Regulatory Basis

Proposed Rulemaking to Amend 10 CFR Part 26, "Fitness for Duty Programs," based on Select Provisions of the 2008 HHS Guidelines

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U.S. Nuclear Regulatory Commission

Office of Nuclear Security and Incident Response

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1. Introduction

This document presents the regulatory basis for recommending a rulemaking to amend Part 26 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Fitness for Duty Programs," (hereafter referred to as "Part 26") to enhance consistency of the Commission's regulations with select drug testing provisions in the U.S. Department of Health and Human Services' (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (i.e., HHS Guidelines). This rulemaking would improve the effectiveness, efficiency, and clarity of Part 26 drug testing requirements. These outcomes would be achieved by: (1) broadening the scope of testing for amphetamine-based controlled substances[1] or drugs[2] to include testing for the street drug *Ecstasy*; (2) lowering the drug testing cutoff levels for amphetamine, methamphetamine, and cocaine to increase the "window of detection;"[3] (3) adding initial testing for 6-acetylmorphine (6-AM) to improve detection of heroin use; (4) enhancing the detection and evaluation of drugs in dilute urine specimens and in specimens collected when reasonable suspicion exists that the donor has attempted to subvert the testing process; (5) requiring medical review officers (MROs) to consider elapsed time and high temperature when evaluating invalid test results due to high solvated hydrogen ion concentration (i.e., pH) to ensure that due process is afforded to individuals whose urine exhibits higher than expected pH; (6) amending Part 26 to correct references to donor specimens, controls, and laboratory analysis in quality assurance and

[1] "Controlled substance" is defined as a drug or other substance or immediate precursor, included in Schedules I-V of Section 202 of the Controlled Substances Act, as amended (21 U.S.C. § 812). In this Regulatory Basis document, "drug" and "controlled substance" are used interchangeably.

[2] "Drug" is defined in the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. § 321(g)(1)), as, in part, articles intended "for use in the diagnosis, cure, mitigation, treatment or prevention of disease" or "to affect the structure or any function of the body" as recognized by the official U.S. Pharmacopoeia. However, as used in this document, "drug" also means a substance (either legal or illegal) that causes changes in physiological or mental performance, behavior, perception, or emotion.

[3] "Window of detection" refers to the time period after the use of a drug for which a target metabolite can be quantified by the detection technology, methodology, and cutoff.

quality control processes; and (7) aligning selected Part 26 definitions and drug testing methodologies with those described in the 2008 HHS Guidelines.[4]

The proposed rulemaking and supporting documentation would be applicable to the following classes of licensees and other entities, as specified in 10 CFR 26.3:

- Operating Power Reactors: Holders of operating licenses for nuclear power reactors under the provisions of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and combined licenses (COLs) under the provisions of 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," after the Commission has made the finding under 10 CFR 52.103(g), except those who have certified that they have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel;

- Power Reactors Under Construction: Applicants for nuclear power plant construction permits (CPs) or COLs that have a limited work authorization (LWA) under the provisions of 10 CFR Part 50; holders of COLs before the Commission has made the finding under 10 CFR 52.103(g); and holders of nuclear power plant CPs and early site permits (ESPs) with an LWA;

- Category I Fuel Cycle Facilities: Licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," and any entity under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants," engaged in activities involving formula quantities of SSNM; and

- Contractors/Vendors (C/Vs): C/Vs that implement fitness for duty (FFD) programs or program elements to the extent that the licensees and other entities listed in 10 CFR 26.3(a)-(c) rely on those C/V FFD programs or program elements.

The proposed rulemaking would be applicable to the following categories of persons:

- All persons who are granted unescorted access to nuclear power reactor protected areas by operating power reactor licensees and, as applicable, licensees of power reactors under construction as specified in 10 CFR 26.4(b).

- All persons who are required by operating power reactor licensees and, as applicable, licensees of power reactors under construction, to physically report to the licensee's Technical Support Center or Emergency Operations Facility by licensee emergency plans and procedures, as specified in 10 CFR 26.4(c).

- Any individual whose duties for Category I fuel cycle facilities require him or her to have the following types of access or perform the following activities, as specified in 10 CFR 26.4(d): persons who are granted access to, measure, transport, escort, or guard Category IA material; and persons who create or have access to procedures or records for safeguarding SSNM.

[4] U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, "Mandatory Guidelines for Federal Workplace Drug Testing Programs," *Federal Register*, Vol. 73, No. 228, November 25, 2008, pp. 71858-71907.

- When construction activities begin, any individual whose duties at power reactors under construction require him or her to have the following types of access or perform the following activities, as specified in 10 CFR 26.4(e): serves as security personnel; performs quality assurance, quality control, or quality verification activities related to safety- or security-related construction activities; monitors the fitness of the individuals who perform construction activities; witnesses or determines inspections, tests, and analyses certification required under 10 CFR Part 52; supervises or manages the construction of safety- or security-related structures, systems, or components (SSCs); directs or implements the access authorization program.

- Any individual who is constructing or directing the construction of safety- or security-related SSCs and is subject to an FFD program meeting the requirements of 10 CFR Part 26, Subpart K, unless the licensee or other entity subjects these individuals to an FFD program that meets all of the requirements of Part 26, except Subparts I and K.
- All FFD program personnel who are involved in the day-to-day operations of the program and whose duties require them to have the following types of access or perform the following activities, as specified in 10 CFR 26.4(g): all persons who can link test results with the individual who was tested; all persons who make determinations of fitness; all persons who make authorization decisions; all persons involved in selecting and notifying individuals for testing; all persons involved in the collection or onsite testing of specimens.

2. Background

Part 26 prescribes the requirements and standards to establish, implement, and maintain FFD programs. Part 26 requires drug and alcohol testing of individuals to provide reasonable assurance that individuals who are granted or maintain the types of access or perform the duties specified in 10 CFR 26.4 are trustworthy and reliable, as demonstrated by the avoidance of substance abuse, and are not under the influence of substances that adversely affect their abilities to safely and competently perform their duties. Drug and alcohol testing directly contributes to public health and safety and the common defense and security by providing reasonable measures for the early detection of individuals who are not fit to perform the duties that require them to be subject to the FFD program.

The U.S. Nuclear Regulatory Commission (NRC) issued a substantial revision to Part 26 in a final rule published on March 31, 2008.[5] These changes were necessary to implement advances in drug and alcohol testing technologies and lessons learned from rule implementation since the rule was first issued in 1989. The changes also were necessary to improve the effectiveness and efficiency of FFD programs; improve consistency with the NRC's access authorization requirements; improve the clarity and organization of the rule; eliminate or modify unnecessary requirements; protect the rights (e.g., privacy, due process) of individuals subject to Part 26; and strengthen the FFD programs by establishing clear and enforceable requirements to manage worker fatigue. These amendments made Part 26 more consistent with other relevant Federal rules and the 2004 HHS Guidelines.[6]

[5] 73 FR 16966

[6] 69 FR 19644; April 13, 2004

The NRC has historically relied on HHS to establish the technical requirements for urine specimen collection, testing, and evaluation because, under Section 503 of Public Law 100-17[7] and Executive Order 12564,[8] HHS is designated as the Federal agency responsible for developing the scientific and technical guidelines for Federal workplace drug testing programs. The HHS Guidelines establish a legal framework for the conduct of drug testing of individuals that provides for the reasonable assurance of privacy, accuracy and precision of testing, custody and control of donor specimens for testing, and due process for individuals subject to drug testing. Furthermore, HHS is responsible for updating the HHS Guidelines to incorporate advances in drug testing technologies; the testing of additional drugs that may affect the Federal workplace; and lessons learned from agencies implementing Federal drug testing programs, specimen collector training organizations, drug testing laboratories, and the professional societies that provide qualification, training, and continuing education to persons implementing the elements of the drug testing program. The HHS Guidelines are used by Federal agencies and many private companies, vetted by independent organizations and the public, and subject to frequent review by drug testing experts[9] and professionals. As a result, the HHS Guidelines can be viewed as the national standard for drug testing in the United States.

On November 25, 2008, approximately 8 months after publication of the NRC's 2008 FFD final rule, HHS issued substantial revisions to the HHS Guidelines (73 FR 71858). These revisions primarily addressed the collection and testing of urine specimens, the creation and certification of Instrumented Initial Test Facilities, and the role of and standards for collectors and MROs. The latest revision of the HHS Guidelines became effective on October 1, 2010.

Problem Discussion

The Part 26 final rule was published on March 31, 2008, and incorporated select provisions from the 2004 HHS Guidelines to improve, in part, specimen collection, drug testing, privacy considerations, and due process. On November 25, 2008, HHS published a final rule amending the 2004 HHS Guidelines to, in part, incorporate state-of-the-art drug testing methodologies, enhance drug testing methodologies, and improve the detection of illegal drug use or the abuse of controlled substances within the Federal workplace. The NRC published the 2008 FFD final rule before HHS published the final rule for the 2008 HHS Guidelines, resulting in three potentially adverse outcomes (PAOs):

PAO 1 The drug testing requirements in Part 26 are less rigorous than those in the 2008 HHS Guidelines;

PAO 2 The evaluation of drug testing results required by Part 26 has diminished potential, as compared to an evaluation under the 2008 HHS Guidelines, to identify individuals attempting to subvert the drug testing process and to afford due process to individuals subject to drug testing; and

PAO 3 Certain administrative requirements in Part 26 are not consistent with the 2008 HHS Guidelines, and may unnecessarily produce a burden on affected licensees and other entities.

[7] 5 U.S.C. Section 7301 note.

[8] 51 FR 32889; September 15, 1986.

[9] Section 3.1 of this Regulatory Basis clarifies the use of "experts."

As described below, if not addressed, these PAOs would result in missed opportunities to identify additional instances of personnel using illegal drugs or misusing controlled substances. Not detecting illegal drug use or misuse of controlled substances increases the possibility that impairment could result in degraded human performance and challenges to safe reactor operation, occupational safety, emergency response, radiological effluent and occupational radiation control, physical security, and material and information safeguards. In addition, the use of illegal drugs or misuse of controlled substances indicates that an individual may not be sufficiently trustworthy and reliable to perform duties that have the potential to impact public health, safety and security. However, licensees cannot prevent such individuals from performing duties under Part 26 unless the substance abuse or misuse is detected.

Summary Evaluation of PAOs with No Action

With no action, PAO 1 represents a safety and security concern. The drug testing required by Part 26 would be less effective in identifying individuals who are subject to Part 26 and are using certain illegal drugs or misusing legal drugs. Without testing for the three amphetamine-based analogues (i.e., the *Ecstasy* drugs), performing initial testing for 6-AM, and establishing lower drug testing cutoff levels (for amphetamine, methamphetamine, and cocaine) than currently required by Part 26, the NRC estimates that approximately 104 additional instances of substance abuse[10] would go undetected, which represents approximately 12 percent more positive test results than were identified in Calendar Year (CY) 2011.

Without action, PAO 1 presents a challenge to the NRC's *Effectiveness Strategy* as described in the NRC's Strategic Plan for Fiscal Years 2008-2013.[11] This strategy helps provide assurance that NRC actions are of high-quality and realistic to better ensure the safe and beneficial civilian use of radioactive materials. To address this challenge, in part, the NRC collaborates with Federal agencies to evaluate and respond to changes in the regulatory and technical environments, gain insights, and effectively resolve issues. If action is not taken on PAO 1, the drug testing panel and cutoff levels required by Part 26 would continue to be less effective than similar drug testing programs implemented by other Federal agencies. Without action, PAO 1 could adversely impact public confidence in the effectiveness of the NRC's regulations in identifying the use and misuse of drugs.

The safety and security issue for PAO 2 is that without action, persons are more able to subvert the Part 26 drug testing process by diluting their urine specimens compared to drug testing processes implemented by other Federal agencies. Dilution can significantly lower the concentration of drug and drug metabolites[12] in urine. Action is therefore necessary to enhance the identification of drugs and drug metabolites when a donor presents a dilute specimen. This change would improve assurance that persons who attempt to subvert drug testing would be identified and subsequently prevented from performing duties that have the potential to affect

[10] This estimate is discussed in Section 4 of this document and is based on an evaluation of data presented in Section 3 of drug use in the Federal workplace, society in general, and the commercial nuclear industry, as documented in NRC-issued reports summarizing industry FFD performance (see http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/performance-reports.html).

[11] NUREG-1614, Vol. 5, pg. 20, February 2012

[12] A drug metabolite is a chemical structure resulting from metabolism or catabolism of a parent substance. Part 26 drug testing often tests for metabolites in lieu of the parent substance. See §§ 26.133 and 26.163 for additional information.

public health and safety or the common defense and security. This change would also result in increased public confidence.

Without action, PAO 2 also represents a challenge to the due process afforded to individuals whose urine exhibits higher than expected pH. The pH of a urine specimen is evaluated as part of specimen validity testing to determine whether the specimen may be invalid. Under Part 26, if the MRO confirms there is no legitimate medical explanation for a pH level that the HHS-certified laboratory has reported as an invalid test result, the donor must provide a second specimen under direct observation. In cases where a urine specimen is exposed to high environmental temperature and/or long storage or transportation times, urine acidity may increase to a level indicating that the specimen is invalid through no fault of the donor. In order to afford due process to the donor, Part 26 should be amended, consistent with the 2008 HHS Guidelines, to require the MRO to evaluate the environmental conditions and length of time between specimen collection and specimen testing to assess whether these factors may have caused an invalid result rather than donor actions. If the MRO determines that time and/or temperature could have likely resulted in the invalid test result, a second specimen collection would be required, but direct observation would not be required. This change affords the individual a greater level of privacy and contributes to due process and regulatory consistency. Similarly, the use of the *Limit of Quantitation* (LOQ) instead of the *Limit of Detection* (LOD) as the decision point of special analysis testing also substantially contributes to the assurance of due process for individuals who have presented a dilute specimen or who have apparently subverted the testing process through an act, such as dilution. The use of LOQ results in the statistical quantitation of a drug test result, thereby better assuring the accuracy and precision of numerical results to inform the review process afforded to individuals subject to Part 26 drug testing. As a result, this change also contributes to due process and regulatory consistency.

Without action, PAO 3 does not represent a safety or security concern, but the proposed amendments can reduce burden on licensees and other entities and improve efficiency without decreasing the effectiveness of Part 26 by making the Part 26 requirements consistent with those of the 2008 HHS Guidelines. Increased consistency with the 2008 HHS Guidelines would reduce testing costs. The majority of Federally-regulated drug tests performed by HHS-certified[13] laboratories are for agencies that must follow the most recent version of the 2008 HHS Guidelines (e.g., U.S. Department of Transportation (DOT)). The NRC licensees and other affected entities are required to use these same HHS-certified laboratories; however, because the Part 26 laboratory testing requirements differ from the 2008 HHS Guidelines, the laboratories must implement specific handling procedures and testing procedures (e.g., different drug testing panel, different drug testing cutoff levels, and different evaluation of dilute specimens) for Part 26 specimens. These special procedures may increase testing costs for licensees and other entities that are subject to Part 26. Aligning certain Part 26 definitions and drug testing process requirements with the 2008 HHS Guidelines would reduce the burden to licensees and other affected entities caused by the differences in testing requirements without reducing the effectiveness of Part 26.

[13] Laboratories conducting Federally-regulated drug tests must be certified and must maintain certification through the National Laboratory Certification Program, a program funded and managed by HHS. Laboratories tend to segregate drug testing into Federal or non-Federal testing.

Summary Evaluation of Possible Actions to Preclude the PAOs

The NRC considered three possible actions to preclude or mitigate the identified PAOs. These possible actions are: (1) incorporation of the identified HHS technical issues into regulatory guidance without amending Part 26; (2) incorporation of the identified HHS technical issues into an industry-developed and industry-maintained guidance document without amending Part 26; and (3) conduct of rulemaking to amend Part 26 and development of implementation guidance. In the following summary evaluation, the recommended action, possible action 3, is used as the baseline for comparison.

Possible Action 1 - The NRC would incorporate the identified HHS technical issues into regulatory guidance without amending Part 26. The NRC determined that this option would result in more disadvantages than benefits. The primary benefits of this possible action would be: a relatively easier development, implementation, and issuance process than that required for rulemaking. The primary disadvantages of possible action 1 are: affected licensees and other entities would have the option to either commit to all, none, or a portion of the NRC-proposed guidance document, which could lead to inconsistent implementation across the industry and challenge regulatory effectiveness; and, implementation of regulatory guidance by an affected licensee or other entity could possibly be subject to union negotiation or grievance, which also could lead to inconsistent rule implementation across the industry and challenge regulatory effectiveness.

Possible Action 2 - The NRC would encourage industry to incorporate the identified HHS Guidelines technical issues into industry-developed guidance without amending Part 26. The NRC determined that this option would result in more significant disadvantages than, and about the same benefits as, possible action 1. A potential benefit would be lower burden on the NRC staff because the industry would be developing, maintaining, and updating the guidance. The burden requiring the NRC to review the industry-proposed guidance, engage internal and external stakeholders, resolve stakeholder comments, and potentially endorse the industry-proposed revision in a regulatory guide would be the same as for possible action 1, should industry request the NRC to evaluate and endorse the guidance. In addition to the disadvantages associated with potential inconsistent implementation of guidance noted regarding possible action 1, if possible action 2 is pursued: the public could be less involved in guidance development because the industry is not required to seek public comment in development or revision of its guidance; the industry would not have access to Federal agency discussions regarding the development and amendment of the HHS Guidelines; and some entities who are subject to Part 26 may not have access to the guidance, if the industry group that develops it determines it is proprietary. If industry did not request NRC to endorse the guidance in a regulatory guide, there is a possibility that it could include inaccurate or incomplete information.

Possible Action 3 - The NRC considered conducting rulemaking to amend Part 26 and developing guidance. The benefits of this proposed action would be: consistent implementation of the Commission's regulations across the industry; early and effective public involvement in guidance development and rulemaking; assurance that the guidance will be publicly available to all entities subject to Part 26; clear and open communication of costs; and effective incorporation of Federal agency decisions regarding future changes to the HHS Guidelines. The primary disadvantage of rulemaking is the staff burden to complete a rulemaking and guidance. However, prescriptive regulations for drug testing help assure, in part, due process, protection of personal information, validity of initial and confirmatory test results, and that

persons who have unescorted access to the protected areas of affected NRC-licensed facilities, materials, or information are fit for duty, trustworthy, and reliable. Provisions in this rulemaking would constitute backfitting as defined in 10 CFR 50.109(a)(1); however, the staff believes that the backfits contained in the proposed rule, when considered in the aggregate, would constitute a substantial increase in public health and safety or common defense and security. A detailed analysis of the requirements constituting backfits will be provided in the regulatory analysis for the proposed rule.

Proposed Action

The NRC determined that possible action 3, as compared to possible actions 1 and 2, would minimize disadvantages and result in increased benefits. Therefore, the NRC proposes to amend Part 26 and develop regulatory guidance.

3. Technical Basis

This section presents the technical basis for recommending the incorporation of select provisions of the 2008 HHS Guidelines into the Part 26 drug testing requirements.

3.1 What are the regulatory and technical considerations justifying use of the HHS Guidelines as a primary technical basis for amending Part 26 drug testing requirements?

By Executive Order 12564[14], President Ronald Reagan, "deeming such action in the best interest of national security, public health and safety . . . and in order to establish standards and procedures to ensure fairness in achieving a drug-free Federal workplace . . ., " ordered that the Secretary of Health and Human Services be authorized to "promulgate scientific and technical guidelines for drug testing programs, and that federal agencies shall conduct their drug testing programs in accordance with these guidelines." The President also ordered the establishment of due process for individuals subject to drug testing.

As the Federal agency responsible for developing and maintaining the requirements and guidance for Federal workplace drug testing programs, HHS is responsible for maintaining and updating its "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (i.e., HHS Guidelines), based on scientific research and lessons learned from Federal agency drug testing programs. The HHS Guidelines, first published on April 11, 1988, established a legally robust framework to conduct drug testing based on established cutoffs and scientific methodologies to provide reasonable assurance of drug testing accuracy and precision, while assuring privacy, custody and control of drug specimens, and due process. By public law[15], the HHS was directed to publish mandatory guidelines that: establish comprehensive standards for all aspects of laboratory drug testing and procedures; specify the drugs for which Federal employees may be tested; and establish standards and procedures for periodic review of laboratories and criteria for certification for laboratories to perform Federally-mandated drug testing.

The HHS periodically updates the HHS Guidelines to incorporate advances in drug testing technologies, processes, methodologies, and instrumentation, as well as lessons learned from

[14] Executive Order 12564, dated September 15, 1986 (51 FR 32889).

[15] Pub. L. 100-71 sec. 503.

the National Laboratory Certification Program (NLCP). The HHS has updated the HHS Guidelines to address emerging drug use trends in the U.S. and problems in drug testing, such as the increasing availability and use of techniques to subvert the drug testing process. The HHS Guidelines are published following a rigorous rulemaking process in which proposed guidelines are developed from scientific, policy, legal, and technical reviews conducted by HHS staff. The proposals are then subject to review by an independent advisory panel to the Secretary of the HHS Substance Abuse and Mental Health Services Administration (SAMHSA), academic peer reviews, public review and comment, and input from Federal agencies that implement the HHS Guidelines. The HHS also collaborates with the DOT, Drug Enforcement Administration (DEA), U.S. Food and Drug Administration (FDA), National Institute on Drug Abuse (NIDA), drug testing industry, and public and private sector employers on an ongoing basis on scientific and program matters to help ensure that the most accurate, reliable drug testing technology and methodologies are used. Following HHS staff evaluation of comments on the proposed guidelines, HHS publishes the final guidelines.

The NRC based its 1989 FFD final rule on the HHS Guidelines and has consistently revised Part 26 to align with the HHS Guidelines to improve the detection and deterrence potential of its FFD program, incorporate editorial changes, and improve efficiency and reduce the burden on licensees and other entities subject to Part 26 associated with inconsistency in regulatory requirements across Federal drug testing programs.

3.2 What are the current Part 26 requirements most affected by the proposed action?

The Part 26 requirements most affected by the proposed rule are in the following sections:

§ 26.5, “Definitions;”

§ 26.133, “Cutoff levels for drugs and drug metabolites;”

§ 26.163, “Cutoff levels for drugs and drug metabolites;” and

§ 26.185, “Determining an FFD policy violation.”

Impact to other sections of Part 26 would be limited to minor and conforming changes related to the proposed action.

3.3 What is the reason for performing initial testing for 6-AM?

The 2008 HHS Guidelines updated the testing protocol for 6-AM (a heroin metabolite) to require initial drug testing for this metabolite. The HHS implemented this change based on an analysis of laboratory data that demonstrated that the prior approach, to only conduct confirmatory drug testing for 6-AM following an initial morphine positive test result with a concentration exceeding 2000 ng/mL, was no longer the most effective means to identify heroin use. Research has shown that 6-AM is detectable in specimens even when the morphine concentration is below 2000 ng/mL. In addition, because the 6-AM metabolite in a urine specimen is only detectable for a short period of time (i.e., 6-AM is metabolized quickly), conducting initial testing for the metabolite increases the chances of identifying heroin use. Compared to the 2008 HHS Guidelines procedure, the current Part 26 testing procedure to use specimen morphine concentration to determine when to conduct 6-AM testing may limit the ability of NRC licensees to identify heroin use.

The need for improved detection of heroin use is supported by two recent incidents of nuclear power plant personnel having confirmed positive test results for heroin as well as data suggesting that heroin use may be increasing, in general, among personnel in safety-sensitive positions. In CY 2011, two 6-AM positives were identified by post-event testing of a security officer and a maintenance technician at two different commercial nuclear power reactor sites. Furthermore, an analysis of DOT data indicates two trends in heroin use. First, 6-AM positives were increasing before DOT aligned 49 CFR Part 40 with the 2008 HHS Guidelines. Second, after implementing the 2008 HHS Guidelines testing protocol for 6-AM, DOT saw an additional increase in the 6-AM positives. Given that the workforce populations subject to DOT testing are similar to the workforces subject to Part 26, the DOT results suggest that heroin use may also be increasing among nuclear personnel but that some use currently is not being detected. Initial testing for 6-AM would improve the detection of heroin use among individuals subject to testing under Part 26.

3.4 What is the justification for including the *Ecstasy*-type drugs methylenedioxymethamphetamine (MDMA), methylenedioxyamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA) into the Part 26 amphetamine testing panel?

The *Ecstasy*-type drugs are amphetamine-based analogues classified as Schedule I controlled substances. As defined in the Controlled Substances Act, Schedule I consists of the drugs and other substances that have a high potential for abuse and have no currently accepted medical use in treatment in the U.S. and for which there is a lack of accepted safety for use of the drug or other substance under medical supervision.

The Federal government, led by the DEA, uses a comprehensive process to determine whether a drug should be considered a Schedule I controlled substance. When requested by the DEA, HHS undertakes a scientific and medical review of the drug and collaborates with FDA, NIDA, the medical community, and other stakeholders to obtain studies, reviews, and other information regarding the physiological and psychological effects of the drug or substance, its prevalence in society, and adverse societal impacts. The HHS then makes a recommendation to DEA whether the drug or substance should be controlled. Based on HHS information and DEA evaluations, DEA then determines how the drug or substance is scheduled.

As with other substances listed on Schedule I, use of MDMA and the related substances by personnel who are subject to Part 26 raises concerns about possible on-the-job impairment as well as the individuals' trustworthiness and reliability.

3.5 What are the physiological and psychological effects of using MDMA, MDA, or MDEA?

The NIDA reports that MDMA has become a popular drug because of the positive effects that a person may experience within an hour or so after taking a single dose. These include mental stimulation, emotional warmth, a general sense of well-being, decreased anxiety, and enhanced sensory perception. However, up to 1 week after use, the NIDA reports that MDMA continues to cause anxiety, restlessness, irritability, impulsiveness, aggression, sleep disturbances, and a significant reduction in mental ability.[16]

[16] National Institute on Drug Abuse, "MDMA (Ecstasy) Abuse," March 2006, http://www.drugabuse.gov/publications/research-reports/mdma-ecstasy-abuse/what-are-effects-mdma.

The NIDA findings parallel those published by the American Association of Medical Review Officers (AAMRO) in its *Medical Review Officer Handbook.*[17] The effects of MDMA ". . . on the human brain and body are complex, interacting with several neurochemical systems. It induces serotonin, dopamine, norepinephrine, and acetylcholine release, and can act directly on a number of receptors, including a2-adrenergic (adrenaline) and 5HT2A (serotonin) receptors."[18] Although there are few clinical studies of these drugs, subjective short-term experiential effects include: mental and physical euphoria; decreased negative emotion, stress, anxiety, fear, and paranoia; an increased urge to communicate; and other distinctive emotional and social effects. Of concern is that "high doses of . . . MDMA produce long-term neurotoxicity in rodents and nonhuman primates. Preclinical studies have revealed long-term decreases in tyrosine and tryptophan hydroxylase activities after . . . MDMA administration."[19] Decreases in these physiological activities can result in depression[20] and depression, without remediation, could adversely affect the safe and competent accomplishment of safety- or security-related activities.

Similar MDMA effects are reported by the DEA in its "Drug Fact Sheet" for Ecstasy:[21]

> Users of MDMA experience many of the same effects and face many of the same risks as users of other stimulants such as cocaine and amphetamines. These include increased motor activity, alertness, heart rate, and blood pressure. Some unwanted physical effects include: muscle tension, tremors, involuntary teeth clenching, muscle cramps, nausea, faintness, chills, sweating, and blurred vision. High doses of MDMA can interfere with the ability to regulate body temperature, resulting in a sharp increase in body temperature (hyperthermia), leading to liver, kidney and cardiovascular failure. Severe dehydration can result from the combination of the drug's effects and the crowded and hot conditions in which the drug is often taken. Studies suggest chronic use of MDMA can produce damage to the serotonin system.

3.6 What are the potential adverse effects on safety and security at a facility subject to Part 26, if a person who has access to such a facility uses MDMA, MDA, or MDEA?

Human Performance Degradation

NIDA reports that "MDMA produces significant reductions in mental abilities [within hours of taking the drug]. These changes, primarily those affecting memory, can last up to a week, and possibly longer in regular users. The fact the MDMA markedly impairs information processing

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[17] Shults, Theodore F, Medical Review Office Handbook, 9th Edition, American Association of Medical Review Officers, Quadrangle Research, Durham, NC, July 2009.

[18] Miller, Frederic P., Agnes F. Vandome, and John McBrewster, *Effects of MDMA on the Human Body*, Alphascript Publishing, Abstract, 2010.

[19] Quinton, Maria S. and Bryan K. Yamamoto, "Causes and Consequences of Methamphetamine and MDMA Toxicity," *American Association of Pharmaceutical Scientists Journal*. 8(2), E338, 2006, http://www.aapsj.org/articles/aapsj0802/aapsj080238/aapsj080238.pdf.

[20] Ledochowski M., Sperner-Unterweger B, Widner B, Fuchs D (1998). "Fructose malabsorption associated with early signs of mental depression", Eur. J. Med. Res. 3 (6):295-8 and Wang L, Erlandsen H, Haavik J, Knappskog PM, Stevens RC (October 2002), "Three-dimensional structure of human tryptophan hydroxylase and its implications for the biosynthesis of the neurotransmitters serotonin and melatonin", *Biochemistry* 41 (42); 12569-74.

[21] Drug Enforcement Administration, "Drug Fact Sheet: Ecstasy or MDMA," http://www.justice.gov/dea/druginfo/drug_data_sheets/Ecstacy.pdf.

emphasizes the potential dangers of performing complex or skilled activities, such as driving a car." [22,23, 24]

Citing several publications,[25, 26, 27] the NIDA further states:

> Over the course of a week following moderate use of the drug, many MDMA users report feeling a range of emotions, including anxiety, restlessness, irritability, and sadness that in some individuals can be as severe as true clinical depression. Similarly, elevated anxiety, impulsiveness, and aggression, as well as sleep disturbances, lack of appetite, and reduced interest in and pleasure from sex have been observed in regular MDMA users. Some of these disturbances may not be directly attributable to MDMA, but may be related to some of the other drugs often used in combination with MDMA, such as cocaine or marijuana, or to adulterants commonly found in MDMA tablets.[28]

Research results and clinical evidence demonstrate that MDMA use adversely impacts human performance by reducing mental and physical capabilities both during use and within a week after use. Therefore, use of MDMA by persons subject to Part 26 will reduce these individuals' abilities to safely and competently perform assigned duties.

As stated in the supplementary information accompanying the 1989 Part 26 final rule, although "the presence of drug metabolites does not necessarily relate directly to a current impaired state, the presence of [a drug] does strongly suggest the likelihood of past, present, or future impairment affecting job activities." [29] Therefore, detection and deterrence of the use of MDMA, MDA and MDEA would provide added assurance that personnel performance is not adversely affected by the use of these substances.

Trustworthiness and Reliability

An underlying assumption of the NRC's regulatory framework, as discussed in the statement of considerations of the 1989 Part 26 rule, is that individuals subject to Part 26 will abide by the policies and procedures of the licensee or other entity.[30] Use of illegal drugs suggests that an

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[22] National Institute on Drug Abuse, "MDMA (Ecstasy) Abuse," March 2006, http://www.drugabuse.gov/publications/research-reports/mdma-ecstasy-abuse/what-are-effects-mdma.

[23] Parrott, AC, "Human psychopharmacology of Ecstasy (MDMA): a review of 15 years of empirical research, " *Human Psychopharmacology: Clinical and Experimental,* 16, 557-577, 2001.

[24] Community Epidemiology Work Group, *Epidemiologic Trends in Drug Abuse: Advance Report,* Bethesda, MD, December 2003.

[25] Lamers, CTJ, et al., "Dissociable effects of a single dose of ecstasy (MDMA) on psychomotor skills and attentional performance," *Journal of Psychopharmacology,* 17, 378-387, 2003.

[26] Parrott, A.C. and J. Lasky, "Ecstasy (MDMA) effect upon mood and cognition: before, during and after a Saturday night dance," *Psychopharmacology*, 139, 261-268, 1998.

[27] Curran, H.V. and R.A. Travill, "Mood and cognitive effects of ±3, 4-methylenedioxymethamphetamine (MDMA, 'ecstasy'): week-end 'high' followed by mid-week low," *Addiction,* 92, 821-831, 1997.

[28] National Institute on Drug Abuse, "MDMA (Ecstasy) Abuse," March 2006, http://www.drugabuse.gov/publications/research-reports/mdma-ecstasy-abuse/what-are-effects-mdma

[29] Id. at 54 FR 24468; June 7, 1989

[30] Id. at 54 FR 24468; June 7, 1989

individual possesses questionable trustworthiness and reliability and therefore cannot be relied upon to comply with the policies, procedures and other requirements necessary to protect public health and safety and the common defense and security. Detecting the use of MDMA, MDA and MDEA would provide greater assurance that only those personnel who demonstrate trustworthiness and reliability by the avoidance of substance abuse are permitted to have the types of access and perform the job duties of concern under Part 26.

3.7 What is the societal prevalence of *Ecstasy*-type drug use and heroin use?

Information about the societal prevalence of drug use is important to understand the likely prevalence of drug use among persons subject to Part 26. The prevalence of drug use in the general U.S. population is relevant to nuclear safety and security because the commercial nuclear industry draws its personnel primarily from U.S. society. Drug use among younger individuals is relevant because they represent the population from which future nuclear employees will be drawn. Several sources provide data on the prevalence of drug use among working adults and younger persons in the U.S., including Quest Diagnostics, Inc. (Quest), NIDA, and HHS.

Quest Diagnostics

Quest drug testing data are used by the NRC as an independent and large data set that shows the societal prevalence of illegal drug use in the general adult U.S. workforce and in the Federal workforce. Quest annually publishes a summary of the drug testing results from its HHS-certified laboratories in its *Drug Testing Index* (DTI), March 2012. The Quest DTI data provide independent information on both the Federal workforce testing that Quest conducts and general population workforce testing conducted for private clients. Quest DTI data are also used by DEA and HHS to evaluate societal drug use trends.

As illustrated in Quest DTI Table 5, MDMA use was identified in the Federal workforce at a percentage equivalent to that in the general population (Quest DTI Table 6) and a similar equivalency was observed for heroin (6-AM) in both populations tested. Data regarding the other drugs presented in the Quest DTI Tables are provided to demonstrate that other drugs in the Part 26 drug testing panel are used by persons in both the general and Federal workforces. The Quest DTI can be viewed at: http://www.questdiagnostics.com/home/physicians/health-trends/drug-testing.

Quest DTI Table 5. Federally Mandated Workforce Urine Drug Testing Positive Rates

The data presented in Quest DTI Table 5 reflect results of drug tests conducted by the HHS-certified laboratories of Quest for Federal agency workplace drug testing programs for safety-sensitive positions. This data set is important because few Federal agency programs regularly publish drug testing results and also because the data set is large (well over a million test results per year).

DRUG CATEGORY	2007	2008	2009	2010	2011
Overall	1.8%	1.6%	1.5%	1.5%	1.7%
6-Acetylmorphine	-	-	-	0.011%[1]	0.012%
Amphetamines	0.25%	0.26%	0.29%	0.35%	0.44%
Cocaine	0.44%	0.32%	0.24%	0.24%	0.32%
Marijuana	0.88%	0.77%	0.69%	0.69%	0.64%
MDMA				0.005%[1]	0.003%
Opiates	0.18%	0.20%	0.21%	0.17%	0.18%
PCP	0.04%	0.04%	0.04%	0.04%	0.04%

Source: Quest Diagnostics, Inc., Drug Testing Index, Table 5, 2011.
Note 1 – Data for the 4th quarter 2010 only.

Quest DTI Table 6. General U.S. Workforce Urine Drug Testing Positive Rates

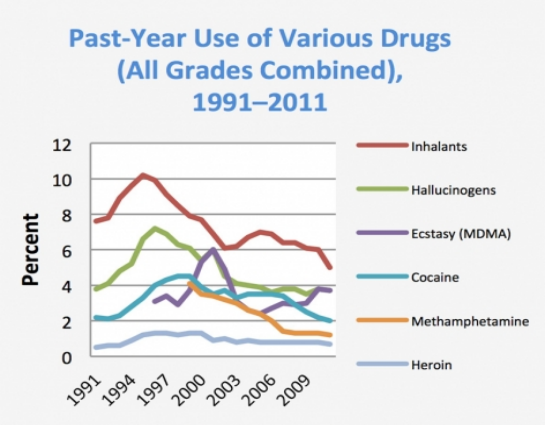
Unlike Quest DTI Table 5, which presents positive results for Federally-mandated workforce drug testing, Quest DTI Table 6 presents drug testing results for testing conducted for private entities. The results from this data set are important because they reflect a large (more than 4.8 million results in 2011) and timely source of information on societal trends in drug use among the general workforce.

DRUG CATEGORY	2007	2008	2009	2010	2011
Overall	4.4%	4.2%	4.2%	4.2%	4.1%
6-AM	-	-	-	0.013%[1]	0.015%[2]
Amphetamines	0.44%	0.48%	0.57%	0.66%	0.77%
Barbiturates	0.24%	0.25%	0.26%	0.25%	0.26%
Benzodiazepines	0.67%	0.70%	0.74%	0.69%	0.68%
Cocaine	0.58%	0.41%	0.29%	0.25%	0.27%
Marijuana	2.3%	2.1%	2.0%	2.0%	1.9%
MDMA	0.020%	0.015%	0.015%	0.009%	0.003%[3]
Methadone	0.23%	0.22%	0.23%	0.22%	0.20%
Opiates	0.35%	0.38%	0.45%	0.39%	0.42%
Oxycodones	0.88%[4]	0.83%[4]	1.0%[4]	1.0%[4]	1.1%[4]
PCP	0.02%	0.02%	0.02%	0.01%	0.01%

Source: Quest Diagnostics, Inc., Drug Testing Index, Table 6, 2011.
Note 1 – Data for the fourth quarter 2010 only.
Note 2 – More than 1 million tests.
Note 3 – More than 750,000 tests.
Note 4 – More than 500,000 tests.

<u>National Institute on Drug Abuse</u>

As reported by NIDA, recent data illustrate that societal use of MDMA by teenagers is prevalent and that MDMA use is seeing resurgence among older teens. For 12th graders, usage increased from 1.4 percent in 2010 to 2.3 percent in CY 2011.[31] From CY 2005 to CY 2011, the percentage of 12th graders who said that trying ecstasy once or twice would be risky dropped from 60.1 percent to 49.0 percent.[32]

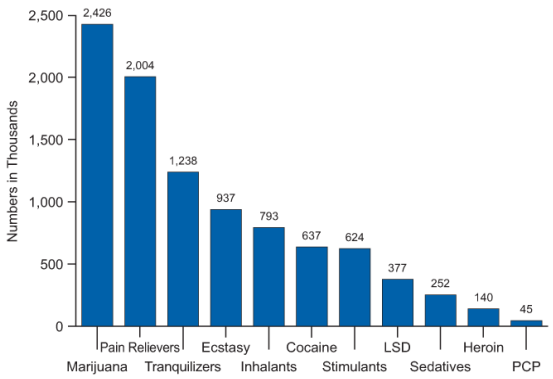


Source: Johnston, L. D., et al., "Monitoring the Future national results on adolescent drug use: Overview of key findings, 2011," The University of Michigan, National Institute on Drug Abuse

[31] Johnston, L. D., et al., "Monitoring the Future national results on adolescent drug use: Overview of key findings, 2011," The University of Michigan, National Institute on Drug Abuse, 62, http://monitoringthefuture.org/pubs/monographs/mtf-overview2011.pdf

[32] Johnston, L. D., et al., "Monitoring the Future national results on adolescent drug use: Overview of key findings, 2011," The University of Michigan, National Institute on Drug Abuse, 69, http://monitoringthefuture.org/pubs/monographs/mtf-overview2011.pdf

These data suggest that younger persons may view *Ecstasy* as less dangerous than other drugs. The NIDA data also show that young persons are using heroin. These trends may be significant as younger people begin entering the workforce and perhaps seek employment in nuclear settings.



Past Year Initiates of Specific Illicit Drugs among Persons Aged 12 or Older: 2010

Source: Substance Abuse and Mental Health Administration, 2010 National Survey on Drug Use and Health: Summary of National Findings, Table 5.2, 2011

Health and Human Services

The HHS also assesses societal prevalence of drug use. As reported by the HHS Substance Abuse and Mental Health Administration (SAMHSA) in its "2010 National Survey on Drug Use and Health: Summary of National Findings," an estimated 22.6 million Americans aged 12 or older were current (i.e., within the past month) drug users.

Hallucinogens (such as *Ecstasy*) were used in the past month by 1.2 million persons (0.5 percent) aged 12 or older in 2010, including 937,000 (0.3 percent) who had used *Ecstasy*. These estimates were similar to estimates in 2009. The rate of current *Ecstasy* use among youths aged 12 to 17 declined from 0.5 percent in 2002 to 0.3 percent in 2004, remained at that level through 2007, and then increased to 0.5 percent in 2009 and 2010.

In addition, the HHS data show heroin use. In 2010, 140,000 persons aged 12 or older reported a first use of heroin.

3.8 Has implementation of lower cutoff levels for amphetamine and cocaine and initial testing for 6-AM from the 2008 HHS Guidelines resulted in increased detection of drug use?

Yes. Data from the DOT and the Quest DTI indicate that implementation of the 2008 HHS Guidelines resulted in the detection of additional instances of use of amphetamine, cocaine and heroin among workers in safety-sensitive positions.

Department of Transportation

The DOT implemented the 2008 HHS Guidelines in October 2010. Therefore, CY 2011 was the first full year in which DOT used the lower initial and confirmatory cutoff levels for amphetamine and cocaine metabolites testing and included initial drug testing for the heroin metabolite 6-AM. Data presented below are "raw" data received directly from HHS laboratories that conducted testing for DOT-regulated entities and were not reviewed by a Medical Review Officer (MRO). Consequently, some of the positive amphetamine and cocaine test results may reflect legitimate prescription use.

The following data were obtained directly from DOT staff and from DOT presentations made at HHS's Drug Testing Advisory Board meetings (see www.samhsa.hhs.gov). The data encompass over five million test results reported in CY 2011 by all DOT agencies subject to 49 CFR Part 40, which include the Federal Motor Carrier Safety Administration, Federal Rail Administration, Pipeline and Hazardous Materials Safety Administration, Federal Aviation Administration, and Federal Transit Administration. The results cover seven million workers employed by over 5,000 employers.

DOT Laboratory Positive Drug Test Results (Amphetamine and Cocaine)

The raw number of positive test results for amphetamine and cocaine increased in the first full year of testing under the lower cutoff levels compared to previous years. As a percentage of the total substances identified in a given year, from 2010 to 2011, amphetamine positives rose by 17.5 percent and cocaine positives rose by 19.1 percent. In comparison to 2009, the percentage of total substances identified in 2011 for amphetamines reflects a 39.7 percent increase and the percentage of total substances identified in 2011 for cocaine reflects a 16.1 percent increase.

	CY 2008*	CY 2009	CY 2010	CY 2011
Total Results	2,850,106	5,163,165	5,463,833	5,688,807
Total Positives (all drugs)	46,858	77,865	84,211	95,427
% of all Positives				
Amphetamine	16.09%	18.23%	21.67%	25.47%
Cocaine	19.19%	16.59%	16.17%	19.26%

* 2008 reflects only 6 months of data (July to December)

DOT Laboratory Positive Heroin (6-AM) Drug Test Results

The number of positive test results for 6-AM, indicating heroin use, in the DOT data increased between 2008 and 2011. The percent positive rate for 6-AM in 2011 was 32.7 percent higher than the rate in 2010. In comparison to the 2009 6-AM positive rate, the positive rate in 2011 increased by 119.4 percent. Note that because DOT did not implement the 2008 HHS Guidelines until October 1, 2010, the increase in 6-AM positive test results from January to June 2010 (and in prior periods) was not the result of the testing change and, instead, appears to reflect an increase in the use of heroin among personnel subject to the DOT drug testing program (i.e., the number of positive test results from 2009 (July-December) to 2010 (January-June) increased by 56.7 percent).

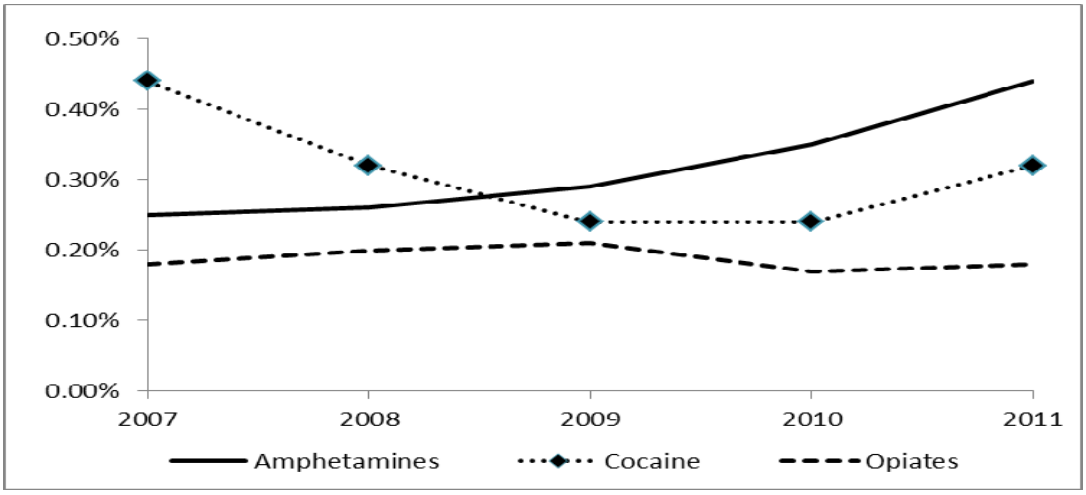
	2008 (July-Dec)	2009 (Jan-June)	2009 (July-Dec)	2010 (Jan-June)	2010 (July-Dec)	2011 (Jan-June)	2011 (July-Dec)
Total Results	2,850,106	2,594,149	2,569,016	2,685,937	2,777,896	2,817,342	2,871,465
6-AM	121	158	173	281	298	371	429
% of all positives	0.0042%	0.0061%	0.0067%	0.0105%	0.0107%	0.0132%	0.0149%

Quest DTI, Federally-Mandated Workforce Tests

The Quest DTI is an annual summary of Federally-mandated workforce drug test results conducted by its HHS-certified laboratories. Like the DOT data described above, the Quest DTI drug test results have not been confirmed by MRO review and so may include test results from legitimate medical uses.

The DTI data show increases in the annual rate of positive test results for both amphetamine and cocaine metabolites after implementation of the 2008 HHS Guidelines, compared to 2009 positive test result rates for these substances (see the chart on the next page).

Quest DTI, Federally-Mandated Workforce Testing, Laboratory Positive Urine Drug Testing Results



Source: U.S. Nuclear Regulatory Commission analysis of data from Quest Diagnostics, Inc., 2012

3.9 What are the Part 26 amphetamine and cocaine drug testing results and how do they relate to the proposed action to incorporate selected portions of the 2008 HHS Guidelines?

The following short- and long-term trend information reflect summary drug testing results from the NRC's licensed facilities that submit testing data on an annual basis in FFD performance reports (10 CFR 26.717 and 26.719). The performance reports present graphs and tables on Part 26 drug testing results and document the NRC staff's observations on trends, management challenges, and laboratory issues. The annual reports can be viewed in the NRC's Agencywide Documents Access and Management System (ADAMS) and can be accessed from the NRC's public Web site at: http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/performance-reports.html.

CY 2011 Positive Test Results at Part 26-regulated Facilities

The following table displays positive test results at Part 26-regulated facilities in CY 2011. The results presented are MRO-verified, as compared to the DOT data which were HHS-certified laboratory test results that had not received MRO verification. The MRO verification process will result in fewer positives because a legitimate medical use of a substance will not be determined to be a positive test result. Therefore, the positive rates reflected in DOT testing data are most likely higher than results undergoing MRO review and verification. Three observations are evident from review of the data:

(1) The CY 2011 amphetamine use in licensee and contractor/vendors (C/V) populations was similar (6.15 percent of all positive test results for licensee employees; 7.74 percent of all positive test results for C/Vs).

(2) For the heroin metabolite, 6-AM, two confirmed positive test results (each at a separate power reactor facility) were identified in post-event tests in CY 2011. Although the number and percentage of 6-AM positives are low, the risk presented causes concern because the individuals were not identified by the licensee's behavioral observation program or through

pre-access or random testing. [Note, heroin positives appear in the table row "opiates". This table row also includes morphine and codeine positive results.]

(3) The NRC staff posits that the lowering of cutoff levels for marijuana and alcohol in the 2008 Part 26 final rule improved the detection of marijuana use and alcohol misuse and resulted in additional positive results for these substances. Likewise, the NRC staff anticipates increases in the positive rates for amphetamine and cocaine because the lower cutoff levels will increase the "window of detection" for the drugs. These anticipated increases would be consistent with DOT test results once the 2008 HHS Guidelines were implemented, beginning in October of 2010.

- The 2008 Part 26 final rule lowered the marijuana cutoff from 100ng/mL to 50ng/ml for initial testing.
- The 2008 Part 26 final rule implemented a time-dependent alcohol concentration limit based on time at work. This lowered the cutoff from 0.04 to time-dependent 0.03, 0.02, and 0.01 BAC values.

CY 2011 Positive Test Results by Substance and Employment Category (All Test Types, including Testing Refusals)

Positive Test Result	Licensee Employees		Contractor/Vendors		Total	
	Number	Percent	Number	Percent	Number	Percent
Marijuana	31	23.85%	499	50.15%	530	47.11%
Alcohol	70	53.85%	192	19.30%	262	23.29%
Cocaine	12	9.23%	115	11.56%	127	11.29%
Refusal to test*	6	4.62%	92	9.25%	98	8.71%
Amphetamines	8	6.15%	77	7.74%	85	7.56%
Opiates	2	1.54%	16	1.61%	18	1.60%
Phencyclidine	0	0.00%	3	0.30%	3	0.27%
Other ‡	1	0.77%	1	0.10%	2	0.18%
Total	**130**	**100.00%**	**995**	**100.00%**	**1,125**	**100.00%**

Source: U.S. Nuclear Regulatory Commission, CY 2011 Fitness for Duty Performance Report data, 2012

* This category includes adulterated and substituted specimen validity test results and refusal-to-test actions (only those events where a specimen was not provided).

‡ In CY 2011, six facilities tested for drugs in addition to the NRC-minimum testing panel (two tests yielded positive results; one for benzodiazepines and one for methadone).

Short-Term Trend in Confirmed Amphetamine Positive Test Results at Part 26-regulated Facilities

The following table presents the short-term trend in amphetamine positive test results (MRO-verified) at Part 26-regulated facilities. The table shows that amphetamine positives, as a percentage of the total positives in a given year, have increased at Part 26-regulated facilities. Therefore, illicit amphetamine use appears to be increasing within the NRC-regulated workforce.

Worker Category	2008	2009	2010	2011
Licensee Employees	2.10%	2.48%	4.03%	6.15%
Contractor / Vendors	3.42%	3.82%	5.45%	7.74%

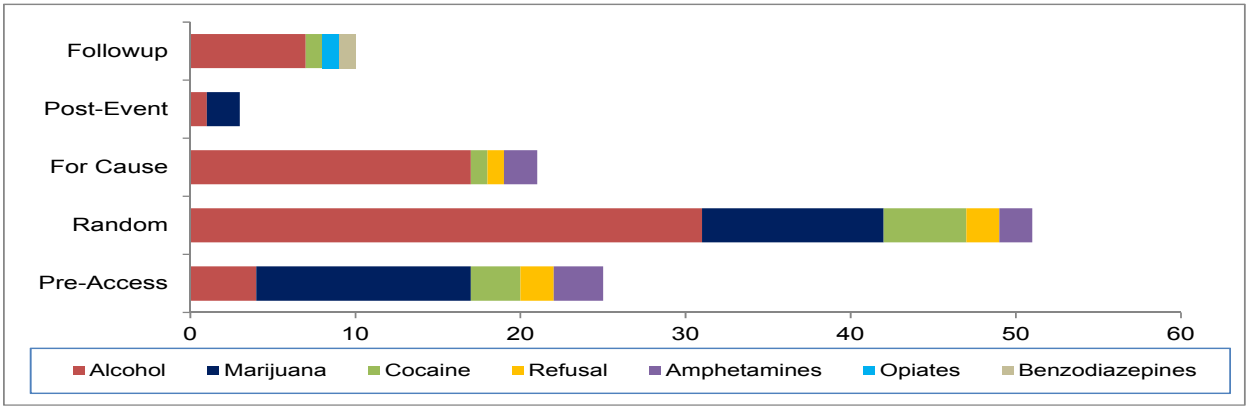
Long-Term Trend in Confirmed Positive Test Results at Part 26-regulated Facilities

The following table presents the long-term trend in confirmed positive test results for cocaine and amphetamine as a percentage of the total number of positive test results at Part 26-regulated facilities in 1990 (the first full year of Part 26 mandated testing) and 2011. The data indicate a long-term increase in amphetamine use. Also, although the NRC is experiencing a decline in positive results for cocaine, Quest and DOT are experiencing increases; this change is likely due to the lower cutoff levels for cocaine and amphetamines from the 2008 HHS Guidelines.

Substance	1990	2011	Percent Change
Cocaine	29.0%	12.4%	- 16.6%
Amphetamines	2.84%	8.29%	+ 5.46%

Licensee Employees – Confirmed Positive Drug Test Results for CY 2011

The next graph illustrates the drugs for which confirmed positive test results were reported for licensee employees in CY 2011. Note that significantly more instances of drug use are being detected by random testing than by pre-access testing. This may indicate that some persons may be subverting the testing process through temporary abstinence from drug use prior to the predictable pre-access test. This is a significant concern for any drug that has a short biological half life such as amphetamines, cocaine, and heroin because the window of detection is so short, thereby lowering the chance of detecting the metabolite. However, by lowering the drug testing cutoffs for cocaine and amphetamine, the window of detection is increased and the NRC staff posits that additional drug positives would occur.

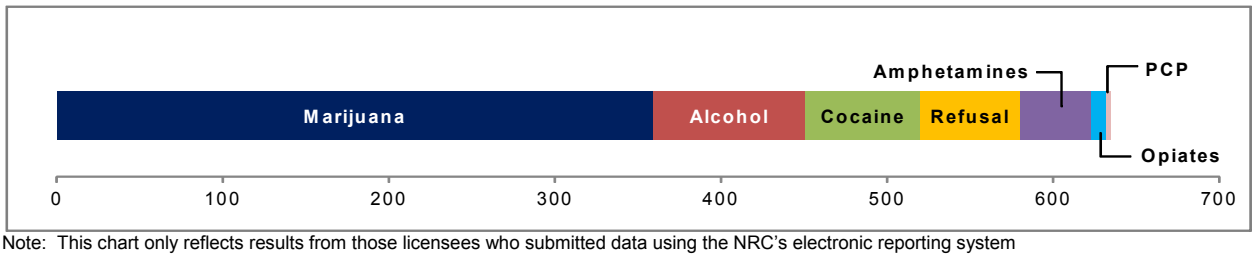


Note: This chart only reflects results from those licensees who submitted data using the NRC's electronic reporting system
Source: U.S. Nuclear Regulatory Commission, Summary of Fitness for Duty Program Performance Reports for CY 2011, 2012

Contractor/Vendor – Confirmed Positive Drug Test Results for CY 2011

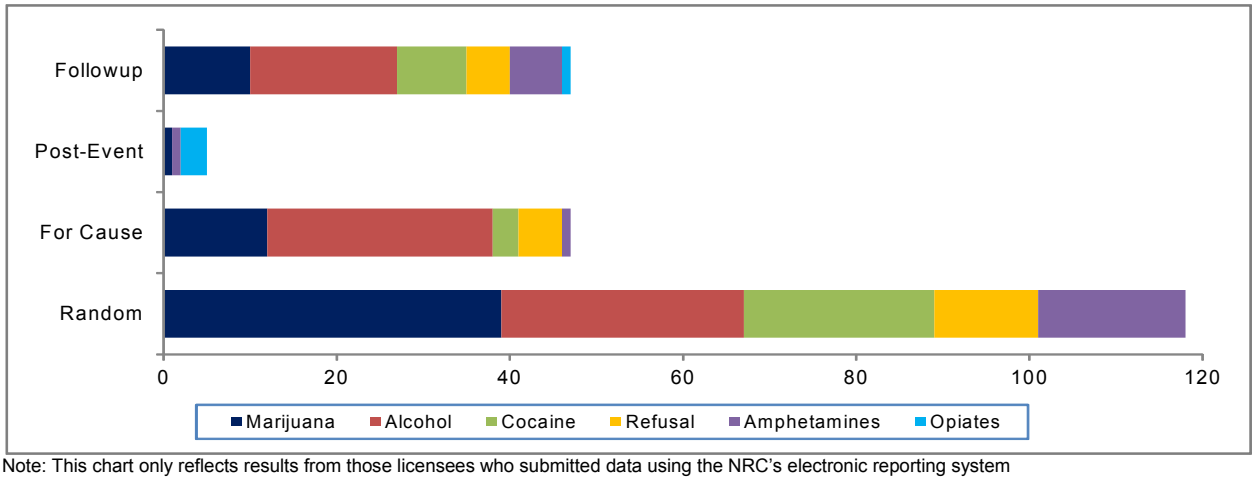
The next two graphs illustrate the drugs for which confirmed positive test results were obtained from C/Vs in CY 2011. Note that cocaine is the third most prevalent drug used and its prevalence exceeds that of amphetamines and opiates. Similar to the NRC's observations on licensee employees above, lowering the drug cutoffs for amphetamine and cocaine would increase the window of detection to increase the detection of amphetamine or cocaine use. The x-axis indicates the number of MRO-verified positive occurrences.

Pre-Access



Note: This chart only reflects results from those licensees who submitted data using the NRC's electronic reporting system
Source: U.S. Nuclear Regulatory Commission, Summary of Fitness for Duty Program Performance Reports for CY 2011, 2012

Random, For Cause, Post-Event, and Followup



Note: This chart only reflects results from those licensees who submitted data using the NRC's electronic reporting system
Source: U.S. Nuclear Regulatory Commission, Summary of Fitness for Duty Program Performance Reports for CY 2011, 2012

3.10 If the proposed action were implemented, would there be any adverse consequences on the effectiveness of the NRC's inspection activities?

No. The proposed changes would be simple: they would revise definitions, drug testing cutoff levels, the drugs for which testing is conducted, and MRO actions (e.g., regarding the evaluation of dilute specimens and high pH urine conditions). As a result, changes to the NRC inspection infrastructure of training, programs, and procedures would be simple and without adverse consequences.

Training: The NRC's inspectors are trained and qualified pursuant to NRC Inspection Manual Chapter (IMC) 1245, "Qualification Program for Operating Reactor Programs," and IMC 2546, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." This training includes applicable regulations. Inspectors also attend periodic counterpart meetings where they are afforded opportunity to discuss technical issues with peers and the NRC staff responsible for inspection program improvements and policy development. Inspectors also have direct access to the NRC technical staff responsible for Part 26 maintenance, interpretation, guidance development, and rulemaking to ask questions and seek clarification of Part 26 requirements. The NRC anticipates that only minor changes would be needed in training materials and IMC chapters.

Programs: The FFD inspection is conducted pursuant to IMC 2201, "Security Inspection Program for Commercial Nuclear Power Reactors;" and IMC 2681, "Physical Protection and Transport of SNM and Irradiated Fuel Inspections of Fuel Facilities." The proposed rule changes would not be expected to result in program changes.

Procedures: These inspection programs implement inspection procedures (IP) 71130.08, "Fitness for Duty Programs," and IP 81502, "Fitness for Duty." The NRC periodically revises its inspection procedures to reflect changes in its regulations and would make minor revisions to the procedures to incorporate the proposed changes.

3.11 If the proposed action were implemented, affected entities would be required to implement special analysis testing of dilute specimens and use *Limit of Quantitation* in lieu of *Limit of Detection*. What are these proposed changes and would there be adverse consequences on due process or implementation of the Part 26 requirements by HHS-certified laboratories?

Dilute – Special Analysis

Currently, licensees and other affected entities have the option to conduct special analyses of a dilute urine specimen to detect drug use under § 26.163(a)(2). The proposed action would require licensees and other affected entities to conduct the special analysis of a dilute urine specimen. An HHS-certified laboratory reports a specimen as dilute when the specimen's creatinine concentration is equal to or greater than 2 mg/dl, but less than 20 mg/dl, and its specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot (§ 26.161(e)).

Based on CY 2011 FFD program performance report data, 90 percent of licensees and other entities have already adopted the optional special analysis testing for dilute specimens. Additionally, the special analysis methodology implemented in 2008 is effective as demonstrated by the identification of illicit drug use by some persons providing dilute specimens. The FFD program performance report also documents that in CY 2011, 143 of 1,080 FFD program violations were associated with donor subversion attempts. The fact that a substantial number of persons (1 of 8 or 13 percent) were sanctioned for violating the FFD program by attempting to subvert the testing process is a significant trend. As a result, the NRC recommends enhancing the testing process because the NRC is concerned by the relative ease with which individuals can subvert the testing process through dilution. Consequently, requiring special analysis would help in the determination of whether a person is fit for duty, trustworthy, and reliable, as demonstrated by the abstinence from illegal drug use, when a donor presents a dilute specimen. This would contribute to the assurance that persons using or misusing drugs would be identified and prevented from performing the duties or having the types of access listed in 10 CFR 26.4.

Dilute – Limit of Quantitation

The proposed action would require HHS-certified laboratories to use the Limit of Quantitation (LOQ) instead of the Limit of Detection (LOD), which is currently used when performing special analyses testing permitted in § 26.163(a)(2), when reporting positive test results from special analyses to the MRO. The difference between LOD and LOQ is the ability to quantify the concentration of an analyte in an aliquot of a urine specimen. At LOD, the confirmatory drug test reliably detects the presence of an analyte by an established testing methodology. At LOQ, however, the confirmatory drug test not only confirms the presence of the analyte, but also permits reporting the precise concentration of the analyte.

In the 2008 HHS Guidelines, HHS justified their change in the decision point for adulterant testing from the LOD to the LOQ by noting that ". . . an LOQ ensures that the adulterant has been both appropriately identified and quantified."[33] Each HHS-certified laboratory must determine both the LOD and LOQ values for each analytical procedure to receive and maintain its HHS certification. Therefore, changing from LOD to LOQ for Part 26 confirmatory testing of dilute specimens would result in minimal changes to the HHS-certified laboratory testing and reporting procedures under Part 26.

The MRO is permitted to request the numerical value of test results for drugs and drug metabolites under 10 CFR 26.163(b)(2) and 10 CFR 26.169(c) to inform his or her review of a positive test result. Obtaining positive test results reported at or above the LOQ rather than the LOD in special analysis testing would similarly provide the MRO with additional information for reviewing special analysis test results to inform the decision making process. This additional information would also inform the impartial review process for tested individuals under 10 CFR 26.39, if a donor seeks such a review.

The U.S. Department of Defense has a useful fact sheet about detection and quantitation concepts: http://www.caslab.com/DOD-ELAP-Fact-Sheet/.

3.12 If the proposed action were implemented, affected entities would be required to change their process for testing of specimens collected under 10 CFR 26.115(a) What is the proposed change and would there be adverse consequences on HHS-certified laboratory implementation of the Part 26 requirements?

The proposed change would require special analysis testing on specimens collected under direct observation (the exclusive grounds for performing an observed collection are detailed in 10 CFR 26.115(a)). The most typical circumstance when an observed collection is permitted by rule is described in 10 CFR 26.111(c). That is, if the collector has reason to believe that the donor may have attempted to dilute, substitute, or adulterate the specimen; the licensee or other entity may require the donor to provide a second specimen under direct observation. If the collection is terminated by the licensee or other entity (i.e., a second specimen is not collected), the donor is determined to have subverted the testing process. If, however, a second specimen is collected under direct observation because sufficient evidence did not exist at the time of the initial collection to make a subversion attempt determination, the proposed action would require that special analysis testing be conducted on the second specimen collected.

3.13 If the proposed action were implemented, affected entities would be required to change their immunoassay percentage response. What is the proposed change and would there be adverse consequences on due process or HHS-certified laboratory implementation of the Part 26 requirements

The proposed action would lower the immunoassay percentage response that the HHS-certified laboratory must use to determine if special analyses in § 26.163(a)(2) can proceed for dilute specimens and specimens collected under direct observation. Lowering the response threshold from greater than or equal to 50 percent of the cutoff calibrator for initial drug testing to 40 percent would be consistent with information received from some HHS-certified laboratories regarding the technological capabilities of immunoassay testing and likely would result in

[33] U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, "Mandatory Guidelines for Federal Workplace Drug Testing Programs," *Federal Register*, Vol. 73, No. 228, November 25, 2008, pp. 71858-71907.

conducting special analyses on additional donor specimens. This change would result in no changes to the tests performed by HHS-certified laboratories, but some administrative changes to testing procedures would be necessary. This change would improve the ability of licensees and other entities to identify illicit drugs in individuals attempting to subvert the testing process through excessive fluid consumption shortly before a collection (dilution) or during the collection process (adulteration or specimen substitution). Confirmatory drug testing would still be conducted to provide a verified result for the presence of a drug or drug metabolite.

The level at which each HHS-certified laboratory sets the LOD and LOQ for each assay is dependent on the equipment and testing processes used to perform each confirmatory drug test. As such, the established LOD and LOQ for each confirmatory drug test would be dependent on the testing laboratory. At a minimum, all HHS-certified laboratories must validate the accuracy and precision of each confirmatory drug test at 40 percent of the cutoff concentration. However, the LOQ may be lower than 40 percent of the cutoff concentration. While the NRC acknowledges this variability and has received some feedback during public meetings to standardize the level at which all laboratories test for the special analyses permitted in § 26.163(a)(2), this position is contrary to a long-standing NRC technical position to enable licensees and other entities to use the most advanced testing capabilities to identify illegal drug use. The LOD and LOQ at each HHS-certified laboratory are scientifically valid measures approved by the NLCP certification process.

3.14 If the proposed action were implemented, would there be adverse consequences on MROs', HHS laboratories', or blind performance test sample suppliers' implementation of the Part 26 requirements?

The NRC finds that the proposed changes to 10 CFR Part 26 would have minimum impact and no adverse consequences on other entities. The proposed changes are simple: they would revise definitions, cutoffs, drugs tested, LOD/LOQ processes for dilute specimens, and MRO actions. Licensees would be required to modify their contracts with HHS-certified laboratories and blind performance specimen providers; however, contract modification and negotiation would be based on drug testing performed by the Federal agencies and private companies already implementing the 2008 HHS Guidelines. As such, modification of contracts, licensee policies, procedures, and training would not result in adverse consequences because of the narrow scope of proposed actions and the fact that Federal agencies and many private companies have already implemented these changes, so the needed modifications are well understood. Furthermore, the proposed revised MRO actions have already been implemented by MROs evaluating positive drug test results in other Federally-mandated drug testing programs and appropriate MRO guidance has already been issued by the HHS and the MRO certification organizations. The NLCP has already revised its certification, inspection, and auditing program consistent with the 2008 HHS Guidelines.

The NRC would not propose substantial changes to the urine collection process, testing methodologies, and fitness determinations. The proposed change to conduct LOQ testing in lieu of LOD testing to assess urine dilution (which can be a form of adulteration and subversion) is not a substantial change. Furthermore, the change to require special analysis testing on dilute specimens is already encompassed within the special analysis of § 26.163(a)(2) and laboratories already have the LOD and LOQ values established for their assays. Expanding the special analysis testing provisions to include specimens collected under direct observation will require a minor procedural change at the collection site in how the custody-and-control form is completed to indicate the LOQ testing should be conducted, and also will require minor system process changes at the laboratory to indicate when LOQ testing is to be performed. The

proposed action would result in minimal changes within the existing training of FFD program personnel and personnel at HHS-certified laboratories and policies and procedures.

3.15 If the proposed action were implemented, would there be any adverse consequences on Collective Bargaining Agreements (CBA) and due process afforded to individuals?

No. There would not be adverse consequences on CBAs or the due process afforded to individuals subject to Part 26 drug testing. The NRC notes that CBAs might need to be revised and therefore re-negotiated to facilitate approval by the affected licensee or other entity. For example, CBA revisions may be necessary to address the testing of additional amphetamine analogues, the lower cutoff limits, initial testing of 6-AM, required LOQ testing of dilute specimens and specimens collected under direct observation, and the specimen collection procedure associated with invalid specimen results due to high pH. LOQ testing provides added assurance that the testing assay is detecting the presence of the drug and precisely quantifying its concentration in the specimen (this applies to special analysis testing of dilute specimens and specimens collected under direct observation). The proposed change to conduct LOQ testing in lieu of LOD testing for adulterant testing also improves the accuracy and precision of adulterant confirmatory testing by providing both detection and accurate quantification of the analyte. The high pH procedural change enhances the due process afforded to persons with an invalid specimen because the MRO may determine that a delay in testing or environmental temperatures likely caused the result and the second specimen to be collected would not be under observed conditions (improving donor privacy). The proposed changes to the regulatory requirements would not be negotiable under a CBA.

3.16 If the proposed action were implemented, would there be any adverse consequences on personal privacy?

No. The proposed action would not adversely affect the privacy afforded to individuals subject to Part 26 drug testing. The Part 26 notification, documentation, reporting, appeal, and privacy requirements would not change. The MRO evaluation of an invalid specimen due to high pH pursuant to the provisions in Subpart H, "Determining Fitness-for-Duty Policy Violations and Determining Fitness," provides a higher degree of assurance that an individual would not be subject to a second collection under direct observation, due to improper handling of the specimen.

4. Assumptions and Calculations

The following assumptions and calculations are based on the best estimates and analysis available at the time of this document. Subsequent revisions may be necessary based on peer review, error analysis, and calculation improvements.

<u>Input common to 6-AM, amphetamines, cocaine, and MDMA testing calculations</u>:

- Total number of Part 26 tests conducted on an annual basis = 169,891
  - Industry conducted an average of 169,891 drug tests per year over the past 3 years (CYs 2009-2011).
  - The total number of tests consists of all pre-access, random, for-cause, follow-up, and post-event drug tests conducted in a year.
  - The analysis assumes a constant number of drug tests are performed each year.

- The NRC used DOT annual drug testing data in the Section 3 calculations because it captures 5.6 million results from tests conducted in CY 2011 by all agencies that are subject to 49 CFR Part 40 (e.g., FAA, FMCSA, FRA, FTA, PHMSA, USCG)[34] and encompasses tests results from most HHS-certified laboratories.
    - The NRC considers the DOT workforce to be reasonably equivalent to the workforce within the commercial nuclear power industry. Both industries require trained and qualified personnel; have the same requirements for drug testing and the laboratories that conduct such testing; and have similar safety sensitive personnel positions that are subject to drug testing requirements.
    - DOT implemented the 2008 HHS Guidelines on October 1, 2010, providing some equivalency to the NRC's proposed action to implement select portions of the 2008 HHS guidelines.

- Although the NRC used the DOT drug testing results, the NRC also considered results from the Quest DTI which represented 1.6 million Federally-mandated workplace drug tests conducted between January and December 2011. The Quest data, however robust, current, and accurate, only represent about one-fourth the number of tests conducted by DOT and reflect test results from only one company that operates HHS-certified laboratories. Many HHS-certified laboratories are used for Federal workplace testing. As such, DOT data was given precedence over the Quest data in the calculations because of the Quest data's smaller sample size, which was less broadly representative of HHS-certified laboratories.

- The NRC notes that the positive rates for drug testing in the Part 26, DOT, and Quest DTI data sets are different as indicated below.
    - DOT positive test result rates are in general lower than the Quest testing rates.
    - The Quest and DOT positive test result rates are higher than the NRC test results

This difference does not affect the analysis for amphetamines and cocaine because: (1) the calculation in this document uses the percent change in the DOT positive rates for both substances and (2) it appears that the changes from CY 2010 to CY 2011[35] were the result of DOT implementing the lower testing cutoff levels.

For 6-AM and MDMA, the NRC is unable to ascertain whether using the DOT testing rates may have overestimated the number of potential positives. However, the DOT data appear to be the best data available for use and the positive rates for these substances are very low.

Summary of Estimated Additional Positive Drug Test Results

If the proposed action is implemented, the NRC estimates the following additional positive drug test results for individuals who are subject to Part 26 drug testing.

[34] 14 CFR Part 120 (Federal Aviation Administration [FAA]); 49 CFR Part 382 (Federal Motor Carrier Safety Administration [FMCSA)] ; 49 CFR 219 (Federal Rail Administration [FRA]); 49 CFR Part 655 (Federal Transit Administration [FTA]); 49 CFR Part 199 (Pipeline and Hazardous Materials Safety Administration [PHMSA]); 46 CFR Parts 4 and 16 (U.S. Coast Guard [USCG])

[35] All Federal Agencies subject to testing under the HHS Guidelines implemented lower cutoff levels for amphetamines and cocaine, and initial testing for 6-AM and MDMA on October 1, 2010.

Estimated Additional Positive, Dilute, and Subverted Drug Test Results

	DOT	Quest
Cocaine	**35.3**	48.2
Amphetamine	**15.0**	15.6
6-AM (heroin)	**23.8**	21
MDMA, MDEA, and MDA	**4.6**	5.4
Dilute specimen	**15.0**	15.2
Subverted specimen	**10.0**	10
Total expected increase	**103.6 per year**	115.6 per year

Cocaine

- The NRC FFD program performance testing data indicate that the annual confirmed positive rate for cocaine, using the 3-year average (CYs 2009-2011) was 0.081 percent. This value is used in the analysis to estimate the current positive rate for cocaine.

- DOT reported a 25.64 percent increase in the number of cocaine positives detected from CY 2010 to CY 2011. This value is used in the analysis to estimate the expected increase in the number of positive cocaine test results due to the NRC aligning its initial and confirmatory cutoff levels for cocaine with those in the HHS Guidelines.

- The estimate of additional cocaine positives is calculated as follows:

Additional Cocaine Positives Industry-Wide =

(Total number of tests conducted) x (Cocaine current positive rate)

X (Cocaine expected increase)

= 169,891 x 0.00081 x 0.2564 = ***35.3***

Amphetamines

- The NRC FFD program performance testing data indicate that the annual confirmed positive rate for amphetamines, using the 3-year average (CYs 2009-2011), was 0.034 percent. This value is used in the analysis to estimate the current positive rate for amphetamines.

- DOT reported a 25.90 percent increase in the number of amphetamines positives detected from CY 2010 to CY 2011. This rate is used in the analysis to estimate the expected increase in the number of positive amphetamine test results due to the NRC aligning its initial and confirmatory amphetamines cutoff levels with those in the HHS Guidelines.

- The estimate of additional amphetamines positives is calculated as follows:

Additional Amphetamines Positives Industry-Wide =

(Total number of tests conducted) x (Amphetamines current positive rate)

X (Amphetamines expected increase)

= 169,891 x 0.00034 x 0.2590 = ***15.0***

6-Acetylmorphine

- DOT reported a 0.014 percent positive rate for 6-AM detected in CY 2011, after implementation of mandatory initial testing for 6-AM beginning on October 1, 2010. This rate is used in the analysis to estimate the expected number of confirmed 6-AM positives due to the NRC adding a requirement to test for 6-AM in initial tests and lowering the confirmatory test cutoff level to be consistent with the HHS Guidelines.

- The analysis does not include a current 10 CFR Part 26 positive rate for 6-AM for two reasons. First, the NRC FFD program performance data do not uniformly reflect 6-AM positives. That is, entities using the electronic reporting (e-reporting) system[36] can report the specific opiate(s) that resulted in a positive testing determination (i.e., codeine, morphine, and 6-AM), but entities that submit FFD program performance data in hard copy reports only report the total number of opiate positive results (not specific to codeine, morphine, or 6-AM). Second, the 6-AM positive rate using e-reporting system data is so low as to not affect the results.

    - The e-reporting data for CY 2011 indicate that two confirmed 6-AM positives were reported for 141,234 tests conducted (2/141,234 = 0.000014).
    - The e-reporting data for CY 2010 indicate that one 6-AM positive was reported for 111,248 tests conducted (1/111,248 = 0.000008)

- The estimate of additional 6-AM positives is calculated as follows:

Additional 6-AM Positives Industry-Wide =

(Total number of tests conducted) x (6-AM expected positive rate)

= 169,891 x 0.00014 = ***23.8***

MDMA

- DOT reported a 0.003 percent positive rate for MDMA detected in CY 2011. This rate is used in the analysis to estimate the expected number of positives due to the NRC adding MDMA to its testing panel to better align with the HHS Guidelines.

- The estimate of MDMA positives is calculated as follows:

[36] The e-reporting system is a voluntary program that enables licensees and other entities to electronically submit § 26.717 FFD performance information to NRC.

Additional MDMA Positives Industry-Wide =

(Total number of tests conducted) x (MDMA expected positive rate)

= 169,891 x 0.00003 = ***4.6***

Dilute Specimens - Limit of Quantitation (LOQ) Testing

- The e-reporting system data provide the best information on dilute and drug-positive test results. In CY 2011, 61 of 76 facilities submitted data using the e-reporting system.

- Twelve confirmed drug positives from dilute specimens were reported in the e-reporting system by the 61 e-reporting facilities, yielding a value of 0.197 confirmed dilute positives per entity (12/61). This value is used in the analysis to estimate the number of additional dilute drug-positive tests results per entity expect due to the NRC required LOQ testing of dilute specimens.

- In CY 2011, 76 facilities conducted FFD testing. This value is used in the analysis to estimate the total number of entities affected by the rule change.

- The estimate of dilute positives is calculated as follows:

Additional Dilute Positives Industry-Wide =

(Dilute positives per entity) x (Number entities affected)

= 0.197 x 76 = ***15.0***

Subversion Attempt - LOQ Testing

- The NRC FFD program performance testing data for CY 2011 indicate that 50 specimen collection events were associated with a subversion attempt (e.g., initial specimen collected is out of temperature range) where a second specimen was collected under direct observation and tested positive 76 entities conducted drug and alcohol testing in CY 2011, and therefore, the average number of subversion attempts per entity subject to LOQ testing under the proposed rule would be 0.658 (50/76). Because the NRC does not have data on the number of instances where a subversion attempt is suspected, but the second specimen collected under direct observation is negative, the analysis uses the rate of 0.658 positive test results associated with a subversion attempt per entity from CY 2011 as the base rate for subversion attempts subject to additional testing.

- The analysis assumes a 20 percent increase in the number of positives detected based on the more stringent cutoff levels used (i.e., special analysis testing) when testing specimens collected under direct observation. This value is used in the analysis to estimate the number of additional positive test results identified due to mandatory LOQ testing of specimens collected during suspected subversion attempts under the new rule.

- In CY 2011, 76 facilities conducted FFD testing. This value is used in the analysis to estimate the number of entities affected by the proposed action that would require LOQ testing of specimens whose collection involved a subversion attempt.

- Therefore, the analysis estimates the additional subversion specimen positives as follows:

Additional Subversion Specimen Positives Industry-Wide =

(Subversions subject to testing per entity) x (Subversion expected increase)

X (Number entities affected)

= 0.658 x 0.2 x 76 = ***10.0***

5. Conclusion

This regulatory basis provides sufficient justification to begin the rulemaking process for the proposed action. The action would enhance FFD programs' abilities to identify drug use and thereby enhance the effectiveness of FFD programs.