[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: Final rule and guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations regarding fitness for duty (FFD) programs for certain NRC licensees and other entities to align the NRC's drug testing requirements more closely with the updates made to the U.S. Department of Health and Human Services' "Mandatory Guidelines for Federal Workplace Drug Testing Programs" in 2008 and as revised in 2017. This final rule also incorporates lessons learned from implementing the NRC's current FFD regulations. These changes 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. This final rule provides additional protections to individuals subject to drug testing and improves the clarity, organization, and flexibility of the NRC's FFD regulations. This final rule provides a new flexibility for the collection and drug testing of an oral fluid specimen as an alternative to the collection and testing of a urine specimen under direct observation conditions. The NRC also is issuing final implementation guidance for this final rule.

DATES: *Effective Date*: This final rule is effective **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. *Compliance Date*: Compliance with this final rule is required by **[INSERT DATE 1 YEAR AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: 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 Website:** Go to https://www.regulations.gov and search for Docket ID NRC-2009-0225. Address questions about NRC dockets to Dawn Forder; telephone: 301-415-3407; email: Dawn.Forder@nrc.gov. For technical questions, contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **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, at 301-415-4737, or by email 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.

- **Attention**: The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at pdr.resource@nrc.gov or call 1-800-397-4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Stewart Schneider, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-4123; email: Stewart.Schneider@nrc.gov; or Brian Zaleski, Office of Nuclear Security and Incident Response, telephone: 301-287-0638; email: Brian.Zaleski@nrc.gov. Both are staff of the 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 amending its regulations regarding fitness for duty (FFD) programs for certain NRC licensees and other entities to align the NRC's drug testing requirements more closely with U.S. Department of Health and Human Services' (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (HHS Guidelines). 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) that test civilians in safety- and security-sensitive positions similar to personnel tested under the NRC's program in part 26 of title 10 of the *Code of Federal Regulations* (10 CFR), "Fitness for Duty Programs". The NRC published a proposed rule (84 FR 48750; September 16, 2019) to align its drug testing provisions under 10 CFR part 26 more closely with HHS Guidelines published in the *Federal Register* on November 25, 2008 (73 FR 71858), effective October 1, 2010 (75 FR 22809; April 30, 2010), and to seek public input on further aligning the NRC's provisions with the HHS Guidelines published January 23, 2017 (82 FR 7920), effective on October 1, 2017. This final rule enhances the ability of licensees and other entities to identify individuals using illegal drugs and misusing legal drugs. This final rule also incorporates 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

The major provisions of this final rule:

- 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 final rule.
- Add initial and confirmatory drug testing for four opioid drugs (hydrocodone, hydromorphone, oxycodone, and oxymorphone).
- Add initial drug testing for 6-acetylmorphine (6-AM), a metabolite of the illegal drug heroin, and update the confirmatory drug testing method for 6-AM.
- Lower the initial and confirmatory drug testing cutoff levels for amphetamine, cocaine metabolite, and methamphetamine.

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

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

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

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

C. Changes from the Proposed Rule to the Final Rule

In response to public comments provided on the proposed rule and in developing this final rule, the NRC has made the following changes to:

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

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

- Set a compliance deadline for this final rule of 1 year, instead of the proposed 60 days.
- Remove the proposed requirement that hydration monitors must be FFD program personnel.

D. Costs and Benefits

The NRC prepared a regulatory analysis to quantify the costs and benefits of this final rule, as well as to examine the qualitative factors to be considered in the NRC's rulemaking decision. This final rule, relative to the regulatory baseline, results in a net benefit to industry of between $418,356, based on a 7-percent net present value, and $692,799, based on a 3-percent net present value. This final rule results in an estimated total one-time industry cost of $136,936, followed by a total annual industry savings of $47,650. On a per licensee or other entity site basis, this final rule results in an average one-time cost of $2,321 and annual savings of $808. Thirteen qualitative factors were evaluated in the 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 regulatory analysis includes a discussion of each qualitative factor.

The regulatory analysis results show that this rulemaking is justified because the total estimated quantified benefits exceed the estimated costs of the rule. The NRC concludes that adopting this final rule will result in an estimated increase of between 16 and 29 percent per year in the number of individuals identified as not fit for duty or trustworthy and reliable because of the use of illegal drugs, misuse of legal drugs, or an attempt to subvert the drug testing process. Based on the average number of

individuals from calendar years 2009 through 2019 with a positive test result or identified as attempting to subvert a test, the estimated increase in detection each year is equivalent to identifying approximately 180 additional individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. This improved detection prevents 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 prevents drug-using individuals from gaining or maintaining unescorted access authorization to strategic special nuclear material or sensitive information. An enhanced drug testing program may also deter drug-using individuals from seeking employment in 10 CFR part 26-regulated workplaces and incentivize those already in regulated positions to cease drug use or to seek medical assistance to address an addiction or misuse issue.

The regulatory analysis is available as indicated in Section XVI, Availability of Documents," of this document.

TABLE OF CONTENTS:

I. Background

A. Health and Human Services Guidelines

Through Executive Order 12564--Drug-Free Federal Workplace (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 U.S. Nuclear Regulatory Commission (NRC), licensees, and other entities that the testing of specimens, under part 26 of title 10 of the *Code of Federal Regulations* (10 CFR), "Fitness for Duty Programs," 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 historically has relied on the HHS Guidelines to establish the technical requirements for urine specimen collection, specimen testing, and test result evaluation; in general, the NRC deviates from the HHS Guidelines only 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 HHS Guidelines ensures 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, the NRC published the "Commission Policy Statement on Fitness for Duty of Nuclear Power Plant Personnel" (51 FR 27921), which outlined the need for nuclear power plant licensees to implement programs to address FFD problems—such as illegal drug use, alcohol abuse, and misuse of legal drugs that could impair job performance. An NRC 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.

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 2008 FFD final rule implemented 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 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.

On January 23, 2017, HHS issued the 2017 HHS Guidelines (82 FR 7920), which included 1) an expanded drug testing panel to include four opioid drugs (hydrocodone, hydromorphone, oxycodone, and oxymorphone) and testing for methylenedioxyamphetamine (MDA) as an initial test analyte, 2) removal of methylenedioxyethylamphetamine (MDEA) from the drug testing panel, 3) a change to the lower pH cutoff for identifying specimens as adulterated (raised from 3 to 4), and 4) MRO requalification training and reexamination.

The 2008 and 2017 HHS Guidelines changes currently are not reflected in 10 CFR part 26.

C. Proposed Rule and Stakeholder Outreach

In June 2019, the Commission issued staff requirements memorandum (SRM)-SECY-2017-0027, "Proposed Rulemaking: Fitness-for-Duty Drug Testing Requirements (RIN 3150-AI67)," approving publication of the proposed rule. On September 16, 2019, the NRC published the proposed rule, "Fitness for Duty Drug

Testing Requirements," in the *Federal Register* (84 FR 48750). The NRC proposed to align the drug testing requirements in 10 CFR part 26 more closely with the 2008 HHS Guidelines. The proposed rule contained changes to enhance the ability of NRC licensees and other entities to identify individuals using illegal drugs or misusing legal drugs. The proposed rule also incorporated lessons learned from implementing the NRC's current FFD regulations with regard to identifying individuals attempting to subvert the drug testing process, and provided additional protections to individuals subject to drug testing. Finally, the NRC proposed changes to improve the clarity, organization, and flexibility of the FFD regulations.

The NRC conducted significant outreach and analysis before issuing the proposed rule, including four public meetings 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. The proposed rule contained a thorough description of the feedback the NRC received during public meetings and how the feedback shaped the proposed rule.

The proposed rule provided a public comment period of 75 days. The NRC received 26 comment submissions on the proposed rule and draft implementation guidance, as discussed in Section II.B of this document.

During the public comment period, the NRC held a Category 3 public meeting on November 7, 2019, to discuss with external stakeholders the proposed rule and associated draft guidance document.[1] On April 13, 2021, the NRC held an information public meeting with a question and answer session on the final rule implementation schedule as it pertains to the Cumulative Effects of Regulation (CER). This meeting

[1] On March 19, 2021, the NRC modified the public meeting categorization system and redefined the three categories of public meetings (86 FR 14964).

occurred during the development of this final rule. Summaries of both public meetings are available in the NRC's Agencywide Documents Access and Management System (ADAMS), as provided in the "Availability of Documents" section of this document. The feedback from these public meetings informed the development of this final rule.

II. Discussion

A. The Need for Rulemaking

1. Alignment with the 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 metabolite, and methamphetamine; 2) establishing an initial testing requirement and revising the confirmatory testing cutoff level for the heroin metabolite 6-acetylmorphine (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, 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).

An NRC analysis of annual FFD program performance reports submitted by licensees and other entities under § 26.717, "Fitness-for-duty program performance data," identified an adverse trend associated with amphetamines positive test results. The NRC report, "Summary of Fitness for Duty Performance Reports for Calendar Year 2013," identified year-over-year increases in amphetamines positive test results from 2009 through 2013. In 2009, 0.023 percent of individuals tested positive for amphetamines and by 2013, the rate increased to 0.053 percent. An NRC analysis of FFD program performance data through calendar year 2019 confirmed that the amphetamines positive test rate has continued to trend higher, with the highest rate reported at 0.095 percent of tested individuals in 2017.

Comparatively, in 2009, 0.095 percent of individuals tested positive for cocaine, with the highest rate from 2009 through 2019 reported at 0.104 percent of tested individuals in 2017. While variable by year, these positive test rates demonstrate that amphetamines and cocaine collectively account for between 23.6 percent and 28.5 percent of drug testing positives[2] each year, from 2015 through 2019.

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

TRENDS IN AMPHETAMINES AND COCAINE USE

Substance	1990	2015	2016	2017	2018	2019
Amphetamines	2.8%	9.9%	13.4%	13.6%	12.9%	12.4%
Cocaine	29.0%	13.8%	14.3%	14.9%	12.6%	11.2%
Total	31.8%	23.7%	27.7%	28.5%	25.5%	23.6%

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 10 CFR part 26 testing, is included as the baseline for comparison.

While most of the changes in the proposed rule were made to better align 10 CFR part 26 with the 2008 HHS Guidelines, some were based on lessons learned during the implementation of the 2008 FFD final rule by licensees and other entities. In particular, the NRC proposed a number of changes to 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[3]) created by the NRC, in collaboration with licensees and other entities, in order to meet the annual FFD program performance reporting requirements in §§ 26.717 and 26.417(b)(2). The use of e-forms provides a uniform way of reporting detailed information on each drug and alcohol testing violation to the NRC. By 2011, over 80 percent of licensees and other entities used e-forms, with full industry adoption achieved by 2014.

The NRC report "Summary of Fitness for Duty Performance Reports for Calendar Year 2015" described a second significant trend: the prevalence of subversion attempts of the drug testing process from 2011 through 2015. In 2011, donor subversion attempts accounted for 13.7 percent of the total testing violations, or 148 of 1,080 testing

[3] NRC Form 890, "Single Positive Test Form;" and NRC Form 891, "Annual Reporting Form for Drug and Alcohol Tests" can be obtained at the following NRC website: https://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/submit-ffd-reports.html.

violations. By 2015, subversion attempts accounted for 19.3 percent of total testing violations, or 232 of 1,200 testing violations. The prevalence of subversion attempts has continued to rise in subsequent years. Since 2016, subversion attempts have exceeded 20 percent of all testing violations (26.1 percent in 2016, 25.9 percent in 2017, 25.1 percent in 2018, and 28.3 percent in 2019), with the highest number of individuals identified attempting to subvert a test in 2019 at 307 individuals.

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 §§ 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 included a number of changes in the proposed rule to enhance the ability of FFD testing programs to detect individuals attempting to subvert the drug testing process.

2. Societal Drug Use

The prevalence of drug use in society is documented in the "Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 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 2019, 20.8 percent of the U.S. population aged 12 or older (approximately 57.2 million Americans) used an illegal drug in the past year. The most commonly used illegal drug in 2019 was marijuana (48.2 million people), followed by the misuse of prescription pain relievers (9.7 million people). Among young

adults aged 18 to 25, 39.1 percent used an illegal drug in 2019. In adults aged 26 or older, 18.3 percent used an illegal drug in 2019. 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 Comment Analysis

As stated in the background section, the NRC published the proposed rule and draft regulatory guide for public comment in the *Federal Register*. The NRC received 26 comment submissions. A *comment submission* is a communication or document submitted to the NRC by an individual or entity, with one or more individual comments addressing a subject or issue. Private citizens provided 18 comment submissions, 4 licensees provided comment submissions, 2 nuclear industry organizations provided comment submissions, and 1 drug and alcohol testing association provided a comment submission.

The comment submissions were generally supportive of the regulatory action, with no comment submissions that objected to this rulemaking activity and one that did not address 10 CFR part 26. Out of the 25 remaining comment submissions, 4 comment submissions specifically noted support of the rulemaking and provided reasons related to the positive changes being proposed, enhanced efficiencies while maintaining the reliability of the FFD program, and enhanced ability to identify individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. Twenty-one comment submissions agreed to or suggested additional changes to include expanding the drug testing panel to include four additional opioids (hydrocodone, hydromorphone, oxycodone, oxymorphone) in the 2017 HHS Guidelines, providing the option to collect an oral fluid specimen for direct observation conditions, or

extending the compliance deadline for this final rule. The NRC received a number of comments that were outside the scope of this rulemaking, such as comments pertaining to marijuana use and legalization. The NRC considers the public comments requesting that the NRC expand the drug testing panel to include four opioids, and to permit the collection of an oral fluid specimen for observed collection conditions to be substantive because of the resultant changes to this final rule.

The public comment submissions are available from the Federal e-Rulemaking website at http://www.regulations.gov under Docket ID NRC-2009-0225. The NRC prepared a summary and analysis of public comments received on the 2019 proposed rule and draft regulatory guide, as provided in the "Availability of Documents" section of this document. Responses to the public comments, including a summary of how the final rule text or guidance changed as a result of the public comments, can be found in the public comment analysis.

For more information about the associated guidance document, see the "Availability of Guidance" section of this document.

In Section V of the Supplementary Information section for the proposed rule, the NRC sought advice and recommendations from stakeholders on the proposed rule. The NRC was particularly interested in comments and supporting rationale from the public on seven topics. The following paragraphs restate each topic and its specific request for comment, summarize comments received from stakeholders, and present the NRC's resolution of these public comments.

1. *Alignment with the HHS Guidelines*

Specific Request for Comment: 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.

Commenter’s Response: One commenter agreed with the proposed changes to remove redundant provisions in 10 CFR part 26 that also appear in the HHS Guidelines, leading to duplicative oversight. In addition, the commenter recommended two new changes for consideration by the NRC. First, the commenter suggested that as long as the HHS Guidelines are followed, the NRC should remove the same-gender observed collection requirement in § 26.115, which is included in Section 4.4(b) of the HHS Guidelines. Second, the commenter stated that the NRC should eliminate the redundant requirements for MRO specimen handling in 10 CFR part 26.

NRC Response: The NRC disagrees. The NRC acknowledges that the HHS Guidelines contain similar provisions regarding the same-gender collector requirement in § 26.115(e) and the MRO specimen handling requirements in 10 CFR part 26. However, NRC licensees and other entities are subject to the requirements in 10 CFR part 26 but are not required to comply with the HHS Guidelines. Because removing these requirements from 10 CFR part 26 would completely eliminate these requirements for NRC licensees and other entities, the NRC will not remove these requirements. No changes were made to this final rule as a result of this comment.

Commenter’s Response: One commenter recommended that the NRC establish a streamlined process other than rulemaking for nuclear facilities to adopt future HHS Guidelines upon issuance.

NRC Response: The NRC disagrees. Streamlining the process to revise 10 CFR part 26 whenever the HHS Guidelines change is outside the scope of this rulemaking. No changes were made to this final rule as a result of this comment.

2. *Special Analyses Testing*

Specific Request for Comment: 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 (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.

Commenter's Response: One commenter supported applying special analyses testing for individuals that have already tested positive and indicated that it should be performed after the immunoassay and gas-chromatography-mass spectrometry (GC-MS) confirmation tests. The commenter suggested that special analyses testing would identify new drugs used and provide trends in drug use by different business departments and employee levels.

NRC Response: The NRC disagrees. The reasons the commenter provided for recommending that special analyses testing be applied to the testing of specimens collected from individuals with a prior drug testing positive result do not apply as follows:

1) Special analyses testing would not identify new drugs; it would only identify the drugs in the drug testing panel used by the licensee or other entity.

2) Special analyses testing would not provide additional transparency regarding the departments or employee levels where drug use is identified. The NRC already collects information in the annual FFD program performance reports that licensees and other entities submit to the NRC under §§ 26.717 and 26.417(b)(2). Performance reports provide the employment type (i.e., licensee employee, contractor/vendor) and labor category (e.g., supervisor, reactor operator, security) of each individual with a positive test result.

Special analyses testing lowers the initial (i.e., immunoassay) and confirmatory (i.e., GC/MS) testing cutoff levels for existing substances in the drug testing panel used by the licensee or other entity. Lower testing cutoff levels increase the timeframe of detection after use of a drug, thereby increasing the likelihood of detecting drug use. Accordingly, no changes were made to this final rule as a result of this comment.

Commenter's Response: One commenter stated that if an individual had already tested positive, direct observation testing would be unnecessary because the individual had already tested positive. The commenter supported using special analyses testing for retesting a specimen.

NRC Response: The NRC disagrees. As described in the proposed rule, the NRC would expand special analyses testing to specimens collected under direct observation as required by § 26.115(a)(1) through (3) and a new paragraph (a)(5). Specimens collected under the conditions described in § 26.115(a)(1) through (3) and (a)(5) would not have already tested positive, as stated by the commenter. Instead, the

specimens subject to special analyses testing would be collected under direct observation for the following reasons:

- The donor presents a specimen 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;
- The donor provides a specimen that falls outside of the acceptable temperature range specified in § 26.111(a);
- Donor conduct during the collection process indicates an attempt to dilute, substitute, or adulterate the specimen; or
- 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.

Accordingly, no changes were made to this final rule in response to this comment.

Commenter's Response: One commenter stated that if an individual reported a problem with illegal drug use, random drug testing should be directly observed, and special analyses testing performed on the specimens collected.

NRC Response: The NRC disagrees. This comment is beyond the scope of this rulemaking because the proposed rule did not include any changes to the exclusive grounds for performing a directly observed collection in § 26.115. As described below, appropriate mechanisms currently exist within 10 CFR part 26 to address a situation where an individual self-reports an illegal drug use problem to the licensee or other entity.

The commenter's scenario most likely would apply to an individual that already had been granted unescorted access (UA) or unescorted access authorization (UAA) by a licensee. In this instance, if the individual was an employee of the licensee, they could utilize the Employee Assistance Program (EAP) that each FFD program must offer under § 26.35. The EAP is designed to achieve early intervention and provide for confidential assistance. If the individual self-refers for assistance to the EAP, then the EAP is required to protect the identity and privacy of the individual except if the individual waives the right to privacy or the individual's condition or actions pose or have posed an immediate hazard to himself or herself or others. If, however, the individual self-reports a problem outside the EAP, then the licensee or other entity would be required to disposition the situation under § 26.69(d), "Maintaining authorization with other potentially disqualifying FFD information." The definition of "potentially disqualifying FFD information" in § 26.5 includes that an individual has used illegal drugs. The licensee or other entity also may consider conducting for-cause testing under § 26.31(c)(2) based on receiving credible information that the individual is engaging in substance abuse. If on the other hand, the individual had not been granted UA or UAA by the licensee, but had already provided a specimen for pre-access testing required under § 26.65, "Pre-access drug and alcohol testing," or § 26.69, "Authorization with potentially disqualifying fitness-for-duty information," and therefore would be subject to random testing, then the licensee would be required to evaluate the individual's disclosure under § 26.69(c), "Granting authorization with other potentially disqualifying FFD information."

The NRC did not propose changes to special analyses testing criteria for random tests, however, a licensee or other entity may use lower testing cutoff levels for any condition for testing if they meet the requirements in § 26.31(d)(3)(iii). Accordingly, no changes were made to this final rule in response to this comment.

Commenter's Response: One commenter indicated that special analyses testing will not provide additional value for random and follow-up testing and asserted that special analyses testing would make it difficult to credit random tests for follow-up tests. However, it is reasonable to conduct special analyses testing for the first observed test.

NRC Response: The NRC disagrees, in part. The NRC sought comment on whether special analyses testing should also apply to follow-up tests conducted on individuals that previously tested positive on a 10 CFR part 26 test and to whom a licensee or other entity subsequently granted unescorted access authorization. Special analyses testing would provide additional value for follow-up tests because it lowers the testing cutoff levels for the substances in the drug testing panel used by the licensee or other entity. Use of lower testing cutoff levels increases the timeframe of detection after use of a drug, thereby increasing the likelihood of detecting drug use.

However, the NRC agrees that because random tests would not be subject to the lower cutoff levels used in special analyses testing, the licensee or other entity could not take credit for a random test to meet the follow-up testing requirement (i.e., count a random test as meeting a follow-up testing requirement), as currently permitted in § 26.69(b)(6).

The NRC did not propose nor request comment on whether an individual with a first or second confirmed positive drug test result under 10 CFR part 26 should be subject to special analyses testing for the pre-access test conducted under § 26.69(b). As a result, this comment is beyond the scope of this rulemaking. Accordingly, no changes were made to this final rule in response to this comment.

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

Specific Request for Comment: 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.

Commenters' Response: Two commenters addressed the issue to provide flexibility to conduct additional specimen validity testing. The first commenter supported providing licensees and other entities with the option to use lower cutoff levels to conduct specimen validity testing. The commenter suggested that licensees and other entities have the flexibility to use different forms of testing such as hair testing. In this case, "the integrity and accountability of the program should be within NLCP Audit parameters. This must be checked and accounted for so there is not mis-representation at any level."

The second commenter stated that providing the option to conduct additional specimen validity tests may result in an inconsistent approach across the industry and preferred a streamlined approach to adopt future updates to the HHS Guidelines.

NRC Response: The NRC agrees, in part. Licensees and other entities should be provided with the option to utilize lower cutoff levels for existing specimen validity tests performed under 10 CFR part 26, as long as those cutoff levels are consistent with the current HHS Guidelines. Affording licensees and other entities with the flexibility to use lower cutoff levels to perform validity testing is consistent with the testing principle that the NRC established in § 26.31(d)(1)(i)(D) for drug testing. Section 26.31(d)(1)(i)(D) permits a licensee or other entity to use lower cutoff levels to test for drugs specified in 10 CFR part 26 and does not require the review of the cutoff levels by a forensic toxicologist if the cutoff levels are consistent with the current HHS Guidelines. Providing

a licensee or other entity with flexibility to adopt improvements in the existing validity tests performed under 10 CFR part 26 is consistent with a key goal of this rulemaking: enhance the methods for detecting subversion attempts. The NRC acknowledges that providing the option to use lower cutoff levels for existing validity tests may result in variability among some licensees and other entities in the performance of such tests, but this approach is consistent with existing practice for drug testing and was consistent with the optional use of special analyses testing under § 26.163(a)(2) until this final rule mandated such testing.

Accordingly, § 26.161(h) in this final rule has been revised to read, "*Validity test cutoff levels*. Licensees and other entities may use more stringent cutoff levels for validity tests than those specified in this section only if the testing is performed at an HHS-certified laboratory." The NRC disagrees that flexibility should be provided to collect and test specimens other than urine as an acceptable alternative to the current validity tests performed under 10 CFR part 26. This comment is beyond the scope of this rulemaking.

4. *Effective Date of the Final Rule*

Specific Request for Comment: 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.

Commenters' Response: Two commenters disagreed with the proposed effective date of 60 days after the publication date of the final rule. The first commenter argued that the proposed 60-day timeframe did not provide sufficient time to understand

the new requirements and completely communicate them to all departments and sections. The commenter recommended at least 120 days and noted that this timeframe is still very aggressive.

The second commenter stated that licensees will need approximately 12 months to fully and effectively implement the new program utilizing established procedures. The commenter explained that once the rule is issued, licensees will need to "evaluate change management plan items to include procedures, union/lab contracts, computer systems, and training."

The second commenter also recommended that the NRC clarify that during the transition period, any program may accept and rely on another program's FFD-related information as long as the information being shared is compliant with the sharing program's current 10 CFR part 26 processes.

NRC Response: The NRC disagrees with these two comments. The information provided by the two commenters was insufficient to support a change to the proposed 60-day implementation timeframe to comply with the final rule changes. However, the public provided substantive information during the April 13, 2021, public meeting on the CER for this rule to justify additional implementation time. Specifically, an industry stakeholder stated that an implementation timeframe of 1 year was more appropriate than 60 days because of operational challenges posed to a licensee's FFD program staff before, during, and after Spring (February to May) and Fall (August to November) refueling outages at operating nuclear power reactors. The licensees of some power reactor sites also impose training and system change blackout periods 2 months before, during, and 2 months after reactor outages. This industry stakeholder also described additional challenges in meeting the 60-day implementation timeframe due to updates to the FFD training system used by the industry, licensee information technology system changes, and the ongoing impacts of the Coronavirus Disease 2019 pandemic such as

the remote work status of some staff. A summary of this meeting is available in ADAMS, as provided in the "Availability of Documents" section of this document. Three comment submissions received after the public comment period closed affirmed the stakeholder feedback presented at the CER public meeting on the implementation timeframe.

Accordingly, the compliance deadline was revised to be 1 year from the date that this final rule is published in the *Federal Register*. Because licensees and other entities can implement the new requirements before the 1-year deadline, licensees and other entities that do so should inform the NRC of their implementation date through their 10 CFR 26.717 annual FFD program performance reports.

The NRC also disagrees with the second commenter's request to clarify that during the implementation period of the final rule, any program may accept and rely on another program's FFD-related information as long as the information being shared is compliant with the sharing program's current 10 CFR part 26 processes. No change is necessary because the existing requirements in 10 CFR part 26 permit the sharing of information. For example, to grant authorization, licensees and other entities shall ensure that a suitable inquiry has been conducted under § 26.63, "Suitable inquiry," to verify an individual's self-disclosed information and to determine whether any potentially disqualifying FFD information is available. A suitable inquiry can involve licensees sharing information about an individual collected under 10 CFR part 26. Accordingly, no changes were made to this final rule as a result of this comment.

5. *Direct Observation of Specimen Collection*

Specific Request for Comment: 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.

Commenters' Response: One commenter responded that a direct observation collection is the only way to ensure the integrity of the specimen collected from the donor and that there were no effective alternatives. The commenter further stated that the highest integrity of the procedure must be maintained between the observer and donor (i.e., no conflicts of interest, no harassment, and no bribery).

Another commenter offered that an oral fluid specimen collection is an effective alternative to collecting a urine specimen under direct observation. The commenter also suggested that an oral fluid specimen should be considered if a donor is unable to provide the minimum quantity of urine on the initial attempt and that 10 CFR part 26 should state that industry can adopt and implement the HHS Guidelines for oral fluid testing within their programs without submitting exemptions or awaiting rulemaking.

NRC Response: The NRC agrees, in part. The NRC agrees that collecting an oral fluid specimen under direct observation of the specimen collector is equivalent to and equally effective as collecting a urine specimen from a donor under the observed collection conditions in § 26.115(a)(1) through (3) and a new paragraph (a)(5). The NRC's basis for this decision is the HHS issuance of the "Mandatory Guidelines for Federal Workplace Drug Testing Program-Oral/Fluid" (2019 HHS OF Guidelines) on October 25, 2019 (84 FR 57554). The 2019 HHS OF Guidelines became effective on January 1, 2020. The 2019 HHS OF Guidelines relied on the technical basis on the acceptability of oral fluid as an alternative specimen in the Federal employee workplace drug testing program that was presented in the proposed revisions to the HHS Guidelines published on May 15, 2015 (80 FR 28101).

Under the conditions permitted in this final rule, the testing of an oral fluid specimen is equally effective in identifying the same substances tested in urine. Oral

fluid is tested at an HHS-certified laboratory, with the same HHS inspection and oversight process used for urine specimen testing laboratories.

Although the NRC is permitting a licensee or other entity to collect a urine or oral fluid specimen under specified direct observation conditions, each specimen chosen has advantages and disadvantages. The intent of the flexibility offered by the changes in this final rule is to provide the licensee or other entity with the ability to collect and test the appropriate specimen for the collection condition encountered. The following discussion describes how both collection methods can detect attempts to subvert the testing process.

- Urine specimen collections are valuable in identifying subversion attempts. Collecting a urine specimen under direct observation requires the donor, in the presence of a same-gender observer, to remove his or her clothing between the waist and the knees. This clothing removal process has revealed cheating paraphernalia, definitive proof of a donor's attempt to subvert the testing process. An NRC analysis of FFD program performance data submitted to the NRC under §§ 26.717 and 26.417(b)(2) determined that the two most likely subversion determination scenarios are either a donor refuses to provide a second urine specimen under direct observation, or the donor's second observed urine specimen tests positive for a drug and the donor's initial unobserved urine specimen tests negative for that drug. The collection and testing of a donor's two urine specimens, the first unobserved and second observed, also provide the MRO with contemporaneous information on the physical characteristics of the specimens that can be used to inform a subversion determination. For example, in rare instances when both the unobserved and observed specimens provided by a donor test negative for drugs, the MRO's comparison of the physical characteristics of the two specimens has identified medically impossible differences in specimen temperature, pH, creatinine, and specific gravity test results that have resulted in subversion

determinations. The existing observed urine collection process has proven effective in identifying subversion attempts and urine drug testing has been successfully conducted by licensees and other entities under 10 CFR part 26 since 1990.

- Oral fluid specimen collections would not be expected to identify subversion attempts. Collecting an oral fluid specimen is always performed under the direct observation of the collector and does not require a same-gender collector (i.e., the donor does not remove his or her clothing from the waist to the knees). It is possible that a donor could retain cheating paraphernalia used during the provision of the initial unobserved urine specimen because clothing is not removed. If the licensee or other entity suspects that a donor may be in possession of subversion paraphernalia, then the licensee or other entity can consider taking additional action to identify the paraphernalia before collecting an oral fluid specimen. In the absence of any identifiable subversion paraphernalia, the licensee or other entity could then conduct an oral fluid specimen collection to meet an observed collection requirement.

The window of detection for drugs and drug metabolites in urine is somewhat longer than in oral fluid. However, this difference is immaterial under the conditions that oral fluid testing is permitted in this final rule. Oral fluid drug testing is permitted for collection conditions warranted by information suggesting a possible subversion attempt. Individuals that attempt to subvert the drug testing process do so because of recent use of one or more of the substances included in the drug-testing panel used by the licensee or other entity. Simply put, it is unlikely that a donor would risk a permanent denial of unescorted access under § 26.75 for an identified subversion attempt unless they likely would test positive on drug testing. As a result, the NRC believes that oral fluid and urine specimen testing likely would be equally effective in identifying recent drug use. It is notable that identifying any given substance through drug testing is dependent on the chemical properties of the substance, the retention of that particular substance in the

human body, frequency of use, and the genetic makeup of the user, which impacts drug metabolism rates. These complexities apply to urine and oral fluid specimen testing.

Another difference between urine and oral fluid drug testing is the volume of the biological specimen needed for testing. An oral fluid specimen collection device must obtain a minimum of 1 milliliter (mL), whereas urine drug testing requires a volume of 30 to 45 mL. This volume difference must be taken into account by licensees and other entities choosing to use oral fluid testing because sufficient specimen volume must be available to support retesting of a specimen should a donor request specimen retesting following a positive test result under § 26.165.

The oral fluid collection process requires fewer steps to complete, and therefore may take less time to complete than for a urine specimen. The stability of oral fluid specimens also may be better than urine specimens because oral fluid specimen collection devices contain a stability buffer, which may reduce the necessity for refrigeration under certain collection and specimen handling conditions.

For each of the directly observed collection conditions in § 26.115(a)(1) through (3) and a new paragraph (a)(5), a licensee or other entity must always collect either urine or oral fluid specimens. For example, a licensee could continue to collect a urine specimen under every § 26.115(a)(2) directly observed collection condition when the initial urine specimen provided is outside the acceptable temperature range, but could choose to collect an oral fluid specimen under every § 26.115(a)(1) directly observed collection condition after an invalid urine specimen test result without a legitimate medical explanation. The required special analyses testing provisions included in this final rule under § 26.163(a)(2) apply to the specimens collected under direct observation regardless of the specimen that is tested (i.e., both for urine and oral fluid).

As a result of including oral fluid specimen collection and testing under specified direct observation conditions in this final rule, the NRC is making the changes discussed in Section II.C of this document, under “Acceptable Specimens for Observed Collection.”

The NRC disagrees with the commenter’s request to revise 10 CFR part 26 to permit the collection of an oral fluid specimen in the instance where a donor is unable to provide the minimum quantity of urine on the initial collection attempt (i.e., a shy bladder). This comment is beyond the scope of this rulemaking.

6. *2017 HHS Guidelines—New Test Analytes*

Specific Request for Comment: 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.

Commenters’ Response: Three commenters expressed support for expanding the 10 CFR part 26 drug testing panel to include the four opioids added to the 2017 HHS Guidelines (i.e., hydrocodone, hydromorphone, oxycodone, and oxymorphone). One commenter stated that adopting this expanded drug testing panel will provide greater reassurances that persons with authorization to access licensed facilities are fit for duty. Another commenter expressly endorsed the cutoff levels recommended in the 2017 HHS Guidelines for these drugs.

NRC Response: The NRC agrees. The NRC evaluated detection changes following implementation of drug testing under the 2017 HHS Guidelines on safety-sensitive worker populations analogous to the individuals subject to 10 CFR part 26. The U.S. Department of Transportation (DOT) began drug testing under the 2017 HHS Guidelines on January 1, 2018 (82 FR 52229; November 13, 2017). The NRC assessment of DOT test results data for 2018 identified a significant increase in the number of testing violations for opioid positive test results. The NRC analyzed drug testing data from the three modal administrations most comparable to the population tested under 10 CFR part 26 (Federal Aviation Administration (FAA), Federal Rail Administration (FRA), and Federal Transit Administration (FTA)). The opioid positive testing violation rate for FAA increased from 0.0196 percent in 2017 to 0.0652 percent in 2018 (233-percent increase), for FRA from 0.0322 percent in 2017 to 0.0904 percent in 2018 (181-percent increase), and for FTA from 0.0349 percent in 2017 to 0.1623 percent in 2018 (365-percent increase). These increases in testing violations demonstrated both the effectiveness of the 2017 HHS Guidelines expanded opioid testing panel and also the prevalence of illicit use of these substances in analogous worker populations to those tested under 10 CFR part 26.

Most FFD programs already require individuals to report the use of any substance (e.g., prescription drug, over-the-counter substance) with product labeling or use information indicating a potential impairing impact on performance, whereby an assessment would be conducted by the MRO to ensure that the individual can safely perform assigned job activities. Required testing for the four additional opioids in the 2017 HHS Guidelines also will likely increase the level of compliance in reporting the use of these impairing substances to the FFD program consistent with the FFD program prescription drug policy. This change is likely because of the uniform testing for these

substances, as well as the consequence for identifying individuals violating the FFD policy and the minimum sanctions that apply under § 26.75 for positive test results.

Accordingly, the NRC revised §§ 26.31(d)(1), 26.133, 26.163(a)(1) and (b)(1), 26.169(h)(3), 26.185(j), and 26.405(d) in this final rule to align with the 2017 HHS Guidelines by adding testing for hydrocodone, hydromorphone, oxycodone, and oxymorphone.

Commenter's Response: One commenter expressed concern with the increasing number of individuals being placed into follow-up testing programs as a result of the opioid epidemic. The commenter asserted that a select few of the nuclear facilities have expanded their panels to address the opioid crisis. The commenter also stated that these facilities place individuals into the follow-up program for the purpose of monitoring abstinence from opiate addiction: "However, when the individual in the follow up program travels to another utility; they are not monitored for the substance for which they were placed in the follow-up program; as these programs have not expanded the panel and have no provision to test for the abused opiate." Therefore, the commenter declared that "industry is currently ill equipped to monitor the problem because of the significant gap in the follow-up program's ability to detect on going opiate abuse."

The commenter recommended that the rule include language that addresses the opiate epidemic and includes provisions for collection and testing under every FFD test condition.

NRC Response: The NRC agrees. See the previous NRC response.

7. *Methylenedioxyethylamphetamine*

Specific Request for Comment: 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.

Commenters' Response: Two commenters responded to the specific request for comment on whether MDEA and MDA testing is needed. The first commenter disagreed that the NRC should not include MDEA in the drug testing panel, and stated that not testing for this substance would provide an opportunity for drug use in a sensitive position.

The second commenter favored aligning with the 2017 HHS Guidelines, which does not include MDEA, even though "Ecstasy drugs" have not been a prevalent issue in the industry. However, the commenter recommended that if blind specimen testing remains a requirement, then NRC should consider eliminating the testing of drugs that are not prevalent issues in the industry.

NRC Response: The NRC disagrees, in part. The 2017 HHS Guidelines established the appropriate minimum testing standard for the drugs and drug metabolites to be tested in the specimens collected from individuals subject to testing under 10 CFR part 26. The 2017 HHS Guidelines (82 FR 7923) stated that HHS "understands that MDA and some other analytes also have a low incidence, but believes that continued testing for these analytes is warranted in a deterrent program. In

particular, inclusion of MDA as an initial and confirmatory test analyte is warranted because, in addition to being a drug of abuse, it is a metabolite of MDEA and MDMA." The NRC agrees with this HHS position.

Further, § 26.31(d)(2) provides flexibility to licensees and other entities to consult with local law enforcement authorities, hospitals, and drug counseling services to determine whether other drugs with abuse potential are being used in the geographical locale of the facility and by the local workforce that may not be detected in the standard testing panel under § 26.31(d)(1). When appropriate, a licensee or other entity may add other drugs to the testing panel, but only if the additional drugs are listed in Schedules I through V of section 202 of the Controlled Substances Act [21 U.S.C. 812]. MDEA is a Schedule I substance. The licensee or other entity must also inform the NRC under 10 CFR 26.717(b)(2) that it is testing for the additional drugs. The NRC has not received information from any licensee or other entity that testing for Ecstasy-type drugs has been performed under a 10 CFR part 26 testing program. Therefore, no basis exists to evaluate the commenter's position regarding the prevalence of Ecstasy-type drugs in the industry, but changes in substance abuse trends do occur over time and testing for substances in the amphetamines drug class supports a deterrent testing program.

The commenter's requested change to the blind performance test sample requirements in § 26.168 is beyond the scope of this rulemaking.

Accordingly, the NRC did not change this final rule in response to these comments.

C. Description of Changes to 10 CFR Part 26

Definitions

This final rule adds seven new definitions and revises seven existing definitions under § 26.5, “Definitions.” The revisions and additions improve consistency with Section 1.5 of the 2008 HHS Guidelines and improve the clarity, consistency, and accuracy of the requirements under 10 CFR part 26. Specifically, this final rule adds definitions for: *Cancelled test*, *Carryover*, *Certifying Scientist*, *Federal custody and control form*, *Lot*, *Rejected for testing,* and *Responsible Person*. This final rule also revises the definitions for: *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 clarifies the actions taken by an MRO and improves consistency between 10 CFR part 26 and the 2008 and 2017 HHS Guidelines. The NRC is also adding 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, “Acceptable devices for conducting initial and confirmatory test for alcohol and methods of use.”

Carryover. This final rule adds 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* also applies 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 definition is similar to the definition in Section 1.5 of the 2008 and 2017 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. This final rule adds 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* is 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 from the HHS Guidelines improves consistency between 10 CFR part 26 and the 2008 and 2017 HHS Guidelines

and the clarity of 10 CFR part 26. A conforming change is 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). This final rule adds 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 more closely aligns 10 CFR part 26 with Section 1.5 of the 2008 and 2017 HHS Guidelines and improves the clarity of the rule by defining the term, which is already used in § 26.153(g). The NRC is using the generic title, *Federal CCF,* to avoid the need for future regulatory changes, should the title of the form change. The definition also provides flexibility in accounting for additional forms that SAMHSA may create for use when conducting drug testing of alternative specimens (e.g., hair). To align with the new definition, "Federal custody-and-control form" is replaced with the term "*Federal CCF"* in § 26.153(g). In addition, to improve the consistency of terminology used throughout 10 CFR part 26, this final rule replaces the term "custody and control form" with the term "*Federal CCF*." The plural versions, "custody and control forms" and "custody and control form(s)," are also replaced with the terms "Federal CCFs" and "Federal CCF(s)," respectively. Finally, this final rule corrects 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. This final rule adds 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 improves consistency between 10 CFR part 26 and the definition of *lot* in Section 1.5 of the 2008 and 2017 HHS Guidelines and enhances the clarity of 10 CFR part 26. This final rule uses 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. This final rule also includes in the definition the parenthetical statement from the 2008 HHS Guidelines definition that provides examples of the term "item." The NRC is changing one of the examples in the parenthetical statement by replacing "quality control material" with "quality control samples." The term "quality control material" is not used in 10 CFR part 26.

Rejected for testing. This final rule adds to § 26.5 a definition for *rejected for testing* that is similar to the definition in Section 1.5 of the 2008 and 2017 HHS Guidelines, referring to a report by an LTF 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 currently is not defined. Including a definition clarifies 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 aligns with two additional 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" is 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” is 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. This final rule adds a definition for *Responsible Person* to § 26.5. The position title is used in § 26.31(d)(1)(D) but currently is not defined. A *Responsible Person* is 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 from the HHS Guidelines improves consistency between 10 CFR part 26 and the 2008 and 2017 HHS Guidelines and the clarity of 10 CFR part 26. A conforming change is made to § 26.167(f)(3) to capitalize the position title in the phrase “a statement by the laboratory’s responsible person.”

Calibrator. This final rule revises the definition for *calibrator* in § 26.5 to align more closely with the definition in Section 1.5 of the 2008 HHS Guidelines and to improve internal consistency of terminology used in 10 CFR part 26. The definition of *calibrator* is revised to include a clarifying statement that a calibrator is a solution of known concentration “in the appropriate matrix.” This change aligns NRC’s definition with the definition in the 2008 HHS Guidelines. The phrase “test specimen/sample” in the definition of *calibrator* is replaced with the phrase “donor specimen or quality control sample” and improves consistency with the terminology used in 10 CFR part 26. The revised definition deletes the last sentence of the current definition, “calibrators may be used to establish a cutoff concentration and/or a calibration curve over a range of interest.” 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. This final rule revises the definition of *control* in § 26.5 to conform to the definition of the term in Section 1.5 of the 2008 and 2017 HHS Guidelines and enhance the clarity of 10 CFR part 26. The term *control* in § 26.5 is 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. This final rule revises the definition of *dilute specimen* in § 26.5 to conform to the definition of the term in Section 1.5 of the 2008 and 2017 HHS Guidelines. The phrase "concentrations that are lower than expected for human urine" is 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 lower than expected 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* citation 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 a

laboratory to the HHS Guidelines that are in effect at the time that HHS certifies the laboratory. In the proposed rule, the NRC corrected 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. This change to the definition of *HHS-certified laboratory* eliminates the need to revise 10 CFR part 26 should future versions of the HHS Guidelines be published. This final rule removes the term "drug and validity" that was included in the proposed definition because the NRC specifies in other sections of 10 CFR part 26 the types of tests that must be performed on specimens. Additionally, this final rule adds the statement "and performs that testing for a licensee or other entity in accordance with the HHS Guidelines, unless otherwise specified in this part." The NRC is adding this new statement to the definition to clarify that not only must an *HHS-certified laboratory* be certified to meet the HHS Guidelines, but the 10 CFR part 26 testing for the licensee or other entity must be performed as required by the HHS Guidelines unless a provision in 10 CFR part 26 states otherwise. This change is based, in part, on a response to a specific request for comment in the proposed rule. As described in Section II.B.3 of this document, the NRC is revising § 26.161(h) to allow licensees and other entities to use more stringent cutoff levels for validity testing than those specified in § 26.161 only if the testing is performed at an *HHS-certified laboratory*. The addition of the new statement in the definition of *HHS-certified laboratory* ensures that the more stringent cutoff levels will be consistent with the HHS Guidelines current as of the date of the validity testing.

This final rule includes two conforming changes made as a result of the revised definition for *HHS-certified laboratory*. First, the phrase "HHS-certified laboratories as defined in § 26.5" is added to §§ 26.4(j)(3) and 26.153(a). Second, the reference in § 26.153(a) to the physical address of SAMHSA's Division of Workplace Programs as

the location to obtain information concerning the certification status of laboratories has been removed.

Invalid result. This final rule revises the definition of *invalid result* in § 26.5 to be consistent with the definition of the term in Section 1.5 of the 2008 and 2017 HHS Guidelines and improve the clarity and accuracy of the NRC's requirements in 10 part 26. The current definition does not include the specific criteria under which a laboratory will report an invalid test result for a specimen. 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" is 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 also corrects an inaccuracy in the current definition of *invalid result*, which does not include "specimen validity test."

Limit of Quantitation. This final rule revises the definition for *limit of quantitation (LOQ)* in § 26.5 to align more closely with Section 1.5 of the 2008 and 2017 HHS Guidelines and enhance the clarity of 10 CFR part 26. In the proposed rule, the NRC noted that its proposed definition would continue to use "analyte" instead of the HHS term, "measurand."[4] However, the 2017 HHS Guidelines replaced "measurand" with "analyte."

Substituted specimen. This final rule revises the definition of *substituted specimen* in § 26.5 to align with the definition of the term in Section 1.5 of the 2008 and 2017 HHS Guidelines. The phrase "specimen with creatinine and specific gravity values

[4] "Analyte" means the drug or drug metabolite measured by an initial or confirmatory drug test.

that are so diminished or so divergent that they are not consistent with normal human physiology" is 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."[5] The revision improves the clarity of the rule by explaining that a substituted specimen is the result of donor action to subvert the testing process: "a specimen that has been submitted in place of the donor's urine."

Drug Testing Panel Additions

This final rule adds 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 and 2017 HHS Guidelines. MDMA (also known as Ecstasy or Molly) and MDA are listed on 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 there is a lack of accepted safety for use of the drug or substance under medical supervision (21 U.S.C. § 812). This final rule adds testing for MDMA and MDA because of their potential adverse effects on human performance, which were detailed by HHS in the notice of proposed revisions to the HHS Guidelines, published in the *Federal Register* on April 13, 2004 (69 FR 19673). The 2008 HHS Guidelines included testing for an additional amphetamine-based chemical compound, methylenedioxyethylamphetamine (MDEA). However, MDEA subsequently was removed in the 2017 HHS Guidelines

[5] "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.

because HHS determined that the number of positive MDEA specimens reported from its certified laboratories did not support continued testing for the substance.

This final rule also adds four opioids (i.e., hydrocodone, hydromorphone, oxycodone, and oxymorphone) to the NRC-required drug testing panel. The NRC made the change in response to comments received on the proposed rule, as discussed in Section II.B.6 of this document, and to fully align with Section 3.4 of the 2017 HHS Guidelines. Each of the opioids is listed on Schedule II of the Schedules of Controlled Substances (21 CFR 1308.12). A Schedule II drug or substance has a high potential for abuse, has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, and abuse of the drug or substance may lead to severe psychological or physical dependence. HHS recommended the addition of these opioids in its notice of proposed revisions to the HHS Guidelines published on May 15, 2015 and based its decision on drug abuse trends and the scientific ability to test for these substances.

By requiring licensees and other entities to test for additional substances, a greater range of addictive drugs that impair human performance can be detected. Testing for additional substances may also identify individuals using illegal drugs, a characteristic of not being trustworthy and reliable.

This final rule revises §§ 26.31(d)(1) and 26.405(d) to include hydrocodone, hydromorphone, MDMA, MDA, oxycodone, and oxymorphone in the list of substances that licensees and other entities are required to test. This final rule adds these six substances to the initial drug testing tables that appear in § 26.133, “Cutoff levels for drugs and drug metabolites,” and § 26.163(a)(1) for LTFs and HHS-certified laboratories, respectively. The six substances also are added to the confirmatory drug testing table that appears in § 26.163(b)(1) for HHS-certified laboratories. This final rule also adds two new tables to § 26.163(a)(1) and (b)(1) that specify the substances and cutoff levels

for initial and confirmatory testing of oral fluid specimens, as further discussed in Section II.C of this document, under “Acceptable Specimens for Observed Collection.” The tables throughout 10 CFR part 26 are accordingly retitled and renumbered.

This final rule replaces the terms “opiate” and “opiates” with “opioid” and “opioids,” respectively. An opiate is a naturally occurring substance found in the opium poppy plant (Papaver somniferum). Codeine and morphine are opiates. The addition of hydrocodone, hydromorphone, oxycodone, and oxymorphone to the required drug testing panel in this final rule necessitates a terminology change because each of these substances is a semi-synthetic opioid, which means it is synthesized in a laboratory using a naturally occurring opium product. It is more accurate to refer to these substances under the more inclusive drug class term “opioid,” which includes the plant-based substances and those synthesized in laboratories. This terminology change is consistent with Section 3.1(b) of the 2017 HHS Guidelines. This final rule replaces the term “opiates” with “opioids” in §§ 26.31(d)(1), 26.163(b)(1), 26.169(h)(3)(iii), and 26.405(d). This final rule replaces the term “opiate metabolites” with “opioids” in the initial test cutoff level tables in §§ 26.133 and 26.163(a)(1).

The reporting requirement for HHS-certified laboratories in § 26.169(c)(2) is revised to remove the word “opiate” from the phrase “confirmatory opiate test results for morphine or codeine.” The word opiate is unnecessary in this sentence because each applicable substance is listed.

This final rule revises § 26.185(j) introductory text to replace “opiates” with “opioids” in the first sentence. Section 26.185(j)(1) is revised to replace “opiates” with “opioids (i.e., codeine and/or morphine)” and to replace the statement “opium, an opiate, or an opium derivative (e.g., morphine/codeine)” with “morphine and/or codeine.” The addition of hydrocodone, hydromorphone, oxycodone, oxymorphone to the drug testing panel in this final rule is the basis for these changes. Clarifying that the evaluation for

the clinical signs of abuse is limited to positive test results for the opiates morphine and codeine is necessary because these two substances can be consumed in food. The HHS document, "Medical Review Officer Manual for Federal Workplace Drug Testing Programs," provides information on the review of opioid tests results, both for the existing substances tested for under 10 CFR part 26 (codeine, morphine, and 6-AM) and also for the additional opioids added in the 2017 HHS Guidelines. The manual states—

> The opioid drug class poses some unique challenges with regard to interpretation because a positive result may be for a legitimate source, including the following: Codeine and morphine may be present due to the consumption of poppy seeds[; and] a positive result for any of the opioid analytes (with the exception of 6-AM) may be from legitimate use of a drug product.

The MRO manual also states that hydrocodone, hydromorphone, oxycodone, and oxymorphone are not found in food products and are therefore subject to review as the only appropriate use is by prescription. The 2017 HHS Guidelines in Section 13.4(d)(1) provided for the MRO review of laboratory test results and stated that if the donor is unable to provide a legitimate medical explanation, then the MRO reports a positive result to the agency for all drugs except codeine and morphine.

This final rule also replaces the term "opiates" with "opioids" in § 26.185(j)(2), which applies to the MRO review of a "positive confirmatory test result for drugs other than opiates," and in § 26.185(j)(4), which states that the MRO may consider the use of medication from a foreign country for "a positive confirmatory test result for opiates."

This final rule also expands the NRC-required drug testing panel to include initial testing for 6-AM, consistent with Section 3.4 of the 2008 and 2017 HHS Guidelines. This change improves the assurance that the testing method used under 10 CFR part 26 identifies individuals 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. Performing initial testing for 6-AM also improves the speed at which testing is completed for this heroin metabolite. Initial drug testing is typically completed on a specimen within 24 hours of receipt at an HHS-certified laboratory. Confirmatory testing can take several days, depending on when the laboratory performs testing on specimens for a particular drug or drug metabolite. Because the current testing for 6-AM is only performed after initial and confirmatory testing of morphine returns a positive test result, it is typical for a laboratory to take the full 5 business days permitted under § 26.169(a) to complete 6-AM testing and then report that result to the MRO for review. This final rule change to conduct initial testing for 6-AM independent of morphine will improve how quickly an HHS-certified laboratory will complete testing, which is of critical importance for any individual actively performing duties that subject them to the requirements of 10 CFR part 26.

This final rule updates the test result information that each HHS-certified laboratory must include in the annual statistical summary report provided to a licensee or other entity under § 26.169(h)(3) by adding hydrocodone, hydromorphone, MDMA, MDA, oxycodone, and oxymorphone to the reporting requirements. This final rule also revises § 26.169(h), as further discussed in Section II.C of this document under the topic "Acceptable Specimens for Observed Collection."

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 testing urine specimens for

amphetamines and cocaine metabolites. This final rule updates the cutoff levels for initial drug testing of urine, as listed in the table in § 26.133 for testing performed at LTFs, and in the table in § 26.163(a)(1) for testing performed at HHS-certified laboratories. The changes to §§ 26.133 and 26.163(a)(1) conform with Section 3.4 of the 2008 and 2017 HHS Guidelines. Specifically, this final rule makes the following changes in each table: 1) lowers the initial test cutoff level for cocaine metabolites, 2) replaces the term "opiate metabolites" with "codeine/morphine" to clarify the existing testing requirement and includes a new footnote 1 to clarify that the target analyte for "codeine/morphine" testing is morphine, 3) lowers the initial test cutoff level for amphetamines (abbreviated in the tables as AMP), 4) clarifies in a new footnote 2 that either a single or multiple initial test kit(s) may be used for amphetamines testing, and 5) includes a new footnote 3 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 each table is revised to "Drugs or drug metabolites" to align with the table title.

Lowering the cutoff levels for these existing drugs and drug metabolites in the NRC-required testing panel increases 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 provides a higher degree of assurance that persons who are using illegal drugs or misusing legal drugs would be identified. The NRC anticipates that the lower testing cutoff levels will 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 final rule.

In addition, this final rule revises §§ 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 and 2017 HHS Guidelines, which require the HHS-certified laboratory to make a determination that each specimen is either "negative" or "positive" 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 testing urine specimens for amphetamine, the cocaine metabolite benzoylecgonine, and methamphetamine.

The NRC is lowering the cutoff levels for confirmatory drug tests for urine, as listed in the table in § 26.163(b)(1), to align with Section 3.4 of the 2008 and 2017 HHS Guidelines. Specifically, this final rule makes the following changes: 1) lowers the confirmatory test cutoff levels for amphetamine, cocaine metabolite, and methamphetamine, 2) eliminates 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;[6] and 3) redesignates table footnote 4 as footnote 3 and updates the text to lower the amphetamine concentration that also must be present in a specimen for it to be determined positive for methamphetamine. Similar to the changes made to the initial testing cutoff levels, lowering the confirmatory testing

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

cutoff levels for amphetamine, cocaine metabolite, and methamphetamine increases 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, this final rule makes two clarifying changes to the initial drug testing cutoff level table for urine specimens in § 26.163(b)(1) by replacing "Opiates" with "Opioids" and adding the abbreviation "(6-AM)" after 6-acetylmorphine. The change to "Opioids" is necessary because of the addition of hydrocodone, hydromorphone, oxycodone, and oxymorphone in this final rule.

Finally, the column header "Drug or metabolites" in the table in § 26.163(b)(1) is revised to "Drugs or drug metabolites" to align with the table title. These changes improve consistency with Section 3.4 of the 2008 and 2017 HHS Guidelines and with the revisions to §§ 26.133 and 26.163(a)(1).

This final rule makes conforming changes to the § 26.169(h)(3) annual statistical summary reporting requirements that apply to HHS-certified laboratories, by improving the clarity and uniformity of the names of the drugs and drug metabolites. Specifically, this final rule adds "(as THCA)"[7] after "Marijuana metabolite," adds "(as benzoylecgonine)" after "Cocaine metabolite," revises "6-AM" to "6-acetylmorphine (6-AM)," and revises "Phencyclidine" to "Phencyclidine (PCP)."

Validity Testing of Adulterants at HHS-Certified Laboratories

This final rule revises 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

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

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 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 changes in this final rule to § 26.161(c)(3) through (c)(6) are consistent with Section 3.5 of the 2008 HHS Guidelines and Section 3.6 of the 2017 HHS Guidelines, which describe the validity testing criteria for the adulterants chromium (VI), halogen (e.g., bleach, iodine, fluoride), glutaraldehyde, and pyridine (pyridinium chlorochromate). The changes in this final rule to § 26.161(f)(5) and (f)(7) are consistent with the validity testing criteria in Section 3.8 of the 2008 HHS Guidelines and Section 3.9 of the 2017 HHS Guidelines for invalid test results due to the possible presence of halogen or an oxidizing adulterant.

The NRC did not 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 did not 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.

This final rule revises § 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." This final rule provides additional flexibility in the confirmatory testing methods that may be used by the laboratory and aligns 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, see 73 FR 17091 and 17102), and Section 11.19(d) of the 2008 and 2017 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 before providing a urine specimen for testing in the hope of diluting the concentration of any drugs and drug metabolites in the specimen below the 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 a dilute specimen 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 before providing a specimen for testing.

This final rule makes four changes to the special analyses testing requirements in § 26.163(a)(2). First, this final rule requires 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 2019 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 2019, 93 percent of licensees and other entities have adopted the special analyses testing policy. This final rule eliminates 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 (3). These tests are now required.

Second, this final rule lowers 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. This final rule lowers 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 improves the ability of licensees and other entities to identify drug-using individuals attempting to subvert the drug testing process. This change does not affect the drug testing assays used by HHS-certified laboratories because under the HHS Guidelines, each laboratory must already validate the accuracy of each assay to 40 percent of the cutoff calibrator. Each laboratory will need to change its administrative procedures that define the initial test result concentrations that trigger special analyses testing.

Third, this final rule replaces 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 does not result in changes to the testing assays used at the laboratories.

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 among 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 public meetings requested a standardized level be used across all laboratories performing special analyses testing. However, this position is 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, this final rule expands 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 requirements, 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 provides additional assurance that drugs and drug metabolites present in the specimen collected under direct observation from a donor will be identified, which improves 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 provide conclusive evidence to the MRO to make a subversion determination on the initial specimen provided. Therefore, this final rule revises § 26.163(a)(2)(i) to require that special analyses testing be performed on specimens collected through directly observed collections under § 26.115(a)(1) through (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 2019 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 provides additional assurance that drug use is 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 2019 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 provides additional assurance that the drug use is 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 provides additional assurance for the same reason described for specimens collected under § 26.115(a)(1).

The change in this final rule to require special analyses testing of specimens collected under direct observation will 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)." This final rule eliminates the *Federal Register* citation from each of these 10 CFR part 26 sections 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 is 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

This final rule revises a number of specimen collection procedures in 10 CFR part 26 to 1) clarify and enhance the instructions for conducting an observed collection, 2) permit the use of mirrors to assist in performing directly observed collections, 3) allow additional 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 improve the clarity, consistency, and flexibility of the collection procedures and align the NRC's requirements more closely with the HHS Guidelines.

This final rule revises § 26.115(e), (f), and (f)(1) through (3) to clarify the instruction for conducting a directly observed specimen collection and provide consistency with Sections 4.4(a) and 8.9 of the 2008 and 2017 HHS Guidelines.

This final rule removes 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." This final rule adds 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)." This change improves the clarity of the existing requirements and ensures that the donor is informed that an individual other than the collector is to observe the specimen provision and that the observer understands the procedures that must be followed to complete the specimen collection.

In § 26.115(f)(2), this final rule adds the following statement to the end of the existing requirement: "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 used for urination is not sufficient to meet this direct observation requirement; the use of a video camera to assist in the observation process is not permitted." This change also incorporates stakeholder feedback at the public meeting on October 11, 2011, during 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 currently are 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 before the provision of a specimen during the observed collection process and that the use of reflective mirrors, but not two-way mirrors, would be acceptable. As required by § 26.115(f)(1), before 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 the integrity of the specimen collection process by verifying that the specimen provided is from the donor. As a result, this final rule revises § 26.115(f)(2) to permit the use of reflective mirrors.

This final rule also revises § 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.

In § 26.115(f)(3), this final rule replaces 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 changes 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 Sections 8.10(d)(3) and (d)(4)(ii) of the 2017 HHS Guidelines and by using terminology consistent with § 26.113(b)(3).

The NRC received two public comments on the proposed rule changes to add § 26.4(g)(6) and revise § 26.109(b)(1) to improve the efficiency of FFD programs by providing licensees and other entities with flexibility in the type of personnel who may monitor a donor during the hydration process. The hydration process 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 (i.e., a shy bladder). During the hydration process, fluid is provided to assist the donor in providing a specimen of adequate volume. Provisions in the proposed rule permitted a staff member designated as FFD program personnel in § 26.4(g) to monitor the donor during the hydration process in place of the original collector. The proposed rule also contained provisions that permitted another specimen collector who met the requirements in § 26.85(a) to monitor the donor in the hydration process. The two commenters recommended that the NRC delete the proposed requirement for hydration monitors to be FFD program personnel under § 26.4(g). The commenters explained that § 26.31, "Drug and alcohol testing," permits an individual who is not designated as FFD program personnel to monitor more significant collection processes, while receiving training only on the activities to be performed. One of the two commenters also referenced the observation process in § 26.115, "Collecting a urine specimen under direct observation," for the same reason. To ensure proper completion of required activities, the commenters suggested that the rule be modified to include instructions to the hydration monitor on observation responsibilities.

The NRC agrees that persons monitoring a donor during the hydration process need not be designated as FFD program personnel, because 10 CFR part 26 already

permits three comparable or more significant observation activities to be performed without such a restriction:

1) Monitoring the collection of a specimen when a donor and collector have a personal relationship (§ 26.31(b)(1)(iii));

2) Observing a donor provide a urine specimen under direct observation when a same-gender collector is not available (§ 26.115(e) and (f)); and

3) In the exceptional event that a designated collection site is inaccessible, an immediate requirement exists to collect a urine specimen (e.g., post-event test), and a same-gender collector is not available to stand outside the area to be used for the specimen collection (§ 26.87(f)(3)).

In these three instances, the individual observing the collection process must receive training or instruction on the applicable collection procedures to be permitted to perform the observation activity.

Accordingly, the NRC modified this final rule to:

1) Remove proposed § 26.4(g)(6), which read: "All persons monitoring a donor during the hydration process described in § 26.109(b)"; and

2) Revise proposed § 26.109(b)(1) to replace the phrase "or to a hydration monitor who meets the requirements in § 26.4(g)(6)" with "or to a hydration monitor."

This final rule retains the proposed rule requirement in § 26.109(b)(1)(i) that the original collector provide instruction to the hydration monitor on the hydration process and acceptable donor behavior.

If a hydration monitor or another collector is used, this final rule requires in § 26.109(b)(1)(ii) that the original collector document the name of the individual on the Federal CCF. The proposed rule then required under § 26.109(b)(1)(ii) that the original specimen collector provide the hydration monitor or second collector with 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). The NRC received one public comment on the proposed § 26.109(b)(1)(ii) requirement that the original specimen collector provide the Federal CCF to that hydration monitor or other collector observing the donor during the hydration process. The commenter stated that the Federal CCF should remain with the original collector during the hydration process.

The NRC agrees that is it unnecessary for another specimen collector or hydration monitor to be provided with the Federal CCF for the hydration process because the Federal CCF would not contain enough space to document observations made during the hydration process (i.e., space on the one line on the Federal CCF for comments would be limited because it already would include the name of the hydration monitor or other collector). A licensee or other entity could, consistent with its collection procedures, establish a documentation method for the hydration monitor or other specimen collector to record information about the hydration process. Accordingly, the NRC updated this final rule by removing the phrases "and then provide the Federal CCF to the individual for the duration of the hydration process" in § 26.109(b)(1)(ii), and "except as provided in § 26.109(b)(1)(ii) for the Federal CCF" in § 26.117(g).

This final rule also makes clarifying changes to § 26.109 by moving the last sentence in § 26.109(b)(1), "The collector shall provide the donor with a separate collection container for each successive specimen," to be 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.

This final rule revises § 26.89(d) in three ways. First, § 26.89(d) is 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 change to § 26.109(b)(1) in this final rule. The NRC received a public comment on a second change in the proposed rule that more precisely described 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 proposed rule replaced 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" 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." The commenter requested that the term "tamper-evident tape" be replaced with the term "tamper-evident seal" to ensure consistent use of the term, which also appears in § 26.117(c). The NRC agrees and corrects this inconsistency. Finally, the phrase "or when a refusal to test has been determined" is added to § 26.89(d) to more accurately describe when the collection process has been completed if a refusal to test has been determined. These three changes 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 included a change to § 26.89(d) to add the phrase "or when a refusal to test has been determined under § 26.107(d)." The addition of an oral fluid specimen collection and testing option in this final rule resulted in a change to the proposed addition to § 26.89(d) because § 26.107(d) applies only to refusal to test actions associated with a urine specimen collection. By removing the words "under

§ 26.107(d)" from the proposed phrase, § 26.89(d) now refers to "refusal to test," a term that applies to all drug testing specimen collections.

This final rule revises § 26.107, "Collecting a urine specimen," to clarify how the donor is observed. First, this final rule redesignates paragraph (b) as paragraph (b)(1). Second, the phrase ", except as provided in § 26.109(b)(1)," is 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 this final rule permits 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) is 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 specimen 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 changes in this final rule provide additional examples of subversion attempt actions that have been reported by licensees and other entities in the annual information reports required by § 26.717, "Fitness-for-duty performance data." More accurate examples of subversion attempts in the regulatory text provide additional clarity on donor actions that may be considered a subversion attempt.

Lastly, this final rule replaces the phrase in § 26.107(b)(1), "the collector shall document the conduct" with "the collector shall document a description of the conduct." This change clarifies the requirement. Related to this § 26.107(b)(1) requirement, the NRC received a public comment that draft regulatory guide (DG)-5040, "Urine Specimen

Collection and Test Result Review under 10 CFR Part 26, 'Fitness for Duty Programs,'" specified an excessive amount of information to be documented on the Federal CCF. The commenter expressed concern that the Federal CCF did not contain sufficient space to document information regarding a subversion attempt and indicated that most licensees have internal documentation processes to capture this information. The commenter requested that the NRC revise Section C.1.B.(3) of DG-5040 to require that "a description of the donor's conduct should be immediately documented."

The NRC agrees, in part, that the available space on the Federal CCF is limited (i.e., a single blank line to write text on the "Remarks" line of the form). Therefore, depending on the number of observations regarding a possible subversion attempt, the Federal CCF may not contain adequate space to record all information. However, the NRC disagrees with the commenter's suggested change to eliminate the reference to documenting information on the Federal CCF in Section C.1.B.(3) of DG-5040 because it is an existing requirement in § 26.107(b)(1). Instead, the NRC revises § 26.107(b)(1) in this final rule and Section C.1.B.(3) in Regulatory Guide (RG) 5.89, "Fitness-for-Duty Programs for Commercial Power Reactor and Category I Special Nuclear Material Licensees," to provide the collector with the option to document information about a subversion attempt on the Federal CCF or through another documentation method that is consistent with the collection procedures of the licensee or other entity. The method used by the licensee or other entity should ensure that all information documented by the collector or hydration monitor on donor actions regarding a possible subversion attempt be provided to FFD program management to assist in the determination of appropriate next steps (e.g., terminate the collection process, collect a specimen under direct observation). This final rule revises §§ 26.107(d)(3) and 26.111(b), which also require the collector to document observations on the Federal CCF.

Section 26.107(b)(2) is 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 final rule change is necessary because the collector must be informed of any unacceptable donor behavior so that appropriate action may be taken.

This final rule revises § 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 is revised to "adulterated, diluted, or substituted the specimen."

This final rule revises § 26.117, "Preparing urine specimens for storage and shipping," in several ways. First, this final rule revises the title of § 26.117, "Preparing urine specimens for storage and shipping," to "Preparing drug testing specimens for storage and shipping," replacing the word "urine" with the phrase "drug testing." Second, this final rule revises § 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 "specimen(s) in view at all times," and remove the word "urine." This revision improves 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 in an unobserved collection, as described in § 26.107(a). Third, this final rule corrects two editorial errors in § 26.117(f): the term "chain-of-custody forms" is replaced with the term "Federal CCFs" and the phrase "or the licensee's testing facility" is replaced with the phrase "or to the licensee testing facility." Fourth, this final rule

revises §§ 26.117(i) and (j) as further discussed in Section II.C of this document, under "Acceptable Specimens for Observed Collection."

With regard to urine specimen acceptability, this final rule revises 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.

This final rule corrects 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" is 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

This final rule adds § 26.107(d) and revises §§ 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) is added by this final rule 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 or through another documentation method consistent with the collection procedures of the licensee or other entity; 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 of the refusal to test. The majority of these changes are consistent with existing collector practice. However, the change to discard any urine specimens, except if collected for a post-event test, is a new requirement that improves 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 addresses this inconsistency. The revisions to § 26.107(d) ensure that if a donor refuses to cooperate with the collection process, uniform action is taken, which makes 10 CFR part 26 more consistent with Section 8.12 of the 2008 HHS Guidelines and Section 8.13 of the 2017 HHS Guidelines.

The final rule change to retain and test any specimen collected for a post-event test under § 26.31(c)(3) helps 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) is revised to remove the word “designated” from the phrase “designated FFD program manager.” This 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). The parenthetical phrase “(e.g., adulterated or diluted)” is added after the word “altered” in the second sentence of § 26.111(c) to provide additional clarity.

Section 26.111(e) specifies that “as much of the suspect specimen as possible must be preserved.” This final rule adds 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 changes to § 26.107(d) in this final rule.

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, or substituted, or that is collected under direct observation must be sent to an HHS-certified laboratory for initial and, if necessary,

confirmatory testing. Therefore, this final rule removes § 26.111(f) to improve the clarity of 10 CFR part 26.

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

Blind Performance Test Sample Lot In-Service Requirement

This final rule revises § 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 indicated that sample lots can remain viable for much longer than 6 months (e.g., 2 years). Further, Section 10.2 of the 2008 and 2017 HHS Guidelines do not impose a time limit on the use of a BPTS lot. This final rule eliminates the 6-month use limit, which enables the BPTS supplier, based on laboratory testing data on lot stability, to establish a specified shelf life for each BPTS lot. Allowing the BPTS supplier to determine the expiration date, instead of the NRC requiring a uniform shelf life, improves the effectiveness of 10 CFR part 26, reduces burden on BPTS suppliers and entities implementing 10 CFR part 26 requirements, and aligns with the HHS Guidelines. Furthermore, if a BPTS is no longer stable and unexpected test results are reported by an HHS-certified laboratory, § 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

This final rule removes § 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 as described in §§ 26.31(d)(3) and 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. This final rule change reduces the potential for dual regulation of HHS-certified laboratories because each laboratory is annually inspected by the licensee or other entity as required in § 26.41(c). Eliminating these redundant requirements improves the regulatory efficiency of 10 CFR part 26 by reducing unnecessary regulatory oversight.

A conforming change based on the removal of § 26.155 eliminates 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). A second conforming change eliminates the records retention requirement for personnel files at HHS-certified laboratories under § 26.715(b)(1).

HHS-Certified Laboratory Procedures

This final rule removes § 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 previously discussed with regard to the § 26.155 changes in this final rule, each HHS-certified laboratory is certified and inspected on a periodic basis by the NLCP. This provides assurance that each laboratory meets the requirements in the HHS Guidelines to develop, implement, and maintain procedures. This final rule change reduces 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.

This final rule revises § 26.157(a) by replacing 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 changes do the following: 1) ensure that each laboratory continues 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) 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 and 2017 HHS Guidelines. The changes to § 26.157(a) in this final rule 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. This final rule makes 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 and 11.15(a)(1) of the 2008 and 2017 HHS Guidelines.

This final rule replaces 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) are replaced with the phrase "the drug or drug metabolite." Similarly, the phrase "no drug" is expanded to "no drug or drug metabolite" in § 26.167(e)(3)(i), and the phrase "no drugs or drug metabolites" is revised to "no drug or drug metabolite" in §§ 26.137(e)(6)(i) and 26.167(d)(3)(i).

This final rule removes 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" is replaced in this final 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)" is replaced in this final 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" is replaced in this final rule with the phrase "at least one control" in § 26.167(e)(3)(iv).

The parenthetical statement “(i.e., calibrators and controls)” is added after the phrase “quality control samples” in §§ 26.137(e)(6) and 26.167(d)(4), and a conforming change is 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) is replaced in this final rule with the phrase “A calibrator with its drug concentration at the cutoff.”

This final rule replaces 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 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 replace 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.” This final rule 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) is 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.”

This final rule also addresses two issues 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), which were described in an NRC enforcement guidance memorandum (EGM 09-003), dated March 31, 2009. A third issue identified in EGM 09-03 on the LTF quality control sample requirements, incorrectly using the term

"laboratory analysts" instead of "licensee testing facility technicians," was addressed in a 10 CFR part 26 final rule correcting amendment (74 FR 38326; August 3, 2009).

The first issue pertains to § 26.137(d)(5) and (e)(6)(v), which require that at least one quality control sample in each analytical run must appear as a "donor 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 10 CFR part 26 regulations do not require that the preparation of quality control samples and the conduct of specimen testing are to be performed by different individuals. Without EGM-09-003, § 26.137(d)(5) and (e)(6)(v) would have placed 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 requirements. Because the LTF technician may prepare quality control samples and perform specimen testing, the technician will know when he or she is testing a quality control sample. Therefore, the appearance of the quality control sample is irrelevant. For this reason, this final rule removes the phrase "that appears to be a donor specimen to the licensee testing facility technicians" in § 26.137(d)(5) and (e)(6)(v).

The second issue 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. This requirement is already met through the requirements in § 26.137(e)(6)(ii) and (e)(6)(iii), which specify the positive quality control samples to be included in each analytical run. Furthermore, as explained in EGM 09-003, the sample required by § 26.137(e)(6)(v) does not need to be positive. This requirement is already

met by § 26.137(e)(6)(i), which requires each analytical run to include sample(s) certified by an HHS-certified laboratory to contain no drugs or drug metabolites. Because the "at least one positive control" requirement in § 26.137(e)(6)(v) is unnecessary and the NRC is removing the phrase "that appears to be a donor specimen to the licensee testing facility technicians" from § 26.137(e)(6)(v), the NRC is deleting § 26.137(e)(6)(v).

The NRC is withdrawing EGM 09-003 upon the effective date of this final rule, which corrects these issues.

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 urine specimen test results. This final rule redesignates paragraph (f)(3) as paragraph (f)(4) and adds 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 and Section 13.5(e) of the 2017 HHS Guidelines. Specifically, if a donor does not provide an acceptable medical explanation to the MRO for a pH value in the range of 9.0 to 9.5, then the MRO must consider if elapsed time and/or high temperature might have caused the test result. This change addresses 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). In this final 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 directs the licensee or other entity to collect a second urine specimen from the donor, as soon as reasonably practicable. The second specimen is not 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 new step to consider technical explanations for a discrepant pH result provides an additional protection to the donor and limits 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). Although Section 13.4(f) of the 2008 HHS Guidelines and Section 13.5(e) of the 2017 HHS Guidelines differ in that a second test in these circumstances is not required, not requiring a second test in these circumstances is inapplicable to 10 CFR part 26 because a valid test is necessary for determining whether to grant or deny FFD authorization.

The NRC included guidance on the methods an MRO could use to review invalid test results reported under § 26.185(f)(3) in new RG 5.89, issued concurrently with this final rule.

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."[8] This final rule includes 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 request for testing ensures that a record is maintained to demonstrate that the donor had made the request

[8] "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.

within the required 3 business days. This final rule change is consistent with the existing practice of MROs to document this information 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 single specimen or testing of the specimen in Bottle B without the donor's written permission, except as permitted in § 26.185(l)." This final rule revises § 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 the single specimen or the testing of the Bottle B split specimen." This final rule addresses an inconsistency in the current requirements 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 the single specimen or to test the Bottle B split specimen, some licensees are interpreting the current provision to require that the MRO must receive written permission from the donor before initiating the retesting of a specimen.

These final rule changes to § 26.165(b)(2) and (b)(3) improve the consistency of 10 CFR part 26 with Section 14.1(b) of the 2008 and 2017 HHS Guidelines and enhance due process by ensuring that the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen can proceed as quickly as possible.

Collection of a Second Specimen under Direct Observation when Bottle B or an Aliquot of the 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. This final rule corrects 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 the 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 and 2017 HHS Guidelines, for this same circumstance, states that no notice is to be given to the donor regarding the second specimen collection until immediately before the collection is to commence. This final rule revises § 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 improves 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 and 2017 HHS Guidelines.

This final rule also revises § 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 also states 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 FFD authorization is

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 has revised 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)(3) and (4). Specifically, the reporting requirements to provide FFD program performance data by populations tested (i.e., individuals in applicant status, permanent licensee employees, contractor/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." This final rule

removes the phrase “individuals in applicant status” from § 26.717(b)(3) and (4) to clarify the existing reporting requirement.

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 (4) do 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, this final rule revises the tested population “licensee employees” to “licensee or other entity employees” in § 26.717(b)(3) and (b)(4).

Acceptable Specimens for Observed Collection

As described in Section II.B.5 of this document, this final rule is permitting a licensee or other entity to collect an oral fluid specimen instead of a urine specimen for any of the observed collection conditions in § 26.115(a)(1) through (3), and (a)(5). To provide the flexibility to conduct oral fluid specimen, the NRC has made conforming and clarifying changes in this final rule, as well as included additional new requirements specific to the testing of oral fluid specimens. These changes, grouped by topic area, include the following:

- **Specimens to be collected**. This final rule revises the § 26.83(b) restriction to “Collect only urine specimens for both initial and confirmatory tests for drugs” by permitting the collection and testing of an oral fluid specimen for any of the observed specimen collection conditions under § 26.115(a)(1) through (3) and (a)(5), as long as the “licensee establishes through its policy and procedures that an oral fluid specimen” can be collected and tested. This final rule also requires, for each of the

directly observed collection conditions in § 26.115(a)(1) through (3) and (a)(5), that a licensee or other entity always collect either urine or an oral fluid specimen.

- **Collector qualifications and responsibilities**. This final rule consolidates the urine collector requirements in § 26.85(a) and the alcohol collector requirements in § 26.85(b) into § 26.85(a), to provide uniform qualifications and responsibilities for collectors based on the specimen the collector is qualified to collect under this part. The existing urine and alcohol collector requirements are the same, with two exceptions. First, different terminology is used for "methods to address problem collections" with respect to a donor's inability to provide a specimen: "shy bladder" for urine and "shy lung" for alcohol. This final rule addresses the terminology differences for a donor's inability to provide a specimen by providing both terms in a parenthetical statement after "inability to provide a specimen" under § 26.85(a)(2)(i). Second, the alcohol collector qualification requirements in current § 26.85(b)(2) include the "operation of the particular testing device(s)," which is not applicable to urine collectors. This final rule revises the "operation of the particular alcohol testing devices [i.e., the alcohol screening devices (ASDs) or EBTs]" in § 26.85(b)(2) to "operation of the particular specimen collection or alcohol testing device(s) (e.g., alcohol screening device (ASD), EBT, oral fluid)" in § 26.85(a)(3). Lastly, this final rule renumbers § 26.85(a)(5), replaces the phrase "specimen collection and transfer process" with "specimen collection process," and adds the phrase ", and the specimen transfer process, if applicable" to the end of the existing requirement. This is a conforming change necessary because "transfer process" does not apply to all specimens collected (e.g., the collection of a breath specimen for alcohol).
- **Collection sites**. This final rule revises three collection site requirements in § 26.87, "Collection sites," to provide flexibility to collect oral fluid specimens in addition to urine specimens for drug testing. The revisions also clarify, if appropriate, that a

requirement is specific to the collection of one specimen type (e.g., urine). First, § 26.87(a) is revised to replace the phrase "shipping or transportation of urine specimens to a drug testing laboratory; the collection of oral fluids or breath specimens; and the security of alcohol testing devices" with "shipping or transportation of specimens to a drug testing laboratory; the testing of specimens for alcohol; the security of specimen collection and testing devices." Second, § 26.87(b) is revised to state that the collection site must provide visual privacy for the donor and collector during an oral fluid specimen collection. This privacy provision is consistent with the provision of individual privacy while the donor submits a urine specimen as described in § 26.87(b). Third, § 26.87(f) is revised in §§ 26.87(f) and (f)(5), to replace the term "urine specimen" with "specimen for drug testing" for an "exceptional event" that a designated collection site is inaccessible. Section 26.87(f)(2) is revised to replace the phrase "If practical, a water coloring agent" with "If practical when a urine specimen is to be collected, a water coloring agent." Section 26.87(f)(3) is revised to replace the phrase "area that will be used for a specimen collection" with "area that will be used for a urine specimen collection." Section 26.87(f)(4) is revised in two ways. First, the phrase "the collector shall inspect the toilet bowl and area to ensure that there is no evidence of a subversion attempt" is replaced with "if the specimen is urine, the collector shall inspect the toilet bowl and area to ensure that there is no evidence of a subversion attempt." This change clarifies the inspection of the toilet bowl and area only applies to urine specimen collections. Second, § 26.87(f)(4) is revised to replace the phrase "the collector shall instruct the donor to participate with the collector" with "for any specimen collected for drug testing, the collector shall instruct the donor to participate with the collector." This change clarifies that donor participation with the

collector in completing the chain of custody procedures applies to any specimen collected for drug testing.

- **Preparing to collect specimens for drug testing**. This final rule revises § 26.89(d) by removing the word "urine" from the phrases "urine collection procedure" and "urine specimen container." These changes provide flexibility to permit the collection of any specimen for drug testing (e.g., urine, oral fluid). This final rule also revises § 26.105, "Prepare for urine collection," to accommodate for the collection of urine and oral fluid specimens. The title of § 26.105, "Preparing for urine collection," is revised to "Preparing for the collection of a specimen for drug testing." In §§ 26.105(a) and (d), the word "urine" is removed from the phrase "urine specimen" where it appears. In § 26.105(c), the phrase "wash and dry his or her hands before urinating" is revised to "wash and dry his or her hands before providing a specimen." In the first sentence of § 26.105(e), the phrase "sealed collection container from the collection kit materials" is replaced with "sealed urine specimen collection container from the collection kit materials or an oral fluid specimen collection device." In the second sentence of § 26.105(e), the phrase "the collection container" is replaced with "urine specimen collection container." The changes in § 26.105(e) ensure that the collection process is consistent for oral fluid and urine specimens.
- **Collecting oral fluid specimens**. This final rule revises § 26.97, "Conducting an initial test for alcohol using a specimen of oral fluids," which was specific to the collection of oral fluid specimens for alcohol testing, by making minor conforming changes to accommodate for the collection of oral fluid specimens for both alcohol and drug testing. The title of § 26.97 is revised to "Collecting oral fluid specimens for alcohol and drug testing." The word "test" is replaced with the phrase "specimen collection" in § 26.97(a), (a)(4), and (b)(1) through (3). Section 26.97(c)(2) is revised to replace the phrase "initial test using an EBT" with "specimen collection (i.e., initial

test using an EBT for alcohol, or urine specimen collection for drug testing)." Section 26.97(d) is revised to replace the phrase "The collector shall read the result" with "For alcohol testing of oral fluids, the collector shall read the result."

- **Preparing specimens for storage and shipping**. This final rule revises § 26.117 to accommodate for the collection of oral fluid specimens. The title of § 26.117, "Preparing urine specimens for storage and shipping," is revised to "Preparing drug testing specimens for storage and shipping." The first sentence in § 26.117(a) is revised to replace the phrase "Both the donor and the collector shall keep the donor's urine specimen(s) in view" with "Once the collector is presented with the specimen from the donor, both the donor and collector shall keep the donor's specimen(s) in view." In § 26.117(i), the phrase "packaged with its associated urine specimen bottle" is replaced with "packaged with its associated specimen bottle." In the third sentence of § 26.117(j), the phrase "Specimens that have not been shipped" is replaced with "Urine specimens that have not been shipped" and the phrase "any specimen" is replaced with "any urine specimen." A new fourth sentence is added to state that "Oral fluid specimens shall be stored under the conditions specified by the oral fluid specimen collection device manufacturer." This new provision is necessary because the refrigeration provision for urine specimens in § 26.117(j) may not be appropriate or necessary given the buffering solution that oral fluid specimen collection devices may contain.
- **FFD program testing requirements**. Section 26.31(d)(3)(i) is revised by adding "urine" to the start of the existing requirement, "Specimens sent to the HHS-certified laboratories must be subject to initial validity and initial drug testing by the laboratory." A new sentence is added in § 26.31(d)(3)(i) that states that "Oral fluid specimens sent to the HHS-certified laboratories must be subject to initial drug testing by the laboratory." Unlike the collection of urine specimens that are typically

provided by the donor in the privacy of a room, stall or enclosure, oral fluid specimens are directly observed by the collector. Standard validity testing is necessary for urine specimens because of the lack of direct observation of all specimens and to provide assurance that a donor has not attempted to subvert the testing process. The 2019 HHS Guidelines for oral fluid testing also do not mandate validity testing of all specimens.

- **HHS-certified laboratory specimen testing**.
  - *Use of HHS-certified laboratories.* This final rule revises § 26.151, "Purpose," to replace the phrase "HHS-certified laboratories that licensees and other entities who are subject to this part use for testing urine specimens for validity and the presence of drugs and drug metabolites" with "HHS-certified laboratories that licensees and other entities use to perform testing under this part." This final rule also revises the title of § 26.153, "Using certified laboratories for testing urine specimens," by removing the word "urine." These changes accommodate the testing of oral fluid specimens at HHS-certified laboratories.
  - *Drug testing cutoff levels*. This final rule includes the testing cutoff levels for initial and confirmatory drug testing consistent with Section 3.3 of the 2019 HHS Guidelines for oral fluid testing. This final rule adds a new table to § 26.163(a)(1), for initial testing of oral fluid specimens, and adds a new table to § 26.163(b)(1), for confirmatory drug testing of oral fluid specimens. Each table lists the drugs and drug metabolites and test cutoff levels, and includes footnotes to define substance names such as "Amphetamine (AMP)" and initial testing specifications.
  - *Validity testing*. This final rule revises §§ 26.161(b), (d), and (e) to clarify that these validity testing provisions only apply to urine specimens. In § 26.161(b), the phrase "Initial validity testing" is replaced with "Initial validity testing of urine."

In § 26.161(d), the phrase “Results indicating a substituted specimen” is replaced with the phrase “Results indicating a substituted urine specimen.” In § 26.161(e), the phrase “Results indicating a dilute specimen” is replaced with the phrase “Results indicating a dilute urine specimen.” Section 26.31(d)(1) is also revised to remove the word “adulterants” from the “substances tested” list. Including adulterants in the substance list is unnecessary because §§ 26.131 and 26.161 describe each validity test that is to be performed on urine specimens at licensee testing facilities and HHS-certified laboratories, respectively. Adulterant testing is only one of the required validity tests performed on urine specimens. A conforming change is made in this final rule to § 26.405(d), which specifies the required substances that FFD programs for construction must test in specimens. “Adulterants” is removed from the first sentence in § 26.405(d), which describes the substances that licensees and other entities must test for in specimens. Instead, the second sentence in § 26.405(d), “Urine specimens collected for drug testing must be subject to validity testing,” is revised to “Urine specimens collected for drug testing must be subject to validity testing that includes testing for adulterants.” This change clarifies that adulterant testing applies to validity testing of urine specimens.

- *Quality assurance and quality control*. Section 26.167(c) is revised in this final rule to replace the phrase “validity tests” with “validity tests on urine.” Validity testing in 10 CFR part 26 only applies to urine specimens. Section 26.167(d)(1) is revised to replace the phrase “Any initial drug test performed by an HHS-certified laboratory” with “Any initial drug test of urine performed by an HHS-certified laboratory.”
- *Annual statistical summary reports*. Section 26.169(h) is revised to remove the word “urinalysis” from the phrase “annual statistical summary of urinalysis

testing." This change ensures that the summary of test results provided by the HHS-certified laboratory includes the results for all urine and oral fluid specimens tested for a licensee or other entity.

III. Section-by-Section Analysis

The following paragraphs describe the specific changes within this final rule:

Nomenclature Changes

Throughout 10 CFR part 26, this final rule removes the term "custody and control form" and replaces it with the term "Federal CCF." This final rule also removes two additional iterations of the term, "custody-and-control forms" and "custody-and-control form(s)," and replaces them with the terms "Federal CCFs" and "Federal CCF(s)," respectively.

Throughout 10 CFR part 26, this final rule replaces the term "chain-of-custody" with the term "chain of custody."

Section 26.4 FFD program applicability to categories of individuals

This final rule amends paragraph (e)(6)(iv) to eliminate the phrase "(65 FR 41944; August 9, 2001)."

This final rule revises paragraph (j)(3) 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."

Section 26.5 Definitions

This final rule adds definitions for *Cancelled test, Carryover*, *Certifying Scientist*, *Federal custody and control form*, *Lot*, *Rejected for testing*, and *Responsible Person*. This final rule also revises the definitions for *Calibrator*, *Control*, *Dilute specimen*, *HHS-certified laboratory*, *Invalid result*, *Limit of quantitation*, and *Substituted specimen*.

Section 26.8 Information Collection Requirements: OMB Approval

This final rule amends paragraph (b) to remove the reference to § 26.155.

Section 26.31 Drug and Alcohol Testing

This final rule amends paragraph (b)(2) to eliminate the phrase "(65 FR 41944; August 9, 2001)."

This final rule revises paragraph (d)(1) introductory text to include hydrocodone, hydromorphone, MDMA, MDA, oxycodone, and oxymorphone as substances for which licensees and other entities are required to test in each specimen. The rule also replaces the term "opiates" with the term "opioids," and removes the term "adulterants."

This final rule amends paragraph (d)(1)(i)(D) to eliminate the phrase "as specified in § 26.155(a)."

This final rule revises the third sentence of paragraph (d)(1)(ii) 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 under §§ 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."

This final rule revises paragraph (d)(3)(i) to add "urine" to the beginning of the second sentence to read "Urine specimens sent to HHS-certified laboratories must be subject to initial validity and initial drug testing by the laboratory," and to add a new third

sentence to read “Oral fluid specimens sent to HHS-certified laboratories must be subject to initial drug testing by the laboratory.”

Section 26.83 Specimens to be Collected

This final rule revises paragraph (b) to add to the end of the existing requirement the phrase “unless the licensee or other entity establishes through its policy and procedures that an oral fluid specimen can be collected and tested for any of the observed specimen collection conditions under § 26.115(a)(1) through (3) and (a)(5).” This final rule also revises paragraph (b) to add a new sentence: read “For each observed collection condition under § 26.115(a)(1) through (3) and (a)(5), the licensee or other entity shall always collect and test the same specimen type.”

Section 26.85 Collector Qualifications and Responsibilities

This final rule revises paragraph (a) introductory text to remove “urine” from the first sentence “Urine collector qualifications.” In the second sentence, the final rule replaces the phrase “Urine collectors” with “Each collector” and replaces the words “urine collection procedures” with the phrase “the collection procedures for each specimen the individual is qualified to collect under this part.” In the third sentence, the final rule replaces the term “Collectors” with “Each collector.”

This final rule revises paragraph (a)(2) to remove the phrase “collections involving ‘shy-bladder’ and attempts to tamper with a specimen.” The final rule adds a new paragraph (a)(2)(i) to specify the “Inability to provide a specimen (e.g., ‘shy bladder’ for a urine specimen, ‘shy lung’ for a breath specimen, dry mouth for an oral fluid specimen),” and a new paragraph (a)(2)(ii) to specify “Attempts to tamper with a specimen.”

This final rule redesignates paragraphs (a)(3) and (4) as paragraphs (a)(4) and (5), respectively, and adds a new paragraph (a)(3). In the renumbered paragraph (a)(5), this final rule replaces the phrase “specimen collection and transfer process” with “specimen collection process,” and adds the phrase “, and the specimen transfer process, if applicable” to the end of the existing requirement.

This final rule removes paragraph (b) and redesignates paragraphs (c), (d), and (e) as paragraphs (b), (c), and (d), respectively. In the redesignated paragraph (b)(1), the final rule replaces the phrase “the requirements of paragraphs (a) and (b) of this section” with the phrase “the requirements of paragraph (a) of this section” as a conforming change.

Section 26.87 Collection sites.

This final rule revises the second sentence of paragraph (a) to replace the phrase “shipping or transportation of urine specimens to a drug testing laboratory; the collection of oral fluids or breath specimens; and the security of alcohol testing devices” with “shipping or transportation of specimens to a drug testing laboratory; the testing of specimens for alcohol; the security of specimen collection and testing devices.”

This final rule revises paragraph (b) to replace the phrase “The collection site must provide for the donor’s visual privacy while the donor and collector are viewing the results of an alcohol test, and for individual privacy while the donor is submitting a urine specimen,” with the sentences “Visual privacy must be provided to the donor and collector when viewing alcohol test results and during the collection of an oral fluid specimen for drug testing. The donor must be provided with individual privacy while the donor is submitting a urine specimen.”

This final rule amends paragraph (f) to replace the term “urine specimen” with “specimen for drug testing.”

This final rule amends paragraph (f)(2) to replace the phrase “If practical, a water coloring agent” with “If practical when a urine specimen is to be collected, a water coloring agent.”

This final rule amends paragraph (f)(3) to replace the phrase “area that will be used for a specimen collection” with “area that will be used for a urine specimen collection.”

This final rule amends paragraph (f)(4) to read “Once the collector has possession of the specimen, if the specimen is urine, the collector shall inspect the toilet bowl and area to ensure that there is no evidence of a subversion attempt and shall then flush the toilet, and for any specimen collected for drug testing, the collector shall instruct the donor to participate with the collector in completing the chain of custody procedures.”

This final rule amends paragraph (f)(5) to replace the phrase “urine specimen” with “specimen for drug testing.”

Section 26.89 Preparing to Collect Specimens for Testing

This final rule amends paragraph (c) to replace the phrase “adulterated, diluted, or adulterated the specimen” with the phrase “adulterated, diluted, or substituted the specimen.”

This final rule revises paragraph (d) to include this phrase at the end of the first sentence: “, except as described in § 26.109(b)(1).” The rule also revises the second sentence in paragraph (d) to replace the phrase “For this purpose, a urine collection procedure is complete when the urine specimen” with the phrase “For the collection of specimen(s) for drug testing, the collection procedure is complete when the specimen”, to replace the phrase “sealed and initialed” with the phrase “sealed with tamper-evident seal, the seal has been dated and initialed”, and to replace the phrase “the chain of custody form has been executed, and the donor has departed the collection site” with

the phrase “and the Federal CCF has been completed or when a refusal to test has been determined.”

Section 26.97 Conducting an initial test for alcohol using a specimen of oral fluids

This final rule revises the section heading to read “Collecting oral fluid specimens for alcohol and drug testing.”

This final rule amends paragraphs (a) introductory text, (a)(4), and (b)(1) through (3), to replace the word “test” with the phrase “specimen collection” wherever it appears.

This final rule revises paragraph (c)(2) to replace the phrase “initial test using an EBT” with “specimen collection (i.e., initial test using an EBT for alcohol, or urine specimen collection for drug testing).”

This final rule revises paragraph (d) to replace the phrase “The collector shall read the result” with “For alcohol testing of oral fluids, the collector shall read the result.”

Section 26.105 Preparing for urine collection.

This final rule revises the section heading to “Preparing for the collection of a specimen for drug testing.”

This final rule amends paragraphs (a) and (d) to remove the word “urine” from the phrase “urine specimen” wherever it appears.

This final rules amends paragraph (c) to replace the phrase “wash and dry his or her hands before urinating” with “wash and dry his or her hands before providing a specimen.”

This final rule revises the first sentence of paragraph (e) to change the phrase “sealed collection container from the collection kit materials” to “sealed urine specimen collection container from the collection kit materials or an oral fluid specimen collection

device", and in the second sentence, replaces the phrase "the collection container" with "the urine specimen collection container."

Section 26.107 Collecting a Urine Specimen

This final rule revises paragraph (b) by redesignating paragraph (b) as paragraph (b)(1) to include the exception provided in § 26.109(b)(1) for a hydration monitor, expand the examples of subversion attempt actions, and add flexibility for other documentation methods. This final rule also adds new paragraph (b)(2) 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).

This final rule adds paragraph (d) to describe the requirements for the actions a collector must take if a refusal to test is determined at any point during the specimen collection process.

Section 26.109 Urine Specimen Quantity

This final rule renames paragraph (b)(1) as introductory text and adds new paragraphs (b)(1)(i) through (iii) 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 (i.e., a shy bladder). For clarity, the last sentence of former paragraph (b)(1) becomes the new first sentence of paragraph (b)(2).

Section 26.111 Checking the Acceptability of the Urine Specimen

This final rule revises paragraph (a) 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.”

This final rule revises the second sentence of paragraph (b) to replace “custody-and-control form” with the phrase “Federal CCF or through another documentation method consistent with the collection procedures of the licensee or other entity” at the end of the existing requirement.

This final rule amends the first sentence of paragraph (c) to remove the word “designated” from the phrase “designated FFD program manager”, and revises the parenthetical phrase in the third sentence to add “(e.g., adulterated or diluted)” after the word “altered”.

This final rule revises paragraph (e) to include the phrase “, except under the conditions described in § 26.107(d)(4)” at the end of the existing requirement, and removes paragraph (f).

Section 26.115 Collecting a Urine Specimen under Direct Observation

This final rule revises paragraph (a)(3) 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, this final rule removes the word “and” at the end of paragraph (a)(3). The rule adds paragraph (a)(5) 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 rule also replaces the period at the end of the sentence in paragraph (a)(4) with “; or” to accommodate adding a new

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

This final rule revises the first sentence of paragraph (f) introductory text, “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)”, and adds it to the end of the existing requirements in paragraph (e).

This final rule revises paragraph (f)(2) to 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 used for urination is not sufficient to meet this direct observation requirement; the use of a video camera to assist in the observation process is not permitted.”

This final rule revises paragraph (f)(3) to 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.”

This final rule revises paragraph (g) to include the phrase “, and the collector shall follow the procedures in § 26.107(d)” at the end of the existing requirement.

Section 26.117 Preparing Urine Specimens for Storage and Shipping

This final rule revises the section heading to “Preparing drug testing specimens for storage and shipping.”

This final rule revises paragraph (a) to replace the phrase “Both the donor and the collector shall keep the donor’s urine specimen(s) in view” with the phrase “Once the collector is presented with the specimen from the donor, both the donor and the collector shall keep the donor’s specimen(s) in view.”

This final rule revises the first sentence in paragraph (f) to replace the term “chain-of-custody forms” with the term “Federal CCFs” and to replace the phrase “or the licensee’s testing facility,” with the phrase “or to the licensee testing facility.”

This final rule amends paragraph (g) to add the phrase “, except as provided in § 26.109(b)(1)(ii) for the Federal CCF,” to the end of the first sentence.

This final rule amends paragraph (i) to replace the phrase “urine specimen bottle” with “specimen bottle.”

This final rule amends paragraph (j) to replace the word “specimens” with the phrase “urine specimens” and the word “specimen” with the phrase “urine specimen” in the third sentence and to add a new fourth sentence to state that “Oral fluid specimens shall be stored under the conditions specified by the oral fluid specimen collection device manufacturer.”

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

This final rule revises paragraph (b)(1)(ii) to replace the phrase “the specimen may not be tested,” with the phrase “the licensee testing facility shall reject the specimen for testing.”

This final rule revises paragraph (b)(2) introductory text to add 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.”

Section 26.133 Cutoff Levels for Drugs and Drug Metabolites

This final rule revises the introductory text to clarify that the specified cutoff level must be used to determine whether the specimen is negative or positive for the indicated drugs or drug metabolites being tested. The rule also revises the table heading to "Table 1 to § 26.133–Urine, Initial Test Cutoff Levels for Drugs and Drug Metabolites" and the column header "Drug or metabolites" to "Drugs or drug metabolites" to align with the table heading. The rule further revises the table to 1) lower the initial test cutoff level for cocaine metabolites from 300 ng/mL to 150 ng/mL, 2) replace "opiate metabolites" with "codeine/morphine" and include a new footnote 1 to clarify the existing requirement that morphine is the target analyte for codeine/morphine testing, 3) add initial testing for hydrocodone and hydromorphone at a cutoff level of 300 ng/mL, 4) add initial testing for oxycodone and oxymorphone at a cutoff level of 100 ng/mL, 5) add the drug class "Opioids:" to appear above the listing for "codeine/morphine," 6) add initial testing for 6-AM at a cutoff level of 10 ng/mL, 7) lower the initial test cutoff level for amphetamines (abbreviated in the table as AMP) from 1000 ng/mL to 500 ng/mL, 8) include a new table footnote 2 regarding initial test kits, 9) include a new table footnote 3 to clarify that for amphetamines testing, methamphetamine (abbreviated in the table as MAMP) is the target analyte, 10) add initial testing for MDMA and MDA at a cutoff level of 500 ng/mL, and 11) provide the full chemical name for MDMA and MDA in new footnotes 4 and 5 to the table, respectively.

Section 26.137 Quality Assurance and Quality Control

This final revises paragraph (d)(5) to remove the phrase "that appears to be a donor specimen to the licensee testing facility technicians."

This final rule revises paragraph (e)(6) introductory text to replace the phrase "A minimum of 10 percent of all specimens in each analytical run" at the start of the first sentence with the phrase "A minimum of 10 percent of the total specimens in each

analytical run" and adds the parenthetical phrase "(i.e., calibrators and controls)" after the phrase "quality control samples". The rule also replaces the word "drugs" in the first sentence and the phrase "drug and metabolite" in the second sentence with the phrases "drugs and drug metabolites" and "drug and drug metabolite," respectively.

This final rule revises paragraph (e)(6)(i) to 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."

This final rule revises paragraph (e)(6)(ii) to replace the phrase "drug(s) or drug metabolite(s)" with the phrase "the drug or drug metabolite."

This final rule revises paragraph (e)(6)(iii) 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."

This final rule removes paragraph (e)(6)(v).

Section 26.151 Purpose

This final rule revises the purpose of Subpart G, "Laboratories Certified by the Department of Health and Human Services," to read "This subpart contains requirements for the HHS-certified laboratories that licensees and other entities use to perform testing under this part."

Section 26.153 Using Certified Laboratories for Testing Urine Specimens

This final rule revises the section heading to read "Using certified laboratories for testing specimens."

This final rule revises paragraph (a) 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 rule also removes 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."

This final rule revises paragraph (g) to replace the term "Federal custody-and-control form" with "Federal CCF" and the term "non-Federal form" with "non-Federal CCF."

Section 26.155 Laboratory Personnel

This final rule removes and reserves § 26.155.

Section 26.157 Procedures

This final rule revises paragraph (a) to replace the phrase "clear and well-documented procedures for" with the phrase "procedures specific to this part that document the" and to remove "urine" in the phrase "testing of urine specimens."

This final rule removes and reserves paragraph (b) and removes paragraphs (c) through (e).

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

This final rule revises paragraph (b)(1)(ii) to replace the phrase "the specimens may not be tested and the licensee or entity shall" with the phrase "the laboratory shall reject the specimens for testing. The licensee or other entity shall".

This final rule revises paragraph (b)(2) introductory text 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.”

This final rule revises the second sentence of paragraph (c) to replace the term “custody-and-control” with the term “chain of custody.”

This final rule revises paragraph (d) to replace the term “custody-and-control” with the term “chain of custody.”

This final rule revises paragraph (e) to replace the term “custody-and-control” with the term “chain of custody” in the two instances that it occurs in the paragraph.

Section 26.161 Cutoff Levels for Validity Testing

This final rule amends paragraph (b) introductory text to replace the phrase “Initial validity testing” with the phrase “Initial validity testing of urine.”

This final rule amends paragraphs (c)(3) through (6) to replace all instances of “LOD” with “LOQ.”

This final rule revises paragraph (c)(5) 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)).”

This final rule revises paragraph (c)(6) to replace the phrase “GC/MS for the confirmatory test” with the phrase “a different confirmatory method (e.g., GC/MS).”

This final rule amends paragraph (d) to replace the phrase “Results indicating a substituted specimen,” with the phrase “Results indicating a substituted urine specimen.”

This final rule amends paragraph (e) to replace the phrase “Results indicating a dilute specimen,” with the phrase “Results indicating a dilute urine specimen.”

This final rule amends paragraphs (f)(5) and (7) to replace all instances of the term “LOD” with the term “LOQ.”

This final rule revises the first sentence of paragraph (h) to replace “More stringent validity test cutoff levels are prohibited” with “Validity test cutoff levels.” The final rule also revises the second sentence to replace the phrase “may not specify more stringent cutoff levels” with “may use more stringent cutoff levels”, and the phrase “only if testing is performed at an HHS-certified laboratory” is added to the end of the sentence.

Section 26.163 Cutoff Levels for Drug and Drug Metabolites

This final rule revises paragraph (a)(1) introductory text 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” and revise the phrase “except if validity testing indicates that the specimen is dilute” to read “except as specified in paragraph (a)(2) of this section.”

This final rule revises the table heading in paragraph (a)(1) to “Table 1 to paragraph (a)(1)–Urine, Initial Test Cutoff Levels for Drugs and Drug Metabolites” and the column header “Drug or metabolites” in Table 1 to “Drugs or drug metabolites” to align with the table heading. This final rule further revises the initial test cutoff level table for urine testing to 1) lower the initial test cutoff level for cocaine metabolites from 300 ng/mL to 150 ng/mL, 2) replace “opiate metabolites” with “codeine/morphine” and include a new footnote 1 to clarify the existing requirement that morphine is the target analyte for codeine/morphine testing, 3) add initial testing for hydrocodone and hydromorphone at a cutoff level of 300 ng/mL, 4) add initial testing for oxycodone and oxymorphone at a cutoff level of 100 ng/mL, 5) add the drug class “Opioids:” to appear above the listing for “codeine/morphine,” 6) add initial testing for 6-AM at a cutoff level of 10 ng/mL, 7) lower the initial test cutoff level for amphetamines (abbreviated in the table as AMP) from 1000 ng/mL to 500 ng/mL, 8) include a new footnote 2 regarding initial test kits, 9) include a new footnote 3 to clarify that for amphetamines testing,

methamphetamine (abbreviated in the table as MAMP) is the target analyte, 10) add initial testing for MDMA and MDA at a cutoff level of 500 ng/mL, and 11) provide the full chemical names for MDMA and MDA in new footnotes 4 and 5 to the table, respectively.

This final rule adds a second table to paragraph (a)(1) titled "Table 2 to paragraph (a)(1)–Oral Fluid, Initial Test Cutoff Levels for Drugs and Drug Metabolites." Table 2 lists each drug and drug metabolite and the cutoff level for initial testing of oral fluid specimens. The table includes the following substances and associated cutoff levels in nanograms (ng) per milliliter (mL): 1) "marijuana (THC)" at 4 ng/mL; 2) "cocaine/benzoylecgonine" at 15 ng/mL; 3) the drug class "opioids" is listed; 4) "codeine/morphine" at 30 ng/mL; 5) "hydrocodone/hydromorphone" at 30 ng/mL; 6) "oxycodone/oxymorphone" at 30 ng/mL; 7) "6-acetylmorphone (6-AM)" at 4 ng/mL, 8) "phencyclidine (PCP)" at 10 ng/mL; 9) the drug class "amphetamines" is listed; 10) "AMP/MAMP" at 50 ng/mL; and 11) "MDMA/MDA" at 50 ng/mL. The table includes five footnotes. Footnote 1 is for column header "Cutoff level [nanograms (ng/mL)]" and describes the requirements for grouped analytes testing. Footnote 2 is for the substance "marijuana (THC)" and describes the target analyte for this testing. Footnote 3 is assigned to the cutoff level for 6-acetylmorphine and describes the alternate technology testing requirements. Footnote 4 presents the full chemical names for AMP (amphetamine) and (MAMP) methamphetamine because the table includes the acronyms for clarity of presentation. Footnote 5 presents the full chemical names for MDMA (methylenedioxymethamphetamine) and MDA (methylenedioxyamphetamine) because the table includes the acronyms for clarity of presentation.

This final rule revises paragraph (a)(2) introductory text 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 HHS-certified laboratory to

conduct special analyses of dilute specimens" and replace it with the phrase "HHS-certified laboratories shall conduct special analyses of specimens".

This final rule revises paragraph (a)(2)(i) to add the phrase ", or if a specimen is collected under direct observation for any of the conditions specified in § 26.115(a)(1) through (3) or (a)(5)," after the phrase "If initial validity testing indicates that a specimen is dilute." The rule also revises paragraph (a)(2)(i) 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 "the laboratory shall compare the immunoassay responses of the specimen to the cutoff calibrator in each drug class tested."

This final rule revises paragraph (a)(2)(ii) 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."

This final rule revises paragraph (b)(1) introductory text to replace the phrase "except if the licensee or other entity requires the special analysis of dilute specimens as permitted in paragraph (a)(2)" with the phrase "except as permitted in paragraph (a)(2)."

This final rule revises the table heading in paragraph (b)(1) to read "Table 3 to paragraph (b)(1)–Urine, Confirmatory Test Cutoff Levels for Drugs and Drug Metabolites" and the column header "Drug or metabolites" in the initial test cutoff level table for urine testing to read "Drugs or drug metabolites." The final rule further revises the initial test cutoff level table for urine testing to 1) lower the confirmatory test cutoff level for cocaine metabolite from 150 ng/mL to 100 ng/mL, 2) revise "Opiates" to read "Opioids," 3) add confirmatory testing for hydrocodone, hydromorphone, oxycodone, and oxymorphone at a cutoff level of 100 ng/mL, 4) 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, 5) lower the confirmatory test cutoff levels for amphetamine and methamphetamine from 500 ng/mL to 250 ng/mL, 6) 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 7) add confirmatory testing for MDMA and MDA at a cutoff level of 250 ng/mL.

This final rule adds another new table to paragraph (b)(1) titled "Table 4 to paragraph (b)(1)–Oral Fluid, Confirmatory Test Cutoff Levels for Drugs and Drug Metabolites." Table 4 lists each drug and drug metabolite and the cutoff level for confirmatory testing of the substance in oral fluid. The table includes the following substances and associated cutoff levels in ng/mL: 1) "marijuana (THC)" at 2 ng/mL; 2) "cocaine" and "benzoylecgonine" each at 8 ng/mL; 3) the drug class "opioids" is listed; 4) "codeine" and "morphine" each at 15 ng/mL; 5) "hydrocodone," "hydromorphone," "oxycodone," and "oxymorphone" each at 15 ng/mL; 6) 6-acetylmorphone (6-AM) at 2 ng/mL, 7) "phencyclidine (PCP)" at 10 ng/mL; 8) the drug class "amphetamines" is listed; and 9) "amphetamine," "methamphetamine," "MDMA," and "MDA" each at 25 ng/mL.

Section 26.165 Testing Split Specimens and Retesting Single Specimens

This final rule adds a new fifth sentence to paragraph (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."

This final rule deletes the first sentence in paragraph (b)(3) and revises the second sentence to state "No entity, other than the MRO as permitted in § 26.185(l), may order the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen."

This final rule revises the last sentence in paragraph (f)(1) introductory text 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.

This final rule revises paragraph (f)(2) to add: 1) instruction for the MRO to “report a cancelled test result to the licensee or other entity for the donor’s specimen”; 2) instruction for the licensee or other entity that “the donor shall receive no notice of the collection requirement before he or she is instructed to proceed to the collection site”; 3) that 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 collection have been received by the MRO”; and 4) 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.

Section 26.167 Quality Assurance and Quality Control

This final rule amends paragraph (c) to replace the phrase “validity tests” with “validity tests on urine.”

This final rule amends paragraph (d)(1) to replace the phrase “Any initial drug test performed by an HHS-certified laboratory” with “Any initial drug test of urine performed by an HHS-certified laboratory.”

This final rule revises paragraph (d)(3)(i) 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.”

This final rule revises paragraph (d)(3)(ii) to replace the phrase “a drug(s) or drug metabolite(s)” with the phrase “the drug or drug metabolite.”

This final rule revises paragraph (d)(3)(iii) 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.”

This final rule revises paragraph (d)(4) to add the parenthetical statement “(i.e., calibrators and controls)” after the phrase “quality control samples.”

This final rule revises paragraph (e)(2) 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).”

This final rule revises paragraph (e)(3)(i) 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.”

This final rule revises paragraph (e)(3)(ii) 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.”

This final rule revises paragraph (e)(3)(iii) to replace the phrase “a drug(s) or drug metabolite(s)” with the phrase “the drug or drug metabolite.”

This final rule revises paragraph (e)(3)(iv) to replace the phrase “At least one calibrator or control that is targeted” with the phrase “At least one control targeted.”

This final rule amends paragraph (f)(3) to correct the capitalization of the “r” and the “p” in the position title in the phrase “the laboratory’s responsible person” to “Responsible Person.”

Section 26.168 Blind Performance Testing

This final rule revises paragraph (h)(1) to remove the phrase “, and for no more than 6 months” from this requirement.

Section 26.169 Reporting Results

This final rule amends paragraph (a) 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."

This final rule amends paragraph (c)(2) to remove the word "opiate" from the phrase "confirmatory opiate test results for morphine or codeine."

This final rule amends paragraph (h) introductory text to remove the word "urinalysis" from the phrase "annual statistical summary of urinalysis testing."

This final rule also makes conforming changes to the names of the drugs and drug metabolites listed in paragraph (h)(3) to include adding "(as THCA)" after "Marijuana metabolite" in paragraph (h)(3)(i); adding "(as benzoylecgonine)" after "Cocaine metabolite" in paragraph (h)(3)(ii); revising "Opiates (total)" to "Opioids (total)" in paragraph (h)(3)(iii) introductory text; removing "and" in paragraph (h)(3)(iii)(B); revising 6-AM to "6-acetylmorphine (6-AM)" in paragraph (h)(3)(iii)(C); adding new paragraphs (h)(3)(iii)(D) through (G) to add hydrocodone, hydromorphone, oxycodone, and oxymorphone to the list of opioid test results; and revising "Phencyclidine" to "Phencyclidine (PCP)" in paragraph (h)(3)(iv).

This final rule revises paragraph (h)(3)(v) to add new paragraphs (h)(3)(v)(C) and (D) to add "Methylenedioxymethamphetamine (MDMA) and "Methylenedioxyamphetamine (MDA)" to the list of amphetamines test results.

Section 26.183 Medical Review Officer

This final rule revises paragraphs (c) introductory text, (c)(1), and (d)(2)(ii) to remove the phrase "at the licensee's or other entity's discretion".

Section 26.185 Determining a Fitness-for-Duty Policy Violation

This final rule redesignates paragraph (f)(3) as paragraph (f)(4) and adds a new paragraph (f)(3) to state that if the MRO and the laboratory agree that further testing would not be useful and there is no legitimate technical or medical explanation for an invalid urine specimen test result based on a pH result 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 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.

This final rule amends paragraph (g)(1) to replace the phrase “paragraph (g)(4)” with the phrase “paragraph (g)(3).”

This final rule revises paragraph (g)(2) introductory text 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.” The rule also revises paragraph (g)(2) to replace the phrase “under paragraph (g)(4)” with the phrase “under paragraph (g)(3).”

This final rule revises paragraph (g)(2)(iii) to remove the phrase “clearly and unequivocally.”

This final rule removes paragraph (g)(3).

This final rule redesignates paragraphs (g)(4) and (5) as paragraphs (g)(3) and (4), respectively. The rule amends newly redesignated paragraph (g)(3) to replace the

phrase “any opium, opiate, or opium derivative (e.g., morphine and/or codeine)” with “opioids (i.e., morphine and/or codeine).”

This final rule revises paragraph (j) introductory text to replace “opiates” with “opioids” and to correct an editorial error in the first sentence.

This final rule revises the first sentence of paragraph (j)(1) to replace “opiates” with “opioids (i.e., morphine and/or codeine)”, and to replace the phrase “opium, an opiate, or an opium derivative (e.g., morphine/codeine)” with “morphine and/or codeine.”

This final rule amends paragraph (j)(2) to replace “opiates” with “opioids”.

This final rule amends paragraph (j)(3) to replace “opiates” with “opioids (i.e., morphine and/or codeine).”

This final rule amends paragraph (j)(4) to replace “opiates” with “opioids.”

Section 26.405 Drug and Alcohol Testing

This final rule revises paragraph (d) to add hydrocodone, hydromorphone, MDMA, MDA, oxycodone, and oxymorphone as substances for which licensees and other entities are required to test in each specimen. The term “opiates” is also replaced with the term “opioids.”

The rule also removes the term “adulterants” from the first sentence in paragraph (d), which describes the substances that licensees and other entities must test for in specimens. Instead, the final rule revises the second sentence “Urine specimens collected for drug testing must be subject to validity testing” to “Urine specimens collected for drug testing must be subject to validity testing that includes testing for adulterants.”

Section 26.415 Audits

This final rule amends paragraph (c) to eliminate the phrase “(65 FR 41944;

August 9, 2001)."

Section 26.715 Recordkeeping requirements for collection sites, licensee testing facilities, and laboratories certified by the Department of Health and Human Services

This final rule amends paragraph (b)(1) to replace the phrase "collection site, licensee testing facility, or HHS-certified laboratory" with the phrase "collection site or licensee testing facility."

Section 26.717 Fitness-for-duty program performance data

This final rule revises paragraph (b)(3) 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)."

This final rule revises paragraph (b)(4) 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)."

IV. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule will not have a significant economic impact on a substantial number of small entities. This final 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 59 entities affected by the rule 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 does not impact a substantial number of small entities.

The NRC requested comment on the proposed rule and accompanying regulatory analysis on the impact of the proposed rule on small entities. The NRC received no comment submissions from an identified small entity.

V. Regulatory Analysis

The NRC has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The regulatory analysis is available as indicated in the "Availability of Documents" section of this document.

VI. Backfitting and Issue Finality

The Commission has completed a backfitting and issue finality assessment for this final rule under §§ 50.109, "Backfitting," 52.98, "Finality of combined licenses; information requests," and 70.76, "Backfitting." This final rule constitutes backfitting for current holders of operating licenses and construction permits for power reactors under 10 CFR part 50, "Domestic licensing of production and utilization facilities," and renewed licenses under 10 CFR part 54, "Requirements for renewal of operating licenses for nuclear power plants," and under § 70.76(a)(1) for applicable current 10 CFR part 70 licensees. This final rule affects the issue finality accorded to current holders of combined licenses under § 52.98. This final rule is being imposed as a cost-justified substantial increase in the overall protection of the public health and safety or common defense and security. The bases for this determination are presented in the backfit and

issue finality assessment, which is available as indicated in the "Availability of Documents" section of this document.

Regulatory Guidance

As explained in Regulatory Guide (RG) 5.89, "Fitness-for-Duty Programs for Commercial Power Reactor and Category I Special Nuclear Material Licensees," applicants and licensees are not required to comply with the positions set forth in RG 5.89. Therefore, issuance of RG 5.89 does not constitute backfitting, as that term is defined in § 50.109 and as described in NRC Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," or affect the issue finality of any approval issued under 10 CFR part 52.

VII. Cumulative Effects of Regulation

Cumulative Effects of Regulation (CER) consists of the challenges licensees may face in addressing the implementation of new regulatory positions, programs, and requirements (e.g., rulemaking, guidance, generic letters, backfits, inspections). The CER may manifest in several ways, including the total burden imposed on licensees by the NRC from simultaneous or consecutive regulatory actions that can adversely affect the licensee's capability to implement those requirements, while continuing to operate or construct its facility in a safe and secure manner.

The goals of the NRC's CER effort were met throughout the development of this final rule. The NRC engaged external stakeholders at public meetings and by soliciting public comments on the proposed rule and associated draft guidance document. The proposed rule and draft guidance (84 FR 48750) were issued on September 16, 2019, for public comment. A public meeting was held on November 7, 2019, to discuss the

proposed rule and draft guidance. A public meeting on implementation was held on April 13, 2021. Summaries of both meetings are available in ADAMS, as provided in the "Availability of Documents" section of this document. The feedback from the April 13, 2021, public meeting informed the NRC's final rule implementation schedule.

Based upon input from the public and affected licensees, the NRC has established a compliance deadline for the requirements in this final rule 1 year from the date of publication of this final rule in the *Federal Register*. See the DATES section of this document.

VIII. 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).

IX. Environmental Impact: Categorical Exclusion

The NRC has determined that this final 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 final rule.

X. Paperwork Reduction Act Statement

This final rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). The collections of

information were approved by the Office of Management and Budget (OMB), control number 3150-0146.

The burden to the public for the information collections is estimated to average 0.8 hours per response for information collection requirements contained in 10 CFR part 26, including the time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the information collections.

The information collection contained in 10 CFR part 26 is impacted by the revision of existing and addition of new requirements to align the NRC's drug testing requirements more closely with updates made to the HHS Guidelines. The NRC updated the drug testing panel and lowered the testing cutoff levels for some drugs tested, which impacts the existing information collections contained in 10 CFR part 26, because additional individuals will likely test positive for drugs. Additional positive test results will increase the burdens associated with the recordkeeping and reporting requirements applicable to licensees and other entities. In addition, the NRC is including new information collection requirements in §§ 26.107(d), 26.157(a), 26.165(b)(2), 26.165(f)(1) and 26.185(f)(3). This information will be used by the NRC 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)), 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)). Confidential

and proprietary information submitted to the NRC is protected in accordance with NRC regulations at §§ 9.17(a) and 2.390(b).

You may submit comments on any aspect of the information collections, including suggestions for reducing the burden, by the following methods:

- **Federal rulemaking website**: Go to https://www.regulations.gov and search for Docket ID NRC-2009-0225.
- **Mail comments to**: FOIA, Library, and Information Collections Branch, Office of the Chief Information Officer, Mail Stop: T6-A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email 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; email: oira_submission@omb.eop.gov.

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.

XI. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act (5 U.S.C 801-808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

XII. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act of 1954, as amended (AEA), the NRC is issuing this final rule that will amend §§ 26.4, 26.31, 26.83, 26.85, 26.87, 26.89, 26.97, 26.105, 26.107, 26.109, 26.111, 26.115, 26.117, 26.129, 26.133, 26.137, 26.153, 26.155, 26.157, 26.159, 26.161, 26.163, 26.165, 26.167, 26.168, 26.169, 26.183, 26.185, 26.405, 26.415, 26.717 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement. Criminal penalties as they apply to regulations in 10 CFR part 26 are discussed in § 26.825, "Criminal penalties."

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 10 CFR, 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 final rule, the NRC updated and enhanced the consistency of 10 CFR part 26 with the HHS Guidelines; improving the effectiveness and efficiency of FFD programs with regard to drug testing; and improving clarity in the organization and language of the rule. This action does not constitute the establishment of a voluntary consensus standard that contains generally applicable requirements.

XV. Availability of Guidance

The NRC is issuing new guidance, Regulatory Guide 5.89, "Fitness-for-Duty Programs for Commercial Power Reactor and Category I Special Nuclear Material Licensees," to support the implementation of the requirements in this final rule. New RG 5.89 is publicly available in ADAMS under Accession No. ML20143A034. Information and public comment submissions related to the guidance can be accessed by searching on the Federal e-Rulemaking website, https://www.regulations.gov, under Docket ID NRC-2009-0225. The associated draft regulatory guide (DG-5040) was published for public comment in conjunction with the proposed rule. The final guidance reflects public comments received on the draft regulatory guide. The NRC's response to the public comments on this guidance is available in ADAMS, as provided in the "Availability of Documents" section of this document.

Regulatory Guide 5.89 describes methods that the NRC considers acceptable for complying with some of the changes in this final rule. For example, guidance is 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
2015 HHS Guidelines – Notice of Proposed Revisions to Mandatory Guidelines (May 15, 2015)	80 FR 28101
2017 HHS Guidelines – Revised Mandatory Guidelines (January 23, 2017)	82 FR 7920
HHS “Medical Review Officer Manual for Federal Workplace Drug Testing Programs,” effective October 1, 2017, revised March 2018	ML21119A058

DOCUMENT	ADAMS ACCESSION NO. / *FEDERAL REGISTER* CITATION
2019 HHS Guidelines – Issuance of Mandatory Guidelines for Federal Workplace Drug Testing Programs—Oral/Fluid (October 25, 2019)	84 FR 57554
2019 NRC 10 CFR Part 26 Proposed Rule (September 16, 2019)	84 FR 48750
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
2017 DOT 49 CFR Part 40 Final Rule, Procedures for Transportation Workplace Drug and Alcohol Testing Program: Addition of Certain Schedule II Drugs to the Department of Transportation's Drug-Testing Panel and Certain Minor Amendments (November 13, 2017)	82 FR 52229
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	https://academic.oup.com/jat/article/31/8/486/757830
Executive Order 12564, Drug-free Federal Workplace (September 17, 1986)	51 FR 32889

DOCUMENT	ADAMS ACCESSION NO. / *FEDERAL REGISTER* CITATION
Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (NSDUH) (September 2020), HHS Publication Number PEP20-07-01-001	ML21166A009
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 Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests" (September 20, 2019)	ML18093B087
NRC Public Meeting Summary and Meeting Materials (October 11, 2011)	ML112930153
NRC Public Meeting Summary (November 7, 2019)	ML19336A003
NRC Public Meeting Summary (April 13, 2021)	ML21096A015
NRC Regulatory Analysis, Fitness for Duty Drug Testing Requirements (June 2021)	ML21111A026
NRC Regulatory Analysis Guidelines, NUREG/BR–0058, Draft Revision 5 (February 2020)	ML19261A277
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 Regulatory Guide 5.89, "Fitness-for-Duty Programs for Commercial Power Reactor and Category I Special Nuclear Material Licensees" (August 2021)	ML20143A034
NRC Responses to Public Comments (June 2021)	ML21111A032
NRC Report "Summary of Fitness for Duty Program Performance Reports for Calendar Year 2013" (September 3, 2014)	ML14246A440
NRC Report "Summary of Fitness for Duty Program Performance Reports for Calendar Year 2015" (November 13, 2017)	ML17313A337

DOCUMENT	ADAMS ACCESSION NO. / *FEDERAL REGISTER* CITATION
Paperwork Reduction Act Statement: 10 CFR Part 26, Fitness for Duty Programs, Information Collections Contained in Fitness for Duty Drug Testing Requirements Final Rule (August 2021)	ML21111A046
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 in 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 adopting 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. In part 26, wherever they may occur:

a. Remove the term “custody-and-control form” and add in its place the term “Federal CCF”;

b. Remove the term “custody-and-control forms” and add in its place the term “Federal CCFs”;

c. Remove the term “custody-and-control form(s)” and add in its place the term “Federal CCF(s)”; and

d. Remove the phrase “chain-of-custody” and add in its place the phrase “chain of custody”.

3. In § 26.4:

a. In paragraph (e)(6)(iv), remove “(65 FR 41944; August 9, 2001)”; and

b. Revise paragraph (j)(3).

The revision reads as follows:

§ 26.4 FFD program applicability to categories of individuals.

* * * * *

(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. In § 26.5, add 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 revise the definitions for *Calibrator*, *Control*, *Dilute specimen*, *HHS-certified laboratory*, *Invalid result*, *Limit of quantitation*, and *substituted specimen* to 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 testing of a specimen is performed for a licensee or other entity and performs that testing for a licensee or other entity in accordance with the HHS Guidelines, unless otherwise specified in this part.

* * * * *

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(b), remove the reference "26.155".

6. In § 26.31:

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

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

c. In paragraph (d)(1)(i)(D), remove the phrase “, as specified in § 26.155(a)”;

d. In paragraph (d)(1)(ii), revise the third sentence; and

e. In paragraph (d)(3)(i), revise the second sentence and add a new third sentence.

The addition and 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, opioids (codeine, morphine, 6-acetylmorphine, hydrocodone, hydromorphone, oxycodone, and oxymorphone), amphetamines (amphetamine, methamphetamine, methylenedioxymethamphetamine, and methylenedioxyamphetamine), phencyclidine, 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.

* * * * *

(3) * * *

(i) * * * Urine specimens sent to HHS-certified laboratories must be subject to initial validity and initial drug testing by the laboratory. Oral fluid specimens sent to HHS-certified laboratories must be subject to initial drug testing by the laboratory.* * *

* * * * *

7. In § 26.83, revise paragraph (b) to read as follows:

§ 26.83 Specimens to be collected.

* * * * *

(b) Collect only urine specimens for both initial and confirmatory tests for drugs, unless the licensee or other entity establishes through its policy and procedures that an oral fluid specimen can be collected and tested for any of the observed specimen collection conditions under § 26.115(a)(1) through (3) and (a)(5). For each observed collection condition under § 26.115(a)(1) through (3) and (a)(5), the licensee or other entity shall always collect and test the same specimen type.

8. In § 26.85:

a. Revise paragraphs (a) introductory text and (a)(2);

b. Redesignate paragraphs (a)(3) and (a)(4) as paragraphs (a)(4) and (a)(5), respectively, and add new paragraph (a)(3);

c. In paragraph (a)(5), remove the phrase “collection and transfer process” and add in its place the phrase “collection process”, and add at the end of the existing requirement the phrase “, and the specimen transfer process, if applicable”;

d. Remove paragraph (b) and redesignate paragraphs (c) through (e) as paragraphs (b) through (d), respectively; and

e. In newly redesignated paragraph (b)(1), remove “paragraphs (a) or (b)” and add in its place “paragraph (a)”.

The addition and revisions read as follows:

§ 26.85 Collector qualifications and responsibilities.

* * * * *

(a) *Collector qualifications*. Each collector shall be knowledgeable of the requirements of this part and the FFD policy and procedures of the licensee or other entity for whom collections are performed, and shall keep current on any changes to the collection procedures for each specimen the individual is qualified to collect under this part. Each collector shall receive qualification training that meets the requirements of this paragraph and demonstrate proficiency in applying the requirements of this paragraph before serving as a collector. At a minimum, qualification training must provide instruction on the following subjects:

* * * * *

(2) Methods to address “problem” collections, including, but not limited to:

(i) Inability to provide a specimen (e.g., “shy bladder” for a urine specimen, “shy lung” for a breath specimen, dry mouth for an oral fluid specimen); and

(ii) Attempts to tamper with a specimen;

(3) Operation of the particular specimen collection or alcohol testing device(s) (e.g., alcohol screening device (ASD), EBT, oral fluid) to be used, consistent with the most recent version of the manufacturers' instructions;

* * * * *

9. In § 26.87:

a. Revise paragraph (a), second sentence, and paragraphs (b) and (f)(4);

b. In paragraph (f) introductory text, remove the phrase “collect a urine specimen” and add in its place the phrase “collect a specimen for drug testing”;

c. In paragraph (f)(2), remove the phrase “If practical, a water coloring agent” and add in its place the phrase “If practical when a urine specimen is to be collected, a water coloring agent”;

d. In paragraph (f)(3), remove the phrase “area that will be used for specimen collection” and add in its place the phrase “the area that will be used for a urine specimen collection”; and

e. In paragraph (f)(5), remove the phrase “urine specimen” and add in its place the phrase “specimen for drug testing”.

The revisions read as follows:

§ 26.87 Collection sites.

(a) * * * Each collection site must provide for the collection, security, temporary storage, and shipping or transportation of specimens to a drug testing laboratory; the testing of specimens for alcohol; the security of specimen collection and testing devices; and test results. * * *

(b) Visual privacy must be provided to the donor and collector when viewing alcohol test results and during the collection of an oral fluid specimen for drug testing. The donor must be provided with individual privacy while submitting a urine specimen, except if a directly observed urine specimen collection is required. Unauthorized personnel may not be present for the specimen collection.

* * * * *

(f) * * *

* * * * *

(4) Once the collector has possession of the specimen, if the specimen is urine, the collector shall inspect the toilet bowl and area to ensure that there is no evidence of a subversion attempt and shall then flush the toilet, and for any specimen collected for drug testing, the collector shall instruct the donor to participate with the collector in completing the chain of custody procedures.

10. In § 26.89:

a. In paragraph (c), remove the words “adulterated, diluted, or adulterated the specimen” and add in their place the words “adulterated, diluted, or substituted the specimen”; and

b. Revise paragraph (d).

The revision reads 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). For the collection of specimen(s) for drug testing, the collection procedure is complete when the specimen container has been sealed with a tamper-evident seal, the seal has been dated and initialed, and the Federal CCF has been completed or when a refusal to test has been determined.

11. In § 26.97:

a. Revise the section heading;

b. In paragraphs (a) introductory text, (a)(4), and (b)(1) through (3), wherever it appears, remove the word “test” and add in its place the phrase “specimen collection”; and

c. Revise paragraph (c)(2), and the first sentence in paragraph (d).

The revisions read as follows:

§ 26.97 Collecting oral fluid specimens for alcohol and drug testing.

* * * * *

(c) * * *

(2) Immediately conduct another specimen collection (i.e., initial test using an EBT for alcohol, or urine specimen collection for drug testing).

(d) For alcohol testing of oral fluids, the collector shall read the result displayed on the device no sooner than the device's manufacturer instructs. * * *

* * * * *

12. In § 26.105:

a. Revise the section heading;

b. In paragraph (a), wherever it appears, remove the word “urine”;

c. In paragraph (c), remove the phrase “wash and dry his or her hands before urinating” and add in its place the phrase “wash and dry his or her hands before providing a specimen”;

d. In paragraph (d) wherever it appears, remove the word “urine”; and

e. Revise paragraph (e).

The revisions read as follows:

§ 26.105 Preparing for the collection of a specimen for drug testing.

* * * * *

(e) The collector may select, or allow the donor to select, an individually wrapped or sealed urine specimen collection container from the collection kit materials or an oral fluid specimen collection device. Either the collector or the donor, with both present, shall unwrap or break the seal of the urine specimen collection container. With the exception of the collection container, the donor may not take anything from the collection kit into the room or stall used for urination.

13. 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 careful 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 specimen 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 or through another documentation method consistent with the collection procedures of the licensee or other entity, 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 or through another documentation method consistent with the collection procedures of the licensee or other entity;

(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.

14. 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. 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

(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. * * *

* * * * *

15. In § 26.111:

a. Revise paragraph (a) and the second sentence in paragraph (b);

b. In paragraph (c), the first sentence, remove the word “designated” and revise the third sentence;

c. Revise paragraph (e); and

d. Remove 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.

(b) * * * The collector shall note any unusual findings on the Federal CCF or through another documentation method consistent with the collection procedures of the licensee or other entity.

(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).

16. In § 26.115:

a. Republish paragraph (a) introductory text, revise paragraphs (a)(3) and (4), and add paragraph (a)(5);

b. Revise paragraph (e);

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

d. Revise paragraph (g).

The addition 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 used for urination 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).

* * * * *

17. In § 26.117:

a. Revise the section heading;

b. In paragraph (a), revise the first sentence and republish the second sentence;

c. Revise the first sentence in paragraph (f);

d. In paragraph (g), at the end of the first sentence, add the phrase “, except as provided in § 26.109(b)(1)(ii) for the Federal CCF”;

e. In paragraph (i), remove the words “urine specimen bottle” and add in their place the words “specimen bottle”; and

f. In paragraph (j) remove the phrase “Specimens that have not been shipped” and add in their place the phrase “Urine specimens that have not shipped”; remove phrase “any specimen” and adding in its place the phrase “any urine specimen”; and add a new fourth sentence.

The addition and revisions read as follows:

§ 26.117 Preparing drug testing specimens 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 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.* * *

* * * * *

(j) * * * Oral fluid specimens shall be stored under the conditions specified by the oral fluid specimen collection device manufacturer.* * *

* * * * *

18. 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:

* * * * *

19. 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 Table 1 to § 26.133 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:

Table 1 to § 26.133—Urine, Initial Test Cutoff Levels for Drugs and Drug Metabolites

Drugs or drug metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana metabolites.....	50
Cocaine metabolites.....	150
Opioids:	
Codeine/Morphine[1].....	2000
Hydrocodone/Hydromorphone.....	300
Oxycodone/Oxymorphone…….……..	100
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.

20. In § 26.137,

a. Revise paragraphs (d)(5), (e)(6) introductory text, and (e)(6)(i) through (iii); and

b. Remove paragraph (e)(6)(v).

The revisions 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.

* * * * *

(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;

* * * * *

21. In § 26.151, revise the section to read as follows:

§ 26.151 Purpose.

This subpart contains requirements for the HHS-certified laboratories that licensees and other entities use to perform testing under this part.

22. In § 26.153, revise the section heading and paragraphs (a) and (g) to read as follows:

§ 26.153 Using certified laboratories for testing 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 [Reserved]

23. Remove and reserve § 26.155.

24. In § 26.157, revise paragraph (a), remove and reserve paragraph (b), and remove paragraphs (c) through (e).

The revision reads 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.

* * * * *

25. In § 26.159, revise paragraphs (b)(1)(ii) and (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.

* * * * *

26. In § 26.161:

a. In paragraph (b) introductory text, remove the phrase “Initial validity testing” and add in its place the phrase “Initial validity testing of urine”;

b. In paragraphs (c)(3) and (4) and (f)(5) and (7), wherever it appears, remove the term “LOD” and add in its place the term “LOQ”;

c. Revise paragraphs (c)(5) and (c)(6);

d. In paragraph (d), remove the phrase “Results indicating a substituted specimen” and add in its place “Results indicating a substituted urine specimen”;

e. In paragraph (e), remove the phrase “Results indicating a dilute specimen” and add in its place the phrase “Results indicating a dilute urine specimen”; and

f. Revise paragraph (h).

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 specimen yields 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 a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents or a cutoff equal to or greater than 50 mcg/mL chromium (VI)-equivalents) 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;

* * * * *

(h) *Validity test cutoff levels*. Licensees and other entities may use more stringent cutoff levels for validity tests than those specified in this section only if the testing is performed at an HHS-certified laboratory.

27. In § 26.163:

a. Republish paragraph (a) introductory text;

b. Revise paragraph (a)(1);

c. Revise paragraph (a)(2) introductory text, (a)(2)(i), and (a)(2)(ii);

d. Republish paragraph (b) introductory text; and

e. Revise 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:

Table 1 to paragraph (a)(1)—Urine, Initial Test Cutoff Levels for Drugs and Drug Metabolites

Drugs or drug metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana metabolites	50
Cocaine metabolites	150
Opioids:	
Codeine/Morphine[1]	2000
Hydrocodone/Hydromorphone	300
Oxycodone/Oxymorphone	100
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.

Table 2 to paragraph (a)(1)—Oral Fluid, Initial Test Cutoff Levels for Drugs and Drug Metabolites

Drugs or drug metabolites	Cutoff level[1] [nanograms (ng)/mL]
Marijuana (THC) [2,3]……..	4
Cocaine/Benzoylecgonine.....	15
Opioids:	
Codeine/Morphine.....	30
Hydrocodone/Hydromorphone.....	30
Oxycodone/Oxymorphone.....	30
6-acetylmorphine (6-AM).....	4[3]
Phencyclidine (PCP).....	10
Amphetamines:	
AMP/MAMP[4].....	50
MDMA/MDA[5].....	50

[1] For grouped analytes (i.e., two or more analytes in the same drug class with the same initial test cutoff):

- Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.
- Alternative technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present.

[2] An immunoassay must be calibrated with the target analyte, delta-9-tetrahydrocannabinol (THC).
[3] Alternate technology (THC and 6-AM): The confirmatory tests cutoff must be used for an alternate technology initial test that is specific for the target analyte (i.e., 2 ng/mL for THC, 2 ng/mL for 6-AM).
[4] Amphetamine (AMP) and methamphetamine (MAMP).
[5] Methylenedioxymethamphetamine (MDMA) and methylenedioxyamphetamine (MDA).

(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 (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.

Table 3 to paragraph (b)(1)—Urine, 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
Opioids:	
Morphine	2000
Codeine	2000
Hydrocodone	100
Hydromorphone	100
Oxycodone	100
Oxymorphone	100
6-acetylmorphine (6-AM)	10
Phencyclidine (PCP)	25
Amphetamines:	
Amphetamine	250
Methamphetamine[3]	250
Methylenedioxymethamphetamine (MDMA)	250
Methylenedioxyamphetamine (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.

Table 4 to paragraph (b)(1)–Oral Fluid, Confirmatory Test Cutoff Levels for Drugs and Drug Metabolites

Drugs or drug metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana (THC) ….....	2
Cocaine….....	8
Benzoylecgonine.....	8
Opioids:	
Codeine…….....	15
Morphine.....	15
Hydrocodone…….....	15
Hydromorphone.....	15
Oxycodone…….....	15
Oxymorphone…….....	15
6-acetylmorphine (6-AM).....	2
Phencyclidine (PCP).....	10
Amphetamines:	
Amphetamine…….....	25
Methamphetamine.....	25
Methylenedioxymethamphetamine (MDMA).....	25
Methylenedioxyamphetamine (MDA).....	25

* * * * *

28. In § 26.165, add a fifth sentence to paragraph (b)(2) and revise 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 the 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 the 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.

29. In § 26.167:

a. In paragraph (c), remove the phrase “validity tests” and add in its place the phrase “validity tests on urine”;

b. In paragraph (d)(1), remove the phrase “Any initial drug test performed by an HHS-certified laboratory” and add in its place the phrase “Any initial drug test of urine performed by an HHS-certified laboratory”;

c. Republish paragraph (d)(3) introductory text, and revise paragraphs (d)(3)(i) through (iii);

d. Revise paragraph (d)(4);

e. Revise paragraph (e)(2), republish paragraph (e)(3) introductory text, and revise paragraphs (e)(3)(i) through (iv); and

f. In paragraph (f)(3), the third sentence, remove the words “responsible person” and add 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.

* * * * *

30. 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;

* * * * *

31. In § 26.169:

a. In paragraph (a), remove the words “certifying scientist” and add in their place the words “Certifying Scientist”;

b. In paragraph (c)(2), remove the word “opiate”;

c. In paragraph (h) introductory text, remove the word “urinalysis”;

d. Republish paragraph (h)(3) introductory text; revise paragraphs (h)(3)(i) and (ii), (h)(3)(iii) introductory text, and (h)(3)(iii)(B) and (C); add new paragraphs (h)(3)(iii)(D) through (G); and revise paragraph (h)(3)(iv);

e. Republish paragraph (h)(3)(v) introductory text, revise paragraph (h)(3)(v)(A), and add new paragraphs (h)(3)(v)(C) and (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);

(iii) Opioids (total);

* * * * *

(B) Morphine;

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

(D) Hydrocodone;

(E) Hydromorphone;

(F) Oxycodone; and

(G) Oxymorphone;

(iv) Phencyclidine (PCP);

(v) Amphetamines (total);

(A) Amphetamine;

* * * * *

(C) Methylenedioxymethamphetamine (MDMA); and

(D) Methylenedioxyamphetamine (MDA);

* * * * *

32. 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.

* * * * *

33. In § 26.185:

a. Redesignate paragraph (f)(3) as paragraph (f)(4) and add new paragraph (f)(3);

b. In paragraph (g)(1), remove the reference “paragraph (g)(4)” and add in its place the reference “paragraph (g)(3)”;

c. Revise paragraphs (g)(2) introductory text and (g)(2)(iii), remove paragraph (g)(3), and redesignate paragraphs (g)(4) and (g)(5) as paragraphs (g)(3) and (g)(4), respectively;

d. In newly redesignated paragraph (g)(3), remove the phrase “any opium, opiate, or opium derivative (e.g., morphine/codeine)” and add in its place “opioids (i.e., morphine and/or codeine)”;

e. Revise paragraph (j) introductory text and the first sentence in paragraph (j)(1); and

f. In paragraph (j)(2), remove the word “opiates” wherever it may appear and add in its place the word “opioids”; in paragraph (j)(3), remove the word “opiates” and add in its place the phrase “opioids (i.e., morphine and/or codeine)”; and in paragraph (j)(4), remove the word “opiates” wherever it may appear and add in its place the word “opioids”.

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.

* * * * *

(j) *Review for opioids and prescription and over-the-counter medications*. (1) If the MRO determines that there is no legitimate medical explanation for a positive confirmatory test result for opioids (i.e., morphine and/or codeine) and before the MRO determines that the test result is a violation of the FFD policy, the MRO or his/her designee, who shall also be a licensed physician with knowledge of the clinical signs of drug abuse, shall determine that there is clinical evidence, in addition to the positive confirmatory test result, that the donor has illegally used morphine and/or codeine.* * *

* * * * *

34. 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, opioids (codeine, morphine, 6-acetylmorphine, hydrocodone, hydromorphone, oxycodone, and oxymorphone), amphetamines (amphetamine, methamphetamine, methylenedioxymethamphetamine, and methylenedioxyamphetamine), phencyclidine, 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 that includes testing for adulterants.

* * * * *

§ 26.415 [Amended]

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

§ 26.715 [Amended]

36. In § 26.715(b)(1), remove the phrase “collection site, licensee testing facility, or HHS-certified laboratory” and add in its place the phrase “collection site or licensee testing facility.”

37. 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 <Month XX, 20XX>.
For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.