NRC Responses to Public Comments

Final Rule:
Fitness for Duty Drug Testing Requirements

NRC-2009-0225; RIN 3150-AI67

U.S. Nuclear Regulatory Commission
Office of Nuclear Security and Incident Response
Office of Nuclear Material Safety and Safeguards
Office of Nuclear Reactor Regulation

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ABBREVIATIONS AND ACRONYMS

ADAMS	Agencywide Documents Access and Management System
BOP	behavioral observation program
BPTS	blind performance test sample
CCF	custody and control form
CFR	*Code of Federal Regulations*
DOF	determination of fitness
DOL	U.S. Department of Labor
DOT	U.S. Department of Transportation
EAP	employee assistance program
FFD	fitness-for-duty
FR	*Federal Register*
HHS	U.S. Department of Health and Human Services
MDA	methylenedioxyamphetamine
MDEA	methylenedioxyethylamphetamine
MRO	medical review officer
NLCP	National Laboratory Certification Program
NRC	U.S. Nuclear Regulatory Commission
OF	Oral/Fluid
SAE	substance abuse expert
UA	unescorted access
UAA	unescorted access authorization

U.S. NUCLEAR REGULATORY COMMISSION
RESPONSE TO PUBLIC COMMENTS RECEIVED ON THE PROPOSED RULE ON FITNESS FOR DUTY DRUG TESTING REQUIREMENTS

Introduction

This document presents the U.S. Nuclear Regulatory Commission's (NRC) responses to written public comments received on the proposed rule, "Fitness for Duty Drug Testing Requirements," to revise Part 26 in title 10 of the *Code of Federal Regulations (10 CFR)*, and Draft Regulatory Guide (DG)-5040, "Urine Specimen Collection and Test Result Review under 10 CFR Part 26, Fitness for Duty Program." The NRC published the proposed rule and DG-5040 in the *Federal Register* on September 16, 2019 (84 FR 48750), for public comment with a 75-day public comment period. The NRC's proposed rule would amend its regulations that govern the fitness-for-duty (FFD) programs for certain licensees and other entities to more closely align the NRC's drug testing requirements with the updates made in 2008 (73 FR 71858 and corrected in 73 FR 75122) and 2017 (82 FR 7920) to the U.S. Department of Health and Human Services' (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (HHS Guidelines). The proposed FFD drug testing requirements rule is available from the Federal e-Rulemaking Web site at https://www.regulations.gov (Docket ID No. NRC-2009-0225) and through the NRC's Agencywide Documents Access and Management System (ADAMS) under Accession No. ML19169A112.

In developing the final rule and supporting guidance, the NRC considered all the comments provided in response to the proposed rule. If, as a result of its review of a public comment, the NRC changed the rule, the supporting statement of considerations, or the supporting guidance, the NRC's response to the comment indicates where the change occurred.

Overview of Public Comments

The NRC received 26 comment submissions on the proposed rule. Table 1 identifies these submissions. The NRC reviewed and annotated the comment submissions to identify separate comments within each submission. Accordingly, a single submission may have several individual comments associated with it. The NRC gave each individual comment within a submission a unique identifier. The NRC's responses use this unique identifier to identify which individual comments are addressed by each response. The annotated versions of the comment submissions can be found at https://www.regulations.gov and ADAMS Accession No. ML20121A017.

Table 1: Comment Submissions on FFD Drug Testing Requirements Proposed Rule

Comment Submission Number	Commenter	Affiliation	Submission Abbreviation[1]	ADAMS Accession No.
1	Anonymous-1	Private Citizen	ANON1	ML19298B661
2	Braeden Clark	Private Citizen	BC	ML19308B430
3	David Bonthron	NextEra Energy	NE	ML19316E072
4	Johnny Rogers	Private Citizen	JR1	ML19338D258
5	Johnny Rogers	Private Citizen	JR2	ML19338D259
6	Johnny Rogers	Private Citizen	JR3	ML19338D260
7	Johnny Rogers	Private Citizen	JR4	ML19338D262
8	Johnny Rogers	Private Citizen	JR5	ML19338D263
9	Anonymous-2	Private Citizen	ANON2	ML19338D245
10	Johnny Rogers	Private Citizen	JR6	ML19338D246
11	Johnny Rogers	Private Citizen	JR7	ML19338D247
12	Johnny Rogers	Private Citizen	JR8	ML19338D248
13	Johnny Rogers	Private Citizen	JR9	ML19338D249
14	Johnny Rogers	Private Citizen	JR10	ML19338D251
15	Johnny Rogers	Private Citizen	JR11	ML19338D252
16	Johnny Rogers	Private Citizen	JR12	ML19338D254
17	William Gross	Nuclear Energy Institute	NEI1	ML19338D255
18	Laura Shelton	Drug and Alcohol Testing Industry Association	DATIA	ML19338D257
19	Megan Barry	Private Citizen	MB	ML20017A342
20	John Nielsen	Institute of Nuclear Power Operations	INPO	ML20017A343
21	Dolores Adams	Exelon Nuclear	EN1	ML20017A344
22	Joseph Chemistry	Private Citizen	JC	ML20017A352
23	Mimi Estrada	Private Citizen	ME	ML21144A288
24	William Gross	Nuclear Energy Institute	NEI2	ML21144A289
25	Maureen Gilday-Gulliford	Energy Harbor	EH	ML21146A134
26	Mary Yerkes	Exelon Nuclear	EN2	ML21146A136

Public Meetings

On November 7, 2019, the NRC held a public meeting at NRC Headquarters to discuss the FFD drug testing requirements proposed rule with external stakeholders (see meeting summary at ADAMS Accession No. ML19336A003). The NRC's goal for conducting this meeting was to explain the proposed rule and supporting guidance and answer questions to enable stakeholders to provide informed comments on the proposed rule.

[1] The NRC has annotated the comments to identify individual comments. Some submissions contained multiple individual comments, and others contained only one. The individual comments are denoted within each annotated comment submission by the submission abbreviation and number (e.g., INPO-1, INPO-2). In some cases, the comment may be denoted as NEI1-CL1, NEI1-A1-1, or NEI1-A2-1. This refers to an NEI comment provided in the comment submission cover letter (CL), an NEI comment provided in the first attachment (A1), or an NEI comment provided in the second attachment (A2).

On April 13, 2021, the NRC held a virtual public meeting under the category of “information meeting with a question and answer session” to discuss the basis for and obtain feedback on the proposed implementation schedule for the final rule (see meeting summary in ADAMS under Accession No. ML21096A015).

Comment Categorization

This comment response document separates the comments into the 25 categories identified below. Within each category, the NRC summarizes each comment and responds to the comment. In general, the NRC addresses each individual comment. However, when similar comments can be readily grouped together, the NRC has binned those comments and treated them as a single comment. The NRC’s response addresses the binned comment. The annotated comment number or numbers appear in a parenthetical list at the end of each comment summary to provide a cross-reference aid to the reader.

The comment summaries are grouped in the following categories:

A. General Comments on the Proposed Rule
B. Responses to Specific Requests for Comment
C. FFD Program Applicability to Categories of Individuals
D. Definitions
E. Written Policy and Procedures
F. Drug and Alcohol Testing
G. Behavioral Observation
H. Sanctions
I. Management Actions Regarding Possible Impairment
J. Preparing to Collect Specimens for Testing
K. Urine Specimen Quantity
L. Collecting a Urine Specimen Under Direct Observation
M. Preparing Urine Specimens for Storage and Shipping
N. Determining “Shy” Bladder
O. Cutoff Levels for Validity Testing
P. Blind Performance Testing
Q. Determining a Fitness for Duty Policy Violation
R. Substance Abuse Expert
S. Determination of Fitness
T. Other Comments
U. Draft Regulatory Guide
V. Draft Regulatory Analysis
W. Information Collections
X. Backfitting and Issue Finality
Y. Cumulative Effects of Regulation

A. General Comments on the Proposed Rulemaking

Comment A-1: One commenter expressed concern that the proposed rule changes were not robust enough and requested the NRC to do more. (ANON1-1)

NRC Response: The comment contained no changes for consideration on the proposed rule.

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

Comment A-2: Four commenters expressed overall support for the proposed rule. One commenter stated that the proposed changes to the FFD program are very positive and should be implemented as soon as practical. Another commenter believed that additional changes should also be considered for inclusion into the 10 CFR Part 26 rulemaking to enhance efficiencies while maintaining the continued reliability of the FFD program. A third commenter was pleased to see guidelines being proposed to enhance the ability of NRC licensees to identify individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. This commenter concluded that the proposed rule change will aid in detection and ultimately lead to enhanced public safety. The fourth commenter believed that drug testing helps to deter individuals from using drugs and therefore the proposed rule will be beneficial. (ANON2-CL10, ANON2-A10, NEI1-CL1, DATIA-1, ME-1)

NRC Response: The NRC agrees that this 10 CFR Part 26 final rule will enhance the ability of NRC licensees to identify individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process, thereby aiding in detection and ultimately lead to enhanced public safety. Regarding one commenter's additional changes for consideration for inclusion in this rulemaking, the NRC responds to those changes in subsequent comment responses.

B. Response to Specific Requests for Comment

In Section V of the Supplementary Information for the proposed rule, the NRC solicited stakeholder comment on seven topics pertaining to the rule. The following paragraphs restate these topics, summarize comments received from stakeholders, and present the NRC's resolution of these comments.

B-1 Alignment with the HHS Guidelines

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

Comment B-1.1: 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 10 CFR 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 Medical Review Officer (MRO) specimen handling in 10 CFR Part 26. (ANON2-CL1, ANON2-A1)

NRC Response: The NRC disagrees. The NRC acknowledges that the HHS Guidelines contain similar provisions regarding the same-gender collector requirement in 10 CFR 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.

As a result, the NRC did not change the final rule in response to this comment.

The NRC discusses the topic of the same-gender observed collection requirement in 10 CFR 26.115(e) in the NRC Response to Comment L-1.

Comment B-1.2: One commenter recommended that the NRC establish a streamlined process other than rulemaking for nuclear facilities to adopt future HHS Guidelines upon issuance. (NEI1-CL3, NEI1-AI-1)

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.

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

B-2 Special Analyses Testing

The proposed rule includes new requirements in 10 CFR 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 10 CFR 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 10 CFR 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 10 CFR 26.69(b)(6), which is conducted to confirm continued abstinence from illegal drug use and/or the misuse of legal drugs.

Comment B-2.1: 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. (ANON2-CL2, ANON2-A2)

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 10 CFR 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, the NRC did not change the final rule in response to this comment.

Comment B-2.2: 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. (ANON2-CL3, ANON2-A3)

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 10 CFR 26.115(a)(1) through (3) and a new paragraph (a)(5). Specimens collected under the conditions described in 10 CFR 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 10 CFR 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, the NRC did not change the final rule in response to this comment.

Comment B-2.3: 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. (ANON2-CL4, ANON2-A4)

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 10 CFR 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 10 CFR 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 10 CFR 26.69(d), "Maintaining authorization with other potentially disqualifying FFD information." The definition of "potentially disqualifying FFD information" in 10 CFR 26.5 includes that an individual has used illegal drugs. The licensee or other entity also may consider conducting for-cause testing under 10 CFR 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 10 CFR 26.65, "Pre-access drug and alcohol testing," or 10 CFR 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 10 CFR 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 10 CFR 26.31(d)(3)(iii).

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

Comment B-2.4: 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. (NEI1-A1-2)

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 10 CFR 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 10 CFR 26.69(b). As a result, this comment is beyond the scope of this rulemaking.

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

B-3 Provide Flexibility to Conduct Specimen Validity Testing

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, 10 CFR 26.161(h) prohibits licensees and other entities from using more stringent cutoff levels for validity tests. The NRC is seeking comment on whether 10 CFR 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.

Comment B-3.1: Two commenters responded to the request for comment on providing flexibility to conduct 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 also suggested that licensees and other entities be provided with 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. (ANON2-CL5, ANON2-A5, NEI1-A1-3)

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 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 10 CFR 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 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 10 CFR 26.163(a)(2) until the final rule mandated such testing.

Accordingly, the final rule has been revised in 10 CFR 26.161(h) 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.

B-4 Effective Date of the Final Rule

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

Comment B-4.1: 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. (ANON2-CL6, ANON2-A6, NEI1-A1-4, NEI2-1, EH-1, EN2-1)

NRC Response: 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 Cumulative Effects of Regulation (CER) for this rule to justify additional implementation

time (see meeting summary in ADAMS under Accession No. ML21096A015). 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. 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 NRC revised the compliance deadline to be 1 year from the date that the 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 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 the final rule as a result of this request.

B-5 Direct Observation of Specimen Collection

The proposed rule retained 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.

Comment B-5.1: 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). (ANON2-CL7, ANON2-A7)

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. (NEI1-A1-5)

NRC Response: 8The 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 collections conditions in 10 CFR 26.115(a)(1) through (3) and a new paragraph (a)(5). The NRC 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 of 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 the 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. Each oral fluid specimen is collected under the direct observation of the specimen collector.

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 the 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 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 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 provides 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 removal of a donor's clothing from waist to knees, the collection of a second urine specimen under the direct observation of the collector, and the testing of the same biological specimen in a contemporaneous testing event has provided conclusive evidence of subversion attempts. 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 the 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, “Sanctions,” 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) of the donor’s saliva, 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

10 CFR 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 10 CFR 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 the final rule under 10 CFR 26.163(a)(2) apply to the specimens collected under direct observation in 10 CFR 26.163(a)(2) 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 the final rule, the NRC revised the following sections in the final rule:

- 10 CFR 26.5, "Definitions" ("HHS-certified laboratory");
- 10 CFR 26.31, "Drug and alcohol testing";
- 10 CFR 26.83, "Specimens to be collected";
- 10 CFR 26.85, "Collector qualifications and responsibilities";
- 10 CFR 26.87, "Collection sites";
- 10 CFR 26.89, "Preparing to collect specimens for testing";
- 10 CFR 26.97, "Conducting an initial test for alcohol using a specimen of oral fluids";
- 10 CFR 26.105, "Prepare for urine collection";
- 10 CFR 26.117, "Prepare urine specimens for storage and shipping";
- 10 CFR 26.151, "Purpose";
- 10 CFR 26.153, "Using certified laboratories for testing urine specimens";
- 10 CFR 26.161, "Cutoff levels for validity testing";
- 10 CFR 26.163, "Cutoff levels for drugs and drug metabolites";
- 10 CFR 26.167, "Quality assurance and quality control";
- 10 CFR 26.169, "Reporting results"; and
- 10 CFR 26.405, "Drug and alcohol testing" (FFD program for construction).

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) is beyond the scope of this rulemaking because the NRC did not propose, nor request comment on, the use of oral fluid specimens when a donor is unable to provide the minimum quantity of urine on the initial collection attempt.

B-6 2017 HHS Guidelines—New Test Analytes

On January 23, 2017, HHS issued its latest revision of the Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Urine Specimens (82 FR 7920). Subpart C, "Urine Drug and Specimen Validity Tests," of the 2017 HHS Guidelines was revised to include additional initial and confirmatory test analytes for certain opioids; specifically, hydrocodone, hydromorphone, oxycodone, and oxymorphone. The NRC is seeking comment on whether 10 CFR 26.31(d)(1) and 26.405(d) should be revised to identify hydrocodone, hydromorphone, oxycodone, and oxymorphone test substances, and whether 10 CFR 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.

Comment B-6.1: 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. (ANON2-CL8, ANON2-A8, NEI1-A1-6, DATIA-2)

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 safety 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 10 CFR 26.75 for positive test results.

Accordingly, the NRC revised 10 CFR 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 the final rule to align with the 2017 HHS Guidelines by adding testing for hydrocodone, hydromorphone, oxycodone, and oxymorphone.

Comment B-6.2: One commenter expressed concern with the increasing number of individuals being placed into follow-up testing programs because 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. (JR6-1)

NRC Response: The NRC agrees. See the NRC Response to Comment B-6.1, which discusses the NRC’s decision to expand the drug testing panel to include the four semi-synthetic opioids included in the 2017 HHS Guidelines (i.e., hydrocodone, hydromorphone, oxycodone, and oxymorphone). See also the NRC Response to Comment F-2, which addresses, in part, a comment on follow-up testing for individuals identified as having abused opioids.

B-7 Methylenedioxyethylamphetamine

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

Comment B-7.1: Two commenters responded to the specific request for comment on whether MDEA and MDA testing is needed. One commenter disagreed and stated that MDEA should be included in the drug testing panel because 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 the NRC should consider eliminating the testing of drugs that are not prevalent issues in the industry. (ANON2-CL9, ANON2-A9, NEI1-A1-7)

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, 10 CFR 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 10 CFR 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 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 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 (BPTS) requirements in 10 CFR 26.168 is beyond the scope of this rulemaking because the NRC did not propose changes to, nor request comment on, the blind performance test sample requirements. Additional discussion on this topic is provided under NRC response to Comment P-1.

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

C. FFD Program Applicability to Categories of Individuals

The following comments pertain to 10 CFR 26.4, "FFD program applicability to categories of individuals."

C-1 Hydration monitors

Comment C-1.1: Several commenters responded to the proposed new activity in 10 CFR 26.4(g)(6) of monitoring a donor during the hydration process as an activity that would require the monitor to be designated as FFD program personnel under 10 CFR Part 26. Two commenters recommended deleting the proposed new activity. The commenters explained that 10 CFR 26.31, "Drug and alcohol testing," permits an individual that is not designated as FFD program personnel to monitor more significant collection processes while only receiving training on the activities to be performed. One commenter also referenced the observation process in 10 CFR 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.

In contrast, another commenter requested that FFD authorization personnel be considered acceptable for monitoring the hydration process because FFD program personnel would not be available after hours or on weekends. The commenter stated that the main difference between FFD program personnel and FFD authorization personnel is that FFD authorization personnel are not subject to psychological testing during qualification for the position. However, FFD authorization personnel receive the psychological test if they have UAA or UA, which most of them do. In addition, personnel performing FFD authorization activities are subject to random

testing and must complete annual FFD behavioral observation program (BOP) training. (NEI1-A1-8, EN1-1, INPO-1)

NRC Response: 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 already permitted to be performed without such a restriction:

(1) Monitoring the collection of a specimen when a donor and collector have a personal relationship (10 CFR 26.31(b)(1)(iii));

(2) Observing a donor provide a urine specimen under direct observation when a same-gender collector is not available (10 CFR 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 (10 CFR 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. Use of a hydration monitor also requires instruction to be provided to the individual, as specified in proposed rule 10 CFR 26.109(b)(1)(i), which would require the original collector to explain the hydration process and acceptable donor behavior to the hydration monitor.

Accordingly, the NRC modified the final rule and RG 5.89 as follows:

- Removed proposed 10 CFR 26.4(g)(6), which read as follows: "All persons monitoring a donor during the hydration process described in 10 CFR 26.109(b)";

- Revised proposed 10 CFR 26.109(b)(1) to replace the phrase "or to a hydration monitor who meets the requirements in 10 CFR 26.4(g)(6)" with "or to a hydration monitor"; and

- Revised guidance in Section C.1.A.(2) of RG 5.89 to replace the text "or to use hydration monitors (10 CFR 26.4(g)(6))" with "or also use hydration monitors."

C-2 Infrequently performed activities

Comment C-2.1: One commenter requested that the NRC revise 10 CFR 26.4(g) to clarify that an individual infrequently performing an activity described in 10 CFR 26.4(g), such as a security officer conducting a specimen collection (e.g., a back shift random test, or a for-cause or a post-event test), not be considered FFD program personnel. The commenter noted confusion among some licensees on this issue. (JR2-1)

NRC Response: The commenter's request to revise 10 CFR 26.4(g) to clarify that an individual infrequently performing an activity described in 10 CFR 26.4(g) not be considered FFD program personnel is outside the scope of this rulemaking because the NRC did not propose changes to, nor request comment on, this provision in 10 CFR 26.4(g).

However, 10 CFR 26.4(g) does require the licensee or other entity to identify in its procedures the individuals involved in the day-to-day operations of the FFD program. If an individual infrequently performing duties listed in 10 CFR 26.4(g) is not identified in the procedures as FFD program personnel, then the individual is not considered FFD program personnel.

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

C-3 Remote collections

Comment C-3.1: One commenter asserted that the remote collection requirements in 10 CFR 26.4(h)(2) are not clearly denoted, and expressed concern that as a result, licensees may choose to define which personnel may provide specimens at a remote collection site for drug and alcohol testing. The commenter stated, "Licensee company's increasingly are placing demands on FFD program personnel to accommodate remote collection conditions that would allow the licensee to meet the definition of critical group, thereby requiring placement in the FFD program." The commenter recommended that the NRC provide guidance to ensure a clear understanding of this issue. (JR3-1)

NRC Response: The NRC disagrees. The regulations in 10 CFR Part 26 permit specimens to be collected at a location other than a designated collection site meeting the requirements in 10 CFR 26.87, which is what the NRC believes the commenter is referring to by using the term "remote collection." However, under 10 CFR 26.31(b)(2), a licensee or other entity is permitted to collect specimens for drug and alcohol testing at a local hospital or other organization that meets the requirements in 49 CFR Part 40, "Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs," but only for individuals identified as "FFD program personnel" in 10 CFR 26.4(g).

Section 26.4, "FFD program applicability to category of individuals," does not contain a paragraph (h)(2). The comment appears to be referring to paragraph (i), which immediately follows 10 CFR 26.4(h) and includes a subparagraph (2). However, 10 CFR 26.4(i) describes the individuals that are not subject to an FFD program under 10 CFR Part 26. Therefore, the commenter's description of the issue is inconsistent with the requirements in 10 CFR Part 26.

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

D. Definitions

The following comments pertain to 10 CFR 26.5, "Definitions."

D-1 Federal custody and control form

Comment D-1.1: One commenter requested that the NRC clarify the proposed new definition for the term "Federal custody and control form (Federal CCF)." Specifically, the commenter recommended that the NRC revise the proposed phrase "any HHS approved form, which has not expired" with the phrase "any HHS-approved form or equivalent form, which has not expired" and add the sentence: "Expired custody and control forms may be used if covered by an active memorandum for the record." (NEI1-A1-9)

NRC Response: The NRC disagrees. The term "Federal custody and control form" is specific to forms approved by HHS. Section 26.153(g) already provides a licensee or other entity with the ability to use a form other than the current Federal CCF, as long as the form contains all of the required information on the Federal CCF and provides the HHS-certified laboratory with a memorandum explaining why a non-Federal form was used.

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

D-2 Lot

Comment D-2.1: One commenter asserted that the blind performance testing requirement in 10 CFR 26.168(h)(1) does not limit a blind performance test sample (BPTS) supplier to certify a lot for only 6 months. Instead, the commenter asserted that the requirement is that any lot certified by the supplier be for a period of no more than 6 months. The commenter requested the following three definitions be added to 10 CFR 26.5 to improve the clarify of the rule:

- Lot (blind specimen) – A controlled and numbered batch prepared by a provider of Blind Specimens that meets specific Part 26 testing parameters for a drug type, metabolite, adulterant, etc. that must be tested and confirmed by an HHS-certified lab as part of the provider's specimen certification process.

- Open Lot – A controlled and numbered batch that meets specific Part 26 testing parameters, and sufficient quantity remains to be tested and confirmed by an HHS-certified lab as part of the provider's specimen certification process.

- Closed Lot – A controlled and numbered batch that previously met specific Part 26 testing parameters, but there is no longer sufficient quantity to support the provider's specimen certification process. (INPO-3)

NRC Response: The NRC disagrees. Before this rulemaking, 10 CFR 26.168(h)(1) stated that "all blind performance test sample lots are placed in service by the supplier only after confirmation by an HHS-certified laboratory, and for no more than 6 months." The final rule eliminates the "6 month" in service time limitation for a BPTS lot. In the proposed rule, the NRC proposed eliminating the in-service limit based on feedback that sample lots can remain viable for much longer than 6 months (e.g., 2 years) and because the 2008 HHS Guidelines did not impose an in-service time limit on BPTS lots.

In the proposed rule, the NRC proposed a new definition in 10 CFR 26.5 for the term "lot," which would mean "a number of units of an item (e.g., drug test kits, reagents, quality control samples) manufactured from the same starting materials within a specific period of time for which the manufacturer states that the items have essentially the same performance characteristics and the same expiration date." The final rule includes this new definition of "lot." The existing definition in 10 CFR 26.5 for "Quality control sample" is "a sample used to evaluate whether an analytical procedure is operating within predefined tolerance limits. Calibrators, controls, negative samples, and blind performance test samples are collectively referred to as 'quality control samples' and each is individually referred to as a 'sample.'"

Section 26.168(h)(2) requires the BPTS supplier to provide an expiration date on each BPTS to ensure that the expected value is received when the licensee or other entity submits the specimen for testing to an HHS-certified laboratory. Under 10 CFR 26.168(h)(3), the BPTS manufacturer must test each open lot every 2 months to ensure that samples remaining in the lot do not fall below 130 percent of the initial cutoff test concentration established by the assay manufacturer. A test result below 130 percent of that standard is unacceptable and licensees and other entities must discard any BPTS from any lot that is outside of the acceptable parameters in 10 CFR 26.168. The testing performed under 10 CFR 26.168(h)(3) ensures that each BPTS provided to a licensee or other entity meets the formulation requirements under 10 CFR 26.168(g) for the duration of the time period that the BPTS supplier has specified on the BPTS.

In addition, the proposed definitions provided by the commenter would use the term "batch" in a manner inconsistent with the existing rule. The term "batch" is specific to the testing of specimens at the same time. In 10 CFR Part 26, the term "batch" is used under the quality assurance and quality control requirements in 10 CFR 26.167(f)(3) and in the 10 CFR 26.5 definition of "analytical run." The "analytical run" definition states, in part, that "an analytical run is defined as no more than an 8-hour period. For a facility that analyzes specimens in batches, an analytical run is defined as a group of specimens that are handled and tested together." In contrast, the proposed use of the term "batch" by the commenter would be equivalent to the term "lot," which the final rule defines in 10 CFR 26.5 as "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."

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

D-3 Potentially disqualifying FFD information

Comment D-3.1: One commenter asserted that the current definition of "Potentially disqualifying FFD information" needed to be amended to address marijuana legalized by state law. The commenter suggested to include the statement "(Including controlled substances determined to be illegal under federal law, such as marijuana, but deemed legal under state law)" after the current definition of "Used, sold, or possessed illegal drugs." (NEI1-A1-10)

NRC Response: The NRC disagrees. The definition of "illegal drug" in 10 CFR 26.5 means, for purposes of 10 CFR Part 26, "any drug that is included in Schedules I to V of section 202 of the Controlled Substances Act [21 U.S.C. 812], but not when used pursuant to a valid prescription or when used as otherwise authorized by law." Marijuana is a Schedule I drug, which means it has "no currently accepted medical use in treatment in the United States…[and t]here is a lack of accepted safety for use of the drug or other substance under medical supervision." So, no valid prescription can be written for a Schedule I drug under Federal law.

In addition, 10 CFR 26.185(j)(6) states, "The MRO may not consider the use of any drug contained in Schedule I of section 202 of the Controlled Substances Act [21 U.S.C. 812] as a legitimate medical explanation for a positive confirmatory drug test result, even if the drug may be legally prescribed and used under State law."

As a result, the NRC did not change the final rule in response to this comment.

Comment D-3.2: One commenter requested that the current definition of "Potentially disqualifying FFD information" be revised to remove "(except for self-referral)" from the statement "(7) Been subjected to a plan for substance abuse treatment (except for self-referral)." The basis for the request was that the current statement is in conflict with two other elements in the existing definition: "(3) Used, sold, or possessed illegal drugs" and "(4) Abused legal drugs or alcohol." (NEI1-A1-11)

NRC Response: The NRC disagrees. The NRC did not propose changes to, nor request comment on, the definition of the term "Potentially disqualifying FFD information" in 10 CFR 26.5. As a result, this comment is beyond the scope of this rulemaking.

However, under 10 CFR 26.35(c), the employee assistance program (EAP) staff shall protect the identity and privacy of any individual (including those who have self-referred) seeking assistance from the EAP, except if the individual waives the right to privacy in writing or EAP personnel determine that the individual's condition or actions pose or have posed an immediate hazard to himself or herself or others. In the latter situation, 10 CFR 26.35(c) requires EAP personnel to inform FFD program management that the individual's condition or actions pose or have posed an immediate hazard to himself or herself or others and need not obtain a written waiver of the right to privacy from the individual. The individual conditions or actions that EAP personnel shall report to FFD program management include, but are not limited to, substantive reasons to believe that the individual has been impaired from using drugs or alcohol while in a work status and has a continuing substance abuse disorder that makes it likely he or she will be impaired while in a work status in the future, or has ever engaged in any acts that would be reportable under 10 CFR 26.719(b)(1) through (b)(3).

Removing "except self-referral" from the "Potentially disqualifying FFD information" definition could be chilling to an individual seeking assistance from the EAP, which exists to provide early intervention and provide for confidential assistance, except as noted above. In the 2008 Part 26 final rule statement of considerations (73 FR 17026), the Commission stated:

> [T]he EAP provides an important means to detect and achieve early resolution of developing substance abuse and other problems, which if left untreated could have the potential to adversely affect an individual's ability to safely and competently perform his or her duties. The knowledge or perception among individuals who are subject to the rule that self-referrals to the EAP will be reported to management and will routinely result in the loss of authorization represents a significant barrier to the effectiveness of the EAP element of FFD programs. Therefore, … an individual's use of the licensee's or other entity's EAP must remain confidential, except in very limited circumstances.

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

D-4 Rejected for testing

Comment D-4.1: One commenter requested that the proposed new definition for "rejected for testing" be modified for clarity. The commenter suggested that the definition read as "the result reported to the MRO by a licensee testing facility or HHS-certified laboratory when a fatal flaw disqualifies a specimen or, any of the required testing cannot be performed on a specimen." (NEI1-A1-12)

NRC Response: The NRC disagrees. The term "fatal flaw" is not used in 10 CFR Part 26, although the term is used in the 2008 and 2017 HHS Guidelines (Subpart O – Criteria for Rejecting a Specimen for Testing, Section 15.1). Instead, 10 CFR Part 26 specifies the "exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen" under 10 CFR 26.129(b)(2) for tests performed at licensee testing facilities, and under 10 CFR 26.159(b)(2) for tests performed at HHS-certified laboratories. The NRC added the definition of "rejected for testing" because, in part, that is the term used by the laboratory in its communication to the licensee or other entity. Under the HHS Guidelines, if an HHS-certified laboratory identifies a fatal flaw, then the laboratory will report on the Federal CCF that the specimen was rejected for testing and the reason for the reported result.

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

D-5 Substance abuse

Comment D-5.1: One commenter requested that the NRC consider amending the current definition of "substance abuse" to specifically include controlled substances, such as marijuana, which has been deemed legal under State law. (NEI1-A1-13)

NRC Response: The NRC disagrees. The NRC did not propose changes to, nor request comment on, the 10 CFR 26.5 definition of "substance abuse," which "means the use, sale, or possession of illegal drugs, or the abuse of prescription and over-the-counter drugs, or alcohol abuse of alcohol." As a result, this comment is beyond the scope of this rulemaking.

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

See also the NRC Response to Comment D-3.1, which discusses the 10 CFR 26.5 definition of "illegal drugs."

E. Written Policy and Procedures

The following comments pertain to 10 CFR 26.27, "Written policy and procedures."

Comment E-1: *5-hour prohibition for the use of impairing substances.* One commenter suggested that the current requirement in 10 CFR 26.27(b)(4) that prohibits the consumption of alcohol within an abstinence period of 5 hours preceding the individual's arrival at the facility, should apply to any substance with known impairing qualities. In particular, the commenter was concerned that there are additional substances with intoxicating effects greater than or equal to alcohol. Some examples given included prescription opiates, inhalant substances, benzodiazepines, sedatives, and sleep aids. To address this concern, the commenter recommended that while naming every impairing substance may not serve the purpose, it would

be more efficacious to stipulate that “any impairing substance ingested within 5 hours of reporting, is prohibited, including alcohol.” (JR4-1)

NRC Response: The NRC disagrees. The NRC did not propose changes to, nor request comment on, the 5-hour abstinence period for alcohol use. As a result, this comment is beyond the scope of this rulemaking.

The NRC does not support establishing a specific abstinence period to prohibit the use of other potentially impairing substances by an individual subject to a Part 26 FFD program. For example, the complexity of the time periods in which impairment may result from use of prescription or over-the-counter (OTC) drugs, makes establishing such an abstinence period impractical. However, 10 CFR Part 26 does not prohibit a licensee or other entity from establishing such a policy.

The requirements in 10 CFR Part 26 establish a robust framework to mitigate potential impairing effects of prescription and OTC medication use. Each licensee and other entity must implement a behavioral observation program under 10 CFR 26.33 to train individuals in detecting behaviors that may indicate impairment from any cause that may constitute a risk to public health and safety or the common defense and security, and to take action under 10 CFR 26.77 to address possible impairment. Section 26.27(b) requires the establishment of an FFD policy to address the factors that could cause impairment, such as the use of prescription and OTC medications, and to describe the consequences to an individual for the misuse of those substances. Section 26.29 requires initial and annual training for each individual on prescription and OTC drugs and dietary factors that have the potential to affect drug and alcohol test results, and the ability to observe and detect performance degradation, indications of impairment, or behavioral changes.

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

F. Drug and Alcohol Testing

The following comments pertain to 10 CFR 26.31, “Drug and alcohol testing.”

F-1 Post-event testing criteria

Comment F-1.1: One commenter indicated that the 10 CFR 26.31(c)(3)(i) criterion to conduct “post-event” testing after an event resulting in illness or injury determined to be reportable under 29 CFR 1904.7, “General recording criteria,” of the U.S. Department of Labor (DOL) is difficult to implement. The requirement to conduct post-event testing within 4 hours after the event is determined to be recordable to DOL is confusing because it may take 24 hours or longer after the event occurs to determine that it is recordable to DOL. In this situation, the commenter questioned whether post-event testing makes sense. (JR5-1)

NRC Response: The NRC did not propose changes to, nor request comment on, the post-event testing criteria in 10 CFR 26.31(c)(3)(i). As a result, this comment is beyond the scope of this rulemaking. However, the commenter’s request could inform future considerations by the NRC.

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

Comment F-1.2: One commenter stated that the 10 CFR 26.31(c)(3)(iii) criteria requiring post-event testing to be conducted for "substantial degradation to the of level of safety" of the plant, has been frequently debated and suggested that the "degradations of plant safety that generally may compromise general safety and security" may be a more appropriate testing criteria. (JR5-2)

NRC Response: The NRC did not propose changes to, nor request comment on, the post-event testing criteria in 10 CFR 26.31(c)(3)(iii). As a result, this comment is beyond the scope of this rulemaking. However, the commenter's request could inform future considerations by the NRC.

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

F-2 Follow-up testing plan

Comment F-2: One commenter requested that personnel in the follow-up testing program for a specific substance under one licensee or other entity's FFD testing program to verify abstinence from substance abuse continue to be monitored through follow-up testing for the applicable substance if they change employment within the industry. The commenter indicated that follow-up testing has worked well when it applies to the standard panel of drugs tested for under 10 CFR Part 26, but it has not adapted to the opioid epidemic. Few sites utilize expanded testing panel testing for opioids and therefore variability exists on whether a subsequent licensee or other entity will continue to monitor abstinence for an addiction issue. (JR6-2)

NRC Response: The NRC disagrees, in part. Under 10 CFR 26.69(e), "Accepting followup testing and treatment plans from another FFD program," a licensee or other entity may rely on the follow-up testing, treatment plan, and determination of fitness for an individual if compliant with 10 CFR 26.189 and conducted under the 10 CFR Part 26 FFD program of another licensee or other entity. The licensee or other entity who imposed a treatment plan, follow-up testing plan, or both, must ensure that the information documenting the plan(s) is identified to any subsequent licensee or other entity who seeks to grant authorization to an individual, which is the case described by the commenter. If it is impractical for the individual to comply with a treatment plan that was developed under another FFD program because of circumstances outside of the individual's or licensee's or other entity's control (e.g., geographical distance, closure of a treatment facility), then the granting FFD program must ensure that a substance abuse expert (SAE) develops a comparable treatment plan, with accountability for monitoring the individual's compliance with the plan assumed by the granting licensee or other entity. If the previous licensee or other entity determined that the individual successfully completed any required treatment and follow-up testing, and the individual's last period of authorization was terminated favorably, the receiving licensee or entity may rely on the previous determination of fitness and no further review or follow-up is required.

However, under 10 CFR 26.69(b), "Authorization after a first confirmed positive drug or alcohol test result or a 5-year denial of authorization," a licensee or other entity is required to: (1) ensure that an SAE has conducted a determination of fitness and concluded that the individual is fit to safely and competently perform his or her duties; (2) ensure that any recommendations for treatment and follow-up testing be initiated before granting authorization;

(3) conduct a minimum number of follow-up tests over a specified period of time; and (4) verify compliance and successful completion of any treatment and follow-up testing.

The NRC Response to Comment B-6.1 describes the changes made in the final rule to expand the drug testing panel to include four semi-synthetic opioids in the 2017 HHS Guidelines (i.e., hydromorphone, hydrocodone, oxycodone, and oxymorphone). These drug testing panel changes apply under all conditions of testing under 10 CFR Part 26 and address, in part, the request of the commenter.

F-3 Random testing collector availability

Comment F-3: One commenter requested that the random testing requirement in 10 CFR 26.31(d)(2)(v) pertaining to individuals who are off- or on-site and not reasonably available for testing when selected, be revised to "clarify availability of the collector performing in a collector capacity." The commenter requested that the phrase "when both the donor and collectors are available to collect specimens for testing and without prior notification to the individual" be replaced with "when collection personnel are scheduled to perform collections and the donor is available for testing and without prior notification to the donor." (NEI1-A1-14)

NRC Response: The NRC did not propose changes to, nor request comment on, the random testing requirements in 10 CFR 26.31(d)(2)(v). As a result, this comment is beyond the scope of this rulemaking.

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

G. Behavioral Observation

The following comment pertains to 10 CFR 26.33, "Behavioral observation."

Comment G-1: *Program elements.* One commenter requested that the NRC revise the behavior observation program requirements in 10 CFR 26.33 to add detecting behaviors indicative of mental illness, as well as impairment from any substance (e.g., inhalants, household substances). Currently, a behavioral observation program must "detect behaviors that may indicate possible use, sale or possession of illegal drugs" or "use or possession of alcohol on site or while on duty." (JR1-1)

NRC Response: The NRC disagrees. The NRC did not propose changes to, nor request comment on, the behavioral observation requirements in 10 CFR 26.33. As a result, this comment is beyond the scope of this rulemaking.

The behavioral observation program requirements in 10 CFR 26.33 include the statement "or impairment from fatigue or any cause that, if left unattended, may constitute a risk to public health and safety or the common defense and security." This statement covers the topics of the commenter's request. However, the commenter's request could inform future considerations by the NRC.

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

H. Sanctions

The following comments pertain to 10 CFR 26.75, "Sanctions."

Comment H-1: *Denial period for first positive result of illegal drug use.* One commenter requested that 10 CFR 26.75 be revised in the final rule. The commenter stated that the minimum denial of authorization for a period of 14 days for a first positive test result for a legal substance (e.g., alcohol) must not be the same as that for a first positive test result for an illegal substance (e.g., cocaine). Instead, the commenter recommended increasing the minimum denial of authorization to 5 years for a first positive test result for an illegal drug. (NE-1)

NRC Response: The NRC disagrees. The NRC did not propose changes to, nor request comment on, the sanctions in 10 CFR 26.75. As a result, this comment is beyond the scope of this rulemaking. The NRC addressed this subject in the initial 10 CFR Part 26 final rule (June 7, 1989; 54 FR 24477). Further, under 10 CFR 26.75(a), a licensee or other entity may impose a more stringent sanction (except as specified in 10 CFR 26.75(h)). The 10 CFR 26.717 annual FFD program performance data reported to the NRC by licensees and other entities indicates that some licensees and other entities institute a sanction far greater than 14 days for a first positive test result.

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

Comment H-2: *Use of other intoxicating agents.* One commenter requested that the conditions requiring a 5-year denial under 10 CFR 26.75 be expanded to include the abuse of any intoxicating substance (e.g., solvents, computer cleaners) and any prescription drug with the sole intent of producing a high to alter consciousness. The commenter reasoned that these conditions should be added because they both jeopardize safety and security. Currently, a 5-year denial of authorization sanction is required for "the sale, use or possession of illegal drugs or the consumption of alcohol within a protected area…" or "while performing duties that require the individual to be subject" to 10 CFR Part 26. (JR7-1)

NRC Response: The NRC did not propose changes to, nor request comment on, the sanctions in 10 CFR 26.75. As a result, this comment is beyond the scope of this rulemaking. However, the commenter's request could inform future considerations by the NRC.

Part 26 does not prohibit a licensee from establishing a sanction under its FFD policy for abuse of an intoxicating substance.

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

I. Management Actions Regarding Possible Impairment

The following comments pertain to 10 CFR 26.77, "Management actions regarding possible impairment."

Comment I-1: *Assessing impairment.* One commenter requested that the NRC consider language that clearly allows for drug and alcohol testing to eliminate the possibility that drugs and alcohol are playing a role in the behavior. Impairment may not be observed, but behavior

that may deviate significantly from the individual's recognized customary character or practice necessitates a drug and alcohol screen. A negative finding on a drug and alcohol screen will eliminate the possibility that drugs or alcohol are playing a role in the observed behavior. Once this factor is eliminated, other contributing factors such as mental or physical health may be considered. The commenter stated that there have been noteworthy cases where behaviors were reported as odd or irregular only to find that, following a drug and alcohol screen, prescription drug abuse, alcohol abuse, or a combination of the two was the contributing cause. In other cases, mental illness was detected, resulting in the need for treatment. In each of these cases, there was no demonstrated impairment. Drug and alcohol screens are a vital data point in a process of next steps in reaching a decision concerning the need for a full determination of fitness. (JR8-1)

NRC Response: The NRC disagrees. The NRC did not propose changes to, nor request comment on, the management actions regarding possible impairment described in 10 CFR 26.77. As a result, this comment is beyond the scope of this rulemaking.

Under 10 CFR 26.77(b)(1), if an observed behavior or physical condition creates a reasonable suspicion of possible substance abuse, then the licensee or other entity must perform drug and alcohol testing, unless the physical condition is the smell of alcohol with no other behavioral or physical indications of impairment, in which case only alcohol testing is required.

Under 10 CFR 26.77(b)(3), a licensee or other entity must perform a determination of fitness for "other indications of possible impairment that do not create a reasonable suspicion of substance abuse (or fatigue, in the case of licensees and [contractor/vendors] who are subject to subpart I of this part)." The determination of fitness requirement under 10 CFR 26.189(a) specifies that the "determination of fitness must be made by a licensed or certified professional who is appropriately qualified and has the necessary expertise … to evaluate the specific fitness issues presented by the individual." Section 26.189(a)(5) also states, "If there is no conclusive evidence of an FFD policy violation but there is a significant basis for concern that the individual may be impaired while on duty, then the subject individual must be determined to be unfit for duty…. [T]he professional who made the determination of fitness shall consult with the licensee's or other entity's management personnel to identify the actions required to ensure that any possible limiting condition does not represent a threat to workplace or public health and safety. Licensee or other entity management personnel shall implement the required actions. When appropriate, the subject individual may also be referred to the EAP."

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

J. Preparing to Collect Specimens for Testing

The following comments pertain to 10 CFR 26.89, "Preparing to collect specimens for testing."

Comment J-1: *Use of the terms label and seal.* One commenter requested that the term "tamper-evident tape" used in proposed rule 10 CFR 26.89(d) be replaced with the term "a tamper-evident seal." This change would ensure consistency with the term that is currently used in 10 CFR 26.117(c). (NEI1-A1-15)

NRC Response: The NRC agrees.

Accordingly, the NRC has corrected the inconsistency in 10 CFR 26.89(d) of the proposed rule by replacing the term "tamper-evident tape" with the phrase "a tamper-evident seal."

K. Urine Specimen Quantity

The following comments pertain to 10 CFR 26.109, "Urine specimen quantity."

K-1 Hydration monitor being a collector

Comment K-1: One commenter stated that the new requirement in proposed rule section 10 CFR 26.109(b)(1), that a hydration monitor be a collector, is unnecessary and an administrative burden. To address this concern, the commenter recommended the following two changes:

First, create a new 10 CFR 26.31(b)(1)(vi) that states, "When a donor is unable to provide an acceptable specimen of 30 mL, they are encouraged to follow the hydration process in 10 CFR 26.109(b). During the hydration period, a donor may be under the observation of a hydration monitor as follows: (A) The donor must be continuously monitored by an individual who does not have a personal relationship with the donor; (B) Individuals who are assigned to monitor donors during a hydration period shall be provided instructions on the monitoring process and control the donor's access to any fluids, and control the hydration process in accordance with 10 CFR 26.109(b); and (C) The hydration monitor shall be responsible for documenting the hydration process in accordance with program procedures."

Second, replace the phrase "a hydration monitor who meets the requirements in 10 CFR 26.4(g)(6)" with "a hydration monitor who meets the requirements in 10 CFR 26.31(b)(1)(vi)" in proposed rule 10 CFR 26.109(b)(1). (NEI1-A1-16)

NRC Response: The NRC disagrees, in part. The proposed requirement in 10 CFR 26.109(b)(1) stated that "the collector may assign responsibility for monitoring a donor during the hydration process to another collector who meets the requirements in 10 CFR 26.85(a) or to a hydration monitor who meets the requirements in 10 CFR 26.4(g)(6)." Under the proposed rule, a hydration monitor would not need to be a collector but would need to be FFD program personnel.

In the final rule, the NRC eliminated the 10 CFR 26.4(g)(6) proposed requirement that a hydration monitor be designated as FFD program personnel (see NRC Response to Comment C-1). Therefore, the commenter's request to include requirements for a hydration monitor in 10 CFR 26.31(b)(1), the section of Part 26 that describes how a licensee or other entity will assure the honesty and integrity of FFD program personnel, is not applicable.

However, in terms of the content of the commenter's proposed 10 CFR 26.31(b)(1)(vi), the proposed and final rules under 10 CFR 26.109(b)(1)(i) do require the specimen collector to "explain the hydration process and acceptable donor behavior to the hydration monitor." The NRC agrees that the hydration monitor should not have a personal relationship with the donor,

as is described in Section 1.A.(6) of DG-5040, which states that "the collector should verbally confirm that the hydration monitor does not have a personal relationship with the donor(s)."

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

K-2 Adding information to the CCF remarks line and CCF control

Comment K-2.1: One commenter requested that the proposed 10 CFR 26.109(b)(1)(ii) requirement that the original specimen collector "record the name of the other collector or hydration monitor on the Federal CCF and then provide the Federal CCF to that individual for the duration of the hydration process" be deleted. The commenter stated that there is insufficient room on the Federal CCF to record the name and that it is both unnecessary and inconsistent with other 10 CFR Part 26 collection provisions that permit the use of a monitor, but do not require the individual's name to be recorded on the Federal CCF. The commenter pointed out that the only instance when the name of an individual is recorded on the Federal CCF is for a directly observed collection. Further, the commenter stated that the Federal CCF should remain with the original collector and not be provided to the hydration monitor or other collector during the hydration process. (NEI1-A1-17, NEI1-A1-18)

NRC Response: The NRC disagrees, in part. As noted by the commenter, 10 CFR 26.115(f)(4) is the only requirement where the name of an observer must be recorded on the Federal CCF if someone other than a collector observes a specimen provided under direct observation. In the other circumstance described by the commenter under 10 CFR 26.31(b)(1)(iii), if a donor and the collector have a personal relationship, the collection must be monitored by an individual who does not have a personal relationship with the donor, but the rule is silent on documenting the monitor's name on the CCF. The difference between these two collection circumstances is that under 10 CFR 26.31(b)(1)(iii), the specimen collector retains their responsibilities during the collection process, whereas under 10 CFR 26.115(f)(4), the individual observing the donor is solely performing the assigned duty.

Under the proposed rule, the collector is permitted to transfer the responsibility to observe a donor during the hydration process to another collector or individual instructed on the required responsibilities (i.e., a hydration monitor). In this situation, the original collector is not performing the observation activity and therefore it is appropriate to document the name of the individual (i.e., hydration monitor or second collector) on the Federal CCF, as required under proposed 10 CFR 26.109(b)(1)(ii). Documenting the name of the hydration monitor or a second collector on the Federal CCF is a donor protection, is a limited amount of text to write on the Federal CCF, and supports NRC inspection for compliance with 10 CFR Part 26 collection requirements. However, the NRC does agree that only limited space exists on the Federal CCF to record more extensive comments on the specimen collection (see NRC Response to Comment U-1.3).

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 the final rule by removing the phrases “and then provide the Federal CCF to the individual for the duration of the hydration process” in 10 CFR 26.109(b)(1)(ii), and “except as provided in 10 CFR 26.109(b)(1)(ii) for the Federal CCF” in 10 CFR 26.117(g).

L. Collecting a Urine Specimen Under Direct Observation

The following comments pertain to 10 CFR 26.115, “Collecting a urine specimen under direct observation.”

Comment L-1: *Donor gender identity.* One commenter requested that the same-gender collection requirement be modified for the circumstance when a donor identifies as one gender but has the physical anatomy of the opposite gender, or those who identify as gender X. In this instance, the commenter suggested permitting a medical professional, such as a doctor or nurse that is of the opposite gender of the donor, to complete the direct observation. The commenter stated that this approach would not be allowed under the proposed wording.

The commenter recommended 10 CFR 26.115(e) be revised as follows: “The collector shall reasonably ensure that the observer is the same gender as the individual donor. 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.” (NEI1-A1-19)

NRC Response: The NRC disagrees. The NRC did not propose changes to, nor request comment on, the requirement in 10 CFR 26.115(e) for the observer of an observed collection be the same gender as the donor. As a result, this comment is beyond the scope of this rulemaking.

However, because 10 CFR Part 26 does not define the term “gender,” a licensee or other entity could establish through its written policy and procedures in 10 CFR 26.27, how to conduct an observed collection when a donor identifies as one gender but has the physical anatomy of the opposite gender, or the donor identifies as gender X.

Licensees and other entities could consider the same-gender collection procedures in the 2017 HHS Guidelines, which were updated to address a donor’s gender identity. Specifically, Section 1.5 was updated to define a new term, “gender identity,” as “an individual’s internal sense of being male or female, which may be different from an individual’s sex assigned at birth.” The direct observation collection procedure in Section 8.10 of the 2017 HHS Guidelines also was revised to allow the donor to be observed by an observer whose gender matches the donor’s gender. Specifically, at the beginning of the observed collection, the collector is to request that the donor document the donor’s gender on the Federal CCF and initial the annotation. An observer of the same gender would then be provided, and the collector would record the name and gender of the observer on the Federal CCF.

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

M. Preparing Urine Specimens for Storage and Shipping

The following comments pertain to 10 CFR 26.117, "Preparing urine specimens for storage and shipping."

Comment M-1: *Specimen handling.* One commenter expressed concern that shipping delays due to multi-day holidays could impact specimen integrity by causing invalid test results. The commenter indicated that the 10 CFR 26.117(j) requirement that a specimen be delivered to the laboratory within 2 business days of shipment may not be protective of the donor. The commenter stated that rather than limiting the rule change to how invalid test results will be handled, the rule should be changed to require a specimen to be received by the laboratory within 24 hours of shipment. On the other hand, the commenter also offered that the licensee or other entity could contractually require the courier service to provide notification whenever the 2-business day receipt requirement could not be met. (INPO-2)

NRC Response: The NRC disagrees. The NRC did not propose changes to, nor request comment on, the requirements in 10 CFR 26.117(j) regarding the timing of the transfer of a urine specimen from a collection site to a testing laboratory. As a result, this comment is beyond the scope of this rulemaking.

A licensee or other entity is responsible for ensuring that a specimen is delivered to an HHS-certified laboratory within 2 business days of shipment from the collection site, "except under unusual circumstances." For example, if a licensee sends a specimen to the HHS-certified laboratory on Friday for delivery on Saturday morning, but the laboratory normally does not accept specimens for testing on Saturday and Sunday, the licensee would not be meeting the 10 CFR 26.117(j) requirement. In this example, the collection site would maintain the specimen in storage until the laboratory would be available to take receipt of the specimen.

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

N. Determining "Shy" Bladder

The following comments pertain to 10 CFR 26.119, "Determining "shy" bladder."

Comment N-1.1: *Medical evaluation*. One commenter expressed concern that meeting the 5-business day requirement for a donor to obtain an evaluation from a licensed physician for a shy bladder presents unique challenges. The commenter indicated that additional time was necessary because of transient workers who do not have health insurance or a personal physician. Workers who are traveling and away from their residence must now (when unable to produce a specimen) attempt to travel home and find a physician who will immediately schedule an appointment and see them. Finding an appointment with a physician in the immediate area of the plant is difficult due to the short time frame. In this frequent scenario, the worker is unable to meet the 5-day standard, which invariably results in a permanent denial.

The commenter recommended that the NRC provide a more realistic time frame to complete the evaluation, such as a minimum of 10 days, not to exceed 30 days, with the approval of the MRO or program manager. (JR9-1)

NRC Response: The NRC did not propose changes to, nor request comment on, any provisions in 10 CFR 26.119. As a result, this comment is beyond the scope of this rulemaking. However, the commenter's request could inform future considerations by the NRC.

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

Comment N-1.2: *Alternative specimen*. One commenter suggested that an acceptable alternative for individuals unable to provide a urine specimen is the collection and testing of oral fluid. The 2019 HHS Guidelines for oral fluid specimen collection and testing should provide MROs and program managers with the needed tools and guidance to address this issue. The commenter requested that the NRC establish requirements for the conditions when oral fluid specimen collection is appropriate for drug testing. Furthermore, the commenter requested that the NRC provide flexibility to collect and test oral fluid under any testing condition. (JR9-2)

NRC Response: The NRC disagrees with the commenter's request that the NRC provide flexibility to collect and test an oral fluid specimen instead of a urine specimen under any testing condition specified under 10 CFR 26.31(c). The NRC did not propose nor request comment on whether to allow this flexibility, so the request is beyond the scope of this rulemaking. However, Part 26 already provides flexibility to collect and test an alternative specimen under three circumstances (see 10 CFR 26.31(d)(5)(i), 26.119(g)(3), and 26.185(f)(2)). In each instance, either a medical condition prevents the donor from providing a urine specimen for testing, or a donor's medical condition affects the ability to test the specimen (i.e., invalid test result). The NRC has chosen not to specify any biological specimen type that is acceptable for collection and testing to provide the most flexibility to the MRO given a donor's unique medical circumstances. However, the commenter's request could inform future considerations by the NRC.

The NRC addresses the commenter's request that the NRC establish requirements for the conditions when an oral fluid specimen is appropriate for collection and drug testing under the NRC Response to Comment B-5.1.

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

O. Cutoff Levels for Validity Testing

The following comments pertain to 10 CFR 26.161, "Cutoff levels for validity testing."

Comment O-1: *Validity testing.* One commenter asked if 10 CFR Part 26 required a quantitative determination to report a dilute validity test result. (JC-1)

NRC Response: The commenter's concern is addressed in 10 CFR 26.161(e), which provides the criteria by which an HHS-certified laboratory determines whether a validity test specimen is dilute and must be reported to the MRO. A dilute specimen is reported when the creatinine

concentration of a specimen is equal to or greater than 2 mg/dL but less than 20 mg/dL and its specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot. Accordingly, the NRC did not change the final rule in response to this comment.

P. Blind Performance Testing

The following comments pertain to 10 CFR 26.168, "Blind performance testing."

Comment P-1: *Eliminate blind performance testing.* Two commenters requested that the NRC eliminate the blind performance test sample (BPTS) requirements in 10 CFR 26.168 or permit industry plants to share results and thus reduce the costs of the program. The commenters stated that the DOT had discontinued the blind specimen submissions ("Procedures for Transportation Workplace Drug and Alcohol Testing Programs: Addition of Certain Schedule II Drugs to the Department of Transportation's Drug-Testing Panel and Certain Minor Amendments," 82 FR 52229; November 13, 2017) for its regulated entities under 49 CFR Part 40 and because of the rigorous HHS oversight of the laboratories. (JR12-1, NEI1-CL2, NEI1-A1-21)

NRC Response: The NRC disagrees. The NRC did not propose to eliminate the BPTS requirements in 10 CFR 26.168 or to permit FFD programs of multiple licensees or other entities to share results. Therefore, this comment is outside the scope of this rulemaking. Further, the NRC disagrees with eliminating the BPTS requirements for the following reasons:

1) The reporting of events under 10 CFR 26.719, "Reporting requirements," demonstrates almost every year that HHS-certified laboratories do not always perform satisfactorily. In most cases, these performance deficiencies were only identified because of the BPTS program.

2) The Part 26 drug testing program is different than what the National Laboratory Certification Program (NLCP) evaluates under the HHS-certified laboratory biannual inspection process and performance testing program. For example, the special analyses testing process in 10 CFR 26.163(a)(2) is not a part of the HHS Guidelines or the DOT testing requirements. Part 26 also permits, and some licensee FFD programs utilize, lower testing cutoff levels than required by 10 CFR Part 26, expansion of the testing panel to include additional substances beyond the minimum panel in 10 CFR Part 26, or both. In each instance, no analogous BPTS measures provided by the NLCP performance testing process would validate the accuracy of testing conducted by HHS-certified laboratories under 10 CFR Part 26.

3) The BPTS requirements in 10 CFR 26.168 ensure that each HHS-certified laboratory used by a licensee or other entity performs testing in compliance with 10 CFR Part 26 drug and validity testing requirements, which maintains assurance of the accuracy of tests performed. Accurate testing of specimens is a fundamental aspect of each FFD program and is a critical donor protection. The assurance to the accuracy of test results is also of paramount importance to the NRC given the required minimum sanctions in 10 CFR 26.75 that apply to individuals based on a first, second, or third positive drug test result, as well as a subversion attempt.

4) Part 26 licensees and other entities rely upon a small number of HHS-certified laboratories. As such, an unsatisfactory test result at one laboratory can have a direct impact on a significant number of testing programs. In addition, beyond the small number of laboratories used, many

multi-site utilities use the same HHS-certified laboratory(ies) for their fleet and as a result, unsatisfactory performance at one laboratory could have a direct impact on the testing program for the entire utility's fleet.

5) While the DOT eliminated the blind performance testing requirements for its regulated entities, the HHS Guidelines continue to maintain the requirement (i.e., 2008 and 2017 HHS Guidelines, Subpart J, "Blind Samples Submitted by an Agency").

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

Q. Determining a Fitness-for-Duty Policy Violation

The following comments pertain to 10 CFR 26.185, "Determining a fitness-for-duty policy violation."

Comment Q-1: *MRO evaluation of invalid results.* One commenter requested that the proposed rule change in 10 CFR 26.185(f)(3) to require MRO review of invalid specimen test results due to pH in the range of 9.0 to 9.5 be deleted unless the process is required by other Federal programs. (NEI1-A1-20)

NRC Response: The NRC disagrees. As discussed in the proposed rule, the review of invalid specimens due to pH in the range of 9.0 to 9.5 is based on scientific evidence that elapsed time, exposure to high temperature, or both, can cause a urine specimen pH in this range. This additional MRO review is necessary to ensure that an individual is not unjustifiably subjected to the collection of a second specimen under direct observation. This MRO review is required by the HHS Guidelines that apply to Federal employee workplace drug testing programs, as well as the DOT's testing requirements in 49 CFR 40.159(a)(6).

However, the required MRO review in 10 CFR 26.185(f)(3) would not be applicable if the licensee or other entity's chosen specimen for observed collections for invalid specimens is oral fluid, as is being permitted in the final rule (see the NRC Response to Comment B-5.1). An MRO evaluation of the handing conditions for the initial urine specimen collected would be unnecessary in this instance because the oral fluid specimen would be observed by the collector.

Accordingly, the NRC did not change 10 CFR Part 26 in response to this comment.

R. Substance Abuse Expert

The following comments pertain to 10 CFR 26.187, "Substance abuse expert."

Comment R-1: *Substance abuse expert qualifications.* One commenter requested an update to the requirements in 10 CFR 26.187 pertaining to substance abuse expert (SAE) qualifications. The commenter recommended that a master's degree in addictions be added as a credential to be qualified to serve as an SAE under 10 CFR Part 26. (JR10-1)

NRC Response: The NRC disagrees. The request to amend the SAE qualification requirements in 10 CFR 26.187 to add a master's degree in addictions as an acceptable

credential to be qualified to serve as an SAE, is beyond the scope of this rulemaking. The NRC did not propose any changes to the SAE qualifications in 10 CFR Part 26. However, the change recommended by the commenter could inform future considerations by the NRC.

Accordingly, the NRC did not change 10 CFR Part 26 in response to this comment.

S. Determination of Fitness

The following comments pertain to 10 CFR 26.189, "Determination of fitness."

Comment S-1: *Conditions for initiating a determination of fitness.* One commenter expressed concern that a determination of fitness (DOF) is often initiated based on observed behavior, but the regulations do not currently define what manner of observed behavior constitutes an evaluation. The commenter suggested that DOFs are being performed in response to reports of observed behaviors such as looking at another worker in an odd manner. The commenter recommended revising the regulations to clarify the role of the FFD program management in obtaining relevant information that will contribute to a formal referral for a DOF. Specifically, describe FFD management responsibility on a preliminary assessment for conducting interviews, ruling out the possibility that drug use may have played a role in the behavior by conducting FFD testing, reviewing past behavior observations, and reviewing past self reports. (JR11-1)

NRC Response: The commenter's request to revise the determination of fitness requirements in 10 CFR 26.189 is outside the scope of this rulemaking. The NRC did not propose changes to, nor request comment on, the determination of fitness requirements. However, the change recommended by the commenter could inform future considerations by the NRC.

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

T. Other Comments

Comment T-1: *Marijuana legalization.* One commenter advocated for the rescheduling of marijuana for legal use. (BC-1)

NRC Response: The action requested by the commenter is outside the regulatory authority of the NRC. The U.S. Drug Enforcement Administration is responsible for the scheduling and rescheduling of drugs under 21 U.S.C. 812, "Schedules of controlled substances."

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

Comment T-2: *U.S. Department of Transportation regulations.* One commenter provided information on a legal action that was taken with regards to the results of a drug test performed under the DOT's 49 CFR Part 40 requirements. This legal action did not involve an NRC regulated entity. (MB-1)

NRC Response: This comment is about testing performed under the authority of another Federal agency. As such, this comment is not responsive to this 10 CFR Part 26 rulemaking.

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

U. Draft Regulatory Guide

In Section XV of the Supplementary Information for the proposed rule, the NRC solicited stakeholder comment on new draft regulatory guidance, DG-5040 dated August 2019 (ADAMS Accession No. ML19116A077), to support the implementation of the proposed requirements. In the final rule, DG-5040 is now RG 5.89, "Fitness-for-Duty Programs for Commercial Power Reactors and Category I Special Nuclear Material Licensees" (ADAMS Accession No. ML20143A034). The title of DG-5040 was revised to more uniformly align with the other applicable regulatory guide issued under 10 CFR Part 26, RG 5.84, "Fitness-For-Duty Programs at Nuclear Reactor Construction Sites."

U-1 Monitoring a donor during the hydration process

Comment U-1.1: One commenter stated that there is no benefit or useful purpose in entering the name of the hydration monitor on the CCF as described in Section C.1.A.(7) of DG-5040. (NEI1-A2-1)

NRC Response: The NRC disagrees. Listing the name of the observer of the hydration process on the Federal CCF is a donor protection and ensures to the transparency of the process. Capturing the name of the observer on the Federal CCF alerts the MRO and FFD program manager that a donor was observed by an individual other than the collector that initiated the collection process. The hydration monitor's name is also important information that an NRC inspector might evaluate during an FFD program inspection. In addition, because proposed 10 CFR 26.107(b)(2) would require the hydration monitor to "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)," the observations and statements made by a hydration monitor could form the basis for a subversion attempt determination, the sanction of which is a permanent denial of authorization under 10 CFR 26.75(b). Therefore, it is appropriate to require the name of the hydration monitor to be written on the Federal CCF, as required in proposed rule 10 CFR 26.109(b)(1)(ii) and described in Section C.1.A.(7) of DG-5040.

Accordingly, the NRC did not change the final rule or RG 5.89 in response to this comment.

See also NRC Response to Comment K-2 for additional discussion on 10 CFR 26.109(b)(1)(ii).

Comment U-1.2: One commenter stated that "synchronizing clocks" during the hydration process "is difficult to manage and is an un-necessary administrative burden." This comment pertained to Section C.1.A.(7) of DG-5040. The commenter recommended revising the guidance to read: "(7) The area used for hydration should have a working clock visible to the donor(s) and the collector or hydration monitor. The collector is ultimately responsible for monitoring the clock." (NEI1 A2-2)

NRC Response: The NRC agrees that it is unnecessarily prescriptive to state that "the clock that is used should be synchronized with the clock that the collector uses to document the start of the 3-hour hydration process." The intent of Section C.1.A.(7) of DG-5040 is to ensure that

an accurate method is used to track the amount of time that a donor is afforded to provide a specimen during the hydration process, which is a donor protection. For example, the collector could use a countdown timer that is initiated upon the first unsuccessful attempt to provide a specimen and that same timer be used during the hydration process. Because the inability to provide a specimen of adequate volume within 3 hours of the initial unsuccessful attempt may result in a permanent denial of authorization sanction under 10 CFR 26.75(b), the time tracking method must be accurate.

Accordingly, the NRC revised the guidance document to specify that the licensee or other entity should use a method that ensures that the 3-hour hydration period is accurately tracked and that the donor and hydration monitor or collector observing the hydration process understand the amount of time remaining in the hydration period.

The NRC did not change the final rule in response to this comment.

Comment U-1.3: One commenter stated that "[t]hroughout the guidance an excessive amount of information is required to be documented on the CCF. There is not adequate room on the CCF to document such information. Most licensees have internal documentation processes for documenting this information." To address this concern, the commenter suggested that the text in Section C.1.B.(3) of DG-5040 be revised to: "(3) If during the hydration process, the collector or hydration monitor observes any action or behavior by the donor that may indicate an attempt to subvert the testing process, a description of the donor's conduct should be immediately documented. If a hydration monitor observes the donor conduct, the hydration monitor shall then inform the collector of the observation. The hydration monitor should communicate this information to the collector while maintaining continuous monitoring of the donor." (NEI1-A2-3)

NRC Response: The NRC agrees that the available space on the Federal CCF to document information about a possible subversion attempt 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 an event, the Federal CCF may not contain adequate space to record all information.

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, which is also an existing rule requirement in 10 CFR 26.107(b)(1). Instead, the NRC has revised 10 CFR 26.107(b)(1) in the final rule and Section C.1.B.(3) in RG 5.89 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). Conforming changes have been made in the final rule to 10 CFR 26.107(d)(3) and 26.111(b), which also require the collector to document observations on the Federal CCF, and to RG 5.89.

Comment U-1.4: One commenter requested that the guidance in Section C.1.D.(3) of DG-5040 be revised to: "(3) If the hydration monitor is not qualified as a collector, the donor shall be transferred to an available collector when the donor is ready to attempt to provide a specimen."

This change would clarify that the collector also needs to be available to start the collection process with the donor. (NEI1-A2-4)

NRC Response: The NRC agrees.

Accordingly, the NRC has replaced the phrase "the donor shall be transferred to a collector" with "then the donor shall be transferred to an available collector" in Section C.1.D.(3) of RG 5.89 in response to this comment.

The NRC did not change the final rule in response to this comment.

U-2 Using mirrors during specimen collections under direct observation

Comment U-2: One commenter stated that permanently affixed mirrors create a perception that could compromise privacy for non-observed tests and suggested that portable mirrors be permitted to facilitate the use of temporary collection facilities. The commenter requested that the NRC permit the use of mirrors that are not secured to a wall or structure. (NEI1-A2-5)

NRC Response: The NRC disagrees. The text in Section C.2.D of DG-5040 stated that "all mirrors should be sufficiently affixed or secured to a wall or structure," but did not require any mirror to be "permanently affixed." Therefore, a mirror could be installed only when needed to effectively implement a directly observed collection, which addresses the commenter's concern regarding donor privacy for non-observed collections.

The use of non-secured mirror(s) during the observed collection process could result in injury, as stated in the draft guidance, but also could result in an observer coming into an unacceptably close proximity to the donor during the collection process or result in an unintentional contact with the donor (e.g., use of a hand-held mirror). Permitting the use of a non-secured mirror during the collection process also could increase the level of anxiety of the donor and interfere with the provision of a specimen, which is contrary to the intent of the provision.

Accordingly, the NRC did not change the final rule or RG 5.89 in response to this comment.

U-3 MRO consideration of factors influencing invalid test results

Comment U-3: One commenter requested that the NRC eliminate Section C.3 of DG-5040, which provided guidance on implementing the proposed new requirement in 10 CFR 26.185(f)(3). This new requirement would have the MRO consider the impacts of time and temperature when evaluating an invalid test result due to pH in the range of 9.0 to 9.5. The commenter asserted that NRC's proposed guidance is unnecessary because of the technical instruction that MROs receive during certification and requalification training. On the other hand, the commenter had no issue with keeping the proposed guidance if it is being used by other Federal programs. (NEI1-A2-6)

NRC Response: The NRC disagrees. The guidance on the MRO review of invalid test results due to pH in the range of 9.0 to 9.5 is provided in Section C.3 of DG-5040 as one acceptable method for the consistent review of these test results by MROs.

Contrary to the commenter's statement, 10 CFR Part 26 does not include a periodic MRO requalification training requirement. Section 26.183(a) does require that an "MRO shall be knowledgeable of this part and of the FFD policies of the licensees and other entities for whom the MRO provides services [and that t]he MRO shall have passed an examination administered by a nationally-recognized MRO certification board or subspecialty board for medical practitioners in the field of medical review of Federally mandated drug tests." Therefore, if an MRO has already passed an examination by a nationally-recognized MRO certification board or subspecialty board before or soon after this 10 CFR Part 26 final rule is published, it is possible that no training on the new invalid test result review requirement would be received.

Accordingly, the NRC did not change the final rule or RG 5.89 in response to this comment.

V. Draft Regulatory Analysis

The NRC received no public comments on the draft regulatory analysis, "Draft Regulatory Analysis and Backfitting and Issue Finality, 10 CFR Part 26 Fitness for Duty Drug Testing Requirements" (ADAMS Accession No. ML19169A115), which examines the costs and benefits of the alternatives considered by the NRC.

W. Information Collections

The NRC requested public comment on the potential impact of the information collections contained in the proposed rule ("Supporting Statement for 10 CFR Part 26, Fitness for Duty Programs, Information Collections Contained in Fitness For Duty Drug Testing Requirements Proposed Rule" (ADAMS Accession No. ML16123A003). The NRC received no public comments in response to this request.

X. Backfitting and Issue Finality

The NRC received no public comments on backfitting or issue finality.

Y. Cumulative Effects of Regulation

The NRC requested public comment on the potential cumulative effects of regulation implications incurred by licenses and other entities due to the proposed rule. The NRC received no public comments in response to this request. (See the NRC Response to Comment B-4.1 regarding the related NRC request for public comment on the "Effective Date of the Final Rule.")