SUPPORTING STATEMENT
FOR
10 CFR PART 26, FITNESS FOR DUTY PROGRAMS

INFORMATION COLLECTIONS CONTAINED IN FITNESS FOR DUTY
DRUG TESTING REQUIREMENTS PROPOSED RULE

3150-0146

REVISION

DESCRIPTION OF THE INFORMATION COLLECTION

The Nuclear Regulatory Commission (NRC) requires certain licensees and other entities[1] to have a fitness-for-duty (FFD) program to provide reasonable assurance that nuclear facility personnel are trustworthy, reliable, and not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way could adversely affect their ability to safely and competently perform assigned duties. The regulations in 10 CFR Part 26 prescribe the requirements for a licensee or other entity to establish, implement, and maintain an FFD program. Section 26.4 describes the personnel subject to an FFD program (e.g., individuals with unescorted access to the protected areas of operating nuclear power plants).

The NRC is proposing to amend 10 CFR Part 26 to enhance the consistency of NRC's FFD drug testing program requirements with the U.S. Department of Health and Human Services' (HHS) 2008 "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (2008 HHS Guidelines) (73 FR 71858). The proposed rule also would incorporate lessons learned from licensees' and other entities' implementation of the 10 CFR Part 26 final rule (73 FR 16966, March 31, 2008). The changes would enhance the ability of licensees and other entities to identify additional individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. The proposed rule also would provide additional protections to individuals subject to testing, and would improve the clarity, consistency, organization, and flexibility of the rule.

The proposed rule would impact the following three types of existing information collection requirements in 10 CFR Part 26:

- FFD program policies and procedures – The licensee or other entity of each FFD program would need to revise FFD program policy and procedures to reflect the updated drug testing requirements, and to distribute the updated FFD program policy to individuals subject to 10 CFR Part 26. These activities would occur on a one-time basis.

[1] Entities that must have a 10 CFR Part 26 FFD program include (1) licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material (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," (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," 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.

- Contracts with HHS-certified laboratories and suppliers – The licensee or other entity of each FFD program would need to revise contracts with the primary and backup HHS-certified laboratory and with the blind performance test sample (BPTS) supplier to reflect the updated drug testing requirements. These activities would occur on a one-time basis.

- Records and reports associated with drug testing violations – The proposed rule would not increase the number of specimens collected for drug testing by licensees and other entities, but it would result in the need for licensees and other entities to document an estimated 95 additional individuals per year that test positive for a drug or drugs, or are identified as attempting to subvert the drug testing process, as well as the actions taken in response to these testing events. These activities would occur on an annual basis.

The proposed rulemaking would affect the reporting and recordkeeping burden of 27 FFD programs, which is based on annual FFD program performance reports of drug and alcohol testing information received by the NRC from each licensee and other entity under 10 CFR 26.417(b)(2) or 10 CFR 26.717. An "FFD program" is the corporate[2]- or licensee-specific program used by individual licensees and other entities to comply with 10 CFR Part 26. These FFD programs encompass a total of 67 sites[3], which consist of 57 operating power reactor sites[4], 2 power reactor construction sites, 5 corporate offices, 2 fuel-cycle facilities, and 1 contractor/vendor (C/V). Hereafter, "licensee" or "licensee and other entity" will be used to describe sites subject to the requirements of 10 CFR Part 26. Only a subset of the recordkeeping and reporting requirements in 10 CFR Part 26, specifically those in Subpart K, apply to the 2 power reactor construction sites.

Most of the recordkeeping and reporting requirements in the proposed rule affect FFD programs. Some requirements only apply to the laboratories that conduct drug and validity testing for licensees and other entities (6 licensee testing facilities (LTFs) and 12 HHS-certified laboratories).

A. JUSTIFICATION

1. Need for and Practical Utility of the Information

[2] Some licensees with multiple power reactor sites administer their FFD programs at locations other than the power reactor sites, and therefore report data for their administrative FFD program personal separately under a "corporate FFD program".

[3] The term "site" used in this analysis corresponds to the term "facility" used by the NRC FFD program performance reporting system. A "site" is a unique location at which covered employees must undergo FFD drug and alcohol testing (e.g., a nuclear power plant containing one or more power reactor units, a licensee corporate office). A single FFD program may cover FFD activities at one or more sites.

[4] This burden statement 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) and is no longer subject to 10 CFR Part 26, or announced early plant closure (i.e., Fitzpatrick, Oyster Creek, and Pilgrim). Subsequent to completing this burden statement, the licensee for FitzPatrick reported that it now plans to continue to operate and the licensee for Fort Calhoun permanently shut down the site in October 2016. Adjustments to the number of operating nuclear power reactors will be made in the burden statement for the final rule.

In general, the recordkeeping and reporting requirements are necessary for the following reasons:

a) *Information describing the FFD drug testing program*. This information (as contained in the licensee's FFD program policy and procedures) is essential to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the FFD program.

b) *Information documenting drug testing protocols with LTFs and HHS-certified laboratories.* This information is necessary to establish the standards and procedures that laboratories must use when conducting drug and validity testing on urine specimens.

c) *Information documenting Blind Performance Test Sample (BPTS) requirements.* This information is necessary to establish standards that BPTS suppliers must meet when formulating BPTSs.

d) *Information documenting drug specimen collection, testing, and review processes*. This information is necessary to maintain specimen chain of custody, record and report test results, and evaluate a licensee's or entity's FFD performance and significant FFD-related events to help maintain public health and safety, promote the common defense and security, and protect the environment.

Each 10 CFR Part 26 recordkeeping and reporting requirement affected by the proposed rule is described below.

10 CFR 26.27(a) requires each licensee or other entity to establish, implement, and maintain written policies and procedures designed to meet the section 26.23 performance objectives and other specified requirements in 10 CFR Part 26. The written FFD policy is the primary means by which a licensee or other entity communicates information on the FFD program to individuals subject to 10 CFR Part 26, and the FFD procedures are the primary means of documenting how the FFD program is to be administered by the licensee or other entity. This requirement ensures that the due process rights of individuals are protected by providing information in sufficient detail on the FFD policy and consequences that may result from not adhering to the FFD policy. The proposed rule would not change this requirement, but it would result in a one-time recordkeeping burden to update written policies and procedures to reflect changes to the drug testing requirements. In addition, licensees and other entities would be required to revise the contracts with the primary and back-up HHS-certified laboratories and BPTS suppliers to incorporate the changes in the drug testing requirements. Section 26.41(d) describes the requirements that each licensee and other entity must include in the contracts that it maintains with contractor/vendors (e.g., BPTS supplier) and HHS-certified laboratories. The proposed rule revisions to the drug testing panel and testing cutoff levels would result in changes to FFD program contracts, the burden of which is reflected in section 26.27(a). The burden associated with this requirement is shown as an incremental one-time recordkeeping burden in Table 1.

10 CFR 26.27(b) requires each licensee or other entity to make the current FFD policy statement readily available to all individuals subject to the policy and specifies the minimum mandatory contents of the written policy statement, which include a description of the consequences of prohibited actions, reporting for testing requirements, alcohol

abstinence requirements, the factors that could affect fitness-for-duty, employee assistance programs, and responsibilities to report FFD concerns to the licensee or other entity. This requirement ensures that the current FFD policy is available for review by all individuals who are subject to the FFD program. The proposed rule would not change this FFD policy requirement, but it would result in a one-time recordkeeping burden for the licensee or other entity to prepare and distribute information to individuals subject to the FFD program that describes the updates to the FFD policy. The burden associated with this requirement is shown as an incremental one-time recordkeeping burden in Table 1. The one-time third-party disclosure burden associated with individuals subject to an FFD program reviewing information on the FFD policy updates is discussed under section 26.29(c)(2) in Table 4.

10 CFR 26.27(c) requires each licensee or other entity to prepare, implement, and maintain written procedures that describe the methods to be used in implementing the FFD policy and requirements of 10 CFR Part 26. This requirement is necessary to ensure that individuals who manage and implement the FFD program and individuals subject to that FFD program are provided specific information such as the methods and techniques to be used in testing for drugs (which would include the drug testing panel and cutoff levels used) and actions taken based on an attempt to subvert the drug testing process. The proposed rule would result in a one-time recordkeeping burden for the licensee or other entity of each FFD program to update written policies and procedures to reflect changes to the drug testing requirements, including required special analyses testing of dilute specimens and specimens collected under direct observation, lower initial and confirmatory drug testing cutoff levels for amphetamine, cocaine, methamphetamine, the addition of 6-acetylmorphine (6-AM) to the initial drug testing panel, a revised confirmatory testing cutoff level for 6-AM, and the addition of Ecstasy-type drugs (i.e., methylenedioxymethamphetamine (MDMA), methylenedioxyamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA)) to the initial and confirmatory drug testing panels. This requirement also contributes to the protection of due process rights for individuals, who are subject to Part 26, provides for prior notice, and ensures documentation for evidence in legal proceedings. The burden associated with this requirement is shown as an incremental one-time recordkeeping burden in Table 1.

The recordkeeping requirement for maintaining superseded FFD procedures is established by section 26.715(b)(4).

10 CFR 26.29(c)(2) requires refresher training to be completed on a nominal 12 month frequency or more frequently where the need is indicated, and allows individuals who pass a comprehensive annual examination to forgo refresher training. Refresher training includes the administration of the comprehensive annual examination and keeping FFD training materials updated. Required training provides reasonable assurance that persons who have unescorted access to the protected area of the facility are trustworthy and reliable as demonstrated by their knowledge of 10 CFR Part 26 requirements. Recordkeeping requirements for section 26.29(c)(2) are established by section 26.713(b)(1). The proposed rule would not change this requirement, but it would result in a one-time third party disclosure burden associated with some of the licensee and other entity FFD programs providing updated information on the FFD policy changes outside of the normal annual refresher training cycle for existing staff, as reflected in Table 4. Most licensee and other entity FFD programs would incorporate the training of staff on the proposed rule changes as part of the normal curriculum in the annual

refresher training and therefore no incremental one-time third-party disclosure burden would result in these instances.

10 CFR 26.75(a), (b), (c), (d), (e)(2) and (g) specify the minimum sanctions that licensees and other entities must impose upon individuals who have violated the drug and alcohol testing provisions of an FFD policy. These requirements establish a uniform set of sanctions for FFD violations and licensees and other entities create a record to document the sanction imposed on each individual. A record of the 10 CFR Part 26 sanction is necessary for later reference if an individual applies for authorization at the same or another facility. Records of sanctions also are shared among FFD programs, in part, through an electronic records system administered by industry to which the licensees and other entities send information concerning employment dates, approvals of authorization, withdrawals of authorization, and if an individual had an FFD policy violation. Recordkeeping requirements for sections 26.75(a), (b), (c), (d), (e)(2), and (g) are established by section 26.713(c). The proposed rule would not change these requirements, but it would result in an incremental recordkeeping burden associated with the 95 additional positive test results per year that are estimated to result from the proposed rule. The burden associated with these requirements is shown as an incremental annual recordkeeping burden in Table 2.

Proposed 10 CFR 26.107(d) would be added to describe the actions the specimen collector must take if a refusal to test was determined at any point during the specimen collection process. The collector would be required to: (1) inform the donor that a refusal to test has been determined; (2) document a description of the refusal to test on the Federal CCF; and (3) immediately inform the FFD program manager. The proposed rule would elaborate on existing steps that already take place when a refusal to test is determined during the collection process. Providing explicit detail in the proposed rule would improve the consistency and effectiveness of 10 CFR Part 26 by ensuring that uniform action is taken by each collector. No change in burden is estimated from the proposed rule change.

10 CFR 26.127(c) and (d) specify the quality assurance/quality control processes to be used by each LTF and require the licensee to document the procedures to be followed to ensure that all steps in the testing and analysis process are carried out in an appropriate manner by all personnel conducting the activities. The proposed rule would not change these requirements, but it would result in one-time recordkeeping burden associated with updates to the LTF testing procedures based on the changes to the drug testing cutoff levels and testing panel. Recordkeeping requirements for sections 26.127(c) and (d) are established by section 26.715(a). The burden associated with these requirements is shown as an incremental one-time recordkeeping burden in Table 1.

- 10 CFR 26.127(c) requires the licensee operating the LTF to develop, implement, and maintain written standard operating procedures for each assay performed for drug and specimen validity testing. The procedures must include detailed descriptions of the principles of each test; preparation of reagents, standards, and controls; calibration procedures; derivation of results; linearity of the methods; cutoff values; mechanisms for reporting results; controls; criteria for unacceptable specimens and results; reagents and expiration dates; and references.

- 10 CFR 26.127(d) requires the licensee operating the LTF to develop, implement, and maintain written procedures for instrument and device setup and normal operation that include a schedule for checking critical operating characteristics for all instruments and devices; tolerance limits for acceptable function checks; and instructions for major troubleshooting and repair.

10 CFR 26.135(b) allows the donor upon notification of a positive, adulterated, or substituted test result from the medical review officer (MRO), to request that Bottle B of a split specimen (as described in section 26.113) be tested at a second HHS-certified laboratory under the procedures in section 26.165(b). The proposed rule would not change this requirement, but it would change the requirements in section 26.165(b). The discussion on sections 26.165(b)(2) and (b)(3) in this burden statement describe the proposed changes to the recordkeeping requirements. Recordkeeping requirements for section 26.135(b) are established by section 26.715(b)(6). Incremental recordkeeping and third-party burdens are estimated to result for licensees and other entities that use an LTF to perform initial testing of specimens and that could account for some of the 95 additional positive test results each year that are estimated to result from the proposed rule. The burden associated with this requirement is shown as an incremental annual recordkeeping burden in Table 2 and as an incremental annual third-party disclosure burden in Table 5.

10 CFR 26.155 (a) – (f) specify, in part, the HHS-certified laboratory recordkeeping requirements associated with laboratory personnel qualifications and responsibilities. The proposed rule would eliminate section 26.155 in its entirety because these third-party disclosure requirements are duplicative with requirements in section 11.1 of the 2008 HHS Guidelines (the burden of which already is captured under OMB Control No. 0930-0158). The NRC's 10 CFR Part 26 information collection request (ICR) does not currently include any burden for section 26.155 requirements because the requirements are covered under OMB Control No. 0930-0158 for the HHS Guidelines.

Proposed 10 CFR 26.157(a) requires HHS-certified laboratories to develop, implement, and maintain clear and well-documented procedures for accession, receipt, shipment, and testing of urine specimens. The proposed rule would revise this recordkeeping requirement to specify that "HHS-certified laboratories shall develop, implement, and maintain procedures specific to Part 26 that document the accession, receipt, shipment, and testing of specimens." This proposed change would ensure that an HHS-certified laboratory only would be required by NRC regulation to maintain laboratory procedures specific to the 10 CFR Part 26 testing program. These records would be necessary to ensure that the laboratory is conforming to 10 CFR Part 26 testing requirements and can be evaluated during licensee or other entity conducted audits of HHS-certified laboratories that are required under section 26.41(c). Recordkeeping requirements for section 26.157(a) are established by section 26.715(b). As a result, the proposed rule would eliminate duplicative recordkeeping requirements that an HHS-certified laboratory already must comply with under section 11.1 of the 2008 HHS Guidelines (the burden of which already is captured under OMB Control No. 0930-0158). The burden associated with this revised requirement is shown as an incremental one-time third-party disclosure burden in Table 4.

10 CFR 26.157(b), (c), (d), and (e) specify the requirements that an HHS-certified laboratory must meet to conduct forensic drug testing and to ensure the scientific supportability of the test results. The proposed rule would eliminate these third party

disclosure requirements because they are duplicative with existing recordkeeping requirements in section 11.1 of the 2008 HHS Guidelines. The NRC's 10 CFR Part 26 ICR does not currently include any burden for 26.155 requirements because the requirements are covered under HHS OMB Control No. 0930-0158).

10 CFR 26.163(a)(2) specifies that if validity testing determines that a specimen is dilute, and the immunoassay response of a drug or drug metabolite is equal to or greater than 50 percent of the initial drug test cutoff, the licensee or other entity may require the HHS-certified laboratory to test the specimen for that drug or drug metabolite to the limit of detection for the confirmatory drug test assay. The laboratory shall report the numerical values (the quantitative test result) obtained from this special analysis to the MRO. This requirement enables the licensee or other entity to validate a dilute result to protect donors from inaccurate results, to provide assurance that specimens of questionable validity are detected, and to ensure the integrity of the testing process. The recordkeeping requirements for section 26.163(a)(2) are established by section 26.715(b)(6). The proposed rule would change section 26.163(a)(1) which currently provides licensees and other entities with the option to conduct special analyses testing on specimens with dilute validity test results, by requiring specimen analyses tests to be performed. The proposed rule also would expand special analyses testing to specimens collected under direct observation for any of the conditions specified in sections 26.115(a)(1) through (a)(3) or (a)(5). The proposed rule would result in an incremental recordkeeping burden associated with some of the additional 95 positive test results per year that are estimated to result from the proposed rule. The burden associated with this requirement is shown as an incremental annual recordkeeping burden in Table 2.

The requirements in sections 26.165(b)(1) through (b)(3), and (b)(6) are necessary to provide donors with the opportunity to request that either Bottle B of a split specimen or an aliquot of a single specimen be tested if a confirmed positive, adulterated, or substituted test result is obtained. These requirements are necessary to protect each donor from inaccurate laboratory test results by permitting additional testing of a specimen at a second HHS-certified laboratory to verify the accuracy of the test results from the initial HHS-certified laboratory. Recordkeeping requirements for test results are established by section 26.715(b)(6). Each of these collections represents incremental recordkeeping and third-party burdens associated with some of the 95 additional positive test results per year that are estimated to result from the proposed rule. The burden associated with these requirements is shown as an incremental annual recordkeeping burden in Table 2.

- 10 CFR 26.165(b)(1) requires that for a confirmed positive, adulterated, or substituted test result reported on a single specimen or Bottle A of a split specimen, a donor may request (through the MRO) that an aliquot from the single specimen or Bottle B of the split specimen be tested by a second HHS-certified laboratory to verify the result reported by the first laboratory.

- Proposed 10 CFR 26.165(b)(2) requires the MRO to inform the donor that he or she may, within 3 business days of notification of a confirmed positive, adulterated, or substituted test result, request that retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen be performed at a second-HHS-certified laboratory. The MRO shall provide the donor with specific instructions for making this request (i.e., providing telephone numbers or other contact information). The MRO is required to have the ability to receive a

telephone call from the donor at all times during the 3-day period (e.g., by use of an answering machine with a time stamp feature when no one in the MRO's office can answer the phone). The donor's request may be oral or in writing. The proposed rule would revise this section to require that if the MRO received an oral request from the donor to initiate additional testing, the MRO must document in his or her records when (i.e., date and time) the oral request was received from the donor. The documentation of the date and time that an oral request is received from a donor is consistent with current MRO practice, but 10 CFR Part 26 did not specifically require the MRO to document this information. The proposed rule would correct this inconsistency.

- Proposed 10 CFR 26.165(b)(3) requires the donor to provide his or her written permission to the MRO before the MRO can initiate the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen. The proposed rule would remove this requirement because section 26.165(b)(2) already permits a donor to provide his or her written or oral permission to the MRO to initiate specimen retesting. Section 26.165(b)(3) also currently specifies that neither the licensee, MRO, NRC, nor any other entity may order retesting of a specimen without the donor's written permission. The proposed rule would revise this section to clarify that "no entity, other than the MRO as permitted in section 26.185(I), may order the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen without the donor's written permission. No change in burden is estimated to result from these rule changes.

- 10 CFR 26.165(b)(6) requires that the second HHS-certified laboratory that re-tests an aliquot of a single specimen or tests Bottle B of a split specimen to provide the quantitative test results to the MRO and then directs the MRO to provide the test results to the donor.

10 CFR 26.165(c)(4) requires that the second HHS-certified laboratory conducting retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen to report all results to the licensee's or other entity's MRO. Recordkeeping requirements for these reports are established by section 26.715(b)(6). The proposed rule would not change this requirement, but it would result in an incremental recordkeeping burden associated with some of the 95 additional positive test results per year that are estimated to result from the proposed rule. The burden associated with this requirement is shown as an incremental annual recordkeeping burden in Table 2.

Proposed 10 CFR 26.165(f)(1) specifies that a licensee or other entity shall administratively withdraw an individual's authorization on the basis of a first confirmed positive, adulterated, or substituted test result until the results of testing Bottle B or retesting an aliquot of a single specimen are available and have been reviewed by the MRO. If the MRO reports that the results of testing Bottle B or retesting the aliquot of a single specimen reconfirm any of the original positive, adulterated, or substituted test result(s), the licensee or other entity shall impose the appropriate sanctions specified in subpart D. The requirement in section 26.165(f)(1) is necessary to protect donors from inaccurate test results. Recordkeeping requirements for section 26.165(f)(1) are established by section 26.713(a)(2) and (a)(3). The proposed rule would include a clarification to an existing requirement in section 26.165(f)(2). Specifically, the proposed rule would replace the statement "If the results of testing Bottle B or retesting the aliquot of a single specimen are negative, the licensee or other entity" with "If the results of

testing Bottle B or retesting the aliquot of a single specimen are negative, the MRO shall report a cancelled test result to the licensee or other entity." This proposed change is a clarification of existing action that the MRO would take in this circumstance, and therefore, no additional burden is estimated to result from the change. However, the proposed rule would result in an incremental recordkeeping burden associated with some of the additional 95 positive test results that are estimated to result each year from the proposed rule, where an individual requests the testing of an aliquot of a single specimen or the Bottle B split specimen at a second HHS-certified laboratory. The burden associated with this requirement is shown as an incremental annual recordkeeping burden in Table 2.

10 CFR 26.169(a), (c)(1), (c)(2), and (g) ensure that the MRO of each licensee or other entity receives all necessary drug and validity test result information from the HHS-certified laboratory performing specimen testing. This information is necessary to enable the MRO to complete the test results review required in section 26.185(a). Recordkeeping requirements for section 26.169 are established by sections 26.715(b)(2), (b)(3), (b)(5), (b)(6), and (b)(8). Each of these collections represents incremental recordkeeping and third-party burdens associated with the 95 additional positive test results per year that are estimated to result from the proposed rule. The burden associated with these requirements is shown as an incremental annual recordkeeping burden in Table 2 and as an incremental annual third-party disclosure burden in Table 5.

- 10 CFR 26.169(a) requires HHS-certified laboratories to report test results to the MRO of the licensee or other entity within 5 business days after receiving the specimen. Before reporting any test result, the laboratory's certifying scientist must certify the result is correct. The report must identify the substances for which testing was performed; the results of the validity and drug tests; the cutoff levels for each test; any indications of tampering, adulteration, or substitution that may be present; the specimen identification number assigned by the licensee or other entity; and the specimen identification number assigned by the laboratory.

- 10 CFR 26.169(c)(1) requires HHS-certified laboratories to report to the MRO all positive, adulterated, substituted, dilute, and invalid test results.

- 10 CFR 26.169(c)(2) requires HHS-certified laboratories to report to the MRO the numerical values for all positive drug test results, if requested by the MRO.

- 10 CFR 26.169(g) requires the HHS-certified laboratory, for a specimen with a positive, adulterated, substituted, dilute, or invalid result, to retain the original Federal custody-and-control form (Federal CCF) and transmit to the MRO a copy of the original Federal CCF signed by the certifying scientist.

10 CFR 26.183(c)(1) requires the MRO to examine alternate causes of a positive, adulterated, substituted, invalid and dilute test results, including reviewing records made available by the donor and documented medical conditions. This requirement is necessary to specify how the MRO performs certain duties such that reasonable assurance is provided in the medical review of drug testing results and protection of information. Recordkeeping requirements for sections 26.183(c)(1) are established by section 26.713(a)(2). The proposed rule would not change this requirement, but it would

result in incremental burdens associated with some additional amphetamine positive test results per year that are estimated to result from the proposed rule, which would be determined by the MRO to be from legitimate documented medical conditions and not FFD testing violations. The burden associated with this requirement is shown as an incremental annual recordkeeping burden in Table 2 and as an incremental annual third-party disclosure burden in Table 5.

10 CFR 26.185(a) requires the MRO to review all positive, adulterated, substituted, and invalid test results from the HHS-certified laboratory to determine whether the donor has violated the FFD policy before reporting the results to the licensee's or other entity's designated representative. This ensures that an appropriate medical review of drug and validity testing results is performed based on all pertinent laboratory testing information. Recordkeeping requirements for Section 26.185 are established by section 26.713(a)(2). The proposed rule would not change this requirement, but it would result in incremental recordkeeping and third-party burdens associated with the additional 95 positive test results that are estimated to result each year from the proposed rule. The burden associated with this requirement is shown as an incremental annual recordkeeping burden in Table 2.

10 CFR 26.185(c) prohibits the MRO from determining that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is a FFD policy violation and reporting it to the licensee or other entity without giving the donor an opportunity to discuss the test result or other occurrence with the MRO. If, after discussion, the MRO determines the result or occurrence is an FFD violation, the MRO shall notify the licensee. These requirements are necessary to ensure that before the MRO notifies a licensee or other entity of an FFD policy violation, the MRO has reviewed the positive, adulterated, substituted, dilute, or invalid result and has discussed the result with the donor to evaluate if any legitimate medical explanation could explain the test results received by the laboratory. These requirements also help to protect the due process rights of individuals who are subject to 10 CFR Part 26, and also to document prior notice for any potential legal proceedings. Recordkeeping requirements for section 26.185 are established by section 26.713(a)(2). Each of these collections represents incremental recordkeeping and third-party burdens associated with the 95 additional positive test results per year that are estimated to result from the proposed rule. The burden associated with these requirements is shown as an incremental annual recordkeeping burden in Table 2 and an incremental annual third-party disclosure burden in Table 5.

Proposed 10 CFR 26.185(f)(3). The proposed rule would redesignate paragraph (f)(3) as paragraph (f)(4) and would add a new paragraph (f)(3) to section 26.185 to align the MRO review of invalid test results with section 13.4(f) of the 2008 HHS Guidelines. Section 26.185(f) describes the process that an MRO is to use to review invalid test results received from the HHS-certified laboratory. The proposed rule would include a new review to be performed by the MRO for an invalid test result due to a pH value in the range of 9.0 to 9.5. In this situation, section 26.185(f)(3) would require the MRO to consider if elapsed time and/or high temperature might have caused the test result (i.e., evaluate specimen handling conditions). If the MRO obtains sufficient information from contact with the licensee or other entity, collection site, LTF, or HHS-certified laboratory that specimen handling conditions (from collection, receipt, transportation, or storage) could have resulted in the invalid test result due to pH, then the MRO would direct the licensee or other entity to collect a second urine specimen from the donor as soon as

reasonably practicable. The second specimen would not be collected under direct observation, because sufficient evidence was obtained to conclude that donor action likely was not the cause of the invalid test result. Therefore, the proposed rule would provide an additional donor protection from the provision of a second specimen under direct observation, which would be required under the current rule if no legitimate medical explanation could explain the invalid test result. The proposed rule would result in an incremental annual burden for the MRO to evaluate if specimen handling conditions could have resulted in an invalid result and to document the information obtained during the evaluation. The NRC staff anticipates that receipt of an invalid specimen of pH 9.0 to 9.5 would be a rare event. Recordkeeping requirements for section 26.185(f)(3) are established by section 26.713(a)(2). The burden associated with this requirement is shown as an incremental annual recordkeeping burden in Table 2.

10 CFR 26.185(j)(3) requires that, if the MRO determines that the donor has used another individual's prescription medication and evidence of drug abuse is found, the MRO must report to the licensee or other entity that the donor has violated the FFD policy. Recordkeeping requirements for section 26.185 are established by section 26.713(a)(2). This provision represents incremental recordkeeping and third-party burdens associated with some of the 95 additional positive test results per year that are estimated to result from the proposed rule. The burden associated with these requirements is shown as an incremental annual recordkeeping burden in Table 2.

10 CFR 26.185(k) requires the MRO to report to the licensee or other entity that no FFD policy violation has occurred if a legitimate medical explanation is obtained by the MRO for a positive drug test result (i.e., use of the drug identified through testing was in the manner and at the dosage prescribed and the results do not reflect a lack of reliability or trustworthiness). Recordkeeping requirements for section 26.185 are established by section 26.713(a)(2). This provision represents incremental recordkeeping and third-party burdens associated with some of the additional positive amphetamine test results per year that are estimated to result from the proposed rule. The burden associated with these requirements is shown as an incremental annual recordkeeping burden in Table 2.

10 CFR 26.185(n) and (p) are necessary to partially meet the legal necessity of protecting the due process rights of individuals subject to Part 26, and also proving prior notice and preserving documented evidence for legal proceedings. These requirements also protect donors from inaccurate results and ensure the integrity of the testing process. Recordkeeping requirements for section 26.185 are established by section 26.713(a)(2). Each of these collections represents incremental recordkeeping and third-party burdens associated with the 95 additional positive test results per year that are estimated to result from the proposed rule. The burden associated with these requirements is shown as an incremental annual recordkeeping burden in Table 2.

- 10 CFR 26.185(n) provides that, if a second HHS-certified laboratory reconfirms any drug-positive, adulterated, substituted, or invalid validity test result, the MRO may report an FFD policy violation to the licensee or other entity; if the second HHS-certified laboratory does not reconfirm the original test results, the MRO shall report that no FFD policy violation has occurred.

- 10 CFR 26.185(p) requires the MRO to review each positive, adulterated, substituted, and invalid test result and, in those instances in which the MRO

determines that the donor has violated the FFD policy of the licensee or other entity, to notify the designated representative of the licensee or other entity in writing within 10 business days of an initial positive, adulterated, or substituted test result.

10 CFR 26.403(a) requires construction site FFD programs under Subpart K of 10 CFR Part 26 to ensure that a clear, concise, written FFD policy statement is provided to individuals who are subject to the program. The policy statement must be written in sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy. The proposed rule would not change this requirement, but it would result in an incremental one-time recordkeeping burden to distribute the updated policy to individuals already subject to the FFD program. The burden associated with these requirements is shown as an incremental one-time recordkeeping burden in Table 1. The one-time third-party disclosure burden associated with individuals subject to an FFD program reviewing information on the FFD policy updates is discussed under section 26.29(c) in Table 4.

10 CFR 26.403(b) requires construction site FFD programs under Subpart K to develop, implement, and maintain written procedures that address drug and alcohol testing program methods and techniques and procedures for ensuring valid results attributable to the correct individual, actions taken and procedures used for FFD violations, and the process to be followed for behavior that may raise concerns of possible FFD violations or impairment. The written FFD policy and procedures required by Subpart K are the primary means by which a licensee or other entity communicates its FFD policy and procedures to individuals who are subject to the policy and procedures. This requirement is necessary to ensure that the due process rights of individuals are protected by informing them in sufficient detail about the licensee FFD policy and the consequences that may result from a lack of adherence to the FFD policy. The proposed rule would not change this requirement, but it would result in a one-time recordkeeping burden to update the written policies and procedures to reflect the new drug testing requirements, including the required special analyses testing for dilute specimens or specimens collected during suspected subversion attempts, the lower initial and confirmatory drug testing cutoff levels for amphetamines and cocaine, the addition of 6-AM to the initial drug testing panel, the revised confirmatory testing cutoff level for 6-AM, and the addition *Ecstasy*-type drugs (i.e., MDMA, MDA, and MDEA) to the initial and confirmatory drug testing panels. In addition, licensees and other entities would be required to revise contracts with BPTS suppliers to include samples with *Ecstasy*-type drugs and with primary and back-up HHS-certified laboratories to adhere to the new specimen testing requirements. The burden associated with this requirement is shown as a one-time recordkeeping burden in Table 1.

10 CFR 26.405(g) requires that construction site FFD programs under Subpart K provide for an MRO review of positive, adulterated, substituted, and invalid confirmatory drug and validity test results to determine if a donor has violated the FFD policy, before reporting the results to licensee or other entity. The requirement to maintain records associated with this reporting requirement is in section 26.417(a). The proposed rule would not change this requirement, but it would result in an incremental recordkeeping burden associated with some of the 95 additional positive test results per year that are estimated to result from the proposed rule. The burden associated with this requirement is shown as an incremental annual recordkeeping burden in Table 2.

10 CFR 26.417(b) requires that construction site FFD programs under Subpart K to provide information to the NRC within 24 hours of the discovery of an act that casts doubt on the integrity of the FFD program or a programmatic weakness (e.g., a laboratory testing error, an identified subversion attempt of the drug testing process by a supervisor); and on an annual basis regarding FFD program summary performance. These reports enable the NRC to ensure that each program is adequately protecting public health and safety, common defense, and security, and are necessary to enable licensees and other entities to review and correct any problems in implementing FFD programs, and to enable the NRC to inspect the licensee's and other entities' FFD programs and to obtain information necessary to evaluate the effectiveness of the FFD programs. Reporting of information on significant FFD events also is necessary to permit a timely response by the NRC staff to ensure that the health and safety of the public is not endangered.

- 10 CFR 26.417(b)(1) requires licensees and other entities who implement a construction site FFD program to make reports to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers any intentional act that casts doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals who are subject to Subpart K. These events must be reported under Subpart K, rather than under the provisions of 10 CFR 73.71, because the events are associated with FFD programs at construction sites. The proposed rule would not change these requirements, but it could result in an incremental reporting burden associated with some of the 95 additional positive test results per year that are estimated to result from the proposed rule. The burden associated with these requirements is shown as an incremental annual reporting burden in Table 3.

- 10 CFR 26.417(b)(2) requires licensees and other entities who implement a construction site FFD program to submit an annual program performance report for the FFD program. Each licensee and other entity is required to collect and compile FFD program performance data, the recordkeeping requirement associated with this reporting requirement is in section 26.417(a). This requirement is necessary to ensure that licensees and other entities are implementing the drug and alcohol testing requirements properly. The proposed rule would not change these requirements, but it could result in an incremental reporting burden associated with preparing additional information to be included in the annual FFD program performance report associated with some of the 95 additional positive test results per year that are estimated to result from the proposed rule. The burden associated with these requirements is shown as an incremental annual reporting burden in Table 3.

10 CFR 26.713(a)(2) requires the retention of records pertaining to the determination of a violation of the FFD policy and related management actions for at least 5 years after the licensee or other entity terminates or denies an individual's authorization or until the completion of all related legal proceedings, whichever is later. This requirement is necessary to ensure that licensees and other entities collect and maintain records that demonstrate they are properly implementing FFD regulatory requirements in a manner adequate to protect public health and safety and the common defense and security. These records are also necessary to enable licensees and other entities to review and

correct any problems in implementing FFD programs and to enable the NRC to review and audit the licensees' and other entities' FFD programs. The proposed rule would not change this requirement, but it would result in an incremental recordkeeping burden associated with the 95 additional positive test results per year that are estimated to result from the proposed rule. The burden associated with this requirement is shown as an incremental annual recordkeeping burden in Table 2.

10 CFR 26.717 establishes the annual FFD program performance data reporting requirements that the licensee and other entity of each site with an FFD program must maintain and report to the NRC. The annual FFD program performance report provides the NRC with timely information on the drug and alcohol testing program to assess if each FFD program meets regulatory requirements. In aggregate, FFD program performance data is analyzed by NRC to evaluate if adverse trends in substance use are occurring that may require regulatory action and/or additional NRC evaluation through inspection or oversight activities. Information in the annual FFD program performance reports is analyzed and used by the NRC to inform the public and industry on FFD program performance trends in a summary report that is publically available. Preparation of the annual FFD program performance report also enables each licensee and other entity to review site performance and address issues, if noted. Site specific FFD program performance data is necessary to enable the NRC to evaluate FFD program compliance and informs the inspection process. The proposed rule would not change these reporting requirements, but it would result in an incremental reporting burden associated with the 95 additional positive test results per year that are estimated to result from the proposed rule. The burden associated with these requirements is shown as an incremental annual reporting burden in Table 3.

10 CFR 26.719(b)(2) requires licensees and other entities to report significant violations of the FFD policy and significant FFD program failures to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers the violation. A report must be made for: Any acts by a person who is licensed under 10 CFR Part 55 to operate a nuclear power reactor, as well as any acts by SSNM transporters, FFD program personnel, or any supervisory personnel who are authorized under 10 CFR Part 26; if such acts result in a determination that the individual has violated the licensee's or other entity's FFD policy. The proposed rule would not change these requirements, but it would result in an incremental reporting burden associated with some of the 95 additional positive test results per year that are estimated to result from the proposed rule. The burden associated with these requirements is shown as an incremental annual recordkeeping burden in Table 2 and an incremental annual reporting burden in Table 3.

2. Agency Use of the Information

The information collections required by 10 CFR Part 26 are necessary to properly manage FFD programs and to enable effective and efficient regulatory oversight over affected licensees and other entities. Regulatory oversight is necessary to protect the public health and safety and the common defense and security. For example, the NRC reviews FFD program records during periodic inspections to assess the adequacy of the licensee's or other entity's FFD program, including training, FFD policies and procedures, personnel access determinations, internal program audit results, and corrective actions taken in response to self-identified deficiencies. The information collections required by 10 CFR Part 26 also focus on protecting individuals subject to an

FFD program (should an FFD program violation be challenged, for example, through arbitration, a court proceeding, or a testing irregularity at a laboratory is discovered). The NRC also uses the information collections to inform the public and the regulated industry on FFD program performance and trends to maintain public trust.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use information technology when it would be beneficial to them. Most licensees collect, store, and format FFD data electronically. Section 26.11 enables licensees, vendors, applicants, and members of the public to make submissions electronically to the NRC via CD-ROM, e-mail, special Web-based interface, or by other means. This section is consistent with the Government Paperwork Elimination Act (Pub.L. 105-277). All annual FFD program performance reports under sections 26.717 and 26.417(b)(2) are electronically submitted to the NRC by licensees and other entities.

4. Effort to Identify Duplication and Use Similar Information

The proposed rule would eliminate section 26.155 and section 26.157(b) through (e) to reduce duplication of recordkeeping requirements pertaining to HHS-certified laboratories, which are third party entities. These requirements were duplicative with information recordkeeping requirements in the HHS Guidelines that all HHS-certified laboratories must comply with to receive and maintain HHS-certification (burden covered by HHS lab certification requirements OMB Clearance # 0930-0158).

5. Effort to Reduce Small Business Burden

The information collection requirements in this proposed rule do not affect small businesses or entities.

6. Consequences to Federal Program or Policy Activities if the Collection Is Not Conducted or Is Conducted Less Frequently

The records required by 10 CFR Part 26 pertaining to drug and alcohol testing, LTFs, and HHS-certified laboratories; the chain of custody of specimens, laboratory test results, and quality assurance and quality control procedures are standard components of all forensic specimen collection and testing programs. If these records are not developed, maintained, and stored in a timely and comprehensive manner, the scientific accuracy and validity of test results and the performance objectives of the FFD program cannot be assessed or verified nor can the rights of individuals subject to the program be protected and assured. Collection of information pertaining to individuals' authorization denial or unfavorable termination must be complete and must take place at the time that FFD authorization decisions are made, or inappropriate authorizations may be granted (i.e., inappropriate permission obtained to gain unescorted access to the protected area of an NRC-licensed facility under 10 CFR Part 73).

The annual report on FFD program performance that each licensee and other entity FFD program provides to the NRC is necessary so that the NRC can assess whether FFD programs meet regulatory requirements, whether adverse trends are occurring that require regulatory action, and/or whether rulemaking is necessary to amend current

requirements. Receiving FFD program performance data at least annually is necessary because a longer period of time could result in substantial program deterioration that could result in adverse conditions to public health and safety, common defense or security, or protection of the environment. Overall, the 10 CFR Part 26 recordkeeping and reporting requirements contribute to the conduct of NRC inspection and licensing review to ascertain whether a licensee or other affected entity is in compliance with the requirements of 10 CFR Part 26.

7. Circumstances which Justify Variations from OMB Guidelines

Several existing 10 CFR Part 26 provisions include recordkeeping and reporting requirements that exceed the OMB guidelines established in 5 CFR 1320.5(d)(2). Under OMB Clearance No. 3150-0146, OMB reviewed and approved these existing requirements as justified variations from the OMB guidelines. This section identifies the existing requirements, approved by OMB as justified variations from OMB guidelines, which would result in incremental recordkeeping and reporting burdens as a result of the 95 additional positive test results per year estimated to result from the proposed rule.

The following requirements vary from OMB provisions described in 5 CFR 1320.5(d)(2)(i) by requiring licensees and other entities to report information to the agency more often than quarterly:

- 10 CFR 26.185(p) requires an MRO to complete the review of positive, adulterated, substituted, and invalid test result and to notify the licensee or other entity's designated representative within 10 business days of receiving the HHS-certified laboratory test result. Notification within 10 days is necessary to ensure that the licensee or other entity can take prompt action to address illegal drug use, legal drug misuse, or a donor attempt to subvert the drug testing process.

- 10 CFR 26.719(b)(2) requires licensees or other entities to report significant FFD policy violations or programmatic failures to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers the violation. This requirement is necessary to ensure that the NRC is informed promptly so that the appropriate NRC managers can address the situation immediately.

The requirement in section 26.169(a) vary from the OMB provisions described in 5 CFR 1320.5(d)(2)(ii) by requiring licensees and other entities to prepare a written response to a collection of information in fewer than 30 days after receipt.

- 10 CFR 26.169(a) requires the HHS-certified laboratory to report test results to the MRO of the licensee or other entity within 5 business days after receiving the specimen for testing. The 5 business day reporting requirement ensures that the laboratory conducts testing in a timely manner which enables the FFD program to take prompt action to ensure that the authorization of an individual is withdrawn or access is not granted to an individual with a positive, adulterated, or substituted test result.

The requirements in sections 26.713(a)(2) and (c) vary from the OMB provisions described in 5 CFR 1320.5(d)(2)(iv) by requiring licensees and other entities to retain records for more than 3 years.

- 10 CFR 26.713(a)(2) requires that records pertaining to the determination of a violation of the FFD policy and related management actions must be retained for at least 5 years after the licensee or other entity terminates or denies an individual's authorization or until the completion of all related legal proceedings, whichever is later. The requirement to retain records for at least 5 years is necessary to ensure that licensees and other entities who may be considering granting authorization to an individual can obtain these records for review as part of the authorization decision-making process. The NRC considers that retention of these records for only 3 years as not sufficient to ensure that individuals are identified who seek reauthorization with a licensee or other entity after previously having violated an aspect of the FFD program. The requirement to retain records until the completion of all related legal proceedings was added at the suggestion of external stakeholders during public meetings. The stakeholders noted that some legal proceedings involving records of the type specified in the paragraph have continued longer than the 5 years and that this recordkeeping protects an individual's right to due process under the rule.

- 10 CFR 26.713(c) requires that licensees and other entities ensure the retention and availability of records pertaining to any 5-year denial of authorization and any permanent denial of authorization for at least 40 years or until, upon application, the NRC determines that the records are no longer needed. Management actions and sanctions to be imposed on individuals who violate the drug and alcohol testing provisions of 10 CFR Part 26 are based on the regulatory significance of the particular occurrence. For example, a 5-year denial of authorization is a minimum sanction for certain significant violations and a permanent denial of authorization would be issued for extremely egregious actions that cause an individual to be permanently denied authorization of unescorted access to NRC-licensed facilities. The 40-year retention requirement covers this latter example which is estimated to be equivalent to the longest expected working life of an individual. Furthermore, requiring the record to be available, even if the license for a particular facility is terminated (i.e., the facility is permanently shut down) is necessary because the individual may attempt to re-enter the industry at a different facility. Requiring retention and availability of the records pertaining to those individuals subject to 5-year and permanent denial of authorization ensures that that these records are available for NRC and licensee or other entity review.

8. Consultations Outside the NRC

During the development of the proposed rule language, the NRC held four public meetings with stakeholders to discuss the 2008 HHS Guidelines changes and potential changes to 10 CFR Part 26. These meetings were held on February 24, 2009, June 24, 2009, October 11, 2011, and September 11, 2013 (meeting summaries are available in the NRC's Agencywide Documents Access and Management System (ADAMS) under Accession Nos. ML090771060, ML091910511, ML112930153, and ML13290A236, respectively). The NRC staff also received emails from various stakeholders throughout the rule development process, which it considered when developing the proposed rule. Based on stakeholder input received at the public meetings and via email, the NRC reconsidered some issues intended for revision and made changes when appropriate.

In addition, the NRC will publish this information collection requirement in the *Federal Register* to provide the public with the opportunity to comment. The NRC will respond to the public comments received.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b).

11. Justification for Sensitive Questions

Not applicable.

12. Estimate of Industry Burden and Cost

The estimated burden and cost associated with administering an FFD drug testing program that meets the requirements of 10 CFR Part 26, Subparts, A – H, M, N, and O (i.e., a full FFD program) is based on the following 25 FFD programs:

- 57 operating commercial nuclear power reactor sites (22 FFD programs)
- 2 Category I fuel-cycle facilities (2 FFD programs)
- 5 corporate offices (covered by the operating power reactor FFD programs)
- 1 C/V (1 FFD program).

The estimated burden and costs associated with administering a drug testing program that meets the requirements of Subpart K (i.e., a reactor construction site drug testing program) is based on 2 FFD programs.

The overall number of respondents to the 10 CFR Part 26 information collection requirements remains unchanged. No additional respondents are anticipated as a result of the proposed rule.

The NRC staff developed the burden estimates in this statement based on data submitted in industry FFD program performance reports submitted under section 26.417(b)(2) or 26.717 and approved under OMB Clearance No. 3150-0146, estimates of NRC licensees as shown in the NRC 2015-2016 Information Digest (ADAMS Accession No. ML15254A321), and feedback from licensees and other entities obtained at public meetings.

The burden associated with the information collections is given in Table 1 for one-time recordkeeping burden, Table 2 for annual recordkeeping burden, Table 3 for annual reporting burden, Table 4 for one-time third-party burden, and Table 5 for annual third-party burden.

Based on the NRC staff's best estimate, the incremental industry burden to generate, maintain, retain, disclose, and provide information related to the FFD program activities

covered by this proposed rule is estimated to total 1,382 hours as detailed in the table below, with an annualized cost estimate to the industry of $366,230 (1,382 hours x $265 per hour).

Table	Burden Area	Annualized Burden Hours	Cost at $265/Hour
1	One-Time Recordkeeping (Annualized)	224	$ 59,360
2	Annual Recordkeeping	335	$ 88,775
3	Annual Reporting	71	$ 18,815
4	One-Time Third-Party	672	$ 178,080
5	Annual Third-Party	80	$ 21,200
	Total	**1,382**	**$ 366,230**

13. Estimate of Other Additional Costs

The quantity of records to be maintained is roughly proportional to the recordkeeping burden and therefore can be used to calculate approximate records storage costs. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to 0.0004 times the recordkeeping burden cost. Therefore, the incremental records storage cost for the FFD records in Tables 1 and 2 is estimated to be $59 (0.0004 x 559 hours x $265).

14. Estimated Annualized Cost to the Federal Government

Not applicable.

15. Reasons for Changes in Burden or Cost

The estimated burden of the information collections contained in the proposed rule is 1,382 hours. This estimate is comprised of one-time and annual requirements of the proposed rule. As a result of the changes associated with the proposed rule, the total estimated annual burden for the information collections in 10 CFR Part 26 would increase by 1,382 hours from 623,943 hours to 625,325 hours.

The factors that account for the increased burden include the following:

The proposed rule requires licensees and other entities to: (1) update FFD program policies and procedures; (2) inform existing employees on the FFD program testing policy changes; (3) revise contracts with HHS-certified laboratories and BPTS suppliers; and (4) document additional positive test results and subversion attempts, as well as the actions taken in response to these testing events. The proposed rule also contains new provisions that include recordkeeping and reporting burdens that were not part of previous estimates.

16. Publication for Statistical Use

This information will not be published for statistical use.

17. Reason for Not Displaying the Expiration Date

The recordkeeping and reporting requirement for this information collection are associated with regulations and are not submitted on instruments such as forms or surveys. For this reason, there are no data instruments on which to display an OMB expiration date. Further, amending the regulatory text of the CFR to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.

Table 1
One-Time Recordkeeping Burden
(Annualized)[5]

Section	Number of Recordkeepers	Burden Hours per Recordkeeper (Annualized)	Total Burden Hours (Annualized)
26.27(a): Prepare FFD policy statement and FFD procedures	25 programs	8.0	200
26.27(b): Make FFD policy statement available to staff subject to FFD requirements	Burden accounted for under section 26.27(a)		
26.27(c): Record updates to policy and procedures	Burden accounted for under section 26.27(a)		
26.127(c): Prepare written procedures for assays performed by LTF	6 LTFs	1.3	8
26.127(d): Prepare written procedures for instrument and test setup by LTF	Burden accounted for under section 26.127(c)		
26.403(a): Construction site FFD programs – Prepare and distribute a written Subpart K FFD policy statement	Burden accounted for under section 26.403(b)		
26.403(b): Construction site FFD programs – Prepare written Subpart K FFD procedures	2 programs	8.0	16
		TOTAL	**224**

[5] All one-time burdens have been annualized over the three year clearance period. For example, a requirement that is performed once and takes 24 hours appears on the one-time table as an 8 hour annualized burden (24 hours in year 1 + 0 hours in year 2 + 0 hours in year 3 = an annualized burden of 8 hours).

Table 2
Annual Recordkeeping Burden

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.75(a), (b), (c), (d), (e)(2), and (g): Records of sanctions for FFD program violations	25 programs	1.0	25
26.135(b): Record of the donor's written or oral permission for the retesting of an aliquot of a single specimen or the testing of Bottle B of a split specimen at a second HHS lab	Burden accounted for under section 26.165(b)(1)		
26.163(a)(2): Record that special analyses testing conducted on dilute specimens and specimens collected under direct observation under sections 26.115(a)(1) through (a)(3) and (a)(5)	Burden accounted for under section 26.169(c)(1)		
26.165(b)(1): Record of donor request to the MRO for the retest of an aliquot of a single specimen or the testing of Bottle B of a split specimen at a second HHS-certified lab	2 programs	0.2	1
26.165(b)(2): Record that the MRO informed the donor of the opportunity to request the retesting of an aliquot of a single specimen or the testing of Bottle B of the split specimen	Burden accounted for under section 26.183(c)(1)		
26.165(b)(6): Record that results of the retesting of an aliquot of a single specimen or the testing of Bottle B of the split specimen were provided to the MRO by the second HHS lab and the MRO informed the donor of the results	2 programs	0.5	1
26.165(c)(4): Record that the second HHS lab reported all results to the MRO on the retesting an aliquot of a single specimen or the Bottle B split specimen	Burden accounted for under section 26.165(b)(6)		

Table 2
Annual Recordkeeping Burden

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.165(f)(1): Adjustments to personnel files and written notifications regarding the results of retesting an aliquot of a single specimen or the Bottle B split specimen associated with, including temporary administrative action	2 programs	0.3	1
26.169(a): Records of reports of test results by HHS lab	Burden accounted for under section 26.169(c)(1)		
26.169(c)(1): HHS lab reports to the MRO of positive, adulterated, substituted, dilute, and invalid test results	12 laboratories	2.0	24
26.169(c)(2): Records of HHS lab reports of the numerical values of all positive drug test results (i.e., quantitative test results) as requested by MRO	Burden accounted for under section 26.169(c)(1)		
26.169(g): Records of HHS lab transmittal of a copy of the original Federal CCF for positive, adulterated, substituted, dilute or invalid test results to the MRO	Burden accounted for under section 26.169(c)(1)		
26.183(c)(1): MRO review of records for positive, adulterated, substituted, invalid, and dilute test results that confirm as an FFD violation	25 programs	2.6[6]	65

[6] The NRC staff estimates that the proposed rule would result in an additional 95 confirmed positive drug test results and identified attempts to subvert the drug testing process each year. Of these results, the NRC staff estimates that 85 results would apply to licensees and other entities with a full FFD program and 10 results would apply to construction site FFD program (see section 26.405(g)).

The NRC staff estimates that an MRO spends, on average, 0.75 burden hour per test result to evaluate the laboratory test result report, discuss the results with the donor, and communicate with the licensee or other entity. This value is lower than the one burden hour listed in the OMB Clearance No. 3150-014 for 10 CFR Part 26 (expiration date of 11/30/2017) for this activity. The lower estimate is based on improved information obtained during this rulemaking process.

[Estimated burden hours = (85 confirmed positive test results and identified attempts to subvert the drug testing process x 0.75 hour) / 25 FFD programs = 2.6 hours per FFD program]

Table 2
Annual Recordkeeping Burden

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.183(c)(1): MRO review of records for amphetamine positive drug test results that confirm negative after discussion with the donor due to a legitimate medical use and valid prescription.	7 programs[7]	1.0	7
26.185(a) Record of MRO review of all positive, adulterated, substituted, or invalid test results and report to licensee or other entity	Burden accounted for under section 26.183(c)(1)		
26.185(c): Record of MRO discussion of test results with the donor and report to licensee, following discussion with donor, of FFD violation	Burden accounted for under section 26.183(c)(1)		
26.185(f)(3): Record of information obtained from MRO contact with licensee, other entity, collection site, and/or HHS lab regarding an invalid result of pH 9.0 to 9.5.	1 program	1.0	1
26.185(j)(3): Record of MRO notification to licensee where evidence of drug abuse or use of another individual's prescription medication	Burden accounted for under section 26.183(c)(1)		
26.185(k): Record of MRO review of some amphetamine positive test results that would not result in an FFD policy violation due to legitimate medical use	Burden accounted for under section 26.183(c)(1) (line item for amphetamine positives that confirm negative upon MRO review)		
26.185(n): Record of MRO evaluation of test results from the second HHS lab that performed retesting on an aliquot of a single specimen or testing of Bottle B of the split specimen and report to the licensee on results of the test	2 programs	0.5	1

[7] The NRC estimates that the proposed rule would result in 7 additional amphetamine positive test results reported by HHS-certified laboratories will be determined by the MRO, after discussion with the donor, to be for a legitimate medical condition and not an FFD policy violation.

Table 2
Annual Recordkeeping Burden

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.185(p): Record of MRO notice to licensee of determination of FFD policy violation	Burden accounted for under section 26.183(c)(1)		
26.405(g): Construction site FFD program – Record of MRO review of positive, adulterated, substituted, and invalid drug and validity test results	2 programs	3.8[8]	8
26.713(a)(2): Retain records on FFD violations	25 programs	8.0	200
26.719(b)(2): Prepare 24-hour event report to submit to the NRC	1 program	1.0	1
		TOTAL	**335**

[8] Estimated burden hours = (10 confirmed positive test results and identified attempts to subvert the drug testing process x 0.75 hour) / 2 FFD programs = 2.6 hours per FFD program]

Table 3
Annual Reporting Burden

Section	Number of Recordkeepers	Responses per Respondent	Total Responses	Burden Hours per Response	Total Annual Burden Hours
26.417(b)(1): Construction site FFD program -- Report to NRC by telephone within 24 hours of a programmatic failure under the Subpart K construction site drug testing program	Burden accounted for under section 26.719(b)(2).				
26.417(b)(2): Construction site FFD program -- Prepare annual program performance report for Subpart K construction site drug testing program	2 sites	1	2	1.0	2
26.717: Annual report of FFD program performance for drug and alcohol testing programs	65 sites	1	65	1.0	65
26.719(b)(2): Report significant drug and alcohol testing program violations by phone within 24 hours	1 program	1	1	4.0	4
				TOTAL	**71**

Table 4
One-Time Third-Party Burden

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.29(c)(2): FFD training for current staff subject to a program to review information on the FFD policy statement changes (outside annual refresher training).	7,495[9]	0.08	600
26.157(a): Written procedures for accession, receipt, shipment, and testing of urine specimens at HHS lab	18[10]	4.0	72
		TOTAL	**672**

[9] The NRC staff estimates that approximately 20 percent of the 67 sites (i.e., 14 sites, with average worker population at each site of 1,606 individuals) with an FFD program would conduct training of existing workers subject to 10 CFR Part 26 outside annual refresher training. The burden reflected for these programs is the time for each worker to certify that they reviewed updated information on the FFD policy (5 minutes per = 0.08 hour).

The reported value is annualized (14 sites x 1,606 individuals per site x 0.08 hour per individual) / 3 years = 600 hours per site per year).

[10] Each licensee or other entity FFD program maintains a contract with one primary and one back-up HHS-certified laboratory (27 FFD programs x 2 HHS labs = 54). Each laboratory would need to update 10 CFR Part 26 specific testing procedures based on the proposed rule changes.

Table 5
10 CFR Part 26 Estimated Annual Third-Party Burden

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.155(a)(1): Document qualifications of lab manager at HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158 The proposed rule would eliminate these requirements.		
26.155(a)(3): HHS lab manager documents training of lab personnel			
26.155(a)(4): HHS lab manager reviews and signs lab procedures			
26.155(a)(5): HHS lab manager maintains QA program			
26.155(b): Certifying scientist to certify test results from HHS lab			
26.155(c): Supervise technical analysts at HHS lab			
26.155(e): Continuing education for staff at HHS lab			
26.155(f): HHS lab personnel records			
26.157(b): Written chain-of-custody procedures for HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158 The proposed rule would eliminate these requirements.		
26.157(c): Written procedures manual for each assay performed by HHS lab			
26.157(d): Written procedures for device set-up and operation at HHS lab			
26.157(e): Written procedures for remedial actions to address systems and instrument errors at HHS lab			
26.165(b)(6): HHS lab provides quantitative results of retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen to the MRO	2	0.5	1
26.169(a): Reports of test results by HHS lab	Burden accounted for under section 26.169(c)(1) and (c)(2)		
26.169(c)(1): HHS lab report to the MRO of positive, adulterated, substituted, dilute, and invalid test results	95	0.25	24
26.169(c)(2): HHS lab record of quantitative results for positive drug tests, provided at the request of the MRO	Burden accounted for under section 26.169(c)(1)		

Table 5
10 CFR Part 26 Estimated Annual Third-Party Burden

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.169(g): HHS lab transmits to the MRO a copy of the original Federal CCF for positive, adulterated, substituted, dilute, and invalid test results	Burden account for under section 26.169(c)(1)		
26.183(c)(1): Donor discussion with MRO on an amphetamine positive drug test result and donor obtains and provides prescription medication information to the MRO (MRO determines negative result due to legitimate medical use)	7	1.0	7
26.185(c): Donor discussion of positive test result with the MRO that is determined to be an FFD program violation	95	0.5	48
		TOTAL	**80**

TOTAL BURDEN: 1,382 hours (224 hours one-time recordkeeping (annualized) + 335 hours annual recordkeeping + 71 hours annual reporting + 672 hours one-time third-party disclosure (annualized) + 80 hours annual third-party disclosure)

TOTAL RESPONSES: 7,813 (33 recordkeepers + 68 reporters + 7,712 third-party responses[11])

NUMBER OF RESPONDENTS: 149 (27 FFD programs + 12 HHS-certified laboratories + 6 LTFs + 104 individuals with a positive drug test result)

[11] The NRC staff estimates that the proposed rule changes would result in additional 95 individuals that test positive for a drug(s) or are identified as having attempted to subvert the drug testing process, 95 reports made by HHS-certified laboratories for those individuals testing positive, 2 individuals who request the retesting of their positive specimen at a second HHS-certified laboratory, 7 individuals who test positive for amphetamines but have a legitimate medical use and prescription, 18 HHS-certified laboratories who update their written procedures in response to the proposed rule, and 7,495 workers would certify receiving updated policy information outside annual refresher training (95 + 95 + 2 + 7 + 18 + 7,495 = 7,712 third-party responses per year).