human being as a result of muscle metabolism and is excreted in urine. The creatinine concentration of each urine specimen is measured by validity testing.

Drug Testing Panel Additions

The proposed rule would add two amphetamine-based chemical compounds: methylenedioxymethamphetamine (MDMA) and methylenedioxyamphetamine (MDA) to the NRC-required drug testing panel, consistent with the drug testing panel in Section 3.4 of the 2008 HHS Guidelines. The 2008 HHS Guidelines also added an additional amphetamine-based chemical compound, methylenedioxyethylamphetamine (MDEA); however, in its 2017 mandatory guidelines (82 FR 7920; January 23, 2017) HHS subsequently removed MDEA from its drug testing panel because HHS determined that the number of positive MDEA specimens reported from its certified laboratories does not support testing specimens for MDEA. MDMA (also known as Ecstasy or Molly) and MDA are listed in Schedule I of the Schedules of Controlled Substances (21 CFR 1308.11). A Schedule I drug or substance has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks an accepted safety for use of the drug or substance under medical supervision (21 U.S.C. § 812 (2012)). The proposed rule would revise §§ 26.31(d)(1) and 26.405(d) to identify MDMA and MDA as substances for which licensees and other entities are required to test; § 26.133, "Cutoff levels for drugs and drug metabolites," and § 26.163(a)(1) to require initial testing for MDMA and MDA; and § 26.163(b)(1) to require confirmatory testing for MDMA and MDA. By requiring licensees and other entities to test for additional substances, a greater range of drugs that impair human performance can be detected. Also, it would assist in the identification of those persons who, because they use illegal drugs, exhibit characteristics of not being trustworthy and reliable. The drugs MDMA and MDA would be added to the NRC-required drug testing panel because of their potential adverse effects on human performance, which were detailed by the HHS in the notice of proposed revisions to the HHS Guidelines, published in the *Federal Register* on April 13, 2004 (69 FR 19673).

The proposed rule would also expand the NRC-required drug testing panel to include initial testing for 6-AM, consistent with Section 3.4 of the 2008 HHS Guidelines. This change would improve the assurance that the testing method used under 10 CFR part 26 would identify an individual using heroin, a Schedule I drug. Currently, 10 CFR part 26 only permits the testing of a specimen for 6-AM when the specimen also tests positive for morphine (i.e., the morphine concentration is greater than the confirmatory testing cutoff level). The HHS implemented initial testing for 6-AM in the 2008 HHS Guidelines based on the analysis of laboratory testing data that demonstrated that 6-AM was detectable in the specimens of some individuals even when the specimens tested negative for morphine.

Revised Initial Drug Testing Cutoff Levels

The 2008 HHS Guidelines established the scientific and technical bases for lowering the initial drug testing cutoff levels for amphetamines and cocaine metabolites. The proposed rule would update the substances and cutoff levels for initial drug testing, as listed in the tables in §§ 26.133 and 26.163(a)(1), to conform with Section 3.4 of the 2008 HHS Guidelines. Specifically, the proposed rule would make the following changes in each table: 1) lower the initial test cutoff level for amphetamines (abbreviated in the tables as AMP), 2) lower the initial test cutoff level for cocaine metabolites, 3) clarify the existing testing requirement for “opiate metabolites” by replacing the term with “codeine/morphine,” 4) include a new footnote 1 to each table to clarify that the target analyte for “codeine/morphine” testing is morphine, 5) clarify in a new footnote 2 to each table that either a single or multiple initial test kit(s) may be used for amphetamines testing, and 6) include a new footnote 3 in each table to clarify that methamphetamine (abbreviated in the tables as MAMP) is the target analyte for amphetamines and methamphetamine testing. The column header “Drug or

metabolites" in the tables in §§ 26.133 and 26.163(b)(1) would also be revised to "Drugs or drug metabolites" to align with the table titles.

Lowering the cutoff levels for these existing drugs and drug metabolites in the NRC-required testing panel would increase the timeframe (i.e., the window of detection) in which these drugs can be detected in an individual's urine after use and may also lead to improved deterrence. Increasing the window of detection for these substances would provide a higher degree of assurance that persons who are using illegal drugs or misusing legal drugs would be identified. The NRC anticipates that the proposed lower testing cutoff levels would increase the number of urine specimens identified as containing amphetamine, cocaine metabolite, and methamphetamine. These anticipated outcomes are based on increases in detection reported by Federal employee workplace drug testing programs and the DOT testing program subsequent to implementing the lower testing cutoff levels in the 2008 HHS Guidelines, as discussed in the regulatory basis and the regulatory analysis for this proposed rule.

In addition, the proposed rule would revise §§ 26.133 and 26.163(a)(1) to clarify that the specified testing cutoff levels are used by an LTF or an HHS-certified laboratory to determine whether a specimen is either "negative" or "positive" for each drug or drug metabolite being tested. This change better aligns 10 CFR part 26 with Section 11.19(b) and (c) of the 2008 HHS Guidelines, which require the HHS-certified laboratory to make a determination that each specimen is either "negative" or "positive," respectively, for each drug and drug metabolite tested.

Revised Confirmatory Drug Testing Cutoff Levels

The 2008 HHS Guidelines established the scientific and technical bases to justify lowering the confirmatory drug testing cutoff levels for amphetamine, cocaine metabolite, and methamphetamine and expanding the testing panel to include confirmatory drug

testing for the Ecstasy drugs MDMA and MDA. The NRC proposes to expand the number of substances in the NRC-required testing panel and to lower the cutoff levels for confirmatory drug tests, as listed in the table in § 26.163(b)(1), to align with Section 3.4 of the 2008 HHS Guidelines. Specifically, the proposed rule would make the following changes: 1) lower the confirmatory test cutoff level for amphetamine from 500 ng/mL[5] to 250 ng/mL; 2) lower the confirmatory test cutoff level for cocaine metabolite from 150 ng/mL to 100 ng/mL; 3) lower the confirmatory test cutoff level for methamphetamine from 500 ng/mL to 250 ng/mL; 4) eliminate table footnote 3, which specified the requirement that confirmatory testing of 6-AM only proceed when confirmatory testing shows a morphine concentration exceeding 2000 ng/mL; 5) redesignate table footnote 4 as footnote 3 and update the text to lower the amphetamine concentration from 200 ng/mL to 100 ng/mL that must also be present in a specimen to be positive for methamphetamine; and 6) include confirmatory testing for MDMA and MDA at a cutoff level of 250 ng/mL. Similar to the changes made to the initial testing cutoff levels, lowering the confirmatory testing cutoff levels for amphetamine, cocaine metabolite, and methamphetamine would increase the timeframe in which these drugs can be detected in an individual's urine after use and may also add to the deterrent effect of the rule. In addition, the proposed rule would make two clarifying changes to the table in § 26.163(b)(1) by revising the term "Opiates" to "Opiate metabolites" and adding the abbreviation "(6-AM)" after 6-acetylmorphine. Finally, the column header "Drug or metabolites" in the table in § 26.163(b)(1) would be revised to "Drugs or drug metabolites" to align with the table title. These changes would improve consistency with Section 3.4 of the 2008 HHS Guidelines and with the proposed revisions to §§ 26.133 and 26.163(a)(1).

[5] The unit ng/mL is nanograms per milliliter or a millionth of a gram per liter.

The proposed rule would update the information that each HHS-certified laboratory must include in the annual statistical summary report of test results provided to each licensee or other entity under § 26.169(h)(3) to reflect the expanded drug testing panel in revised §§ 26.31(d)(1) and 26.405. Specifically, the proposed rule would require each HHS-certified laboratory to include, in the annual statistical summary of urinalysis testing provided to each licensee and other entity, the number of specimens reported as positive for MDMA and MDA. Additional conforming changes would improve the clarity and uniformity of the names of the drugs and drug metabolites listed in § 26.169(h)(3), to include adding "(as THCA)"[6] after "Marijuana metabolites," adding "(as benzoylecgonine)" after "Cocaine metabolite," revising "6-AM" to "6-acetylemorphine (6-AM)," and revising "Phencyclidine" to "Phencyclidine (PCP)."

Validity Testing of Adulterants at HHS-Certified Laboratories

The proposed rule would revise the decision point used in the validity tests performed by HHS-certified laboratories, as described in § 26.161(c)(3) through (c)(6) and § 26.161(f)(5) and (f)(7), by replacing the limit of detection (LOD) with the limit of quantitation (LOQ) as the decision point for determining if a specimen contains an adulterant (i.e., adulterated test result) or the possible presence of an adulterant (i.e., invalid test result). The difference between the LOD and the LOQ for a testing assay is the ability to reliably quantify the analyte. At the LOD, the validity test must meet all HHS-certified laboratory criteria for result acceptance, except quantitation. At the LOQ, the validity test must reliably confirm the presence of the analyte, reliably quantify the concentration of the analyte, and meet all HHS-certified laboratory criteria for result

[6] THCA is an abbreviation for delta-9-tetrahydrocannabinol-9-carboxylic acid.

acceptance. Use of the LOQ provides an additional donor protection on the accuracy of validity testing (i.e., in making the conclusion that results are adulterated or invalid).

The proposed changes to § 26.161(c)(3) through (c)(6) are consistent with Section 3.5 of the 2008 HHS Guidelines, which describes the validity testing criteria for the adulterants chromium (VI), halogens (e.g., bleach, iodine, fluoride), glutaraldehyde, and pyridine (pyridinium chlorochromate). The proposed changes to § 26.161(f)(5) and (f)(7) are consistent with the validity testing criteria in Section 3.8 of the 2008 HHS Guidelines for the same adulterants described in the previous sentence but as applied to invalid results.

The NRC is not proposing to change the initial validity testing requirement in § 26.131(b)(5) that applies to LTF testing for the possible presence of halogen. Section 26.131(b)(5) currently permits an LTF to use a "halogen colorimetric test (halogen concentration equal to or greater than the limit of detection (LOD))." The NRC is not proposing to change the use of LOD in this instance, because LTFs already must send any specimen identified with the possible presence of an adulterant to an HHS-certified laboratory for initial and confirmatory validity testing, where the LOQ of the test would be utilized.

The proposed rule would also revise § 26.161(c)(5) and (c)(6) to permit HHS-certified laboratories to conduct confirmatory validity testing for the adulterants glutaraldehyde and pyridinium chlorochromate using "a different confirmatory method (e.g., gas chromatography/mass spectrometry (GC/MS))" instead of what is currently required, which is only "GC/MS for the confirmatory test." The proposed changes would provide additional flexibility in the confirmatory testing methods that may be used by the laboratory and would align with similar testing requirements in § 26.167(e)(1), the current version of § 26.153(c) as described in the Statement of Considerations for the 2008 FFD

final rule (73 FR 17091 and 17102; March 31, 2008), and Section 11.19(d) of the 2008 HHS Guidelines.

Special Analyses Testing of Urine Specimens

Special analyses testing is an NRC testing methodology introduced in the 2008 FFD final rule to address the circumstance where a donor consumes a large quantity of fluid just prior to providing a urine specimen for testing in the hope of diluting the concentration of any drugs and drug metabolites in the specimen below the standard testing cutoff levels to avoid detection (i.e., to produce a negative drug test result). This testing methodology is not included in the HHS Guidelines but provides licensees and other entities with an added level of assurance that an individual with a dilute specimen is not attempting to hide drug use. Section 26.163(a)(2) currently provides each licensee and other entity with the option to require the HHS-certified laboratory to conduct special analyses of dilute specimens (i.e., conduct confirmatory testing to the LOD for drugs and drug metabolites when the immunoassay response of the initial drug test is equal to or greater than 50 percent of the cutoff calibrator). For example, if a specimen is dilute and the initial test for marijuana metabolites measured a concentration of 25 ng/mL (the initial cutoff level for marijuana metabolites is 50 ng/mL), special analyses testing would then be performed on the specimen. Using a lower cutoff level for the testing of dilute specimens enhances the ability of licensees and other entities to identify drug-using individuals attempting to avoid detection through the consumption of large quantities of fluid just prior to providing a specimen for testing. The proposed rule would make four changes to the special analyses testing requirements in § 26.163(a)(2).

First, the proposed rule would require all licensees and other entities to conduct special analyses testing of dilute specimens. An analysis of the NRC's FFD program

performance reports for calendar years 2011 through 2014 demonstrates the effectiveness of special analyses testing because these data show that additional positive results were identified for pre-access, random, and post-event special analyses tests. As of 2014, 92 percent of licensees and other entities have adopted the special analyses testing policy. The proposed rule would eliminate references to the option for licensees and other entities to conduct special analyses testing of specimens with dilute validity test results that appear in §§ 26.31(d)(1)(ii); 26.163(a)(1) and (b)(1); 26.183(c), (c)(1), and (d)(2)(ii); and 26.185(g)(2) and (g)(3). These tests would instead be required.

Second, the proposed rule would lower the immunoassay percentage response for initial testing in § 26.163(a)(2)(ii) that HHS-certified laboratories must use to determine if special analyses testing is to be conducted. The proposed rule would lower the immunoassay response from "equal to or greater than 50 percent of the cutoff calibrator" to "equal to or greater than 40 percent of the cutoff calibrator." Use of a lower cutoff level to evaluate the immunoassay response could increase the number of specimens subject to special analyses testing and would improve the ability of licensees and other entities to identify drug-using individuals attempting to subvert the drug testing process. This change would not affect the drug testing assays used by HHS-certified laboratories because under the 2008 HHS Guidelines, each laboratory must already validate the accuracy of each assay to 40 percent of the cutoff calibrator. Laboratories would need to change their administrative procedures to define the initial test result concentration that would trigger special analyses testing.

Third, the proposed rule would replace the LOD with the LOQ as the confirmatory drug testing cutoff level to be used by HHS-certified laboratories when conducting special analyses testing. Currently, § 26.163(a)(2)(ii) requires the use of the LOD as the cutoff level for special analyses testing of dilute specimens. The difference between the LOD and the LOQ for a drug testing assay is the ability to reliably quantify the analyte.

At the LOD, the confirmatory drug test must meet all HHS-certified laboratory criteria for result acceptance except quantitation. At the LOQ, the confirmatory drug test must reliably confirm the presence of the analyte, reliably quantify the concentration of the analyte, and meet all HHS-certified laboratory criteria for result acceptance. The LOQ provides an additional donor protection on the accuracy of special analyses test results. To receive and maintain laboratory certification by the NLCP, HHS-certified laboratories must already determine both the LOD and LOQ for each drug testing assay. Therefore, changing the decision point from the LOD to the LOQ for reporting confirmatory drug test results would not require laboratories to change the testing assays used.

The NLCP also requires all HHS-certified laboratories to validate the accuracy and precision of each confirmatory drug test at or below 40 percent of the cutoff. To meet this testing specification, the laboratory must establish both the LOD and the LOQ below the 40 percent cutoff, which results in variability amongst laboratories on how far below the 40 percent cutoff the LOD and LOQ are established. This is dependent, in part, on the instrumentation and testing processes used at the laboratory. The NRC acknowledges this variability. Some attendees at the public meetings requested a standardized level be used across all laboratories performing special analyses testing. However, this position would be contrary to the 10 CFR part 26 regulatory framework that enables licensees and other entities to use lower cutoff levels in the testing for drugs and drug metabolites, as permitted under § 26.31(d)(3)(iii).

Fourth, the proposed rule would expand the special analyses testing requirement in § 26.163(a)(2)(i) to include the testing of some specimens collected under direct observation. Section 26.115(a) describes the exclusive grounds for performing a directly observed collection. Under the current rule, a directly observed collection may be performed when sufficient information has been obtained during the collection process or in the testing of a previous specimen to indicate a possible subversion attempt by the

donor or when an individual has a confirmed positive drug test result on a prior occasion. As such, a directly observed collection after either of these circumstances provides additional assurance that the subsequent specimen obtained for testing came directly from the donor's body and was not altered to avoid detection of drug use. Likewise, special analyses testing would provide additional assurance that drugs and drug metabolites present in the specimen collected under direct observation from a donor would be identified, which would improve the MRO's ability to determine whether a subversion attempt was made on the initial specimen collected from the donor. For example, an initial unobserved specimen provided by a donor is determined by the collector to be out of the acceptable temperature range specified in § 26.111(a) and tests negative for drugs, and the second specimen collected under direct observation from the donor tests positive for a drug. In this example, the differences in test results from the initial and second specimen collected provides conclusive evidence to the MRO to make a subversion determination on the initial specimen provided. Therefore, the proposed rule would revise § 26.163(a)(2)(i) to require that special analyses testing be performed on specimens collected under § 26.115(a)(1) through (a)(3), and (a)(5).

Section 26.115(a)(1) describes the situation where a donor has presented a specimen that has been reported by an HHS-certified laboratory as adulterated, substituted, or invalid, and the MRO determines that no adequate medical explanation exists for the result and that another specimen should be collected from the donor. An analysis of the NRC's FFD program performance reports for calendar years 2011 through 2014 identified subversion attempts where the HHS-certified laboratory reported an invalid test result for the initial specimen provided by the donor and either the donor refused to provide a second specimen under direct observation or the second specimen collected under direct observation tested positive for a drug. Use of special analyses testing on the second specimen collected would provide additional assurance that drug

use would be detected because a period of days would lapse from the point of collection of the initial specimen, testing of that specimen at a laboratory, MRO review of the test results and discussion with the donor, MRO determination that a second specimen should be collected, and the donor appearance at a collection site to provide a second specimen under direct observation.

Section 26.115(a)(2) describes the situation where a donor provides a specimen that falls out of the acceptable temperature range specified in § 26.111(a). Section 26.115(a)(3) describes the situation where donor conduct during the collection process indicates an attempt to dilute, substitute, or adulterate the specimen. An analysis of the NRC's FFD program performance reports for calendar years 2011 through 2014 demonstrates that the majority of subversion attempts are identified based on information obtained during the specimen collection process by the collector (e.g., specimen temperature) and the collection of a second specimen from the donor under direct observation. Use of special analyses testing in these two instances would provide additional assurance that drug use would be detected in the second specimen collected under direct observation because the information from the initial collection process indicated a possible subversion attempt.

Section 26.115(a)(5) addresses the situation where the MRO verifies that a specimen is positive, adulterated, or substituted; the donor requests that a retest of the specimen be performed at a second HHS-certified laboratory; but the specimen is not available for testing. As a result, the confirmed test result from the initial testing laboratory must be cancelled by the MRO because the donor was not afforded the opportunity to verify the test results through additional testing at a second HHS-certified laboratory. Use of special analyses testing in this instance would provide additional assurance for the same reason described for specimens collected under § 26.115(a)(1).

The proposed change to require special analyses testing of specimens collected under direct observation would require licensees and other entities to establish an approach for the licensee or other entity to use when notifying a laboratory that special analyses testing is required for a specimen.

Alternative Specimen Collection Sites

Sections 26.4(e)(6)(iv) and 26.31(b)(2) include the statement that ‘‘licensees and other entities may rely on a local hospital or other organization that meets the requirements of 49 CFR Part 40, ‘Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs’ (65 FR 41944; August 9, 2001).” Section 26.415(c) also includes a statement that licensees and other entities need not audit “the specimen collection and alcohol testing services that meet the requirements of 49 CFR Part 40, ‘Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs’ (65 FR 41944; August 9, 2001).” The proposed rule would eliminate the *Federal Register* citation from each part 26 section because the DOT final rule found on page 41944 in the August 9, 2001, edition of the *Federal Register* no longer represents the current version of 49 CFR part 40. The intent of these provisions was to provide licensees and other entities with flexibility to utilize collection sites that meet the DOT specimen collection requirements in 49 CFR part 40. Listing the specific *Federal Register* notice of the applicable DOT final rule is not necessary because the existing requirements in §§ 26.4(e)(6)(iv), 26.31(b)(2), 26.405(e), and 26.415(c) already specify that the local hospital or other organization must meet the requirements in 49 CFR part 40.

Specimen Collection Procedures

The proposed rule would make a number of revisions to the specimen collection procedures in 10 CFR part 26: 1) clarify and enhance the instructions on conducting an observed collection, 2) permit the use of mirrors to assist in performing directly observed collections, 3) allow FFD program personnel to observe a donor who is in the hydration process following the donor's inability to provide a specimen of adequate volume, and 4) clarify urine specimen quantity and acceptability provisions. The revisions would improve the clarity, consistency, and flexibility of the collection procedures and to align more closely with the 2008 HHS Guidelines.

Section 26.115(e), (f), and (f)(1) through (f)(3) would be revised to improve the clarity of instruction on conducting a directly observed specimen collection, which would improve consistency with Sections 4.4(a) and 8.9 of the 2008 HHS Guidelines.

The proposed rule would remove the first sentence in § 26.115(f), which states, "If someone other than the collector is to observe the collection, the collector shall instruct the observer to follow the procedures in this paragraph." The NRC proposes to add the following sentence to the end of the existing requirements in § 26.115(e): "If the observer is not a trained collector, the collector shall, in the presence of the donor, instruct the observer on the collection procedures in paragraph (f) of this section." The proposed change would improve the clarity of the existing requirements and ensure that the donor is informed that an individual other than the collector is to observe the specimen provision and understands the procedures that must be followed to complete the specimen collection. The proposed change also incorporates feedback received at the October 11, 2011, public meeting, at which a participant suggested using the phrase "who has received instruction" instead of the phrase "who has received training," when referring to the information that is provided to a same-gender observer by the collector. "Training" implies a formal process rather than providing oral or written instructions. The

NRC agrees that the commenter's proposed wording conveys a more accurate description of how the collector would convey the information regarding specimen collection to a same-gender observer. The collector would only be required to give the same-gender observer instructions, rather than formal training.

In § 26.115(f)(2), the proposed rule would add the parenthetical statement "(a mirror may be used to assist in observing the provision of the specimen only if the physical configuration of the room, stall, or private area is not sufficient to meet this direct observation requirement; the use of a video camera to assist in the observation process is not permitted)" to the end of the existing requirement. This proposed change also incorporates stakeholder feedback at the public meeting on October 11, 2011, at which the NRC proposed to prohibit the use of mirrors and video cameras to aid an observer in conducting a directly observed specimen collection, to align with Section 8.9(b) of the 2008 HHS Guidelines. Several industry participants commented that mirrors are currently used at some collection facilities, where the configuration of the stall does not provide adequate space for the collector to directly observe the provision of a specimen from the donor's body into the specimen container. These participants suggested that if the NRC prohibited the use of a mirror to aid in the direct observation process, physical configuration changes at some collection sites would be needed.

Based on subsequent licensee and NRC inspector feedback, the NRC has concluded that the observed collection process in § 26.115(f)(1) continues to ensure that subversion paraphernalia would be identified prior to the provision of a specimen during the observed collection process and that the use of reflective mirrors, not two-way mirrors, would be acceptable. As required by § 26.115(f)(1), prior to conducting the directly observed collection, the donor already must adjust his or her clothing to expose the area between his or her waist and knees. This step ensures that no materials to subvert the testing process (e.g., a prosthetic device, a container of synthetic urine, an

ampule of an oxidizing chemical, or other subversion paraphernalia) are concealed on the donor's body and could be used during the specimen collection. Subsequent to this step, the observer would then watch urine flow from the donor's body into the collection cup. To accomplish this, the collector (or same-gender observer) must be in close proximity (in the stall or room where the specimen is provided) to meet this observation requirement. The use of a reflective mirror only aids in this assurance by preventing the donor's body or the configuration of the stall or room from obstructing the collector's view of urine flowing from the donor's body directly into the specimen collection container. By observing the area where the urine leaves the body, the direct observation process ensures that the specimen provided is from the donor and ensures the integrity of the specimen collection process. As a result, the NRC is proposing to revise § 26.115(f)(2) to permit the use of reflective mirrors.

The NRC also proposes to revise § 26.115(f)(2) to prohibit the use of video cameras to assist in visualizing the provision of a specimen under direct observation. The NRC does not consider a video camera to be an acceptable means of providing direct observation, in part, because the conversion of visible light to an electronic format, through a video camera, is not a direct observation. The use of a video camera for direct observation would be inconsistent with the intent of the rule because the collector or observer would not be in the room or stall with the donor. Further, a video feed is an incomplete source of information because it may not detail the physiological characteristics associated with a subversion attempt and also cannot guarantee the privacy of the donor beyond the individual conducting the observation.

During the public meeting on October 11, 2011, one participant requested that the NRC consider eliminating the requirement in § 26.115(f)(1) that the donor adjust his or her clothing during the observed collection process to expose the area of the donor's body from the waist to the knees. The NRC considered this request but is not proposing

to eliminate this provision for three reasons. First, the purpose of directly observing the provision of a specimen is to ensure that the drug testing process is not being subverted. The NRC's collection procedure requires the donor to remove his or her clothing between the waist and knees so that the collector can identify any paraphernalia on the individual's body that may be used to subvert the testing process, such as a prosthetic device, a container of synthetic urine, or ampule of an oxidizing chemical. Second, materials used to subvert a drug test are easily available for purchase, and licensees and other entities have reported in annual performance reports required by § 26.717 that subversion attempts have been identified during the directly observed collection process. Finally, the prevalence of subversion attempts demonstrates that individuals are actively attempting to thwart the drug testing process by specimen adulteration, substitution, and dilution.

In § 26.115(f)(3), the proposed rule would replace the phrase "If the observer is not the collector, the observer may not take the collection container from the donor, but shall observe the specimen as the donor takes it to the collector," with the phrase "If the observer is not the collector, the observer may not touch or handle the collection container but shall maintain visual contact with the specimen until the donor hands the collection container to the collector." The proposed rule changes would improve the clarity of the existing requirement by more closely aligning with Sections 8.9(c) and (d)(2) of the 2008 HHS Guidelines and by using terminology consistent with § 26.113(b)(3).

The proposed rule would add § 26.4(g)(6) and would revise § 26.109(b)(1) to improve the efficiency of FFD programs by providing licensees and other entities with additional flexibility in the personnel who may monitor a donor during the hydration process, which is the 3-hour period of time that is initiated after a donor is unable to provide an acceptable quantity of urine during the initial specimen collection attempt,

during which fluid is provided to assist the donor in providing a specimen of adequate volume. In addition to the specimen collector that initiated the specimen collection process with the donor, a staff member designated as FFD program personnel in § 26.4(g) would be allowed to monitor the donor during the hydration process in place of the original collector. All FFD program personnel must meet honesty and integrity requirements in § 26.31(b) and have familiarity with the collection facility, specimen collectors, and 10 CFR part 26 requirements sufficient to monitor the donor during the hydration process. The additional flexibility of collection monitoring provided by the rule change would enable the collector, who initiated the collection process with a donor, to complete additional specimen collections with other donors while the initial donor hydrates. Another specimen collector, who meets the requirements in § 26.85(a), could also monitor the donor in the hydration process. The proposed change could reduce the regulatory burden on FFD programs by affording licensees and other entities additional staffing options to better manage the collection process, while maintaining appropriate oversight of the collection process. If a hydration monitor or another collector is used, the original collector would be required to note the name of the individual on the Federal CCF and the hydration monitor or second collector then would maintain control of the Federal CCF during the observation process (e.g., to document the time and volume of fluid provided to the donor, to note any unusual donor behavior, and to verify that the donor is provided with 3 hours to provide a specimen). In addition, to improve the clarity of § 26.109, the NRC is also proposing that the last sentence of § 26.109(b)(1), “The collector shall provide the donor with a separate collection container for each successive specimen,” would become the new first sentence of § 26.109(b)(2). Section 26.109(b)(1) describes the procedures for providing fluid to a donor who is in the hydration process and includes the instruction to the collector to provide a separate collection container for each successive specimen provided by the donor. The

instruction to provide a separate collection container for each specimen is more appropriate in § 26.109(b)(2), which describes the provision of subsequent specimens once a donor is in the hydration process.

The proposed rule would revise § 26.89(d) in three ways. First, § 26.89(d) would be revised to clarify that a collector shall conduct only one collection procedure at any given time, except in the instance when another collector who meets the requirements in § 26.85(a) or a hydration monitor is observing the donor during the hydration process, as permitted by the proposed change to § 26.109(b)(1). Second, § 26.89(d) would be revised to more precisely describe the actions taken by the collector when sealing the collection container with tamper-evident tape and completing the Federal CCF to end the collection process. The phrase "the urine specimen container has been sealed and initialed, the chain of custody form has been executed, and the donor has departed the collection site" would be replaced with the phrase "the urine specimen container has been sealed with tamper-evident tape, the seal has been dated and initialed, and the Federal CCF has been completed." Third, the phrase "or when a refusal to test has been determined under § 26.107(d)" would be added to § 26.89(d) to more accurately describe when the collection process has been completed if a refusal to test has been determined. The three changes would improve the clarity of the existing collection requirements, correct an editorial error in the name of the form that is used to document the specimen collection, and include a reference to a refusal to test as another circumstance when the collection process is complete.

The proposed rule would revise § 26.107, "Collecting a urine specimen," in four ways related to how the donor is observed. First, the proposed rule would redesignate paragraph (b) as paragraph (b)(1) of this section. Second, the phrase ", except as provided in § 26.109(b)(1)," would be added in the first sentence after "The collector shall pay careful attention to the donor during the entire collection process." This

revision is necessary because of the proposed rule change to permit an individual other than the original specimen collector to monitor a donor in the hydration process; as a result, the original collector may not be present with the donor during the entire collection process. Third, § 26.107(b)(1) would be revised to replace the phrase "to note any conduct that clearly indicates an attempt to tamper with a specimen (e.g., substitute urine is in plain view or an attempt to bring an adulterant or urine substitute into the private area used for urination)" with the phrase "to observe any conduct that indicates an attempt to subvert the testing process (e.g., tampering with a specimen; having a substitute urine in plain view; attempting to bring an adulterant, urine substitute, temperature measurement device, and/or heating element into the room, stall, or private area used for urination)." The proposed changes would provide additional examples of subversion attempt actions that have been reported by licensees and other entities in the annual information reports required by § 26.719, "Reporting requirements." More accurate examples of subversion attempts in the regulatory text provide additional clarity on donor actions that may be considered a subversion attempt. Lastly, the phrase "the collector shall document the conduct" in proposed § 26.107(b)(1) would be revised to "the collector shall document a description of the conduct," which would improve the clarity of the existing regulatory requirement.

Section 26.107(b)(2) would be added to ensure that if a hydration monitor is used to observe a donor during the § 26.109(b) hydration process, this individual would immediately inform the collector of any donor conduct that may indicate an attempt to subvert the testing process, such as the donor leaving the collection site or refusing to follow directions. This rule change would be necessary because the collector must be informed of any unacceptable donor behavior so that appropriate action may be taken.

The proposed rule would revise § 26.89(c) to correct an editorial error in the instructions that a collector must provide to the donor regarding refusing to cooperate

with the testing process. Currently, the word “adulterated” is used twice in the phrase “adulterated, diluted, or adulterated the specimen,” which describes the situation where a donor admits to subverting the testing process. The phrase would be revised to “adulterated, diluted, or substituted the specimen.”

The proposed rule would revise § 26.117, “Preparing urine specimens for storage and shipping,” in three ways. First, the proposed rule would revise § 26.117(a) to add the phrase “Once the collector is presented with the specimen from the donor” at the beginning of the first sentence to clarify when the collector would begin to keep the donor’s “urine specimen(s) in view at all times.” This revision would improve the clarity of an existing activity in the collection process. For example, the collector would not be able to keep the donor’s urine specimen in view at all times when the donor is in the room, stall, or private area used for urination, as described in § 26.107(a). Second, two editorial errors would also be corrected in § 26.117(f): the term “chain-of-custody forms” would be replaced with the term “Federal CCFs” and the phrase “or the licensee’s testing facility” would be replaced with the phrase “or to the licensee testing facility.” Third, the proposed rule would revise § 26.117(g) to add the phrase “except as provided in § 26.109(b)(1)(ii), for the Federal CCF,” to describe an instance when the custody documents would not be under the control of the collector. This change is needed because the proposed rule change to § 26.109(b)(1)(ii) would permit another collector or hydration monitor to observe the donor during the hydration process and to maintain the Federal CCF during that time period.

With regard to urine specimen acceptability, the proposed rule would revise the term “altered,” as used in § 26.111(a) and (c), to clarify that the term means that the collector has determined that a specimen may have been adulterated and/or diluted. This determination by a collector is not equivalent to the determination that a specimen

is an *adulterated specimen* as defined in § 26.5, which is a specimen testing determination made by an HHS-certified laboratory.

The proposed rule would correct an editorial error in § 26.111(a) associated with the minimum volume requirement for a urine specimen. Specifically, the phrase "but greater than 15 mL" would be replaced with "but equal to or greater than 15 mL." This change conforms with the existing minimum specimen volume requirements in §§ 26.109(b)(4) and 26.111(b) and (d).

Collector Actions Following a Refusal to Test

The proposed rule would add § 26.107(d) and revise §§ 26.111(c) and (e) and 26.115(g) to more explicitly describe the actions that a collector must take when a refusal to test is determined during the specimen collection process, including the retention or disposal of any specimen(s) provided by the donor.

Section 26.107(d) would be added to state that if the collector determines a refusal to test during the specimen collection process, the collector shall do the following: 1) inform the donor that a refusal to test has been determined; 2) terminate the collection process; 3) document a description of the refusal to test on the Federal CCF; 4) discard any urine specimen(s) provided by the donor, unless provided for a post-event test in § 26.31(c)(3); and 5) immediately inform the FFD program manager of the refusal to test. The majority of these proposed changes are consistent with existing collector practice. However, the proposed change to discard any urine specimens, except if collected for a post-event test, would be a new requirement to improve the uniformity of licensee and other entity actions taken once a refusal to test had been determined. The NRC is aware of instances in which a licensee or other entity would conduct specimen testing, even though a refusal to test had already been determined at the collection site. This change would address this inconsistency. The proposed

revisions to § 26.107(d) would help ensure that if a donor refuses to cooperate with the collection process, uniform action is taken, which would make 10 CFR part 26 consistent with Section 8.12 of the 2008 HHS Guidelines and improve its effectiveness.

The proposed change to retain and test any specimen collected for a post-event test in § 26.31(c)(3) would help to inform licensee root cause determinations, as required by other parts of the NRC's regulations, such as §§ 20.2203(b), 50.73(b), and 70.50(c). Although a refusal to test determination at the collection site subsequent to a specimen being provided for a post-event test is a very rare occurrence, a regulatory framework is needed to enable the testing of an individual's urine (or other specimen matrix such as oral fluid) to assist in determining whether the individual who committed or contributed to the event may have been impaired from the use of alcohol, an illegal drug, or prescription or over-the-counter medication. This assessment (which is informed by the requirements in §§ 26.185, "Determining a fitness-for-duty policy violation" and 26.189, "Determination of fitness") is very important because post-event testing is conducted, in part, in response to the occurrence of a very significant event such as, but not limited to: 1) a death, 2) a significant illness or personal injury, 3) a radiation exposure or release of radioactivity in excess of regulatory limits, or 4) an actual or potential substantial degradation of the level of safety of the plant.

Section 26.111(c) would be revised to remove the word "designated" from the phrase "designated FFD program manager." This proposed change conforms with the existing terminology used in §§ 26.105(b), 26.109(b)(3), 26.111(c), 26.115(a), (b), and (h), and 26.139(b).

Section 26.111(e) specifies that "as much of the suspect specimen as possible must be preserved." The proposed rule would add the clarifying phrase "except under the conditions described in § 26.107(d)(4)" to reference the conditions when a collector

is to discard any urine specimen(s) collected. This change aligns with the proposed changes to § 26.107(d).

Some participants at the public meeting on October 11, 2011, requested that the NRC consider eliminating § 26.111(f) because they believe this particular requirement is unnecessary. Section 26.111(f) defines the criteria for an acceptable urine specimen as free from apparent contaminants, of at least 30 mL in quantity, and within the acceptable temperature range. However, this requirement does not aid in the implementation of 10 CFR part 26 and is not used in the NRC's drug testing requirements. The participants stated that this provision is unnecessary because other sections in 10 CFR part 26 require specimens that do not meet the criteria in § 26.111(f) to be sent to an HHS-certified laboratory for testing. The NRC agrees that this requirement is unnecessary because other sections in the rule already provide explicit detail as to the determination of whether a specimen is valid or invalid, as well as the specific steps required if either determination is made. Section 26.109, "Urine specimen quantity," contains provisions regarding urine specimen quantity; § 26.111(a) contains provisions regarding specimen temperature; and § 26.111(d) requires that any specimen a collector suspects has been adulterated, diluted, substituted, or that is collected under direct observation must be sent to an HHS-certified laboratory for initial and, if necessary, confirmatory testing. Therefore, the NRC is proposing to remove § 26.111(f) to improve the clarity of 10 CFR part 26.

Section 26.115(g) states that a donor declining to allow a directly observed collection is an act to subvert the testing process. The proposed rule would include a new requirement that in this instance "the collector shall follow the procedures in § 26.107(d)." This proposed requirement describes the actions that the collector must take when a refusal to test has been determined during the specimen collection process.

The NRC also received a public comment regarding the retention or disposal of a urine specimen. The commenter recommended that the initially collected specimen be retained, unless the MRO or FFD program manager determined that a directly observed collection was necessary and the donor refused to comply, which the NRC interpreted as a reference to § 26.111(c) of the regulations. Section 26.111(c) requires the collector to contact the FFD program manager if there is reason to believe that a donor may have attempted to adulterate, dilute, or substitute a specimen based on the physical characteristics of a specimen (e.g., temperature, color, odor, presence of a precipitant) or other observations made during the collection. The FFD program manager may consult with the MRO to determine if the donor has attempted to subvert the testing process, and the FFD program manager or the MRO may require the donor to provide a second specimen, as soon as possible, and under direct observation. This section also requires the collector to inform the donor that he or she may volunteer to submit a second specimen under direct observation. The NRC has determined that there is no regulatory necessity to maintain any specimen provided by a donor, who has subsequently refused to cooperate or otherwise subverted the testing process, unless this specimen was for a post-event test, as required by § 26.31(c)(3). This approach is justified because upon such a determination, the donor who refuses to test is permanently denied authorization to have the types of access or perform the activities described in paragraphs (a) through (d) of § 26.4, "FFD program applicability to categories of individuals," regardless of the outcome of the drug test. Therefore, the NRC is not proposing a rule change based on the public comment.

Blind Performance Test Sample Lot In-Service Requirement

The proposed rule would revise § 26.168(h)(1), which currently requires blind performance test sample (BPTS) suppliers to place a sample lot in service for no more

than 6 months. Feedback received from industry and BPTS suppliers indicates that sample lots can remain viable for much longer than 6 months (e.g., 2 years). Further, Section 10.2 of the 2008 HHS Guidelines does not impose an in-service limit on BPTS lots. The NRC is proposing to eliminate the 6 month use limit and to enable the BPTS supplier, based on laboratory testing data on lot stability, to establish a specified shelf-life for each BPTS sample lot. Allowing the BPTS supplier to determine the expiration date, instead of the NRC requiring a uniform shelf life, would improve the effectiveness of 10 CFR part 26, reduce burden on BPTS suppliers and entities implementing 10 CFR part 26 requirements, and align with the 2008 HHS Guidelines. Furthermore, if a BPTS is no longer stable and unexpected test results were reported by the laboratory inconsistent with the formulation, § 26.719(c) already requires the licensee or other entity to report to the NRC the testing error and the results of the investigation. The § 26.719(c) reporting requirement ensures that the NRC receives timely information on any BPTS formulation irregularities.

HHS-Certified Laboratory Personnel Qualifications and Responsibilities

The proposed rule would remove § 26.155, “Laboratory personnel,” which re-states the qualifications and responsibilities of HHS-certified laboratory personnel (e.g., Responsible Person, Certifying Scientist) included in the HHS Guidelines. The NRC finds that it is unnecessary to restate these HHS Guidelines requirements in 10 CFR part 26 because licensees and other entities are required to use HHS-certified laboratories to conduct drug and validity testing in § 26.153(a). Each laboratory is certified and then inspected every 6 months by the NLCP, which provides assurance that laboratory personnel are appropriately trained, qualified, and meet acceptable academic and technical requirements. The proposed change would reduce the potential for dual regulation of HHS-certified laboratories because each laboratory is also annually

inspected by the licensee or other entity as required in § 26.41(c). Eliminating these redundant requirements would improve the regulatory efficiency of 10 CFR part 26 by reducing unnecessary regulatory oversight.

A conforming change based on the removal of § 26.155 would be to eliminate the reference to § 26.155 in § 26.8, "Information collection requirements; OMB approval," which lists the information collection requirements in 10 CFR part 26 that were approved by the Office of Management and Budget (OMB).

HHS-Certified Laboratory Procedures

The proposed rule would remove § 26.157(b) through (e), which re-state the laboratory procedures requirements included in the HHS Guidelines. Section 26.157, "Procedures," describes the written procedures that HHS-certified laboratories must develop, implement, and maintain. The NRC finds that it is unnecessary to restate these HHS Guidelines requirements in 10 CFR part 26 because licensees and other entities are required to use HHS-certified laboratories to conduct drug and validity testing in § 26.153(a). As discussed for the proposed changes to § 26.155, each HHS-certified laboratory is certified and then inspected on a periodic basis by the NLCP, which provides assurance that the procedures requirements in the HHS Guidelines are developed, implemented, and maintained by the laboratory. The proposed change would reduce the potential for dual regulation of HHS-certified laboratories with respect to maintaining a duplicative set of laboratory procedures already required to be maintained by the HHS Guidelines and reviewed and evaluated by the NLCP.

The proposed rule would revise § 26.157(a) to replace the phrase "develop, implement, and maintain clear and well-documented procedures for accession, receipt, shipment, and testing of urine specimens" with "develop, implement, and maintain procedures specific to this part that document the accession, receipt, shipment, and

testing of specimens." The proposed changes would do the following: 1) ensure that each laboratory would continue to maintain procedures specific to 10 CFR part 26, such as for special analyses testing in § 26.163(a) and the use of more stringent testing cutoff levels and/or the testing of additional substances permitted in § 26.31(d)(3); 2) remove the word "urine" from the phrase "testing of urine specimens" to provide additional flexibility, should the testing of additional specimen matrices (e.g., hair, oral fluids) be allowed by future changes to the HHS Guidelines and subsequent amendments to 10 CFR part 26 requirements; and 3) replace "clear and well-documented" with "documented" laboratory procedures to better align with the terminology in § 26.27(c) and the 2008 HHS Guidelines. The proposed changes to § 26.157(a) would enhance regulatory efficiency and reduce burden by clarifying that each laboratory must maintain procedures specific only to 10 CFR part 26 testing.

Quality Control Samples for Validity and Drug Testing

Section 26.137(e)(6) lists the specifications for the quality control samples to be included in each analytical run of initial drug testing performed at an LTF, and § 26.167(d)(3) and (e) list the quality control sample specifications to be included in each analytical run of initial and confirmatory drug tests performed at an HHS-certified laboratory, respectively. The proposed rule would make a number of conforming changes to these quality control sample requirements to improve the clarity of 10 CFR part 26 and its consistency with Sections 11.12, 11.14, and 11.15(a)(1) of the 2008 HHS Guidelines.

The proposed rule would replace the word "drugs" in the first sentence of § 26.137(e)(6) and the phrase "drug and metabolite" in the second sentence of § 26.137(e)(6) with "drugs and drug metabolites" and "drug and drug metabolite," respectively. The phrases "drug(s) or drug metabolite(s)" in § 26.137(e)(6)(ii) and

(e)(6)(iii) and “a drug(s) or drug metabolite(s)” in § 26.167(d)(3)(ii), (d)(3)(iii), and (e)(3)(iii) would be replaced with the phrase “the drug or drug metabolite.” Similarly, the phrase “no drug” would be expanded to “no drug or drug metabolite” in § 26.167(e)(3)(i), and the phrase “no drugs or drug metabolites” would be revised to “no drug or drug metabolite” in §§ 26.137(e)(6)(i) and 26.167(d)(3)(i).

The proposed rule would remove the parenthetical phrase “(i.e., negative urine samples)” from §§ 26.137(e)(6)(i) and 26.167(d)(3)(i) and (e)(3)(i). Each of those requirements already specifies that the quality control sample is to contain no drug or drug metabolite, so the parenthetical is redundant.

The phrase “targeted at 25 percent below the cutoff” would be replaced in the proposed rule with the phrase “targeted at 75 percent of the cutoff” in §§ 26.137(e)(6)(iii) and 26.167(d)(3)(iii).

The term “sample(s)” would be replaced in the proposed rule with the phrase “at least one control” in §§ 26.137(e)(6)(i) and 26.167(d)(3)(i) and (e)(3)(i). Similarly, the phrase “at least one calibrator or control that is” would be replaced in the proposed rule with the phrase “at least one control” in § 26.167(e)(3)(iv).

The parenthetical statement “(i.e., calibrators and controls)” would be added after the phrase “quality control samples” in §§ 26.137(e)(6) and 26.167(d)(4), and a conforming change would be made in § 26.167(e)(2) to the phrase “calibrators and controls” by replacing it with the phrase “quality control samples (i.e., calibrators and controls).”

The phrase “Positive calibrator(s) and control(s) with a drug(s) or drug metabolite(s)” in § 26.167(e)(3)(ii) would be replaced in the proposed rule with the phrase “A calibrator with its drug concentration at the cutoff.”

The proposed rule would replace the phrase “A minimum of 10 percent of all specimens in each analytical run” in § 26.137(e)(6) with the phrase “A minimum of

10 percent of the total specimens in each analytical run," to more clearly describe how to determine the number of quality control samples to include in each analytical run of initial drug testing performed at an LTF. Conforming changes would be made in § 26.167(e)(2) to the quality control samples that are to be included in each analytical run of confirmatory drug tests performed at an HHS-certified laboratory, by replacing the phrase "At least 10 percent of the samples in each analytical run of specimens" with the phrase "A minimum of 10 percent of the total specimens in each analytical run." The proposed change to § 26.167(e)(2) is consistent with the existing terminology used in the quality control sample requirement for initial drug testing in § 26.167(d)(4).

Section 26.167(f)(3) would be revised to make an editorial correction to the phrase "a statement by the laboratory's responsible person" by capitalizing the "r" and the "p" in the position title, so that it reads as follows: "Responsible Person."

The proposed rule would also correct two of three inaccuracies described in an NRC enforcement guidance memorandum (EGM-09-003, dated March 31, 2009) that pertain to the LTF quality control sample requirements for initial validity testing in § 26.137(d)(5) and for initial drug testing in § 26.137(e)(6)(v). The third inaccuracy, incorrectly using the term "laboratory analysts" instead of "licensee testing facility technicians," has already been addressed in a 10 CFR part 26 final rule correcting amendment, which was published in the *Federal Register* on August 3, 2009 (74 FR 38326).

The first inaccuracy pertains to the requirements in § 26.137(d)(5) and (e)(6)(v), which require that at least one quality control specimen in each analytical run must appear as a "donor specimen" instead of as a "normal specimen" to the LTF technician. To meet this requirement, a different individual would be required to prepare the quality control sample to ensure that the LTF technician that is conducting the specimen testing would be unaware of the origin of the sample. The current rule does not require that

different individuals prepare quality control samples and conduct specimen testing. Without EGM-09-003, § 26.137(d)(5) and (e)(6)(v) would place an unnecessary burden on licensees and other entities because additional LTF procedural changes would be necessary, including the use of an additional qualified person, either to prepare quality control samples or to conduct specimen testing. The majority of LTFs use a single LTF technician to prepare quality control samples and to perform specimen testing, which is consistent with the intent of the current rule. To correct this inaccuracy and to address the currently applicable enforcement discretion, the proposed rule would replace the phrase "donor specimen" with the phrase "normal specimen" in § 26.137(d)(5) and (e)(6)(v).

The second inaccuracy pertains to the requirement in § 26.137(e)(6)(v) that "at least one positive control" is to be included in each analytical run of initial drug testing of specimens at an LTF. The intent of this requirement is to verify the custody and control procedures and confirm the accuracy of initial drug testing performed at an LTF, neither of which require the use of only a positive quality control sample. Since § 26.137(e)(6)(ii) and (e)(6)(iii) already specify the positive quality control samples to be included in each analytical run, the proposed rule would replace the phrase "at least one positive control, certified to be positive by an HHS-certified laboratory" with the phrase "at least one quality control sample" in § 26.137(e)(6)(v).

The NRC would rescind EGM-09-003 if the proposed rule changes correcting these inaccuracies are finalized.

Additional MRO Review for Invalid Specimens with pH of 9.0 to 9.5

Section 26.185(f) describes the process that an MRO is to use to review invalid specimen test results. The proposed rule would redesignate paragraph (f)(3) as paragraph (f)(4) and would add a new paragraph (f)(3) to § 26.185, to align the MRO

review process for invalid specimen test results with Section 13.4(f) of the 2008 HHS Guidelines. Specifically, if a donor did not provide an acceptable medical explanation to the MRO for a pH value in the range of 9.0 to 9.5, the MRO would then have to consider if elapsed time and/or high temperature might have caused the test result. This change is being proposed because of research that demonstrated that exposing a urine specimen to high temperature and/or an extended delay in specimen testing from the time of collection may result in a pH in the range of 9.0 to 9.5 (Cook, et al., 2007). The 2008 HHS Guidelines addressed this topic in Section 13.4(f). In the proposed rule, if the MRO obtains sufficient information from the licensee or other entity, collection site, LTF, or HHS-certified laboratory regarding elapsed time and/or temperature conditions at specimen collection, receipt, transportation, or storage to conclude that an acceptable technical explanation exists for the invalid test result due to pH, then the MRO would direct the licensee or other entity to collect a second urine specimen from the donor, as soon as reasonably practicable. The second specimen would not be collected under direct observation because sufficient evidence was obtained to conclude that donor action likely was not the cause of the invalid test result. This proposed new step to consider technical explanations for a discrepant pH result would provide an additional protection to the donor and limit the instances in which a second collection under direct observation is necessary (i.e., only for invalid specimen test results where no legitimate medical or technical explanation has been determined by the MRO). While Section 13.4(f) of the 2008 HHS Guidelines differs in that it does not require a second test in these circumstances, this approach is inapplicable because a valid test is necessary for determining whether to grant or deny authorization.

Based on feedback received during the October 11, 2011, public meeting, the NRC has chosen not to propose adding detailed instructions in 10 CFR part 26 on how the MRO is to interpret time and temperature information with respect to specimen pH.

Meeting participants commented that the draft instructions presented by the NRC at the public meeting were too prescriptive and unnecessary and that the MRO should be provided with flexibility in making this determination. The NRC agreed and instead is proposing to include guidance on the methods an MRO could use to review invalid test results reported in § 26.185(f)(3) in draft regulatory guide (DG) 5040, "Urine Specimen Collection and Test Result Review under 10 CFR Part 26, Fitness for Duty Programs." This draft guidance is being issued concurrently for comment with this proposed rule.

The NRC also discussed at the October 11, 2011, public meeting the potential to change § 26.131(b)(2) to assist in the documentation of time and/or temperature information for invalid test results, based on a pH of 9.0 or greater obtained at an LTF. However, participants opposed these documentation requirements because they would be burdensome to implement. The NRC agreed and instead is proposing to include in DG-5040 the methods that LTF staff may use to document information to support the MRO review of invalid test results in § 26.185(f)(3).

Donor Request for Specimen Retesting or Bottle B Testing

Section 26.165(b)(2) instructs the MRO to "inform the donor that he or she may, within 3 business days of notification by the MRO of the confirmed positive, adulterated, or substituted test result, request the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen."[7] The proposed rule would include a new requirement in § 26.165(b)(2) for the MRO to document in his or her records the date and time a request was received from the donor to retest an aliquot of the single specimen or to test the Bottle B split specimen. Documenting when a donor initiated the

[7] "Aliquot" means a portion of a specimen that is used for testing. It is taken as a sample representing the whole specimen. "Bottle B testing" means the drug or validity testing performed by a second HHS-certified laboratory on the split (Bottle B) specimen to verify the test results reported by the first HHS-certified laboratory that tested the Bottle A specimen.

request for testing would ensure that a record was maintained to demonstrate that the donor had made the request within the required 3 business days timeframe. This rule change would document an existing practice of MROs when receiving such a request.

Section 26.165(b)(3) requires the donor to provide his or her permission for the retesting of an aliquot of the single specimen or the testing of Bottle B and states that "Neither the licensee, MRO, NRC, nor any other entity may order retesting of the single specimen or testing of the specimen in Bottle B without the donor's written permission, except as permitted in § 26.185(l)." The proposed rule would revise § 26.165(b)(3) to state that "No entity, other than the MRO as permitted in § 26.185(l), may order the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen." The proposed change would address an inconsistency in the current rule because § 26.165(b)(2) already states that the "donor's request may be oral or in writing." At present, even though the MRO may have received an oral request from the donor to proceed with the retesting of an aliquot of a single specimen or to test the Bottle B split specimen, some licensees are interpreting the current rule to require that the MRO must receive written permission from the donor before initiating the retesting of a specimen.

These proposed changes to § 26.165(b)(2) and (b)(3) would improve the consistency of 10 CFR part 26 with Section 14.1(b) of the 2008 HHS Guidelines and would enhance due process by ensuring that the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen could proceed as quickly as possible.

Collection of a Second Specimen under Direct Observation when Bottle B or an Aliquot of a Single Specimen Is Not Available for Testing

Section 26.115(a) lists the exclusive grounds for collecting a urine specimen under direct observation. However, the list does not include an existing requirement in

§ 26.165(f)(2) in which an observed collection is required when a donor requests a retest and either Bottle B or the single specimen is not available, due to circumstances outside of the donor's control. The proposed rule would correct this omission by including a new paragraph (a)(5) to reference the direct observation requirement in § 26.165(f)(2).

Section 26.165(f)(2) requires MRO action for a positive drug test result or an adulterated or substituted validity test result when the Bottle B of a split specimen or an aliquot of a single specimen is not available for testing at the donor's request. In this instance, the MRO is required to cancel the initial test result and inform the licensee or other entity that a second specimen must be collected under direct observation "as soon as reasonably practical." Section 14.1(c) of the 2008 HHS Guidelines, for this same circumstance, states that no advanced notice is to be provided to the donor regarding the second specimen collection until immediately before the collection is to commence. The proposed rule would revise the requirement in § 26.165(f)(2) to specify that no prior notice shall be given to a donor until immediately before the collection. Clarifying the procedure to follow in this circumstance would improve the effectiveness of licensees' or other entities' testing programs to detect illegal drug use and/or the misuse of legal drugs and would align 10 CFR part 26 with the 2008 HHS Guidelines.

The proposed rule would also revise § 26.165(f)(2) to state that the MRO is to report a cancelled test result to the licensee or other entity. The process in § 26.165(f)(2) already states that the licensee or other entity may not impose any sanctions on the donor for a cancelled test result. This revision clarifies the existing action that the MRO must take to report the results of the testing of a donor's specimen to the licensee or other entity. Subsequent action by the licensee or other entity cannot be taken until the MRO provides the test result information for a donor's specimen. The revision would also state that the licensee or other entity must continue the administrative withdrawal of an individual's FFD authorization until the test results from

the second specimen collection are determined. Continuing to administratively withdraw an individual's authorization would be consistent with § 26.165(f)(1), which requires the licensee or other entity to administratively withdraw an individual's FFD authorization on the basis of the first confirmed positive, adulterated, or substituted test result until the results of a donor-requested Bottle B split specimen test or single specimen retest are available and have been reviewed by the MRO.

A participant at the October 11, 2011, public meeting also requested that the NRC include in § 26.165(f)(2) a reference to §§ 26.129(b)(2) and 26.159(b)(2) to clarify that the action of the licensee or other entity was taken based on the test results of the second specimen collected under direct observation. The NRC agrees with this request and is proposing to revise this section accordingly.

FFD Program Performance Data Reporting

The NRC has periodically received questions from licensees and other entities on the annual drug and alcohol testing reporting requirements on "populations tested" in § 26.717(b) and (c). Specifically, the reporting requirements to provide FFD program performance data by populations tested "(i.e., individuals in applicant status, permanent licensee employees, [contractors/vendors] C/Vs)" has resulted in two types of questions.

First, licensees already report the pre-access testing results separately for the licensee employee and C/V tested populations, so they requested clarification on the term "individuals in applicant status." Applicant status is not a distinct tested population category, rather, it is the status of individuals that are subject to pre-access testing. Currently, licensees and other entities must report the test results by tested population for each condition of testing (i.e., pre-access, random, for-cause, post-event, and follow-up) as required by § 26.717(b)(5). By reporting the pre-access test results for each of the two tested populations (i.e., licensee employees, C/Vs), licensees and other entities

are already reporting the results for individuals in "applicant status." To improve the clarity of the existing reporting requirement, the proposed rule would remove the phrase "individuals in applicant status" from § 26.717(b)(3) and (b)(4).

Second, the NRC has received questions from entities other than the licensees that report § 26.717 drug and alcohol test results. Because § 26.717(b)(3) and (b)(4) does not specify "other entity" in the parenthetical statements defining the tested populations, these entities were unclear on how to classify their tested populations on the § 26.717 annual summary reports to the NRC. To correct this oversight, the proposed rule would revise the tested population "licensee employees" to "licensee or other entity employees" in § 26.717(b)(3) and (b)(4).

IV. Section-by-Section Analysis

Nomenclature Changes

Throughout 10 CFR part 26, the NRC is proposing to revise the term "custody and control form" to read "Federal CCF." Two additional iterations of the term, "custody-and-control forms" and "custody-and-control form(s)," would also be revised to read "Federal CCFs" and "Federal CCF(s)," respectively.

Throughout 10 CFR part 26, the NRC is proposing to revise the term "chain-of-custody" to read "chain of custody."

The nomenclature changes to "custody-and-control form" and "chain-of-custody" would align with the spelling of these terms in the 2008 HHS Guidelines and would also improve consistency in 10 CFR part 26.

The proposed rule would also correct a number of instances where "chain-of-custody form" was used instead of "custody and control form," and vice versa. These

corrections pertain to §§ 26.89(d); 26.117(f); and 26.159(c), (d) and (e), as described later in this section.

§ 26.4 FFD program applicability to categories of individuals

Section 26.4(e)(6)(iv) would be revised to eliminate the phrase "(65 FR 41944; August 9, 2001)."

Section 26.4(g)(6) would be added to describe a new activity that the FFD program personnel could perform: monitoring a donor during the hydration process described in § 26.109(b). The punctuation at the end of § 26.4(g)(4) and (5) would be updated to accommodate the addition of § 26.4(g)(6).

Section 26.4(j)(3) would be revised to replace the phrase "laboratory certified by the Department of Health and Human Services (HHS)" with "Department of Health and Human Services (HHS)-certified laboratory as defined in § 26.5."

§ 26.5 Definitions

As described in Section III.C of this document, the NRC is proposing to add definitions for *Cancelled test, Carryover*, *Certifying Scientist*, *Federal custody and control form*, *Lot*, *Rejected for testing*, and *Responsible Person*.

The definition for *calibrator* would be revised to include a clarifying statement that a calibrator is a solution of known concentration "in the appropriate matrix." The phrase "test specimen/sample" would be replaced with the phrase "donor specimen or quality control sample." The last sentence of the current definition which states that "calibrators may be used to establish a cutoff concentration and/or a calibration curve over a range of interest" would be deleted.

The definition for *control* would be revised by replacing the phrase "a sample used to monitor the status of an analysis to maintain its performance within predefined

limits" with the phrase "a sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits."

The definition for *dilute specimen* would be revised by replacing the phrase "concentrations that are lower than expected for human urine" with the phrase "values that are lower than expected but are still within the physiologically producible ranges of human urine."

The definition for *HHS-certified laboratory* would be revised to eliminate the *Federal Register* citations for each final version of the HHS Guidelines. Instead, the definition would state that "*HHS-certified laboratory* means a laboratory that is certified to meet the standards of the *Mandatory Guidelines for Federal Workplace Drug Testing Programs* (the HHS Guidelines) at the time that drug and validity testing of a specimen is performed for a licensee or other entity."

The definition for *invalid result* would be revised to replace the phrase "for a specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, contains inconsistent physiological constituents, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result" with the phrase "in accordance with the criteria established in § 26.161(f) when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test."

The definition for *limit of quantitation (LOQ)* would be revised to replace the phrase "the lowest concentration of an analyte at which the concentration of the analyte can be accurately determined under defined conditions" with the phrase "for quantitation assays, the lowest concentration at which the identity and concentration of the analyte can be accurately established."

The definition for *substituted specimen* would be revised to replace the phrase "with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human physiology" with the phrase "a specimen that has been submitted in place of the donor's urine, as evidenced by creatinine and specific gravity values that are outside the physiologically producible ranges of human urine."

§ 26.8 Information collection requirements: OMB approval

Section 26.8(b) would be revised to remove the reference to § 26.155.

§ 26.31 Drug and Alcohol Testing

Section 26.31(b)(2) would be revised to eliminate the phrase "(65 FR 41944; August 9, 2001)."

Section 26.31(d)(1) would be revised to include MDMA and MDA as substances for which licensees and other entities are required to test in each specimen.

Section 26.31(d)(1)(i)(D) would be revised to eliminate the phrase "as specified in § 26.155(a)."

Section 26.31(d)(1)(ii) would be revised to replace the phrase "except if the specimen is dilute and the licensee or other entity has required the HHS-certified laboratory to evaluate the specimen in §§ 26.163(a)(2) or 26.168(g)(3) with the phrase "except if special analyses of the specimen is performed under § 26.163(a)(2) by the HHS-certified laboratory."

§ 26.89 Preparing to Collect Specimens for Testing

Section 26.89(c) would be revised to replace the phrase "adulterated, diluted, or adulterated the specimen" with the phrase "adulterated, diluted, or substituted the specimen."

Section 26.89(d) would be revised to include this phrase at the end of the first sentence: ", except as described in § 26.109(b)(1)." The second sentence in § 26.89(d) would be revised in three ways. First, the phrase "For this purpose, a urine collection" would be replaced with the phrase "The urine collection." Second, the phrase "sealed and initialed" would be replaced with the phrase "sealed with tamper-evident tape, the seal has been dated and initialed." Finally, the phrase "the chain of custody form has been executed, and the donor has departed the collection site" would be replaced with the phrase "and the Federal CCF has been completed or when a refusal to test has been determined under § 26.107(d)."

§ 26.107 Collecting a Urine Specimen

Section 26.107(b) would be revised in four ways. First, the proposed rule would redesignate paragraph (b) as paragraph (b)(1) of this section. Secondly, the phrase "except as provided in § 26.109(b)(1)" would be added in the first sentence after "The collector shall pay careful attention to the donor during the entire collection process." Third, § 26.107(b) would be revised to replace the phrase "to note any conduct that clearly indicates an attempt to tamper with a specimen (e.g., substitute urine is in plain view or an attempt to bring an adulterant or urine substitute into the privacy area)" with the phrase "to observe any conduct that indicates an attempt to subvert the testing process (e.g., tampering with a specimen; having a substitute urine in plain view; attempting to bring an adulterant, urine substitute, heating element, and/or temperature measurement device into the room, stall, or private area used for urination)." Lastly, the phrase "the collector shall document the conduct" would be revised to read as follows: "the collector shall document a description of the conduct."

Section 26.107(b)(2) would be added to ensure that if a hydration monitor is used to observe a donor during the § 26.109(b) hydration process, this individual shall

immediately inform the collector of any donor conduct that may indicate an attempt to subvert the testing process (e.g., donor leaves the collection site, donor refuses to follow directions).

Section 26.107(d) and (d)(1) through (d)(5) would be added to describe requirements regarding the actions a collector must take if a refusal to test is determined at any point during the specimen collection process. Specifically, the collector shall: 1) inform the donor that a refusal to test has been determined, 2) terminate the collection process, 3) document a description of the refusal to test on the Federal CCF, 4) discard any urine specimen(s) provided by the donor unless the specimen was collected for a post-event test required by § 26.31(c)(3), and 5) immediately inform the FFD program manager of the refusal to test.

§ 26.109 Urine Specimen Quantity

Section 26.109(b)(1) would be revised, and new paragraphs (b)(1)(i) through (b)(1)(iii) would be added to provide a licensee or other entity with new flexibility in the personnel that may be used to monitor a donor during the hydration process that is initiated when a donor is unable to provide an acceptable quantity of urine during the initial collection attempt. For clarity, the last sentence of § 26.109(b)(1) would become the new first sentence of § 26.109(b)(2). The proposed rule would permit another staff member designated as FFD program personnel, as described in § 26.4(g)(6), or another specimen collector meeting the requirements in § 26.85(a), instead of the specimen collector who initiated the collection process, to monitor a donor during the hydration process. The collector shall 1) explain the hydration process and acceptable donor behavior to the hydration monitor and 2) record the name of the individual observing the donor on the Federal CCF and then provide the Federal CCF to the observer for the duration of the hydration process. The original collector may then perform other

collections while the donor is in the hydration process.

§ 26.111 Checking the Acceptability of the Urine Specimen

Section 26.111(a) would be revised to replace the phrase "greater than 15 mL" with the phrase "equal to or greater than 15 mL" and to add the phrase "(e.g., adulterated or diluted)" after the word "altered."

Section 26.111(c) would be revised to remove the word "designated" from the phrase "designated FFD program manager" in the first sentence. The parenthetical phrase "(e.g., adulterated or diluted)" would be added after the word "altered" in the second sentence.

Section 26.111(e) would be revised to include the phrase ", except under the conditions described in § 26.107(d)(4)" at the end of the existing requirement.

Section 26.111(f) would be removed.

§ 26.115 Collecting a Urine Specimen under Direct Observation

Section 26.115(a)(3) would be revised to replace the phase "The collector observes conduct clearly and unequivocally indicating an attempt to dilute, substitute, or adulterate the specimen" with the phrase "The collector, or the hydration monitor if one is used as permitted in § 26.109(b)(1), observes conduct by the donor indicating an attempt to subvert the testing process." Also, the proposed rule would remove the word "and" at the end of § 26.115(a)(3). Paragraph (a)(5) would be added to include an additional instance when an observed collection is required: "The donor requests a retest and either Bottle B or the single specimen is not available due to circumstances outside of the donor's control, as specified in § 26.165(f)(2)." The period at the end of the sentence in § 26.115(a)(4) would be replaced with a "; or" to accommodate for the

new paragraph (a)(5) of this section in the list of exclusive grounds for performing a directly observed collection.

In § 26.115(f), the proposed rule would revise the first sentence, “If someone other than the collector is to observe the collection, the collector shall instruct the observer to follow the procedures in this paragraph,” so that it reads “If the observer is not a trained collector, the collector shall, in the presence of the donor, instruct the observer on the collection procedures in paragraph (f) of this section.” The revised sentence would be added to the end of existing requirements in § 26.115(e).

In § 26.115(f)(2), the proposed rule would add the following statement to the end of the existing requirement: “A reflective mirror may be used to assist in observing the provision of the specimen only if the physical configuration of the room, stall, or private area is not sufficient to meet this direct observation requirement; the use of a video camera to assist in the observation process is not permitted.”

In § 26.115(f)(3), the proposed rule would replace the phrase “If the observer is not the collector, the observer may not take the collection container from the donor, but shall observe the specimen as the donor takes it to the collector” with the phrase “If the observer is not the collector, the observer may not touch or handle the collection container but shall maintain visual contact with the specimen until the donor hands the collection container to the collector.”

Section 26.115(g) would be revised to include the phrase “, and the collector shall follow the procedures in § 26.107(d)” at the end of the existing requirement.

§ 26.117 Preparing Urine Specimens for Storage and Shipment

Section 26.117(a) would be revised to add the phrase “Once the collector is presented with the specimen from the donor” at the beginning of the first sentence to

clarify when the collector would begin to keep the donor's "urine specimen(s) in view at all times."

Section 26.117(f) would be revised to replace the term "chain-of-custody forms" with the term "Federal CCFs." Section 26.117(f) would also be revised to replace the phrase "or the licensee's testing facility," with the phrase "or to the licensee testing facility."

Section 26.117(g) would be revised to add the phrase ", except as provided in § 26.109(b)(1)(ii) for the Federal CCF," to the end of the first sentence.

§ 26.129 Assuring Specimen Security, Chain of Custody, and Preservation

Section 26.129(b)(1)(ii) would be revised by replacing the phrase "the specimen may not be tested," with the phrase "the licensee testing facility shall reject the specimen for testing."

Section 26.129(b)(2) would be revised by adding the phrase "and report a cancelled test result to the licensee or other entity," after the phrase "requiring the MRO to cancel the testing of a donor's urine specimen."

§ 26.133 Cutoff Levels for Drugs and Drug Metabolites

The introductory paragraph under § 26.133 would be revised to clarify that the specified cutoff level must be used to determine whether the specimen is negative "or positive" for the indicated drug or drug metabolite being tested. The table in § 26.133 would be revised to: 1) lower the initial test cutoff level for cocaine metabolites from 300 ng/mL to 150 ng/mL, 2) include a new footnote 1 to clarify that the initial test cutoff level for opiate metabolites is for codeine/morphine and that morphine is the target analyte, 3) lower the initial test cutoff level for amphetamines (abbreviated in the table as AMP) from 1000 ng/mL to 500 ng/mL, 4) add initial testing for 6-AM at a cutoff level of

10 ng/mL, 5) include a new table footnote 2 regarding initial test kits, 6) include a new table footnote 3 to clarify that for amphetamines testing, methamphetamine (abbreviated in the table as MAMP) is the target analyte, 7) add initial testing for MDMA and MDA at a cutoff level of 500 ng/mL, and 8) provide the full chemical name for MDMA and MDA in new footnotes 4 and 5 to the table, respectively. The column header "Drug or metabolites" in the table in § 26.133 would also be revised to "Drugs or drug metabolites" to align with the table title.

§ 26.137 Quality Assurance and Quality Control

Section 26.137(d)(5) would be revised to replace the term "donor specimen" with the term "normal specimen."

Section 26.137(e)(6) would replace the phrase "A minimum of 10 percent of all specimens" at the start of the first sentence with the phrase "A minimum of 10 percent of the total specimens." The parenthetical phrase "(i.e., calibrators and controls)" would be added after the phrase "quality control samples" in the first sentence of § 26.137(e)(6). The word "drugs" in the first sentence of § 26.137(e)(6) and the phrase "drug and metabolite" in the second sentence of § 26.137(e)(6) would be replaced with the phrases "drugs and drug metabolites" and "drug and drug metabolite," respectively.

Section 26.137(e)(6)(i) would replace the phrase "Sample(s) certified by an HHS-certified laboratory to contain no drugs or drug metabolites (i.e., negative urine samples)" with the phrase "At least one control certified by an HHS-certified laboratory to contain no drug or drug metabolite."

Section 26.137(e)(6)(ii) would be revised to replace the phrase "drug(s) or drug metabolite(s)" with the phrase "the drug or drug metabolite."

Section 26.137(e)(6)(iii) would be revised to replace the phrase “the drug(s) or drug metabolite(s) targeted at 25 percent below the cutoff” with the phrase “the drug or drug metabolite targeted at 75 percent of the cutoff.”

Section 26.137(e)(6)(v) would be revised to replace the phrase “At least one positive control, certified to be positive by an HHS-certified laboratory, which appears to be a donor specimen” with the phrase “At least one quality control sample that appears to be a normal specimen.”

§ 26.153 Using Certified Laboratories for Testing Urine Specimens

Section 26.153(a) would be revised to replace the phrase “laboratories certified under the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs [published in the *Federal Register* on April 11, 1988 (53 FR 11970), and as amended, June 9, 1994 (59 FR 29908), November 13, 1998 (63 FR 63483), and April 13, 2004 (69 FR 19643)]” with the phrase “HHS-certified laboratories as defined in § 26.5.” The sentence “Information concerning the current certification status of laboratories is available from the Division of Workplace Programs, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration, Room 815, 5600 Fishers Lane, Rockwall 2 Bldg., Rockville, Maryland 20857” would be removed.

Section 26.153(g) would be revised to replace the term “Federal custody-and-control form” with “Federal CCF” and the term “non-Federal form” with “non-Federal CCF.”

§ 26.155 Laboratory Personnel

Section 26.155 would be removed and reserved.

§ 26.157 Procedures

Section 26.157(a) would be revised to replace the phrase “clear and well-documented procedures for” with the phrase “procedures specific to this part that document the.” Section 26.157(a) would also be revised to remove “urine” in the phrase “testing of urine specimens.”

Section 26.157(b) would be removed and reserved, and § 26.157(c) through (e) would be removed.

§ 26.159 Assuring Specimen Security, Chain of Custody, and Preservation

Section 26.159(b)(1)(ii) would be revised to replace the phrase “the specimens may not be tested” with the phrase “the laboratory shall reject the specimens for testing” when the integrity or identity of the specimens is in question.

Section 26.159(b)(2) would be revised to add after “The following are exclusive grounds requiring the MRO to cancel the testing of a donor’s urine specimen,” the phrase “and report a cancelled test to the licensee or other entity.”

Section 26.159(c) would be revised in the second sentence of the paragraph to replace the term “custody-and-control” with the term “chain of custody.” Also, the term “custody-and-control form” would be replaced with the term “Federal CCF” in the third sentence of the paragraph.

Section 26.159(d) would be revised to replace the term “custody-and-control” with the term “chain of custody.”

Section 26.159(e) would be revised to replace the term “custody-and-control” with the term “chain of custody” in the two instances that it occurs in the paragraph.

§ 26.161 Cutoff Levels for Validity Testing

Sections 26.161(c)(3) through (c)(6) would be revised to replace all instances of "LOD" with "LOQ."

Sections 26.161(c)(5) would be revised to replace the phrase "GC/MS for the confirmatory test" with the phrase "a different confirmatory method (e.g., gas chromatography/mass spectrometry (GC/MS))."

Sections 26.161(c)(6) would be revised to replace the phrase "GC/MS for the confirmatory test" with the phrase "a different confirmatory method (e.g., GC/MS)."

Sections 26.161(f)(5) and (f)(7) would be revised to replace all instances of the term "LOD" with the term "LOQ."

§ 26.163 Cutoff Levels for Drug and Drug Metabolites

Section 26.163(a)(1) would be revised to replace the phrase "negative for the indicated drugs and drug metabolites" with the phrase "negative or positive for the indicated drugs and drug metabolites." The phrase "except if validity testing indicates that the specimen is dilute" would also be revised to "except as specified in paragraph (a)(2) of this section."

The table in § 26.163(a)(1) would be revised to: 1) lower the initial test cutoff level for cocaine metabolites from 300 ng/mL to 150 ng/mL, 2) include a new footnote 1 to clarify that the initial test cutoff level for opiate metabolites is for codeine/morphine and that morphine is the target analyte, 3) lower the initial test cutoff level for amphetamines (abbreviated in the table as AMP) from 1000 ng/mL to 500 ng/mL, 4) add initial testing for 6-AM at a cutoff level of 10 ng/mL, 5) include a new footnote 2 regarding initial test kits, 6) include a new footnote 3 to clarify that for amphetamines testing, methamphetamine (abbreviated in the table as MAMP) is the target analyte, 7) add initial testing for MDMA and MDA at a cutoff level of 500 ng/mL, and 8) provide the full

chemical names for MDMA and MDA in new footnotes 4 and 5 to the table, respectively. The column header “Drug or metabolites” in the table in § 26.163(a)(1) would also be revised to “Drugs or drug metabolites” to align with the table title. Section 26.163(a)(2) would be revised to remove the phrase “At the licensee’s or other entity’s discretion, as documented in the FFD program policies and procedures, the licensee or other entity may require the” and replace the provision with “HHS-certified laboratories shall conduct special analyses of specimens as follows:.”

Section 26.163(a)(2)(i) would be revised to replace the phrase “the HHS-certified laboratory shall compare the responses of the dilute specimen to the cutoff calibrator in each of the drug classes” with the phrase “or if a specimen is collected under direct observation for any of the conditions specified in § 26.115(a)(1) through (a)(3) or (a)(5).”

Section 26.163(a)(2)(ii) would be revised to state “If any immunoassay response is equal to or greater than 40 percent of the cutoff calibrator, the laboratory shall conduct confirmatory drug testing of the specimen to the LOQ for those drugs and/or drug metabolites; and.”

The table in § 26.163(b)(1) would be revised to: 1) lower the confirmatory test cutoff level for cocaine metabolite from 150 ng/mL to 100 ng/mL, 2) revise “Opiates” to read “Opiate metabolites,” 3) remove footnote 3 regarding the requirement that confirmatory testing of 6-AM only proceed when confirmatory testing shows a morphine concentration exceeding 2000 ng/mL, 4) lower the confirmatory test cutoff levels for amphetamine and methamphetamine from 500 ng/mL to 250 ng/mL, 5) redesignate footnote 4 as footnote 3 and revise the text to lower the concentration of amphetamine that must be present in the specimen from 200 ng/mL to 100 ng/mL, and 6) add confirmatory testing for MDMA and MDA at a cutoff level of 250 ng/mL. The column header “Drug or metabolites” in the table in § 26.163(b)(1) would also be revised to “Drugs or drug metabolites.”

§ 26.165 Testing Split Specimens and Retesting Single Specimens

A new fifth sentence would be added to § 26.165(b)(2) that states, "The MRO shall document in his or her records when (i.e., date and time) the request was received from the donor to retest an aliquot of the single specimen or to test the Bottle B split specimen."

The first sentence in § 26.165(b)(3) would be deleted. The second sentence in § 26.165(b)(3) would be revised to state "No entity, other than the MRO as permitted in § 26.185(l), may order the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen."

The last sentence in § 26.165(f)(1) would be revised by adding the phrase "the MRO shall report a cancelled test result to the licensee or other entity, and" to indicate that the MRO must report the cancelled test.

Section 26.165(f)(2) would be revised to clarify the actions that an MRO is to take when a donor requests testing of Bottle B or a retest of a single specimen and the specimen to be tested is unavailable due to circumstances outside of the donor's control. Specifically, the proposed rule would: 1) add instruction for the MRO to report a cancelled test to the licensee or other entity for the donor's specimen; 2) add instruction for the licensee or other entity to perform a second collection without prior notice to the donor and to continue to administratively withdraw the individual's authorization until the results of the second collection are received by the MRO; and 3) add a reference to §§ 26.129(b)(2) and 26.159(b)(2), which describes the circumstances that require the MRO to cancel a test result.

§ 26.167 Quality Assurance and Quality Control

Section 26.167(d)(3)(i) would be revised to replace the phrase "Sample(s) certified to contain no drugs or drug metabolites (i.e., negative urine samples)" with the phrase "At least one control certified to contain no drug or drug metabolite."

Section 26.167(d)(3)(ii) would be revised to replace the phrase "a drug(s) or drug metabolites" with the phrase "the drug or drug metabolite."

Section 26.167(d)(3)(iii) would be revised to replace the phrase "a drug(s) or drug metabolite(s) targeted at 25 percent below the cutoff" with the phrase "the drug or drug metabolite targeted at 75 percent of the cutoff."

Section 26.167(d)(4) would be revised to add the parenthetical statement "(i.e., calibrators and controls)" after the phrase "quality control samples."

Section 26.167(e)(2) would be revised to replace the phrase "At least 10 percent of the samples in each analytical run of specimens must be calibrators and controls" with the phrase "A minimum of 10 percent of the total specimens in each analytical run must be quality control samples (i.e., calibrators and controls)."

Section 26.167(e)(3)(i) would be revised to replace the phrase "Sample(s) certified to contain no drug (i.e., negative urine samples)" with the phrase "At least one control certified to contain no drug or drug metabolite."

Section 26.167(e)(3)(ii) would be revised to replace the phrase "Positive calibrator(s) and control(s) with a drug(s) or drug metabolite(s)" with the phrase "A calibrator with its drug concentration at the cutoff."

Section 26.167(e)(3)(iii) would be revised to replace the phrase "a drug(s) or drug metabolites" with the phrase "the drug or drug metabolite."

Section 26.167(e)(3)(iv) would be revised to replace the phrase "At least one calibrator or control that is targeted" with the phrase "At least one control targeted."

Section 26.167(f)(3) would be revised to make an editorial correction to the phrase “a statement by the laboratory’s responsible person” by capitalizing the position title in that phrase to “Responsible Person.”

§ 26.168 Blind Performance Testing

Section 26.168(h)(1) would be revised to remove the phrase “and for no more than 6 months” from this requirement.

§ 26.169 Reporting Results

Section 26.169(a) would be revised to correct the capitalization of the “c” and the “s” in the position title in the phrase “the laboratory’s certifying scientist” to “Certifying Scientist.”

The HHS-certified laboratory annual statistical summary reporting requirements in § 26.169(h)(3) would be revised to add MDMA and MDA to the list of amphetamines test results that a laboratory must report as required by § 26.169(h)(3)(v). Additional conforming changes would be made to the names of the drugs and drug metabolites listed in § 26.169(h)(3) to include adding “(as THCA)” after “Marijuana metabolite” in § 26.169(h)(3)(i), adding “(as benzoylecgonine)” after “Cocaine metabolite” in § 26.169(h)(3)(ii), revising 6-AM to “6-acetylmorphine (6-AM)” in § 26.169(h)(3)(iii)(C), and revising “Phencyclidine” to “Phencyclidine (PCP)” in § 26.169(h)(3)(iv).

§ 26.183 Medical Review Officer

Section 26.183 would be revised to remove the phrase “at the licensee’s or other entity’s discretion” from § 26.183(c), (c)(1), and (d)(2)(ii).

§ 26.185 Determining a Fitness-for-Duty Policy Violation

Section 26.185(f)(3) would be redesignated as (f)(4), and a new paragraph (f)(3) would be added to state that if there is no legitimate technical or medical explanation for an invalid test result based on a pH result greater than or equal to 9.0 but less than or equal to 9.5, the MRO shall consider whether there is evidence of elapsed time, exposure of the specimen to high temperature, or both that could account for the pH value. If the MRO obtains objective and sufficient information regarding elapsed time, temperature conditions, or both to conclude that an acceptable explanation exists for the invalid test result due to pH, the MRO would direct the licensee or other entity to collect a second urine specimen from the donor as soon as reasonably practicable. This second specimen may not be collected from the donor under direct observation conditions.

Section 26.185(g)(2) would be revised to replace the phrase "If the licensee or other entity requires the HHS-certified laboratory to conduct the special analysis of dilute specimens permitted by § 26.163(a)(2), the results of the special analysis are positive," with the phrase "If the results of the special analysis testing required by § 26.163(a)(2) are positive."

Section 26.185(g)(2)(iii) would be revised to remove the phrase "clearly and unequivocally."

Section 26.185(g)(3) would be removed.

Section 26.185(g)(4) and (g)(5) would be redesignated as § 26.185(g)(3) and (g)(4), respectively, and the cross-reference under § 26.163(a)(1) would be updated to reflect these changes.

§ 26.405 Drug and Alcohol Testing

Section 26.405(d) would be revised to add MDMA and MDA as substances for which licensees and other entities are required to test in each specimen.

§ 26.415 Audits

Section 26.415(c) would be revised to eliminate the phrase "(65 FR 41944; August 9, 2001)."

§ 26.717 Fitness-for-duty program performance data

Section 26.717(b)(3) would be revised to replace the phrase "(i.e., individuals in applicant status, permanent licensee employees, C/Vs)," with the phrase "(i.e., licensee and other entity employees, C/Vs)."

Section 26.717(b)(4) would be revised to replace the phrase "(i.e., individuals in applicant status, permanent licensee employees, C/Vs)," with the phrase "(i.e., licensee and other entity employees, C/Vs)."

V. Specific Requests for Comment

The NRC is seeking advice and recommendations from stakeholders on this proposed rule. We are particularly interested in comments and supporting rationale from the public on the following:

1. *Alignment with the HHS Guidelines*

Two proposed changes in this rule would eliminate redundant provisions in 10 CFR part 26 that also appear in the HHS Guidelines (i.e., HHS-certified laboratory personnel qualifications requirements in § 26.155, "Laboratory personnel," and HHS-certified laboratory procedures requirements specific to the HHS Guidelines in § 26.157,

"Procedures"). Because the NLCP inspection process verifies laboratory compliance with the HHS Guidelines, additional review and oversight by NRC licensees and other entities (e.g., of laboratory security requirements) would be duplicative. The NRC is seeking comment on additional provisions in 10 CFR part 26 that are consistent with the HHS Guidelines and could be eliminated from 10 CFR part 26.

2. *Special Analyses Testing*

The proposed rule includes new requirements in § 26.163(a)(2) for the special analyses testing of urine specimens for drugs and drug metabolites. The first would require special analyses testing of specimens with dilute validity test results when initial drug testing identifies a drug or drug metabolite within 40 percent of the testing cutoff level. Currently, special analyses testing of dilute specimens is optional. The second new requirement would expand special analyses testing to specimens collected under direct observation as required by § 26.115(a)(1) through (a)(3) and new paragraph (a)(5). The NRC is seeking comment on whether special analyses testing should also apply to the testing of individuals that already have tested positive on a 10 CFR part 26 test (i.e., denied unescorted access authorization by § 26.75(d) for a first or second drug testing positive result). Requiring special analyses testing in this case would add a level of assurance to follow-up testing required by § 26.69(b)(6), which is conducted to confirm continued abstinence from illegal drug use and/or the misuse of legal drugs.

3. *Provide Flexibility to Conduct Additional Specimen Validity Tests*

Section 26.31(d)(1)(i)(D) permits a licensee or other entity to utilize lower cutoff levels and drug testing assays without forensic toxicologist review if the HHS Guidelines are revised to authorize use of the assay and testing cutoff levels. However, § 26.161(h) prohibits licensees and other entities from using more stringent cutoff levels for validity

tests. The NRC is seeking comment on whether § 26.161(h) should be revised to provide a licensee or other entity with the option to conduct additional specimen validity tests and/or to utilize lower cutoff levels if the HHS Guidelines are revised in the future to include such testing.

4. *Effective Date of the Final Rule*

If the proposed rule is finalized, the NRC anticipates providing a 60-day implementation period from the date that the final rule is published in the *Federal Register*. The effective date of the final rule and the compliance date for licensees and other entities would be 60 days after the date that the final rule is published in the *Federal Register*. The NRC is seeking comment on whether this implementation time period is appropriate based on the proposed rule changes.

5. *Direct Observation of Specimen Collection*

The proposed rule retains the requirement for direct observation during the collection of a second sample when there are indications of a subversion attempt during the initial collection. The NRC is seeking comment on whether there are any effective alternatives to direct observation that will assist in preventing subversion of the drug testing process.

6. *2017 HHS Guidelines—New Test Analytes*

On January 23, 2017, HHS issued its latest revision of the Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Urine Specimens (82 FR 7920). Subpart C, “Urine Drug and Specimen Validity Tests,” of the 2017 HHS Guidelines was revised to include additional initial and confirmatory test analytes for certain opioids; specifically, hydrocodone, hydromorphone, oxycodone, and oxymorphone. The NRC is

seeking comment on whether §§ 26.31(d)(1) and 26.405(d) should be revised to identify hydrocodone, hydromorphone, oxycodone, and oxymorphone test substances, and whether §§ 26.133 and 26.163(a)(1) and (b)(1) should be revised to require initial and confirmatory testing of these drugs at the cutoff levels recommended in the 2017 HHS Guidelines.

7. *Methylenedioxyethylamphetamine*

The 2008 HHS Guidelines adds methylenedioxyethylamphetamine (MDEA) as a confirmatory analyte to the drug testing panel in Section 3.4. However, when the HHS revised the mandatory guidelines in 2017, HHS removed MDEA from Section 3.4 stating that "[t]he Department has evaluated the comments and has removed MDEA from the Guidelines (i.e., MDEA is no longer included as an authorized drug in Section 3.4). The number of positive MDEA specimens reported by HHS-certified laboratories (*i.e.*, information provided to the Department through the NLCP) does not support testing all specimens for MDEA in federal workplace drug testing programs." (82 FR 7920, 7923; January 23, 2017). The NRC is not proposing to adopt the 2008 HHS Guidelines' addition of MDEA as a confirmatory test analyte at this time. As a result, the NRC is also proposing to add MDA to the initial testing panel to fully align with the "Ecstasy drugs" testing panel in the 2017 guidelines. The NRC is seeking comment on these changes.

VI. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed rule affects the licensing and operation of nuclear power plants and Category I fuel cycle facilities. The companies that own these facilities do not

fall within the scope of the definition of “small entities” set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810).

The NRC estimates that none of the 67 entities affected by the rule would fall within the scope of the definition of ‘‘small entities’’ set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810). Therefore, the rule would not impact a substantial number of small entities.

VII. Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The NRC requests public comment on the draft regulatory analysis. The regulatory analysis is available as indicated in the “Availability of Documents” section of this document. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES caption of this document.

VIII. Backfitting and Issue Finality

The proposed rule would apply to all current nuclear power plant licensees (including holders of renewed licenses under 10 CFR part 54, “Requirements for Renewal of Operating Licenses for Nuclear Power Plants,” and combined licenses under 10 CFR part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants”) and holders of licenses authorizing the possession, use, or transport of formula quantities of SSNM under 10 CFR part 70, “Domestic Licensing of Special Nuclear Material.” The proposed rule would apply to holders of a certificate of compliance or an approved compliance plan under the provisions of 10 CFR part 76, “Certification of Gaseous Diffusion Plants,” if the holder engages in activities involving formula quantities of SSNM. Some or all of the proposed rule would apply to: (i) current and future applicants for

combined licenses under 10 CFR part 52 who have been issued a limited work authorization (LWA) under § 50.10(e), if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related structures, systems, and components (SSCs) under the LWA; (ii) combined license holders before the Commission has made the finding under § 52.103(g); (iii) power reactor construction permit applicants (under 10 CFR part 50, "Domestic Licensing of Production and Utilization Facilities") who have been issued an LWA, if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA; (iv) power reactor construction permit holders; and (v) early site permit holders who have been issued an LWA, if the LWA authorizes the early site permit holder to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA.

The rule would constitute backfitting as defined under § 50.109(a)(1) for current holders of 10 CFR part 50 operating licenses and construction permits for power reactors and under § 70.76(a)(1) for applicable current 10 CFR part 70 licensees. The NRC has performed a backfit analysis consistent with NUREG/BR-0058, Revision 4, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." The backfit analysis can be found at appendix E of the regulatory analysis. The NRC has determined the backfitting is justified because: 1) there would be a substantial increase in the overall level of protection of the public health and safety or the common defense and security to be derived from the backfitting and 2) the costs of implementation and the annual costs would be justified in view of this increase.

Imposing the requirements of the proposed rule on current holders of combined licenses would represent an inconsistency with the issue finality provision applicable to combined licenses under § 52.98, "Finality of combined licenses; information requests." Therefore, the NRC has addressed the criteria in § 52.98 that would allow imposition of

the proposed rule on current holders of combined licenses, despite the issue finality accorded to the combined license holders. The NRC believes that the proposed rule may be imposed as a cost-justified substantial increase in the protection of the public health and safety or common defense and security. The bases for this determination are presented in the backfit analysis found in appendix F of the regulatory analysis.

Imposing the requirements of the proposed rule on current and future applicants for power reactor construction permits under 10 CFR part 50, part 70 licenses, or early site permits or combined licenses under 10 CFR part 52 would not constitute backfitting. Neither § 50.109, "Backfitting," nor the issue finality provisions for early site permits or combined licenses under 10 CFR part 52 protect either a current or prospective applicant for a construction permit, part 70 license, early site permit, or combined license from changes in the NRC rules and regulations. The NRC has long adopted the position that § 50.109 does not protect current or prospective applicants from changes in NRC requirements or guidance because the policies underlying § 50.109 are largely inapplicable in the context of a current or future application. This position also applies to each of the issue finality provisions under 10 CFR part 52.

The provisions under 10 CFR part 26 also apply to applicants for construction permits, early site permits, or combined licenses who have been issued an LWA, if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA. As of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, no LWAs have been issued to an applicant for a construction permit, early site permit, or combined license, so no such entity is protected by the backfitting and issue finality provisions from the changes proposed in this rulemaking.

Similarly, no entity holds a certificate of compliance or an approved compliance plan under the provisions of 10 CFR part 76, so no entity is protected by the backfitting provisions of § 76.76, “Backfitting,” from the changes proposed in this rulemaking.

Draft Regulatory Guidance

The guidance in DG-5040 presents methods acceptable to the NRC for implementing portions of this proposed rule. The draft guide would apply to current holders of nuclear power plant licenses (including holders of renewed licenses under 10 CFR part 54 and combined licenses under 10 CFR part 52) and current holders of licenses authorizing the possession, use, or transport of formula quantities of SSNM under 10 CFR part 70. The DG would also apply to holders of a certificate of compliance or an approved compliance plan under the provisions of 10 CFR part 76 if the holder engages in activities involving formula quantities of SSNM.

The DG would also apply to the following current and future entities: 1) applicants for combined licenses under 10 CFR part 52 who have been issued an LWA under § 50.10(e), if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA; 2) combined license holders before the Commission has made the finding under § 52.103(g); 3) power reactor construction permit applicants (under 10 CFR part 50) who have been issued an LWA, if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA; 4) power reactor construction permit holders; and 5) early site permit holders who have been issued an LWA, if the LWA authorizes the early site permit holder to install the foundations, including the placement of concrete, for safety- and security-related

SSCs under the LWA, if these entities elect to implement an FFD program that meets the requirements of subparts A through H, N, and O of 10 CFR part 26.

Issuance of the DG in final form would not constitute backfitting under 10 CFR part 50, 70, or 76 and would not otherwise be inconsistent with the issue finality provisions under 10 CFR part 52. As discussed in the "Implementation" section of the DG, the NRC has no current intention to impose the DG, if finalized, on current holders of 10 CFR part 50 operating licenses or construction permits, 10 CFR part 52 combined licenses or early site permits, 10 CFR part 70 licenses, or 10 CFR part 76 certificates of compliance or approved compliance plans.

The DG, if finalized, could be applied to applicants for 10 CFR part 50 operating licenses or construction permits for power reactors, 10 CFR part 52 combined licenses or early site permits, licenses issued under 10 CFR part 70, or 10 CFR part 76 certificates of compliance or approved compliance plans. Such action would not constitute backfitting as defined under § 50.109, § 70.76, or § 76.76, or be otherwise inconsistent with the applicable issue finality provisions under 10 CFR part 52, inasmuch as such applicants are not within the scope of entities protected by § 50.109, § 70.76, § 76.76, or the relevant issue finality provisions under 10 CFR part 52, except in one circumstance. The exception to this principle is a combined license, early site permit, or construction permit applicant that has been issued an LWA, if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA. However, that exception would provide backfitting and issue finality protection for the LWA holder only to the extent that it conducts activities under the LWA.

IX. Cumulative Effects of Regulation

The NRC seeks to minimize any potential negative consequences resulting from the cumulative effects of regulation (CER). The CER describes the challenges that licensees, or other impacted entities such as State partners, may face while implementing new regulatory positions, programs, or requirements (e.g., rules, generic letters, backfits, inspections). The CER is an organizational effectiveness challenge that may result from a licensee or impacted entity implementing a number of complex regulatory positions, programs, or requirements within limited available resources.

In an effort to better understand the potential CER implications incurred due to this proposed rule, the NRC is requesting comment on the following questions. Responding to these questions is voluntary, and the NRC will respond to any comments received in the final rule.

1. In light of any current or projected CER challenges, does the proposed rule's effective date provide sufficient time to implement the new proposed requirements, including changes to programs, procedures, and the facility?

2. If current or projected CER challenges exist, what should be done to address this situation? For example, if more time is required for implementation of the new requirements, what period of time is sufficient?

3. Do other regulatory actions (from the NRC or other agencies) influence the implementation of the proposed rule's requirements?

4. Are there unintended consequences? Does the proposed rule create conditions that would be contrary to the proposed rule's purpose and objectives? If so, what are the unintended consequences, and how should they be addressed?

5. Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports the proposed rule.

X. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31885). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

XI. Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described under § 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed rule.

XII. Paperwork Reduction Act Statement

This proposed rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This proposed rule has been submitted to the Office of Management and Budget (OMB) for review and approval of the information collection(s).

Type of submission, new or revision: Revision.

The title of the information collection: 10 CFR Part 26, Fitness for Duty Drug Testing Requirements.

The form number if applicable: Not applicable.

How often the collection is required: Once and annually. One-time information collections include the licensee or other entity of each FFD program completing revisions to the FFD program policy and FFD procedures, to distribute information on the FFD program policy updates to individuals subject to 10 CFR part 26, and for those subject individuals to review the information on the FFD program policy changes. Annual information collections include the licensee or other entity of each FFD program submitting an FFD program performance report to the NRC to provide information on the additional positive drug test results that would result from the proposed rule changes. On occasion, a third party disclosure would be made for each additional positive drug test result from the proposed rule changes. Also, on occasion, the license or other entity would report information to the NRC in the form of a 24-hour event report when some individuals (e.g., licensed reactor operators, supervisors) test positive as a result of the proposed rule changes.

Who will be required or asked to report: Licensees of nuclear power reactor sites (operating and under construction), licensees of Category I fuel cycle facilities, contractors/vendors, HHS-certified laboratories, and individuals with a positive drug test result.

An estimate of the number of annual responses: 7,813 (33 recordkeepers + 68 reporting responses + 7,712 third-party disclosures).

The estimated number of annual respondents: 149 (27 FFD programs, 12 HHS-certified laboratories, 6 licensee testing facilities, and 104 individuals with a positive drug test result).

An estimate of the total number of hours needed annually to complete the requirement or request: 1,382 (559 hours recordkeeping + 71 hours reporting + 752 hours third-party disclosure).

Abstract: 10 CFR part 26 contains the NRC's requirements for licensee and other entity FFD programs, which focus on preventing and detecting the impairment of personnel from the misuse of legal drugs and alcohol, use of illegal drugs, fatigue, and any other causes such as mental or psychological distress. The NRC is seeking to update the drug testing panel and to lower the testing cutoff levels for some drugs tested, which would impact the information collections contained in 10 CFR part 26, because additional individuals would likely test positive for drugs. The expected additional positive test results would increase the recordkeeping and reporting burdens on licensees and other entities. The NRC is proposing to include new information collection requirements in §§ 26.107(d), 26.157(a), 26.165(b)(2) and (b)(3), 26.165(f)(1) and 26.185(f)(3). This information is needed to uniformly address subversion attempts identified at the collection site (§ 26.107(d)), clarify that HHS-certified laboratories are to maintain testing procedures specific to 10 CFR part 26 (§ 26.157(a)), permit the MRO to initiate retesting of a donor specimen upon receiving an oral request from the donor and maintaining a record of receiving that request (§ 26.165(b)(2) and (b)(3)), document the existing process that the MRO is to report a cancelled test result to the licensee or other entity if the results of specimen retesting fail to confirm the test results from the initial laboratory (§ 26.165(f)(1)), and establish procedures to review invalid specimen test results due to high pH values (§ 26.165(f)(3)).

The NRC is seeking public comment on the potential impact of the information collection(s) contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of burden of the proposed information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the OMB clearance package and proposed rule is available in ADAMS under Accession No. ML16123A003 or may be viewed free of charge at the NRC's PDR, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, MD 20852. You may obtain information and comment submissions related to the OMB clearance package by searching on https://www.regulations.gov under Docket ID NRC-2009-0225.

You may submit comments on any aspect of these proposed information collection(s), including suggestions for reducing the burden and on the above issues, by the following methods:

- **Federal rulemaking Web Site**: Go to https://www.regulations.gov and search for Docket ID NRC-2009-0225.

- **Mail comments to**: Information Services Branch: T6-A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0146), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e-mail: oira_submission@omb.eop.gov.

Submit comments by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XIII. Compatibility of Agreement State Regulations

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' approved by the Commission on June 30, 1997, and published in the *Federal Register* (62 FR 46517; September 3, 1997), this rule is classified as compatibility ''NRC.'' Compatibility is not required for Category ''NRC'' regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of title 10 of the *Code of Federal Regulations*, and although an Agreement State may not adopt program elements reserved to the NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws but does not confer regulatory authority on the State.

XIV. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is

inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC is proposing to update and enhance the consistency of 10 CFR part 26 with the 2008 HHS Guidelines; improve the effectiveness and efficiency of FFD programs with regard to drug testing; and improve clarity in the organization and language of the rule. This action would not constitute the establishment of a voluntary consensus standard that contains generally applicable requirements.

XV. Availability of Guidance

The NRC is issuing for comment new draft regulatory guidance, Draft Regulatory Guide DG-5040, "Urine Specimen Collection and Test Result Review under 10 CFR Part 26, Fitness for Duty Programs," to support the implementation of the proposed requirements in this rulemaking. You may access information and comment submissions related to the DG by searching on https://www.regulations.gov under Docket ID NRC-2009-0225. Comments on the DG may be submitted to the NRC as indicated under the ADDRESSES caption of this document.

The guidance describes methods that the NRC would consider acceptable for complying with some of the proposed changes in this notice. For example, guidance would be provided concerning monitoring of a donor during the 3-hour hydration period, use of reflective mirrors for directly observed collections, use of a same-gender observer other than the collector during a directly observed collection, and MRO review of invalid test results due to high pH.

XVI. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

DOCUMENT	ADAMS ACCESSION NO. / *FEDERAL REGISTER* CITATION
1988 HHS Guidelines – Final Guidelines (April 11, 1988)	53 FR 11970
1994 HHS Guidelines – Revised Mandatory Guidelines (June 9, 1994)	59 FR 29908
1998 HHS Guidelines – Revised Mandatory Guidelines (November 13, 1998)	63 FR 63483
2004 HHS Guidelines – Notice of Proposed Revisions to Mandatory Guidelines (April 13, 2004)	69 FR 19673
2004 HHS Guidelines – Revised Mandatory Guidelines (April 13, 2004)	69 FR 19643
2008 HHS Guidelines – Revised Mandatory Guidelines (November 25, 2008)	73 FR 71858
2008 HHS Guidelines – Revised Mandatory Guidelines, Correction of Effective Date (December 10, 2008)	73 FR 75122
2008 HHS Guidelines – Revised Mandatory Guidelines, Change in Effective Date (April 30, 2010)	75 FR 22809
2017 HHS Guidelines – Revised Mandatory Guidelines (January 23, 2017)	82 FR 7920
1989 NRC 10 CFR Part 26 final rule (June 7, 1989)	54 FR 24468
1993 NRC 10 CFR Part 26 final rule (June 3, 1993)	58 FR 31467
2008 NRC 10 CFR Part 26 final rule (March 31, 2008)	73 FR 16966
2009 NRC 10 CFR Part 26 final rule, correcting amendment (August 3, 2009)	74 FR 38326
Policy Statement on Adequacy and Compatibility of Agreement State Programs (September 3, 1997)	62 FR 46517
Presidential Memorandum, “Plain Language in Government Writing” (June 10, 1998)	63 FR 31885
2001 DOT 49 CFR Part 40 final rule, Procedures for Transportation Workplace Drug and Alcohol Testing Programs; Technical Amendments (August 9, 2001)	66 FR 41944
2010 DOT 49 CFR Part 40 final rule, Procedures for Transportation Workplace Drug and Alcohol Testing Programs (August 16, 2010)	75 FR 49850
2014 National Drug Control Strategy (July 9, 2014)	ML19169A230

DOCUMENT	ADAMS ACCESSION NO. / *FEDERAL REGISTER* CITATION
Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health (September 2015), HHS Publication No. SMA 15-4927	ML19169A160
Commission Policy Statement on Fitness for Duty of Nuclear Power Plant Personnel (August 4, 1986)	51 FR 27921
Cook J.D., Strauss K.A., Caplan Y.H., LoDico C.P., and Bush D.M. (2007), "Urine pH: the effects of time and temperature after collection," Journal of Analytical Toxicology, Vol. 31, 486 – 496.	ML19169A178
Executive Order 12564 (September 17, 1986)	51 FR 32889
NRC Draft Regulatory Guide DG-5040, "Urine Specimen Collection and Test Result Review under 10 CFR Part 26, 'Fitness for Duty Programs'" (August 2019).	ML19116A077
NRC Enforcement Guidance Memorandum – Dispositioning Violations of NRC Requirements for Initial Validity and Drug Tests at Licensee Testing Facilities (EGM-09-003) (March 31, 2009)	ML090760728
NRC Public Meeting Summary (February 24, 2009)	ML090771060
NRC Public Meeting Summary (June 24, 2009)	ML091910511
NRC Public Meeting Summary and Meeting Materials (October 11, 2011)	ML112930153
NRC Public Meeting Summary (September 11, 2013)	ML13290A236
NRC Regulatory Analysis and Backfit Analysis, Fitness For Duty Drug Testing Requirements (August 2019)	ML19169A115
NRC Regulatory Analysis Guidelines, NUREG/BR–0058, Revision 4 (September 30, 2004)	ML042820192
NRC Regulatory Basis: Proposed Rulemaking to Amend 10 CFR Part 26, "Fitness for Duty Programs," based on Select Provisions of the 2008 HHS Guidelines (May 10, 2013)	ML13066A703
NRC report "Summary of Fitness for Duty Program Performance Reports for Calendar Year 2013" (September 3, 2014)	ML14246A440

DOCUMENT	ADAMS ACCESSION NO. / *FEDERAL REGISTER* CITATION
NRC report "Summary of Fitness for Duty Program Performance Reports for Calendar Year 2012" (August 13, 2013)	ML13225A131
NRC report "Summary of Fitness for Duty Program Performance Reports for Calendar Year 2011" (August 1, 2012)	ML12151A270
Quest Diagnostics (2011). Impacts of Panel Changes – The First Three Months (January 25, 2011)	ML19169A153
Quest Diagnostics (2012). Cocaine Positives Spike 33% After New Government Rule for Safety-Sensitive Workers (March 13, 2012)	ML19169A156
Quest Diagnostics. (2014). Workforce Drug Test Positivity Rate Increases for the First Time in 10 Years, Driven by Marijuana and Amphetamines, Finds Quest Diagnostics Drug Testing Index™ Analysis of Employment Drug Tests (Press Release and Drug Testing Index, 2014 Report) (September 11, 2014)	ML19169A147

List of Subjects

10 CFR Part 26

Administrative practice and procedure, Alcohol abuse, Alcohol testing, Appeals, Chemical testing, Drug abuse, Drug testing, Employee assistance programs, Fitness for duty, Management actions, Nuclear power plants and reactors, Privacy, Protection of information, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553 the NRC is proposing to adopt the following amendments to 10 CFR part 26:

PART 26—FITNESS FOR DUTY PROGRAMS

1. The authority citation for part 26 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 103, 104, 107, 161, 223, 234, 1701 (42 U.S.C. 2073, 2133, 2134, 2137, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

2. Amend part 26, wherever they may occur by:
   a. Removing the term “custody-and-control form” and adding in its place the term “Federal CCF”;
   b. Removing the term “custody-and-control forms” and adding in its place the term “Federal CCFs.”
   c. Removing the term “custody-and-control form(s)” and adding in its place the term “Federal CCF(s)”; and
   d. Removing the phrase “chain-of-custody” and adding in its place the phrase “chain of custody”.

3. Amend § 26.4 by:
   a. Removing in paragraph (e)(6)(iv), the phrase “(65 FR 41944; August 9, 2001)”;
   b. Removing in paragraph (g)(4), word “and” at the end;
   c. Removing in paragraph (g)(5), the period at the end and add in its place “; and”;

d. Adding new paragraph (g)(6); and

e. Revising paragraph (j)(3).

The additions and revisions read as follows:

§ 26.4 FFD program applicability to categories of individuals.

***** ***** ***** ***** *****

(g) * * *

(6) All persons monitoring a donor during the hydration process described in § 26.109(b).

***** ***** ***** ***** *****

(j) * * *

(3) Urine specimens are tested for validity and the presence of drugs and drug metabolites at a Department of Health and Human Services (HHS)-certified laboratory, as defined in § 26.5;

***** ***** ***** ***** *****

4. Amend § 26.5 by:

a. Adding the definitions for *cancelled test*, *carryover*, *Certifying Scientist*, *Federal custody and control form (Federal CCF), lot*, *rejected for testing*, and *Responsible Person* in alphabetical order; and

b. Revising the definitions for *calibrator*, *control*, *dilute specimen*, *HHS-certified laboratory*, *invalid result*, *limit of quantitation*, and *substituted specimen*.

The additions and revisions read as follows:

§ 26.5 Definitions.

*** * * * ***

Calibrator means a solution of known concentration in the appropriate matrix that is used to define expected outcomes of a measurement procedure or to compare the response obtained with the response of a donor specimen or quality control sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation.

*** * * * ***

Cancelled test means the test result reported by the MRO to the licensee or other entity when a specimen has been reported to the MRO by the HHS-certified laboratory as an invalid result (for which the donor has no legitimate explanation), a specimen has been rejected for testing by the licensee testing facility or HHS-certified laboratory, or the retesting of a single specimen or the testing of Bottle B of a split specimen fails to reconfirm the original test result. For alcohol testing only, *cancelled test* means a test result that was not acceptable because testing did not meet the quality assurance and quality control requirements in § 26.91.

* * * * *

Carryover means the effect that occurs when a test result has been affected by a preceding sample or specimen during analysis.

* * * * *

Certifying Scientist means the individual at an HHS-certified laboratory responsible for verifying the chain of custody and scientific reliability of any test result reported by an HHS-certified laboratory.

* * * * *

Control means a sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

* * * * *

Dilute specimen means a urine specimen with creatinine and specific gravity values that are lower than expected but are still within the physiologically producible ranges of human urine.

* * * * *

Federal custody and control form (Federal CCF) means any HHS-approved form, which has not expired, that is published in the *Federal Register* and is used to document the collection, custody, transport, and testing of a specimen.

* * * * *

HHS-certified laboratory means a laboratory that is certified to meet the standards of the *Mandatory Guidelines for Federal Workplace Drug Testing Programs* (the HHS Guidelines) at the time that drug and validity testing of a specimen is performed for a licensee or other entity.

* * * * *

Invalid result means the result reported by an HHS-certified laboratory in accordance with the criteria established in § 26.161(f) when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

* * * * *

Limit of quantitation (LOQ) means for quantitation assays, the lowest concentration at which the identity and concentration of the analyte can be accurately established.

* * * * *

Lot means a number of units of an item (e.g., drug test kits, reagents, quality control samples) manufactured from the same starting materials within a specified period of time for which the manufacturer states that the items have essentially the same performance characteristics and the same expiration date.

* * * * *

Rejected for testing means the result reported to the MRO by a licensee testing facility or HHS-certified laboratory when no tests can be performed on a specimen.

* * * * *

Responsible Person means the person at the HHS-certified laboratory who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory.

* * * * *

Substituted specimen means a specimen that has been submitted in place of the donor's urine, as evidenced by creatinine and specific gravity values that are outside the physiologically producible ranges of human urine.

* * * * *

§ 26.8 [Amended]

5. In § 26.8, remove the reference "26.155" in paragraph (b).

6. Amend § 26.31 by:

a. Removing in paragraph (b)(2) the phrase “(65 FR 41944; August 9, 2001)”;

b. Revising paragraph (d)(1) introductory text;

c. Removing in paragraph (d)(1)(i)(D) the phrase “, as specified in § 26.155(a)” at the end of the second sentence; and

d. Revising in paragraph (d)(1)(ii) the third sentence.

The revisions read as follows:

§ 26.31 Drug and alcohol testing.

*** * * * ***

(d) * * *

(1) *Substances tested*. At a minimum, licensees and other entities shall test for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, and 6-acetylmorphine), amphetamines (amphetamine, methamphetamine, methylenedioxymethamphetamine, and methylenedioxyamphethamine), phencyclidine, adulterants, and alcohol.

*** * * * ***

(ii) * * * Test results that fall below the established cutoff levels may not be considered when determining appropriate action under subpart D of this part, except if

special analyses of the specimen is performed under § 26.163(a)(2) by the HHS-certified laboratory.

* * * * *

7. Amend § 26.89 by:

   a. Removing in paragraph (c) in the first sentence, the words “adulterated, diluted, or adulterated the specimen” and adding in its place the words “adulterated, diluted, or substituted the specimen”; and

   b. Revising paragraph (d) to read as follows:

§ 26.89 Preparing to collect specimens for testing.

* * * * *

(d) In order to promote the security of specimens, avoid distraction of the collector, and ensure against any confusion in the identification of specimens, a collector shall conduct only one collection procedure at any given time, except as described in § 26.109(b)(1). The urine collection procedure is complete when the urine specimen container has been sealed with tamper-evident tape, the seal has been dated and initialed, and the Federal CCF has been completed or when a refusal to test has been determined under § 26.107(d).

8. In § 26.107, revise paragraph (b) and add paragraph (d) to read as follows:

§ 26.107 Collecting a urine specimen.

*** * * * ***

(b)(1) The collector shall pay attention to the donor during the entire collection process, except as provided in § 26.109(b)(1), to observe any conduct that indicates an attempt to subvert the testing process (e.g., tampering with a specimen; having a substitute urine in plain view; attempting to bring an adulterant, urine substitute, heating element, and/or temperature measurement device into the room, stall, or private area used for urination). If any such conduct is detected, the collector shall document a description of the conduct on the Federal CCF and contact FFD program management to determine whether a directly observed collection is required, as described in § 26.115.

(2) If a hydration monitor is used to observe a donor during the § 26.109(b)(1) hydration process, this individual shall immediately inform the collector of any donor conduct that may indicate an attempt to subvert the testing process (e.g., donor leaves the collection site, donor refuses to follow instructions).

*** * * * ***

(d) If a refusal to test is determined at any point during the specimen collection process, the collector shall do the following:

(1) Inform the donor that a refusal to test has been determined;

(2) Terminate the collection process;

(3) Document a description of the refusal to test on the Federal CCF;

(4) Discard any urine specimen(s) provided by the donor, unless the specimen was collected for a post-event test under § 26.31(c)(3); and

(5) Immediately inform the FFD program manager.

9. In § 26.109, revise paragraph (b)(1) and add a new first sentence to paragraph (b)(2) to read as follows:

§ 26.109 Urine specimen quantity.

*** * * * ***

(b) * * *

(1) The collector shall encourage the donor to drink a reasonable amount of liquid (normally, 8 ounces of water every 30 minutes, but not to exceed a maximum of 40 ounces over 3 hours) until the donor provides a specimen of at least 30 mL. Alternatively, as specified in the licensee's or other entity's FFD program procedures, the collector may assign responsibility for monitoring a donor during the hydration process to another collector who meets the requirements in § 26.85(a) or to a hydration monitor who meets the requirements in § 26.4(g)(6). If another collector or hydration monitor is used, the collector:

(i) Shall explain the hydration process and acceptable donor behavior to the hydration monitor;

(ii) Shall record the name of the other collector or hydration monitor on the Federal CCF and then provide the Federal CCF to that individual for the duration of the hydration process; and

(iii) May perform other collections while the donor is in the hydration process;

(2) The collector shall provide the donor with a separate collection container for each successive specimen. * * *

*** * * * ***

10. Amend § 26.111 by:

a. Revising paragraph (a);

b. Removing in paragraph (c) the first sentence the word “designated” and revising the third sentence;

c. Revising paragraph (e); and

d. Removing paragraph (f).

The revisions read as follows:

§ 26.111 Checking the acceptability of the urine specimen.

(a) Immediately after the donor provides the urine specimen to the collector, including specimens of less than 30 mL but equal to or greater than 15 mL, the collector shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement may not exceed 4 minutes. If the temperature of a urine specimen is outside the range of 90 °F to 100 °F (32 °C to 38 °C), that is a reason to believe the donor may have altered (e.g., adulterated or diluted) or substituted the specimen.

***** ***** ***** ***** *****

(c) * * * In addition, the collector shall inform the donor that he or she may volunteer to submit a second specimen under direct observation to counter the reason to believe the donor may have altered (e.g., adulterated or diluted) or substituted the specimen.

* * * * *

(e) As much of the suspect specimen as possible must be preserved, except under the conditions described in § 26.107(d)(4).

11. Amend § 26.115 by:

a. Republishing paragraph (a) introductory text, revising paragraphs (a)(3) and (4), and adding paragraph (a)(5);

b. Revising paragraph (e);

c. Revising paragraph (f) introductory text, republishing paragraph (f)(1), and revise paragraphs (f)(2) and (3); and

d. Revising paragraph (g).

The additions and revisions read as follows:

§ 26.115 Collecting a urine specimen under direct observation.

(a) Procedures for collecting urine specimens must provide for the donor's privacy unless directed by this subpart or the MRO or FFD program manager determines that a directly observed collection is warranted. The following circumstances constitute the exclusive grounds for performing a directly observed collection:

* * * * *

(3) The collector, or the hydration monitor if one is used as permitted in § 26.109(b)(1), observes conduct by the donor indicating an attempt to subvert the testing process;

(4) A directly observed collection is required under § 26.69; or

(5) The donor requests a retest and either Bottle B or the single specimen is not available due to circumstances outside of the donor's control, as described in § 26.165(f)(2).

***** ***** ***** ***** *****

(e) The collector shall ensure that the observer is the same gender as the donor. A person of the opposite gender may not act as the observer under any conditions. The observer may be a different person from the collector and need not be a qualified collector. If the observer is not a qualified collector, the collector shall, in the presence of the donor, instruct the observer on the collection procedures in paragraph (f) of this section before proceeding with the directly observed collection.

(f) The individual who observes the collection shall follow these procedures:

(1) The observer shall instruct the donor to adjust his or her clothing to ensure that the area of the donor's body between the waist and knees is exposed;

(2) The observer shall watch the donor urinate into the collection container. Specifically, the observer shall watch the urine go from the donor's body into the collection container. A reflective mirror may be used to assist in observing the provision of the specimen only if the physical configuration of the room, stall, or private area is not sufficient to meet this direct observation requirement; the use of a video camera to assist in the observation process is not permitted;

(3) If the observer is not the collector, the observer may not touch or handle the collection container but shall maintain visual contact with the specimen until the donor hands the collection container to the collector; and

* * * * *

(g) If a donor declines to allow a directly observed collection that is required or permitted under this section, the donor's refusal constitutes an act to subvert the testing process, and the collector shall follow the procedures in § 26.107(d).

* * * * *

12. Amend § 26.117 by:

a. Revising paragraph (a);

b. Revising the first sentence in paragraph (f); and

c. Adding in paragraph (g) the phrase “, except as provided in § 26.109(b)(1)(ii) for the Federal CCF” to the end of the first sentence.

The revisions read as follows:

§ 26.117 Preparing urine specimen for storage and shipping

(a) Once the collector is presented with the specimen from the donor, both the donor and the collector shall keep the donor’s urine specimen(s) in view at all times before the specimen(s) are sealed and labeled. If any specimen or aliquot is transferred to another container, the collector shall ask the donor to observe the transfer and sealing of the container with a tamper-evident seal.

* * * * *

(f) The specimens and Federal CCFs must be packaged for transfer to the HHS-certified laboratory or to the licensee testing facility.* * *

* * * * *

13. In § 26.129, revise paragraphs (b)(1)(ii) and (b)(2) introductory text to read as follows:

§ 26.129 Assuring specimen security, chain of custody, and preservation.

* * * * *

(b) * * *

(1) * * *

(ii) If there is reason to believe that the integrity or identity of a specimen is in question (as a result of tampering or discrepancies between the information on the specimen bottle and on the accompanying Federal CCFs that cannot be resolved), the licensee testing facility shall reject the specimen for testing. The licensee or other entity shall ensure that another collection occurs as soon as reasonably practical, except if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine. In this instance, the licensee testing facility shall forward the intact specimen for testing to the HHS-certified laboratory and may not conduct any testing at the licensee testing facility.

(2) The following are exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen and report a cancelled test result to the licensee or other entity:

* * * * *

14. Revise § 26.133 to read as follows:

§ 26.133 Cutoff levels for drugs and drug metabolites.

Subject to the provisions of § 26.31(d)(3)(iii), licensees and other entities may specify more stringent cutoff levels for drugs and drug metabolites than those in the table below and, in such cases, may report initial test results for only the more stringent cutoff levels. Otherwise, the following cutoff levels must be used for initial testing of urine specimens to determine whether they are negative or positive for the indicated drugs and drug metabolites:

INITIAL TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drugs or drug metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana metabolites	50
Cocaine metabolites	150
Opiate metabolites:	
Codeine/Morphine[1]	2000
6-acetylmorphine (6-AM)	10
Phencyclidine (PCP)	25
Amphetamines[2]:	
AMP/MAMP[3]	500
MDMA[4]/MDA[5]	500

[1] Morphine is the target analyte for codeine/morphine testing.
[2] Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.
[3] Methamphetamine (MAMP) is the target analyte for amphetamine (AMP)/MAMP testing.
[4] Methylenedioxymethamphetamine.
[5] Methylenedioxyamphetamine.

15. In § 26.137, revise paragraphs (d)(5), (e)(6)(i) through (iii), and (e)(6)(v) to read as follows:

§ 26.137 Quality assurance and quality control.

* * * * *

(d) * * *

(5) Each analytical run performed to conduct initial validity testing shall include at least one quality control sample that appears to be a normal specimen to the licensee testing facility technicians.

* * * * *

(e) * * *

(6) A minimum of 10 percent of the total specimens in each analytical run of specimens to be initially tested for drugs and drug metabolites by the licensee testing facility must be quality control samples (i.e., calibrators and controls), which the licensee testing facility shall use for internal quality control purposes. (These samples are not forwarded to the HHS-certified laboratory for further testing, other than for performance testing of the samples.) Licensee testing facilities shall ensure that quality control samples that are positive for each drug and drug metabolite for which the FFD program conducts testing are included in at least one analytical run each calendar quarter. The quality control samples for each analytical run must include—

(i) At least one control certified by an HHS-certified laboratory to contain no drug or drug metabolite;

(ii) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff;

(iii) At least one positive control with the drug or drug metabolite targeted at 75 percent of the cutoff;

* * * * *

(v) At least one quality control sample that appears to be a normal specimen to the licensee testing facility technicians.

* * * * *

16. In § 26.153, revise paragraphs (a) and (g) to read as follows:

§ 26.153 Using certified laboratories for testing urine specimens.

(a) Licensees and other entities who are subject to this part shall use only HHS-certified laboratories as defined in § 26.5.

* * * * *

(g) If licensees or other entities use a form other than the current Federal CCF, licensees and other entities shall provide a memorandum to the laboratory explaining why a non-Federal CCF was used, but must ensure, at a minimum, that the form used contains all the required information on the Federal CCF.

§ 26.155 [Removed and Reserved]

17. Remove and reserve § 26.155.

18. Amend § 26.157 by:

a. Revising paragraph (a),

b. Removing and reserving paragraph (b), and removing paragraphs (c) through (e).

The revisions read as follows:

§ 26.157 Procedures.

(a) HHS-certified laboratories shall develop, implement, and maintain procedures specific to this part that document the accession, receipt, shipment, and testing of specimens.

(b) [Reserved]

19. In § 26.159, revise paragraphs (b)(1)(ii), (b)(2) introductory text, the second sentence in paragraph (c), and paragraphs (d) and (e) to read as follows:

§ 26.159 Assuring specimen security, chain of custody, and preservation.

*** * * * ***

(b) * * *

(1) * * *

(ii) If the licensee or other entity has reason to question the integrity and identity of the specimens, the laboratory shall reject the specimens for testing. The licensee or other entity shall ensure that another collection occurs as soon as reasonably practical, except if a split specimen collection was performed, either the Bottle A or Bottle B seal

remains intact, and the intact specimen contains at least 15 mL of urine. In this instance, if the licensee testing facility has retained the specimen in Bottle B, the licensee testing facility shall forward the intact specimen for testing to the HHS-certified laboratory and may not conduct any testing at the licensee testing facility.

(2) The following are exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen and report a cancelled test to the licensee or other entity:

* * * * *

(c) * * * Laboratory personnel shall use aliquots and laboratory internal chain of custody forms when conducting initial and confirmatory tests.* * *

(d) The laboratory's internal chain of custody form must allow for identification of the donor and documentation of the testing process and transfers of custody of the specimen.

(e) Each time a specimen is handled or transferred within the laboratory, laboratory personnel shall document the date and purpose on the chain of custody form and every individual in the chain shall be identified. Authorized technicians are responsible for each urine specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

* * * * *

20. Amend § 26.161 by:

a. Removing in paragraphs (c)(3) and (c)(4), (f)(5), and (f)(7) the term “LOD” and adding in its place the term “LOQ”; and

b. Revising paragraphs (c)(5) and (c)(6).

The revisions read as follows:

§ 26.161 Cutoff levels for validity testing.

*** * * * ***

(c) * * *

(5) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and a different confirmatory test (e.g., gas chromatography/mass spectrometry (GC/MS)) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(6) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)- equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., GC/MS) for the confirmatory test with the pyridine concentration equal to or greater than the LOQ of the analysis on the second aliquot;

*** * * * ***

21. Amend § 26.163 by:

a. Republishing paragraph (a) introductory text,

b. Revising paragraphs (a)(1), (a)(2) introductory text, (a)(2)(i), and (ii),

c. Republishing paragraph (b) introductory text, and

d. Revising paragraph (b)(1).

The revisions read as follows:

§ 26.163 Cutoff levels for drugs and drug metabolites.

(a) *Initial drug testing.* (1) HHS-certified laboratories shall apply the following cutoff levels for initial testing of specimens to determine whether they are negative or positive for the indicated drugs and drug metabolites, except as specified in paragraph (a)(2) of this section or the licensee or other entity has established more stringent cutoff levels:

INITIAL TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drugs or drug metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana metabolites	50
Cocaine metabolites	150
Opiate metabolites:	
Codeine/Morphine[1]	2000
6-acetylmorphine (6-AM)	10
Phencyclidine (PCP)	25
Amphetamines[2]:	
AMP/MAMP[3]	500

MDMA[4]/MDA[5].....	500

[1] Morphine is the target analyte for codeine/morphine testing.
[2] Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.
[3] Methamphetamine (MAMP) is the target analyte for amphetamine (AMP)/MAMP testing.
[4] Methylenedioxymethamphetamine.
[5] Methylenedioxyamphetamine.

(2) HHS-certified laboratories shall conduct special analyses of specimens as follows:

(i) If initial validity testing indicates that a specimen is dilute, or if a specimen is collected under direct observation for any of the conditions specified in § 26.115(a)(1) through (a)(3) or (a)(5), the laboratory shall compare the immunoassay responses of the specimen to the cutoff calibrator in each drug class tested;

(ii) If any immunoassay response is equal to or greater than 40 percent of the cutoff calibrator, the laboratory shall conduct confirmatory drug testing of the specimen to the LOQ for those drugs and/or drug metabolites; and

***** ***** ***** ***** *****

(b) *Confirmatory drug testing*. (1) A specimen that is identified as positive on an initial drug test must be subject to confirmatory testing for the class(es) of drugs for which the specimen initially tested positive. The HHS-certified laboratory shall apply the confirmatory cutoff levels specified in this paragraph, except as permitted in paragraph (a)(2) of this section or the licensee or other entity has established more stringent cutoff levels.

CONFIRMATORY TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drugs or drug metabolites	Cutoff level (ng/mL)
Marijuana metabolite[1]	15
Cocaine metabolite[2]	100
Opiate metabolites:	
Morphine	2000
Codeine	2000
6-acetylmorphine (6-AM)	10
Phencyclidine (PCP)	25
Amphetamines:	
Amphetamine	250
Methamphetamine[3]	250
MDMA	250
MDA	250

[1] As delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).
[2] As benzoylecgonine.
[3] To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.

* * * * *

22. In § 26.165, revise the fourth sentence in paragraph (b)(2), paragraph (b)(3), the last sentence in paragraph (f)(1) introductory text, and paragraph (f)(2) to read as follows:

§ 26.165 Testing split specimens and retesting single specimens.

* * * * *

(b) * * *

(2) * * * The MRO shall document in his or her records when (i.e., date and time) the request was received from the donor to retest an aliquot of the single specimen or to test the Bottle B split specimen.

(3) No entity, other than the MRO as permitted in § 26.185(l), may order the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen.

* * * * *

(f) * * *

(1) * * * If the results of testing Bottle B or retesting the aliquot of a single specimen are negative, the MRO shall report a cancelled test result to the licensee or other entity, and the licensee and other entity—

* * * * *

(2) If a donor requests that Bottle B be tested or that an aliquot of a single specimen be retested, and either Bottle B or the single specimen are not available due to circumstances outside of the donor's control (including, but not limited to, circumstances in which there is an insufficient quantity of the single specimen or the specimen in Bottle B to permit retesting, either Bottle B or the original single specimen is lost in transit to the second HHS-certified laboratory, or Bottle B has been lost at the HHS-certified laboratory or licensee testing facility), the MRO shall cancel the test, report a cancelled test result to the licensee or other entity for the donor’s specimen, and inform the licensee or other entity that another collection is required under direct observation as soon as reasonably practical. The donor shall receive no notice of the collection requirement before he or she is instructed to proceed to the collection site. The licensee or other entity shall continue to administratively withdraw the individual’s authorization, as required by § 26.165(f)(1) until the results of the second specimen collection have been received by the MRO. The licensee or other entity shall eliminate from the donor's personnel and other records any matter that could link the donor to the

original positive, adulterated, or substituted test result(s) and any temporary administrative action, and may not impose any sanctions on the donor for a cancelled test. If test results from the second specimen collected are positive, adulterated, or substituted and the MRO determines that the donor has violated the FFD policy, the licensee or other entity shall impose the appropriate sanctions specified in subpart D of this part, but may not consider the original confirmed positive, adulterated, or substituted test result that was reported as a cancelled test by the MRO under §§ 26.129(b)(2) or 26.159(b)(2) in determining the appropriate sanctions.

23. Amend § 26.167 by:

a. Republishing paragraph (d)(3) introductory text, and revising paragraphs (d)(3)(i) through (iii);

b. Revising paragraph (d)(4);

c. Revising paragraph (e)(2), republishing paragraph (e)(3) introductory text, and revising paragraphs (e)(3)(i) through (iv); and

d. Removing in paragraph (f)(3) the third sentence, the words “responsible person” and adding in their place the words “Responsible Person”.

The revisions read as follows:

§ 26.167 Quality assurance and quality control.

*** * * * ***

(d) * * *

(3) Quality control samples for each analytical run of specimens for initial testing must include—

(i) At least one control certified to contain no drug or drug metabolite;

(ii) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff;

(iii) At least one positive control with the drug or drug metabolite targeted at 75 percent of the cutoff;

***** ***** ***** ***** *****

(4) A minimum of 10 percent of the total specimens in each analytical run must be quality control samples (i.e., calibrators and controls), as defined by paragraphs (d)(3)(i) through (iv) of this section.

(e) * * *

(2) A minimum of 10 percent of the total specimens in each analytical run must be quality control samples (i.e., calibrators and controls).

(3) Each analytical run of specimens that are subjected to confirmatory testing must include—

(i) At least one control certified to contain no drug or drug metabolite;

(ii) A calibrator with its drug concentration at the cutoff;

(iii) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff; and

(iv) At least one control targeted at or below 40 percent of the cutoff.

* * * * *

24. In § 26.168, revise paragraph (h)(1) to read as follows:

§ 26.168 Blind performance testing.

* * * * *

(h) * * *

(1) Ensure that all blind performance test sample lots are placed in service by the supplier only after confirmation by an HHS-certified laboratory;

* * * * *

25. Amend § 26.169 by:

a. Removing in paragraph (a), wherever they may appear, the words “certifying scientist” and adding in their place the words “Certifying Scientist”.

b. Republishing paragraph (h)(3) introductory text, and revising paragraphs (h)(3)(i) and (ii), (h)(3)(iii)(C), and (h)(3)(iv);

c. Republishing paragraph (h)(3)(v) introductory text and revising paragraph (h)(3)(v)(A); and

d. Adding new paragraphs (h)(3)(v)(C) through (D).

The additions and revisions read as follows:

§ 26.169 Reporting results.

* * * * *

(h) * * *

(3) Number of specimens reported as positive on confirmatory tests by drug or drug metabolite for which testing is conducted, including, but not limited to—

(i) Marijuana metabolite (as THCA);

(ii) Cocaine metabolite (as benzoylecgonine);

*****

(C) 6-acetylmorphine (6-AM);

(iv) Phencyclidine (PCP);

(v) Amphetamines (total);

(A) Amphetamine;

* * * * *

(C) Methylenedioxymethamphetamine (MDMA); and

(D) Methylenedioxyamphetamine (MDA);

* * * * *

26. In § 26.183, revise paragraphs (c) introductory text, (c)(1), and (d)(2)(ii) to read as follows:

§ 26.183 Medical review officer.

*** * * * ***

(c) *Responsibilities*. The primary role of the MRO is to review and interpret positive, adulterated, substituted, invalid, and dilute test results obtained through the licensee's or other entity's testing program and to identify any evidence of subversion of the testing process. The MRO is also responsible for identifying any issues associated with collecting and testing specimens, and for advising and assisting FFD program management in planning and overseeing the overall FFD program.

(1) In carrying out these responsibilities, the MRO shall examine alternate medical explanations for any positive, adulterated, substituted, invalid, or dilute test result. This action may include, but is not limited to, conducting a medical interview with the donor, reviewing the donor's medical history, or reviewing any other relevant biomedical factors. The MRO shall review all medical records that the donor may make available when a positive, adulterated, substituted, invalid, or dilute test result could have resulted from responsible use of legally prescribed medication, a documented condition or disease state, or the demonstrated physiology of the donor.

*** * * * ***

(d) * * *

(2) * * *

(ii) The staff reviews of positive, adulterated, substituted, invalid, and dilute test results must be limited to reviewing the Federal CCF to determine whether it contains any errors that may require corrective action and to ensure that it is consistent with the information on the MRO's copy. The staff may resolve errors in Federal CCFs that require corrective action(s), but shall forward the Federal CCFs to the MRO for review and approval of the resolution.

***** ***** ***** ***** *****

27. Amend § 26.185 by:

a. Redesignating paragraph (f)(3) as (f)(4), and adding new paragraph (f)(3);

b. Removing in paragraph (g)(1) the reference "paragraph (g)(4)" and adding in its place the reference "paragraph (g)(3)"; and

c. Revising paragraphs (g)(2) introductory text and (g)(2)(iii), removing paragraph (g)(3), and redesignating paragraphs (g)(4) and (g)(5) as paragraphs (g)(3) and (g)(4), respectively.

The addition and revisions read as follows:

§ 26.185 Determining a fitness-for-duty policy violation.

***** ***** ***** ***** *****

(f) * * *

(3) If the MRO and the laboratory agree that further testing would not be useful and there is no legitimate technical or medical explanation, and the invalid result is

based on pH in the range of 9.0 to 9.5, the MRO shall consider whether there is evidence of elapsed time, exposure of the specimen to high temperature, or both that could account for the pH value. If an acceptable explanation exists for the invalid test result due to pH, based on objective and sufficient information, that elapsed time, high temperature, or both caused the high pH and donor action did not result in the invalid pH result, the MRO shall report a cancelled test result to the licensee or other entity, cancel the test result, and direct the licensee or other entity to collect a second urine specimen from the donor as soon as reasonably practicable. The second specimen collected may not be collected under direct observation.

***** ***** ***** ***** *****

(g) * * *

(2) If the results of the special analysis testing required by § 26.163(a)(2) are positive, the MRO determines that there is no legitimate medical explanation for the presence of the drug(s) or drug metabolite(s) in the specimen, and a clinical examination, if required under paragraph (g)(3) of this section, has been conducted under paragraph (j) of this section, the MRO shall determine whether the positive and dilute specimen is a refusal to test. If the MRO does not have sufficient reason to believe that the positive and dilute specimen is a subversion attempt, he or she shall determine that the drug test results are positive and that the donor has violated the FFD policy. When determining whether the donor has diluted the specimen in a subversion attempt, the MRO shall also consider the following circumstances, if applicable:

***** ***** ***** ***** *****

(iii) The collector observed conduct indicating an attempt to dilute the specimen.

* * * * *

28. In § 26.405, revise paragraph (d) to read as follows:

§ 26.405 Drug and alcohol testing.

* * * * *

(d) At a minimum, licensees and other entities shall test specimens for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, and 6-acetylmorphine), amphetamines (amphetamine, methamphetamine, methylenedioxymethamphetamine, and methylenedioxyamphetamine), phencyclidine, adulterants, and alcohol at the cutoff levels specified in this part, or comparable cutoff levels if specimens other than urine are collected for drug testing. Urine specimens collected for drug testing must be subject to validity testing.

* * * * *

§ 26.415 [Amended]

29. In § 26.415 paragraph (c), remove the citation, “(65 FR 41944; August 9, 2001)”.

30. In § 26.717, revise paragraphs (b)(3) and (4) to read as follows:

§ 26.717 Fitness-for-duty program performance data.

* * * * *

(b) * * *

(3) Populations tested (i.e., licensee or other entity employees, C/Vs);

(4) Number of tests administered and results of those tests sorted by population tested (i.e., licensee or other entity employees, C/Vs);

* * * * *

Dated at Rockville, Maryland, this 22nd day of August, 2019.

For the Nuclear Regulatory Commission.

Russell E. Chazell,
Acting Secretary of the Commission.

[FR Doc. 2019-18491 Filed: 9/13/2019 8:45 am; Publication Date: 9/16/2019]