Draft Regulatory Analysis and Backfitting and Issue Finality

10 CFR Part 26
Fitness for Duty Drug Testing Requirements

[Docket ID NRC-2009-0225]

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

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Abbreviations and Acronyms

6-AM	6-acetylmorphine
ADAMS	Agencywide Documents Access and Management System
AMP	Amphetamine
BPTS	blind performance test sample
CFR	*Code of Federal Regulations*
CPI-U	Consumer Price Index for all urban consumers
CRGR	Committee to Review Generic Requirements
CSAP	Center for Substance Abuse and Prevention
C/V	contractor/vendor
CY	calendar year
D&A	drug and alcohol
dL	deciliter(s)
DOT	U.S. Department of Transportation
DSP	Division of Security Policy
FAA	Federal Aviation Administration
FFD	fitness for duty
FR	*Federal Register*
FRA	Federal Railroad Administration
FTA	Federal Transit Administration
FTE	full-time equivalent
HHS	U.S. Department of Health and Human Services
INPO	Institute of Nuclear Power Operations
LOD	limit of detection
LOQ	limit of quantitation
LTF	licensee testing facility
MAMP	Methamphetamine
MDA	Methylenedioxyamphetamine
MDMA	Methylenedioxymethamphetamine
mg	milligram(s)
mL	milliliter(s)
MRO	Medical Review Officer
NEI	Nuclear Energy Institute
ng	nanogram(s)
NLCP	National Laboratory Certification Program
NPV	net present value
NRC	U.S. Nuclear Regulatory Commission
NSIR	Office of Nuclear Security and Incident Response
OMB	Office of Management and Budget
OSHA	U.S. Occupational Safety and Health Administration
PERT	program evaluation and review technique
pH	a measure of the acidity or basicity of an aqueous solution
Ref.	Reference
SAMHSA	Substance Abuse and Mental Health Services Administration
SSC	structure, system, and component
SSNM	special strategic nuclear material
TVA	Tennessee Valley Authority

Abstract

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 26, "Fitness for Duty Programs," to more closely align the NRC's drug testing requirements with updates made to the U.S. Department of Health and Human Services (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (HHS Guidelines). The proposed rule would enhance the ability of licensees and other entities to identify additional individuals using drugs and would incorporate lessons learned from implementation of the 10 CFR Part 26 rule (published in 2008) to include enhanced methods in identifying attempts to subvert the drug testing process.

The requirements of the 10 CFR Part 26 fitness-for-duty (FFD) program focus, in part, on preventing and detecting impairment among personnel subject to an FFD program by providing reasonable assurance that the workplace is free of drugs and the effects of such substances. These requirements contribute to reasonable assurance that persons who have been granted unescorted access to the protected areas of NRC-licensed facilities (i.e., operating nuclear power reactors, nuclear power reactors under construction, and Category I fuel cycle facilities), who are required by a licensee to physically report to other locations (e.g., Emergency Operations Facilities, Technical Support Centers), or who have access to strategic special nuclear material or sensitive information are trustworthy and reliable and can safely and competently perform their assigned duties. These regulations also establish due process to protect individual rights.

The effectiveness of a drug testing program may weaken over time if individuals in the workplace (1) use impairing substances not included in the testing panel or (2) use products and techniques to successfully subvert the drug testing process. Program effectiveness may also weaken if the program does not incorporate technological advancements that enhance the sensitivity of drug testing. HHS is designated as the Federal agency responsible for developing the scientific and technical guidelines for Federal employee workplace drug testing programs. HHS is responsible for maintaining its guidelines based on the most recent research and lessons learned from Federal employee workplace and Federal agency drug testing programs. The 2008 HHS Guidelines are a national drug testing standard used by all Federal employee workplace drug testing programs (more than 100 Federal agencies) and all comparable Federal agency drug testing programs that test civilians in safety- and security-sensitive positions. The drug testing provisions in 10 CFR Part 26 should align with the national drug testing standard (i.e., the HHS Guidelines) to maintain reasonable assurance of a drug-free workplace.

The proposed rule would maintain the performance objective in 10 CFR 26.23(d) that requires FFD programs to "provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs." The NRC staff estimates that the lower testing cutoff levels, expanded drug testing panel, and enhanced subversion detection methods in the proposed rule would result in the detection of additional individuals (potential employees and employees of licensees) using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. The proposed changes also could deter 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.

This proposed rule would contribute to a drug-free workplace by doing the following:

- enhancing the capabilities to detect drugs already in the testing panel (i.e., amphetamine, cocaine, the heroin metabolite (6-acetylmorphine), and methamphetamine) and expanding the testing panel to include two amphetamine-based Ecstasy drugs

- maintaining alignment with the Federal employee workplace drug testing program and those programs implemented by comparable Federal agencies that test civilians in safety- and security-sensitive positions (e.g., U.S. Department of Transportation) (i.e., entities using the HHS Guidelines)

- addressing trends in societal drug use that demonstrate an increasing use of amphetamines, methamphetamines, and heroin

- addressing the prevalence of subversion attempts reported by the 10 CFR Part 26 drug testing programs since 2011 (approximately 13.2 to 16.5 percent of violations per year; 143 to 187 individuals per year)

Enhancing drug testing capabilities of the FFD program would maintain the effectiveness of 10 CFR Part 26 by identifying an additional 10 to 12 percent of individuals using drugs each year. The enhancements can be accomplished at low cost (i.e., an average one-time cost per site of $5,031 and an average annual cost per site of $2,516). As a result, the NRC staff concludes that the benefit of the proposed improvements would maintain the performance objective in 10 CFR 26.23(d), and outweigh the low cost of implementation.

This document is the draft regulatory analysis for the proposed rule and the associated Draft Regulatory Guide 5040, "Urine Specimen Collection and Test Result Review under 10 CFR Part 26, 'Fitness for Duty Programs.'"

Executive Summary

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend Title 10 of the *Code of Federal Regulations* (10 CFR) Part 26, "Fitness for Duty Programs" (Ref. 1), to accomplish three objectives:

(1) enhance 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

(2) harmonize select drug testing requirements under 10 CFR Part 26 with the U.S. Department of Health and Human Services (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (HHS Guidelines)

(3) enhance fitness for duty (FFD) program donor protection and due process requirements for individuals subject to drug testing

Updates to the HHS Guidelines were published on November 25, 2008, in Volume 73, page 71,858, of the *Federal Register* (73 FR 71858; Ref. 2) (hereafter referred to as the "2008 HHS Guidelines"). The NRC has relied on the HHS Guidelines as the technical basis to establish and update the requirements in 10 CFR Part 26 for urine specimen collection, laboratory testing, and results review. In general, the NRC has only deviated from the HHS Guidelines for considerations specific to the nuclear industry. At the time the 2008 HHS Guidelines were published, the NRC had recently issued the 10 CFR Part 26 final rule (March 31, 2008; 73 FR 16966; Ref. 3). Therefore, the NRC determined that postponing a rulemaking to adopt the 2008 HHS Guidelines would promote regulatory stability and provide the NRC staff time to collect data on the rule's effectiveness and to assess lessons learned from implementing the 2008 FFD final rule and the 2008 HHS Guidelines (which became effective in October 2010). These results have now been obtained, such that it is appropriate to propose a revision to 10 CFR Part 26.

The major provisions of the proposed rule include changes to do the following:

- Lower the initial and confirmatory drug testing cutoff levels for amphetamines (i.e., amphetamine and methamphetamine) and cocaine metabolites to increase the "window of detection"[1] for these substances.
- Add initial drug testing for 6-acetylmorphine (6-AM), a metabolite of the illegal drug heroin, and update the confirmatory drug testing method for 6-AM.
- Add initial and confirmatory drug testing for two illegal amphetamine-based Ecstasy-type drugs.[2]

[1] The "window of detection" refers to the time period after use during which the established detection technologies, methodologies, and cutoff levels can identify and quantify a target drug metabolite.

[2] Ecstasy-type drugs included within the scope of this rule are the Schedule I illegal drugs methylenedioxymethamphetamine (MDMA) and methylenedioxyamphetamine (MDA). A Schedule I drug, as defined by the Controlled Substances Act (Ref. 4), has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision.

- Strengthen methods for detecting subversion attempts by enhancing the testing for drugs and drug metabolites in urine specimens with dilute validity test results and in specimens collected under direct observation.

- Enhance donor protection by requiring Medical Review Officer evaluation of elapsed time from specimen collection to testing and exposure to high temperature as possible causes for some invalid test results due to a high solvated hydrogen ion concentration (i.e., pH).

The proposed rule also focuses on improving the clarity, consistency, and organization of the 10 CFR Part 26 rule text (e.g., resolving inconsistencies in quality control sample terminology, adding and revising definitions) and increasing regulatory flexibility (e.g., in the assignment of personnel who may monitor a hydrating donor in a shy-bladder situation).

Workplace Free of Drugs and the Effects of Such Substances

The general performance objective of an FFD program, as described in the original 10 CFR Part 26 final rule (54 FR 24468; June 7, 1989; Ref. 5), "is to provide reasonable assurance that nuclear power plant personnel are reliable, trustworthy, and not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties." This 1989 final rule also stated that an FFD program "developed under the requirements of this rule is intended to create an environment which is free of drugs and the effects of such substances" (54 FR 24468). The regulations in 10 CFR 26.23, "Performance objectives," establish these drug-free workplace requirements. Specifically, 10 CFR 26.23(d) states that an FFD program must "provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal[3] drugs." Preventing and detecting impairment among personnel subject to an FFD program by conducting drug testing provides reasonable assurance that the workplace is free of drugs and the effects of such substances. An FFD program contributes to the reasonable assurance that persons who have been granted unescorted access to the protected areas of NRC-licensed facilities (i.e., operating nuclear power reactors, nuclear power reactors under construction, and Category I fuel cycle facilities), who are required by a licensee to physically report to other locations (e.g., Emergency Operations Facilities, Technical Support Centers), or who have access to strategic special nuclear material (SSNM) or sensitive information are trustworthy and reliable and can safely and competently perform their assigned duties.

HHS is designated as the Federal agency responsible for developing the scientific and technical guidelines for Federal employee workplace drug testing programs. HHS is responsible for

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3 The regulations in 10 CFR 26.5, "Definitions," define the use of any Schedule I to V drug when not used pursuant to a valid prescription as an "illegal drug."

A Schedule I drug, as defined by the Controlled Substances Act, is a substance that has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks an accepted safe use of the drug or substance under medical supervision (21 U.S.C. § 812 (2012). Schedule II through V substances have accepted safe uses under medical subversion, pursuant to a valid prescription.

To improve the clarity of the discussion of the proposed rule changes, use of a Schedule I drug is referred to as "use of an illegal drug," while use of a Schedule II through V drug without a valid prescription is referred to as "misuse of a legal drug."

maintaining its guidelines based on the most recent research and lessons learned from Federal employee workplace and Federal agency drug testing programs. The 2008 HHS Guidelines are a national drug testing standard used by all Federal employee workplace drug testing programs (more than 100 Federal agencies[4]) and comparable Federal agency drug testing programs that test civilians in safety- and security sensitive positions, such as those programs implemented by the U.S. Department of Transportation (DOT), U.S. Department of Energy, U.S. Department of Defense, and U.S. Department of Homeland Security. These tested populations transport people and hazardous materials; operate and maintain our Nation's electrical, pipeline, and hydrodynamic infrastructure; protect property and national resources; serve in the armed forces; and make decisions and execute emergency response plans that contribute to public health and safety or protection of the environment following a natural disaster or security activity.

The effectiveness of a drug testing program may weaken over time if individuals in the workplace (1) use impairing substances not included in the testing panel or (2) use products and techniques to successfully subvert the drug testing process. Program effectiveness may also weaken if the program does not incorporate technological advancements that enhance the sensitivity of drug testing. The drug testing provisions in 10 CFR Part 26 should use the national drug testing standard established by the HHS Guidelines and existing defense-in-depth methods (e.g., behavioral observation, background checks, collection site security, and specimen collections) to maintain reasonable assurance of a drug-free workplace.
Based on the analysis of recent annual performance data for FFD programs submitted by licensees and other entities under 10 CFR 26.717, "Fitness-for-duty program performance data," workplaces subject to 10 CFR Part 26 are not free from the presence and effects of drugs.

Historically, the NRC has incorporated the appropriate provisions of the HHS Guidelines into 10 CFR Part 26 to effectively use advancements in drug testing technology and detection methods to address societal changes in drug use and in the methods and techniques used to subvert the drug testing process. The NRC amended 10 CFR Part 26 in 2008 to align with the 2004 HHS Guidelines, the testing standard used at that time to test Federal employees and the majority of civilians tested by Federal agencies. However, the current drug testing panel and cutoff levels specified in 10 CFR Part 26 do not align with the 2008 HHS Guidelines. Therefore, the improvements contained in the proposed rule would enable licensees to maintain reasonable assurance of a drug-free workplace.

Safety Vulnerability

The proposed rule would enhance the ability of NRC licensees and other entities to identify additional individuals using illegal drugs, misusing legal drugs, or attempting to subvert the testing process to conceal drug use and who, as a result, would be determined as not fit for duty or not trustworthy and reliable, or both. Such a determination would result in a denial of unescorted access to the protected areas of NRC-licensed facilities and other locations, access to SSNM, or access to sensitive information. The identification of these individuals enhances the existing regulatory framework to prevent drug-induced impairment (i.e., acute intoxication and the consequences of recent drug use, such as withdrawal effects) from causing or contributing to human performance errors that may result in unplanned occupational exposure;

[4] The number of Federal agencies using the 2008 HHS Guidelines appears in the Office of Management and Budget (OMB) information collection's supporting statement (OMB No. 0930-0158) filed by the Substance Abuse and Mental Health Services Administration for the "Mandatory Guidelines for Federal Workplace Drug Testing Programs," on May 28, 2014. The supporting statement is available at the OMB Web site http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201406-0930-001.

personal safety issues (e.g., injuries); unplanned radiological releases; or improper operation, maintenance, or surveillance of safety-related structures, systems, or components (SSCs).

This safety outcome is consistent with the original 10 CFR Part 26 rule (Ref. 4), which stated that "[t]he NRC cannot be confident of the individual's ability to limit the use of addictive substances to situations that do not adversely affect plant safety" (54 FR 24470; June 7, 1989), and that "there is an underlying assumption that workers will abide by the licensee's policies and procedures, [therefore] any involvement with illegal drugs shows that the worker cannot be relied upon to obey laws of a health and safety nature, indicating that the individual may not scrupulously follow rigorous procedural requirements with the integrity required in the nuclear power industry to assure public health and safety" (54 FR 24468; June 7, 1989).

Security Vulnerability

The proposed rule would enhance the ability of NRC licensees and other entities to identify additional individuals determined not to be fit for duty or not to be trustworthy and reliable, or both, because of their use of illegal drugs, misuse of legal drugs, or attempts to subvert the drug testing process. A potential security vulnerability exists because persons of questionable honesty, integrity, and motive may have unescorted access authorization to enable (either physically or remotely through electronic means) a loss of SSCs and facility control, cause radiological sabotage at a commercial power reactor, or steal or divert formula quantities of SSNM from a Category I fuel cycle facility.

A security vulnerability also exists if security personnel use illegal drugs or misuse legal drugs. Failure to maintain a robust and up-to-date FFD program could significantly challenge the effectiveness of the site insider mitigation program (10 CFR 73.55(b)(9)), security plan (10 CFR 73.55(c)), security search program (10 CFR 73.55(h)), and detection and assessment systems that include requirements to conduct surveillance, observation, and monitoring to identify tampering and to detect and deter intruders (10 CFR 73.55(i)). These requirements cannot be effectively implemented if site security personnel are not fit for duty, because many security duties and responsibilities are conducted by security officers who operate alone (i.e., individually) and, therefore, do not benefit from a team environment, second checks, or backup. As a result, a security officer who is mentally, physically, or psychologically impaired or who does not possess the characteristics of honesty, integrity, trustworthiness, and reliability cannot be relied upon to competently execute site security requirements. Furthermore, such a security officer cannot be relied upon to maintain positive control of his or her weapons, access controls, communication devices, and security-related knowledge and to safely and competently make decisions about contingency response and the use of deadly force. This argument also applies to individuals who perform the duties and responsibilities listed in 10 CFR 73.56(i)(1)(v)(B) and those who perform nonsafety or nonsecurity-related job functions.

Identifying Subversion Attempts

The proposed rule would enhance the ability of NRC licensees and other entities to identify additional individuals attempting to hide their drug use by subverting the drug testing process (e.g., consuming large quantities of fluid just before submitting a specimen for testing to reduce the level of a drug in his or her urine below detectable limits or submitting the urine of a nondrug-using individual in place of his or her own specimen). The proposed rule would require all specimens with a dilute validity test result (dilute specimens) and specimens collected under the direct observation requirements in 10 CFR 26.115(a)(1) through (a)(3) or (a)(5) (i.e., instances where a subversion attempt is suspected) to be tested to the limit of

quantification, which is the lowest concentration at which the identity and concentration of a drug can be accurately established by testing. The identification of persons attempting to subvert the drug testing process is significant because this action is undeniable evidence of a lack of integrity and honesty and a willful act to refuse to comply with an NRC-required drug test. Consequently, these individuals present a potential vulnerability to the safe and secure conduct of NRC-licensed activities.

Safety Goal Evaluation

The NRC staff estimates that if the proposed rule is adopted in its current form, it would result in a 10- to 12-percent increase in the number of individuals identified each year using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process, as compared to the 10 CFR Part 26 test results for calendar year (CY) 2013 and CY 2014.[5] The NRC staff used this projected increase in the ability to detect additional individuals using drugs as the basis for meeting the substantial increase criterion for achieving reasonable assurance that the workplaces subject to the NRC's FFD program are free from the presence and effects of drugs. The NRC staff acknowledges that a small percentage of individuals subject to drug testing test positive; however, the number of individuals that would be identified as a result of the changes in the proposed rule meets the substantial increase criterion based on the effects on facility safety and security that impairment of these individuals could have.

Based on the FFD program performance information reported to the NRC and a comparison of this information to that from the previous years, as well as other indicators, the commercial nuclear industry continues to effectively implement the 10 CFR Part 26 drug testing provisions, and the FFD program has directly contributed to public health and safety and the common defense and security. Testing data do indicate that persons potentially impaired from the use of amphetamine, cocaine, methamphetamine, and heroin (as evident from positive for-cause and post-event test results from CY 2010 through CY 2014) continue to be identified and removed from the protected area of NRC-licensed facilities. Enhancing the ability to detect additional amphetamine, cocaine, heroin, and methamphetamine drug users would strengthen the drug testing program in areas in which the annual FFD program performance data have indicated impacts related to human performance.

Benefits and Costs

The NRC staff finds that, considered together, the detection of additional drug users and the qualitative benefits of doing so continue to maintain reasonable assurance of a drug-free workplace and outweigh the low costs of the proposed rule. The analysis quantified benefits and costs associated with three affected attributes—industry implementation, industry operation, and NRC implementation. However, the NRC staff had difficulties in monetizing the benefits associated with seven affected attributes—public health (accident), occupational health (accident), offsite property, onsite property, regulatory efficiency, safeguards and security considerations, and other considerations. The "other considerations" attribute includes public perception, workplace productivity, workplace safety, and improved protection of individual

[5] For example, in the "Summary of Fitness for Duty Program Performance Reports for Calendar Year 2013," dated September 3, 2014 (Ref.6), the total number of drug positive test results and subversion attempts in CY 2013 was 769 (i.e., 1,007 individuals had a drug and/or alcohol testing violation in CY 2013, and 238 of those individuals tested positive for alcohol; the difference equals the total number of drug positive test results and subversion attempts). For CY 2014, the total number of drug positive test results and subversion attempts was 885 (i.e., 1,133 individuals had a drug or alcohol testing violation, or both, with 248 of those individuals testing positive for alcohol).

rights. The NRC staff performed a qualitative assessment of these attributes, which is consistent with the Commission's direction in the staff requirements memorandum on SECY-14-0087, "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," dated March 4, 2015 (Ref. 7). Because the staff could not rigorously quantify and monetize the benefits, it could not perform a quantified comparison of costs and benefits. However, for example, preventing the shutdown of a single reactor unit for 1 day as a result of the actions of an impaired individual would far exceed the annual cost to industry of the proposed rule changes.

The regulatory analysis resulted in the following key findings:

- Benefits. The direct benefit of this proposed rule would be to enhance the effectiveness of NRC-required FFD drug testing programs by identifying additional individuals using drugs. The NRC staff estimates that the proposed rule would result in a 10- to 12-percent increase in the number of individuals identified each year using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. The proposed rule also would improve regulatory efficiency by aligning 10 CFR Part 26 with the 2008 HHS Guidelines and by applying lessons learned from implementation of the NRC's 2008 FFD final rule by licensees and other entities. A more robust drug testing program also may deter additional individuals using drugs from seeking employment for positions subject to 10 CFR Part 26 and incentivize those in regulated positions to cease drug use or seek medical assistance to address an addiction or misuse issue, or both. While this analysis quantifies the benefit of identifying additional individuals using drugs, it cannot monetize the safety and security benefits of identifying these additional individuals, beyond training costs that would be averted because the individuals would not be given access. The staff recognizes that there would be additional costs to the organization from replacing an employee that is identified as using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process; while these are not quantified in this analysis, they represent an additional benefit of identifying these individuals before they gain access to the facility. Additionally, regulatory efficiency would be gained by clarifying ambiguous rule language and providing additional regulatory flexibility.

- Total Cost to Industry. The proposed rule is estimated to result in a total one-time cost of approximately ($337,100), followed by total annual costs of approximately ($168,600). The net present value of these costs is approximately ($2.4 million) using a 7-percent discount rate and approximately ($3.4 million) using a 3-percent discount rate over the average remaining reactor license period of 25 years. These costs include averted industry training costs as a result of pre-access testing (industry operations saving) of approximately $87,800 annually, which reduces the cost of the proposed rule by between $1.1 million (using a 7-percent discount rate) and $1.6 million (using a 3-percent discount rate).

- Average Cost per Site. The industry would incur a one-time average cost per site of ($5,031), followed by an average annual cost of ($2,516). The net present value of these costs per site is approximately ($36,400) using a 7-percent discount rate and approximately ($50,200) using a 3-percent discount rate over the average remaining reactor license period of 25 years.

- Total Cost to the NRC. The proposed rule is estimated to result in a total one-time cost of ($273,000) to the NRC to complete the final rulemaking (i.e., analyze public

comments, hold public meeting(s), develop the final rule) and issue final regulatory guidance.

- Uncertainty Analysis. The simulation analysis shows that the estimated mean cost for this proposed rule is ($2.51 million), with a 90-percent confidence interval that the total cost is between ($1.64 million) and ($3.37 million) assuming a 7-percent discount rate. The costs of performing initial drug testing for 6-AM and the testing of Ecstasy drive the largest variation in costs.

Decision Rationale

The proposed rule would maintain the performance objective 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" by (1) enhancing 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; (2) harmonizing select drug testing requirements under 10 CFR Part 26 with the 2008 HHS Guidelines; and (3) enhancing FFD program donor protection and due process requirements for individuals subject to drug testing.

While the full benefit of identifying additional drug-using individuals cannot be monetized, the detection of these individuals supports the safety and security goals discussed above as well as ensures the achievement of the goal of the drug testing program (i.e., provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of drugs). Table ES-1 (Table F-1 in Appendix F) shows, from a quantitative standpoint, that the proposed rule alternative is a cost-effective way of achieving incremental improvements in the detection of illegal drug use, legal drug misuse, and attempts to subvert the drug testing process. Note that Table ES-1 presents the net present value results for the 25-year time period of the analysis, while it presents the estimated benefit in the detection of additional drug users by regulatory initiative on an annual basis.

Table ES-1 Cost-Benefit Comparison of Alternative 2 (Proposed Rule)

Regulatory Initiative	7% Net Present Value (25-year time period of the analysis)			Estimated Benefit (Annual Basis)
	5%	Mean	95%	
Enhance detection of existing paneled drugs by lowering cutoff levels (amphetamine, cocaine, methamphetamine)	($247,653)	($176,723)	($110,715)	43 additional positive results (i.e., 22 amphetamines positives and 21 cocaine positives)
Expand testing panel to include initial testing of 6-AM (and revise confirmatory testing cutoff level)	($2,105,447)	($1,685,517)	($1,269,515)	27 additional positive results
Expand testing panel to include testing for Ecstasy drugs	($1,550,350)	($931,248)	($316,821)	7 additional positive results
Enhance detection of subversion attempts by requiring special analyses testing of dilute specimens and specimens collected under direct observation	($175,444)	($123,307)	($71,013)	18 additional positive results (8 positives from dilute specimens and 10 positives from suspect specimens)
To incorporate all drug testing program changes, sites would incur one-time costs to change policies, procedures, and conduct training	($353,436)	($338,330)	($324,339)	Required activities to implement drug testing changes at laboratories. Also informs all subject employees of drug testing program changes.
Averted training costs (pre-access testing)	$647,688	$1,034,618	$1,492,936	Historically, 68 percent of positive test results each year are identified at pre-access testing. Individuals testing positive before completion of training would result in savings to licensees and other entities.
Total Industry Results	**($3,088,766)**	**($2,220,507)**	**($1,358,859)**	**95 additional positive results per year and additional non-quantified benefits**
Average Cost Per Site[6]	**($46,100)**	**($33,142)**	**($20,281)**	

[6] Section 4.2.2 provides a discussion on affected sites.

Backfitting and Issue Finality

The provisions of this proposed rule would not impose modifications or additions to existing structures, components, designs, or organizations. The proposed rule would require licensees to update existing 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 make modifications to the drug testing panel. Therefore, it would constitute a "new or amended provision in the Commission's regulations" and meet the definition of "backfitting" in 10 CFR 50.109(a).

The changes in the proposed rule fall under the backfitting requirements in 10 CFR 50.109(a)(3) (Ref. 8), 10 CFR 50.109(c), and 10 CFR 70.76, "Backfitting" (Ref. 9), and the issue finality requirement in 10 CFR 52.98, "Finality of combined licenses; information requests." This requires the NRC staff to make a finding that (1) there is a substantial increase in the overall protection of public health and safety or the common defense and security, and (2) the costs are justified in view of this increase in protection.

First, the NRC staff concludes that the proposed rule would result in an estimated 10- to 12-percent increase in the number of individuals identified each year using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. This is a substantial increase in the overall protection of public health and safety and the common defense and security. This conclusion is based on the following:

- A comparison of the CY 2014 FFD program performance data received by the NRC with that from previous years, as well as other indicators, indicates year-over-year increases in amphetamines positive results, a significant number of subversion attempts that have been identified since CY 2011, and other adverse trends, as summarized in Table F-2.

- The proposed changes to the drug testing panel are broad based (i.e., the cutoff levels for multiple substances are being lowered and additional substances are being added) and address trends in FFD program performance data.

- Aligning 10 CFR Part 26 with the 2008 HHS Guidelines ensures that the NRC FFD drug testing program is consistent with this national drug testing standard implemented by all comparable safety- and security-sensitive workforces tested in the United States (e.g., Federal employee workplace drug testing programs such as that at DOT).

- The detection of drugs in the workplace subject to 10 CFR Part 26 testing is a proactive, risk-informed FFD strategy. Since testing began in 1990, approximately 68 percent of individuals who test positive for drugs or alcohol each year are identified before they receive unescorted access authorization (i.e., at pre-access testing).

Second, the analysis of net benefits (i.e., benefits minus costs) shows that five of the six regulatory initiatives that comprise the proposed rule are not cost beneficial because the benefits could not be quantified (see Table ES-1). If the proposed rule is adopted as a final rule, the safety and security value that the Commission assigns to detecting 10 to 12 percent more individuals using drugs must be greater than $2.2 million (mean value) using a 7-percent discount rate for the total quantified net benefit result to be positive.

The NRC staff concludes that the low cost of the proposed rule is justified in view of the substantial increase in the detection of additional individuals using drugs, as shown in Table ES-1.

1. Introduction

This document presents the draft regulatory analysis of the U.S. Nuclear Regulatory Commission's (NRC's) proposed amendments to the fitness-for-duty (FFD) requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 26, "Fitness for Duty Programs" (Ref. 1), and the associated Draft Regulatory Guide 5040, "Urine Specimen Collection and Test Result Review under 10 CFR Part 26, 'Fitness for Duty Programs.'"

The objectives of the rulemaking are to (1) 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 attempt to subvert the drug testing process; (2) harmonize select drug testing requirements under 10 CFR Part 26 with those established by the 2008 U.S. Department of Health and Human Services (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs," published on November 25, 2008, in Volume 73, page 71858, of the *Federal Register* (73 FR 71858; Ref. 2) (hereafter referred to as the "2008 HHS Guidelines") and implemented by other Federal agencies; and (3) enhance FFD program integrity and the protection of individual rights (i.e., donor protection and due process). In support of these three objectives, the proposed rule would also improve the clarity, organization, and flexibility of 10 CFR Part 26 rule language.

This introduction contains two sections. Section 1.1 provides background information, and Section 1.2 states the problem and the objectives for the proposed rulemaking.

1.1 Background

The regulations at 10 CFR Part 26 contain the NRC's requirements for the FFD programs of licensees and other entities (also referred to in this document as "licensees" or "affected entities"[7]). The regulations focus, in part, on preventing and detecting impairment among personnel subject to an FFD program by providing reasonable assurance that the workplace is free of drugs and the effects of such substances.

The general performance objective of an FFD program, as described in the original 10 CFR Part 26 final rule (54 FR 24468; June 7, 1989; Ref. 5), "is to provide reasonable assurance that nuclear power plant personnel are reliable, trustworthy, and not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties." This 1989 final rule also states that an FFD program "developed under the requirements of this rule is intended to create an environment which is free of drugs and the effects of such substances" (54 FR 24468). The regulations at 10 CFR 26.23, "Performance objectives," establish these drug-free workplace requirements.

[7] The entities subject to 10 CFR Part 26 requirements include (1) licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) (e.g., Category I fuel cycle facilities), (2) holders of, and certain applicants for, a combined license for a nuclear power plant under the provisions of 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (Ref. 10), (3) holders of, and certain applicants for, nuclear power plant construction permits and operating licenses under the provisions of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities" (Ref. 8), and (4) contractor/vendors (C/Vs) that implement FFD programs or program elements to the extent that the licensees rely on C/V FFD programs or program elements.

The drug-free workplace performance objectives contribute to the ability to provide reasonable assurance that persons who have been granted unescorted access to the protected areas of NRC-licensed facilities (i.e., operating nuclear power reactors, nuclear power reactors under construction, and Category I fuel cycle facilities), who are required by a licensee to physically report to other locations (e.g., Emergency Operations Facilities, Technical Support Centers), or who have access to SSNM or sensitive information are trustworthy and reliable and can safely and competently perform their assigned duties.

The NRC issued a significant revision to the original 1989 FFD rule (Ref. 5) in a final rule published on March 31, 2008 (Ref. 3). The 2008 revision to the FFD requirements had several objectives. The revision enhanced the effectiveness of FFD programs by applying advancements in drug and alcohol testing technologies and lessons learned from licensees' implementation of the 1989 FFD rule. It also improved the efficiency of FFD regulations by eliminating unnecessary requirements and by harmonizing the NRC's original FFD rule with other Federal drug testing rules and guidelines. Furthermore, it improved the consistency between FFD requirements and the access authorization requirements established in 10 CFR 73.56, "Access authorization," as supplemented by NRC orders to nuclear power plant licensees dated January 7, 2003, thereby strengthening regulatory assurance that persons of questionable integrity, honesty, trustworthiness, and reliability are not granted unescorted access authorization to the protected areas of commercial nuclear power plants and Category I fuel cycle facilities or to SSNM or sensitive information. In addition, the 2008 FFD final rule helped to protect the privacy and other rights (including due process) of individuals subject to the NRC FFD requirements, and it established clear and enforceable requirements for the management of worker fatigue.

NRC FFD Program and the HHS Guidelines

HHS is designated as the Federal agency responsible for developing the scientific and technical guidelines for Federal employee workplace drug testing programs. HHS is responsible for maintaining its guidelines based on the most recent research and lessons learned from Federal employee workplace and Federal agency drug testing programs. The 2008 HHS Guidelines establish a legal framework to conduct drug testing that provides reasonable assurance of privacy, drug test accuracy and precision, and custody and control of specimens collected and tested. It also provides for due process to individuals subject to drug testing. The 2008 HHS Guidelines can be viewed as the national standard for drug testing based on use by all Federal employee workplace drug testing programs, prevalence of use by Federal agency drug testing programs of civilians in safety- and security-sensitive positions, and use by the private sector. Furthermore, HHS has presented the 2008 HHS Guidelines to segments of the international community to share testing and policy considerations (Ref. 11).

The NRC has relied on HHS to establish the technical requirements for urine specimen collection, testing, and evaluation and has only deviated from the 2008 HHS Guidelines for considerations that are specific to the nuclear industry. One goal of the 2008 FFD final rule (Ref. 3) was to "update and enhance the consistency of 10 CFR Part 26 with advances in other relevant Federal rules and guidelines, including the HHS Guidelines and other Federal drug and alcohol testing programs (e.g., those required by the U.S. Department of Transportation [DOT]) that impose similar requirements on the private sector" (73 FR 16970; March 31, 2008). On November 25, 2008, nearly 8 months after publication of the NRC's 2008 FFD final rule, HHS issued the 2008 HHS Guidelines (Ref. 2), which incorporated advancements in drug testing technologies to improve the detection of drugs. The 2008 HHS Guidelines became effective on

October 1, 2010. The NRC's 10 CFR Part 26 regulation predates and does not fully reflect this subsequent revision of the HHS Guidelines.

Following publication of the 2008 HHS Guidelines, the NRC held four public meetings, on February 24, 2009 (Ref. 12), June 24, 2009 (Ref. 13), October 11, 2011 (Ref. 14), and September 11, 2013 (Ref. 15), to review the changes in the 2008 HHS Guidelines and to discuss the potential impacts on the NRC FFD drug testing requirements. Based on external stakeholder feedback and an NRC staff assessment, the NRC staff elected to forego another 10 CFR Part 26 rulemaking so soon after publishing the 2008 FFD final rule. This decision helped promote regulatory stability and allowed time for the NRC staff to evaluate the effectiveness of Federal agency programs implementing the revised 2008 HHS Guidelines since October 2010. Additionally, it allowed time for the NRC and licensees and other entities to learn lessons from implementing the 2008 FFD final rule.

During the public meetings, representatives from the commercial nuclear power industry expressed support for revising 10 CFR Part 26 to (1) incorporate select provisions from the 2008 HHS Guidelines, (2) enhance the detection of illegal drug use and misuse of prescription drugs, and (3) enhance the methods to identify attempts to subvert the drug testing process.

1.2 Statement of the Problem and U.S. Nuclear Regulatory Commission Objectives for the Rulemaking

The 2008 HHS Guidelines (Ref. 2) incorporated advancements in drug testing technologies to enhance the detection of drug use within the Federal employee workplace. These revisions were not incorporated into the 2008 FFD final rule (Ref. 3), which was published earlier. Therefore, the drug detection and deterrence provisions in 10 CFR Part 26 are not equivalent to those in the 2008 HHS Guidelines.

Consequently, the 10 CFR Part 26 drug testing program does not conform with (1) the workplace drug testing programs implemented by more than 100 Federal agencies[8] that test Federal employees, (2) other Federal agency programs that drug test civilians such as those implemented by the U.S. Department of Transportation (DOT) U.S. Department of Energy, U.S. Department of Defense, and U.S. Department of Homeland Security, and (3) programs run by private entities that use the 2008 HHS Guidelines as a technical basis for their drug testing programs. These tested populations transport people and hazardous materials (e.g., motor carriers, aviation, railroad, public transit, and maritime workers); operate and maintain our Nation's electrical, oil and gas pipeline, and hydrodynamic infrastructure; protect property and national resources; serve in the armed forces, and make decisions and execute emergency response plans that contribute to public health and safety or protection of the environment following a natural disaster or security activity.

Because some individuals seeking employment in or already working in the commercial nuclear workforce may use illegal drugs or misuse legal drugs, or both, this proposed rule focuses on enhancing the identification of those individuals using illegal drugs whose potential impairment could result in unsafe or unsecure conditions at NRC-licensed facilities. Granting or maintaining

[8] The number of Federal agencies using the 2008 HHS Guidelines appears in the Office of Management and Budget (OMB) information collection's supporting statement (OMB No. 0930-0158) filed by the Substance Abuse and Mental Health Services Administration for the "Mandatory Guidelines for Federal Workplace Drug Testing Programs," on May 28, 2014. The supporting statement is available at the OMB Web site http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201406-0930-001.

access authorization to these individuals 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, or components (SSCs). Additionally, granting or maintaining unescorted access authorization to these individuals also 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 these characteristics cannot be granted unescorted access authorization[9] (either physically or electronically) because it would challenge the defense in depth afforded by the FFD authorization requirements in 10 CFR Part 26 and access authorization requirements in 10 CFR Part 73, "Physical Protection of Plants and Materials" (Ref. 16).

The first objective of this rulemaking is to maintain reasonable assurance of a drug-free workplace at licensee facilities through the enhanced detection of individuals who are not fit for duty because of illegal drug use, legal drug misuse, or attempt to subvert the drug testing process. Enhancing the detection of additional individuals using drugs also includes strengthening the methods used to identify individuals attempting to subvert the drug testing process, which is a lesson learned from implementing the current 10 CFR Part 26 rule.

The second objective of this rulemaking is to harmonize select drug testing requirements under 10 CFR Part 26 with the 2008 HHS Guidelines. Updating 10 CFR Part 26 with the testing improvements in the 2008 HHS Guidelines would align the NRC's FFD program with this national drug testing standard, and therefore, enhance licensees' ability to maintain reasonable assurance that the workplace is free of drugs and the effects of such substances.

The third objective is to enhance 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 medical review officer (MRO) review 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.

In support of these three objectives, the proposed rule would also improve the clarity, organization, and flexibility of 10 CFR Part 26 rule language.

[9] Under 10 CFR 26.69(b), a licensee or other entity may (but is not required to) restore FFD authorization to an individual who tests positive on a drug or alcohol test, or both, after completion of the sanction under 10 CFR 26.75, "Sanctions," satisfactory completion of any assigned treatment program (10 CFR 26.189, "Determination of Fitness"), and inclusion of the individual in a followup testing program (10 CFR 26.31(c)(5)).

2. Identification and Preliminary Analysis of Alternative Approaches

The NRC staff considered the following three alternatives to address the regulatory problem identified in Section 1.2:

- Alternative 1: Take No Action
- Alternative 2: Amend 10 CFR Part 26
- Alternative 3: Address issues through means other than amending 10 CFR Part 26 (e.g., regulatory guides, generic communications, and stakeholder meetings)

2.1 Alternative 1: Take No Action

The first alternative is the status quo alternative. This alternative is the regulatory baseline from which the other alternatives are measured. Under this alternative, the NRC would not amend the current FFD regulations; and licensees and other entities would continue to comply with the existing requirements in 10 CFR Part 26 (Ref. 1). As a result, the 10 CFR Part 26 drug testing provisions would not include the drug testing advancements and donor protections in the 2008 HHS Guidelines or conform with the other Federal agency testing programs that follow them.

Taking no action would not incorporate the improvements in drug testing detection in the 2008 HHS Guidelines. Because the NRC requires all licensees to use HHS-certified laboratories for confirmatory specimen testing, specimens submitted by licensees and other entities must be treated differently than the specimens submitted by more than 100 Federal agency employee workplace drug testing programs. Laboratories would continue to segregate the 10 CFR Part 26 specimens from all other Federal agency specimens because of the different testing parameters (e.g., drug testing panel and cutoff levels, initial testing protocol for heroin, calibrators and controls used for assays) and would have to maintain amended procedures and training.

Under the no-action alternative, the NRC would not require licensees to test for additional substances or use lower cutoff levels to test for existing drugs and drug metabolites in the testing panel. Currently, 10 CFR 26.31(d) provides licensees and other entities with the flexibility to test for additional drugs or use lower testing cutoff levels than specified by rule for the NRC-required drug testing panel, or both. However, no licensee or other entity testing program has incorporated the use of the lower testing cutoff levels or tests for the additional substances included in the 2008 HHS Guidelines. Subsequent to the second public meeting held on this proposed rulemaking in 2009, the Nuclear Energy Institute submitted a letter on May 31, 2009 (Ref. 17), detailing the results of a survey it had conducted of its members and stating the following:

> While many of the respondents are in favor of expanding the panel, all companies responding to the survey responded that they would change their panel ***only*** if the NRC mandated the expansion of the panel to the 7 drugs specified in the HHS Guidelines. The reason is that many of the companies have had to negotiate with bargaining units on the drug testing process and expansion

of the panel by the company without a mandate within the rule would subject the panel to the negotiation process and not guarantee its adoption.

Regardless of whether this rulemaking is promulgated, the NRC will continue to inform the public about 10 CFR Part 26 FFD program performance to maintain the public's trust. The NRC publishes data on the NRC Web site of domestic operating events, including significant FFD policy violations or programmatic failures, drug and alcohol testing errors, and indicators of programmatic weaknesses (i.e., 24-hour and 30-day reportable events under 10 CFR 26.719, "Reporting requirements"). The agency also provides analysis, trending, and summary of annual FFD program performance data submitted under 10 CFR 26.717, "Fitness-for-duty program performance data," through the publication of the NRC's Summary of Fitness for Duty Program Performance Reports (Ref. 5). This information also is used to inform NRC oversight programs.

In 2009, the NRC developed (with input from industry) and implemented a voluntary electronic reporting (e-reporting) system to submit 10 CFR 26.717 information. This enhanced data collection method has led to the NRC's receipt of much more precise, detailed, and uniform information on site-specific performance. The staff has also used these data throughout this analysis. The NRC also regularly consults with regulatory partners (e.g., HHS, DOT, and the Office of National Drug Control Policy) to assess the effectiveness of the 2008 HHS Guidelines, societal changes in drug use, and the prevalence of products in the marketplace to enable test subversion and sample adulteration. The agency periodically provides this information to the NRC inspectors assigned to commercial power reactors and Category I fuel cycle facilities during training sessions. Collectively, these efforts have enhanced oversight of existing licensee and other entity FFD programs. However, FFD programs and NRC oversight programs cannot benefit under the current regulations from the enhancement in the effectiveness of the laboratory testing methods or the choice of drugs included in the testing panel (i.e., the aspects of Alternative 2 that are estimated to result in the majority of the quantified benefit).

Lastly, not pursuing rulemaking at this time would not incorporate lessons learned from implementation of the 2008 FFD final rule that would improve the efficiency of the regulatory framework and enhance the detection of subversion attempts.

By definition, this alternative has no incremental benefits or costs, as it does not change the status quo.

2.2 Alternative 2: Amend 10 CFR Part 26

This alternative would resolve the problems described in Section 1 about the current 10 CFR Part 26 rule and its implementation. The requirements for licensee FFD programs focus on preventing and detecting impairment among personnel subject to an FFD program by providing reasonable assurance that the workplace is free of drugs and the effects of such substances. This alternative would enhance 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. Specifically, rulemaking would align 10 CFR Part 26 drug testing requirements with the 2008 HHS Guidelines (Ref. 2) that are used by more than 100 Federal employee workplace drug testing programs and all comparable Federal agency drug testing programs that test civilians in safety- and security-sensitive positions. Rulemaking would also incorporate lessons learned from implementation of the 2008 FFD final rule (Ref. 3).

The NRC staff performed a comprehensive review and comparison of 10 CFR Part 26 and the 2008 HHS Guidelines to identify the specific 10 CFR Part 26 provisions that should be revised. The NRC staff also analyzed the DOT testing policies in 49 CFR Part 40, "Procedures for Transportation Workplace Drug and Alcohol Testing Programs" (Ref. 19), and the technical and policy issues identified during implementation of the 2008 FFD final rule. These efforts resulted in a list of potential changes to 10 CFR Part 26 (Ref. 18), which the NRC staff presented to stakeholders in a series of public meetings to elicit feedback to further inform the decisionmaking process on potential regulatory changes.

Based on the evaluations presented in Section 5 of this document, the NRC staff expects that the proposed revisions to 10 CFR Part 26 would substantially enhance safety and security at NRC-licensed facilities by identifying approximately 10 to 12 percent more individuals (potential employees and employees of licensees and other entities) each year using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. The changes to the drug testing program (e.g., lower testing cutoff levels, expanded drug testing panel, subversion detection methods) also could deter additional individuals using drugs from seeking employment in 10 CFR Part 26-regulated workplaces 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.

The proposed rule also would improve regulatory efficiency (e.g., by adding and updating definitions, incorporating lessons learned from implementation of the 2008 FFD final rule, increasing flexibility) and enhance donor protection and due process requirements (e.g., by 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, requiring the limit of quantitation (LOQ) for special analyses testing of drugs and testing for adulterants, adding a provision for MRO review of invalid test results due to high pH values (9.0 to 9.5)).

2.3 Alternative 3: Address Issues through Means Other than Rulemaking

Under this alternative, the NRC staff would not amend 10 CFR Part 26. This alternative differs from the Take No Action alternative (Alternative 1) because it would attempt to address FFD concerns through other means, such as a new regulatory guide, generic communications, stakeholder meetings, NRC inspections, or other agency initiatives, or a combination of approaches.

This alternative is not desirable for the following reasons:

- It would not address all identified issues (see Section 1.2 of this document), because resolving many issues, such as inconsistencies with the 2008 HHS Guidelines, require changes to 10 CFR Part 26.

- It would not incorporate comments from affected entities received by the NRC staff at public meetings that advocate promulgating rule changes to update the drug testing panel, testing methodologies, and evaluation criteria to help assure integrity, accuracy, sensitivity, and due process (Refs. 12–15, and 17).

- It would not address an NRC enforcement guidance memorandum dated March 31, 2009 (Ref. 20), which describes inconsistencies in terminology associated with quality control samples used at licensee testing facilities.

- It likely would result in inconsistencies in FFD program implementation. Under this alternative, affected entities could choose to commit to all, none, or a portion of the proposed guidance document, which could lead to inconsistent implementation across the industry and challenge regulatory effectiveness. However, as stated in the discussion of Alternative 1, 10 CFR 26.31(d) currently provides licensees with the flexibility to test for additional drugs or to use lower testing cutoff levels than required by 10 CFR Part 26, or both, but no FFD program has incorporated the changes in the 2008 HHS Guidelines. In addition, variability in drug testing programs could lead to additional burden on the NRC staff to assess and address compliance issues, answer questions from licensees, and answer questions from personnel subject to FFD program testing (especially for individuals, such as outage workers, who work for a variety of licensee programs).

3. Safety Goal Evaluation

A safety goal evaluation determines whether a regulatory requirement should not be imposed generically on nuclear power plants because the residual risk is already acceptably low. The 1989 FFD rule (Ref. 5) addressed the significance of drug and alcohol testing on public health and safety by stating the following on page 24468 of the final rule *Federal Register* notice:

> The Commission is taking this action to significantly increase assurance of public health and safety. The scientific evidence is conclusive that significant detriments in cognitive and physical task performance result from intoxication due to illicit drug abuse, as well as the use and misuse of legal substances. Given the addictive and impairing nature of certain drugs, while recognizing that the presence of drug metabolites does not necessarily relate directly to a current impaired state, the presence of drugs does strongly suggest the likelihood of past, present, or future impairment affecting job activities. In addition, the NRC believes that the reliability, integrity, and trustworthiness of persons working within nuclear power plants is important to assure public health and safety.

The calendar year (CY) 2013 performance report (Ref. 6), summarizes the performance of the FFD drug testing program and states the following:

> Based on the fitness-for-duty (FFD) performance information reported to the NRC and a comparison of this information to previous years and other indicators, the commercial nuclear industry continues to effectively implement the Part 26 drug and alcohol (D&A) provisions and FFD program results have directly contributed to public health and safety and the common defense and security. The data indicates no adverse trends;[10] persons under the influence of illicit drugs and/or alcohol are being identified and removed from the protected area (PA) of NRC-licensed facilities; and, persons of questionable trustworthiness and reliability are being identified through aggressive testing methods (e.g., limit-of-detection testing, lower cutoffs, and effective monitoring during specimen collections). Industry identification and communication of program weaknesses, lessons learned, and corrective actions demonstrate commitment to improved performance and a drug-free work environment.

The CY 2013 performance report also discussed the year-over-year increases in results that were positive for amphetamines and the significant number of subversion attempts that were identified since CY 2011. In terms of potential impairment from substance use and abuse, the CY 2013 report included data on for-cause and post-event testing positives. These tests are conducted in response to possible impairment or an adverse safety or security outcome, or both, as a result of substance use. For-cause testing, as described in 10 CFR 26.31(c)(2) (Ref. 1), is required when observed behavior, physical condition, or credible information, or a combination, indicate the potential for substance use. Post-event testing is required after certain workplace safety events, as described in 10 CFR 26.31(c)(3), which include but are not limited to events that cause death, days away from work, restricted work, medical treatment

[10] "An adverse trend is one in which the NRC would evaluate the necessity to undertake a scalable response based on the severity or significance of the trend. The NRC response could include, but not be limited to: inspection, issuance of guidance, licensing, or rulemaking."

beyond first aid, loss of consciousness, radiation exposure or release in excess of regulatory limits, or actual or potential substantial degradations of the plant safety level.

Table 3-1 presents data on FFD program performance from CY 2011 through CY 2014 for the number of for-cause and post-event testing violations (i.e., drug positive results, subversion attempts). This analysis does not include alcohol positive results because testing for this substance would not change in the proposed rule. The table presents the number of individuals who tested positive for any of the drugs that would be modified through lower testing cutoff levels, improved testing methods, and improved detection of subversion attempts.

Table 3-1 FFD Program Performance Data on Possible Impairment from Substance Use

Test Type	Performance Data	2011	2012	2013	2014
For-Cause	Total results (drug & alcohol positives & subversions)	66	65	80	83
	Total results (drug positives & subversions)	27	19	30	36
	Test results associated with proposed rule changes (panel of drugs, subversions)	12 of 27 (44%) • 1 AMP & MAMP • 3 cocaine • 1 cocaine & marijuana • 1 MAMP • 6 subversions	12 of 19 (64%) • 1 AMP • 3 AMP & MAMP • 1 cocaine & marijuana • 7 subversions	15 of 30 (50%) • 1 AMP & MAMP • 1 AMP, MAMP, & marijuana • 3 cocaine • 2 cocaine & alcohol • 1 MAMP • 7 subversions	16 of 36 (44%) • 1 AMP & cocaine • 1 AMP & codeine • 1 AMP & MAMP • 1 AMP, MAMP, & hydrocodone • 3 cocaine • 1 MAMP • 8 subversions
Post-Event	Total results (drug & alcohol positives & subversions)	7	7	5	13
	Total results (drug positive & subversions)	6	7	4	11
	Test results associated with proposed rule changes (panel of drugs & subversion)	3 of 6 (50%) • 6-AM • 6-AM & morphine • AMP	3 of 7 (43%) • 1 cocaine • 2 subversions	3 of 4 (75%) • 1 AMP • 2 cocaine	6 of 11 (55%) • 1 cocaine • 2 MAMP • 3 subversions

Notes: 1. 6-AM = 6-acetylmorphone; AMP = amphetamine; MAMP = methamphetamine.
2. This table only presents testing event data that were reported through the e-reporting system. Sufficient data were not provided using other reporting means to evaluate testing positives on an event-specific basis.

The data on for-cause testing show that between 44 and 64 percent of positive drug test results and subversion attempts from CY 2011 through CY 2014 were associated with the panel of drugs that would be updated in the proposed rule. For post-event testing, 43 to 75 percent of

the positive drug test results and subversion attempts from CY 2011 through CY 2014 were associated with the panel of drugs that would be updated by the proposed rule.

The NRC staff estimates that if the proposed rule is adopted, an additional 95 individuals using drugs would be detected per year. This represents an estimated 10- to 12-percent increase in detection over the number of individuals with a positive drug test result or identified as attempting to subvert a test in CY 2013 and CY 2014. These estimated benefits in detection apply to the seven qualitatively analyzed attributes described in Section 4.1. Specifically, the seven attributes are: public health (accident), occupational health (accident), offsite property, onsite property, regulatory efficiency, safeguards and security considerations, and other considerations (public perception, workplace productivity, workplace safety, and improved protection of individual rights). The proposed rule would accomplish this by lowering the testing cutoff levels and improving the methods of detection for amphetamine, cocaine, methamphetamine, and heroin. Enhanced testing capabilities may result in the identification of additional individuals before testing as a result of events based on possible impairment (i.e., identifying individuals during pre-access, random, and followup testing). The dominant safety effect of the proposed rule would be to maintain reasonable assurance of a workplace free of impairing drugs and the effects of such substances (both illegal drugs and the misuse of legal drugs).

4. Evaluation of Benefits and Costs

This section examines the benefits and costs estimated to result from this rulemaking when compared to Alternative 1 (Take No Action). Section 4.1 identifies attributes that are expected to be affected by the rulemaking. Section 4.2 describes how the staff analyzed benefits and costs.

4.1 Identification of Affected Attributes

This section identifies the factors within the public and private sectors that the regulatory alternatives discussed in Section 2 are expected to affect. These factors are classified as "attributes" using the list of potential attributes provided in Chapter 5 of NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," issued January 1997 (Ref. 21). Each of the following 10 attributes is quantified when possible and an uncertainty analysis is performed to report benefit and cost estimate confidence levels and to identify those variables that most affect the variation in the results distribution:

(1) Public Health (Accident): The proposed rule would reduce the risk to public health by helping to prevent events that may initiate or contribute to accidents or transients that could result in radiological releases to the environment. The proposed changes would reduce this public health risk by identifying additional individuals that may be impaired by their use of illegal drugs or misuse of legal drugs, thereby enabling licensees to deny or remove unescorted access authorization from these persons. This licensee action not only prevents individuals using drugs from being granted or maintaining unescorted access to the protected areas of NRC-licensed facilities, SSNM, or sensitive information, it prevents these individuals from conducting the safety- and security-sensitive duties and responsibilities described in 10 CFR 26.4, "FFD program applicability to categories of individuals." If individuals are impaired during the conduct of these activities, they would have a higher potential to initiate accidents and transients as a result of human performance errors.

The NRC established a strong link between the FFD-related authorization provisions in 10 CFR Part 26 and the physical protection access authorization requirements described in 10 CFR Part 73 (Ref. 16). This relationship between FFD and access authorization strengthens the defense in depth associated with the enhanced ability to identify individuals using drugs who are not fit for duty or are not trustworthy and reliable, or both. As described in the original 10 CFR Part 26 rule (54 FR 24470; Ref. 5):

> The NRC believes that the reliability, integrity, and trustworthiness of persons working within nuclear power plants are important to assure public health and safety. The granting of a license is based on the assumption that workers will abide by the licensees' policies and procedures in all areas. Indications of lack or reliability, integrity, or trustworthiness, therefore, even so far as they pertain to off-site behaviors, are relevant to the NRC's need to assure that nuclear power plants are operated safely.

The NRC further discussed these positions in the 2008 FFD final rule (73 FR 16971; Ref. 3):

> Part 26 and the access authorization requirements [of Part 73] each contain provisions that require establishing the trustworthiness and reliability of personnel before granting unescorted access authorization to the protected area of nuclear power plants.

Consequently, unless the NRC FFD program is robust in the identification of these individuals, security and safety vulnerabilities could exist because individuals of questionable motives may have unescorted access authorization.

The identification of additional individuals with confirmed positive test results would result not only in the denial of their unescorted access to that licensee's facility in accordance with the site FFD program (see 10 CFR 26.75, "Sanctions"), but it also would address these security and safety vulnerabilities at other commercial power reactor facilities. This occurs, in part, because denial of authorization information is shared with other NRC licensees and these licensees must meet the authorization requirements described in both 10 CFR Part 26 and 10 CFR Part 73 before granting unescorted access authorization to any individual who was previously found to be in violation of a licensee's FFD policy. Therefore, this program provision assures that individuals of questionable honesty and integrity would not represent a safety or security concern at a different facility without adjudication by the licensee reviewing official.

(2) Occupational Health (Accident): The proposed rule could reduce the risk that occupational health would be adversely affected by radiological releases and workplace mishaps, events, or occurrences. Risk reduction would be accomplished by identifying additional individuals using drugs who are subject to the 10 CFR Part 26 drug testing requirements.

The identification of additional individuals who are not fit for duty facilitates licensee action to prevent drug-induced impairment from causing or contributing to human performance errors that may result in unplanned occupational radiation exposure; personal safety issues; or improper operation, maintenance, or surveillance of safety- and security-related SSCs. This outcome also assures that timely and effective actions will be initiated in response to accidents, transients, environmental conditions, and security threats and that human performance during these exigent situations will not degrade with time because of substance-induced impairment or withdrawal symptoms.

Although non-radiological occupational health is not within the scope of the NRC's regulatory authority (Refs. 22 and 23), a beneficial consequence of the 10 CFR Part 26 drug testing program is that it provides assurance that individuals are fit for duty. As described in 10 CFR 26.23(d) and (b), the FFD program must, in part, "[p]rovide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs" and "that individuals are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties," respectively.

Consequently, the identification of additional persons not fit for duty through the conduct of drug testing and the subsequent denial of unescorted access authorization to these

individuals would reduce the risk of occupational health (radiological and non-radiological) accidents.

(3) Offsite Property: The proposed rule could reduce the risk that offsite property would be affected by radiological releases by identifying additional individuals impaired from using illegal drugs or misusing legal drugs among persons applying for unescorted access and those already granted unescorted access to an NRC-licensed facility. Identifying additional individuals using drugs would reduce the risk of accidents and security incidents resulting from impairment that could adversely affect offsite property.

(4) Onsite Property: The proposed rule could reduce the risk of damage to onsite property by identifying additional individuals impaired by using illegal drugs or misusing legal drugs among individuals applying for unescorted access and those already granted unescorted access to an NRC-licensed facility. Identifying additional individuals using drugs would reduce the risk of accidents and security incidents resulting from impairment that could adversely affect onsite property.

(5) Industry Implementation: The proposed rule would require licensees to revise their policies, procedures, training, and contracts with HHS-certified laboratories and blind performance test sample (BPTS) suppliers. Licensees that use a licensee testing facility (LTF) also would train laboratory technicians on the drug testing panel changes and perform a validation of the updated drug testing assays. Though licensees would incur the implementation costs of HHS-certified laboratories by their inclusion in the costs charged to the licensee when the laboratories test specimens (see "Industry Operation" below), the increased detection of impaired individuals would reduce the risk of accidents and security incidents resulting from that impairment. Section 5.1.1 and Appendix C provide the quantitative analysis of this attribute.

(6) Industry Operation: The proposed rule would result in an increase in the cost to test each specimen because the testing panel would include more drugs. The changes to the drug testing panel also would result in an increase in the number of individuals identified as using illegal drugs or misusing legal drugs and the number of 10 CFR Part 26 actions that each licensee must take subsequent to a positive drug test result or a confirmed subversion attempt. However, the increased detection of impaired individuals would reduce the risk of accidents and security incidents resulting from that impairment. The proposed rule would result in savings during pre-access testing from averted training costs associated with additional individuals testing positive as a result of the proposed rule changes.[11] Sections 5.1.2 through 5.1.6 and Appendix C provide the quantitative analysis of this attribute.

(7) NRC Implementation: NRC implementation actions would consist of completing the rulemaking (i.e., analyzing public comments on the proposed rule, holding public meeting(s) on the rulemaking, and developing the final rule) and developing regulatory guidance. The staff anticipates that changes to the agency's FFD inspection program would be minor (e.g., revisions to internal NRC training or inspection procedures are expected to be an insignificant incremental burden). Section 5.1.1 and Appendix C provide the quantitative analysis of this attribute.

[11] The NRC staff does not anticipate false positive results (i.e., errors in the laboratory testing process) as a result of the proposed testing changes. Historical FFD program performance data demonstrate the rigor of the laboratory testing process and the rarity of such a testing error.

(8) Regulatory Efficiency: The proposed rule would result in improved regulatory efficiency by achieving better consistency and less redundancy with select drug testing procedures in the 2008 HHS Guidelines, as well as better internal consistency within 10 CFR Part 26. The proposed rule also would harmonize some of the NRC's definitions with those in the 2008 HHS Guidelines, prevent dual regulation of HHS-certified laboratories in the areas of laboratory personnel and procedures, and clarify ambiguous or imprecise regulatory language in 10 CFR Part 26 (such as the proposed changes to the 10 CFR Part 26 definitions). Lastly, the proposed changes would improve the protections afforded to individuals by requiring certain drug tests to be evaluated to the limit of quantification (LOQ) instead of the limit of detection (LOD) and requiring the MRO perform an additional review of an invalid test results due to high urine pH. These donor protection changes could improve regulatory efficiency by reducing the potential for appeals associated with FFD policy violations and any subsequent followup NRC inspections.

(9) Safeguards and Security Considerations: The proposed rule would increase the ability of affected entities to identify additional individuals who are not trustworthy and reliable by enhancing the detection of illegal drug use, legal drug misuse, and attempts to subvert the drug testing process. The proposed changes also may enhance deterrence through the training of subject personnel on the rule changes. This could occur because the requirements in 10 CFR 26.29, "Training," necessitate the communication of the panel of drugs to be tested, the drug testing cutoffs, required sanctions, and licensee actions that would be taken if an individual violates the licensee's FFD policy.

The benefit of the proposed rule related to safeguards and security considerations is reflected qualitatively under the "Other Considerations" attribute listed below.

(10) Other Considerations

– Public Perception: The proposed changes would provide the public with additional assurance that the NRC is addressing potential safety concerns that could result from worker use of impairing drugs and security concerns by identifying individuals who display or demonstrate characteristics of not being fit for duty, or not being trustworthy and reliable, or both. Furthermore, the proposed rule changes would more closely align 10 CFR Part 26 with existing Federal agency drug testing programs for individuals in positions analogous to those covered by the NRC testing program. These Federal agency drug testing programs include, but are not limited to, those implemented by over 100 Federal agencies that test Federal employees, and all comparable Federal agencies testing civilians in safety- and security-sensitive positions. An example of such a comparable Federal agency is DOT, with testing for airline pilots, armed security guards, bus drivers, rail and transit engineers, and commercial truck drivers hauling hazards materials. Parity with all comparable Federal agency drug testing programs improves public perception of the effectiveness of 10 CFR Part 26.

– Public Trust: The proposed changes would strengthen the defense-in-depth regulatory framework associated with the identification of individuals using illegal drugs, misusing legal drugs, or attempting to subvert the testing process and who are determined not to be fit for duty, or not to be trustworthy and reliable, or both. Therefore, the proposed changes would reinforce the link between the

FFD-related authorization provisions in 10 CFR Part 26 and the physical protection access authorization requirements in 10 CFR Part 73. This rulemaking would address these safety and security vulnerabilities and should boost public trust, because once unescorted access authorization is denied, an individual cannot act as an insider threat to challenge the safe and secure operation of the facility and the transportation of SSNM, the safety and security of licensee employees and C/Vs, or the safeguarding of sensitive information.

– Worker Productivity: Affected licensees may accrue benefits from using the proposed expanded drug testing panel and the increased testing sensitivities, which could result in deterring additional individuals from using the drugs included in the NRC testing panel. A beneficial outcome is that this could result in improved workforce productivity, reduced employee turnover, and reduced absenteeism related to the health effects associated with drug use and possible addiction (Ref. 24). The effects of productivity loss caused by undetected amphetamine, cocaine, heroin, Ecstasy drugs, or methamphetamine drug use could have direct and indirect effects on operating costs. Furthermore, the impact of employee drug use is a problem that extends beyond the drug-using employee. Coworkers may have to work harder, redo work, or cover a shift for a coworker as a result of a fellow employee's absence (Ref. 24). In addition, enhancing the detection of illegal drug use, legal drug misuse, and subversion attempts may deter individuals using drugs from seeking employment and existing employees from starting to use drugs. It may also encourage existing employees to seek medical assistance to address an addiction or misuse issue, which could result in a lower turnover rate for individuals possessing requisite skills, knowledge, and experience that contribute to the safe and secure operation of the NRC-licensed facility. With a lower turnover rate, licensees may accrue benefits from not having to expend resources in recruiting, hiring, and training replacement employees (Refs. 25 and 26).

– Improved Protection of Individual Rights: Individuals subject to 10 CFR Part 26 may accrue benefits from the revised MRO review procedures for invalid test results due to high pH values and from clearer requirements describing MRO actions when a donor requests testing of Bottle B or a retest of a single specimen and the specimen is unavailable. Additionally, workers may accrue benefits from the proposed change to use the LOQ instead of the LOD in various test scenarios. The LOQ reliably detects and quantifies an analyte (the substance tested), whereas the LOD reliably detects an analyte but does not precisely quantify it. This change provides an additional measure of accuracy in the testing process. The proposed changes improve consistency with the 2008 HHS Guidelines, provide additional protection of individual rights, and may reduce the number of potential appeals of drug testing results (10 CFR 26.39, "Review process for FFD policy violations").

The staff does not expect this rulemaking to affect the attributes of public health (routine), occupational health (routine), NRC operation, other government, general public, improvements in knowledge, antitrust considerations, and environmental considerations.

4.2 Analytical Methodology

This section describes the process used to evaluate benefits and costs associated with the proposed alternatives. The benefits include any desirable changes in affected attributes (e.g., monetary savings, improved safety, improved security) while the costs include any undesirable changes in affected attributes (e.g., monetary costs, increased exposures).

Of the 10 affected attributes discussed in Section 4.1, the analysis evaluates three on a quantitative basis—industry implementation, industry operation, and NRC implementation. Quantitative analysis requires a baseline characterization of the affected universe (see Table 5-9 and Appendices B and C of this document), including the characterization of factors such as the number of affected entities, the nature of the activities being conducted, and the types of systems and procedures that licensees would implement or would no longer implement (if the proposed rule alternative was chosen). Affected entities differ from each other in a variety of ways, such as FFD program management (e.g., specific to a site, or centrally managed at a corporate office by a licensee that owns multiple sites) and testing laboratories used (e.g., LTF, HHS-certified laboratory). As a result, affected entities may respond to the proposed rule in different ways. Sections 4.2.1 through 4.2.6 present the analytical data and assumptions used in the quantitative analysis of these attributes, which the staff then used in performing the uncertainty analysis contained in Section 5.2.

The analysis relies on non-quantitative techniques for the remaining seven affected attributes (public health (accident), occupational health (accident), offsite property, onsite property, regulatory efficiency, safeguards and security considerations, and other considerations (which include public perception, workplace productivity, workplace safety, and improved protection of individual rights)). Non-quantitative techniques are used because monetizing the full impact of each attribute is not possible or practical. Monetizing the impact of these attributes would require the estimation of factors such as the frequency of accidents and other safety- and security-related events caused by drug-induced impairment and the consequences of such events. These data do not exist. However, improving the detection of individuals who use impairing drugs supports the general performance objective of 10 CFR Part 26, to "provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs." Sections 4.2.1 through 4.2.6 describe the analytical method and assumptions used in the quantitative and non-quantitative analysis of these attributes. Appendices B through D present the analysis calculations, unit costs, data sources, and assumptions used.

To estimate the costs associated with the evaluated alternative, the NRC staff used a work breakdown approach to deconstruct the activities for each requirement. For each required activity, the NRC staff further subdivided the work across labor categories (e.g., FFD manager, facility worker). The NRC staff estimated the necessary level of effort for each required activity and labor rates for personnel performing these activities to develop cost estimates.

The NRC staff gathered data from a number of sources to develop levels of effort and unit cost estimates. The NRC staff applied several cost estimation methods in this analysis. The NRC staff used professional knowledge and judgment to estimate some of the costs and benefits. Additionally, the staff used an engineering buildup method, solicitation of licensee input, and extrapolation techniques to estimate costs and benefits. The engineering buildup method used a step-by-step, bottom-up description of task requirements and estimated resources for labor, materials, and other direct costs to estimate a total cost. The NRC staff also consulted subject matter experts within and outside of the agency to develop inputs used in the analysis. For

example, the NRC staff collected industry wage data, cost for specimen testing and other inputs for this analysis.

The NRC staff extrapolated to estimate some cost activities, which rely on past or current costs to estimate the future cost of similar activities. For example, to estimate the cost to conduct testing for Ecstasy-type drugs at an HHS-certified laboratory, the NRC staff used the testing cost published by DOT in its final rule aligning 49 CFR Part 40 with the 2008 HHS Guidelines (75 FR 49850; Ref. 27) and increased that cost based on operational data for current drug testing costs and the projected number of future positive test results. However, for steps in the current and proposed alternative with no data, the NRC staff estimated the level of effort based on similar steps in the process for which data are available.

To evaluate the effect of uncertainty in the model, the NRC staff employed a Monte Carlo simulation, which is an approach to uncertainty analysis in which input variables are expressed as distributions. The simulation was run 5,000 times, and values were chosen at random from the distributions of the input variables provided in Section 5.2 of this document. The result is a distribution of values for the output variable of interest. A Monte Carlo simulation also makes it possible to determine the input variables that have the greatest effect on the value of the output variable. Section 5.2 gives a detailed description of the Monte Carlo simulation methods and the results.

4.2.1 Baseline for Analysis

This draft regulatory analysis measures the incremental impacts of the proposed alternative relative to a baseline that reflects the anticipated behavior if the NRC undertakes no other regulatory action (Alternative 1, Take No Action). As part of the regulatory baseline used in this analysis, the NRC staff assumes licensee compliance with existing NRC regulations. Section 5.1 presents the estimated incremental costs and benefits of the proposed rule relative to this baseline.

4.2.2 Affected Entities (Sites and Fitness-for-Duty Programs)

For use in this analysis, the NRC staff created the following groupings based on how the alternative affects NRC licensees:

- *Sites*[12]: The analysis modeled 67 sites covered by the 10 CFR Part 26 FFD program requirements, including 59 power reactor sites (includes 57 operating sites and 2 construction sites),[13,14] 5 corporate offices, 2 Category I fuel cycle facilities, and 1 C/V

[12] The term "site" corresponds to the term "facility," which is used to describe licensees and other entities that are subject to the reporting requirements in 10 CFR 26.717 and that submit drug and alcohol testing data to the NRC in annual FFD program performance summary reports. The number of sites used in this analysis is based on information in the "Summary of Fitness for Duty Program Performance Reports for Calendar Year 2013" (Ref. 6).

[13] The two power reactor construction sites are the Vogtle Electric Generating Plant (Vogtle), Units 3 and 4, and the Virgil C. Summer Nuclear Station (Summer), Units 2 and 3. Vogtle Units 3 and 4 are assumed to begin commercial operation in CY 2019 and CY 2020, respectively. Summer Units 2 and 3 are assumed to begin commercial operation in CY 2019 and CY 2020, respectively.

[14] This analysis does not include the Bellefonte Nuclear Power Station (Bellefonte) because the site does not have any operating units and new construction is indefinitely delayed. Bellefonte Units 1 and 2 are covered

that maintains its own FFD program. Appendix A to this document contains site-specific FFD program performance data supporting this quantification. These site counts include Watts Bar Nuclear Power Plant Unit 2, which received its operating license in October 2015 and is scheduled to begin commercial operation in CY 2016. These site counts exclude the FitzPatrick, Oyster Creek, and Pilgrim reactors because their licensees have decided to permanently cease power operations before or during CY 2019.[15] The net result is that beginning in CY 2020, the analysis models 67 sites with FFD programs, which by that time includes 59 operating power reactor sites and no power reactor construction sites.

- *FFD Programs*: The analysis models 27 FFD programs for the 67 sites covered by 10 CFR Part 26. FFD programs are based on corporate ownership. If a corporate entity operates multiple sites, the entity will maintain one FFD program for all of its sites (Ref. 6 and Appendix A to this document).

- *Drug Testing Laboratories*: Each licensee and other entity may choose to conduct initial urine specimen testing at an LTF; then, it must conduct confirmatory testing at an HHS-certified laboratory. Alternatively, the licensee or entity may conduct all urine testing at an HHS-certified laboratory. The analysis models that 61 sites will conduct all urine testing at HHS-certified laboratories and that 6 sites will use an LTF for initial testing and an HHS-certified laboratory for confirmatory testing.

4.2.3 Cost and Benefit Calculations

This section describes the method used to estimate the quantifiable costs and benefits associated with the proposed alternative.

- All licensees are assumed to be in compliance with the existing regulatory requirements. Therefore, this analysis only presents the incremental costs associated with the proposed rule changes.

- The *Total Industry Cost or Benefit* associated with each proposed rule requirement is calculated using the following five-step approach:

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under the Commission Policy Statement on Deferred Plants (52 FR 38077; October 14, 1987). The analysis also excludes Fermi Unit 3 because, although as of May 1, 2015, the NRC issued a combined license to DTE Electric Company, DTE Electric Company has no immediate plans to begin construction. South Texas Project Units 3 and 4 are excluded because, although as of February 12, 2016, the NRC issued a combined license to Nuclear Innovation North America, LLC, the company has no immediate plans to begin construction. If the construction plans for these units change during the final rule phase, the staff will update the regulatory analysis accordingly to reflect the costs and benefits of the rule considering these additional units.

[15] On November 18, 2015, Entergy Nuclear Operations, Inc. certified to the NRC that it had decided to permanently cease power operations at James A. FitzPatrick (one reactor) on January 27, 2017 (Ref. 28). During CY 2019, the licensees for the Oyster Creek (one reactor) and Pilgrim (one reactor) operating reactor sites plan to permanently cease power operations. The licensees for FitzPatrick, Oyster Creek, and Pilgrim had announced intentions to begin decommissioning before the end 2019. This set of sites reflects the NRC's understanding of licensees' plans to decommission at the time this regulatory analysis was prepared. Subsequent to completing the analysis, the licensee for FitzPatrick reported that it now plans to continue to operate and the licensee for Fort Calhoun permanently shut down in October 2016. Adjustments to the number of operating power reactors will be made in the analysis for the final rule. However, the costs and benefits of the rule would be further affected if the number of facilities that decommission change over time.

– Step 1: Estimate the average incremental cost or benefit per affected entity (i.e., a site or FFD program) to comply with the new requirement (e.g., the cost to conduct initial urine drug testing for Ecstasy). The use of average incremental cost or benefit per entity is a simplification, with some affected entities incurring higher or lower costs.

– Step 2: Estimate the number of times an affected entity would incur the incremental cost or benefit associated with the new requirement in a year (e.g., how many individuals will be drug tested for Ecstasy at each site).

– Step 3: Estimate the number of affected entities that would incur the incremental cost or receive the benefit associated with the new requirement in a year.

– Step 4: Estimate the number of years the incremental cost or benefit would be incurred.

– Step 5: Multiply the outcomes of Steps 1 through 4.

Not all proposed rule requirements apply to all 67 sites or all 27 FFD programs. For example, some proposed rule changes would only impact the six sites that conduct initial drug and validity testing at LTFs and not the 61 sites that only use HHS-certified laboratories to conduct all drug and validity testing. The cost calculations for the proposed rule requirements in Appendix C reflect these differences.

- The *Average Cost per Site* to comply with each proposed rule requirement is calculated by dividing the *Total Industry Cost or Benefit* per requirement by the total number of affected sites. While the *Average Cost or Benefit per Site* does not present the potential variability for an estimated value based on facility type (e.g., corporate office, fuel cycle facility, operating power reactor), the NRC staff believes that this is a reasonable measure to present the potential impact to the nuclear industry of each proposed rule change for the following reasons:

  (1) The majority of sites included in the analysis are operating power reactors (59 of 67 sites).

  (2) The proposed rule changes (beyond the implementation activities in the initial year of the rule associated with policy updates, contract revisions, and training) only pertain to conducting drug tests and the associated positives that result from those tests. Therefore, the impact of the rule is directly dependent on the number of individuals tested at each site and the resulting positive tests. Typically, a multiunit nuclear power reactor site will use a larger workforce than a single-unit site. However, the workforce at any site is affected by plant outages because of the additional workers brought on site. Appendix A gives site-specific testing data from CY 2009 through CY 2014.

  (3) The number of positive test results may vary from year to year at a site. Possible reasons for changes in the positive testing rate at a site might include changes in the characteristics of the workforce (e.g., age of workers, job duties, and employment types), number of new hires, or changes in the availability of illegal drugs in the local area. For example, the analysis of FFD program performance data has consistently identified that C/Vs, on average, have a higher rate of

positive test results (i.e., approximately 3.7 times more) than licensee employees (Ref. 6). In outage years at a site, it is typical to see an increase in the number of positive results because of the surge in the number of short-term contractors used to support the outage.

(4) The size of the workforce at the two Category I fuel cycle facilities, five corporate offices, and one C/V (Institute of Nuclear Power Operations (INPO)) is much smaller and more stable than at operating power reactor sites and power reactor construction sites because these sites do not experience periodic workforce surges for refueling outages or new construction. Drug use is also very low, as presented in Appendix A. As a result, the NRC staff anticipates a lower than the average cost per site for these types of facilities.

- *Testing Data by Facility Type*: To evaluate variability among facility types, the NRC staff analyzed testing data for CY 2009 through CY 2014 and calculated the average number of tests performed and the average number of positive results for each of the 67 sites. Table 4-1 summarizes the results of the site-specific testing data analysis. Appendix A includes the site-specific testing data summarized in this table.

Table 4-1 Range of Testing Data by Facility Type (CY 2009–2014)

Facility Type	Number of Units	Tests/Year			Positives/Year		
		Minimum (10%)	Maximum (90%)	Average	Minimum (10%)	Maximum (90%)	Average
Power Reactor - Operating	All	1,218	3,973	2,566	5.0	27.0	14.9
	1	927	2,776	1,774	3.0	19.5	10.5
	2	1,949	4,013	2,894	8.0	29.0	17.0
	3	3,310	4,825	4,102	14.3	27.7	20.6
Power Reactor - Construction		232	6,181	3,961	3.6	131.1	76.7
Corporate Office		289	716	500	0	2.0	0.8
Fuel Cycle		747	865	811	0	3.0	1.6
C/V (INPO)		203	374	310	0	1.0	0.5

– Operating power reactors have the largest variability in the number of tests conducted by facility type. This variability primarily depends on the number of reactors at the site (e.g., one to three units), although an analysis of the data in Appendix A shows that a single-unit site may perform more tests annually than a two-unit site, and a two-unit site may conduct more tests annually than a three-unit site.

– Variability in the size of the workforce at a reactor construction site depends on the stage of construction. The NRC FFD program performance data for CY 2009 through CY 2014 reflect construction on Vogtle Units 3 and 4, which began in CY 2009, and Summer Units 2 and 3, which began in CY 2011.

– Reactor construction sites have the largest number of positive tests of any facility type. Reactor construction sites primarily rely on C/V personnel, and the positive testing rates for these workers have been higher than comparable C/V workforces used at operating power reactor sites (including during outages) (see Appendix A).

- *Analysis Horizon*: Licensees would incur costs and savings over a 25-year period, which is the average remaining license term of the 67 sites[16] included in the analysis. The time period that each site will be in operation is dependent on the term of the operating license and whether the licensee chooses to operate the site for the duration of the licensed period. The average life term is based on the following assumptions:

  – The licensee for each operating nuclear power reactor is known or assumed to apply for and receive a 20-year license extension beyond the original 40-year licensed term.

  – Each nuclear power reactor currently under construction is assumed to operate for the 40-year period of the original operating license and to receive a 20-year license extension. As part of the uncertainty analysis, the staff assumed that each reactor currently under construction will apply for and receive a 20-year license extension beyond the original 40-year licensed term.

  – Each licensee for a Category I fuel cycle facility is assumed to request and receive operating license extensions to support the possession, use, and manufacturing of nuclear material. As these facilities provide nuclear material for noncommercial nuclear power reactors, the NRC staff assumed that their operations would continue (assumed at 63 years) independent of activities associated with civilian nuclear power reactors.

- *Base Year*: The base year of this analysis is CY 2017. Monetized benefits and costs in this analysis are expressed in 2017 dollars. The NRC staff assumes that the final rule is effective in CY 2017. One-time implementation costs are assumed to be incurred in CY 2017. Ongoing and annual costs of operation related to the alternatives are assumed to begin in CY 2017, unless otherwise stated. Calculated benefits and costs are then discounted into 2017 dollars.

- *Discounting of Costs and Savings*: The costs or savings incurred in each year of the analysis are discounted back at a 7-percent and 3-percent discount rate to the base year. These discount rates are in accordance with NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 4, issued September 2004 (Ref. 29). Section 5.1 gives these results.

- *Cost/Benefit Inflators*: To evaluate the costs and benefits consistently, the analysis inputs are put into base year dollars. The most common inflator is the Consumer Price Index for all urban consumers (CPI-U), developed by the U.S. Department of Labor, Bureau of Labor Statistics. The formula to determine the amount in base year dollars is as follows:

$$\frac{\mathrm{CPI}_{\mathrm{Base\ Year}}}{\mathrm{CPI}_{\mathrm{Value\ Year}}} * \mathrm{Value}_{\mathrm{Value\ Year}} = \mathrm{Value}_{\mathrm{Base\ Year}}$$

[16] The NRC analyzed data on power reactors (operating, under construction) and Category I fuel cycle facilities from NUREG-1350, Volume 27, "2015–2016 Information Digest," issued August 2015 (Ref. 30), which is adjusted for early plant retirement announcements.

- *Sign conventions*: The sign convention used in this analysis is that all favorable consequences for the alternative are positive and all adverse consequences for the alternative are negative. Negative values are shown using parentheses (e.g., negative $500 is displayed as ($500)).

- *Labor rates*: In estimating the incremental costs of the alternatives, the analysis uses hourly labor rates that include salary, fringe benefits (e.g., paid leave and health benefits), and overhead (e.g., payroll costs). Table 5-9 provides the labor rates used for the uncertainty analysis, and Appendix B gives the labor rates for the base case. The labor rates are in 2017 dollars.

4.2.4 Incremental Requirements in the Proposed Rule

The NRC quantitatively evaluated the impacts of the following four proposed rule changes relative to the baseline described in Section 4.2.1:

(1) Lowered initial and confirmatory drug testing cutoff levels for amphetamines and cocaine metabolites.

The proposed rule would update the cutoff levels for initial drug testing, listed in 10 CFR 26.133, "Cutoff levels for drugs and drug metabolites," and 10 CFR 26.163(a)(1), and for confirmatory drug testing, listed in 10 CFR 26.163(b)(1), to conform with the changes to Section 3.4 of the 2008 HHS Guidelines as follows:

- lower the initial drug testing cutoff level for cocaine metabolites by 50 percent (from 300 nanograms (ng) per milliliter (mL) to 150 ng/mL)

- lower the initial drug testing cutoff level for amphetamines by 50 percent (from 1,000 ng/mL to 500 ng/mL)

- lower the confirmatory drug testing cutoff level for cocaine metabolites by 33 percent (from 150 ng/mL to 100 ng/mL)

- lower the confirmatory drug testing cutoff levels for amphetamine and methamphetamine by 50 percent (from 500 ng/mL to 250 ng/mL)

Significantly lowering the drug testing cutoff levels for amphetamines and cocaine metabolites would increase the timeframe in which these drugs would be identified after use (i.e., the window of detection). Increasing the window of detection would increase the number of individuals identified with urine specimens containing amphetamines or cocaine metabolites, or both. Increased detection of amphetamines and cocaine use would provide a higher degree of assurance that persons subject to 10 CFR Part 26 testing are not using these drugs and would contribute to a licensee determination of whether each individual is fit for duty and trustworthy and reliable.[17]

[17] Sections 3.8 and 3.9 of the Regulatory Basis for this proposed rulemaking (Ref. 31) provide additional information on the technical basis for lowering the initial and confirmatory drug testing cutoff levels for amphetamines and cocaine metabolites.

(2) Expanded initial drug testing panel to include 6-acetylmorphine (6-AM) and revised confirmatory drug testing cutoff level for 6-AM.

The proposed rule would add testing for 6-AM to the initial drug testing panel in 10 CFR 26.31(d)(1) and 10 CFR 26.405(d); make conforming changes to the substances for initial testing listed in 10 CFR 26.133 and 10 CFR 26.163(a)(1) and for confirmatory drug testing listed in 10 CFR 26.163(b)(1); and make conforming changes to the annual statistical summary reporting requirements for HHS-certified laboratories to include the revised drug testing panel in 10 CFR 26.169(h)(3). These changes would ensure that 10 CFR Part 26 is consistent with Section 3.4 of the 2008 HHS Guidelines.

The proposed rule would revise the list of substances to be tested as follows:

- Include initial drug testing for 6-AM with a 10-ng/mL testing cutoff level.
- Eliminate the requirement to conduct confirmatory drug testing of 6-AM only when the confirmatory drug test result for morphine exceeded 2,000 ng/mL. (If initial testing for 6-AM is positive, confirmatory testing for 6-AM is to proceed independent of the morphine concentration.)

The enhanced testing capability would enable the identification of additional instances of heroin use (6-AM is a metabolite of heroin). Enhancing the detection of 6-AM is important given the increasing prevalence of heroin use among individuals performing safety-sensitive duties in other sectors of the economy and the adverse effect of these illegal drugs on persons in the workplace.[18] In addition, improved testing for 6-AM could deter additional individuals from seeking employment in 10 CFR Part 26 regulated workplaces.

(3) Expanded initial and confirmatory drug testing panels to include Ecstasy.

The proposed rule would add testing for Ecstasy-type drugs methylenedioxymethamphetamine (MDMA), and methylenedioxyamphetamine (MDA), to the drug testing panel in 10 CFR 26.31(d)(1) and 10 CFR 26.405(d). MDMA and MDA would be added to the substances for initial drug testing listed in 10 CFR 26.133 and 10 CFR 26.163(a)(1), and MDMA and MDA would be added to the substances for confirmatory drug testing listed in 10 CFR 26.163(b)(1). Conforming changes would be made to the annual statistical summary reporting requirements for HHS-certified laboratories to include the revised drug testing panel in 10 CFR 26.169(h)(3). These changes would ensure that 10 CFR Part 26 is consistent with Section 3.4 of the 2008 HHS Guidelines, with the exception of not listing methylenedioxyethylamphetamine (MDEA), which HHS subsequently removed from the list of authorized test analytes in the 2017 HHS mandatory guidelines (Ref. 35).

[18] Sections 3.3, 3.7 and 3.8 of the Regulatory Basis for this proposed rulemaking (Ref. 31) provide additional information on the technical basis for expanding the initial drug testing panel to include 6-AM and revising the confirmatory drug testing cutoff level for 6-AM.

The proposed rule would revise the list of substances to be tested as follows:

- Include initial drug testing for MDMA and MDA with a 500-ng/mL testing cutoff level.

- Include confirmatory drug testing for MDMA and MDA with 250-ng/mL testing cutoff levels.

Testing for this additional substance would enable the identification of a greater range of illegal drugs that could impair human performance. Ecstasy would be added to the drug testing panels because of its increasing prevalence and adverse effects on persons in the workplace.[19] Testing for Ecstasy also may deter additional individuals from seeking employment in 10 CFR Part 26 regulated workplaces.

(4) Required special analyses testing of dilute specimens and specimens collected during suspected subversion attempts.

Existing regulations in 10 CFR 26.163(a)(2) provide licensees with the *option* to conduct special analyses testing on any urine specimen with a dilute validity test result (i.e., a creatinine concentration greater than or equal to 2 milligrams per deciliter (mg/dL) but less than 20 mg/dL). Special analyses testing consists of conducting confirmatory drug testing to the LOD for any drug with an initial test result (i.e., immunoassay response) equal to or greater than 50 percent of the testing cutoff level.

The NRC is proposing three changes:

(1) Require special analyses testing for any drug in a dilute specimen with an initial drug test result that is equal to or greater than 40 percent of the testing cutoff level.

(2) Expand special analyses testing to circumstances in which a subversion attempt is suspected during the specimen collection process (e.g., if the initial specimen is out of the expected temperature range, the second specimen collected under direct observation would be subject to the special analyses provisions).

(3) Use the LOQ instead of the LOD as the level at which confirmatory drug testing is to be conducted.

These three changes would enhance the detection of individuals using illegal drugs or misusing legal drugs, or both, in circumstances in which the urine specimens provided do not present normal physiological characteristics. The 2008 HHS Guidelines do not address special analyses testing, but the proposed changes are based on industry experience (i.e., high industry adoption of the voluntary 10 CFR 26.163(a)(2) special analyses testing of dilute specimens and the additional dilute positive test results

[19] Sections 3.4 through 3.7 of the Regulatory Basis for this proposed rulemaking (Ref. 31) provides additional information on the technical basis for expanding initial and confirmatory drug testing panels to include Ecstasy.

identified each year) and feedback received from HHS-certified laboratories in implementing the 2008 FFD final rule.[20]

The NRC staff developed equations to estimate costs and savings using available data and described any assumptions used, when necessary. Appendices B, C, and D document this analysis, including the specific per-site or per-FFD-program cost assumptions used to quantify costs and savings.

The proposed rule also would include the following changes, which would result in either no or negligible incremental costs to licensees but would lead to some benefits as discussed below:

- The proposed rule would add and revise definitions in 10 CFR Part 26 to improve consistency with the definitions in the 2008 HHS Guidelines and also improve internal consistency in 10 CFR Part 26. These changes would be administrative, are estimated to result in negligible incremental costs, and could result in savings. The changes would lead to improved regulatory efficiency, in part, by promoting clear and unambiguous communications.

- The proposed rule would replace the LOD with the LOQ as the decision point for determining whether a specimen contains an adulterant or is invalid (i.e., a valid test result cannot be determined) based on the possible presence of a halogen or an oxidizing adulterant. This would entail minor procedural changes with negligible incremental costs (see Section 4.2.4). The change to LOQ enhances the protection afforded to individuals subject to validity testing because the test result reliably identifies and quantifies the substance tested.

- The proposed rule would clarify the procedures for observed urine specimen collections, as well as specimen quantity, altered specimens, and refusals to test. These changes would take the form of clarifications to existing procedures, and the staff therefore expects incremental costs to be negligible. The changes would enhance consistency with the 2008 HHS Guidelines and allow for increased flexibility in licensee implementation of the proposed rule.

- The proposed rule would permit additional trained licensee or other entity staff at the collection site (i.e., FFD program personnel) to observe a donor in the hydration process. An individual enters the hydration process when he or she is unable to provide a urine specimen of adequate volume for testing (i.e., a shy bladder). Currently, the specimen collector must remain with the donor for the duration of the hydration period (a maximum of 3 hours) and not conduct an additional collection until the first collection (of the hydrating individual) has been completed. The proposed changes add flexibility to the collection process by permitting a specimen collector to conduct additional collections while the donor is hydrating. The NRC staff finds that the savings associated with this proposed change would be minimal because the incidence of shy-bladder events is infrequent.

[20] Sections 3.11 through 3.13 of the Regulatory Basis for this proposed rulemaking (Ref. 7) provide additional information on the technical basis for requiring special analyses testing of dilute specimens and specimens collected during suspected subversion attempts.

- The proposed rule would eliminate the 6-month in-service limit for BPTSs and allow BPTS suppliers to specify the shelf life of sample lots. The option to specify shelf life adds flexibility to the rule and would not impose any incremental costs because current practice would still be acceptable. The change also would result in enhanced consistency with the 2008 HHS Guidelines, which do not require similar in-service limits on BPTS lots.

- The proposed rule would remove 10 CFR 26.155, "Laboratory personnel," and paragraphs (b) through (e) of 10 CFR 26.157, "Procedures," which repeat requirements contained in the HHS Guidelines that the National Laboratory Certification Program (NLCP) verifies in order for a laboratory to achieve and maintain HHS certification. This would eliminate dual regulation of an HHS-certified laboratory (a private entity) and reduce the regulatory burden on licensees.

- The proposed rule would clarify terminology associated with quality control samples. This change would be administrative and would correct inconsistencies in 10 CFR Part 26 that are described in the enforcement guidance memorandum dated March 31, 2009 (Ref. 20).

- The proposed rule would clarify MRO actions with regard to invalid validity test results due to high pH values (between 9.0 and 9.5). This would result in some incremental effort on the part of the MRO (e.g., on the order of an hour per occurrence to review such results), but the cost would be incurred infrequently (i.e., for a subset of invalid specimens) so the total cost of the change would be small. This change would enhance FFD program integrity and the protection of individual rights.

- The proposed rule would require the MRO to document a verbal request from a donor to test Bottle B of a split specimen or retest a single specimen. This change would ensure that a record of the donor's request is documented and would confirm that the request was made in a timely manner (required by 10 CFR 26.165(b)(2) to be within 3 business days of the donor being informed of the MRO-verified drug positive, adulterated, or substituted validity test result). This change would enhance consistency with the 2008 HHS Guidelines, transparency of the testing process, and due process afforded to the donor.

- The proposed rule would require the testing of any specimen collected during a post-event testing situation in which a testing refusal was determined during the collection process. Previously, any specimen collected would be discarded. In an effort to improve the root-cause evaluation process associated with accidents, testing of any urine specimen collected would be required in order to ensure that all available information is obtained to support the evaluation of human performance associated with the event. 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, the incremental cost associated with this rule change would be negligible (i.e., the cost of testing a specimen for an infrequent event).

4.2.5 Data Sources

The analysis used the following data sources:

- *Affected entities*: The determination of 67 affected entities, also called sites in the analysis, is based on the CY 2014 FFD program performance information reported to the NRC under 10 CFR 26.717. The analysis does not include data for any site that already has entered decommissioning (i.e., Crystal River Unit 3, Kewaunee, San Onofre Units 2 and 3, and Vermont Yankee), or announced early plant closure (i.e., FitzPatrick, Oyster Creek, and Pilgrim) and would cease operations before or during calendar year 2019 and no longer be subject to 10 CFR Part 26.[21]

- *Site-specific drug and alcohol testing data*: Appendix A to this document presents the NRC FFD program performance data on the total number of drug tests conducted as well as the total number of positive, adulterated, substituted, and refusal to tests results by site for CY 2009 through CY 2014. The NRC staff used the average of 6 years of testing data, which accounts for several outage cycles for an operating power reactor.

- *Workforce to receive training on policy changes*: Each site reports its workforce subject to 10 CFR Part 26 random testing in its annual FFD program performance report submission to the NRC as required by 10 CFR 26.717. This information is the best source available to the NRC of the workforce size that would require training on the rule changes. The NRC's analysis of CY 2009 through CY 2014 submissions determined that the average overall workforce size subject to 10 CFR Part 26 testing in a year is 107,620.

- *NRC drug testing information*: The "Summary of Fitness for Duty Program Performance Reports for Calendar Year 2013" (Ref. 6) and FFD program performance data received for CY 2014 (the agency has not yet published the summary report) are the sources of NRC licensee and other entity drug testing data used in the analysis. In the base case estimate, the NRC staff used the 6-year average of data from CY 2009 through CY 2014 for the following:

  – number of drug tests conducted annually = 157,632
  – positive rate for amphetamines (0.047 percent)
  – positive rate for cocaine (0.072 percent).

- *Reactors under construction (test results)*: The NRC staff has modeled the drug tests to be performed and the positive results to be expected for the units currently under construction at Summer (Units 2 and 3) and Vogtle (Units 3 and 4) based on the FFD program performance data of the co-located operating sites. Because these units under construction are anticipated to be completed in CY 2019 and CY 2020, the workforces subject to testing and the drug use profile of those individuals are expected to be more analogous to the workforce at the co-located operating sites than the current construction workforce. For example, for Vogtle Units 3 and 4, the analysis used the test results at Vogtle Units 1 and 2 as the anticipated testing performance of these units once operational. The effect of this assumption is a slightly lower baseline of positive drug tests.

- *Percent change in positive rates (amphetamines and cocaine)*: These rates are based on an NRC staff analysis of MRO-verified drug test results from CY 2010 and CY 2011

[21] As stated in Note 15, this set of sites reflects the NRC's understanding of licensees' plans to decommission at the time this regulatory analysis was prepared. The costs and benefits of the rule would change if the number of facilities that decommission changes over the timeframe considered in this analysis.

for three DOT modal administrations (i.e., Federal Aviation Administration (FAA), Federal Transit Administration (FTA), and Federal Railroad Administration (FRA)). Use of MRO-verified results is important for Schedule II drugs because these drugs can be legally prescribed to treat a medical condition (e.g., amphetamines may be prescribed to treat attention deficit disorder) and so the results could be downgraded to a negative result upon medical doctor review. Use of MRO-verified results ensures that the detection improvements modeled are based on illegal drug use and not legitimate prescription use. In addition, to limit the potential differences between drug use among the NRC- and DOT-covered workforces, the change in positive testing rate from CY 2010 through CY 2011 is used to estimate detection improvements from lower testing cutoff levels. The use of positive test result data for modeling over longer periods of time (e.g., CY 2010 through CY 2014) would more likely include other factors, such as workforce use trends.

  – The NRC staff assumes that positive laboratory test results for amphetamines will be confirmed as illegal drug use or legal drug misuse by an MRO 75 percent of the time.

  – The NRC staff assumes that all cocaine positive laboratory test results will be confirmed as illegal drug use or legal drug misuse by an MRO. It is unlikely that an individual subject to 10 CFR Part 26 would have recently been subject to a medical procedure for which cocaine might have been used (e.g., nasal or throat surgery, an intubation procedure) and then returned to work before the medical condition had resolved and the individual was able to physically return to work.

- *Expected positive rates for the new drugs included in the testing panel (6-AM and Ecstasy drugs)*: The NRC staff based these rates on its analysis of HHS-certified laboratory drug test results from DOT testing after DOT implemented the 2008 HHS Guidelines changes starting October 1, 2010. While an MRO did not verify these laboratory data, these substances are Schedule I (illegal drugs with no medical use permitted in the United States). Also, MRO-verified data for the DOT modal administrations were not available for these substances, unlike for the amphetamines and cocaine positive results. The positive rate used in the analysis for each drug is based on the average positive rate for CY 2010 through CY 2014:

  – 6-AM = 0.017 percent
  – Ecstasy drugs = 0.004 percent.

- *Specimen testing costs*: The analysis used input from stakeholders received during and after public meetings held on the proposed rule and the professional judgment of the NRC staff, when necessary. Appendix B lists the data sources for these inputs.

- *Special analyses testing of specimens collected under direct observation (suspect specimens)*: E-reported FFD program performance data provide detailed information on each subversion attempt. Table 4-2 presents information on the total number of subversion attempts confirmed in CY 2011 through CY 2014, the number of subversion attempts confirmed through the testing of specimens collected under direct observation, the percentage of subversion attempts determined through the testing of specimens collected under direct observation, and the percentage of all specimens collected each year that are suspect specimens collected under direct observation and that test positive.

Table 4-2. Suspect Specimens Collected Under Direct Observation

Year	Total Number of Subversion Attempts	Number of Subversion Attempts Confirmed by Testing of Specimens Collected under Direct Observation	Percentage of Subversion Attempts Confirmed Through the Testing of Specimens Collected under Direct Observation	Percentage of Total Specimens Collected Each Year that are Suspect Specimens Collected under Direct Observation and Test Positive
2011	123	42	34.1%	0.030%
2012	158	55	34.8%	0.035%
2013	145	44	30.3%	0.029%
2014	187	63	33.7%	0.038%

- *Special analyses testing of dilute specimens:* Beginning in CY 2013, changes to the e-reporting forms permitted the uniform collection of data on the number of dilute specimens subject to specimen analyses testing (i.e., 652 specimens in CY 2013 and 834 specimens in CY 2014). By comparison, the number of dilute specimens that tested positive during special analyses testing has been collected uniformly in the e-reporting system since CY 2011. Based on CY 2014 FFD program performance report data, 92 percent of licensees and other entities (69 of 75 sites) have voluntarily adopted the optional special analyses testing of dilute specimens in 10 CFR 26.163(a)(2).

Appendices B, C, and D give the assumptions and data sources used in the analysis.

4.2.6 Assumptions

The NRC staff made the following assumptions to quantify the costs and benefits of the proposed rule alternative:

- The NRC staff estimates on the expected positive testing rates for 6-AM and Ecstasy drugs are based on the HHS-certified laboratory test results for DOT drug tests performed from CY 2010 through CY 2014. These testing data represent a comprehensive set of annual drug testing results (approximately 5 to 6 million tests per year) for a federally regulated industry (the transportation industry) with safety- and security-sensitive positions comparable to those in the commercial nuclear industry. Comparison of DOT and NRC drug testing data documented in the Regulatory Basis (Ref. 31) for this proposed rule reveals that, in general, DOT positive testing rates historically have been higher than in the workforce subject to testing under 10 CFR Part 26. In CY 2011, for example, DOT positive testing rates were about 4.5 times greater than the NRC rates for cocaine and about 9 times greater for amphetamines. This difference can be explained in part by the fact that DOT data are laboratory results that have not been MRO verified (i.e., positive rates can be higher for Schedule II drugs, which can be medically downgraded by the MRO if an acceptable medical explanation for use exists), whereas the NRC results are MRO verified. In the case of 6-AM and Ecstasy drugs, each is a Schedule I drug and therefore must be verified by an MRO as positive (no medical use is authorized in the United States for these substances). In the case of the expected increase in positive results for amphetamines and cocaine, the NRC staff believes that it is reasonable to use the incremental change in DOT positive testing rates after the Department implemented the 2008 HHS Guidelines as a basis for forecasting the increased number of expected

positive test results that would result from the proposed rule changes. Using a limited timeframe to measure the detection improvement changes (from CY 2010 through CY 2011) minimizes differences in drug use that may be occurring between these populations. For heroin and Ecstasy drugs, the analysis modeled the detection of these drugs by taking the average annual DOT positive rate from October 2010 (when the Department began implementing the 2008 HHS Guidelines) through CY 2014.

- The NRC staff evaluated 6 years of site-specific FFD program performance testing data (CY 2009 through CY 2014) to establish the baseline estimates used for tested populations and positive testing rates for substances evaluated in the regulatory analysis. The staff also used this time series of data to determine how certain inputs could be expected to vary in order to establish realistic ranges for use in the uncertainty analysis.

- The NRC staff used FFD program performance testing data (Ref. 6) as the basis to forecast the future positive testing rates for amphetamines, cocaine, dilute specimens, and suspect specimens (subversion attempts). The FFD program performance data include results from construction sites, which have had higher positive testing rates than all other types of sites. However, as is evident in Appendix A, the number of tests conducted and the number of positive results each year were most influential on results in CY 2012 through CY 2014 (the analysis models testing data from a longer period of time, CY 2009 through CY 2014, when construction site testing was low or comparable to that of operating sites). Also, only 2 of the 59 power reactor sites included in the analysis have power reactors under construction. Therefore, while including the construction site test results with the other site results yields higher values for the number of positive test results than the values that would be expected when the current nuclear plant construction programs complete construction in CY 2020, the impact on the results is limited because of the time period of the data used in the analysis and the variability in testing conducted at each of the sites during the various phases of construction. It is also important to note that the test results reflected in Appendix A include alcohol positive results. For example, an analysis of FFD program performance data for construction sites from CY 2010 through CY 2014 indicates that approximately 14.3 to 16.7 percent of the positive results each year were from alcohol positive tests.

- Because of the prevalence of attempts to subvert the drug testing process, the positive test rates used as the current FFD program testing rates for amphetamines, methamphetamines, and cocaine could be higher than reported. The model forecasts detection improvements using the average positive rate for these substances from CY 2010 through CY 2014. Because two-thirds of those identified as subverting a test do not submit a specimen for testing (approximately 80 to 100 individuals per year), the drug(s) in a donor's body will not be detected and captured in the total results for the year.

Appendices B, C, and D document the assumptions used in the analysis. Section 5.2 documents the inputs and results of the uncertainty analysis.

5. Results

This section organizes the analytical results into five sections. Section 5.1 presents results on the benefits and costs of the proposed rule. Section 5.2 evaluates the uncertainties in the benefit and cost estimate and identifies those uncertain variables that most affect the variation in the results. Section 5.3 addresses the disaggregation results for each of the regulatory initiatives that comprise the proposed rule. Section 5.4 contains the evaluation of changes in the proposed rule in accordance with 10 CFR 50.109, "Backfitting" (Ref. 8), 10 CFR 52.98, "Finality of combined licenses; information requests" (Ref. 10), and 10 CFR 70.76, "Backfitting" (Ref. 9). Section 5.5 describes the information required for review by the Committee to Review Generic Requirements (CRGR).

5.1 Benefits and Costs of the Proposed Rule

This section discusses the benefits and costs estimated for the proposed rule (as summarized in Tables 5-1 and 5-2) and for each quantifiable regulatory initiative contained in the proposed rule (as summarized in Table 5-3). Sections 5.1.7 through 5.1.10 describe the qualitatively evaluated attributes in the analysis.

The proposed rule (Alternative 2) would result in an estimated net cost of between ($2.7 million) and ($3.6 million), at a 7-percent and 3-percent discount rate, respectively. These costs are associated with three affected attributes—industry implementation, industry operation, and NRC implementation. These numbers include averted training costs (i.e., quantified benefits) to industry operation associated with additional individuals testing positive during pre-access drug testing.

Appendix C provides details on the industry's and the NRC's incremental activities that would be required under the proposed rule and estimates the one-time and annual costs associated with these activities. This analysis considers the potential costs associated with required sanctions resulting from additional positive test results. The regulations in 10 CFR 26.75(e) require that a first positive drug or alcohol test result must lead to termination of the individual's unescorted access authorization for at least 14 days. For a second positive drug or alcohol test result, 10 CFR 26.75(e) requires a 5-year denial of access (Ref. 1).[22]

[22] In practice, some affected entities may take additional actions in response to positive drug test results, which may involve staffing actions such as compensating other staff for overtime to cover the assignments of the individual who committed the FFD violation or hiring and training a replacement. The NRC staff assumes that the costs associated with staffing actions in response to any additional positive drug test results each year from the proposed rule would be negligible for the following reasons. First, data collected by the NRC on existing FFD programs indicate that approximately 68 percent of positive test results occur during pre-access testing (Ref. 6). The NRC staff assumes that this historical trend will continue, such that 68 percent of the additional positive drug test results would not result in costs associated with staffing actions because these individuals are detected during pre-access testing. Second, existing FFD program performance data indicate that C/V staff account for 70 percent of the remaining (non-preaccess) positive drug test results, and the NRC staff assumes that this historical trend will continue. Licensees typically impose a "zero tolerance" policy on C/Vs, which are primarily fungible employees, so individuals with positive test results are immediately replaced with another C/V employee. Removing the estimated positive test results associated with pre-access testing and C/V staff leaves 10 percent of the estimated additional positive test results attributable to licensee employees under random, for-cause, post-event, and followup testing conditions. For this analysis, the NRC staff assumes that these additional positive test results are evenly distributed across the industry, resulting in an average of approximately 0.1 positive test result per site per year.

The NRC staff assumes that Alternative 2 would 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.

As benefits, the proposed rule is estimated to result in a 10- to 12- percent increase in the number of individuals identified each year using illegal drugs, misusing illegal 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 proposed rule would maintain the existing performance objective in 10 CFR 26.23(d) that requires FFD programs to "provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs." Based on the analysis of annual FFD program performance data submitted to the NRC by licensees and other entities, the workplaces subject to 10 CFR Part 26 testing are not free from the presence and effects of illegal drugs.

Licensees and other entities also may 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 followup testing: Unlike C/V workers, licensees may provide a second chance to their employees who test positive for a drug. As a result, each of these individuals who successfully received treatment and returns to the workforce will be subject to a 10 CFR Part 26 followup testing program. If pre-access testing detects drug use by the individual, then the cost of conducting followup testing on an individual would be averted.

The proposed rule changes also would improve regulatory efficiency through regulatory and compliance improvements, including by harmonizing definitions and procedures with those described in the 2008 HHS Guidelines, eliminating dual regulation of HHS-certified laboratories, and clarifying ambiguous or imprecise regulatory language in 10 CFR Part 26.

Table 5-1. Summary of Overall Benefits and Costs (Quantitative and Qualitative), Alternative 2 (Proposed Rule)

Benefits	(Costs)
Estimated 10- to 12-percent increase in detection of individuals using drugs or attempting to subvert the drug testing process. This equates to approximately 95 individuals per year or 2,375 individuals over the 25-year time period of the analysis. **Public Health (Accident):** Identification of additional individuals using drugs and denying them unescorted access authorization would reduce the risk that public health would be affected by an accident resulting from human performance issues associated with drug-induced impairment. **Occupational Health (Accident):** Identification of additional individuals using drugs and denying them unescorted access authorization would reduce the risk that occupational health would be affected by an accident resulting from human performance issues associated with drug-induced impairment. **Offsite Property:** Identification of additional individuals using drugs and denying them unescorted access authorization would reduce the risk that offsite property would be affected by an accident resulting from human performance issues associated with drug-induced impairment. **Onsite Property:** Identification of additional individuals using drugs and denying them unescorted access authorization would reduce the risk that onsite property would be affected by radiological releases resulting from human performance issues associated with drug-induced impairment. **Regulatory Efficiency:** Harmonizing definitions and procedures with those in the 2008 HHS Guidelines, addressing dual regulation of HHS-certified laboratories, clarifying ambiguous rule language, providing additional regulatory flexibility in 10 CFR Part 26, and enhancing donor due process provisions would improve regulatory efficiency. **Safeguards and Security Considerations:** Increased assurance that individuals are trustworthy and reliable by enhancing the detection and deterrence of illegal drug use, legal drug misuse, and attempts to subvert the drug testing process would improve safeguards and security. **Other Considerations:** The deterrent of a drug testing program would provide benefits to industry in that it would eliminate additional individuals prone to illegal drug use and legal drug misuse from seeking employment in 10 CFR Part 26 regulated positions. Industry benefits from fewer drug users in the workforce may include increased worker productivity, fewer sick days, less turnover in positions, reduced number of job-related accidents, reduced number of disability claims, and reduced likelihood of equipment damage as a result of impairment from the use of drugs (6-AM, amphetamine, cocaine, Ecstasy, and methamphetamine).	**Industry Implementation, Industry Operation** (25-year time period of the analysis) ($2.4 million) using a 7% discount rate ($3.4 million) using a 3% discount rate **NRC Implementation** ($273,000) **Total Net Costs** ($2.7 million) using a 7% discount rate ($3.6 million) using a 3% discount rate

Table 5-2. Summary of Total Benefits and Costs to Industry (One-Time and Annual)

Total Benefits and (Costs)				Average per Site[1]	
One-Time Benefit (Cost)	Annual Benefit (Cost)	Net Present Value (7 percent)	Net Present Value (3 percent)	One-Time Benefit (Cost)	Annual Benefit (Cost)
($337,090)	($168,594)	($2,439,343)	($3,360,912)	($5,031)	($2,516)

1 *Average cost per site calculated by dividing the total industrywide cost by the number of sites (67).*
2 *In addition to these industry costs, the NRC implementation costs as a result of the final rule are estimated to be ($273,000).*
3 *Results stated in 2017 dollars.*

Table 5-3. Summary of One-Time and Annual Benefits and Costs to Industry, by Regulatory Initiative

Total Benefits and (Costs)			Average per Site[1]
Annual Benefit (Cost)	Net Present Value (7 percent)	Net Present Value (3 percent)	Annual Benefit (Cost)
Costs to implement drug testing program changes (One-time policy, procedure, and training costs)			
-	($337,090)	($337,090)	-
1. Lowered initial and confirmatory testing cutoff levels for amphetamines and cocaine metabolites			
($13,733)	($171,241)	($246,309)	($205)
2. Expanded initial drug testing panel to include 6-AM and revised confirmatory testing cutoff level for 6-AM			
($136,555)	($1,702,750)	($2,449,188)	($2,038)
3. Expanded initial and confirmatory drug testing panels to include Ecstasy			
($94,871)	($1,182,978)	($1,701,563)	($1,416)
4. Required special analyses testing of dilute specimens and specimens collected during suspected subversion attempts			
($11,256)	($140,355)	($201,882)	($168)
5. Averted training costs as a result of pre-access testing			
$87,821	$1,095,071	$1,575,120	$1,311
TOTAL			
($168,594)	*($2,439,343)*	*($3,360,912)*	*($2,516)*

1 *Average cost per site is calculated by dividing the total industrywide cost by the number of sites (67).*
2 *Results stated in 2017 dollars.*

Sections 5.1.1 through 5.1.6 discuss the quantified one-time costs and annual costs associated with each of the five regulatory initiatives. Sections 5.1.7 through 5.1.10 present further discussion on qualitatively evaluated elements in the analysis. Appendices B, C, and D provide the specific inputs and calculations that resulted in the summary results presented in the tables in this section.

5.1.1 One-Time Policy, Procedure, and Training Costs

The five regulatory initiatives would impact FFD program policies, procedures, and training. Specifically, licensees would need to update FFD program policies and procedures to account for the new drug testing protocols and inform individuals who are covered by the FFD program

of the changes in policies and procedures. In addition, the proposed rule changes would require each FFD program to update three contracts—two with its HHS-certified laboratories (the primary and secondary labs) and one with its BPTS supplier to reflect the new drug testing criteria. Additionally, sites using LTFs for initial drug testing would need to train laboratory technicians on the new protocols and validate the immunoassays that would change because of lower cutoff levels and the inclusion of additional substances in the testing panel.

The NRC staff assumes that licensees would pursue the least-cost approach to implementing the proposed rule. With respect to informing individuals already subject to an FFD program on the changes in the FFD program policies and procedures, the analysis estimates that 80 percent of sites would incorporate this information into the annual refresher training required by 10 CFR 26.29(c). This approach would not result in an incremental change in costs of training individuals on the FFD policy changes because the refresher training already includes time to update individuals on changes in the FFD program from the previous training. However, the NRC staff does estimate that the remaining 20 percent of sites would distribute information on FFD program changes outside the annual refresher training process and would provide each individual a summary of the FFD policies and procedures to read and sign an acknowledgment of receipt of the information.[23]

In addition to one-time industry costs, the NRC would incur implementation costs. The staff expects the proposed rule to result in a total one-time cost of ($273,000) to the NRC to complete the rulemaking (i.e., analyze public comments, hold public meeting(s), and develop the final rule) and issue regulatory guidance.

In summary, the one-time costs include the following:

- one-time cost to industry: ($337,090)[24]
- one-time average cost per site: ($5,031)
- one-time cost to the NRC: ($273,000).

Table 5-4 summarizes the one-time costs by implementation activity for industry and the NRC.

[23] The NRC staff estimates that approximately 20 percent of sites (i.e., 14 of 67 sites) would conduct an independent training on the rule changes (in accordance with labor agreements) instead of including the information update as part of annual FFD refresher training.

[24] This cost could be as high as ($1.4 million) if all sites choose to hold trainings and distribute information on FFD program changes outside of annual refresher training required by 10 CFR 26.29(c) (i.e., if sites do not pursue the least-cost approach).

Table 5-4. One-Time Implementation Costs

Affected Entity	Implementation Activity	Base Estimate Cost (Undiscounted, 2017 dollars)
Industry	Update policies and procedures	($6,102)
	Inform employees of policy change	($289,720)
	Revise contract with the primary HHS-certified laboratory	($12,177)
	Revise contract with the backup HHS-certified laboratory	($12,177)
	Revise contract with BPTS supplier	($6,102)
	Train LTF technicians	($3,438)
	Validate drug testing assays at LTF	($7,374)
	Total for all sites	**($337,090)**
	Average cost per site	**($5,031)**
NRC	Final rule and regulatory guide development	**($273,000)**

5.1.2 Lowered Initial and Confirmatory Drug Testing Cutoff Levels for Amphetamines and Cocaine Metabolites

Lowering the testing cutoff levels for amphetamines and cocaine metabolites would increase the timeframe (i.e., the window of detection) in which these drugs can be detected in an individual's urine specimen after use. As a result, the NRC staff anticipates that the use of lower testing cutoffs will increase the number of individuals who test positive for amphetamines and cocaine metabolites. Licensees will incur the costs associated with confirmatory testing and subsequent actions taken when an individual tests positive (i.e., on the part of the FFD program staff, the MRO, and the donor). These incremental costs are estimated as follows:

- total annual cost to industry: ($13,733)
- average annual cost per site: ($205)

In making these changes to maintain reasonable assurance of a drug-free workplace, the NRC staff estimates that this regulatory initiative would result in 43 additional confirmed positive test results, as presented in Table 5-5. Therefore, lowering the testing cutoff levels for amphetamines and cocaine metabolites would provide additional assurance that persons who are using illegal drugs or misusing legal drugs would be identified and denied unescorted access authorization than under the current 10 CFR Part 26 framework. Appendices B and C provide additional information on the estimated increase in positive test results.

Table 5-5. Additional Amphetamines and Cocaine Positives from Lower Testing Cutoff Levels (Estimated Total for All Sites)

Substance	Number of Additional Confirmed Positive Test Results Projected per Year
Amphetamines	22
Cocaine	21

5.1.3 Expanded Initial Drug Testing Panel to Include 6-AM and Revised Confirmatory Testing Cutoff Level for 6-AM

Licensees would incur costs to conduct initial testing of each urine specimen for 6-AM (the metabolite of the illegal drug heroin), which would increase the number of urine specimens identified as containing 6-AM. Licensees also would incur costs associated with any specimens that test positive on confirmatory testing and the subsequent actions taken when an individual tests positive (i.e., on the part of the FFD program staff, the MRO, and the donor). These incremental costs are estimated as follows:

- total annual cost to industry: ($136,555)
- average annual cost per site: ($2,038)

In making these changes to maintain reasonable assurance of a drug-free workplace, the NRC staff estimates that this regulatory initiative would result in an additional 27 confirmed positive test results per year, as presented in Table 5-6. Therefore, expanding the initial drug testing panel to include 6-AM and revising the confirmatory testing cutoff level for 6-AM would provide additional assurance that persons who are using the illegal drug heroin would be identified and denied unescorted access authorization than under the current 10 CFR Part 26 framework. Appendices B and C provide additional information on the estimated increase in positive test results.

Table 5-6. Additional 6-AM Positive Results from Expanded Drug Testing Panel (Estimated Total for All Sites)

Substance	Number of Additional Confirmed Positive Test Results Projected per Year
6-AM	27

5.1.4 Expanded Initial and Confirmatory Drug Testing Panels to Include Ecstasy

Licensees would incur costs to conduct initial testing of each urine specimen for MDMA. Licensees also would incur costs associated with any specimens that test positive on confirmatory testing and the subsequent actions taken when an individual tests positive (i.e., on

the part of the FFD program staff, the MRO, and the donor). These incremental costs are estimated as follows:

- total annual cost to industry: ($94,871)
- average annual cost per site: ($1,416)

In making these changes to maintain reasonable assurance of a drug-free workplace, the NRC staff estimates that this regulatory initiative would result in an additional seven confirmed positive test results per year, as presented in Table 5-7. As a result, this proposed change would provide additional assurance that persons who are using illegal drugs would be identified and denied unescorted access authorization than under the current 10 CFR Part 26 framework. Appendices B and C provide additional information on the estimated increase in positive test results.

Table 5-7. Additional Ecstasy Positive Results from Expanded Drug Testing Panel (Estimated Total for All Sites)

Substance	Number of Additional Confirmed Positive Test Results Projected per Year
Ecstasy	7

5.1.5 Required Special Analyses Testing of Dilute Specimens and Specimens Collected during Suspected Subversion Attempts

Licensees would incur costs to conduct mandatory special analyses testing of dilute specimens (presently 10 CFR 26.163(a)(2) provides licensees with the option to conduct this testing, and 92 percent of licensees instituted this testing policy as of CY 2014). Licensees also would incur incremental costs to conduct special analyses testing of specimens collected under direct observation (i.e., specimens collected during suspected subversion attempts). These special analyses requirements would result in incremental improvement with additional costs associated with the newly required confirmatory testing and subsequent actions associated with additional positive test results (i.e., on the part of the FFD program staff, the MRO, and the donor). These incremental costs are estimated as follows:

- total annual cost to industry: ($11,256)
- average cost per site: ($168)

In making these changes to maintain reasonable assurance of a drug-free workplace, the NRC staff estimates that this regulatory initiative would result in an additional 18 confirmed positive test results, as presented in Table 5-8.[25] Therefore, this proposed change would provide additional assurance that persons who are using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process would be identified and denied unescorted access authorization than under the current 10 CFR Part 26 framework. Appendices B and C provide additional information on the estimated increase in positive test results.

[25] Based on trends in subversion attempts (Ref. 6), the majority of the 18 additional confirmed positive test results would be expected to occur during pre-access testing.

Table 5-8. Additional Positive Results from Special Analyses Testing of Dilute and Subversion Specimens (Estimated Total for All Sites)

Specimen Type	Number of Additional Confirmed Positive Test Results Projected per Year
Dilute Specimens	8
Suspect Specimens	10

5.1.6 Averted Costs

The NRC estimates that the proposed rule would result in savings to licensees and other entities (i.e., averted costs) associated with training during the in-processing of licensee employees and C/Vs. Approximately 68 percent of positive test results each year are identified during pre-access testing. As a result, if an individual tests positive for a drug during pre-access testing, any remaining training not completed by that individual at the time of receipt of the confirmed positive test result would result in savings to the licensee or other entity because the individual would immediately be denied unescorted access authorization for failing the required FFD drug test. Appendix E provides additional information.

These incremental savings (averted costs) are estimated to be as follows:

- total annual savings to industry: $87,821
- average savings per site: $1,311

The projected savings associated with the proposed rule are based on the estimated increase in the number of individuals testing positive each year and would be distributed based on the projected number of additional confirmed positives detected.

5.1.7 Workplace Free of Drugs and the Effects of Such Substances

The proposed rule would maintain the performance objective in 10 CFR 26.23(d) that requires FFD programs to "provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs." Based on the analysis of annual FFD program performance data submitted to the NRC by licensees and other entities, the workplaces subject to 10 CFR Part 26 testing are not free from the presence and effects of illegal drugs.

The effectiveness of a drug testing program may erode over time if the workforce uses impairing substances not in the testing panel, if individuals use products and techniques to successfully subvert the drug testing process, and if testing programs do not use technological advancements that enhance drug testing sensitivity. Therefore, the drug testing provisions in 10 CFR Part 26 should remain at least as effective as the national drug testing standard of the 2008 HHS Guidelines and should apply defense-in-depth requirements (e.g., behavioral observation, background checks, collection site security, and specimen collections) to maintain reasonable assurance of a drug-free workplace.

The 2008 HHS Guidelines are a national drug testing standard used by all Federal employee workplace drug testing programs (over 100 Federal agencies[26]) and comparable Federal agency drug testing programs that test civilians, such as those programs implemented by the U.S. Department of Defense, U.S. Department of Energy, U.S. Department of Homeland Security, and DOT. HHS is responsible by law[27] to maintain its guidelines based on the most recent research and lessons learned from Federal employee workplace drug testing programs and from implementation of the HHS Guidelines by HHS-certified laboratories and private entities. HHS also revises its guidelines to address findings and observations from the NLCP and in response to expert and public review.

The NRC historically has incorporated appropriate provisions of the HHS Guidelines into 10 CFR Part 26 apply advancements in drug testing technology and detection methods to address societal changes in drug use, as well as to align the methods and techniques used to subvert the drug testing process with a standard used for testing Federal employees and the majority of civilians tested by Federal agencies. The drug testing panel and cutoff levels specified in 10 CFR Part 26 are currently not in alignment with the 2008 HHS Guidelines.

5.1.8 Safety Vulnerability

The proposed rule would enhance the identification of additional individuals subject to 10 CFR Part 26 who are using illegal drugs, misusing legal drugs, or attempting to subvert the testing process and who are determined not to be fit for duty or not to be trustworthy and reliable, or both. Such a determination would result in a denial of unescorted access to the protected areas of NRC-licensed facilities and other locations and a denial to have access to SSNM or sensitive information. Of the approximately 95 additional individuals determined to be using drugs, 65 would be identified during pre-access testing, preventing each from entering an NRC-licensed facility or accessing information and potentially challenging safety.[28] The remaining 30 individuals would be identified after being granted authorization (i.e., identified during random, for-cause, followup, or post-event testing), during the performance of safety- and security-sensitive duties as described in 10 CFR 26.4.

The identification of these 30 individuals performing safety- and security-sensitive duties enhances the existing regulatory framework to prevent drug-induced impairment (both acute intoxication, as well as the consequences of recent drug use such as withdrawal effects) from causing or contributing to human performance errors that may result in consequences to the safe operation of a licensed facility. For example, an impaired individual could introduce or fail to identify latent failures during maintenance, surveillance, modification, or operation of safety-

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26 The number of Federal agencies using the HHS Guidelines appears in the Office of Management and Budget (OMB) information collection's supporting statement (OMB No. 0930-0158) filed by the Substance Abuse and Mental Health Services Administration for the "Mandatory Guidelines for Federal Workplace Drug Testing Programs," on May 28, 2014. The supporting statement is available at the OMB Web site http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201406-0930-001.

27 Section 503 of Public Law 100–71, 5 U.S.C. Section 7301 note.

28 Most licensees impose a sanction for a pre-access positive drug test result that is more stringent than that required by 10 CFR 26.75 (i.e., the minimum NRC sanction for a first positive drug test result is a 14 day denial of unescorted access). The NRC analysis of historical FFD program performance data indicates that approximately 68 percent of positive test results occur during pre-access testing (Ref. 6); therefore, the NRC staff estimates that 65 of the 95 additional positive drug test results and subversion attempts each year would be identified at pre-access testing.

and security-related SSCs, and these failures could contribute to an unplanned occupational exposure, personal safety issues, unplanned radiological releases, an accident, or a transient.

Similarly, the labor categories of individuals identified as testing positive for drugs includes licensed operators, supervisors, and managers whose job performance includes facility operations; responding to accidents, transients, and fires; directing the workforce; and staffing the Emergency Operations Facility and Technical Support Center upon execution of the site emergency plan. An evaluation of FFD program performance data from CY 2012 through CY 2014 (i.e., 24-hour events reported to the NRC under 10 CFR 26.719) demonstrates that more than 30 individuals each year test positive for drugs (including amphetamine and cocaine, the cutoff levels for which would be lowered by the proposed rule) or alcohol. Consequently, any programmatic assurance that helps ensure that the workforce is fit for duty reduces the safety vulnerability.

This safety outcome is consistent with the original 10 CFR Part 26 rule (Ref. 5), which stated "[t]he NRC cannot be confident of the individual's ability to limit the use of addictive substances to situations that do not adversely affect plant safety" (54 FR 24470; June 7, 1989) and that "there is an underlying assumption that workers will abide by the licensee's policies and procedures, [therefore] any involvement with illegal drugs shows that the worker cannot be relied upon to obey laws of a health and safety nature, indicating that the individual may not scrupulously follow rigorous procedural requirements with the integrity required in the nuclear power industry to assure public health and safety" (54 FR 24468; June 7, 1989).

5.1.9 Security Vulnerability

The proposed rule would lead to the identification of additional individuals determined not to be fit for duty or not to be trustworthy and reliable, or both, because of their use of illegal drugs, misuse of legal drugs, or attempts to subvert the drug testing process. This would strengthen the defense-in-depth regulatory framework provided by the authorization requirements in 10 CFR Part 26, Subpart C, "Granting and Maintaining Authorization," and 10 CFR Part 73 (Ref. 16) for both commercial power reactors and Category I fuel cycle facilities.

This security vulnerability would also be reduced, in part, because once unescorted access authorization is denied, the individual cannot act as an insider threat—an important security determination linked to the conduct of drug testing. To help identify an insider threat, as required by 10 CFR 73.55(b)(1), commercial power reactor licensees "shall establish and maintain a physical protection program...which will have its objective to provide high assurance that activities involving special nuclear material are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety." One requirement that helps achieve this general performance objective is the provision in 10 CFR 73.55(b)(9) that licensees shall establish, maintain, and implement an insider mitigation program (Ref. 32). This program, as described in 10 CFR 73.55(b)(9)(i), "must monitor the initial and continuing trustworthiness and reliability of individuals granted or retaining unescorted access authorization to a protected or vital area, and implement defense-in-depth methodologies to minimize the potential for an insider to adversely affect, either directly or indirectly, the licensee's capability to prevent significant core damage and spent fuel sabotage." The insider mitigation program shall also include, in part, elements from the FFD program described in 10 CFR Part 26. Consequently, the regulatory framework establishes a strong link between the FFD-related authorization provisions in 10 CFR Part 26 and the physical protection access authorization requirements described in 10 CFR Part 73.

An insider threat is an individual who cannot be trusted or relied upon to follow licensee policies and procedures or Federal regulations designed, implemented, and maintained to protect public health and safety, promote the common defense and security, and protect the environment. An insider threat could physically or remotely (through electronic means) cause inoperable safety- or security-related SSCs, a loss of facility control, radiological sabotage at a commercial power reactor, or the theft or diversion of formula quantities of SSNM from a Category I fuel cycle facility. Additionally, individuals who use illegal drugs may be co-opted or subverted by adversaries.

The original 10 CFR Part 26 rule (54 FR 24470; Ref. 5) states the following:

> The NRC believes that the reliability, integrity, and trustworthiness of persons working within nuclear power plants is important to assure public health and safety. The granting of a license is based on the assumption that workers will abide by the licensees' policies and procedures in all areas. Indications of lack or reliability, integrity or trustworthiness, therefore, even so far as they pertain to off-site behaviors, are relevant to the NRC's need to assure that nuclear power plants are operated safely.

The NRC further discussed these positions in the 2008 FFD final rule (73 FR 16971; Ref. 3):

> Part 26 and the access authorization requirements [of 10 CFR Part 73] each contain provisions that require establishing the trustworthiness and reliability of personnel before granting unescorted access authorization to the protected area of nuclear power plants.

Consequently, the FFD program objective to identify individuals using illegal drugs reduces a potential security vulnerability. The failure to identify security personnel who use illegal drugs or misuse legal drugs could significantly challenge the effectiveness of the site insider mitigation program (10 CFR 73.55(b)(9)); security plan (10 CFR 73.55(c)); security search program (10 CFR 73.55(h)); and the detection and assessment systems that include requirements to conduct surveillance, observation, and monitoring to identify tampering and to detect and deter intruders (10 CFR 73.55(i)). These requirements cannot be effectively implemented if site security personnel are not fit for duty. This is important because many security duties and responsibilities are conducted by security officers who operate alone (i.e., individually) and therefore do not benefit from a team environment, second checks, or backup. As a result, a security officer who is mentally, physically, or psychologically impaired or who does not possess the characteristics of honesty, integrity, trustworthiness, and reliability cannot be relied upon to competently execute site security requirements.

5.1.10 Improve Subversion Detection

The proposed rule would strengthen the methods used to identify persons attempting to subvert the drug testing process. The proposed rule would require all suspect urine specimens to be tested to the LOQ, which is the lowest concentration at which the identity and concentration of a drug can be accurately established. This proposed change increases the licensees' ability to identify individuals who attempt to hide their drug use through subversive techniques or temporary abstention from drug use. The NRC staff estimates that approximately 18 of the additional 95 individuals each year will be identified as attempting to subvert the drug testing process (10 additional individuals with dilute specimens and 8 additional individuals with suspect specimens). An attempt to subvert the drug testing process is a willful act by an

individual to refuse to comply with an NRC-required drug test (see 10 CFR 50.5, "Deliberate Misconduct" (Ref. 8), 10 CFR 26.89(c), and 10 CFR 26.825, "Criminal penalties"). Consequently, these individuals present a potential security vulnerability to the safe and secure conduct of NRC-licensed activities. LOQ testing is consistent with the reasonable assurance performance objectives in 10 CFR 26.23 as the proposal would proactively resolve a known hazard, leverage a testing method used in HHS-certified laboratories, and achieve these improvements at low incremental cost.

5.2 Uncertainty Analysis

To determine the robustness of the costs and net benefits (i.e., benefits minus costs) of the proposed rule, the NRC staff examined how the industry and the NRC costs change as a result of uncertainties associated with the NRC staff's analytical assumptions, input data, and worker drug use behavior. As mentioned in Section 4.2, the NRC staff used Monte Carlo simulation to examine the impact of uncertainty on the estimated net benefits of the proposed rule. These Monte Carlo simulations were performed using the @RISK® software program.[29]

Monte Carlo simulations involve introducing uncertainty into the analysis by replacing the point estimates of the variables used to estimate base case costs and benefits with probability distributions. By defining input variables as probability distributions instead of as point estimates, the researcher can effectively model the effect of uncertainty on the results of the analysis (i.e., the net benefits).

The probability distributions chosen to represent the different variables in the analysis were bounded by the range-referenced input, DOT and FFD historical data, and the NRC staff's professional judgment. When defining the probability distributions for use in the Monte Carlo simulation, summary statistics are needed to characterize the distributions. These summary statistics include the minimum, most likely, and maximum values of a program evaluation and review technique (PERT) distribution[30], the minimum and maximum values of a uniform distribution, and the specified integer values of a discrete population.

For the majority of uncertain variables, the staff used the PERT distribution to reflect the relative spread and skewness of the distribution defined by the three estimates. In cases for which the likelihood of the result was judged to be equally likely within a range, the data were modeled using a uniform distribution defined by the low and high values. In a few cases, the staff used a discrete distribution to model possible outcomes and their likelihood, such as the number of sites using an LTF.

Table 5-9 identifies the data elements, the distribution and summary statistic, and the mean value of the distribution that the staff used in the uncertainty analysis.

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29 Information about this software is available online at www.palisade.com.

30 A PERT distribution is a special form of the beta distribution with a minimum and maximum value specified. The shape parameter is calculated from the defined *most likely* value. The PERT distribution is similar to a triangular distribution in that it has the same set of three parameters. Technically, it is a special case of a scaled beta (or beta general) distribution. It can generally be considered to be superior to the triangular distribution when the parameters result in a skewed distribution, as the smooth shape of the curve places less emphasis in the direction of skew. Similar to the triangular distribution, the PERT distribution is bounded on both sides and therefore may not be adequate for some modeling purposes, such as those intended to capture tail or extreme events.

Table 5-9. Variables Used in the Uncertainty Analysis

Data Element	Distribution	Low Estimate	Base Case	High Estimate
Regulated Universe				
Number of sites using an LTF	Discrete	3	6	6
NRC FFD Program Data				
Number of workers subject to a 10 CFR Part 26 FFD program	PERT	101,642	107,620	113,949
Number of drug tests conducted per year under 10 CFR Part 26	PERT	150,211	157,632	168,879
Average percentage of total positive, adulterated, substituted, and refusal to test results occurring at pre-access testing	PERT	64.8%	67.8%	69.0%
Hourly Wage Rates (dollars per hour)				
Clerical	PERT	$20.66	$21.69	$22.73
Facility Worker (weighted average of licensee employees and C/V workers)	PERT	$61.85	$63.86	$68.45
FFD Manager	PERT	$34.43	$44.21	$49.66
FFD Staff	PERT	$33.19	$36.87	$44.25
LTF Laboratory Technician	PERT	$32.90	$36.55	$43.86
LTF Laboratory Supervisor	PERT	$55.31	$61.45	$73.74
Legal	PERT	$110.62	$122.91	$147.49
MRO	PERT	$103.30	$137.73	$172.17
Industry Implementation—Training				
Cost of LTF training materials (per LTF)	PERT	$400	$500	$800
Industry Operations—FFD Drug Testing Costs				
Initial testing for one additional drug at an LTF	PERT	$1.25	$1.50	$1.75
Initial and confirmatory drug testing, HHS-certified laboratory (sites using an LTF for initial testing)	PERT	$23.00	$29.00	$36.00
Testing for 6-AM (sites only using an HHS-certified laboratory)	Uniform	$0.50	$0.75	$1.00
Testing for Ecstasy drugs (sites only using an HHS-certified laboratory)	Uniform	$0.00	$0.50	$0.75
Special analyses testing at an HHS-certified laboratory	PERT	$0.00	$7.75	$15.00
Industry Operations—FFD Drug Testing Rates				
6-AM				
Projected confirmed positive test rate	PERT	0.010%	0.017%	0.022%
Amphetamines				
FFD current confirmed positive test rate	PERT	0.032%	0.047%	0.067%
Projected percent increase in confirmed positive test rate	PERT	0.00%	39.38%	62.35%
Projected percentage of additional positive results that will confirm positive after MRO interview with donor	PERT	50%	75%	75%

Data Element	Distribution	Low Estimate	Base Case	High Estimate
Cocaine				
FFD current confirmed positive test rate	PERT	0.064%	0.072%	0.077%
Projected increase in positive test rate	PERT	11.60%	18.38%	32.85%
Ecstasy Drugs				
Projected confirmed positive test rate	PERT	0.002%	0.004%	0.005%
Dilute Specimens and Specimens Collected during Suspected Subversion Attempts				
Average annual percentage of specimens tested that are dilute and special analyses testing is performed	PERT	0.431%	0.466%	0.501%
Average annual percentage of specimens tested that are dilute and test positive on special analyses testing	PERT	0.001%	0.005%	0.007%
Average annual percentage of specimens tested that are determined to be a subversion attempt and that test positive (suspect specimens that test positive on special analyses testing)	PERT	0.029%	0.033%	0.038%
Projected percent increase in confirmed positive test rate for specimens collected under direct observation	Uniform	0%	20%	25%
Labor Following a Laboratory Positive Test Result or Subversion Event				
MRO subsequent action labor hours	PERT	0.25	0.75	1.00
NRC Implementation				
Staff hours, reflected in full-time equivalent (FTE), to complete the final rulemaking (i.e., analyze public comments, hold public meeting(s), develop the final rule) and issue final regulatory guidance. One FTE is equal to one staff person working full time for 1 year.	PERT	1.4	1.5	2.0

5.2.1 Uncertainty Analysis Results

The staff performed the Monte Carlo simulation by repeatedly recalculating the results, up to 5,000 times. For each analysis iteration, the values identified in Table 5-9 were chosen randomly from the probability distributions that define the input variables. The value of the output variables was recorded for each iteration, and these resulting output variable values were used to define the resultant probability distribution.

For each figure below, 5,000 Monte Carlo simulations were run in which the key variables were changed to assess the resulting effect on costs. The cost distributions illustrated in Figures 5-1 through 5-6 represent the incremental costs from the regulatory baseline of Alternative 1 (Take No Action). As can be seen from Figures 5-1 through 5-6, none of the curves are net beneficial because of the inability to monetize the benefits of this proposed rule.

Figure 5-1. Industry implementation costs

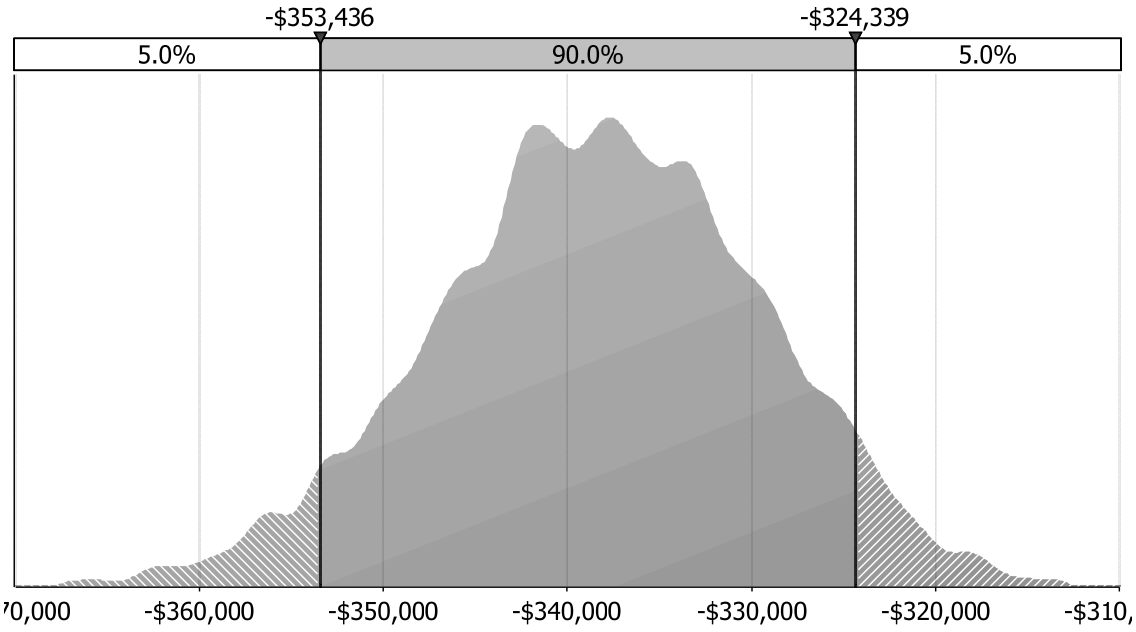

Figure 5-2. NRC implementation costs

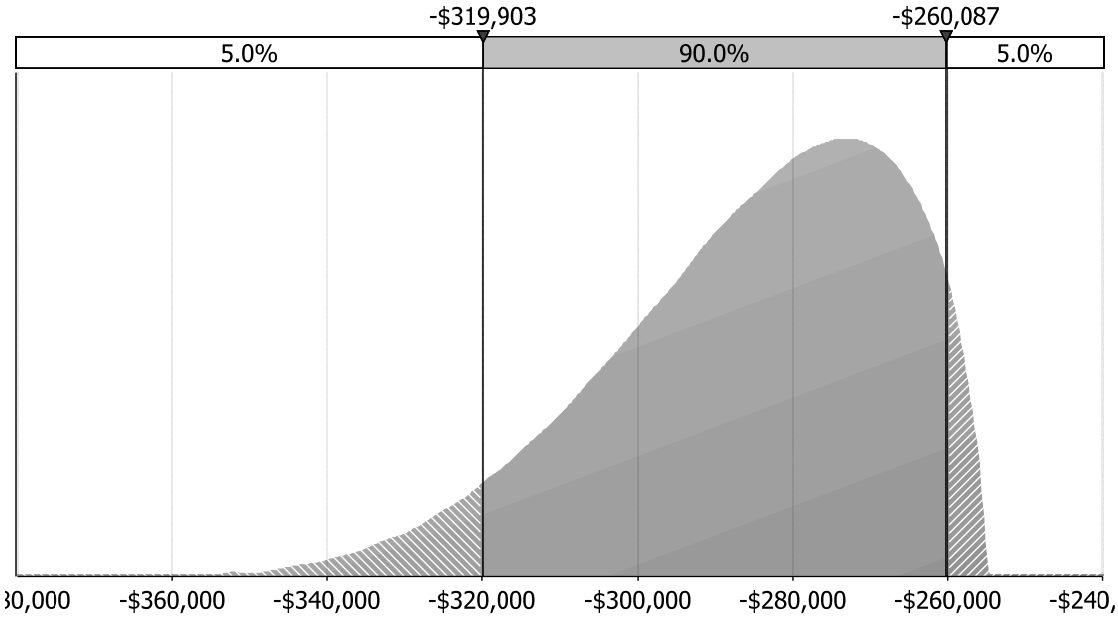

Figure 5-3. Industry operations costs (7-percent discount rate)

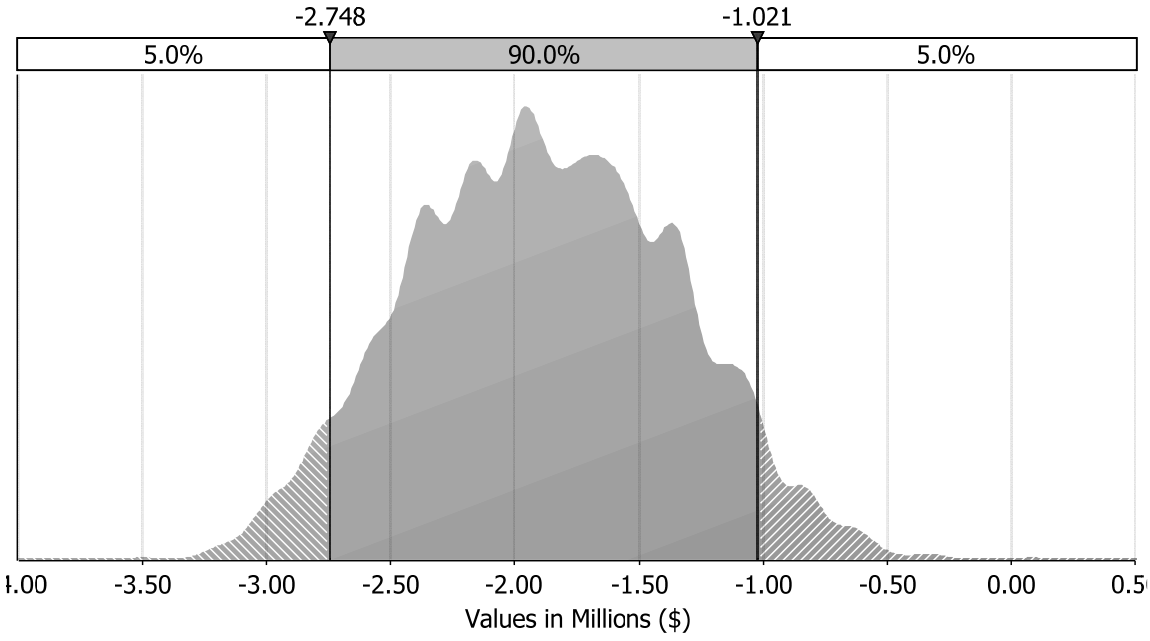

Figure 5-4. Industry operations costs (3-percent discount rate)

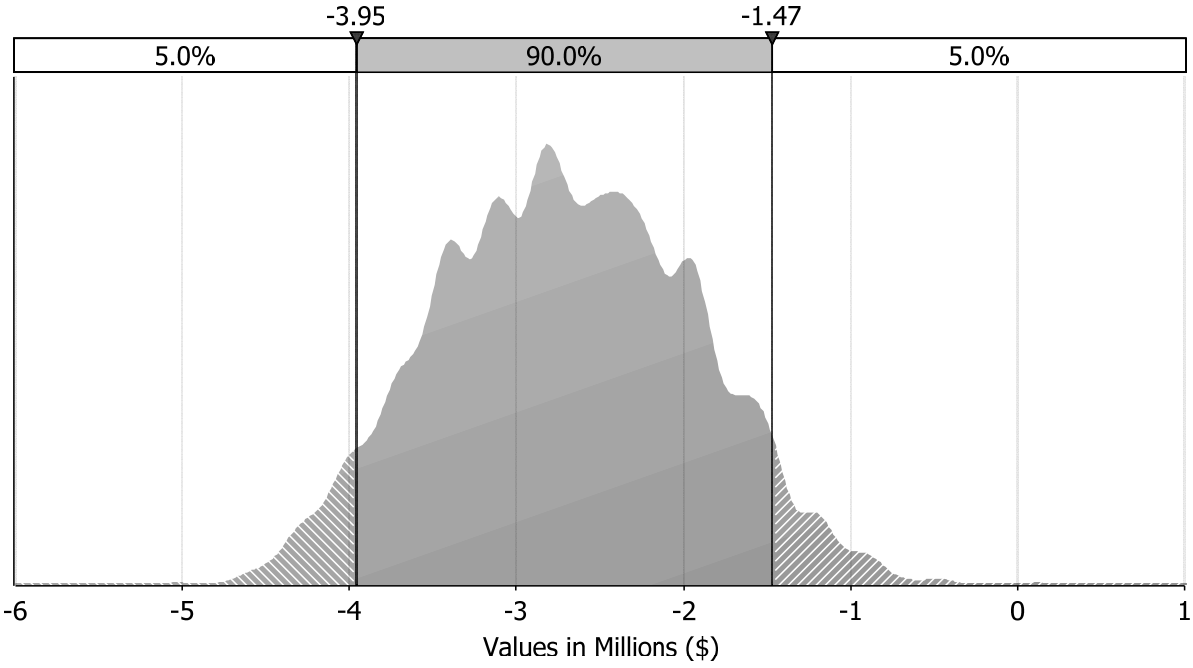

Figure 5-5. Total (7-percent discount rate)

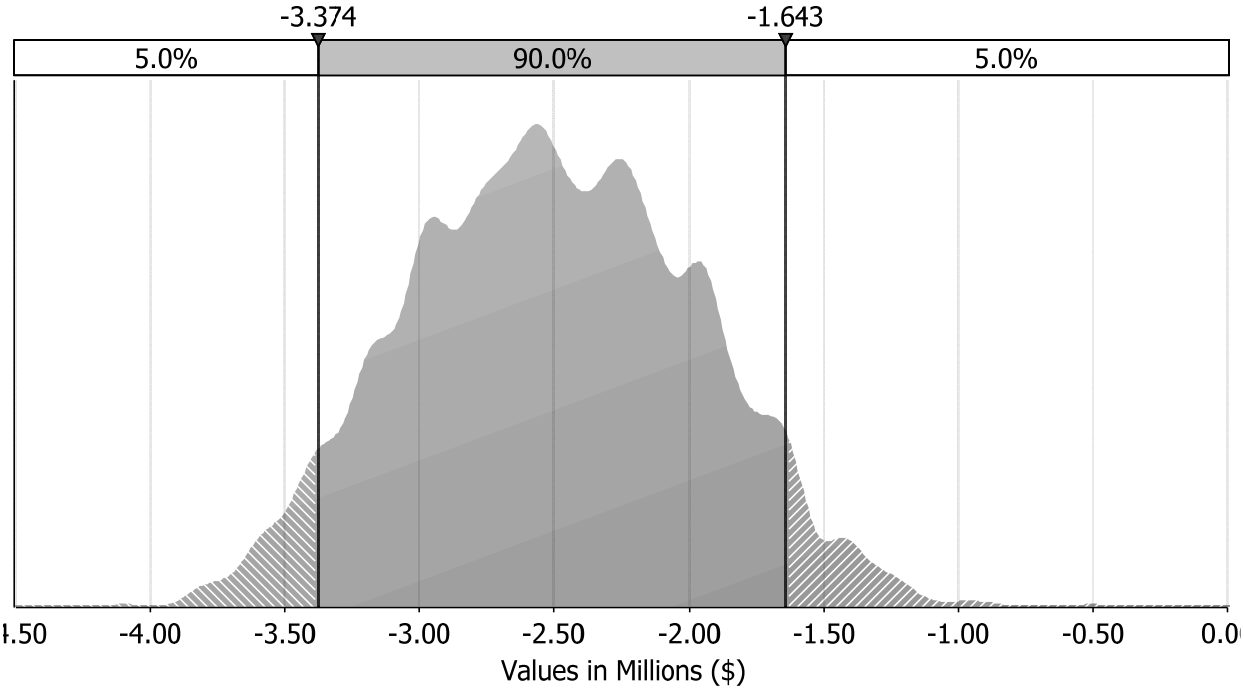

Figure 5-6. Total (3-percent discount rate)

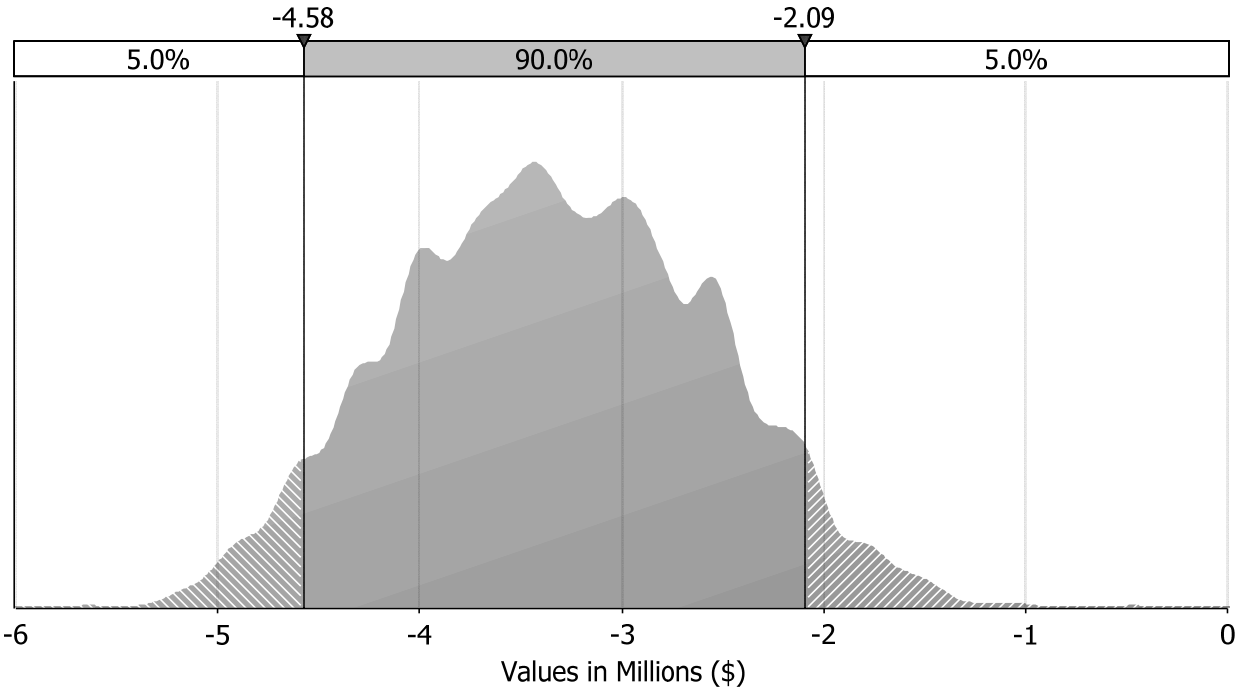

Table 5-10 presents descriptive statistics on the uncertainty analysis. Note that the 5.0 percent and the 95 percent values that appear as vertical lines with a numerical value at the top in Figures 5-1 through 5-6 are reflected in Table 5-10 as the 0.05 and 0.95 values, respectively.

Table 5-10. Uncertainty Results Descriptive Statistics

Uncertainty Result	Uncertainty Results (2017 million dollars)						
	Min	Mean	Mode	Median	Max	0.05	0.95
Industry Implementation	($0.37)	($0.34)	($0.34)	($0.34)	($0.31)	($0.35)	($0.32)
NRC Implementation	($0.35)	($0.29)	($0.29)	($0.28)	($0.25)	($0.32)	($0.26)
Industry Operation (7% Discount Rate)	($3.55)	($1.88)	($2.01)	($1.89)	$0.14	($2.75)	($1.02)
Industry Operation (3% Discount Rate)	($5.11)	($2.71)	($2.89)	($2.72)	$0.21	($3.95)	($1.47)
Total (7% Discount Rate)	($4.16)	($2.51)	($2.52)	($2.52)	($0.45)	($3.37)	($1.64)
Total (3% Discount Rate)	($5.72)	($3.33)	($3.60)	($3.34)	($0.39)	($4.58)	($2.09)

By examining the range of the resulting output distribution in Table 5-10, it is possible to more confidently discuss the potential costs and benefits of the proposed rule. This table displays the key statistical results, including the 90 percent confidence interval in which the net benefits would fall between the 0.05 and 0.95 percentile values.

Figures 5-7 and 5-8 identify the key variables whose uncertainty drives the largest impact on total costs (and averted costs) for this proposed rulemaking. These figures rank the variables based on their contribution to cost uncertainty. Two variables—the costs that HHS-certified laboratories charge sites to conduct testing for Ecstasy and 6-AM—drive the most uncertainty in the costs; the rest of the key variables have less variation.

In addition to estimating the probability distributions for the net benefits of the proposed rule, the staff used the Monte Carlo simulation to determine the variables with the greatest impact on the resulting net benefits. Variables shown to have a large effect on the resulting net benefits may deserve more attention and scrutiny than variables shown to have a small or minimal effect.

To estimate the effect of each variable on the net benefits, the staff performed a regression, with the net benefits modeled as the dependent variable and the inputs as the independent variables. The result of this regression is called a tornado diagram, and it represents in vertical order the variables with the greatest influence on the net benefits. The tornado diagram also displays the resulting impact on the calculated mean value for each of the input variables. Figure 5-7 presents the tornado diagram for the total cost of the proposed rule using a 7-percent discount factor. Similarly, Figure 5-8 presents the tornado diagram for the total cost of the proposed rule using a 3-percent discount factor.

Examining the tornado diagrams provides insight into which inputs have the largest impacts on the results of this quantitative analysis. Figure 5-7 shows that the parameters having the greatest impact on the net benefits of the proposed rule when using a 7-percent discount factor are the uncertainties associated with the potential costs an HHS-certified laboratory may charge a site to perform testing for Ecstasy and 6-AM. The influence of a variable on the output is not only a function of the value of that variable but also of the spread of its distribution. In Figure 5-8, using a 3-percent discount factor, the same parameters appear in the same ranked order as in Figure 5-7.

Figure 5-7. Key variables whose uncertainty drives the largest impact on costs (7-percent net present value)

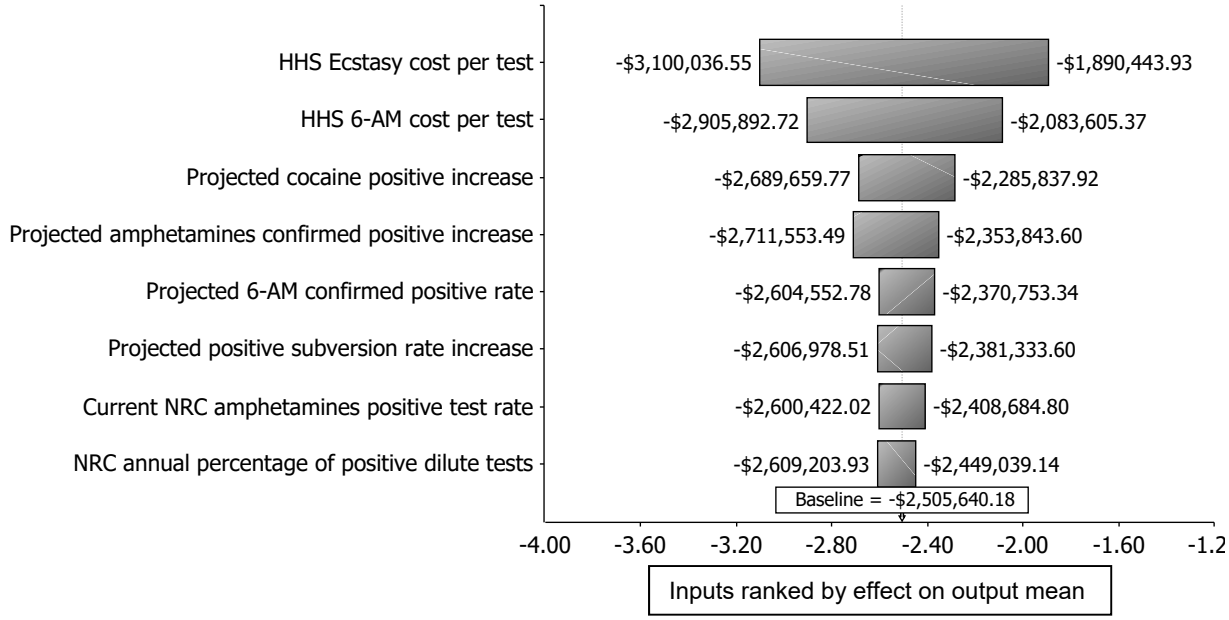

Figure 5-8. Key variables whose uncertainty drives the largest impact on costs (3-percent net present value)

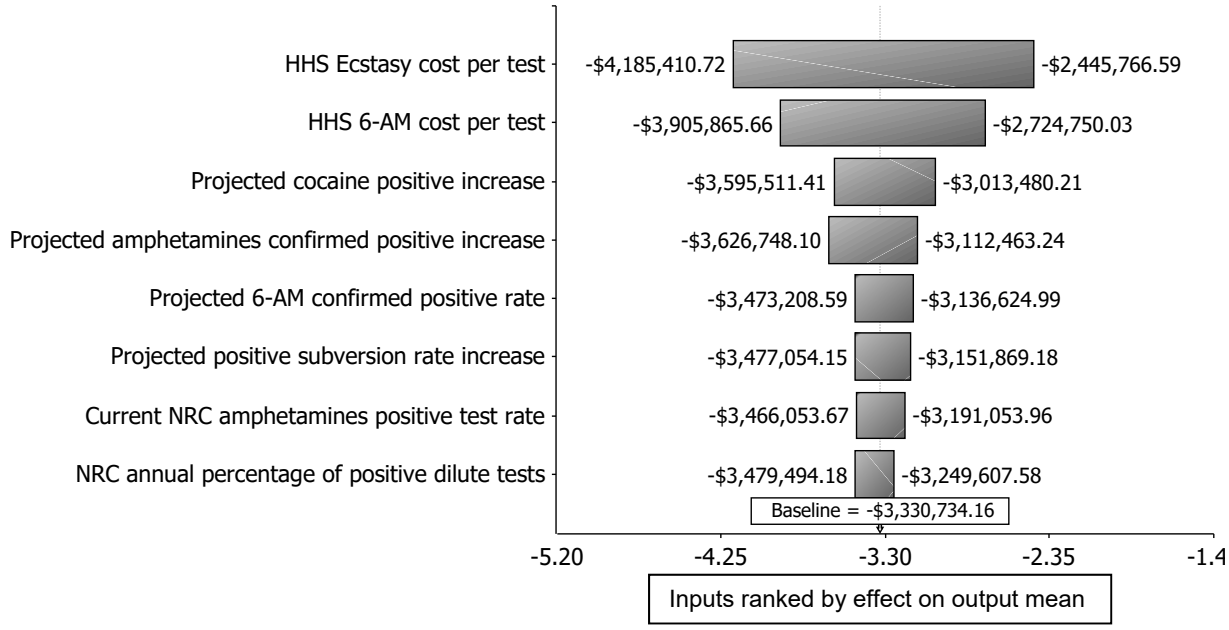

Table 5-11 presents the range of additional positive results that are estimated to be detected if the proposed rule is implemented. These estimates of additional positive results are based on the uncertainty estimate inputs and distributions in Table 5-9 and reflect the uncertainties associated with using historical DOT test results data to forecast future FFD test results.

Table 5-11. Estimated Number of Additional Confirmed Positives per Year

Substance	Minimum	Mean	Maximum
6-AM	16.8	26.7	34.9
Amphetamines	1.5	19.7	41.8
Cocaine	12.0	25.2	40.6
Ecstasy drugs	3.2	6.3	9.0
Dilute	2.6	7.3	10.7
Subversion specimens	0	6.5	14.9
Total	54.4	91.7	133.2

Figure 5-9 presents three plots that summarize the distribution of the undiscounted net benefits, the net benefits discounted at 3 percent, and net benefits discounted at 7 percent. As illustrated by this figure, regardless of discount rate, the proposed rule has a negative monetized net benefit (i.e., 100 percent of the distributions informed by these data are less than zero).

Figure 5-9. Relative frequency of the net benefits of the proposed rule

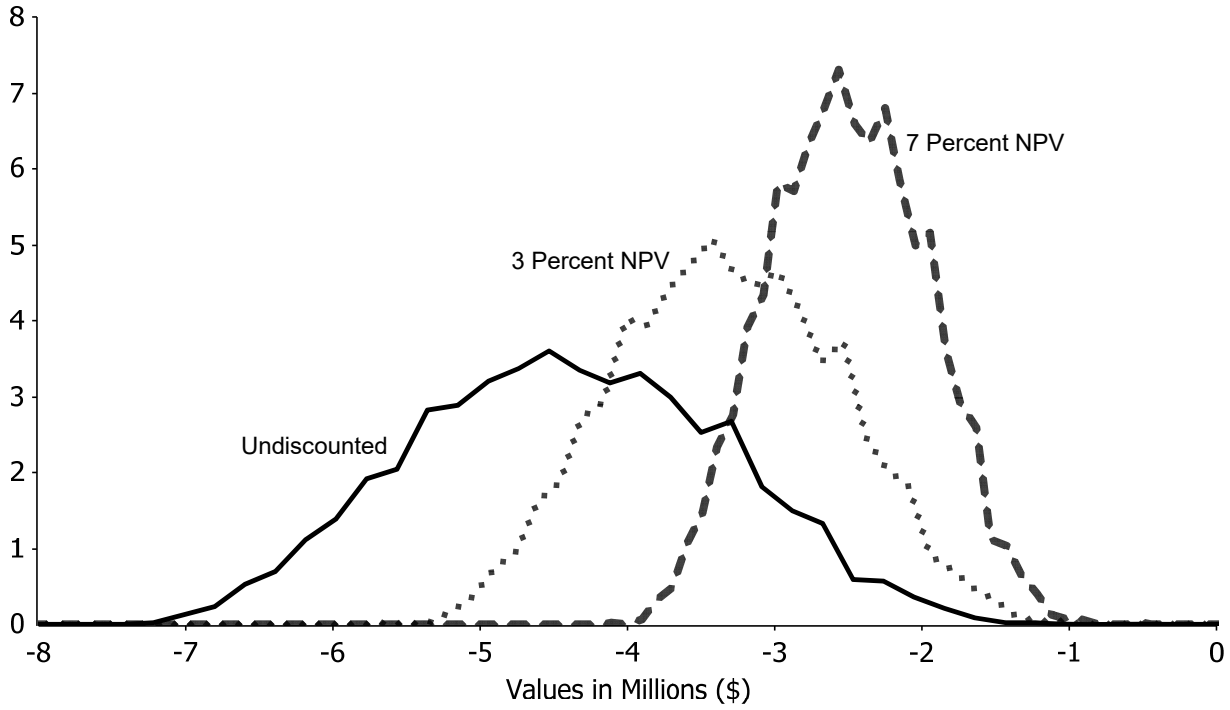

Figure 5-9 also displays the sensitivity of the uncertainty analysis to the discount rates used for the net benefits (i.e., benefits minus costs) of the proposed rule based on 5,000 simulations. By allowing uncertain assumptions and inputs to vary across a distribution, the results are no longer static and instead are spread across a range with varying degrees of certainty. For this simulation, the analysis indicates that for the attributes that could be quantified, the proposed rule is estimated to result in a net cost of between ($0.30 million) and ($7.73 million).

5.2.2 Summary of Uncertainty Analysis

The simulation analysis shows that the estimated mean cost for this proposed rule is ($2.51 million), with 90-percent confidence that the cost is between ($1.64 million) and ($3.37 million) using a 7-percent discount rate.

The NRC staff assessed which variables have the largest impact on total costs (and averted costs) for the proposed rulemaking. As shown in Figures 5-7 and 5-8, the two largest uncertainties in cost are associated with the potential costs that an HHS-certified laboratory may charge a site to perform testing for Ecstasy and 6-AM. The next three largest variations in costs are associated with the projected increase in confirmed positive tests for 6-AM, amphetamine, cocaine, and methamphetamine, based on detection improvements seen after DOT implemented the 2008 HHS Guidelines. The next three variables have lesser and comparable impacts on the total cost of implementing the proposed rule.

As illustrated in Figure 5-9, variation in the key variables results in cost distributions that range from ($0.30 million) and ($7.73 million) from the regulatory baseline of Alternative 1 (Take No Action) when accounting for different discount factors.

5.3 Disaggregation

In order to implement the guidance in Section 4.3.2, "Criteria for the Treatment of Individual Requirements," in NUREG/BR-0058, Revision 4 (Ref. 29), the NRC staff performed a screening review to determine whether any of the individual requirements (or set of integrated requirements) of the rule would be unnecessary to achieve the objectives of the rulemaking. The NRC staff concludes that each of the proposed rule changes would be necessary to achieve one or more of the objectives of the rulemaking, as described in Section 1.2 and summarized in Table 5-12. The objectives of the rulemaking are achieved by maintaining reasonable assurance of a drug-free workplace through the improved detection of persons who are not fit for duty because of illegal drug use or legal drug misuse; harmonizing select drug testing requirements under 10 CFR Part 26 with those implemented by the 2008 HHS Guidelines and other Federal agencies; and improving the clarity, organization, and flexibility of the 10 CFR Part 26 rule language.

Table 5-12. Disaggregation

Revised Requirement	Improve Detection	Align Requirements	Individual Rights and Lessons Learned
Lower drug testing cutoff levels for amphetamine, cocaine, and methamphetamine	X	X	
Expand initial drug testing panel to include 6-AM and revise confirmatory testing cutoff level for 6-AM	X	X	
Expand testing panel to include Ecstasy-type drugs	X	X	
Require special analyses testing of dilute specimens and specimens collected during suspected subversion attempts	X		X
Add and revise definitions to improve consistency with definitions in the 2008 HHS Guidelines		X	X

Revised Requirement	Improve Detection	Align Requirements	Individual Rights and Lessons Learned
Replace the LOD with the LOQ as the decision point in special analyses testing and adulterant testing of specimens		X	X
Clarify procedures for observed collections of urine specimens, specimen quantity, altered specimens, and refusal to test situations		X	X
Permit use of additional qualified staff beyond the specimen collector to observe a donor in the hydration process subsequent to an inability to provide a urine specimen of adequate volume for testing (i.e., a shy bladder)			X
Eliminate 6-month in service requirement for blind performance test samples and permit the suppliers to specify the shelf life		X	X
Eliminate dual regulation of HHS-certified laboratory by removing documentation requirements for laboratory personnel and procedures that are already contained in the 2008 HHS Guidelines and verified in the HHS laboratory certification process			X
Clarify the terminology for laboratory quality control samples to address inconsistencies raised in an enforcement guidance memorandum (Ref. 20)			X
Enhance donor protection by requiring MRO review of specimens with invalid validity test results due to high pH values (between 9.0 and 9.5)		X	X
Enhance donor protection and the transparency of the retesting process by requiring the MRO to document an oral request made by a donor for a second laboratory to test Bottle B of a split specimen or to retest an aliquot of a single specimen		X	X
Require retention of any specimen collected during a post-event testing (even if the donor refuses to complete the test after providing a specimen) to enhance the root-cause evaluation process associated with accidents	X		

5.4 Backfitting and Issue Finality

Appendix F presents the NRC staff's evaluation of changes in the proposed rule in accordance with the backfitting and issue finality requirements in 10 CFR 50.109, "Backfitting" (Ref. 8), 10 CFR 52.98, "Finality of combined licenses; information requests" (Ref. 10), and 10 CFR 70.76, "Backfitting" (Ref. 9).

5.5 Results for the Committee to Review Generic Requirements

This section addresses the regulatory analysis information requirements for rulemaking actions or NRC staff positions subject to CRGR review. All information called for by the CRGR charter (Ref. 33) is presented in this regulatory analysis or in the *Federal Register* notice for the

proposed rule. As a reference aid, Table 5-13 provides a cross-reference between the relevant information and its location in this document or the *Federal Register* notice.

Table 5-13. Specific CRGR Regulatory Analysis Information Requirements

CRGR Charter Citation (Ref. 33)	Information Item to be Included in a Regulatory Analysis Prepared for CRGR Review	Where Item Is Discussed
Appendix C, (i)	Proposed generic requirement or staff position as it is proposed to be sent out to licensees.	Proposed rule text in *Federal Register* notice.
Appendix C, (ii)	Draft papers or other documents supporting the requirements or staff positions.	*Federal Register* notice for the proposed rule.
Appendix C, (iii)	The sponsoring office's position on each proposed requirement or staff position as to whether the proposal would modify requirements or staff positions, implement existing requirements or staff positions, or relax or reduce existing requirements or staff positions.	Regulatory Analysis, Section 5.1 and Backfit Analysis, Appendix F.
Appendix C, (iv)	The proposed method of implementation.	Regulatory Analysis, Section 7.
Appendix C, (vi)	Identification of the category of power reactors, new reactors, or nuclear materials facilities or activities to which the proposed generic requirement or staff position is applicable.	Regulatory Analysis, Section 4.2.2.
Appendix C, (vii)–(viii) III.	If the proposed action involves a power reactor backfit and the exceptions at 10 CFR 50.109(a)(4) are not applicable, the items required at 10 CFR 50.109(c) and the required rationale at 10 CFR 50.109(a)(3) are to be included. For proposed generic relaxations or decreases in current requirements or staff positions, provide a determination along with the rationale that (a) the public health and safety and the common defense and security would be adequately protected if the proposed relaxations were implemented and (b) the cost savings attributed to each action would be significant enough to justify the action.	Backfit Analysis, Appendix F. *Federal Register* notice for the proposed rule.
Appendix C, (xi)	Preparation of an assessment of how the proposed action relates to the Commission's Safety Goal Policy Statement (Ref. 34).	Regulatory Analysis, Section 3.

6. Decision Rationale

6.1 Regulatory Analysis

This analysis is based on the qualitative consideration of the benefits resulting from seven affected attributes (i.e., public health (accident), occupational health (accident), offsite property, onsite property, regulatory efficiency, safeguards and security considerations, and other considerations, which include public perception, workplace productivity, workplace safety, and improved protection of individual rights). The staff performed a qualitative analysis because of the difficulties associated with monetizing these seven affected attributes as well as the full benefit to industry operations that would result from the detection each year of additional individuals using illegal drugs, misusing legal drugs, or subverting the testing process. For example, monetizing the impact of these attributes would require estimation of factors such as the frequency and consequences of accidents and other safety- or security-related events (e.g., an insider threat) caused by drug-induced impairment, and the benefits of deterring additional individuals using drugs from seeking employment in positions that require testing under 10 CFR Part 26 (Ref. 1).

The staff was able to quantify the costs resulting from three other affected attributes (industry implementation, industry operation, and NRC implementation). Relative to Alternative 1 (Take No Action), the proposed rule is estimated to result in an incremental cost to industry of approximately ($2.4 million) total present value over a 25-year period, assuming a 7-percent discount rate, or approximately ($3.4 million), assuming a 3-percent discount rate. The cost includes a one-time industry implementation cost of ($337,090) (averaging $5,031 per site) and annual industry operations cost of ($2,516) per site.[31] In addition, the NRC is estimated to incur a total one-time cost of ($273,000) to complete the final rulemaking (i.e., analyze public comments, hold public meeting(s), and develop the final rule) and issue regulatory guidance. The estimated total cost for this proposed rule ranges from ($2.7 million) assuming a 7-percent discount rate to ($3.6 million) assuming a 3-percent discount rate.

Because the staff cannot monetize the benefit of an additional 10- to 12-percent increase each year in the number of individuals (approximately 95) identified as using illegal drugs, misusing

[31] The NRC staff assumes that the licensee or other entity for each site would incur an average cost per requirement. This assumption is a simplification; some licensees and other entities would incur a higher or lower operations cost depending on the size of the population drug tested at the site (e.g., an operating power reactor site conducts more drug tests than a corporate office). The licensees and other entities subject to 10 CFR Part 26 includes 57 operating power reactor sites, 2 power reactor construction sites, 5 corporate offices, 2 Category I fuel cycle facilities, and 1 C/V (see Appendix A). Corporate offices, Category I fuel cycle facilities, and C/Vs use much smaller workforces than operating power reactor sites and power reactor construction sites (see Table 4-1 and Appendix A). They also do not incur periodic workforce surges as a result of changing site conditions, unlike power reactor sites (e.g., refueling outages, various states of site construction). An analysis of CY 2013 and CY 2014 FFD program performance data indicated that between 23 and 25 percent of drug positive test results for operating power reactor sites and between 33 and 40 percent of drug positive test results for power reactor construction sites were associated with substances in the current testing panel that will be affected by the proposed rule (i.e., amphetamine, cocaine metabolites, methamphetamine, 6-AM). The proposed rule changes would have limited impact on additional detection at other facility types given the very low number of positive results (see Table 4-1). As a result, the NRC staff anticipates improvement in detection at operating power reactor and power reactor construction sites. By using an average cost per site, the analysis overestimates the operations costs for smaller workforce sites and underestimates the costs for larger workforce sites, but on balance it provides a reasonable estimate of the incremental testing costs associated with the proposed rule given that the majority of the sites and tested workforces (57 of 67) are at operating power reactors.

legal drugs, or attempting to subvert the drug testing process, a net cost-beneficial determination is not meaningful. However, the NRC staff concludes that the proposed rule has merit relative to the non-monetized benefit of identifying additional individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process each year. The proposed rule would benefit public health and safety and the common defense and security at a low average cost per site[32] for the following reasons:

- The proposed rule would enhance FFD program effectiveness (i.e., detection) by identifying additional individuals each year determined not to be fit for duty or not to be trustworthy and reliable, or both, because of illegal drug use, legal drug misuse, or attempts to subvert the drug testing process, which would benefit public health and safety and the common defense and security by reducing safety and security vulnerabilities.

- The proposed rule would improve regulatory effectiveness and efficiency through regulatory and compliance improvements. Updating 10 CFR Part 26 to be consistent with the 2008 HHS Guidelines (Ref. 2) would improve the effectiveness of the 10 CFR Part 26 drug testing provisions by aligning it with a national drug testing standard used by all Federal employee workplace drug testing programs (more than 100 Federal agencies) and by comparable Federal agency drug testing programs that test civilians in safety- and security-sensitive positions. Alignment with the 2008 HHS Guidelines would ensure that drug testing provisions in 10 CFR Part 26 continue to be scientifically and technically sound, reduce administrative burden on licensees and HHS-certified laboratories, and help maintain the public trust.

- A more robust drug testing program may deter individuals from seeking employment in 10 CFR Part 26 regulated positions by doing the following:

  – *Expanding the drug testing panel and lowering the testing cutoff levels for select drugs.* Lowering the testing cutoff levels for amphetamines, cocaine metabolites, and 6-AM would increase the timeframe (i.e., the window of detection) in which these drugs can be detected in an individual's body after use. This would reduce the likelihood that individuals would be able to subvert the testing process through temporary abstinence from a drug. Expanding the initial drug testing panel to include 6-AM, MDMA, and MDA and the confirmatory drug testing panel to include MDMA and MDA would improve the trustworthiness and reliability of the workforce through the identification of individuals using illegal drugs or misusing legal drugs who would be denied unescorted access authorization.

  – *Requiring and expanding special analyses testing*. Requiring special analyses testing on dilute specimens and expanding special analyses testing to specimens collected under direct observation would 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 would increase the assurance provided by special analyses testing by adding a level of precision to the testing method. These changes would further enhance the detection of drugs in specimens that do not present normal physiological characteristics. The identification of additional persons using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process would

[32] Each site would incur an average one-time cost of ($5,031) and an average annual cost of ($2,516).

improve the trustworthiness and reliability of the workforce by denying unescorted access authorization to these individuals.

– *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 proposed rule would enhance consistency with the 2008 HHS Guidelines, FFD program integrity, and the protection of individual rights. Requiring the use of the LOQ instead of the LOD as the decision point for validity testing protocols for dilute and adulterated specimens also enhances the protection of individual rights because the LOQ adds a level of precision to the testing method.

– *Improving regulatory efficiency between 10 CFR Part 26 and other related Federal rules and guidelines.* The proposed rule would improve regulatory efficiency by (1) harmonizing select 10 CFR Part 26 definitions and drug testing procedures with those described in the 2008 HHS Guidelines; (2) clarifying ambiguous or imprecise regulatory language in 10 CFR Part 26, such as the terminology related to quality control samples, applying lessons learned during implementation of the 2008 FFD final rule; and (3) eliminating dual regulation of HHS-certified laboratories (private entities) and reducing the regulatory burden on licensees by removing select 10 CFR Part 26 requirements also included in the 2008 HHS Guidelines that the NLCP verifies in order for a laboratory to achieve and maintain HHS-certification.

– *Enhancing root-cause analysis in post-event testing situations associated with a refusal to test determination at the collection site*. Under the current rule, if a refusal to test is determined during the specimen collection process, any specimen(s) obtained from the donor are discarded. The proposed rule would require the retention and testing of any specimen collected during post-event situations in which a refusal to test determination was made at the collection site. This change would enhance the ability of the licensee or other entity to determine whether substance use could have been a contributing factor to an accident.

The NRC staff concludes that the benefit of the proposed improvements to the measures designed to meet the general performance objective of the 10 CFR Part 26 drug testing program, to "provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs," outweighs the low cost of implementation.

6.2 Backfitting and Issue Finality

The NRC staff conducted an analysis of the proposed rule pursuant to the backfitting and issue finality requirements in 10 CFR 50.109 (Ref. 8), 10 CFR 52.98 (Ref. 10), and 10 CFR 70.76 (Ref. 9) (see Appendix F). The proposed rule constitutes a backfit because it would impose new requirements on licensees. These new measures include lowering the initial and confirmatory drug testing cutoff levels for amphetamines and cocaine metabolites; expanding the initial drug testing panel to include 6-AM and revising the confirmatory testing cutoff levels for 6-AM; expanding the initial and confirmatory drug testing panels to include Ecstasy; requiring special analyses testing of dilute specimens and specimens collected during suspected subversion attempts; and requiring additional MRO review of invalid validity test results stemming from high pH values (9.0 to 9.5) and MRO actions when a donor requests testing of

Bottle B or a retest of a single specimen and the specimen is unavailable. These measures fall under the definition of "backfitting" in 10 CFR 50.109(a)(1) because such efforts are new or amended provisions in the Commission's regulations.

In light of the substantial benefits of the proposed rule as summarized in Section 5.1, the NRC staff finds that the backfits contained in the proposed rule, when considered in the aggregate, would substantially enhance safety and security by maintaining reasonable assurance of a workplace free from drugs and the effects of such substances by resulting in an estimated 10- to 12-percent increase each year in the number of individuals identified as using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. As a consequence, each of these individuals would be denied unescorted access authorization.

7. Implementation

The proposed NRC regulatory instrument for implementing the proposed action is to amend select provisions of 10 CFR Part 26 (Ref. 1) through rulemaking and to develop a regulatory guide to describe a method that is acceptable to the NRC for 10 CFR Part 26 implementation.

The regulatory analysis for the proposed rule was based on completion of this regulatory activity in 2017. Adjustments to the implementation dates will be made in the analysis accompanying the final rule.

The dates used in this analysis for the proposed rule are as follows:

- publication of the final rule: CY 2017
- effective date of the final rule: CY 2017 (60 days after publication date of the final rule)
- compliance date of the final rule: CY 2017 (60 days after publication date of the final rule)

This schedule would give licensees and other entities time to revise site policies and procedures, conduct training, and revise contracts with HHS-certified laboratories and BPTS suppliers.

The staff does not expect the proposed implementation schedule to result in a cumulative impact on affected entities because (1) no other pending 10 CFR Part 26 regulatory actions exist that would impact the site professionals responsible for implementing the proposed requirements and (2) the changes to FFD policy, procedures, contracts, and training are minimal. This implementation schedule also enables the NRC staff to finalize updates to NRC inspector guidance.

8. References

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5. U.S. Nuclear Regulatory Commission, "Fitness for Duty Programs," *Federal Register*, Vol. 54, No. 108, June 7, 1989, pp. 24468–24508.

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SUBJECT: Draft Regulatory Analysis and Backfitting and Issue Finality, 10 CFR Part 26, Fitness for Duty Drug Testing Requirments [Docket ID NRC-2009-0025], dated August 9, 2019

ADAMS Accession Numbers: Package: ML19169A110; Regulatory Analysis: ML19169A115. ***via email**

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DATE	7/12/2016	7/8/2016	7/11/2016	8/15/2016
OFFICE	ADM/DAS/RADB/BC*	OCFO/D*	OCIO/CSD/FPIB/CO*	QTE*
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DATE	8/8/2016	7/11/2016	10/27/2016	9/22/2016
OFFICE	OGC (NLO)*	NRR/D	EDO	
NAME	HBenowitz	WDean	VMcCree	
DATE	10/7/2016	12/1/2016	2/22/2017	

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Appendices

Appendix A: Site-Specific Fitness-for-Duty Program Performance Data (Calendar Years 2009–2014)

(Table sorted by Facility Type, then FFD Program, and then Units)

Facility Type	FFD Program	Facility	Units	2009 Total		2010 Total		2011 Total		2012 Total		2013 Total		2014 Total		Average 2009–2014	
				Tested	Positive	Tested	Positive	Tested	Positive	Tested	Positive	Tested	Positive	Tested	Positive	Tested	Positive
Corporate Office	Duke Energy	Duke Energy	1	337	0	373	1	402	0	443	1	475	0	612	2	440	0.7
	Exelon	Exelon	2	444	0	431	2	459	0	525	0	580	0	537	0	496	0.3
	Southern Nuclear	Southern Nuclear	1	656	1	716	1	781	2	717	1	691	2	649	1	702	1.3
	Tennessee Valley Authority (TVA)	TVA	1	649	1	787	1	557	0	250	3	585	2	590	0	570	1.2
	Xcel Energy	Xcel Energy	1	160	0	225	2	293	1	311	0	370	0	399	1	293	0.7
C/V	Institute of Nuclear Power Operations (INPO)	INPO	1	81	0	348	1	367	0	362	0	380	1	324	1	310	0.5
Fuel Cycle	BWX Technologies, Inc.	Lynchburg, VA	1	710	2	765	0	747	1	852	1	847	0	830	0	792	0.7
	Nuclear Fuel Services	Erwin, TN	1	849	1	866	2	874	4	858	3	790	3	747	2	831	2.5
Reactor	Ameren UE	Callaway	1	1,005	3	1,766	6	1,924	7	924	3	1,840	8	2,044	18	1,584	7.5
	Arizona Public Service	Palo Verde	3	6,961	18	4,873	19	4,422	11	4,377	16	4,171	18	4,194	21	4,833	17.2
	Detroit Edison	Fermi Unit 2	1	2,550	1	2,922	19	1,625	9	2,855	15	1,842	10	3,030	15	2,471	11.5
	Dominion Generation	Millstone	2	2,206	9	2,206	16	2,917	25	2,403	7	2,384	19	3,526	22	2,607	16.3
		North Anna	2	1,828	12	3,085	14	2,031	6	2,121	14	2,305	12	2,269	5	2,273	10.5
		Surry	2	2,069	17	2,147	18	2,744	48	2,306	19	1,520	15	1,869	8	2,109	20.8
	Duke Energy	H.B. Robinson	1	734	3	1,596	10	1,368	7	2,458	16	2,771	15	1,266	3	1,699	9.0
		Shearon Harris	1	1,114	3	2,460	12	1,128	0	1,943	6	1,870	6	1,481	4	1,666	5.2
		Brunswick	2	2,311	16	2,603	10	2,697	15	2,779	17	3,789	18	3,546	13	2,954	14.8
		Catawba	2	2,976	14	2,670	16	2,453	16	3,054	20	3,007	17	2,091	11	2,709	15.7
		McGuire	2	2,703	17	2,536	16	4,370	18	3,568	6	2,965	10	4,198	19	3,390	14.3
		Oconee	3	3,742	22	3,309	21	2,643	16	3,443	14	3,106	15	3,792	28	3,339	19.3
	Energy Northwest	Columbia	1	3,209	29	1,494	6	3,835	32	1,171	2	2,083	23	1,354	7	2,191	16.5
	Entergy Nuclear	Grand Gulf	1	1,202	2	2,080	18	2,427	19	5,314	22	1,230	11	2,380	15	2,439	14.5
		Palisades	1	2,019	7	2,060	24	893	8	1,855	22	1,083	7	1,894	7	1,634	12.5
		River Bend	1	2,083	16	1,632	13	1,421	5	1,054	8	2,184	11	1,078	10	1,575	10.5
		Waterford	1	1,623	15	1,475	7	1,451	11	2,918	30	930	8	1,511	21	1,651	15.3
		Arkansas Nuclear One	2	2,309	14	2,628	14	2,820	25	2,407	16	3,182	32	2,331	23	2,613	20.7
		Indian Point	2	2,211	14	2,485	16	2,090	17	2,032	9	2,071	18	2,088	10	2,163	14.0

Facility Type	FFD Program	Facility	Units	2009 Total		2010 Total		2011 Total		2012 Total		2013 Total		2014 Total		Average 2009–2014	
				Tested	Positive	Tested	Positive	Tested	Positive	Tested	Positive	Tested	Positive	Tested	Positive	Tested	Positive
Reactor (continued)	Exelon	Clinton	1	1,265	11	1,958	8	1,743	13	755	3	2,018	11	952	3	1,449	8.2
		R.E. Ginna	1	1,890	30	933	11	1,306	2	1,217	15	778	1	1,035	10	1,193	11.5
		Three Mile Island	1	2,699	32	1,002	5	1,618	12	837	3	1,556	7	911	5	1,437	10.7
		Braidwood	2	3,511	33	2,510	17	2,053	9	3,013	15	2,491	5	1,804	8	2,564	14.5
		Byron	2	2,290	18	1,841	7	3,974	30	2,694	9	1,894	12	3,010	21	2,617	16.2
		Calvert Cliffs	2	2,343	10	2,305	14	2,225	13	2,504	13	2,463	15	2,231	8	2,345	12.2
		Dresden	2	1,631	11	2,046	5	2,294	8	1,876	9	1,894	12	1,807	13	1,925	9.7
		LaSalle	2	2,440	9	2,698	18	3,270	11	2,829	9	2,360	11	2,583	5	2,697	10.5
		Limerick	2	2,526	16	2,599	16	3,049	23	3,622	23	2,751	24	2,551	9	2,850	18.5
		Nine Mile Point	2	2,520	20	3,132	31	2,552	13	3,141	24	2,678	16	2,256	16	2,713	20.0
		Peach Bottom	2	3,075	21	2,912	14	3,802	19	3,643	18	4,123	19	3,836	14	3,565	17.5
		Quad Cities	2	2,247	19	2,476	17	2,014	10	2,111	11	2,242	19	1,854	10	2,157	14.3
	FirstEnergy Nuclear	Davis-Besse	1	863	3	2,662	9	2,903	15	1,545	3	1,867	10	3,017	14	2,143	9.0
		Perry	1	2,512	12	1,126	2	2,066	16	1,192	5	2,561	19	1,265	3	1,787	9.5
		Beaver Valley	2	2,924	21	2,149	11	2,129	9	3,391	19	2,736	12	2,683	9	2,669	13.5
	Indiana Michigan Power	DC Cook	2	4,337	52	4,017	30	3,565	22	3,012	17	4,482	29	3,493	15	3,818	27.5
	Luminant Generation	Comanche Peak	2	2,248	15	2,274	6	3,119	16	2,351	10	2,490	7	3,837	17	2,720	11.8
	Nebraska Public Power District	Cooper	1	2,478	12	1,070	2	1,681	10	2,173	13	793	4	1,734	4	1,655	7.5
	NextEra Energy	Duane Arnold	1	1,418	6	1,339	2	745	1	1,730	14	537	2	1,704	21	1,246	7.7
		Seabrook	1	2,628	19	1,050	6	2,021	18	2,293	19	848	3	1,597	10	1,740	12.5
		Point Beach	2	2,340	4	2,214	5	4,831	12	1,290	3	1,260	0	1,771	8	2,284	5.3
		St. Lucie	2	2,525	17	4,534	26	5,204	22	4,887	14	2,809	13	2,504	15	3,744	17.8
		Turkey Point Units 3 & 4	2	3,813	19	3,827	20	4,718	21	8,216	40	2,247	10	2,904	10	4,288	20.0
	Omaha Public Power District	Fort Calhoun	1	1,839	7	1,186	5	2,643	20	1,758	10	1,705	9	1,063	6	1,699	9.5
	Pacific Gas & Electric	Diablo Canyon	2	4,731	28	3,105	14	2,973	17	2,826	14	2,937	10	3,486	25	3,343	18.0
	PSEG Nuclear	Salem/Hope Creek	3	3,768	24	4,291	28	4,199	23	4,288	34	4,252	24	4,195	27	4,166	26.7
	South Carolina Electric & Gas	V.C. Summer Unit 1	1	1,667	13	1,112	4	1,792	11	2,016	11	1,867	16	2,781	28	1,873	13.8

Facility Type	FFD Program	Facility	Units	2009 Total		2010 Total		2011 Total		2012 Total		2013 Total		2014 Total		Average 2009–2014	
				Tested	Positive	Tested	Positive	Tested	Positive	Tested	Positive	Tested	Positive	Tested	Positive	Tested	Positive
Reactor (continued)	Southern Nuclear	E.I. Hatch	2	2,823	7	3,187	31	3,592	47	3,114	18	3,205	17	3,078	23	3,167	23.8
		Joseph M. Farley	2	2,513	29	3,968	43	3,724	39	2,681	42	2,797	11	1,935	16	2,936	30.0
		Vogtle Units 1 & 2	2	2,774	30	2,837	26	3,856	21	3,284	57	2,605	27	3,749	34	3,184	32.5
	STP Nuclear	South Texas Project	2	2,672	17	2,757	8	3,082	15	2,302	17	2,629	17	2,428	13	2,645	14.5
	Talen Energy	Susquehanna	2	3,167	14	3,324	13	3,327	8	2,914	9	2,985	11	3,435	15	3,192	11.7
	TVA	Sequoyah	2	2,916	18	2,974	22	2,849	20	5,048	28	2,660	14	1,942	14	3,065	19.3
		Watts Bar	2	4,799	19	6,506	40	5,918	26	5,628	38	4,477	27	5,244	34	5,429	30.7
		Browns Ferry	3	3,313	16	4,958	17	3,607	9	4,713	25	3,922	27	3,897	22	4,068	19.3
	Wolf Creek	Wolf Creek	1	2,117	5	1,246	1	2,667	17	1,756	7	3,286	8	2,017	9	2,182	8
	Xcel Energy	Monticello	1	2,452	11	1,234	8	3,329	17	1,019	5	2,794	18	835	4	1,944	10.5
		Prairie Island	2	1,663	9	1,625	5	1,260	6	2,057	9	2,822	11	1,824	4	1,875	7.3
Reactor—Construction	South Carolina Electric & Gas	V.C. Summer Units 2 & 3	2					252	4	2,724	52	3,532	80	5,484	127	2,998	65.8
	Southern Nuclear	Vogtle Units 3 & 4	2	47	0	3,277	57	3,933	80	5,440	101	5,862	98	9,055	168	4,602	84.0
		Totals	110	148,525	894	150,799	889	165,624	1,008	167,190	1,057	153,266	967	158,417	1,084	158,303	1,005

Notes on Appendix A:

1. Site construction at Vogtle Units 3 and 4 began in calendar year (CY) 2009.
2. Site construction at V.C. Summer Units 2 and 3 began in CY 2011.
3. Watts Bar Unit 2 construction restarted in CY 2008 and completed in CY 2015; the licensee did not report separately for the construction site.

Appendix B: General Inputs

Model Inputs	Value	Data Source
Final Rule—Effective Date and Scope		
Year rule finalized	2017	U.S. Nuclear Regulatory Commission (NRC) staff assumption
Year rule effective	2017	NRC staff assumption
Total number of fitness-for-duty (FFD) programs	27	NRC FFD Program Performance Results Calendar Year (CY) 2014
Total number of sites	67	NRC FFD program Performance Data CY 2014 (see Appendix A). Total sites = 57 operating power reactor sites, 2 power reactor construction sites, 2 Category I fuel cycle facilities, 5 corporate offices, and 1 contractor/vendor (C/V). (This analysis excludes sites that are in decommissioning or sites with announced dates when their unit will permanently cease commercial operation, as described in Section 4.2.2.)
Number of sites using a licensee testing facility (LTF)	6	NRC FFD Program Performance Results CY 2014
Number of sites only using a U.S. Health and Human Services (HHS)-certified laboratory	61	NRC FFD Program Performance Results CY 2014
Number of workers subject to a 10 CFR Part 26 FFD program	107,620	NRC FFD Program Performance Results CY 2009–2014. In the annual 10 CFR 26.717 FFD program performance report submitted to the NRC, each licensee or other entity reports the average number of licensee employees and C/Vs subject to random testing in the reporting year. The average of the yearly total for all 67 sites in CY 2009–2014 is the best approximation of the total number of individuals in the workforce who would require training on policy changes resulting from the proposed rule. Adjusted for construction sites going operational in CY 2019 and CY 2020.
Average number of workers subject to a 10 CFR Part 26 FFD program per site	1,606 individuals per site	Calculated from the NRC FFD Program Performance Results CY 2009–CY 2014 [(total number of individuals subject to random testing per year) / (total number of sites)]
Number of drug tests conducted per year	157,632 tests	NRC FFD Program Performance Results (average of total number of tests conducted for CY 2009–CY 2014), adjusted for construction sites going operational (used operating site data at the co-located reactors to model test results)
Number of drug tests conducted per site per year	2,353 tests per site	Calculated from the NRC FFD Program Performance Results CY 2009–CY 014. [(total number of drug tests conducted per year) / (total number of sites)]
Industry Implementation (One-Time)—Hourly Wage Rates		
Clerical	$21.69	Model facility data: "Inputs—Wages" (from January to May 2002) provided to the NRC by the Nuclear Energy Institute on FFD drug and alcohol testing programs. These data were used in the regulatory impact analysis for the 10 CFR Part 26 FFD final rule (March 2008), converting wage data from 2002 to 2017 dollars.
Facility Worker (weighted average of licensee and C/V workers)	$63.86	
FFD Manager	$44.21	
FFD Staff	$36.87	
LTF Laboratory Technician	$36.55	
LTF Laboratory Supervisor	$61.45	
Legal	$122.91	
Medical Review Officer (MRO)	$137.73	
Industry Implementation (One-Time)—Training		
Number of sites that distribute a summary of FFD program rule changes to employees outside of routine training	14	NRC staff assumption. Based on the implementation timeframe, most licensees and other entities will incorporate training on the new FFD program requirements into existing annual training/refresher training opportunities, as well as post information at the collection sites and on bulletin boards, etc. Estimate that 20% of sites will conduct training specifically on rule changes and outside routine training. (0.2 x 67 sites = 14 sites)
Number of FFD programs with a blind performance test sample (BPTS) supplier contract	27	NRC staff assumption (all sites have a contract with a BPTS supplier)

Model Inputs	Value	Data Source
Cost of LTF training materials	$500.00 per LTF	NRC staff assumption based on the 2008 10 CFR Part 26 FFD final rule regulatory impact analysis (March 2008)
Number of Laboratory Technicians per LTF	2	NRC staff assumption based on communications in CY 2016 with licensees using LTFs
NRC Implementation (One-Time)—Wage Rate		
Annual Full-Time Equivalent (FTE) Rate for NRC Regulatory Analysis	$182,000 per FTE	For fiscal year 2016 regulatory analyses (as of October 2015) [1 FTE = 1,420 annual productive hours x $128 hour NRC staff rate]
Industry Operations (Annual)—Costs		
Initial testing for one additional drug at an LTF	$1.50 per test	NRC staff assumption based on industry feedback received in CY 2015 and CY 2016 from licensees using LTFs
Initial and confirmatory drug testing, HHS-certified laboratory (sites using an LTF for initial testing)	$29.00 per specimen	NRC staff assumption, based on industry feedback received in CY 2015 and CY 2016 (weighted average of LTF testing costs for positive results from CY 2009–CY 2014)
Testing for 6-AM (sites only using an HHS-certified laboratory)	$0.75 per test	NRC staff assumption, partially informed by the August 16, 2010, 49 CFR Part 40 Final Rule (Ref. 27) that aligned the U.S. Department of Transportation (DOT) drug testing panel with the 2008 HHS Guidelines (it reported an average cost per 6-AM test as $0.26)
Testing for Ecstasy (sites only using an HHS-certified laboratory)	$0.50 per test	NRC staff assumption, partially informed by the August 16, 2010, 49 CFR Part 40 Final Rule (Ref. 27) that aligned the DOT drug testing panel with the 2008 HHS Guidelines (it reported an average cost per Ecstasy test as $0.09)
Special analyses testing at an HHS-certified laboratory	$7.75 per specimen	NRC staff assumption based on industry feedback received in CY 2015 and CY 2016
Cost of subsequent actions (per positive result)	$283.24 per test	Hours estimates based on information in the 10 CFR Part 26 Office of Management and Budget Clearance Supporting Statement (No. 3150-0146) approved on November 13, 2014, as well as the NRC staff assumption on MRO review time
Industry Operations (Annual)—Drug Testing Rates		
6-Acetylmorphine (6-AM)		
Projected confirmed positive test rate	0.017%	DOT laboratory test results Average positive rate for 6-AM (CY 2010–2014) [2010 = 0.010%; 2011 = 0.014%; 2012 = 0.016%; 2013 = 0.019%; 2014 = 0.022%]
Amphetamines		
FFD current confirmed positive test rate	0.047%	NRC FFD Program Performance Results Average positive rate for amphetamines (CY 2010–CY 2014) [CY 2010 = 0.032%; CY 2011 = 0.048%; CY 2012 = 0.036%; CY 2013 = 0.052%; CY 2014 = 0.067%]
Projected percent increase in confirmed positive test rate	39.38%	MRO-verified test results for CY 2010 and CY 2011 for DOT (Federal Aviation Administration (FAA), Federal Railroad Administration (FRA), and Federal Transit Administration (FTA)). Did not use DOT laboratory test results (not verified by MRO) because amphetamines results may be downgraded to negative results following MRO review because of legitimate prescription use. [Average positive rate for amphetamines by year: CY 2010 = 0.057%; CY 2011 = 0.080%]
Projected percentage of additional positive results that will confirm positive after MRO interview with donor	75%	NRC staff assumption based on FFD program performance data on amphetamine and methamphetamine positive results
Cocaine		
FFD current confirmed positive test rate	0.072%	NRC FFD Program Performance Results Average positive rate for cocaine (CY 2010–CY 2014) [CY 2010 = 0.075%; CY 2011 = 0.071%; CY 2012 = 0.075%; CY 2013 = 0.076%; CY 2014 = 0.064%]
Projected percent increase in confirmed positive test rate	18.38%	MRO-verified test results for CY 2010 and CY 2011 for DOT (FAA, FRA, and FTA). Change in average cocaine positive rate for CY 2011, using CY 2010 as the baseline year for comparison [Average positive rate for cocaine by year: CY 2010 = 0.175%; CY 2011 = 0.207%]

Model Inputs	Value	Data Source
Ecstasy Drugs		
Projected confirmed positive test rate	0.004%	DOT laboratory test results Average positive rate for Ecstasy drugs (MDMA, MDA, MDEA) (CY 2010–CY 2014) [CY 2010 = 0.003%; CY 2011 = 0.005%; CY 2012 = 0.004%; CY 2013 = 0.005%; CY 2014 = 0.005%]
Dilute Specimens (Special Analyses Testing)		
Average annual percentage of specimens tested that are dilute and special analyses testing performed	0.466%	NRC FFD Program Performance Data on dilute specimens subject to special analyses testing (an e-form change was made to collect this data starting in CY 2013): • CY 2013: special analyses testing performed on 652 specimens of the 137,642 specimens collected by 65 sites with a special analyses testing policy • CY 2014: special analyses testing performed on 834 specimens of the 153,629 specimens collected by 69 sites with a special analyses testing
Average annual percentage of specimens tested that are dilute and test positive on special analyses testing	0.005%	NRC FFD Program Performance Data for CY 2011–CY 2014 (began collecting e-reported data on special analyses testing of dilute positive test results in CY 2011): • CY 2011: 2 positive specimens of 151,581 tested • CY 2012: 8 positive specimens of 148,067 tested • CY 2013: 9 positive specimens of 137,642 tested • CY 2014: 10 positive specimens of 153,269 tested
Subversion Attempts (Special Analyses Testing of Suspect Specimens)		
Average annual percentage of specimens tested that are determined to be a subversion attempt and that test positive (suspect specimens that test positive on special analyses testing)	0.037%	The proposed rule would require special analyses testing in two circumstances: (1) On the second specimen collected under direct observation when the initial specimen collected exhibits unusual characteristics (e.g., temperature out of range, unusual color or odor) (2) On the second specimen collected under direct observation when the initial specimen is reported as an invalid test result. NRC FFD Program Performance e-reported data (only includes those sites that e-reported provided sufficient information to analyze subversion attempts in this manner) for CY: • 2011: 42 suspect specimens/141,234 tests (at 62 sites) = 0.030% • 2012: 55 suspect specimens/157,528 tests (at 67 sites) = 0.035% • 2013: 44 suspect specimens/151,323 tests (at 71 sites) = 0.029% • 2014: 63 suspect specimens/166,590 tests (at 75 sites) = 0.038%
Project percent increase in confirmed positive test rate for specimens collected under direct observation	20%	NRC staff assumption
Averted Training Costs—Pre-Access Testing		
Percentage of total positive, adulterated, substituted, and refusal to test results occurring at pre-access testing (6-year average)	67.8%	NRC FFD Program Performance Data (CY 2009–CY 2014) [CY 2009= 68.2%; CY 2010 = 69.0%; CY 2011 = 68.6%; CY 2012 = 68.8%; CY 2013 = 64.8%; CY 2014 = 67.3%]
Entity-Specific Information		
Average remaining life per site	25 years	Calculated based on license expiration date (assumes all operating power reactor licenses are extended for 20 years), the fuel cycle facilities continue to operate as long as any reactor is operating, and the new power reactors under construction operate for the original 40-year operating license and a 20-year license extension.
Inflation Rates		
Ratio of 2017 Annual Average CPI-U to 2006 Annual Average CPI-U	1.23	U.S. Bureau of Labor Statistics (Table 24. Historical Consumer Price Index for All Urban Consumers (CPI-U): U.S. city average, all items) [CPI-U: CY 2002 = 179.9; CY 2006 = 201.6; CY 2017 = 247.783]
Ratio of 2017 Annual Average CPI-U to 2002 Annual Average CPI-U	1.38	

Appendix C: Assumptions and Results by Regulatory Initiative

C.1 Policy, Procedure, and Training Costs

The U.S. Nuclear Regulatory Commission's (NRC's) proposed rule would impose one-time costs on industry as a result of the following activities:

(1) updating fitness-for-duty (FFD) program policies and procedures
(2) training employees on the revised drug testing policies
(3) revising contracts with primary and backup U.S. Department of Health and Human Services (HHS)-certified laboratories, and blind performance test sample (BPTS) suppliers
(4) training licensee testing facility (LTF) technicians on new drug testing protocols
(5) validating newly implemented drug testing assays at the LTFs

Activity	*Labor Category*	*Wage Rate or Unit Cost*	*Quantity*	*Benefits (Cost)*	*Entities Affected*	*Total Benefits (Costs)*
INDUSTRY IMPLEMENTATION (ONE-TIME)						
(1) Update policies and procedures	FFD Manager	$44.21/hour	1 hour/program	($44)	27	($1,188)
	FFD Staff	$36.87/hour	1 hour/program	($37)	27	($999)
	Clerical	$21.69/hour	1 hour/program	($22)	27	($594)
	Legal	$122.91/hour	1 hour/program	($123)	27	($3,321)
(2) Inform employees of policy change	FFD Manager	$44.21/hour	0.5 hours/program	($22)	27	($594)
	Clerical	$21.69/hour	0.5 hours/program	($11)	27	($297)
	Legal	$122.91/hour	0.5 hours/program	($61)	27	($1,647)
	Facility Worker	$63.86/hour	0.2 hours/worker and 1,606 workers per site	($20,513)	14	($287,182)
(3) Revise contract with primary HHS-certified laboratory	FFD Manager	$44.21/hour	2 hours/program	($88)	27	($2,376)
	FFD Staff	$36.87/hour	2 hours/program	($74)	27	($1,998)
	Clerical	$21.69/hour	2 hours/program	($43)	27	($1,161)
	Legal	$122.91/hour	2 hours/program	($246)	27	($6,642)
(3) Revise contract with HHS-certified laboratory	FFD Manager	$44.21/hour	2 hours/program	($88)	27	($2,376)
	FFD Staff	$36.87/hour	2 hours/program	($74)	27	($1,998)
	Clerical	$21.69/hour	2 hours/program	($43)	27	($1,161)
	Legal	$122.91/hour	2 hours/program	($246)	27	($6,642)
(3) Revise contract with BPTS supplier	FFD Manager	$44.21/hour	1 hour/program	($44)	27	($1,188)
	FFD Staff	$36.87/hour	1 hour/program	($37)	27	($999)
	Clerical	$21.69/hour	1 hour/program	($22)	27	($594)
	Legal	$122.91/hour	1 hour/program	($123)	27	($3,321)
(4) Train LTF Technicians	LTF Technician	$36.55/hour	1 hour/technician (2 technicians/LTF)	($73)	6	($438)
	Training Materials	$500.00/LTF	1 per LTF	($500)	6	($3,000)
(5) Validate drug test assays at the LTF	LTF Supervisor	$61.45/hour	5 hours per drug assay (4 drug assays per LTF)	($1,174)	6	($7,374)
					Total Industry Implementation Cost	***($337,090)***
					Average Implementation Cost Per Site	***($5,031)***
NRC IMPLEMENTATION (ONE-TIME)						
Rule Development and Regulatory Guide	NRC Staff	$182,000 per full-time equivalent (FTE)	1.5 FTE	-	-	($273,000)
					Total NRC Implementation Cost	($273,000)

Calculations (totals may not add because of rounding):

- Benefits (Cost) Per Entity = Unit Cost x Unit(s) [rounded]
- Total Benefits (Cost) = Benefits (Cost) Per Entity x Entities Affected
- Total Industry Implementation Cost = Sum (Total Industry Benefits (Cost))
- Average Implementation Cost Per Site = Total Industry Implementation Cost / Total Number of Sites
- Total NRC Implementation Cost = Sum (Total NRC Benefits (Cost))

Assumptions:

- One-time policy, procedure, and training costs accrue to different entities—programs, sites, and LTFs. Most of these costs accrue at the corporate level (i.e., FFD program), with the exception of the costs for facility workers to review policy change information (which accrue to sites) and the costs for LTFs to train technicians on new requirements and validate drug assays (which accrue to sites with LTFs).
- NRC implementation costs would include analyzing public comments received on the proposed rule, holding public meeting(s), developing the final rule, and issuing final regulatory guidance.
- Hour estimates are based on the best professional judgment of NRC staff.
- Appendices B and D give additional information on inputs used in these estimates.

C.2 Lower Initial and Confirmatory Testing Cutoff Levels for Amphetamines and Cocaine

The proposed rule would revise the cutoff levels for initial testing (10 CFR 26.133, "Cutoff Levels for Drugs and Drug Metabolites," and 10 CFR 26.163(a)(1)) and confirmatory testing (10 CFR 26.163(b)(1)) to align with Section 3.4 of the 2008 HHS Guidelines as follows:

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

Lower cutoff levels for amphetamines and cocaine metabolites would increase the window of detection in which these drugs might be identified in the urine specimens provided by individuals. The changes also would provide additional assurance that persons will be unable to subvert the drug testing process through temporarily abstaining from using these drugs. As a result, the lower cutoffs are estimated to result in an increase in the number of urine specimens identified as containing amphetamines or cocaine metabolites, or both. The rule changes would improve the detection of drug users and may increase the deterrent effect of the testing program under 10 CFR Part 26, "Fitness for Duty."

Activity	*Parameter*	*Value*	*Benefits (Cost)*	*Sites Affected*	*Total Benefits (Costs)*
INDUSTRY OPERATIONS (ANNUAL)					
Amphetamines					
Additional testing at HHS-certified laboratory for amphetamines positive results (sites using LTFs)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($13)	6	($78)
	FFD current positive test rate	0.047%			
	Projected percent increase in positive testing rate	39.38%			
	Initial and confirmatory drug testing, HHS-certified laboratory	$29.00			
Medical Review Officer (MRO) review of result, donor interview, and medical downgrade for valid prescription use of amphetamines	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($22)	67	($1,474)
	FFD current positive test rate	0.047%			
	Projected percent increase in positive test rate	39.38%			
	Expected percent of additional positive results that will be negative after MRO interview with donor	25%			
	MRO activities (1 hour per positive): review laboratory result, interview donor, and evaluate medical information from donor	$137.73 per hour			
	Facility Worker activities (1 hour per positive): participate in interview with MRO, obtain medical information on valid use, and provide to MRO)	$63.86 per hour			
Subsequent actions by FFD program personnel for additional amphetamines confirmed positive test results (all sites)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($92)	67	($6,164)
	FFD current positive test rate	0.047%			
	Projected percent increase in confirmed positive test rate	39.38%			
	Projected percent of additional positive results that will confirm positive after MRO interview with donor	75%			
	Cost of subsequent actions (per positive result)	$283.24			
Cocaine					
Additional testing at HHS-certified laboratory for cocaine positive results (sites using LTFs)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($9)	6	($54)
	FFD current positive test rate	0.072%			
	Projected percent increase in positive test rate	18.38%			
	Initial and confirmatory drug testing, HHS-certified laboratory	$29.00			
Subsequent actions by FFD program personnel for additional cocaine positive test results (all sites)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($89)	67	($5,963)
	FFD current positive testing rate	0.072%			
	Projected percent increase in positive test rate	18.38%			
	Cost of subsequent actions (per positive result)	$283.24			
				Total Industry Operations Cost	***($13,733)***
				Average Operations Cost Per Site	***($205)***

Calculations (totals may not add because of rounding):

- Benefits (Cost) Per Site = Product (Data Inputs)
- Total Benefits (Cost) = Benefits (Cost) Per Site x Sites Affected
- Total Industry Operations Cost = Sum (Total Benefits (Cost))
- Average Operations Cost Per Site = Total Industry Operations Cost / Total Number of Sites

Assumptions:

- Licensees that only use HHS-certified laboratories for all drug testing pay a per-specimen cost, which includes initial drug testing of all specimens and confirmatory drug testing when applicable. Licensees that use LTFs for initial drug testing and HHS-certified laboratories for confirmatory testing would incur an incremental cost to conduct confirmatory testing at an HHS-certified laboratory for any additional specimens that screen positive at the LTF as a result of the rule changes.
- Lowering the testing cutoff levels would not change the LTF assay costs, nor would it require equipment upgrades. LTFs would purchase different standards and controls to comply with the new testing cutoff levels; however, purchasing standards, controls, and assays is a normal cost of operations and occurs on a regular basis.
- For amphetamines, 75 percent of HHS-certified laboratory positive tests results would be confirmed positive by the MRO (i.e., 25 percent of laboratory positives would be medically downgraded by the MRO based on a valid medical condition and prescription).
- For cocaine, all HHS-certified laboratory positive results would be confirmed positive by the MRO.
- Appendices B and D give additional information on parameters used in these calculations.

C.3 Expand Initial Drug Testing Panel to Include 6-AM and Revise Confirmatory Testing Cutoff Level for 6-AM

The proposed rule would add testing for 6-acetylmorphine (6-AM) to the initial testing panel (10 CFR 26.31(d)(1) and 10 CFR 26.405(d)); make conforming changes to the substances for initial testing (10 CFR 26.133 and 10 CFR 26.163(a)(1)) and confirmatory testing (10 CFR 26.163(b)(1)); and make conforming changes to the annual statistical summary reporting requirements for HHS-certified laboratories to include the revised testing panel (10 CFR 26.169(h)(3)). These changes would align 10 CFR Part 26 with Section 3.4 of the 2008 HHS Guidelines as follows:

(1) Include initial testing for 6-AM (10 ng/mL cutoff level).

(2) Remove the requirement that confirmatory testing of 6-AM only proceed when confirmatory testing shows a morphine concentration exceeding 2,000 ng/mL (such that, under the proposed rule, if initial testing for 6-AM is positive, confirmatory testing for 6-AM proceeds independent of the morphine concentration).

Conducting initial testing for an additional substance, 6-AM, would enable the improved detection of the illegal drug heroin, which has been increasing in use in society. The performance of initial testing for 6-AM is estimated to result in an increase the number of urine specimens identified as containing 6-AM. The rule change also may increase the deterrent effect of the 10 CFR Part 26 testing program.

Activity	*Parameter*	*Value*	*Benefits (Cost)*	*Sites Affected*	*Total Benefits (Costs)*
INDUSTRY OPERATIONS (ANNUAL)					
6-AM					
6-AM initial testing (sites using LTFs)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($3,530)	6	($21,180)
	Initial testing for one additional drug at an LTF	$1.50			
6-AM testing (sites only using HHS-certified laboratories)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($1,765)	61	($107,665)
	Testing for 6-AM (sites only using an HHS-certified laboratory)	$0.75			
Additional testing at HHS-certified laboratory for 6-AM positive results (sites using LTFs)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($12)	6	($72)
	Projected confirmed positive test rate	0.017%			
	Initial and confirmatory drug testing, HHS-certified laboratory (sites using an LTF for initial testing)	$29.00			
Subsequent actions by FFD program personnel for additional 6-AM positive test results (all sites)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($114)	61	($7,638)
	Projected confirmed positive test rate	0.017%			
	Cost of subsequent actions (per positive result)	$283.24			
			Total Industry Operations Cost		***($136,555)***
			Average Operations Cost Per Site		***($2,038)***

Calculations (totals may not add because of rounding):

- Benefits (Cost) Per Site = Product (Data Inputs)
- Total Benefits (Cost) = Benefits (Cost) Per Site x Sites Affected
- Total Industry Operations Cost = Sum (Total Benefits (Cost))
- Average Operations Cost Per Site = Total Industry Operations Cost / Total Number of Sites

Assumptions:

- Initial drug testing of each urine specimen for 6-AM would result in an incremental cost per test performed at LTFs and HHS-certified laboratories.
- Licensees that only use HHS-certified laboratories for all drug testing pay a per-specimen cost, which includes initial drug testing of all specimens and confirmatory drug testing when applicable. Licensees that use LTFs for initial drug testing and HHS-certified laboratories for confirmatory drug testing would incur an incremental cost to conduct confirmatory testing at an HHS-certified laboratory for any additional specimens that screen positive at the LTF as a result of the rule changes.
- All HHS-certified laboratory positive results for 6-AM would be confirmed positive by the MRO (i.e., no medical downgrades possible for heroin, a Schedule I drug—that is, an illegal drug).
- Appendices B and D give additional information on parameters used in these calculations.

C.4 Expand the Initial and Confirmatory Drug Testing Panels to Include Ecstasy

The proposed rule would add testing for two Ecstasy-type drugs (MDMA/MDA) to the testing panel (10 CFR 26.31(d)(1) and 10 CFR 26.405(d)); make conforming changes to the substances for initial testing (10 CFR 26.133 and 10 CFR 26.163(a)(1)) and confirmatory testing (10 CFR 26.163(b)(1)); and make conforming changes to the annual statistical summary reporting requirements for HHS-certified laboratories to include the revised testing panel (10 CFR 26.169(h)(3)). These changes would ensure that 10 CFR Part 26 is consistent with Section 3.4 of the 2008 HHS Guidelines.

The rule would revise the list of substances to be tested as follows:

- Include initial testing for MDMA and MDA (500 ng/mL testing cutoff level).
- Include confirmatory testing for MDMA and MDA (250 ng/mL cutoff levels).

Testing for Ecstasy would enable the detection of additional illegal drugs that could impair employee performance and that have been increasing in use in society. The performance of testing for Ecstasy drugs is estimated to result in an increase in the number of urine specimens identified as containing MDMA or MDA, or a combination. The rule change also may increase the deterrent effect of the 10 CFR Part 26 testing program by including these additional substances in the testing panel.

Activity	*Parameter*	*Value*	*Benefits (Cost)*	*Sites Affected*	*Total Benefits (Costs)*
INDUSTRY OPERATIONS (ANNUAL)					
Ecstasy					
Ecstasy initial testing (sites using LTFs)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($3,530)	6	($21,180)
	Initial testing for one additional drug at an LTF	$1.50			
Ecstasy testing (sites only using HHS-certified laboratories)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($1,177)	61	($71,797)
	Testing for Ecstasy (sites only using an HHS-certified laboratory)	$0.50			
Additional testing at HHS-certified laboratory for Ecstasy positive results (sites using LTFs)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($3)	6	($18)
	Projected confirmed positive test rate	0.004%			
	Initial and confirmatory drug testing, HHS-certified laboratory (sites using an LTF for initial testing)	$29.00			
Subsequent actions by FFD program personnel for additional Ecstasy positive test results (all sites)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($28)	67	($1,876)
	Projected confirmed positive test rate	0.004%			
	Cost of subsequent actions (per positive result)	$283.24			
				Total Industry Operations Cost	***($94,871)***
				Average Operations Cost Per Site	***($1,416)***

Calculations (totals may not add because of rounding):

- Benefits (Cost) Per Site = Product (Data Inputs)
- Total Benefits (Cost) = Benefits (Cost) Per Site x Sites Affected
- Total Industry Operations Cost = Sum (Total Benefits (Cost))
- Average Operations Cost Per Site = Total Industry Operations Cost / Total Number of Sites

Assumptions:

- Initial drug testing of each urine specimen for MDMA would result in an incremental cost per test performed at LTFs and HHS-certified laboratories.
- Licensees that only use HHS-certified laboratories for all drug testing pay a per-specimen cost, which includes initial drug testing of all specimens and confirmatory drug testing when applicable. Licensees that use LTFs for initial drug testing and HHS-certified laboratories for confirmatory drug testing also would incur an incremental cost to conduct confirmatory testing at an HHS-certified laboratory for any additional specimens that screen positive at the LTF as a result of the rule change.
- All HHS-certified laboratory positive results for Ecstasy would be confirmed positive by the MRO (i.e., no medical downgrades possible for MDMA/MDA, each is a Schedule I drug—that is, an illegal drug).
- Appendices B and D give additional information on parameters used in these calculations.

C.5 Special Analyses Testing of Dilute Specimens and Specimens Collected during Suspected Subversion Attempts

The regulations in 10 CFR 26.163(a)(2) provide licensees and other entities with the option to conduct special analyses testing on a donor specimen with a dilute validity test result (i.e., specimens with a creatinine concentration greater than or equal to 2 milligrams per deciliter (mg/dL) but less than 20 mg/dL). The special analyses testing consists of conducting confirmatory testing to the limit of detection (LOD) if the immunoassay response during initial drug testing is equal to or greater than 50 percent of the cutoff calibrator in a drug class.

The proposed rule would do the following:

(1) Require special analyses testing of dilute specimens if the immunoassay response for a drug is equal to or greater than 40 percent of the cutoff calibrator for initial drug testing.

(2) Expand the use of special analyses testing to circumstances where a subversion attempt is suspected during the specimen collection process (e.g., if the initial specimen provided is out of temperature range, the second specimen collected under direct observation would be subject to the special analyses testing provisions).

(3) Increase the assurance of special analyses testing by using the limit of quantitation (LOQ) instead of the LOD as the level at which confirmatory testing is to be conducted. Each HHS-certified laboratory must establish both the LOD and the LOQ for each assay and both measures are scientifically valid. However, the LOQ requires that the analyte be reliably detected and reliably quantified. The LOD only requires that a drug analyte be reliably identified but not quantified.

These changes would further enhance the detection of drugs when specimens do not present normal physiological characteristics. The 2008 HHS Guidelines do not address special analyses testing, but the proposed changes are based on industry experience and feedback received from HHS-certified laboratories in implementing the 2008 FFD final rule.

Activity	*Parameter*	*Value*	*Benefits (Cost)*	*Sites Affected*	*Total Benefits (Costs)*
INDUSTRY OPERATIONS (ANNUAL)					
Special Analyses Testing of Dilute Specimens					
LOQ special analyses testing at an HHS-certified laboratory (all sites)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($85)	67	($5,695)
	Average annual percentage of specimens tested that are dilute and special analyses testing performed	0.466%			
	Special analyses testing at an HHS-certified laboratory	$7.75			
Subsequent actions by FFD program personnel for additional dilute positive test results (all sites)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($33)	67	($2,211)
	Average annual percentage of specimens tested that are dilute and test positive on special analyses testing	0.005%			
	Cost of subsequent actions (per positive result)	$283.24			
Special Analyses Testing of Specimens Collected during Suspected Subversion Attempts					
LOQ special analyses testing at an HHS-certified laboratory (all sites)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($6)	67	($402)
	Average annual percentage of specimens tested that are determined to be a subversion attempt and that test positive (suspect specimens that test positive on special analyses testing)	0.033%			
	Special analyses testing at an HHS-certified laboratory	$7.75			
Subsequent actions by FFD program personnel for additional positive drug test results (all sites)	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	($44)	67	($2,948)
	Average annual percentage of specimens tested that are determined to be a subversion attempt and that test positive (suspect specimens that test positive on special analyses testing)	0.033%			
	Projected percent increase in confirmed positive test rate	20%			
	Cost of subsequent actions (per positive result)	$283.24			
				Total Industry Operations Cost	***($11,256)***
				Average Operations Cost Per Site	***($168)***

Calculations (totals may not add because of rounding):

- Benefits (Cost) Per Site = Product (Data Inputs)
- Total Benefits (Cost) = Benefits (Cost) Per Site x Sites Affected
- Total Industry Operations Cost = Sum (Total Benefits (Cost))
- Average Operations Cost Per Site = Total Industry Operations Cost / Total Number of Sites

Assumptions:

- Appendices B and D give additional information on parameters used in these calculations.

Appendix D: Costs of Subsequent Actions

Subsequent Action Labor Hours and Costs per Positive, Adulterated, Substituted, or Refusal to Test Result

"Subsequent actions” refers to the activities completed by staff of the licensee or other entity and the Medical Review Officer (MRO) following a drug or alcohol positive result, an adulterated or substituted validity test result, or refusal to test (as required by 10 CFR Part 26, “Fitness for Duty Programs”).

Subsequent actions consist of activities performed by the licensee or other entity staff and the MRO regarding the review and confirmation of a test result, communications with the donor throughout the verification and sanctioning process, and recordkeeping and reporting. For example, subsequent actions include MRO communications with the donor about the result, the communications between the MRO and the licensee about a confirmed test result (recording and reporting the result), licensee or other entity administrative actions implemented by the 10 CFR 26.75, “Sanctions,” and any request by the donor to request the retesting of an aliquot of a single specimen or the testing of Bottle B of the split specimen, or appeal of the result.

Labor Category	Wage Rate	Labor Per Result	Total Benefits (Cost) Per Result
MRO	$137.73/hour	0.75 hours	$103.30
FFD Manager	$44.21/hour	2.00 hours	$88.42
FFD Staff	$36.87/hour	0.75 hours	$27.65
Facility Worker	$63.86/hour	1.00 hours	$63.86
Total		**4.50 hours**	**$283.24**

Calculations:

- Benefits (Cost) Per Entity = Unit Cost x Unit(s)

Assumptions:

- Hour estimates based on best professional judgment of the U.S. Nuclear Regulatory Commission staff.

Appendix E: Averted Costs

Averted Training Costs—Pre-Access Testing

The proposed rule is estimated to result in savings to licensees and other entities (i.e., averted costs) associated with training during the in-processing of licensee employees and contractor/vendors (C/Vs). Approximately 68 percent of positive test results each year are identified during pre-access testing. As a result, if an individual tests positive for a drug during pre-access testing, any remaining training not completed by that individual at the time of the confirmed positive test result is received would result in savings because access authorization immediately would be denied to the individual for failing the required fitness-for-duty (FFD) drug test.

The staff estimated averted training costs by calculating the "Total Additional Positive Test Results Expected from the Proposed Rule Changes" and multiplying that value by the cost of labor that would be averted for each positive result.

Activity	*Parameter*	*Value*	*Positives Per Site*	*Sites Affected*	*Total Positives*
INDUSTRY OPERATIONS (ANNUAL)					
Total Additional Positive Test Results Projected from Proposed Rule Changes					
Additional 6-AM positive results	Number of drug tests conducted per site per year under 10 CFR Part 26, "Fitness for Duty Programs"	2,353	0.40	67	27
	Projected confirmed positive test rate	0.017%			
Additional Amphetamine Positive Results	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	0.33	67	22
	FFD current confirmed positive test rate	0.047%			
	Projected percent increase in positive test rate	39.38%			
	Projected percentage of additional positive results that will confirm positive after Medical Review Officer (MRO) interview with donor	75.0%			
Additional Cocaine Positive Results	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	0.31	67	21
	FFD current confirmed positive test rate	0.072%			
	Projected percent increase in positive test rate	18.38%			
Additional Ecstasy Positive Results	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	0.10	67	7
	Projected confirmed positive test rate	0.004%			
Additional Dilute Specimen Positives	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	0.12	67	8
	Average annual percentage of specimens tested that are dilute and test positive on special analyses testing	0.005%			
Additional Suspect Specimen Positives	Number of drug tests conducted per site per year under 10 CFR Part 26	2,353	0.15	67	10
	Average annual percentage of specimens that are determined to be a subversion attempt and that test positive (suspect specimens that test positive on special analyses testing)	0.033%			
	Projected percent increase in confirmed positive test rate	20%			
			Total Additional Positive Test Results Projected from Proposed Rule Changes		*95*
Averted Training Costs—Pre-Access Testing					
Averted training costs for new licensee employees and C/Vs with positive pre-access drug test results	Change in number of positive results per site based on proposed rule changes (division of "Total Additional Positive Test Results Projected from Proposed Rule Changes" by the number of sites)	1.42/site	$923	67	$87,821
	Percentage of total positive test results occurring at pre-access testing	67.8%			
	Weighted average of total in-processing training time for a new licensee employee or C/V	43 hours			
	Average number of training hours until receipt of MRO-verified positive drug test result after collection	28 hours			
	Training time (in hours) averted for an individual with a positive drug test during in-processing. (Difference between "Weighted average of total in-processing training time for a new licensee employee or C/V" and the "Average number of training hours until receipt of MRO-verified positive drug test result after collection)	15 hours			
	Facility Worker hourly wage rate	$63.86			
				Total Industry Operations Benefit	***$87,821***
				Average Operations Benefit Per Site	***$1,311***

Calculations (totals may not add because of rounding):

- Benefits (Cost) Per Site = Product (Data Inputs)
- Total Benefits (Cost) = Benefits (Cost) Per Site x Sites Affected
- Total Industry Operations Cost = Sum (Total Benefits (Cost))
- Average Operations Cost Per Site = Total Industry Operations Cost / Total Number of Sites

Assumptions (all values based on the judgement of the NRC staff):

- In-processing personnel work 8 hours per day to complete training activities.
- FFD drug and alcohol testing is performed on the first day of in-processing.
- A positive drug test result is confirmed by the MRO within 3.5 days of specimen collection, on average. This means that, on average, in-processing personnel would have completed 28 hours of training by the time the positive result was reported to the licensee or other entity.
- The weighted average of training time (in hours) per person during in-processing is based on the following assumptions:
  - (1) All personnel require 5 days (40 hours) to complete in-process training (i.e., arrival, electronic personal history questionnaire review and follow up if needed, general employee training (access authorization, FFD drug and alcohol testing, emergency evacuation, site awareness, and site access badging), and site access (consent, fingerprints, personally disqualifying information review) = 40 hours total training days
  - (2) 25 percent of in-processing personnel require 4 additional hours of confined space, Occupational Safety and Health Administration (OSHA), and radiological training = 44 hours in total training time (total of 1 + 2)
  - (3) 25 percent of in-processing personnel require 8 additional hours of training (4 hours for confined space, OSHA, and radiological training and 4 hours for dynamic demonstration training (e.g., in-shop demonstration training) = 48 hours in total training time (total 1 + 2 + 3)

    Weighted average of total training days per person during in-processing = (50% x 40 hours) + (25% x 44 hours) + (25% x 48 hours) = 43 hours
- Appendices B and D give additional information on parameters used in these calculations.

Appendix F: Backfitting and Issue Finality

This appendix presents the evaluation by the staff of the U.S. Nuclear Regulatory Commission (NRC) of the proposed changes to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 26, "Fitness for Duty Programs" (Ref. 1), in accordance with backfitting provisions in 10 CFR 50.109, "Backfitting" (Ref. 8), and 10 CFR 70.76, "Backfitting" (Ref. 9), and the issue finality provision in 10 CFR 52.98, "Finality of Combined Licenses; Information Requests" (Ref. 10) (hereinafter the "Backfit Rule"). The backfitting provision of 10 CFR 70.76 is applicable to currently licensed Category I fuel fabrication facilities. The staff has considered these facilities in the aggregated backfit analysis.

Because some individuals seeking employment in or already working in the commercial nuclear workforce may use illegal drugs or misuse legal drugs, or both, this proposed rule focuses on enhancing the identification of those individuals using illegal drugs whose potential impairment could result in unsafe or unsecure conditions at NRC-licensed facilities. Granting or maintaining access authorization under 10 CFR Part 73 is contingent on an individual meeting the FFD authorization requirements in 10 CFR Part 26, which in part, require the individual to have negative test results for drugs and alcohol. An individual that 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. Additionally, granting or maintaining unescorted access authorization to these individuals also 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, "Physical Protection of Plants and Materials" (Ref. 16).

The proposed rule is projected to result in an estimated 10- to 12-percent increase in the number of individuals identified each year using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process (as compared to the 10 CFR Part 26 test results in calendar year (CY) 2013 and CY 2014). As demonstrated in Section F.2 of this appendix, in light of the benefits of the proposed rule, the NRC staff finds that the backfits under 10 CFR 50.109 or 10 CFR 70.76 and violations of issue finality under 10 CFR 52.98 (hereinafter "backfits") contained in the proposed rule, when considered in the aggregate, would constitute a substantial increase in public health and safety or the common defense and security based on: (1) reducing the risk that the public would be affected by an accidental offsite release of radioactive material as a result of human performance issues associated with drug-induced impairment, and (2) reducing security vulnerability by identifying additional individuals demonstrating characteristics of not being trustworthy and reliable through the use of illegal drugs, misuse of legal drugs, or attempts to subvert the drug testing process. Further, the direct and indirect costs of implementing the proposed rule would be justified in view of this increased protection, thereby satisfying the criteria of 10 CFR 50.109(a)(3), 70.76(a)(3), and 52.98(a) to allow the imposition of the backfits.

The backfits would enhance the effectiveness of the NRC fitness-for-duty (FFD) testing program to maintain reasonable assurance of a workplace free of drugs and the effects of such substances. The staff finds that the backfits can be accomplished at a low cost—an average

one-time cost per site[33] of ($5,031) and an average annual cost per site[34] of ($2,516). The estimated net present value cost of the proposed rule over the 25-year time period of the analysis is approximately ($2.4 million) to industry,[35] assuming a 7-percent discount rate, or approximately ($3.4 million) assuming a 3-percent discount rate.

With regard to benefits, the proposed rule is expected to enhance FFD program effectiveness by increasing the detection of individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process, who would be identified and denied unescorted access authorization. The proposed rule would benefit public health and safety and the common defense and security by increasing the panel of drugs tested; increasing the timeframe (i.e., the window of detection) in which some drugs can be detected in an individual's body after use; reducing the likelihood that individuals would be able to subvert the drug testing process; improving regulatory clarity, organization, and flexibility; and enhancing program integrity and protection of individual rights.

The backfit analysis examines the aggregation of the subset of regulatory requirements that constitute backfits. The analysis excludes individual requirements that are not subject to the Backfit Rule or that do not fall within the definition of "backfitting" as defined in the Backfit Rule, which include requirements that fall into one or more of the following categories:

(1) *Administrative matters* are revisions that make minor administrative changes (such as correction of typographic errors, correction of inconsistencies, relocating requirements from one section to another, and combining existing requirements into a single section)

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33 The term "site" used in this analysis corresponds to the term "facility" used by the NRC FFD performance reports (Ref. 6). "Site" refers to a unique location at which personnel subject to an FFD program must undergo drug and alcohol testing (e.g., a nuclear power reactor containing one or more units, a licensee corporate office). A single FFD program may cover FFD activities at one or more sites (e.g., a corporate office may develop one drug and alcohol testing policy for all sites).

34 The NRC staff assumes that the licensee or other entity of each site would incur an average cost per requirement. This assumption is a simplification; some licensees and other entities would incur a higher or lower operations cost depending on the size of the population drug tested at the site (e.g., an operating power reactor site conducts more drug tests than a corporate office). The licensees and other entities subject to 10 CFR Part 26 includes 57 operating power reactor sites, 2 power reactor construction sites, 5 corporate offices, 2 Category I fuel cycle facilities, and 1 contractor/vendor (C/V) (see Appendix A). Corporate offices, Category I fuel cycle facilities, and C/Vs use much smaller workforces than operating power reactor sites and power reactor construction sites (see Table 4-1 and Appendix A). They also do not incur periodic workforce surges as a result of changing site conditions, unlike power reactor sites (e.g., refueling outages, various states of site construction). An analysis of CY 2013 and CY 2014 FFD program performance data indicated that between 23 and 25 percent of drug positive test results for operating power reactor sites and between 33 and 40 percent of drug positive test results for power reactor construction sites were associated with substances in the current testing panel that will be affected by the proposed rule (i.e., amphetamine, cocaine, methamphetamine, 6-acetylmorphine (6-AM)). The proposed rule changes would have limited impact on additional detection at other facility types given the very low number of positive results (see Table 4-1). As a result, the NRC staff anticipates improvement in detection at operating power reactor and power reactor construction sites. By using an average cost per site, the analysis overestimates the operations costs for smaller workforce sites and underestimates the costs for larger workforce sites, but on balance it provides a reasonable estimate for the incremental testing costs associated with the proposed rule given that the majority of the sites and tested workforces (59 of 67) are at power reactors.

35 This estimate includes one-time industry implementation costs incurred in CY 2017 and annual industry operations costs incurred over an average of 25 years, which represents the average remaining license term for the current power reactor operating fleet (see Section 4.2.3 for details).

or changes in NRC administrative requirements (such as acceptable document formats, number of copies to be submitted, or an NRC administrative process).

(2) *Information collection and reporting requirements* are revisions that either amend existing information collection and reporting requirements or impose new information and collection and reporting requirements, as set forth in the charter for the Committee to Review Generic Requirements (Ref. 33).

(3) *Clarifications* are revisions that clarify current requirements to assure consistent understanding and implementation of the original intent for these requirements. These revisions remove the ambiguities that produced regulatory uncertainty without changing the underlying requirements stated in these sections.

(4) *Permissive relaxations/voluntary alternatives* are revisions that permit, but do not require, relaxations or alternatives to current requirements (i.e., licensees or other entities are free to either comply with current requirements or adopt the relaxed requirements/voluntary alternatives as a binding requirement).

F.1 Rule Provisions that Constitute Backfits

The seven requirements in the proposed rule that are discussed in this section qualify as backfits because they result in modifications to procedures required to operate the facility.

Section 5.1 of the regulatory analysis quantitatively estimates the costs and benefits of each of these provisions, except for proposed requirements associated with the Medical Review Officer (MRO) review of invalid validity test results due to high pH values (9.0 to 9.5), MRO documentation of receipt of an oral request from a donor to conduct retesting of a specimen, the requirement to conduct testing of any specimen collected during a post-event testing situation associated with a refusal to test determination at the time of the collection, and changes to improve the clarity, consistency, and flexibility of the 10 CFR Part 26 rule (e.g., addition and revision of definitions and terms). As discussed in Section 4.2.3 of the regulatory analysis, the MRO provisions would result in some incremental effort (e.g., time to perform a new review for specimens with an invalid validity test result due to high pH values), but the cost would be incurred only infrequently (i.e., for a subset of specimens with invalid validity test results) so the total cost of the change would be minor. Nonetheless, these new requirements qualify as backfits and are included in the backfit analysis.

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

The proposed rule would update 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 November 25, 2008, revisions to the U.S. Department of Health and Human Services' (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (Volume 72 of the *Federal Register*, page 1858 (73 FR 71858); Ref. 2) (hereafter referred to as the "2008 HHS Guidelines"). Section 3.4 of the 2008 HHS Guidelines describes these changes as follows:

- Lower the initial drug testing cutoff level for amphetamines from 1,000 nanograms (ng) per milliliter (mL) to 500 ng/mL.

- Lower the initial drug testing cutoff level for cocaine metabolites from 300 ng/mL to 150 ng/mL.

- Lower the confirmatory drug testing cutoff level for cocaine metabolites from 150 ng/mL to 100 ng/mL.

- Lower the confirmatory drug testing cutoff levels for amphetamine and methamphetamine from 500 ng/mL to 250 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 proposed rule would not require more specimen collections, but it would require each urine specimen to be tested for 6-AM. The drug testing panel would be revised to include initial testing for 6-AM at a cutoff level of 10 ng/mL. The proposed rule also would remove the requirement that confirmatory testing of 6-AM only proceed when confirmatory testing shows a morphine concentration exceeding 2,000 ng/mL (i.e., under the proposed rule, if initial testing for 6-AM is positive, confirmatory testing for 6-AM is to proceed independent of the morphine concentration). The proposed rule would make conforming changes to the annual statistical summary reporting requirements for HHS-certified laboratories to include the revised drug testing panel in 10 CFR 26.169(h)(3).

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

The proposed rule would not require more specimen collections, but it would require each urine specimen to be tested for Ecstasy.[36] The list of substances to be tested for would be revised to include initial testing for MDMA and MDA at a cutoff level of 500 ng/mL. The proposed rule also would include confirmatory testing for MDMA and MDA at a confirmatory test cutoff level of 250 ng/mL. The proposed rule would make conforming changes to the annual statistical summary reporting requirements for HHS-certified laboratories to include the revised drug testing panel in 10 CFR 26.169(h)(3).

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

The proposed rule would require 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 would increase the number of specimens that are subject to confirmatory testing and may thereby improve the ability of licensees to identify instances in which individuals may be attempting to subvert the testing process.

5. 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 proposed rule would require 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,

[36] Ecstasy-type drugs that would be included in the drug testing panel are methylenedioxymethamphetamine (MDMA) and one of its derivatives methylenedioxyamphetamine (MDA).

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 an additional donor protection on the accuracy of special analyses and adulterant test results.

6. 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 of an aliquot of a single specimen.

The proposed rule would require additional actions by the MRO in two circumstances. First, 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, the MRO must document the date and time that the request was received from the donor (this action is consistent with existing MRO practice, but this documentation requirement was not specified in the current rule).

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

The proposed rule would require the testing of any specimen collected during a post-event testing situation when a refusal to test has been determined during the collection process. Previously, any specimen collected would be discarded. In an effort to improve the root-cause evaluation process associated with accidents, testing of any urine specimen collected would be required to ensure that all available information is obtained to support the evaluation of human performance associated with the accident.

F.2 Aggregated Backfit Analysis

The NRC staff evaluated the aggregated set of requirements that constitutes backfits to determine whether the costs of implementing the proposed rule would be justified by a substantial increase in public health and safety or the common defense and security. The NRC staff considered the following nine factors:

1. Statement of the specific objectives that the backfit is designed to achieve.

The NRC would amend certain provisions in 10 CFR Part 26 to align with the 2008 HHS Guidelines and to reflect lessons learned from implementation of the 2008 FFD final rule (Ref. 3) to (1) improve the effectiveness and efficiency of licensee FFD drug testing programs, (2) improve the clarity, organization, and flexibility in the rule requirements, and (3) enhance FFD program integrity and protection of individual rights.[37]

[37] The majority of the requirements constituting backfits achieve at least two, and in some cases all three, of the rule objectives, as presented in Table 5-12. As a result, disaggregation of the costs and benefits according to the rulemaking objectives does not have meaningful implications on the cost-benefit results.

2. General description of the activity that would be required by the licensee or applicant in order to complete the backfit.

The backfits would 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.

In addition, with regard to special analyses testing, licensees would need to conduct mandatory limit of quantitation (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.

Finally, with regard to MRO reviews, licensees would need to require an updated MRO review process for invalid validity specimen test results. Specifically, if an acceptable medical explanation is not provided by the donor 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 and the specimen to be tested is unavailable because of circumstances outside of the donor's control, licensees would 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.

3. Potential change in the risk to the public from the accidental offsite release of radioactive material.

The rulemaking would not directly affect the likelihood of core damage or spent fuel damage. The rulemaking could reduce the risk that the public would be affected by an accidental offsite release of radioactive material as a result of human performance issues associated with drug-induced impairment.

4. Potential impact on radiological exposure of facility employees.

The rulemaking would not directly affect the likelihood of core damage or spent fuel damage. The rulemaking 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 backfit, including the cost of facility downtime or the cost of construction delay.

The estimated one-time industry cost associated with the backfits would be approximately ($337,100), and the annually recurring cost would be approximately ($168,600). Combining these initial and annual costs, this analysis estimates that the backfits associated with the proposed rule would cost industry approximately ($2.4 million) (present value, assuming a 7-percent discount rate) to ($3.4 million) (present value, assuming a 3-percent discount rate).

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

The proposed rule would make minor changes to drug testing operations that would enhance safety and security by identifying additional individuals using drugs and then denying their

unescorted access authorization. This would 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 backfit and the availability of such resources.

The NRC will prepare a regulatory guide and develop proposed and final rule changes. The NRC's implementation costs will be approximately ($273,000). The staff 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 backfit.

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

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

The backfit is final.

Collectively, the individual requirements in the proposed rule that qualify as backfits would result in an estimated present value cost of approximately ($2.4 million) to industry, assuming a 7-percent discount rate, or approximately ($3.4 million) assuming a 3-percent discount rate. The NRC staff estimates that the backfits would result in a one-time cost of ($5,031) per site, followed by an annual cost of ($2,516) per site.

The proposed rule is estimated to result in 10- to 12-percent increase in the number of individuals identified each year using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process, thereby enhancing safety and security at affected facilities. The proposed rule also would benefit public health and safety and 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 amphetamines, cocaine metabolites, 6-AM, and methamphetamines would increase the timeframe (i.e., the window of detection) in which these drugs can be detected in an individual's body after use. This would reduce the likelihood that individuals could subvert the testing process through temporary abstinence from a drug. Expanding the initial drug testing panel to include 6-AM, MDMA and MDA and the confirmatory drug testing panel to include MDMA and MDA also would improve the ability of licensees and other entities to identifying additional persons using illegal drugs. These changes would improve the trustworthiness and reliability of the workforce through the identification of additional individuals using drugs who would be denied unescorted access authorization. In addition, the improved detection of drugs is a proactive risk-informed FFD strategy—since testing began in 1990, approximately 68 percent of individuals who test positive for drugs each year are identified before they receive unescorted access authorization (i.e., at pre-access testing).

- *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, would reduce the likelihood that individuals would be able to subvert the testing process. Additionally, using the LOQ instead of the limit of detection as the level at which confirmatory drug testing is to be conducted would increase the assurance provided by special analyses testing by adding a level of precision to the testing method. These changes would 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 would improve the trustworthiness and reliability of the workforce through the identification of individuals using illicit drugs who would 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 proposed rule would enhance 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 proposed rule would improve regulatory efficiency by (1) harmonizing select 10 CFR Part 26 definitions and drug testing procedures with those described in the 2008 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 FFD 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 2008 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 current rule, if a refusal to test is determined during the specimen collection process, any specimen(s) obtained from the donor are discarded. The proposed rule would require 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 would improve the ability of the licensee or other entity to determine if substance use could have been a contributing factor to an accident.

In light of the direct benefit of improving the detection of drug users, as well as the efficiencies, flexibilities, and donor protections included in the proposed rule, the NRC staff finds that the backfits contained in the proposed rule, when considered in the aggregate, would constitute a substantial increase in public health and safety or the common defense and security.

Tables F-1 and F-2 present information that supports the NRC staff's determination that the proposed rule alternative (Alternative 2) would result in a substantial increase in public health and safety or the common defense and security.

Table F-1 summarizes the quantified benefits and costs of each regulatory initiative under the proposed rule alternative. It also summarizes, by regulatory initiative, the projected benefit in the detection of additional individuals using drugs. In interpreting these results, it is important to understand that the net present value results in Table F-1 are presented for the 25-year time period of the analysis, while the estimated benefit, by regulatory initiative, in the detection of additional drug users is presented on an annual basis. The broad-based improvements in detection across the regulatory initiatives, as well as the magnitude of the total increase in comparison to drug testing positive results in CY 2013 and CY 2014, support the NRC staff's determination of a substantial increase in public health and safety or the common defense and security to be derived from the backfits and that the direct and indirect costs of implementation are justified in view of this increased protection.

Table F-1. Cost-Benefit Comparison of Alternative 2 (Proposed Rule)

Regulatory Initiative	7% Net Present Value (25-year time period of the analysis)			Estimated Benefit (Annual Basis)
	5%	Mean	95%	
Enhance detection of existing paneled drugs by lowering cutoff levels (amphetamine, cocaine, methamphetamine)	($247,653)	($176,723)	($110,715)	43 additional positive results (22 amphetamines positives and 21 cocaine positives)
Expand testing panel to include initial testing of 6-AM (and revise confirmatory testing cutoff level)	($2,105,447)	($1,685,517)	($1,269,515)	27 additional positive results
Expand testing panel to include testing of Ecstasy drugs	($1,550,350)	($931,248)	($316,821)	7 additional positive results
Enhance detection of subversion attempts by requiring special analyses testing of dilute specimens and specimens collected under direct observation	($175,444)	($123,307)	($71,013)	18 additional positive results (8 positives from dilute specimens and 10 positives from suspect specimens)
To incorporate all drug testing program changes, sites would incur one-time costs to change policies, procedures, and conduct training	($353,436)	($338,330)	($324,339)	Required activities to implement drug testing changes at laboratories and inform all subject employees of testing program changes
Averted training costs (pre-access testing)	$647,688	$1,034,618	$1,492,936	Historically, 68% of positive test results each year are identified at pre-access testing. Individuals testing positive before completion of training would result in savings to licensees and other entities.
Total Industry Results	**($3,088,766)**	**($2,220,507)**	**($1,358,859)**	**95 additional positive results, and additional non-quantified benefits**
Average Cost per Site	**($46,100)**	**($33,142)**	**($20,281)**	

Table F-2 summarizes the trends addressed by the proposed rule alternative. FFD program performance data for CY 2014, a comparison of this information to previous years, and other indicators show year-over-year increases in amphetamines positive results, a significant number of subversion attempts that have been identified since CY 2011, and other adverse trends. This information supports the NRC staff's determination that the proposed rule would result in a substantial increase in public health and safety or the common defense and security.

Table F-2. Summary of FFD Program Performance Trends and Rulemaking Options Addressing Each Trend

Trend Addressed by Proposed Rule	Lower Testing Cutoff levels	Add Drug(s) to Testing Panel	Revised Testing Method
Amphetamine/Methamphetamine Positives (2010–2014) • Year-over-year increases in positive rates (0.032% in CY 2010; 0.067% in CY 2014) • 6.2 to 10.6% of drug test positives each year (use of these substances is growing in the tested population) • High prevalence in multi-substance positives (see below)	X		
Subversion Attempts (2011–2014) • 143 to 187 individuals per year attempted to subvert the testing process (approximately 17 to 21% of drug testing positives each year) • 36 to 47 sites with at least one subversion each year (site prevalence) • 72 to 76% of subversion attempts at pre-access testing • 17 to 18% of subversion attempts at random testing • Based on prevalence of subversion attempts at pre-access testing, it is likely that some individuals are successfully subverting the pre-access testing process (i.e., other testing methods are relied on to identify these individuals—random, for-cause, post-event testing)	X	X	X
Cocaine Positives • Third most detected substance in testing panel since CY 2008; second most detected substance in panel from CY 1990 (first year of NRC testing) through CY 2007 • Use in critical group (i.e., two to six licensed reactor operators and supervisors tested positive for cocaine each year from 2012 to 2014)	X		
Multi-substance Positive Results (2011–2014) • 83 to 93% of individuals with a multi-substance result tested positive for amphetamine, methamphetamine, or cocaine, or a combination • 14 to 23 sites with at least one multi-substance positive each year (site prevalence) • 34 to 48 individuals test positive for more than one substance each year • Approximately 28 to 53% of individuals with a multi-substance positive were identified by random, for-cause, post-event, or followup testing (i.e., after unescorted access was granted)	X	X	