Backfitting and Issue Finality Assessment for the 10 CFR Part 26 Fitness for Duty Drug Testing Requirements Final Rule

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I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is amending Part 26 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Fitness for Duty Programs," to more closely align the drug testing requirements with the U.S. Department of Health and Human Services' (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (HHS Guidelines). The amendments require nuclear power plant licensees, Category I special nuclear material licensees, and contractors/vendors subject to the requirements of 10 CFR Part 26 to update existing fitness for duty (FFD) program policies and procedures, conduct training, revise contracts with HHS-certified laboratories and blind performance test sample providers, perform mandatory special analyses testing on some specimens, and modify the drug testing panel. The final rule constitutes new or amended provisions in the Commission's regulations that result in licensees modifying the procedures required to operate a facility. Therefore, it meets the definition of "backfitting" in 10 CFR 50.109(a)(1) and 10 CFR 70.76(a)(1) and affects the issue finality of combined license holders under 10 CFR 52.98, "Finality of combined licenses; information requests." This backfitting and issue finality assessment examines the aggregation of the subset of the final rule's requirements that constitute backfits, which are identified in Section III.B. of this document.[1] The backfit analysis in this assessment concludes that the changes in the final rule will result in a substantial increase in the overall protection of public health and safety or the common defense and security and that the costs of implementing these changes are justified in view of this increase in protection. Moreover, because the final rule is supported by a backfit analysis under 10 CFR 50.109, "Backfitting," the final rule meets the issue finality criteria in 10 CFR 52.98(a).

II. Background

The NRC relies on the HHS Guidelines as the technical basis for establishing and updating the FFD program requirements in 10 CFR Part 26. The NRC has deviated from the HHS Guidelines only for considerations specific to the nuclear industry. Updates to the HHS Guidelines were published in the *Federal Register* on November 25, 2008 (73 FR 71858) (2008 HHS Guidelines), and on January 23, 2017 (82 FR 7920) (2017 HHS Guidelines). The final rule harmonizes select drug testing requirements in 10 CFR Part 26 with the 2008 and 2017 HHS Guidelines and reflects lessons learned from implementing the 2008 10 CFR Part 26 final rule ("Fitness for Duty Programs; Final Rule" (73 FR 16966; March 31, 2008)).

By aligning many of the NRC regulations with the HHS Guidelines, the final rule enhances the detection of individuals who are not fit for duty because of illegal drug use, legal drug misuse, or an attempt to subvert the drug testing process. This enables the NRC to maintain the FFD program performance objectives in 10 CFR 26.23(c), to "provide reasonable measures for the early detection of individuals who are not fit to perform the duties that require them to be subject to the FFD program," and in 10 CFR 26.23(d), to "provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs." The final rule enhances the ability of licensees to identify individuals seeking employment in or already working in the commercial nuclear workforce who are using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. Furthermore, the changes could deter

[1] The majority of the requirements constituting backfits achieve two of the three rule objectives, as presented in Table 5-19, "Disaggregation," in the regulatory analysis. As a result, disaggregation of the costs and benefits according to the rulemaking objectives does not have meaningful implications for the cost-benefit results.

additional individuals using drugs from seeking employment in workplaces covered by 10 CFR Part 26 and could either deter existing employees from beginning to use drugs or encourage them to cease undetected use or seek medical assistance to address an addiction or misuse issue, or both.

By maintaining reasonable assurance of a drug-free workplace by strengthening the ability of licensees to detect individuals who are not fit for duty because of illegal drug use, legal drug misuse, or an attempt to subvert the drug testing process, the final rule enhances licensees' FFD authorization and access authorization programs. Granting or maintaining access authorization under 10 CFR Part 73, "Physical Protection of Plants and Materials," is contingent on an individual meeting the FFD authorization requirements in 10 CFR Part 26, which, in part, mandate that the individual have negative test results for drugs. An individual who uses an illegal drug or misuses a legal drug represents a safety vulnerability because drug-induced impairment may cause or contribute to human performance errors that may result in unplanned occupational exposure; personal safety issues; unplanned radiological releases; or improper operation, maintenance, or surveillance of safety- or security-related structures, systems, and components (SSCs). Additionally, granting or maintaining unescorted access authorization for these individuals presents a security vulnerability because the use of illegal drugs, misuse of legal drugs, and subversion of the 10 CFR Part 26 drug testing program are indicators that an individual is not trustworthy and reliable. An individual exhibiting one or more of these characteristics cannot be granted unescorted access authorization (either physically or electronically) because it would challenge the defense in depth afforded by the access authorization requirements in 10 CFR Part 26 and 10 CFR Part 73.

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

The final rule applies to all current nuclear power plant licensees (i.e., holders of operating licenses under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," renewed licenses under 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants," and combined licenses under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants") and holders of licenses authorizing the possession, use, or transport of formula quantities of strategic special nuclear material under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." The final rule also applies to holders of a certificate of compliance or an approved compliance plan under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants," if the holder engages in activities involving formula quantities of strategic special nuclear material. Some or all of the final rule would apply to (1) current and future applicants for combined licenses under 10 CFR Part 52 that have been issued a limited work authorization (LWA) under 10 CFR 50.10(e), if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA; (2) combined license holders before the Commission has made the finding under 10 CFR 52.103(g); (3) construction permit applicants under 10 CFR Part 50 that have been issued an LWA, if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA; (4) construction permit holders, and (5) early site permit holders that have been

issued an LWA, if the LWA authorizes the early site permit holder to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA. The final rule also applies to contractor/vendors who implement FFD programs or program elements, to the extent that the licensees and other entities described in this paragraph rely on those contractor/vendor FFD programs or program elements to meet the requirements of this 10 CFR Part 26.

III. Backfitting

A. Applicable Entities

The final rule constitutes backfitting as defined under 10 CFR 50.109(a)(1) for holders of 10 CFR Part 50 operating licenses and construction permits and 10 CFR Part 54 renewed licenses, and under 10 CFR 70.76(a)(1) for applicable 10 CFR Part 70 licensees, as of the final rule's effective date. The final rule also affects the issue finality accorded to holders of a combined license under 10 CFR Part 52 as of the final rule's effective date.

The final rule is not backfitting for applicants for construction permits or operating licenses under 10 CFR Part 50 or 10 CFR Part 70 licenses and does not affect issue finality of applicants for early site permits or combined licenses under 10 CFR Part 52. These applicants are not, with certain exceptions not applicable here, within the scope of the backfitting or issue finality provisions. The backfitting and issue finality regulations include language delineating when the backfitting and issue finality provisions begin; with some exceptions, they begin after the issuance of a license, permit, or other approval (e.g., 10 CFR 50.109(a)(1)(iii), 10 CFR 52.98(a)). Furthermore, neither the backfitting provisions nor the issue finality provisions, with certain exceptions not applicable here, are intended to apply to NRC actions that substantially change the expectations of current and future applicants. Applicants cannot reasonably expect that future requirements will not change.

The provisions under 10 CFR Part 26 also apply to applicants for construction permits, early site permits, or combined licenses that have been issued an LWA if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA. However, as of the final rule's effective date, no applicant for a construction permit, early site permit, or combined license holds an LWA, so no such entity is within the scope of a backfitting or issue finality provision. Similarly, no entity holds a certificate of compliance or an approved compliance plan under the provisions of 10 CFR Part 76, so no entity is within the scope of the backfitting provisions of 10 CFR 76.76, "Backfitting."

B. Description of Backfits

The final rule consists of nine categories of amendments to the NRC's regulations. These amendments will result in modifications to the procedures required to operate a facility. Thus, they meet the definition of "backfitting" under 10 CFR 50.109(a)(1) and 10 CFR 70.76(a)(1) or affect the issue finality of a holder of a combined license under 10 CFR Part 52.

1. Lower initial and confirmatory testing cutoff levels for amphetamines and cocaine metabolites.

The final rule updates the cutoff levels for initial testing, listed in 10 CFR 26.133, "Cutoff levels for drugs and drug metabolites," and 10 CFR 26.163(a)(1), and confirmatory testing, listed in 10 CFR 26.163(b)(1), to conform with changes to the 2008 HHS Guidelines. The final rule does the following:

- lowers the initial drug testing cutoff level for amphetamines from 1,000 nanograms (ng) per milliliter (mL) to 500 ng/mL
- lowers the confirmatory drug testing cutoff levels for amphetamine and methamphetamine from 500 ng/mL to 250 ng/mL
- lowers the initial drug testing cutoff level for cocaine metabolites from 300 ng/mL to 150 ng/mL
- lowers the confirmatory drug testing cutoff level for cocaine metabolite from 150 ng/mL to 100 ng/mL

2. Expand initial drug testing panel to include heroin metabolite 6-acetylmorphine (6-AM) and revise confirmatory testing cutoff level for 6-AM.

The final rule requires each urine specimen to be tested for 6-AM. The NRC revised the drug testing panel in 10 CFR 26.133 and 10 CFR 26.163(a) to include initial testing for 6-AM at a cutoff level of 10 ng/mL. The final rule also removes the requirement that confirmatory testing of 6-AM only proceed when confirmatory testing shows a morphine concentration exceeding 2,000 ng/mL (i.e., if initial testing for 6-AM is positive, confirmatory testing for 6-AM is to proceed independent of the morphine concentration).

3. Expand initial and confirmatory drug testing panels to include Ecstasy-type drugs.

The final rule requires each urine specimen to be tested for Ecstasy-type drugs. The NRC revised the list of substances for which each urine specimen is tested in 10 CFR 26.133 and 10 CFR 26.163(a) to include initial testing for methylenedioxymethamphetamine (MDMA) and methylenedioxyamphetamine (MDA), identified in the final rule as Ecstasy-type drugs, at a cutoff level of 500 ng/mL. The final rule also amends 10 CFR 26.163(b) to include confirmatory testing for MDMA and MDA at a confirmatory test cutoff level of 250 ng/mL. The NRC made conforming changes to add MDMA and MDA to the annual statistical summary reporting requirements for HHS-certified laboratories in 10 CFR 26.169(h)(3).

4. Expand initial and confirmatory opioid testing panel to include hydrocodone, hydromorphone, oxycodone, and oxymorphone.

The final rule requires each urine specimen to be tested for four opioids: hydrocodone, hydromorphone, oxycodone, and oxymorphone. The NRC revised the list of substances for

which each urine specimen is tested in 10 CFR 26.133 and 10 CFR 26.163(a) to include initial testing for hydrocodone and hydromorphone at a cutoff level of 300 ng/mL and oxycodone and oxymorphone at a cutoff level of 100 ng/mL. The final rule also amends 10 CFR 26.163(b) to include confirmatory testing for hydrocodone, hydromorphone, oxycodone, and oxymorphone at a confirmatory test cutoff level of 100 ng/mL. In 10 CFR 26.169(h)(3), the NRC made conforming changes to add hydrocodone, hydromorphone, oxycodone, and oxymorphone to the annual statistical summary reporting requirements for HHS-certified laboratories.

5. Require special analyses testing of dilute specimens and specimens collected during suspected subversion attempts.

The final rule requires mandatory special analyses testing of specimens involving subversion attempts and dilute specimens with an immunoassay response that is equal to or greater than 40 percent of the cutoff calibrator in a drug class. This change to 10 CFR 26.163(a)(2) increases the number of specimens that are subject to confirmatory testing and thereby improves the ability of licensees to identify instances in which individuals may be attempting to subvert the testing process.

6. Require the use of the limit of quantitation (LOQ) instead of the limit of detection (LOD) as the decision point for special analyses testing and adulterant testing of specimens.

The final rule requires the use of the LOQ instead of the LOD as the level at which special analyses testing and adulterant testing would be performed. The difference between the LOD and the LOQ for a testing assay is the ability to reliably quantify the analyte (e.g., drug, adulterant). At the LOD, the test must meet all HHS-certified laboratory criteria for result acceptance except quantitation. At the LOQ, the test must reliably confirm the presence of the analyte, reliably quantify the concentration of the analyte, and meet all HHS-certified laboratory criteria for result acceptance. Use of the LOQ provides additional donor protection with regard to the accuracy of special analyses and adulterant test results.

7. Require additional MRO review for specimens with invalid validity test results due to high pH values (9.0 to 9.5) and MRO actions when a donor requests testing a Bottle B specimen or retesting an aliquot of a single specimen.

The final rule requires additional actions by the MRO in three circumstances. First, under 10 CFR 26.185(f)(3), the MRO must consider whether elapsed time or high temperature, or both, could have caused an invalid validity test result due to high pH (9.0 to 9.5). Second, if a donor makes an oral request to the MRO for the testing of the Bottle B specimen or a retest of an aliquot of a single specimen, then, under 10 CFR 26.165(b)(2), the MRO must document the date and time that the request was received from the donor. In practice, MROs had been performing this action already, but the former rule did not specify the documentation requirement. Third, if a donor requests testing of Bottle B or retesting a single specimen, and the specimen to be tested is unavailable because of circumstances outside of the donor's control, then, under 10 CFR 26.165(f)(2), the MRO must report a cancelled test to the licensee for the donor's specimen and order a second collection without prior notice to the donor.

8. Require the testing of any specimen(s) collected during post-event testing when a refusal to test has been determined during the collection process.

The final rule requires, in 10 CFR 26.107(d)(5), the testing of any specimen collected during a post-event testing situation, even if a refusal to test has been determined during the collection process. Previously, any specimen collected could be discarded. In an effort to improve the root-cause evaluation process associated with accidents, the NRC is requiring testing of any collected urine specimen to ensure that all available information is obtained to support the evaluation of human performance associated with the accident.

9. Implement the drug testing program changes.

As a result of the above changes to 10 CFR Part 26, licensees will need to make several one-time changes to their FFD program policies and procedures, conduct training, and revise contracts with HHS-certified laboratories and blind performance test sample providers.

IV. Basis for Not Performing a Documented Evaluation

The NRC determined that the final rule's amendments to 10 CFR Part 26 are not necessary to ensure that the subject facilities provide adequate protection to the public health and safety and are in accord with the common defense and security, define or redefine the level of protection to the public health and safety or the common defense and security deemed to be adequate, or bring a facility into compliance with a license or the rules or orders of the Commission or into conformance with written commitments by the licensee. The current requirements in 10 CFR Part 26 do not present a condition of undue risk to public health and safety, and the final rule is not necessary to address a compliance issue. Therefore, the final rule does not involve the adequate protection or the compliance exceptions to the requirement in 10 CFR 50.109(a)(2)–(3) to justify the backfits with a backfit analysis.

V. Benefits

As explained in the regulatory analysis supporting the final rule (Agencywide Documents Access and Management System Accession No. ML22133A044), the NRC identified quantitative and qualitative benefits of the final rule. The final rule is estimated to result in a 16- to 29-percent increase in the number of individuals identified each year using illegal drugs, misusing legal drugs, or attempting to subvert the testing process and who would be determined not to be fit for duty or not trustworthy and reliable, or both, as compared to the average number of individuals with a positive test result or identified as attempting to subvert a test for calendar year (CY) 2009 through CY 2019. The 16- to 29-percent increase equates to an average of approximately 180 individuals each year.

Between 2009 and 2019, pre-access testing accounted for (on average) 67 percent of positive test results each year. The 16- to 29-percent increase in additional positive test results or identified subversion attempts each year means that an average of approximately 120 individuals per year will test positive or be identified as attempting to subvert a test before receiving unescorted access authorization and completion of training, thereby saving licensees and other entities approximately $4.3 million in averted training costs using a 7-percent discount rate (approximately $6.5 million using a 3-percent discount rate) over a 24-year period, as

shown in Table 5-3, “Summary of One-Time and Annual Benefits and Costs to Industry, by Regulatory Initiative,” in the regulatory analysis.

The NRC also identified and qualitatively analyzed several factors, or attributes, within the public and private sectors that the final rule is expected to affect. The NRC conducted a qualitative analysis because of the difficulties associated with monetizing these affected attributes and the full benefit to industry operations that results from the detection each year of additional individuals using illegal drugs, misusing legal drugs, or subverting the testing process. The NRC determined that the final rule will result in qualitative benefits in the attributes of public health (accident), occupational health (accident), offsite property, onsite property, regulatory efficiency, safeguards and security considerations, and other considerations, which include public perception, public trust, workplace productivity, workplace safety, and improved protection of individual rights.

The final rule also benefits public health and safety or the common defense and security in the following ways:

- *expanding the drug testing panel and lowering the testing cutoff levels for select drugs*

  Lowering the testing cutoff levels for amphetamine, cocaine metabolites, and methamphetamine increases the timeframe in which these drugs can be detected in an individual’s body after use (i.e., the window of detection). Increasing the window of detection reduces the likelihood that individuals could subvert the testing process through temporary abstinence from a drug. Adding 6-AM to the initial drug testing panel and revising the confirmatory testing cutoff together improves the testing method to identify use of the illegal drug heroin. Expanding the initial and confirmatory testing panels to include hydrocodone, hydromorphone, MDMA, MDA, oxycodone, and oxymorphone also improves the ability of licensees and other entities to identify additional persons using illegal drugs or misusing legal drugs. These changes improve the trustworthiness and reliability of the workforce through the identification of additional individuals who will be denied unescorted access authorization.

- *requiring and expanding special analyses testing*

  Requiring special analyses testing on dilute specimens and expanding special analyses testing to include specimens collected during suspected subversion attempts reduce the likelihood that individuals would be able to subvert the testing process. Additionally, using the LOQ instead of the LOD as the level at which confirmatory drug testing is to be conducted increases the assurance provided by special analyses testing by adding a level of precision to the testing method. These changes further enhance the ability of licensees and other entities to identify additional individuals using illegal drugs and misusing legal drugs when specimens do not present normal physiological characteristics, as well as enhance donor protections when special analyses testing is conducted. These changes improve the trustworthiness and reliability of the workforce through the identification of individuals using illicit drugs who will be denied unescorted access authorization.

- *enhancing FFD program integrity and protection of individual rights*

  By adding MRO review procedures for invalid validity test results due to high pH values and clarifying the requirements for MRO actions when a donor requests the testing of a

Bottle B specimen or a retest of a single specimen, the final rule enhances consistency with the 2008 HHS Guidelines, FFD program integrity, and the protection of individual rights.

- *improving regulatory efficiency between 10 CFR Part 26 and other related Federal rules and guidelines*

  The final rule improves regulatory efficiency by (1) harmonizing select 10 CFR Part 26 definitions and drug testing procedures with those described in the HHS Guidelines; (2) clarifying ambiguous or imprecise regulatory language in 10 CFR Part 26, such as the terminology related to quality control samples, to reflect lessons learned during implementation of the 2008 10 CFR Part 26 final rule; and (3) addressing dual regulation of HHS-certified laboratories (private entities) and the associated regulatory burden on licensees by removing select 10 CFR Part 26 requirements already included in the HHS Guidelines and verified through National Laboratory Certification Program inspections at each laboratory to receive and maintain HHS certification.

- *improving root-cause analysis by testing any specimen(s) collected during a post-event test when a refusal to test has been made at the collection site*

  Under the former rule, if a refusal to test were determined during the specimen collection process, any specimen(s) obtained from the donor could be discarded. The final rule requires the retention and testing of any specimens collected during post-event tests for which a refusal to test determination was made at the collection site. This change improves the ability of the licensee or other entity to determine whether substance use could have been a contributing factor to an accident.

Licensees and other entities may also recognize a variety of other benefits, such as those associated with the following types of activities:

- *permanent denial*

  If an individual is identified as having subverted the testing process, the individual will be permanently denied access under 10 CFR 26.75(b). As a result, the entire industry benefits from no longer incurring the potential risk of this individual working at any sites or any of the associated costs.

- *second chance policy and follow-up testing*

  Although they typically do not do so for contractor/vendor workers, licensees may provide a second chance to their employees who test positive for a drug. As a result, individuals who successfully received treatment and return to the workforce will be subject to a 10 CFR Part 26 follow-up testing program. If pre-access testing detects drug use by the individual, then the cost of conducting follow-up testing on an individual would be averted.

VI. Costs

The NRC quantified the cost of six sets of backfits in the final rule, as shown in Table 1. This information is based on Table 5-3 in the regulatory analysis for the final rule. The other backfits

are expected to result in no costs or negligible costs, as explained below, and are not included in Table 1:

- Requiring the use of the LOQ instead of the LOD entails minor procedural changes with negligible incremental costs.

- Requiring additional MRO review for specimens with invalid validity test results due to high pH values will result in some incremental effort on the part of the MRO (e.g., on the order of an hour per occurrence to review specimen handling conditions), but the cost will be incurred infrequently because an invalid specimen test result is a rare event. Therefore, the total cost of the change will be small.

- Requiring the MRO to document the time and date of a donor's request for testing a Bottle B specimen or retesting an aliquot of a single specimen will have negligible implementation costs.

- Requiring the MRO to report a cancelled test for the donor's specimen and order a second collection without prior notice to the donor, when a donor requests testing of Bottle B or a retest of a single specimen and the specimen to be tested is unavailable because of circumstances outside of the donor's control, will have negligible implementation costs because this situation rarely occurs.

- Requiring the testing of any specimen(s) collected during post-event testing when a refusal to test has been determined during the collection process will have negligible incremental costs because post-event testing situations are rare, and an event in which a donor provides a specimen and then refuses to cooperate with the collector after providing the specimen is even rarer.

Table 1 Quantitative Costs of the Final Rule's Backfits

Regulatory Initiative	7% Net Present Value	3% Net Present Value
Implement one-time drug testing program changes	($136,936)	($136,936)
Lower cutoff levels for amphetamine, cocaine, and methamphetamine	($185,898)	($277,775)
Expand testing panel to include initial testing of 6-AM (and revise confirmatory testing cutoff level)	($935,375)	($1,397,666)
Expand initial and confirmatory testing panel to include Ecstasy-type drugs	($702,980)	($1,050,415)

Regulatory Initiative	7% Net Present Value	3% Net Present Value
Expand initial and confirmatory testing panel to include oxycodone, oxymorphone, hydrocodone, and hydromorphone	($1,829,243)	($2,733,312)
Require special analyses testing of dilute specimens and specimens collected under direct observation	($109,322)	($163,353)
TOTALS	($3,899,754)	($5,759,457)

VII. Cost-Justification Determination

The NRC finds that the final rule provides a cost-justified substantial increase in overall protection to the public health and safety or the common defense and security. The determination that the final rule results in a substantial increase in overall protection is based on the following factors:

- The final rule is estimated to result in a 16- to 29-percent increase in the number of individuals identified each year using illegal drugs, misusing legal drugs, or attempting to subvert the testing process and who would be determined not to be fit for duty or not trustworthy and reliable, or both.

- The final rule is expected to result in approximately $4.3 million in averted training costs for licensees using a 7-percent discount rate (approximately $6.5 million using a 3-percent discount rate).

- Expanding the drug testing panel and lowering the testing cutoff levels for select drugs will reduce the likelihood that individuals will be able to subvert the testing process through temporary abstinence from a drug and will improve the ability of licensees and other entities to identify additional persons using illegal drugs.

- Requiring special analyses testing on dilute specimens and expanding special analyses testing to include specimens collected during suspected subversion attempts will reduce the likelihood that individuals will be able to subvert the testing process.

- Using the LOQ instead of the LOD as the level at which confirmatory drug testing is conducted will increase the assurance provided by special analyses testing by adding a level of precision to the testing method.

- The final rule enhances consistency with the HHS Guidelines, FFD program integrity, and the protection of individual rights.

- Requiring the testing of any specimen(s) collected during a post-event test when a refusal to test has been made at the collection site improves root-cause analysis.

With the costs of the backfits to industry expected to approximate ($3.9 million) using a 7-percent discount rate and ($5.8 million) using a 3-percent discount rate, the final rule's backfits are estimated to result in an incremental benefit to industry of approximately $0.4 million total present value over a 24-year period, assuming a 7-percent discount rate ($0.7 million total present value over a 24-year period, assuming a 3-percent discount rate). Therefore, given the substantial increase in overall protection and cost savings to the industry afforded by the final rule, the NRC concludes that the costs of implementing the final rule's backfits are justified given the substantial increase in overall protection to the public health and safety or the common defense and security attributable to the final rule.

VIII. Consideration of Backfitting Factors

When imposing backfits, the Commission requires, under 10 CFR 50.109(a)(2) and 10 CFR 70.76(a)(2), consideration of the nine factors in 10 CFR 50.109(c)(1) through (9) and 10 CFR 70.76(b)(1) through (9), respectively.

1. Statement of the specific objectives that the backfits are designed to achieve.

The NRC amended certain provisions in 10 CFR Part 26 to (1) harmonize select drug testing requirements in 10 CFR Part 26 with the 2008 and 2017 HHS Guidelines and reflect lessons learned from implementation of the 2008 10 CFR Part 26 final rule; (2) maintain reasonable assurance of a drug-free workplace through the enhanced detection of individuals who are not fit for duty because of illegal drug use, legal drug misuse, or an attempt to subvert the drug testing process; and (3) enhance FFD program donor protection and due process requirements for individuals subject to drug testing.

2. General description of the activities required by the licensee to complete the backfits.

The backfits require licensees to update policies and procedures, conduct training, and revise contracts with laboratories and blind performance test sample suppliers to reflect the new drug testing criteria described in Sections III.B.1–III.B.4 of this document.

In addition, with regard to special analyses testing, licensees need to conduct mandatory LOQ testing of dilute specimens with an immunoassay response equal to or greater than 40 percent of the cutoff calibrator for each drug and for specimens collected during suspected subversion attempts, as described in Sections III.B.5–III.B.6 of this document.

Section III.B.7 of this document describes new requirements involving MRO reviews. Licensees need to require an updated MRO review process for invalid validity specimen test results. Specifically, if the donor does not provide an acceptable medical explanation to explain a pH in the range of 9.0 to 9.5, the MRO must consider whether elapsed time and high temperature might have caused the test result. In addition, if a donor requests testing of Bottle B or a retest of a single specimen, the MRO must document the donor's verbal request. If the specimen to be tested is unavailable because of circumstances outside of the donor's control, licensees need to require MROs to report a cancelled test to the licensee for the donor's specimen and order a second collection without prior notice to the donor.

The final rule requires the testing of any specimen collected during a post-event testing situation even if a refusal to test has been determined during the collection process, as described in Section III.B.8 of this document.

3. Potential change in the risk to the public from the accidental offsite release of radioactive material and, for 10 CFR Part 70 licensees, hazardous chemicals produced from licensed materials.

The final rule will not directly affect the likelihood of core damage or spent fuel damage. The final rule could reduce the risk that the public would be affected by an accidental offsite release of radioactive material and, for 10 CFR Part 70 licensees, hazardous chemicals produced from licensed materials, as a result of human performance issues associated with drug-induced impairment.

4. Potential impact on radiological exposure or, for 10 CFR Part 70 licensees, exposure of facility employees to hazardous chemicals produced from licensed material.

The final rule will not directly affect the likelihood of core damage or spent fuel damage. The final rule could reduce the risk that NRC-licensed facility employees could be affected by an occupational accident or a radiological exposure as a result of human performance issues associated with drug-induced impairment.

5. Installation and continuing costs associated with the backfits, including the cost of facility downtime or, for power reactor licensees, the cost of construction delay.

The NRC expects the estimated one-time industry cost associated with the backfits to be ($136,936) and the annually recurring cost to be approximately ($322,889). Combining these initial and annual costs, this analysis estimates that the backfits associated with the final rule will cost industry approximately ($3.8 million) (present value, assuming a 7-percent discount rate) to ($5.6 million) (present value, assuming a 3-percent discount rate) over a 24-year period.

6. The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements.

The final rule makes minor changes to drug testing operations that enhance safety and security by identifying additional individuals using drugs and then denying their unescorted access authorization. This will reduce the risk of accidents and security incidents as a result of human performance issues associated with drug-induced impairment.

7. The estimated resource burden on the NRC associated with the backfits and the availability of such resources.

The NRC is not expected to incur any incremental costs resulting from the final rule. The NRC costs to complete the final rule (i.e., analyze public comments, hold public meeting(s), and develop the final rule) and to issue regulatory guidance are sunk costs. The NRC expects

changes to the agency's FFD inspection program to be minor (e.g., minor revisions to internal NRC training or inspection procedures).

8. The potential impact of differences in facility type, design, or age on the relevancy and practicality of the backfits.

The FFD requirements in 10 CFR Part 26 do not relate to, and are independent of, the facility's type, design, or age. Therefore, the benefits and costs attributable to the final rule do not vary based upon the facility's type, design, or age.

9. Whether the backfits are interim or final and, if interim, the justification for imposing the backfits on an interim basis.

The backfits are final.

IX. Issue Finality Assessment

Under 10 CFR 52.98(a), the NRC may not modify any term or condition of a combined license except in accordance with the provisions of 10 CFR 52.103, "Operation under a combined license," or 10 CFR 50.109, as applicable. Section 52.103 is not applicable to this rulemaking, so the NRC must satisfy 10 CFR 50.109 to impose this final rule on holders of combined licenses.

X. Conclusion

In light of the direct benefit of improving the detection of individuals using illegal drugs, misusing legal drugs, or attempting to subvert the testing process; the savings to the industry through averted costs; and the efficiencies, flexibilities, and donor protections included in the final rule, the NRC finds that the backfits contained in the final rule, when considered in the aggregate, constitute a cost-justified, substantial increase in public health and safety or the common defense and security under 10 CFR 50.109 and 10 CFR 70.76, "Backfitting." Moreover, because the NRC determines that the final rule satisfies 10 CFR 50.109, the final rule meets the issue finality criteria in 10 CFR 52.98(a).