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

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

3150-0252

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 NRC regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 26, "Fitness for duty programs," 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 final rule amends 10 CFR Part 26 to enhance the consistency of the 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) and revisions to those guidelines published on January 23, 2017 (2017 HHS Guidelines) (82 FR 7920). The final rule also incorporates lessons learned from implementing the 10 CFR Part 26 2008 final rule (73 FR 16966, March 31, 2008). The changes 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. In addition, the final rule enhances donor protection and due process requirements for individuals subject to drug testing, improves the clarity, organization, and flexibility of the rule, and provides a new flexibility to collect and drug test an oral fluid specimen as an alternative to collecting and testing a urine specimen under direct observation conditions.

The final rule impacts recordkeeping, reporting, and third-party disclosure requirements that apply to the following types of information collections in 10 CFR Part 26:

[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 special nuclear material licensees), (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.

- FFD program policies and procedures – For each FFD program, the licensee or other entity will revise its FFD program policy and procedures to reflect the final rule changes to the drug testing requirements, to distribute information on the updated FFD program policy to individuals subject to 10 CFR Part 26, and to train these individuals on the policy changes. Each activity is performed on a one-time basis.

- Laboratory testing protocols – Each licensee testing facility (LTF) and each HHS-certified laboratory that performs testing under 10 CFR Part 26 will revise its testing protocols to reflect the changes in the final rule. Each activity is performed on a one-time basis.

- Contracts with HHS-certified laboratories and suppliers – For each FFD program, the licensee or other entity will revise its contracts with its HHS-certified laboratories (primary and backup) and blind performance test sample (BPTS) supplier to reflect the final rule changes to the drug testing requirements. Each activity is performed on a one-time basis.

- Drug specimen collection, testing, and results reviews – For each FFD program, the licensee or other entity will revise its procedures to reflect the final rule changes, such as updating the procedures for medical review officer (MRO) review of invalid test results. These activities are performed on a one-time basis.

- Records and reports associated with drug testing violations (ongoing/annual) – The final rule does not increase the number of specimens collected for drug testing by licensees and other entities, but it will result in licensees and other entities documenting an estimated 176 additional individuals per year that test positive for one or more drugs or are identified attempting to subvert the drug testing process, as well as the actions taken in response to these testing events. The final rule changes resulting in this increase include:

    - Adding testing for two amphetamine-based Ecstasy-type drugs (methylenedioxymethamphetamine (MDMA) and methylenedioxy-amphetamine (MDA)) and four opioids (hydrocodone, hydromorphone, oxycodone, and oxymorphone).
    - Adding initial drug testing for 6-acetylmorphine (6-AM), a metabolite of the illegal drug heroin, and updating the confirmatory drug testing method for 6-AM.
    - Lowering the drug testing cutoff levels for amphetamine, cocaine metabolite, and methamphetamine.

  The final rule changes do not increase the number of specimens collected for drug testing by licensees and other entities, but the changes to the drug testing panel will result in licensees and other entities documenting an estimated 176 additional individuals per year that test positive for one or more drugs, or are identified attempting to subvert the drug testing process, as well as the actions taken in response to these testing events.

The final rule affects the recordkeeping and reporting burdens of 24 FFD programs. 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 59 sites:[3] 51 operating power reactor sites[4], 5 corporate offices, 2 Category I special nuclear material licensees, and 1 contractor/vendor (C/V). Hereafter, the term "licensee" or "licensee and other entity" is used to describe sites subject to the requirements of 10 CFR Part 26. Information on the number of licensee and other entities subject to 10 CFR Part 26 is based on data that licensees and other entities collect, compile, and annually submit to the NRC under 10 CFR 26.717, "Fitness-for-duty program performance data."

Most recordkeeping and reporting requirements in the final rule affect each licensee or other entity's FFD program. Some requirements only apply to the laboratories that perform drug testing of specimens for licensees and other entities (i.e., 3 LTFs and 9 HHS-certified laboratories).

A. JUSTIFICATION

1. Need for and Practical Utility of the Information

The information collections contained in 10 CFR Part 26 enable effective and efficient regulatory oversight of affected licensees and other entities through inspection and the assessment of FFD program performance to maintain public health and safety, promote the common defense and security, and protect the environment. The NRC uses these information collections to assess licensee and other entity compliance with 10 CFR Part 26 through periodic NRC inspections and to take corrective actions, as needed. The NRC also uses these information collections to evaluate the effectiveness of the regulations and to take additional actions, as needed, such as issuing guidance or amending 10 CFR Part 26 through rulemaking. The information collections also provide due process protections to each individual subject to an FFD program.

Licensees and other entities must perform certain tasks, maintain records, and submit reports to comply with 10 CFR Part 26 drug testing requirements. The 10 CFR Part 26 recordkeeping and reporting requirements are mandatory for licensees and other entities subject to the rule and include developing and maintaining:

[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 employees subject to 10 CFR Part 26 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 has already permanently ceased operations because these sites are no longer subject to 10 CFR Part 26 (e.g., Crystal River, Duane Arnold, Indian Point, Kewaunee, Oyster Creek, Pilgrim, San Onofre, Three Mile Island, Vermont Yankee), or announced early plant closure before the start of this clearance period (i.e., Byron, Dresden, Palisades).

- FFD program policies and procedures;

- Records on training, authorization, and any FFD violations of individuals subject to 10 CFR Part 26;

- Records on specimens collected for drug testing, laboratory tests, and test result reviews;

- Records and reports on FFD program performance (annual summary performance reports and more frequent reports of significant violations and programmatic failures); and

- Records of audits (e.g., internal FFD program, testing laboratory, collection site).

Each recordkeeping and reporting requirement in 10 CFR Part 26 affected by the final 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 10 CFR 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 final rule did not change this requirement, but it will result in a one-time recordkeeping burden to update FFD policies and procedures to reflect final rule changes. In addition, licensees and other entities will revise contracts with the primary and back-up HHS-certified laboratories and BPTS suppliers to incorporate changes to the drug testing requirements in the final rule. 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 final rule changes to the drug testing panel, testing cutoff levels, and special analyses testing conditions require revisions to FFD program contracts, the burden of which is reflected under 10 CFR 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 subject to the FFD program. The final rule did not change this FFD policy requirement, but it results in a one-time recordkeeping burden for each licensee and other entity to prepare information on the updates made to the FFD policy as a result of the final rule and distribute this information to individuals subject to the FFD program. This incremental one-time recordkeeping burden for each licensee and other

entity is accounted for in Table 1. The incremental one-time third-party disclosure burden associated with individuals subject to an FFD program reviewing information on the FFD policy updates is accounted for under 10 CFR 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 ensures 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 includes the drug testing panel and testing cutoff levels used) and actions taken based on an attempt to subvert the drug testing process. The final rule will 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, and 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 two Ecstasy-type drugs (i.e., MDMA and MDA) and four opioid drugs (hydrocodone, hydromorphone, oxycodone, and oxymorphone) 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 10 CFR Part 26, provides for prior notice, and ensures documentation for evidence in legal proceedings. The licensee or other entity of each FFD program will incur an incremental one-time recordkeeping burden to complete the changes to its FFD program policy and procedures, as reflected in Table 1.

10 CFR 26.29(c)(2) requires each individual subject to an FFD program to receive refresher training on a nominal 12-month frequency or more often, if needed. Refresher training includes the administration of a comprehensive annual examination and maintenance of records of the updated FFD training materials and training completion. 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 10 CFR 26.29(c)(2) are established by 10 CFR 26.713(b)(1). The final rule did not change this requirement, but will result in a one-time third-party disclosure burden associated with some 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. Given the 1-year implementation period for a licensee or other entity to come into compliance with the final rule changes, most FFD programs will incorporate minor adjustments into the annual refresher training curriculum to meet the final rule changes, with no change in burden estimated to result to the licensees and other entities of these FFD programs.

10 CFR 26.39(b) requires each licensee or other entity to establish a review process for FFD policy violations. The review procedure must provide notice to the individual of the grounds for the determination that the individual violated the licensee or other entity's FFD policy and must provide an opportunity for the individual to respond and submit additional relevant information. The notification requirement affords due process to each individual with an FFD policy violation by requiring specific information on the FFD policy violation be reported to the individual, and a process for an independent review of the determination if sought by the individual. Section 26.713(a)(2) establishes the

recordkeeping requirements for 10 CFR 26.39(b). The final rule did not change these requirements but will result in an incremental increase in recordkeeping burden associated with the 176 additional individuals per year estimated to test positive for one or more drugs or be identified attempting to subvert the drug testing process due to the final rule changes. This annual recordkeeping burden is accounted for in Table 2.

10 CFR 26.75(a) – (e) 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. To verify compliance with the imposition of a sanction meeting the requirements in 10 CFR 26.75, "Sanctions," documentation of the sanction imposed on each individual must be maintained by the licensee or other entity. A record of the 10 CFR Part 26 sanction is also necessary should an individual apply for authorization at the same or another facility in the future. A record of the sanction(s) imposed on an individual under 10 CFR 26.75 is shared among FFD programs through an electronic records system administered by industry, which contains information on employment dates, approvals of authorization, withdrawals of authorization, and if an individual had an FFD policy violation. The recordkeeping requirement to maintain information on a sanction imposed under 10 CFR 26.75(a) – (e) and (g) is established under 10 CFR 26.713(c). The final rule did not change these requirements but will result in an incremental increase in recordkeeping burden associated with the 176 additional individuals per year estimated to test positive for one or more drugs or be identified attempting to subvert the drug testing process due to the final rule changes. This annual recordkeeping burden is accounted for in Table 2.

New - 10 CFR 26.107(b) requires the collector to document on the Federal custody and control form (Federal CCF) any conduct that indicates an attempt to tamper with a specimen. Documentation of the collector's observations regarding subversion attempt actions is necessary to support the 10 CFR 26.75 sanction determination made by the licensee or other entity, as well as to support appeals, records reviews, audits, and NRC inspections. The final rule did not change the requirement to document information regarding a subversion attempt, but provides a new flexibility to document subversion attempt information either on the Federal CCF or through another documentation method that is consistent with the collection procedures of the licensee or other entity. No change in annual recordkeeping burden is estimated to result from this final rule change because the documentation of this information remains the same, but any licensee or other entity that chooses to modify its collection procedures to document information on a form other than the Federal CCF would need to develop procedures to support the change. Changes to the FFD policy and procedures is accounted for as incremental one-time recordkeeping burden under 10 CFR 26.27(a) in Table 1.

New - 10 CFR 26.107(d) is added in the final rule to describe the actions that a specimen collector must take if a refusal to test is determined during the specimen collection process. The collector must: (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 final rule elaborates on the existing steps that already take place when a refusal to test is determined during the collection process. Providing explicit detail in the final rule improves the consistency and effectiveness of 10 CFR Part 26 by ensuring that uniform action is taken by a collector when a subversion attempt is identified during the specimen collection process. The NRC received a public comment on the proposed rule provision in 10 CFR 26.107(d)(3) regarding documenting refusal to test information on the Federal CCF, with the

commenter indicating that the limited space available on the form may not be sufficient for observations on an event. The NRC agreed and revised the final rule to provide flexibility to document subversion attempt information either on the Federal CCF or through another documentation method that is consistent with the collection procedures of the licensee or other entity. An incremental one-time recordkeeping burden will be incurred by any licensee or other entity that changes its specimen collection procedures to incorporate the new documentation flexibility. The one-time burden to modify FFD policy and procedures is covered under 10 CFR 26.27(a) in Table 1.

10 CFR 26.111(b) requires the specimen collector to inspect each urine specimen provided by a donor to determine its color and clarity, and to look for any signs of contaminants or adulteration. This collector is required to note any unusual findings on the Federal CCF. This requirement is an integral part of the collection procedure and ensures that accurate and timely recording of the collector's observations of unusual findings during the specimen collection process. An accurate and timely recording of unusual findings ensures that FFD management is provided information on which to take appropriate action regarding a potential observed collection under 10 CFR 26.115 and to support a possible subversion attempt determination under 10 CFR 26.75. Recording information on the collection event is also a donor protection and provides documentation for an appeal, internal FFD program audits, and NRC inspection. Recordkeeping requirements for section 26.111(b) are established by section 26.715(b)(2). As described above under 10 CFR 26.107(d), the final rule addressed a public comment on a proposed rule provision regarding the documentation of information on the Federal CCF and provided a new flexibility to document subversion attempt information either on the Federal CCF or using another documentation method consistent with the collection procedures of the licensee or other entity. An analogous change was made in the final rule to 10 CFR 26.111(b). An incremental one-time recordkeeping burden will be incurred by any licensee or other entity that changes its specimen collection procedures to incorporate the new documentation flexibility. This one-time burden to modify FFD policy and procedures is covered under 10 CFR 26.27(a) in Table 1.

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 final rule did not change these requirements, but it will 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 10 CFR 26.127(c) and (d) are established by 10 CFR 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 MRO, to request that Bottle B of a split specimen (as described in 10 CFR 26.113, "Splitting the urine specimen") be tested at a second HHS-certified laboratory under the procedures in 10 CFR 26.165(b). The final rule did not change this requirement, but the requirements in 10 CFR 26.165(b) were revised in the final rule. Recordkeeping requirements for 10 CFR 26.135(b) are established by 10 CFR 26.715(b)(6). Incremental recordkeeping and third-party burdens are estimated to result for licensees that use an LTF to perform initial testing of specimens and some of the 176 additional individuals per year estimated to test positive for one or more drugs or be identified attempting to subvert the drug testing process as a result of the final rule changes. 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 final rule eliminated 10 CFR 26.155, "Laboratory personnel," in its entirety because these third-party disclosure requirements are duplicative with requirements in sections 11.2, 11.3, 11.5 and 11.6 of the 2008 and 2017 HHS Guidelines (the burden of which already is captured under OMB Control No. 0930-0158). The 10 CFR Part 26 information collection request (ICR) does not include any burden for the requirements in 10 CFR 26.155 because each is already covered under OMB Control No. 0930-0158 for the HHS Guidelines.

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 final rule revises this recordkeeping requirement to specify that "HHS-certified laboratories shall develop, implement, and maintain procedures specific to 10 CFR Part 26 that document the accession, receipt, shipment, and testing of specimens." This change ensures that an HHS-certified laboratory only maintains under NRC regulation the laboratory procedures specific to the 10 CFR Part 26 testing program. These records 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 required under 10 CFR 26.41(c). Recordkeeping requirements for 10 CFR 26.157(a) are established by 10 CFR 26.715(b). As a result, the final rule eliminated duplicative recordkeeping requirements that an HHS-certified laboratory already must comply with under section 11.1 of the 2008 and 2017 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) – (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 final rule eliminated these third-party disclosure requirements because

each is duplicative with an existing recordkeeping requirement in section 11.1 of the 2008 and 2017 HHS Guidelines. The NRC's 10 CFR Part 26 ICR does not include any burden for 10 CFR 26.155 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 conduct confirmatory drug testing of the specimen for that drug or drug metabolite to the limit of detection for the test assay (i.e., special analyses testing). 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 ensure that a donor is not attempting to subvert the testing process by consuming large amounts of fluid just before providing a urine specimen for testing to avoid detection of drug use by reducing the detectible amount of drug or drug metabolites below the testing cutoff level. The recordkeeping requirements for 10 CFR 26.163(a)(2) are established by 10 CFR 26.715(b)(6). The final rule requires licensees and other entities to conduct testing of dilute specimens under 10 CFR 26.163(a)(1), which previously was optional. The final rule also expands special analyses testing to specimens collected under direct observation for any of the conditions specified in 10 CFR 26.115(a)(1) through (3) and (a)(5). The final rule will result in an incremental recordkeeping burden associated with some of the 176 additional individuals per year estimated to test positive for one or more drugs or be identified attempting to subvert the drug testing process due to the final rule changes. This annual recordkeeping burden is accounted for in Table 2.

10 CFR 26.165(b)(1) through (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 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 10 CFR 26.715(b)(6). Each of these collections represents incremental recordkeeping and third-party burdens associated with some of the 176 additional individuals per year estimated to test positive for one or more drugs or be identified attempting to subvert the drug testing process due to the final rule changes. The burden associated with these requirements is shown as an incremental annual recordkeeping burden in Table 2.

- 10 CFR 26.165(b)(1) specifies that for a confirmed positive, adulterated, or substituted test result reported on a single specimen (or Bottle A of a split specimen), the donor may request that the MRO verify the results from the initial laboratory by requiring the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen at a second HHS lab.

- 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 final rule revised 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 final rule corrected this inconsistency.

- 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 final rule removed this requirement because 10 CFR 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 final rule revised this section to clarify that "No entity, other than the MRO as permitted in 10 CFR 26.185(I), may order the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen." No change in burden is estimated to result from these final 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 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 10 CFR 26.715(b)(6). The final rule did not change this requirement, but it will result in an incremental recordkeeping burden associated with some of the 176 additional individuals per year estimated to test positive for one or more drugs or be identified attempting to subvert the drug testing process due to the final rule changes. The burden associated with this requirement is shown as an incremental annual recordkeeping burden in Table 2.

New - 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 of 10 CFR Part 26. The requirement in 10 CFR 26.165(f)(1) is a donor protection against inaccurate test results. Recordkeeping requirements for 10 CFR 26.165(f)(1) are established by 10 CFR 26.713(a)(2) and (a)(3). The final rule includes a clarification to the former requirement in 10 CFR 26.165(f)(1) by replacing 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 change clarifies an existing action that the MRO takes in this circumstance, and therefore, no additional burden is estimated to result from the change. No incremental recordkeeping burden is estimated to result from this final rule change because this type of event is exceptionally rare. The burden associated with this requirement is shown as an incremental annual recordkeeping burden in Table 2.

10 CFR 26.168(g) specifies that each licensee or other entity must use BPTSs that have been certified by the BPTS supplier to meet the various formulation criteria (e.g., drug positive, adulterated, dilute, substituted). The BPTS supplier, a third-party entity, provides documentation that the BPTSs provided meet the formulation criteria and each licensee or other entity maintains these records. This documentation verifies that each BPTS is formulated correctly, which ensures that the licensee or other entity is effectively challenging the testing laboratory to ensure that all substances in the testing panel can be correctly identified. Maintaining these records is necessary for problem identification should a BPTS fail to confirm as formulated at the testing laboratory, for internal FFD program audits, and NRC inspection. The final rule did not change this requirement, but it will result in incremental recordkeeping and third-party burdens associated with records created and maintained for the new BPTSs prepared and submitted for testing each quarter as a result of the new substances added to the drug testing panel in the final rule. The burdens associated with these requirements are shown as an incremental annual recordkeeping burden in Table 2 and incremental annual third-party disclosure burden in Table 5.

10 CFR 26.168(i)(2) requires for each BPTS that is to be submitted for testing, that the licensee or other entity complete a Federal CCF, place fictional initials on the specimen bottles' labels/seals, and indicate on the MRO's copy of the Federal CCF that the specimen is a BPTS. These requirements ensure that the testing laboratory cannot identify that a specimen it receives for testing is a BPTS and also ensures that the MRO is aware that the Federal CCF is for a BPTS and then takes appropriate review action to confirm the accuracy of the test results. The final rule did not change these requirements, but it will result in incremental recordkeeping burdens associated with the completion of additional Federal CCFs for the BPTSs for the new substances added to the drug testing panel that must be submitted for testing each quarter. The burdens associated with these requirements are shown as incremental annual recordkeeping burden in Table 2 and as incremental annual third-party disclosure burden in Table 5.

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 10 CFR 26.185(a). Recordkeeping requirements for 10 CFR 26.169, "Reporting results," are established by 10 CFR 26.715(b)(2) and (3), (b)(5) and (6), and (b)(8). Each of these collections represents incremental recordkeeping and third-party burdens associated with the 176 additional individuals per year estimated to test positive for one or more drugs or be identified attempting to subvert the drug testing process due to the final rule changes. The burden associated with each 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 26.169(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 CCF and transmit to the MRO a copy of the original Federal CCF signed by the certifying scientist.

New - 10 CFR 26.169(h) requires each HHS-certified laboratory performing tests for a licensee or other entity under 10 CFR Part 26 to prepare an annual statistical summary report of testing results for that year. The statistical summary report must be sent within 14 calendar days after the end of the one-year period covered by the report. The statistical summary report is needed by the licensee or other entity to prepare the annual FFD program performance report submission to the NRC required under 10 CFR 26.717. Each HHS-certified laboratory performing testing under 10 CFR Part 26 will incur a one-time third-party burden to update the required information in the summary report to include the new substances added to the drug testing panel as a result of the final rule (MDMA, MDA, oxycodone, oxymorphone, hydrocodone, and hydromorphone). The burden associated with this requirement is shown as an incremental one-time third-party disclosure burden in Table 5.

10 CFR 26.183(c)(1) requires the MRO to examine alternate causes of positive, adulterated, substituted, invalid and dilute test results, including reviewing records made available by the donor and documented medical conditions. This required review is a donor protection by providing the donor the opportunity to present information to support a legitimate medical explanation determination by the MRO for a test result and not an FFD policy testing violation. Recordkeeping requirements for 10 CFR 26.183(c)(1) are established by 10 CFR 26.713(a)(2). The final rule did not change this requirement, but will result in incremental burdens associated with some additional amphetamine and opioid positive test results per year estimated to result from the final rule that are 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 10 CFR 26.185, "Determining a fitness-for-duty policy violation," are established by 10 CFR 26.713(a)(2). The final rule did not change this requirement, but it will result in incremental recordkeeping and third-party burdens associated with the 176 additional individuals per year estimated to test positive for one or more drugs or be identified attempting to subvert the drug testing process due to the final rule changes. 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 10 CFR 26.185 are established by 10 CFR 26.713(a)(2). Each of these collections represents incremental recordkeeping and third-party burdens associated with the 176 additional individuals per year estimated to test positive for one or more drugs or be identified attempting to subvert the drug testing process due to the final rule changes. 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.

New - 10 CFR 26.185(f)(3). The final rule redesignated paragraph (f)(3) as paragraph (f)(4) and added a new paragraph (f)(3) to 10 CFR 26.185 to align the MRO review of invalid test results with section 13.4(f) of the 2008 and section 13.5.(f) of the 2017 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 final rule includes 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, 10 CFR 26.185(f)(3) requires 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 final rule provides an additional donor protection from the provision of a second urine specimen under direct observation, which would have been required under the previous rule if no legitimate medical explanation could explain the invalid test result. The final rule will 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 anticipates that receipt of an invalid specimen of pH 9.0 to 9.5 would be a rare event. Recordkeeping requirements for 10 CFR 26.185(f)(3) are established by 10 CFR 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) 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 10 CFR 26.185 are established by 10 CFR 26.713(a)(2). This provision may result in incremental recordkeeping and third-party burdens associated with some of the 176 additional individuals per year estimated to test positive for one or more drugs or be identified attempting to subvert the drug testing process due to the final rule changes. The burden associated with this requirement 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 10 CFR 26.185 are established by 10 CFR 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 final 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 10 CFR 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 10 CFR 26.185 are established by 10 CFR 26.713(a)(2). Each of these collections represents incremental recordkeeping and third-party burdens associated with the 176 additional individuals per year estimated to test positive for one or more drugs or be identified attempting to subvert the drug testing process due to the final rule changes. 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 test result or reconfirms an adulterated, substituted, or invalid validity test result, the MRO is to 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; or if the second HHS lab does not reconfirm the adulterated, substituted, or invalid validity test result, 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 from the HHS-certified laboratory.

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 final rule did not change this requirement, but it will result in an incremental recordkeeping burden associated with the 176 additional individuals per year estimated to test positive for one or more drugs or be identified attempting to subvert the drug testing process due to the final rule changes. The burden associated with this requirement is shown as an incremental annual recordkeeping burden in Table 2.

New - 10 CFR 26.715(b) requires the retention of records pertaining to licensees and other entities that maintain collection sites and/or LTFs, and for HHS-certified laboratories that conducted testing for licensees and other entities under 10 CFR Part 26. These records enable licensees, other entities, and the NRC to inspect HHS-certified laboratory compliance with 10 CFR Part 26 requirements. The final rule revised 10 CFR 26.715(b)(1), which describes the records retention requirement for personnel files, including training records, for all individuals who have been authorized to have access to specimens, but are no longer under contract to or employed by the collection site, LTF, or HHS-certified laboratory. The final rule removed the reference to HHS-certified laboratories because of the elimination of 10 CFR 26.155, "Laboratory personnel" in the final rule. No change in burden will result from removing this records retention requirement from 10 CFR Part 26 because the HHS-certified laboratories must already maintain these records under HHS Guidelines.

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 the 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 final rule did not change these reporting requirements, but it will result in an incremental reporting burden associated with the 176 additional individuals per year estimated to test positive for one or more drugs or be identified attempting to subvert the drug testing process due to the

final rule changes. The burden associated with these requirements is shown as an incremental annual reporting burden in Table 3.

10 CFR 26.719(b) 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 transporters of strategic special nuclear material, 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 final rule did not change these requirements, but it will result in an incremental reporting burden associated with some of the 176 additional individuals per year estimated to test positive for one or more drugs or be identified attempting to subvert the drug testing process due to the final rule changes. 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 or a court proceeding, or if 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

The NRC has issued Guidance for Electronic Submissions to the NRC, which provides direction for the electronic transmission and submittal of documents to the NRC. Electronic transmission and submittal of documents can be accomplished via the following avenues: the Electronic Information Exchange (EIE) process, which is available from the NRC's "Electronic Submittals" Web page; optical storage media (e.g. CD-ROM, DVD); facsimile; or e-mail. The NRC estimates that approximately 99 percent of the potential responses are filed electronically.

Since 2015, all annual FFD program performance reports submitted by licensees and other entities to the NRC pursuant to 10 CFR 26.717 were completed using fillable-fileable forms and electronically transmitted. Use of these fillable-fileable forms has improved reporting efficiency, enhanced the consistency and accuracy of reported information, and enabled the use of information technology for data assessment and evaluation. Only one report required under 10 CFR 26.719(b) cannot be submitted

electronically (i.e., the licensee or other entity must notify the NRC by telephone within 24 hours of an event occurrence).

4. Effort to Identify Duplication and Use Similar Information

The final rule eliminated 10 CFR 26.155, "Laboratory personnel" and 10 CFR 26.157(b) through (e) to reduce duplication of recordkeeping requirements pertaining to HHS-certified laboratories, which are third-party entities. The final rule also made a conforming change to 10 CFR 26.715(b)(1) by eliminating the records retention requirement for personnel files at HHS-certified laboratories given the elimination of 10 CFR 26.155. 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 control # 0930-0158).

5. Effort to Reduce Small Business Burden

The information collection requirements in this final 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 NRC anticipates four consequences if the records and reports required by 10 CFR Part 26 are not collected or collected less frequently. These consequences would be adverse effects on the NRC's ability to:

- independently monitor licensee and other entity compliance and ensure that each FFD program is adequate to protect public health and safety, promote the common defense and security, and protect the environment;

- verify the scientific accuracy and validity of test results and ensure that the rights of individuals subject to testing are protected;

- complete timely evaluations of FFD-related performance issues and implement regulatory actions to restore compliance, assess corrective actions, inform the public, and/or propose changes to regulations or guidance; and

- inform the public in a timely manner on FFD program performance trends, lessons learned, and site-specific or industry-wide issues.

Complete and accurate information for each individual must be available at the time that FFD authorization decisions under 10 CFR Part 26 are made by a licensee. If the information on an individual is not complete at the time of an FFD authorization decision, the inappropriate granting of unescorted access authorization to an NRC-licensed facility may occur.

7. Circumstances which Justify Variations from OMB Guidelines

Seven existing 10 CFR Part 26 recordkeeping and reporting requirements impacted by the final rule vary from the OMB provisions in 5 CFR 1320.5(d)(2). No changes were made in the final rule to the records retention or reportability timeframes for these requirements. Under OMB control No. 3150-0146, OMB reviewed and approved these existing requirements as justified variations from the OMB guidelines. This section identifies the existing requirements under which incremental recordkeeping and reporting burdens will result due to the 176 additional individuals per year estimated to test positive for one or more drugs, or be identified attempting to subvert the drug testing process due to the final rule changes.

Five requirements vary from the OMB provisions 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 26.165(b)(2) specifies that following notification by the MRO of positive, adulterated, or substituted test result, a donor may request the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen at a second HHS-certified laboratory. If the donor wishes to request this additional testing, the request must be provided by oral or written means within 3 business days. This time requirement ensures that the specimen(s) are retested quickly and do not deteriorate before retesting. The requirement also protects the due process rights of the donor.

- 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 a specimen for testing. The 5-business day reporting requirement ensures that the MRO can promptly review the test results and notify the FFD program to take prompt action required under 10 CFR 26.75 if an individual has violated the FFD policy (i.e., the denial or withdrawal of authorization). This reporting requirement also ensures that the MRO and FFD program can take prompt action if evidence of a specimen collection or testing irregularity is identified to ensure that future tests are not affected in the same way.

- 10 CFR 26.169(h) requires the HHS-certified laboratory to provide the licensee or other entity with a statistical summary of the drug and validity test results for the calendar year within 14 calendar days of the end of the year. This reporting timeframe is necessary because the licensee or other entity is required to submit an annual FFD program performance report to the NRC within 2 months of the end of the previous calendar year, as required under 10 CFR 26.717(e), and the laboratory statistical summary is necessary to complete that report in a timely manner.

- 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's or other entity's designated representative within 10 business days of receiving the HHS-certified laboratory test result. Notification within 10 days ensures that the licensee or other entity can take prompt action to address an FFD testing violation.

- 10 CFR 26.719(b) requires the licensee or other entity of an FFD program to report a significant FFD policy violation or programmatic failure to the NRC Operations Center by telephone within 24 hours of discovering the violation or failure. This requirement ensures that the NRC receives information in a timely manner so that appropriate NRC staff can assess and respond to the situation if needed.

Two requirements 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) requires the licensee or other entity of each FFD program to maintain records for 5 years after it terminates or denies an individual's authorization, or until the completion of legal proceedings, whichever is longer. These records include determinations of FFD policy violations and related management actions, documentation of the granting and termination of authorization, and fitness determinations. This 5-year records retention requirement ensures that licensees and other entities who may be considering granting authorization to an individual can access records from another FFD program on a previous FFD policy violation under 10 CFR Part 26. The requirement to retain records until the completion of all related legal proceedings was added at the suggestion of external stakeholders during public meetings. Stakeholders have noted that some legal proceedings involving records of the type specified in 10 CFR 26.713(a) have continued longer than the 5 years and that this recordkeeping protects an individual's right to due process.

- 10 CFR 26.713(c) requires the licensee or other entity of each FFD program to retain and make available 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. Section 26.75 specifies the minimum sanctions (i.e., denials of authorization) imposed on individuals who violate the testing provisions of 10 CFR Part 26 and are based on the regulatory significance. A 5-year denial of authorization is the minimum sanction for certain significant violations (e.g., a confirmed second positive drug or alcohol test result; sale, use, or possession of illegal drugs or consumption of alcohol within the protected area of a nuclear power reactor). A permanent denial of authorization is a sanction issued for extremely egregious actions such as attempting to subvert a required drug or alcohol test. The 40-year retention requirement covers the longest expected working life of any individual. Also 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 an individual may seek to apply for authorization at another NRC-licensed facility. Requiring retention and availability of the records pertaining to those individuals subject to 5-year and permanent denial of authorization ensures that these records are available for NRC and licensee review.

8. Consultations Outside the NRC

During the development of the proposed rule, 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 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.

On September 16, 2019, the NRC published a proposed rule, "Fitness for Duty Drug Testing Requirements," in the *Federal Register* (84 FR 48750). The NRC requested public comment on the potential impact of the information collections contained in the proposed rule. During the 75-day public comment period for the proposed rule, the NRC held a public meeting on November 7, 2019. A meeting summary of the November 7, 2019, public meeting is available in ADAMS under Accession No. ML19336A003.

The NRC prepared a summary and analysis of public comments received on the 2019 proposed rule and a draft regulatory guide (available in ADAMS under Accession No. ML22133A052).

Changes made to the final rule in response to public comments received on the proposed rule that resulted in changes to information collections included the following:

- Expanding the drug testing panel to align with the 2017 HHS Guidelines. This final rule change resulted in required testing for additional substances under the FFD program of each licensee and other entity, as well as an estimated increase in the number of individuals testing positive for the additional substances.

- Affording licensees and other entities the option to collect and drug test an oral fluid specimen instead of a urine specimen for directly observed specimen collections conducted under 10 CFR 26.115(a)(1) through (3) and (a)(5).

- Providing flexibility on the documentation method used to record information on subversion attempts. The final rule permits a licensee or other entity to record information on the Federal CCF or using another method consistent with the licensee or other entity's collection procedures. Flexibility is being provided because the available space on the Federal CCF to document information is limited (i.e., a single blank line to write text on the "Remarks" line of the form). The NRC revised 10 CFR 26.107(b)(1) and (d)(3) and 10 CFR 26.111(b) in the final rule.

The NRC received no public comments on the Paperwork Reduction Act statement published with the proposed rule. A full summary of comments received and NRC responses has been uploaded as a supplementary document with this submission.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Section 26.37, "Protection of information," requires that each licensee or other entity that collects personal information about an individual for the purposes of complying with

10 CFR Part 26 to establish and maintain a system of files and procedures that protects the privacy of each individual's information. Personal information collected under 10 CFR Part 26 is not submitted to the NRC.

Confidential and proprietary information is protected in accordance with the 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 is based on 24 FFD programs that apply to the following 59 sites:

- 51 operating commercial nuclear power reactor sites (21 FFD programs)
- 2 Category I special nuclear material licensees (2 FFD programs)
- 5 corporate offices (covered by the operating power reactor FFD programs)
- 1 C/V (1 FFD program).

The NRC developed the burden estimates in this statement based on data submitted in industry FFD program performance reports submitted under 10 CFR 26.717 and approved under OMB control No. 3150-0146.

The incremental burdens associated with the information collections in the final rule are accounted for 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 disclosure burden, and Table 5 for annual third-party disclosure burden.

Based on the NRC's best estimate, the incremental industry burden to generate, maintain, retain, disclose, and provide information related to the FFD program activities covered by this final rule is estimated to total 1,672 hours as detailed in the table below, with an annualized cost estimate of $481,536 (1,672 hours x $288 per hour).

Table	Description	Annualized Burden Hours
1	Recordkeeping (One-Time)	376
2	Recordkeeping (Annual)	748
3	Annual Reporting	63
4	Third-Party Disclosure (One-Time)	250
5	Third-Party Disclosure (Annual)	235
	Total	**1,672**

13. Estimate of Other Additional Costs

The quantity of records retained under 10 CFR Part 26 is roughly proportional to the recordkeeping burden and is used to calculate the approximate cost to store records. The records storage cost has been determined to be equal to 0.0004 times the recordkeeping burden cost. Therefore, the storage cost for the FFD records accounted

for in Tables 1 and 2 of the current clearance is estimated to be $129 (0.0004 x 1,124 hours x $288 per hour).

14. Estimated Annualized Cost to the Federal Government

There are no additional costs to the Federal government beyond the current costs associated with the 10 CFR Part 26 information collection.

15. Reasons for Changes in Burden or Cost

The estimated burden of the information collections contained in the final rule is 1,672 hours. This estimate is comprised of one-time and annual requirements of the final rule.

The final rule aligns the NRC's drug testing requirements more closely with updates made to the U.S. Department of Health and Human Services "Mandatory Guidelines for Federal Workplace Drug Testing Programs" in 2008 and as revised in 2017. The final rule does not increase the number of specimens collected for drug testing by licensees and other entities, but due to the changes in the drug testing panel, it will result in licensees and other entities documenting an estimated 176 additional individuals per year that test positive for one or more drugs, or are identified attempting to subvert the drug testing process, as well as the actions taken in response to these testing events.

In addition, the final rule changes require licensees and other entities to: (1) update FFD program policies and procedures; (2) inform existing employees on the FFD program testing policy changes; and (3) revise contracts with HHS-certified laboratories and BPTS suppliers.

The final rule changes resulted in updates to NRC Form 890 – Single Positive Test Form (SPTF), and NRC Form 890 – Annual Reporting Form for Drug and Alcohol Tests (ARF). This forms are used by licensees and other entities to report FFD program performance testing information to the NRC on an annual basis under 26.717 and 26.417(b)(2). As a result of the changes to the drug testing panel under 26.31(d)(1) and required special analyses testing under 26.163(a)(2) for dilute specimens and specimen collected under direct observation collection conductions, the ARF and SPTF have been revised as follows:

- SPTF: "Substance" drop-down menu items were updated to reflect each of the required new substances (MDMA, MDA, oxycodone, oxymorphone, hydrocodone, and hydromorphone).
- SPTF: The form field "Was LOD testing conducted – 26.163(a)(2)" was revised to "Was special analyses LOQ testing conducted – 26.163(a)(2)". Additional mouse-over guidance was provided for this form field that describes the conductions under which special analyses testing is required. This form field also now appears when a form user answers "Yes" to the question "Was this collection observed?".
- SPTF: In the "Substances" tested table, the column header "Limit of Detection" was revised to read "Limit of Quantiation". The final rule updated the required cutoff level that applies to special analyses testing, changing it from the "Limit of Detection" to the "Limit of Quantitation."

- ARF: In the “Substances Tested” form section, eliminated the question, “Does your program conduct LOD testing permitted in 26.163(a)(2)?”. This field is no longer needed because the final rule now requires all licensees and other entities to conduct testing under 26.163(a)(2).
- ARF: In the “Substances Tested” table that appears if a form user answers “No” to the question “Did your program only test for NRC-required substances AND at the NRC-specified minimum cutoff levels?”, added the following new substances included in the drug testing panel in the final rule (MDMA, MDA, oxycodone, oxymorphone, hydrocodone, and hydromorphone).
- ARF: In the “Substances Tested” table, removed the column titled “Limit of Detection (LOD) testing?” This “Yes” or “No” question is no longer needed because the final rule requires all licensees and other entities to conducted special analyses testing under 26.163(a)(2).
- ARF: The “Special Analyses Testing Results” form section now always appears on the form as this testing is now required under 26.163(a)(2). Previously the form section only would appear if a response of “Yes” was provided for the form field “Does your program conduct LOD testing permitted in 26.163(a)(2)?”.
- ARF: In the “Special Analyses Testing Results” form section, revised the form field “Total Number of “Dilute” Specimens (Special Analyses Testing Conducted” to “Total Number of Specimens (Special Analyses Testing Conducted)”. The final rule requires special analyses testing under 26.163(a)(2) for dilute specimens and specimens collected under direct observation conditions.

Because licensees and other entities will not be required to implement the final rule for up to 1 year from the date of publication in the Federal Register, two versions of NRC Form 890 and 891 will be available for use by the licensees and other entities (i.e., the current and the revised versions). Licensees and other entities will be able to identify which of the two versions of each form that they should use by evaluating information in the footer of each form (i.e., form versions to use for the current rule is 1.10; form versions to use for the final rule is 1.11).

16. Publication for Statistical Use

None.

17. Reason for Not Displaying the Expiration Date

NRC Forms 890 and 891 display the OMB clearance approval expiration date. The remaining recordkeeping and reporting requirements for this information collection do not use instruments such as forms or surveys.

18. Exceptions to the Certification Statement

There are no exceptions to the certification statement.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods have not been 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): Develop FFD policy statement and procedures	24 FFD programs	14.7	352
26.27(b): Make FFD policy statement readily available to subject personnel	Burden accounted for under 10 CFR 26.27(a)		
26.27(c): Updates to FFD policy and procedures			
26.127(c) and (d): Develop LTF procedures for assays performed and instrument and test setup	3 LTFs	8.0	24
		TOTAL	**376**

[5] An annualized one-time burden is calculated by dividing each burden hour by the 3 years covered by this clearance. For example, under 10 CFR 26.27(a), the NRC estimates that a licensee or other entity will incur an incremental one-time burden of 44 hours to update its FFD policy statement and procedures. This one-time burden appears annualized as 14.7 hours [(44 hours in year 1 + 0 hours in year 2 + 0 hours in year 3) / 3 years = an annualized burden of 14.7 hours].

Table 2
Annual Recordkeeping Burden

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.39(b): FFD program provides notice to an individual of the grounds of an FFD policy violation determination and review procedures	24 FFD programs	20.2[6]	484
26.75(a) – (e) and (g): Records of sanctions for FFD violations	Burden accounted for under 10 CFR 26.39(b)		
26.135(b): LTF record of direction from MRO to send the Bottle B of a split specimen to a second HHS lab	Burden accounted for under 10 CFR 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(3) and (a)(5)	Burden accounted for under 10 CFR 26.169(c)(1)		
26.165(b)(1): Record of donor request for the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen at a second HHS-certified lab	Burden accounted for under 10 CFR 26.165(b)(6)		
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 at a second HHS lab	Burden accounted for under 10 CFR 26.185(c)		
26.165(b)(6): MRO reviews HHS lab results on the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen, informs the donor of the results, and notifies FFD management	9 sites[7]	1.0	9

[6] The NRC estimates that a licensee or other entity will spend 2.75 hours per testing violation (176 confirmed positive test results and identified attempts to subvert the drug testing process per year x 2.75 hours per testing violation = 484 hours per year / 24 FFD programs = 20.2 hours).

[7] The NRC estimates that for 5 percent of confirmed positive test results, the donor will request retesting of an aliquot of a single specimen or the testing of Bottle B of the split specimen at a second HHS-certified laboratory (176 confirmed positive test results and identified attempts to subvert the drug testing process per year x 5 percent of results = 9 results per year). Upon receiving the donor's request, an MRO is estimated to spend 1.0 hour to contact the initial testing laboratory (LTF or HHS lab) to request that the donor's specimen be sent to a second HHS lab, to review the test results received from the second HHS lab, communicate the test result to the donor, and notify FFD management.

Table 2
Annual Recordkeeping Burden

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.165(c)(4): Results report received from the second HHS lab that performed retesting on an aliquot of a single specimen or the Bottle B split specimen	Burden accounted for under 10 CFR 26.165(b)(6)		
26.168(g) Maintain documentation of HHS lab certification of BPTS formulation	59 sites	1.0	59
26.168(i)(2): Licensee or other entity completes Federal CCF for a BPTS, places fictional initials on specimen labels, and indicates on the MRO copy of the CCF that the specimen is a BPTS	59 sites	1.0[8]	59
26.169(a): Records of reports of test results by HHS lab	Burden accounted for under 10 CFR 26.183(c)(1)		
26.169(c)(1): Records of HHS lab reports of positive, adulterated, substituted, dilute, and invalid test results received by the MRO			
26.169(c)(2): Records of HHS lab reports of the numerical values of all positive drug test results (i.e., quantitative test results requested by MRO)			
26.169(c)(2): Records of HHS lab reports of quantitative test results for opiates to MRO			
26.169(g): HHS lab copy of the original Federal CCF for each positive, adulterated, substituted, dilute, and invalid test result to the MRO			

[8] Each site will prepare three new BPTSs per quarter because of the final rule changes (one BPTS containing the Ecstasy-type drugs MDMA and MDA, one BPTS containing the opioids hydrocodone and hydromorphone, and one BPTS containing the opioids oxycodone and oxymorphone). The NRC estimates that it takes about 5 minutes (5 minutes/60 minutes = 0.083 hour) to complete a Federal CCF for a BPTS. [59 sites x 3 BPTS per site per quarter x 4 quarters in a year x 0.083 hour per BPTS = 59 hours per year]

Table 2
Annual Recordkeeping Burden

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.183(c)(1): MRO review of HHS lab test result record for a positive, adulterated, substituted, invalid, or dilute specimen result that confirms as an FFD violation	24 FFD programs	0.6[9]	15
26.183(c)(1): MRO review of HHS lab test result record for amphetamine positive drug test result that confirms negative after discussion with the donor due to a legitimate medical use and valid prescription.	7 sites[10]	1.0	7
26.183(c)(1): MRO review of HHS lab test result record for an opioid positive drug test result that confirms negative after discussion with the donor due to a legitimate medical use and valid prescription.	26 sites[11]	1.0	26
26.185(a) Record of MRO review of a drug positive, adulterated, substituted, dilute or invalid test result with donor	Burden accounted for under 10 CFR 26.183(c)(1)		

[9] The NRC estimates that the final rule will result in an additional 176 confirmed positive drug test results and identified attempts to subvert the drug testing process each year. The NRC estimates that an MRO spends, on average, 5 minutes (0.083 hour) to review an individual's laboratory test results.

[Estimated burden hours = (176 confirmed positive test results and identified attempts to subvert the drug testing process x 0.083 hour per test result or subversion attempt) / 24 FFD programs = 0.61 hours per FFD program]

[10] The NRC estimates that the final rule will result in 7 additional amphetamine positive test results reported by HHS-certified laboratories that will be determined by the MRO, after discussion with the donor, to be for a legitimate prescription medication used in a manner and at the dosage prescribed and not an FFD policy violation.

[11] The NRC estimates that the final rule will result in 26 additional opioid positive test results reported by HHS-certified laboratories that will be determined by the MRO, after discussion with the donor, to be for a legitimate prescription medication used in a manner and at the dosage prescribed 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(c): Record of MRO discussion of positive, adulterated, substituted, dilute or invalid test results with the donor	24 FFD programs	3.7[12]	88
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 FFD program	1.0	1
26.185(j): Record of MRO notification to licensee where evidence of drug abuse or use of another individual's prescription medication	Burden accounted for under 10 CFR 26.183(c)(1)		
26.185(k): Record of MRO report to the licensee that no FFD policy violation has occurred (i.e., legitimate prescription medication used in a manner and at the dosage prescribed). If the individual poses a potential risk to public health and safety because of impairment while on duty – the MRO will ensure that a determination of fitness is performed	Burden accounted for under 10 CFR 26.183(c)(1) (line items for amphetamine and opioid positives that confirm negative upon MRO review)		
26.185(n): Record of MRO review of a positive, adulterated or substituted test result from a second HHS lab (results of retesting an aliquot of a single specimen or testing of a Bottle B of the split specimen), and MRO communication of the test results to FFD management	Burden accounted for under 10 CFR 26.165(b)(6)		
26.185(p): Record of MRO notice to licensee of determination of FFD policy violation	Burden accounted for under 10 CFR 26.185(c)		

[12] The NRC estimates that an MRO will spend an average of 30 minutes (0.5 hour) per test result to contact the donor, discuss the HHS lab test results, and document the discussion and determination.
[(176 positive test results and identified attempts to subvert the drug testing process per year x 0.5 hour per test result or subversion attempt) = 88 hours/24 FFD programs = 3.7 hours per FFD program per year]

Table 2
Annual Recordkeeping Burden

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.713(a)(2): Retain records on FFD violations	Burden accounted for under 10 CFR 26.39(b)		
		TOTAL	**748**

Table 3
Annual Reporting Burden

Section	Number of Recordkeepers	Responses per Respondent	Total Responses	Burden Hours per Response	Total Annual Burden Hours
26.717 Annual FFD program performance report for drug and alcohol testing programs	59 sites	1	59	1.0	59
26.719(b): Report to the NRC by telephone within 24 hours of identifying a significant drug and alcohol testing program violation	1 site	1	1	4.0	4
				TOTAL	**63**

Table 4
One-Time Third-Party Burden

Section	Number of Responses	Burden Hours per Response (Annualized)	Total Annual Burden Hours (Annualized)
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)	4,695[13]	0.08	130
26.157(a): Written procedures for accession, receipt, shipment, and testing of urine specimens at HHS lab	9[14]	13.3	120
26.169(h): HHS lab prepares and submits annual statistical summary report of testing results to the licensee or other entity	Burden accounted for under 10 CFR 26.157(a)		
		TOTAL	**250**

[13] The NRC estimates that approximately 5 percent of the 59 sites with an FFD program (i.e., 3 sites, with average worker population at each site of 1,565 individuals) will conduct training of existing workers subject to 10 CFR Part 26 outside annual refresher training. The burden for the FFD program of each site is the time for each worker to certify that they reviewed updated information on the FFD policy (5 minutes per worker = 0.083 hour).

[The reported value is annualized (3 sites x 1,565 individuals per site) = 4,695 workers x 0.083 hour per worker = 391 hours / 3 years = 130 hours per site per year]

[14] Each of the nine HHS-certified laboratory performing testing for licensees and other entities under 10 CFR Part 26 is estimated to spend 40 hours to update the laboratory's testing procedures based on the final rule changes (9 laboratories x 40 hours per laboratory = 360 hours/3 years = 120 hours per year).

Table 5
Annual Third-Party Burden

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.135(b): Donor request to MRO for the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen at a second HHS lab (initial specimen testing performed at an LTF)	Burden accounted for under section 26.165(b)(1)		
26.165(b)(1): At the direction of the MRO, the initial HHS lab that conducted testing sends a donor's specimen (i.e., an aliquot of a single specimen or Bottle B of the split specimen) to a second HHS lab for further testing	9 sites	1.0	9
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	Burden accounted for under 10 CFR 26.185(n)		
26.168(g): Blind performance test sample (BPTS) supplier provides HHS lab certification letter of BPTS formulation to licensee or other entity	59	1.0	59
26.169(a): Reports of test results by HHS lab	Burden accounted for under 10 CFR 26.169(c)(1)		
26.169(c)(1): HHS lab report to the MRO of positive, adulterated, substituted, dilute, and invalid test results	176	0.25	44
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 10 CFR 26.169(c)(1)		
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			
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
26.183(c)(1): Donor discussion with MRO on an opioid positive drug test result and donor obtains and provides prescription medication information to the MRO (MRO determines negative result due to legitimate medical use)	26	1.0	26

Table 5
Annual Third-Party Burden

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.185(c): Donor discussion of positive test result with the MRO that is determined to be an FFD program violation	176	0.5	88
26.185(n): Second HHS lab provides the MRO with test result report (for retesting of an aliquot of a single specimen or the testing of a Bottle B split specimen)	9	0.25	2
		TOTAL	**235**

TOTAL ANNUAL BURDEN: 1,672 hours (376 hours one-time recordkeeping (annualized) + 748 hours annual recordkeeping + 63 hours annual reporting + 250 hours one-time third-party disclosure (annualized) + 235 hours annual third-party disclosure)

TOTAL ANNUAL RESPONSES: 2,046 (24 recordkeepers + 60 reporting responses + 1,962 third-party responses[15]). Note that all recordkeepers were included in the previous totals in ROCIS, therefore ROCIS reflects an increase of 2,022 responses (60 reporting responses + 1,962 third-party responses.)

NUMBER OF RESPONDENTS: 246 (24 FFD programs + 9 HHS-certified laboratories + 1 BPTS supplier + 3 LTFs + 209 individuals with a positive drug test result or identified attempting to subvert the drug testing process)

[15] The NRC estimates that the final rule results in an additional 176 individuals that test positive for a drug(s) or are identified as having attempted to subvert the drug testing process, 176 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 and 26 individuals who test positive for opioids but have legitimate medical uses and prescriptions, 9 HHS-certified laboratories that update written procedures in response to the final rule changes, 1 BPTS supplier, and 1,565 workers certifying receipt of updated policy information outside annual refresher training (176 + 176 + 2 + 7 + 26 + 9 + 1+ 1,565 = 1,962 third-party responses per year).