

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

(OMB Clearance No. 3150-0146)

EXTENSION

DESCRIPTION OF THE INFORMATION COLLECTION

The Nuclear Regulatory Commission (NRC) requires certain licensees and other entities to have a fitness-for-duty (FFD) program that provides reasonable assurance that subject personnel are trustworthy, reliable, and not under the influence of any substance (legal or illegal), or mentally or physically impaired from any cause that 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 prescribe the requirements for a licensee or other entity to establish, implement, and maintain an FFD program.

Part 26 applies, in whole or in part, to the following licensees and other entities:

- (1) 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"
- (2) 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"
- (3) licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material;" and corporations, firms, partnerships, limited liability companies, associations, or other organizations that obtain a certificate of compliance or an approved compliance plan under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants," if the entity engages in activities involving formula quantities of SSNM
- (4) contractor/vendors (C/Vs) that implement FFD programs or program elements to the extent that licensees rely on C/V FFD programs or program elements to meet the requirements of this part

This clearance covers recordkeeping, reporting, and third-party disclosure requirements that apply to the following types of information collections:

- *Information describing the FFD drug and alcohol (D&A) testing program of a licensee or other entity.* FFD program policy, FFD program procedures, and trainings provided on the FFD program.
- *Information documenting testing protocols and testing personnel qualifications at Licensee Testing Facilities (LTFs) and U.S. Department of Health and Human Services'*

(HHS)-certified laboratories. Laboratory testing policies and procedures, laboratory personnel qualification and training records, quality assurance (QA) and quality control (QC) records, and licensee and other entity contracts with testing laboratories.

- *Information documenting D&A specimen collection, testing, and results review processes.* Specimen chain of custody records, laboratory testing results, test results reviews, qualification and training records of personnel performing roles in the FFD program (e.g., Medical Review Officers (MROs), Substance Abuse Expert (SAEs), FFD program personnel), and contracts with service providers.
- *Reports on FFD program performance.* Periodic reports to the NRC on the D&A testing program and fatigue management program (annual reports on program performance), and more timely reports (24 hours, 30 days) for significant FFD policy violations or programmatic failures.
- *Information on personnel subject to an FFD program.* Records for authorization (signed consent forms to access or release information, self-disclosure, employment history, credit history, criminal background check, suitable inquiry); training and examination records, fitness determinations, FFD program violations).
- *Information on audits.* Records on audits performed on a periodic basis of the FFD program, testing laboratories, collection site, and employee assistance program (EAP).
- *Records on work hour controls (fatigue management).* Records of work hours of individuals, records of shift schedules and cycles, documentation of waivers issued, work hour reviews, and fatigue assessments.

This clearance also includes three Portable Document Form (PDF) electronic reporting forms (i.e., fillable-fileable PDFs) that were approved by the Office of Management and Budget (OMB) under Information Collection Request (ICR) 3150-0146 on November 13, 2014:

- NRC Form 890 – Single Positive Test Form
- NRC Form 891 – Annual Reporting Form for Drug and Alcohol Tests
- NRC Form 892 – Annual Fatigue Reporting Form

Licensees and other entities can voluntarily use these fillable-fileable PDFs to report information required under sections 26.417(b)(2) and 26.717 for FFD D&A testing programs, and section 26.203(e) for fatigue management programs. As of the calendar year 2015 annual reporting cycle, all sites now use fillable-fileable PDFs.

A. JUSTIFICATION

1. Need for and Practical Utility of the Collection of Information

The information collections contained in Part 26 enable effective and efficient regulatory oversight of affected licensee 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 to protect the environment. The NRC uses these information collections to assess licensee and other entity compliance with Part 26 through periodic NRC inspections, and to take

corrective actions, as needed. 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 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 Part 26 D&A testing and fatigue management requirements. The Part 26 recordkeeping and reporting requirements are mandatory for licensees and other entities subject to the rule and include developing and maintaining:

- FFD program policies and procedures (D&A testing, fatigue program);
- records on the qualification, training, authorization, fitness determinations, and any FFD violations of individuals subject to Part 26;
- records on D&A specimen collections, laboratory tests, and test result reviews;
- records and reports on D&A testing program performance (annual summary performance reports and more frequent reports of significant violations and programmatic failures);
- records of audits (internal FFD program, testing laboratory, collection site, and EAP); and
- records and reports required under the fatigue management program for evaluation of work schedules and hours worked, licensee work hour reviews, waivers, self-declarations, fatigue assessments, and annual program performance.

Appendix A of this supporting statement, "Description of Information Collection Requirements in 10 CFR Part 26," includes a description of each recordkeeping and reporting requirement.

While the majority of the recordkeeping and reporting requirements in Part 26 are contained in Subpart I "Managing Fatigue," Subpart K "FFD Programs for Construction," and Subpart N "Recordkeeping and Reporting Requirements," most required activities that generate those records and reports are located elsewhere in Part 26. To be more precise and transparent in the estimated burden associated with each information collection, the burden of each activity that generates a record or report is associated with the specific regulatory requirement for that activity. For each regulatory requirement, a cross reference also is included to the specific recordkeeping or reporting requirement.

2. Agency Use of Information

The NRC uses the information included in the records and reports required by Part 26 for one or more of the following reasons:

- To monitor licensee and other entity compliance with Part 26 requirements to ensure that each FFD Program is adequate to protect public health and safety, promote the common defense and security, and protect the environment;
- To be informed of FFD-related performance issues in order to evaluate the need to implement timely regulatory actions to restore compliance, verify corrective actions, implement licensing actions, conduct public outreach, and/or inspect NRC-licensed activities; and,

- To evaluate the performance of D&A testing programs and fatigue management programs through the collection and analysis of annual program performance information to identify trends, lessons learned, and site-specific or industry-wide issues requiring NRC licensing or inspection response, generic communication, or rulemaking. The NRC staff also develops summaries of the D&A testing program performance to inform the public on industry performance.

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, by Optical Storage Media (OSM) (e.g. CD-ROM, DVD), by facsimile or by e-mail. NRC staff estimates that approximately 97 percent of the potential responses are filed electronically.

As of 2015, 100 percent of the annual FFD program performance reports that licensees and other entities submitted to the NRC pursuant to sections 26.417(b)(2) and 26.717 (D&A testing programs) and section 26.203(e) (fatigue management programs) 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. The only reports not received electronically are made under section 26.719, which requires a licensee or other entity to notify the NRC by telephone within 24 hours of an event occurrence.

4. Efforts to Identify Duplication and Use Similar Information

Certain records described in Subpart G of Part 26 pertain to HHS-certified laboratories¹ also are required to be maintained pursuant to the U.S. Department of Health and Human Services' (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines), to enable a records review under the standards of the National Laboratory Certification Program (a program administered by HHS). All other records maintained by NRC licensees and other entities subject to Part 26 are not duplicated by other Federal information collection requirements and are not available from any other source.

5. Effort to Reduce Small Business Burden

The requirements in Part 26 do not affect small businesses or entities.

6. Consequences to Federal Programs or Policy Activities if the Collection is Not Conducted or is Collected Less Frequently

The NRC staff anticipates four consequences if the records and reports required by Part 26 are not collected or collected less frequently. Each consequence would adversely affect the NRC's ability to:

¹ In this clearance, the terms "HHS lab" or "HHS labs" are used interchangeably with "HHS-certified laboratory" or "HHS-certified laboratories."

- 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 to 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 (i.e., past employment, past periods of authorization, any authorization denial or unfavorable termination, past arrest record, and other potentially disqualifying FFD information (PDI)) must be available at the time that FFD authorization decisions are made. 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.

Records and reports associated with fatigue management ensure that persons are capable of performing their assigned tasks safely and competently. If fatigue management records and reports are not collected or collected less frequently, internal licensee reviews or NRC oversight during inspections may not identify programmatic weaknesses that may result in persons who are fatigued being assigned to perform covered duties. This could result in conditions adverse to safety and/or security at operating nuclear power reactors.

7. Circumstances which Justify Variation from OMB Guidelines

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

- 10 CFR 26.77(c) requires a licensee or other entity of a D&A testing program that has a reasonable belief that an NRC employee or NRC contractor may be under the influence of any substance, or is otherwise unfit for duty, to immediately notify the appropriate Regional Administrator by telephone, followed by written notification (e.g., email or fax) to document the verbal notification. If the Regional Administrator cannot be reached, the licensee or other entity must notify the NRC Operations Center. This notification is necessary to enable immediate actions by the NRC to address this situation.
- 10 CFR 26.185(p) requires an MRO to complete the review of a positive, adulterated, substituted, or invalid test result and to notify the licensee or other entity's designated representative within 10 business days of receiving the HHS-certified laboratory test result. Notification within 10 business days ensures that the licensee or other entity can take prompt action to address an FFD testing violation.
- 10 CFR 26.417(b)(1) requires the licensee or other entity of a reactor construction site D&A testing program to report to the NRC Operations Center by telephone within

24 hours of discovering any intentional act that casts doubt on the integrity of the testing program and any programmatic failure, degradation, or discovered vulnerability of the program that may permit undetected drug or alcohol use or abuse by individuals subject to testing. This requirement ensures that, in part, the NRC is timely informed so that appropriate regulatory actions can be initiated, if needed.

- 10 CFR 26.719(b) requires the licensee or other entity of a D&A testing 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.
- 10 CFR 26.719(c)(2) requires the licensee or other entity of a D&A testing program to make a report to the NRC Operations Center by telephone within 24 hours of discovering a false positive testing error on a blind performance test sample (BPTS) tested by an HHS-certified laboratory. A false positive test results is a significant programmatic error warranting immediate action by the licensee to ensure that the accuracy of laboratory testing of specimens is consistent with the requirements of Part 26. A false positive result also may affect other FFD programs that utilize the same testing laboratory. Timely reporting ensures that the NRC can take immediate actions with the licensee reporting the testing error, as well as to provide notice to other FFD programs that rely on the same testing laboratory, if necessary.
- 10 CFR 26.719(c)(3) requires the licensee or other entity of a D&A testing program to make a report to the NRC Operations Center by telephone within 24 hours of discovering a false negative testing error on a BPTS tested by an HHS-certified laboratory. A false negative test result is a significant programmatic error warranting immediate action by the licensee to ensure that the accuracy of laboratory testing of specimens is consistent with the requirements of Part 26. A false negative result also may impact other licensees and other entities that utilize the same testing laboratory for Part 26 testing. Timely reporting ensures that the NRC can take immediate actions with the licensee reporting the testing error, as well as to provide notice to other FFD programs that rely on the same testing laboratory, if necessary.

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

- 10 CFR 26.165(b)(2) 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. This 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 section 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 to 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 section 26.717(e), and the laboratory statistical summary is necessary to complete that report in a timely manner.

Eleven 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 26.203(d) requires that records pertaining to the fatigue management program (records of work hours of individuals, records of shift schedules and cycles, documentation of waivers issued, work hour reviews, and fatigue assessments) be retained for at least 3 years, which is consistent with OMB guidance, or until the completion of all related legal proceedings, whichever is later. The latter requirement ensures to the availability of records for legal or regulatory proceedings, and affords due process to individuals subject to a fatigue management program.
- 10 CFR 26.711(a) states that if a retention period is not specified in the appropriate section of Part 26, the records must be retained until the Commission terminates the facility license. This retention requirement ensures to records availability for legal or regulatory proceedings.
- 10 CFR 26.713(a) requires the licensee or other entity of each D&A testing 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 self-disclosures, employment histories, suitable inquiries, determination 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 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. The stakeholders noted that some legal proceedings involving records of the type specified in the paragraph have continued longer than the 5 years and that this recordkeeping protects an individual's right to due process.
- 10 CFR 26.713(b)(1) and (b)(2) requires the licensee or other entity of each D&A testing program to retain records of FFD training and examinations, and FFD audit information (including findings and corrective actions) for at least 3 years, which is consistent with OMB guidelines, or until the completion of all related legal proceedings, which is later.

This retention requirement ensures to the availability of records should an individual, the NRC, a licensee, or another entity require access in response to a legal or regulatory proceeding.

- 10 CFR 26.713(c) requires the licensee or other entity of each D&A testing 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 D&A provisions of 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 that these records are available for NRC and licensee review.
- 10 CFR 26.713(d) requires the licensee or other entity of each D&A testing program to retain superseded FFD policies and procedures for at least 5 years (or longer if needed to respond to a legal challenge). This records retention requirement is necessary to evaluate licensee and other entity compliance with Part 26 through NRC inspection, and ensures to records availability for use in legal and regulatory proceedings.
- 10 CFR 26.713(e) requires the licensee or other entity of each D&A testing program to retain written agreements for the provision of services under Part 26 for the life of the agreements (or longer if needed to respond to legal proceedings related to an FFD violation that involved the services). This records retention requirement is necessary to evaluate licensee and other entity compliance with Part 26 through NRC inspection. It also ensures that written agreements are preserved until any legal or regulatory proceeding is complete.
- 10 CFR 26.713(f) requires the licensee or other entity of each D&A testing program to retain records pertaining to background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel, conducted under section 26.31(b)(1)(i), for the length of the individual's employment by or contractual relationship with the licensee or other entity, or until the completion of all related legal proceedings, whichever is later. The retention period is based on the NRC's need to have access to the records for inspection purposes and the potential need for the records for legal or regulatory proceedings.
- 10 CFR 26.713(g) requires that a licensee or other entity of a D&A testing program that chooses to test for additional drugs not in the NRC testing panel, to use lower testing cutoff levels for drugs in the NRC testing panel, or both, to retain records on the

certification of scientific and technical suitability of the assays and cutoff levels used. The retention period for these records is for the period when this testing is performed, or until the completion of all related legal proceedings, whichever is later. The retention period ensures that the NRC has access to these records during inspection, and ensures records availability for legal or regulatory proceedings.

- 10 CFR 26.715(a) requires entities providing services to the licensee or other entity of a D&A testing program (e.g., collection site, LTF, HHS-certified laboratory) to maintain and provide access to documentation on all aspects of the testing process for at least 2 years (consistent with OMB guidance), or until the completion of legal proceedings associated with the determination of an FFD violation, whichever is later. Upon written notification to the service provider, the NRC or the licensee or other entity may extend the 2-year records retention period. This requirement provides the licensee or other entity and the NRC with access to service provider records for inspection and regulatory proceedings, in needed.
- 10 CFR 26.717(c) requires a licensee or other entity that has a licensee-approved FFD program to analyze FFD program performance data at least annually and to retain records of the data, analyses, and corrective actions taken for at least three years (consistent with OMB guidelines), or until the completion of any related legal proceedings (ensures records access to affected parties).

8. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package was published in the *Federal Register* (FR) on June 1, 2017 (82 FR 25345). The NRC staff also e-mailed a total of nine licensees and other entities. No comments were received.

During the normal course of business, NRC staff regularly interacts with representatives from affected stakeholders such as FFD program personnel from operating nuclear power reactors, fuel cycle facilities, and C/Vs; and third-party entities such as HHS-certified laboratories. For example, staff attends periodically held Nuclear Energy Institute (NEI) meetings and industry conferences. The NRC staff also consults with HHS, the Office of National Drug Control Policy, National Institute on Drug Abuse, and U.S. Department of Transportation to ensure that Part 26 is consistent with other Federally-mandated D&A testing programs.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

Section 26.37 requires, in part, that each licensee or other entity who collects personal information about an individual for the purpose of complying with 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 Part 26 is not submitted to the NRC.

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

11. Justification for Sensitive Questions

Sections 26.31, 26.35, 26.39, 26.61 through 26.70, 26.75, 26.77, 26.85, 26.115, 26.117, 26.119, 26.165, 26.183, 26.185, 26.189, 26.211, 26.411, 26.713, and 26.719 require each licensee or other entity to collect personal information (e.g., personally identifiable, medical, criminal, financial) for the purpose of complying with Part 26. Obtaining personally identifiable information is necessary for the effective implementation of a D&A testing program, affords due process to individuals subject to testing, and contributes to the determination of a licensee's determination of authorization. The outcome of these collections contributes to the Part 26 performance objectives that each FFD program provide reasonable assurance that:

- individuals are trustworthy and reliable as demonstrated by the avoidance of substance abuse;
- individuals are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;
- the workplaces are free from the presence and effects of illegal drugs and alcohol; and
- the effects of fatigue and degraded alertness on individuals' abilities to safely and competently perform their duties are managed commensurate with maintaining public health and safety.

While licensees and other entities may collect personal information to comply with Part 26, the NRC does not collect any personally identifiable information on the individuals subject to the rule. Also note that the electronic reports received under sections 26.417(b)(2) and 26.717 that detail individual D&A testing violations, do not contain any personally identifiable information.

12. Estimate of Industry Burden and Costs

The estimated burden hours and costs associated with administering D&A testing programs that meet the requirements of Part 26, Subparts, A – H, M, N, and O (i.e., a D&A testing program) is based on the following 26 programs:

- operating nuclear power reactor sites (23 programs)²
- fuel-cycle facilities (2 programs)
- C/Vs (1 program).

The estimated burden hours and costs associated with administering reactor construction site D&A testing programs that meet the requirements of Part 26, Subpart K, is based on 2 programs.

² This clearance includes 99 currently operating nuclear power reactors located at 59 sites (i.e., a site has one or more power reactors). A licensee or other entity will maintain one FFD program per site. That is, an FFD program is not based on the number of power reactors at a site. In addition, a licensee or other entity with multiple power reactor sites will maintain a single FFD program that covers all of its sites. As a result, the number of FFD programs for operating nuclear power reactors is less than the number of sites.

The estimated burden hours and costs associated with administering fatigue management programs that meet the requirements of Part 26, Subpart I, is based on 21 programs for operating nuclear power reactors.³

The estimated number of respondents per year for this clearance period is 88,229 and consists of 28 D&A testing programs (26 + 2 = 28 from above), 21 fatigue management programs, and 88,180 third-party respondents.⁴

Multiplying the total number of burden hours by \$265 per hour results in the following estimates for the 2017–2020 clearance:

| Table | Description | Burden Hours | Cost at \$265/hour |
|--------------|-------------------------------|---------------------|---------------------------|
| 1 | One-Time Recordkeeping | 112.0 | \$ 29,680 |
| 2 | Annual Recordkeeping | 220,886.5 | \$ 58,534,918 |
| 3 | Annual Reporting | 6,168.0 | \$ 1,634,520 |
| 4 | Annual Third-Party Disclosure | 492,029.4 | \$ 130,387,785 |
| TOTAL | | 719,195.9 | \$ 190,586,904 |

13. Estimates of Other Additional Costs

The quantity of records retained under Part 26 is roughly proportional to the recordkeeping burden and is used to calculate the approximate cost to store records. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to 0.0004 times the recordkeeping burden cost. Therefore, the storage cost for the FFD records accounted for in Tables 1, 2, and 4 of the current clearance is estimated to be \$75,581 (0.0004 x 719,195.9 hours x \$265 per hour).

14. Estimated Annualized Cost to the Federal Government

Table 5 presents the estimated annual cost to the NRC for performing regulatory oversight of the reporting and recordkeeping requirements in Part 26. The cost for regulatory oversight of Part 26 requirements is recovered through fee assessments to NRC licensees and other entities pursuant to 10 CFR Part 170. Using \$265 per hour, the total estimated annualized cost to the Federal government is:

| Table | Burden Area | Hours | Cost |
|--------------|--------------------|--------------|-------------|
| 5 | NRC | 1,872.0 | \$ 496,080 |

³ The difference in the number of D&A testing programs (23) and fatigue management programs (21) appears to relate to licensee management practices.

⁴ The NRC staff estimates 88,180 third-party respondents for this clearance period (i.e., 81,219 persons subject to pre-access testing at D&A testing programs + 6,898 individuals subject to pre-access testing at reactor construction site D&A testing programs + 9 HHS labs + 2 BPTS suppliers + 26 EAPs + 26 non-licensee collection sites). The previous clearance reported 98,565 third-party respondents.

The estimated number of persons subject to pre-access testing per year is the average number of pre-access tests performed for calendar year (CY) 2013 through CY 2015.

15. Reasons for Change in Burden or Cost

As summarized below, the total burden for Part 26 changed from 623,943.1 hours to 719,195.9 hours, an increase of 95,252.8 hours.

| Table | Description | Clearance Period | | Change in Burden Hours |
|--------------|-------------------------------|-------------------|-------------------|------------------------|
| | | 2014-2017 (hours) | 2017-2020 (hours) | |
| 1 | One-Time Recordkeeping | 41.4 | 112.0 | + 70.6 |
| 2 | Annual Recordkeeping | 314,177.4 | 220,886.5 | - 93,290.9 |
| 3 | Annual Reporting | 6,165.2 | 6,168.0 | + 2.8 |
| 4 | Annual Third-Party Disclosure | 303,559.1 | 492,029.4 | + 188,470.3 |
| TOTAL | | 623,943.1 | 719,195.9 | + 95,252.8 |

Approximately 46 percent of the decrease in estimated burden in Table 2 is the result of correcting an inaccurate assumption associated with the burden for section 26.53(h), obtaining written consent from each individual before initiating any actions under Subpart C of Part 26. The previous clearance estimated that each licensee or other entity spent 30 minutes to file a signed consent form received from an individual. This assumption incorrectly included the time spent by an individual to read the consent form and sign it. The burden to read and sign the form already was accounted for as third-party disclosure burden in Table 4, Annual Third-Party Disclosure Burden. As a result, the previous clearance double counted the burden to read and sign the form – once on the recordkeeping table and once on the third-party disclosure table. For this clearance, recordkeeping burden for a licensee or other entity to file a signed consent form is estimated at 3 minutes per applicant (reduced from 30 minutes). This assumption change resulted in a decrease in estimated annual burden of 42,895 recordkeeping hours. The remaining burden change in Table 2 is the result of smaller decreases in estimated burden across a number of requirements (i.e., reductions of 1,000 hours or more for approximately 30 requirements).

The increase in burden in Table 4, Annual Third-Party Disclosure Burden, is primarily associated with the inclusion of two information collections absent from the previous clearance. Adding the initial FFD policy training requirement in section 26.29(b) resulted in an increase in estimated burden of 162,439 hours. Adding the annual refresher training on the FFD policy in section 26.29(c)(2) resulted in an increase in estimated burden of 155,899 hours. These requirements are not new; however, in the staff review of Part 26 for this renewal, these sections were newly identified as containing information collection requirements. The increase in annual burden from newly identified sections 26.29(b) and 26.29(c)(2) was partially offset by a decrease in annual burden of 93,555 hours that resulted from correcting an inaccurate assumption in section 26.31(b)(1)(i), which pertained to applying for access to serve as FFD program personnel. The NRC staff estimates that annually, an average of 5 individuals per full D&A testing program will apply for authorization to serve as FFD program personnel. The previous clearance incorrectly estimated this requirement applied to all individuals applying for authorization.

Six reasons account for the changes to the total estimated burden.

(1) Reactor Construction Site D&A Testing Programs (Part 26, Subpart K)

The NRC anticipates that the four nuclear power reactors at two sites (V.C. Summer Units 2 and 3; Vogtle Units 3 and 4) will remain under construction for the duration of this collection period. Construction activities began at Vogtle in 2009 and at V.C. Summer in 2011. On or about July 31, 2017, the licensee for V.C. Summer Units 2 and 3 informed the NRC staff that it intended to cease construction at the site. The NRC staff has chosen to retain the burden hour estimates and costs applicable to this site for the period of this clearance because insufficient information is available regarding the timing of the change and because activities covered by this clearance period will be incurred in 2017 and 2018. NRC also anticipates no new reactor construction at additional sites during this clearance period. The licensee of each reactor construction site maintains one reactor construction site D&A testing program (i.e., 2 programs in total).

This NRC is estimating an increase in the burden associated with reactor construction site D&A testing programs for this clearance period. This increase is based on FFD program performance data from 2013, 2014 and 2015, which demonstrated an increasing number of personnel subject to testing.

These changes affect the burden reported in Tables 2 – 5.

(2) Operating Nuclear Power Reactors

The NRC estimates that the 99 currently operating nuclear power reactors located at 59 sites (i.e., a site has one or more power reactors) will continue to operate for the duration of this clearance period. The previous clearance included 100 operating nuclear power reactors.

- The number of operating nuclear power reactors changed because Fort Calhoun (a single reactor unit site) shutdown in October 2016. A decommissioning site is not subject to Part 26. As was the case with the previous clearance, the following decommissioning sites are not included in this clearance (Crystal River Unit 3, Kewaunee, San Onofre Units 2 and 3, and Vermont Yankee).
- Construction of Watts Bar Unit 2 completed in 2016 and the reactor has been operating since October 2016. The completion of construction has not resulted in any recordkeeping or reporting burden changes because the licensee had already elected to include the construction site workforce in the co-located operating site's D&A testing program for the duration of construction activities. Therefore, the previous clearance and the current clearance treated this site as an operating site because of how the FFD program was implemented.
- While the NRC is aware that some licensees are considering permanently ceasing operations at additional operating nuclear power reactor sites (e.g., Palisades, Pilgrim, Oyster Creek), these sites are included in this clearance.

This change affects the burden estimates in Tables 2 – 5.

(3) Decommissioning Reactor Site Subject to Part 26

One permanently shutdown facility undergoing decommissioning (Zion Units 1 and 2) is not included in this clearance. A security order issued after the terrorist attacks on September 11, 2001, required the licensee to maintain a D&A testing program under Part 26. Since 2014, this security order no longer applies to the site (i.e., all spent fuel had been transferred to dry storage in the independent spent fuel storage installation). The previous clearance estimated recordkeeping and reporting burden for this site at approximately 60 hours per year.

This change affects the burden estimates in Tables 2 – 5.

(4) Fatigue Management Programs

For the current clearance period, the number of fatigue management programs had decreased from 23 to 21. The reduction in the number of fatigue management programs is the result of the following:

- Exelon Generation acquired Constellation Energy Nuclear Group in 2014 (this acquisition reduced the number of fatigue management programs by one)
- Progress Energy was incorrectly counted as an independent program in the previous clearance, even though it had been acquired by Duke Energy in 2012
- South Carolina Electric & Gas (V.C. Summer 1) was mistakenly excluded from the previous clearance (i.e., one program was excluded), but is included in the current clearance estimates
- Institute of Nuclear Power Operations (INPO) was incorrectly included as program in the previous reporting period (i.e., it is not subject to the fatigue management requirements)

(5) Drug Testing Laboratories

A licensee or other entity may use a LTF to conduct initial drug and validity testing (as permitted under Part 26, Subpart F), but must use an HHS-certified laboratory to conduct confirmatory drug and validity testing of specimens.

- Licensee Testing Facilities (LTFs). Since the last clearance period, one D&A testing program ceased using LTFs and is now only conducting drug testing at HHS-certified laboratories. As a result, the number of sites with an LTF has decreased from 7 to 6. NRC staff knowledge of current industry practices does not suggest any change in the number of LTFs during the current clearance period.
- HHS-Certified Laboratories. Based on the 2015 site-specific D&A testing data obtained through annual FFD program performance reports, the number of HHS-certified laboratories used by licensees and other entities has decreased from 12 to 9. NRC staff does not anticipate that any additional HHS laboratories will begin to perform testing for Part 26 regulated entities during the current clearance period.

The reductions in the number of HHS-certified laboratories and LTFs used by licensees and other entities affects the burden estimates in Tables 2 – 5.

(6) Burden Consolidation

A number of recordkeeping and reporting requirements were consolidated to improve the accuracy and clarity of burden presentations.

The most significant of these consolidations pertains to activities performed by MROs. The previous clearance apportioned MRO burden between Table 2, “Annual Recordkeeping Burden” and Table 4, “Annual Third-Party Disclosure Burden.” Burdens for MROs considered to work at licensee sites were accounted for in Table 2 and burdens for MROs not working at licensee sites were accounted for in Table 4. Since both MRO types provide labor services directly to the licensee or other entity, the distinction is unnecessary. Therefore, the NRC staff is no longer making a distinction between these two types of MRO and all MRO burdens have been consolidated in this clearance under Table 2. These consolidations did not change the estimated burden for the affected sections. Sections affected include: 26.183(a), 26.183(c)(1), 26.183(d)(2)(i) - (d)(2)(ii); 26.185(a), (c), (d)(1), (f)(1) and (f)(2), (h)(1) - (h)(3), (i)(1) - (i)(3), (j)(3), (k), and (m) - (o).

When appropriate, the NRC includes footnotes to specific recordkeeping and reporting requirements in Tables 1 through 5 to describe what performance data were used to develop burden hour estimates and to describe changes to the estimates from the prior clearance.

The NRC staff provides the following table-by-table summary comments:

Table 1. One-time Recordkeeping Burden (annualized)

For this clearance period, burden is estimated for the information collections in Table 1 based on one D&A testing program changing to a new HHS lab, program using the flexibility afforded under Part 26 to expand the drug testing panel to test for additional substances, and using lower testing cutoff levels for existing paneled drugs required to be tested under Part 26.

For this clearance period, no one-time recordkeeping burden is anticipated for fatigue management programs. All fatigue management programs have been implemented and no further activity is anticipated.

Burdens added to Table 1:

To improve accuracy, the following burdens were moved to Table 1 (One-Time Recordkeeping Burden) from Table 2 (Annual Recordkeeping Burden). These burdens are one-time burdens:

- *10 CFR 26.31(d)(1)(i)(D) and (d)(1)(ii): Record of forensic toxicologist review and certification of additional drug(s) to be included in the licensee or other entity's drug testing panel.*
- *10 CFR 26.31(d)(3)(iii)(A) and (d)(3)(iii)(C): Record of forensic toxicologist review and certification of lower drug testing cutoff levels than specified by Part 26, and inclusion of cutoff levels in the FFD policy and procedures.*

- *10 CFR 26.153(e): Record of pre-award inspection of new HHS lab (completed prior to awarding contract for services).*
- *10 CFR 26.153(f): Record that Part 26 specified requirements included in licensee's or other entity's contract with HHS lab.*
- *10 CFR 26.713(g): Documentation on testing for additional drugs as permitted under section 26.31(d)(1), use of more stringent testing cutoff levels as permitted under section 26.31(d)(3), or both.*

Burdens removed from Table 1:

- *10 CFR 26.29(b): Complete initial training on FFD policy and take comprehensive examination.* The previous clearance incorrectly accounted for this annual burden as one-time burden in Table 1. This burden is now accounted for in Table 4, "Annual Third-Party Disclosure Burden."
- *10 CFR 26.29(c)(2): Complete annual refresher training on FFD policy.* The previous clearance incorrectly accounted for this annual burden as one-time recordkeeping burden in Table 1. This burden is now accounted for in Table 4, "Annual Third-Party Disclosure Burden."
- *10 CFR 26.37(b): Obtained signed consent for release of information.* This is not a one-time burden. This annual burden is already accounted for in Table 2, "Annual Recordkeeping Burden."
- *10 CFR 26.403(a): Provide FFD policy to individuals subject to a reactor construction site D&A testing program.* The previous clearance incorrectly accounted for this annual burden as one-time burden in Table 1. This burden is now accounted for in Table 2, "Annual Recordkeeping Burden."

Table 2, Annual Recordkeeping Burden

The burden estimate in Table 2 decreased by approximately 29.7 percent (from 314,177 hours to 220,887 hours).

Changes resulted from decommissioning, the number of HHS labs and LTFs used for testing, and the number of activities conducted (e.g., samples submitted, background checks conducted, consent forms completed, documents associated with MRO reviews). Corrections to a number of inaccurate assumptions had the largest impacts on burden estimate changes (see significant burden estimate changes below).

When possible, the NRC staff adjusted burden-hour estimates for activities to correlate more precisely with the level of effort to create and maintain required records and reports. On March 31, 2008, the NRC published a major revision to Part 26 (73 FR 16966), with implementation of the rule required by 2009. Since that time, NRC staff has gained extensive knowledge and experience with the implementation of the rule by licensees and other entities. In addition, the implementation of the e-reporting system to uniformly collect annual D&A and fatigue reporting

information under sections 26.203(e), 26.417(b)(2), and 26.717 has vastly improved the precision and accuracy of estimations included in this clearance.

In the previous clearance, the NRC staff estimated that two fatigue programs per year would voluntarily implement the 54-hour/week work control provision, and that these respondents would incur an annual reporting burden for information collection activities covered under section 26.203(a)-(c). All fatigue management programs have implemented the 54-hour/week work control provision and no further activity is anticipated, resulting in a reduction of 22 hours of annual recordkeeping burden.

Significant burden estimate changes in Table 2:

- *10 CFR 26.29(b): Record of training completion (initial training on FFD policy) and results of comprehensive examination.* The previous clearance estimated burden for this activity at 2.0 hours per D&A testing program, and estimated an additional 160 hours per D&A testing program under section 26.713(b)(1) for “records of FFD training and examinations under section 26.29.” In this clearance, the NRC staff has combined the burden for these requirements under section 26.29(b) and calculated estimated burden based on the number of individuals that complete training each year. This change to the burden calculation method resulted in an increase of 411 hours in total estimated annual burden for this recordkeeping requirement.
- *10 CFR 26.29(c)(2): Record of training completion (annual refresher training on FFD policy).* The previous clearance estimated burden for this activity at 2.0 hours per D&A testing program, and estimated an additional 160 hours per D&A testing program under section 26.713(b)(1) for “records of FFD training and examinations under section 26.29.” In this clearance, the NRC staff has chosen to include all burden for these requirements under section 26.29(c)(2) and to calculate estimated burden on a per person basis. This change to the burden calculation method resulted in an increase of 1,168 hours in total estimated annual burden for this recordkeeping requirement.
- *10 CFR 26.31(b)(1)(v): Record results of behavioral observation for FFD program personnel.* The previous clearance estimated 80 hours of burden per D&A testing program. This provision simply requires that FFD program personnel staff be subject to a behavioral observation program (BOP). The burden associated with BOP identification of potential impairment already is accounted for under section 26.189(c) in Table 2. This assumption change reduced estimated annual burden by 2,240 hours.
- *10 CFR 26.53(h): Record that written consent obtained from each individual before initiating any actions under Subpart C.* The previous clearance estimated that each licensee or other entity spent 30 minutes to file a signed consent form received from an individual. This assumption incorrectly accounted for this third-party disclosure burden (i.e., the individual reads the consent form and signs it), which is already accounted for in Table 4, Annual Third-Party Disclosure Burden. For this clearance, licensee or other entity burden to file a signed consent form is estimated at 3 minutes per applicant. This assumption change reduced estimated annual burden by 42,895 hours.
- *10 CFR 26.75(i): Record of temporary administrative withdrawal of an individual's authorization due to an initial positive test result for marijuana and/or cocaine at an LTF.*

The previous clearance assumed that this recordkeeping requirement applied to all D&A testing programs; however, this requirement only applies to LTFs. For this clearance, no licensees or other entities with an LTF utilize this policy. This assumption change reduced estimated annual burden by 2,240 hours.

- *10 CFR 26.117(c) – (e): Collector prepares ID labels and CCF forms for specimen shipment.* The previous clearance underestimated burden for this activity at 60 hours per D&A testing program. In this clearance, the NRC staff has calculated estimated burden based on the number of individuals tested each year. This change to the burden calculation method resulted in an estimated increase in annual burden by 3,214 hours.

Significant burdens eliminated from Table 2

- *10 CFR 26.33: Behavioral observation program.* Burden already accounted for under section 26.189(c) in Table 2. Elimination of this duplicative burden resulted in a reduction of 11,200 hours of annual burden.
- *10 CFR 26.713(a)(1): Records of self-disclosures, employment histories, and suitable inquiries (under sections 26.55, 26.57, 26.59, and 26.69) that result in the granting of authorization.* Burden already accounted for under sections 26.61(a) and 26.63(a), (c), and (e) in Table 2. Elimination of this duplicative burden resulted in a reduction of 2,240 hours of annual burden.
- *10 CFR 26.713(b)(2): Records of audits, audit findings, and corrective actions taken under section 26.41.* Burden already accounted for under sections 26.41(a)-(d), (f) and (g) in Table 2. Elimination of this duplicative burden resulted in a reduction of 2,240 hours of annual burden.
- *10 CFR 26.713(f): Records of background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel conducted under section 26.31(b)(1)(i).* Burden already accounted for under section 26.31(b)(1)(i). Elimination of this duplicative burden resulted in a reduction of 2,240 hours of annual burden.
- *10 CFR 26.713(g): Documentation on testing for additional drugs as permitted under section 26.31(d)(1), use of more stringent testing cutoff levels as permitted under section 26.31(d)(3), or both.* This is a one-time burden incurred whenever a licensee or other entity chooses to modify the testing panel, testing cutoff levels, or both. The previous clearance overestimated burden at 40 hours of annual burden per FFD program. Elimination of this duplicative burden resulted in a reduction of 1,120 hours of annual burden.
- *10 CFR 26.715(b)(3): Retain LTF QA/QA records.* An inaccurate description of this requirement in the previous clearance resulted in an incorrect assumption that it applied to all D&A testing programs. It only applies to D&A testing programs that use an LTF. This assumption change reduced estimated annual burden by 2,640 hours.
- *10 CFR 26.715(b)(5): Retain all test data from LTF (including calibration curves and any calculations used in determining test results).* An inaccurate description of this

requirement in the previous clearance resulted in an incorrect assumption that it applied to all D&A testing programs. It only applies to D&A testing programs that use an LTF. This assumption change reduced estimated annual burden by 5,280 hours.

- *10 CFR 26.715(b)(6): LTF test reports.* An inaccurate description of this requirement in the previous clearance resulted in an incorrect assumption that it applied to all D&A testing programs. It only applies to D&A testing programs that use an LTF. This assumption change reduced estimated annual burden by 5,280 hours.
- *10 CFR 26.715(b)(7): LTF performance testing records.* An inaccurate description of this requirement in the previous clearance resulted in an incorrect assumption that it applied to all D&A testing programs. It only applies to D&A testing programs that use an LTF. This assumption change reduced estimated annual burden by 1,760 hours.
- *10 CFR 26.715(b)(10): Records of preventative maintenance on LTF instruments.* An inaccurate description of this requirement in the previous clearance resulted in an incorrect assumption that it applied to all D&A testing programs. It only applies to D&A testing programs that use an LTF. This assumption change reduced estimated annual burden by 1,760 hours.
- *10 CFR 26.715(b)(12): LTF retains computer-generated data.* An inaccurate description of this requirement in the previous clearance resulted in an incorrect assumption that it applied to all D&A testing programs. It only applies to D&A testing programs that use an LTF. This assumption change reduced estimated annual burden by 2,640 hours.

Newly identified burdens added to Table 2:

- *10 CFR 26.39(b): D&A testing program provides notice to an individual of the grounds of an FFD policy violation determination and review procedures.* This requirement was not included in the previous clearance, but burden for this activity was accounted for under sections 26.75(a) - (d), (e)(2) and (g); 26.713(a)(2), and 26.713(c) in Table 2.
- *10 CFR 26.137(d)(6): LTF records that 1 in 10 specimens that test negative on initial validity testing is sent to an HHS lab for testing as part of the LTF's QA program.* The previous clearance did not include this burden. Instead, the previous clearance accounted for the burden of this QA activity under validity screening testing in section 26.137(b)(3). Because no LTFs conduct validity screening testing, the burden for this same QA activity has been correctly moved to section 26.137(d)(6) for initial validity testing.
- *10 CFR 26.168(a): Maintain documentation of HHS lab certification of BPTS formulation.* The previous clearance did not account for this licensee or other entity burden. The previous clearance assumed this activity only applied as third-party burden under Table 4.
- *10 CFR 26.168(i)(2): Licensee or other entity completes (custody-and-control form) 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.* The previous clearance incorrectly listed this activity under Table 4 as third-party burden incurred by HHS labs. This burden is only

incurred by the licensee or other entity when preparing a BPTS for shipment to an HHS lab for testing.

- *10 CFR 26.403(a): Updates to FFD policy and procedures (reactor construction site D&A testing program).* The previous clearance did not account for this licensee or other entity burden. An analogous burden for D&A testing programs is included in Table 2 under section 26.27(c).
- *10 CFR 26.403(a): Provide FFD policy to individuals subject to a reactor construction site D&A testing program.* The previous clearance incorrectly accounted for this annual burden as one-time burden in Table 1.
- *10 CFR 26.417(b)(1) Maintain documentation on a 24-hour event report to the NRC.* The previous clearance did not include a reference to this recordkeeping requirement.

Table 3, Annual Reporting Burden

Estimated burden remained consistent with the previous clearance, only increasing by approximately 3 hours per year (from 6,165 hours to 6,168 hours).

Table 4, Annual Third-Party Burden

Burden in Table 4 increased by 62 percent (from 303,559 hours to 492,029 hours) and was primarily due to the inclusion of missing training burdens in section 26.29(b) and (c)(2).

Significant changes in burden:

- *10 CFR 26.29(b): Complete initial training on FFD policy and take comprehensive examination.* The previous clearance did not include this annual burden (it was included as one-time burden for a new D&A testing program in Table 1, but no new programs were accounted for in that clearance). Although this activity is completed one time for each individual applying for access to a D&A testing program, a program grants access to new individuals each year (thus, this is an annual burden). The NRC staff estimates 81,219 individuals will complete this training each year, with an estimated increase in annual burden of 162,439 hours.
- *10 CFR 26.29(c)(2): Complete annual refresher training on FFD policy.* The previous clearance did not include this annual burden (it was included in Table 1 as one-time burden for a new D&A testing program). The NRC staff estimates that 103,933 individuals complete this training each year, with an estimated increase in annual burden of 155,899 hours.
- *10 CFR 26.31(b)(1)(i): Individual applying for access to serve as FFD program personnel provides background check information.* An inaccurate description of this requirement resulted in an incorrect assumption that it applied to all 93,890 individuals applying for authorization each year. The requirement only applies to individuals designated as FFD program personnel (a very small subset of individuals applying for authorization each year). The assumption change resulted in the annual estimated burden for this activity decreasing from 93,890 hours to 335 hours per year.

Missing burdens added in Table 4

- *10 CFR 26.29(b): Complete initial training on FFD policy and take comprehensive examination.* Change described in the previous section on significant burden changes in Table 4.
- *10 CFR 26.29(c)(2): Complete annual refresher training on FFD policy.* Change described in the previous section on significant burden changes in Table 4.
- *10 CFR 26.715(a): Documentation of all aspects of HHS lab testing process, not specified elsewhere in section 26.715(b).* The previous clearance incorrectly included this annual third-party disclosure burden in Table 2.
- *10 CFR 26.715(b)(1): Retain personnel files on HHS lab staff.* The previous clearance incorrectly included this annual third-party disclosure burden in Table 2.
- *10 CFR 26.715(b)(2): Retain HHS lab chain-of-custody documents.* The previous clearance incorrectly included this annual third-party disclosure burden in Table 2.
- *10 CFR 26.715(b)(3): Retain HHS lab QA/QC records.* The previous clearance incorrectly included this annual third-party disclosure burden in Table 2.
- *10 CFR 26.715(b)(4): Retain HHS lab superseded procedures.* The previous clearance incorrectly included this annual third-party disclosure burden in Table 2.
- *10 CFR 26.715(b)(5): Retain all test data from HHS lab (including calibration curves and any calculations used in determining test results).* The previous clearance incorrectly included this annual third-party disclosure burden in Table 2.
- *10 CFR 26.715(b)(6): HHS lab test reports.* The previous clearance incorrectly included this annual third-party disclosure burden in Table 2.
- *10 CFR 26.715(b)(7): HHS lab performance testing records.* The previous clearance incorrectly included this annual third-party disclosure burden in Table 2.

Burdens eliminated from Table 4

- *10 CFR 26.31(d)(6): Donor provides written permission to conduct another analysis or test with specimen.* The previous clearance incorrectly described this requirement, which lists limitations on the testing of a donor's specimen but does not include any third-party disclosure burden.
- *10 CFR 26.168(i)(2): Licensee or other entity completes 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.* The previous clearance incorrectly listed this activity under Table 4 as third-party burden incurred by HHS labs. This requirement has been moved to Table 2.

The estimated burden-hour cost for the current clearance period is \$265 (see 10 CFR 170.20, "Average Cost per Professional Staff Hour"), which is 2.6 percent less than the \$272 burden-hour cost used for the previous clearance period.

16. Publication for Statistical Use

None.

17. Reasons for Not Displaying the Expiration Date

NRC Forms 890, 891, and 892 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. For this reason, there are no data instruments on which to display an OMB expiration date.

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)**

| Section | Number of Programs | Burden Hours per Program (Annualized) ⁵ | Total Burden Hours (Annualized) |
|---|---|--|---------------------------------|
| 26.27(a): Develop FFD policy statement | 0 programs | 112 | 0 |
| 26.27(a): Develop FFD procedures | 0 programs | 212 | 0 |
| 26.29(a) and (b): Develop FFD training course and exam | 0 programs | 100 | 0 |
| 26.31(b)(1)(v): Develop behavioral observation program (BOP) procedures | Burden accounted for under section 26.27(a) | | |
| 26.31(d)(1)(i)(C): Develop rigorous testing procedures to ensure that the MRO can evaluate the use of substances not included in the NRC-required testing panel (if additional substance testing is performed) | | | |
| 26.31(d)(1)(i)(D) and (d)(1)(ii): Documentation of forensic toxicologist review and certification of additional drug(s) to be included in the licensee or other entity's drug testing panel | 3 programs ⁶ | 5.3 | 16 |
| 26.31(d)(3)(iii)(A) and (d)(3)(iii)(C): Documentation of forensic toxicologist review and certification of lower drug testing cutoff levels than specified in Part 26, and inclusion of cutoff levels used in the FFD policy and procedures | 3 programs ⁷ | 5.3 | 16 |
| 26.37(a): Develop a system of files and procedures to protect personal information collected under Part 26 | 0 programs | 24 | 0 |

⁵ An annualized one-time burden is calculated by dividing each burden hour estimate by the 3 years covered by this clearance. While the recordkeeping burdens in Table 1 are not applicable to most D&A testing programs or any fatigue management programs during this clearance period, the "Burden Hours per Program (Annualized)" information is retained for future reference.

⁶ The NRC staff estimates that one (1) full FFD D&A testing program per year will test for additional substances beyond the minimum drug-testing panel required by Part 26. The previous clearance incorrectly included this one time burden in Table 2 as annual recordkeeping burden. The previous clearance also estimated that seven (7) FFD programs over 3 years would test for additional substances. FFD program performance data from CY 2013 through CY 2015 demonstrated that fewer programs implemented expanded drug testing panels.

⁷ The NRC staff estimates that one (1) D&A testing program per year will use more stringent drug testing cutoff level(s) than required by Part 26. The previous clearance estimated two (2) D&A testing programs per year would use more stringent drug testing cutoff levels. The previous clearance incorrectly included this one time burden in Table 2 as annual recordkeeping burden.

**Table 1
One-Time Recordkeeping Burden
(Annualized)**

| Section | Number of Programs | Burden Hours per Program (Annualized) | Total Burden Hours (Annualized) |
|--|--|--|--|
| 26.39(a) and (b): Develop procedures for the review of a determination that an individual has violated the FFD policy | 0 programs | 120 ⁸ | 0 |
| 26.85(a): Develop urine collector qualification training | 0 programs | 13.3 | 0 |
| 26.85(b): Develop alcohol collector qualification training | 0 programs | 5.3 | 0 |
| 26.127(a) – (e): Develop LTF procedures for specimen handling and chain-of-custody, assays performed, instrument and test setup, and remedial actions for systems and testing device | 0 programs | 80 | 0 |
| 26.137(a): Develop LTF procedures for quality assurance/quality control (QA/QC) program | 0 programs | 13.3 | 0 |
| 26.153(e): Record of pre-award inspection of new HHS lab (completed prior to awarding contract for testing services) | 3 programs ⁹ | 13.3 | 40 |
| 26.153(f): Record that Part 26 specified requirements included in a licensee's or other entity's contract with a new HHS lab | 3 programs | 13.3 | 40 |
| 26.155(a)(1), (a)(3) – (a)(5), (b), (c), (e), and (f): Confirm HHS lab personnel qualifications and procedures pursuant to HHS laboratory certification also meet Part 26 requirements (new HHS lab) | Burden accounted for under section 26.153(e) | | |

8 The NRC staff has increased to 360 hours (annualized over 3 years = 120 hours) the estimated burden to develop the procedures for reviewing FFD policy violations. The previous clearance estimated 40 hours of effort (annualized over 3 years = 13.3 hours per year). This change is consistent with the existing one-time burden estimate for a reactor construction site D&A testing program to develop these same procedures under section 26.413.

9 NRC review of FFD program performance information from CY 2013 through CY 2015 indicated that an average of one (1) D&A testing program per year changed one of its two existing HHS labs. The previous clearance estimated that each FFD program obtained a new HHS lab each year. This assumption also applies to the requirements in Table 1 for sections 26.153(f); 26.155(a)(1), (a)(3)-(a)(5), (b), (c), (e) and (f); 26.157(a) – (e); and 26.159(a), (c), (e), and (f). The previous clearance incorrectly listed this one-time recordkeeping activity in Table 2, "Annual Recordkeeping Burden".

**Table 1
One-Time Recordkeeping Burden
(Annualized)**

| Section | Number of Programs | Burden Hours per Program (Annualized) | Total Burden Hours (Annualized) |
|--|--|---------------------------------------|---------------------------------|
| 26.157(a) – (e): Confirm HHS lab procedures in place for accession, receipt, shipment, and testing of specimens pursuant to HHS laboratory certification also meet Part 26 requirements (new HHS lab) | | | |
| 26.159(a), (c), (e), (f): Confirm HHS lab procedures for specimen security, chain of custody, and preservation in place pursuant to HHS laboratory certification requirements also meet Part 26 requirements (new HHS lab) | | | |
| 26.203(a): Prepare fatigue management policy (in addition to 26.27 burden) | 0 programs ¹⁰ | 7.3 | 0 |
| 26.203(b): Prepare fatigue management procedures (in addition to 26.27 burden) | 0 programs | 1.7 | 0 |
| 26.203(c): Prepare training on fatigue management | 0 programs | 2.0 | 0 |
| 26.205(b): Develop work hour tracking system | 0 programs | 7.7 | 0 |
| 26.205(c): Develop individual work scheduling system | 0 programs | 2.0 | 0 |
| 26.401(b): Prepare a reactor construction site D&A testing program plan | Burden accounted for under section 26.403(a) and (b) | | |
| 26.403(a): Develop FFD policy statement (reactor construction site D&A testing program) | 0 programs | 112 | 0 |
| 26.403(b): Develop FFD procedures (reactor construction site D&A testing program) | 0 programs | 216 | 0 |
| 26.405(d): Record of testing for specified drugs, adulterants, and alcohol, at Part 26 specified cutoff levels | Burden accounted for under section 26.403(a) | | |

¹⁰ All fatigue management programs have implemented the 54-hour/week work hour control provision and no additional changes are anticipated. For the prior clearance, the NRC staff estimated that two (2) fatigue management programs each year would voluntarily implement the 54-hour/week work hour control provision. This statement also applies to section 26.203(b) and (c), and section 26.205(b) and (c) requirements in Table 1.

**Table 1
One-Time Recordkeeping Burden
(Annualized)**

| Section | Number of Programs | Burden Hours per Program (Annualized) | Total Burden Hours (Annualized) |
|---|---|---------------------------------------|---------------------------------|
| 26.405(e): Develop specimen collection and D&A testing procedures to protect the donor's privacy, integrity of the specimen, and stringent quality controls to ensure accurate test results | Burden accounted for under section 26.403(b) | | |
| 26.406(a), (b), and (d): Develop a fitness monitoring program (applies if reactor construction site D&A testing program does not conduct random testing) | 0 programs | 40 | 0 |
| 26.406(c): Develop procedures for fitness monitors (applies if reactor construction site D&A testing program does not conduct random testing) | 0 programs | 40 | 0 |
| 26.407: Develop procedures for behavioral observation (reactor construction site D&A testing program) | 0 programs | 40 | 0 |
| 26.411(a): Develop procedures for maintaining a system of files to protect personal information collected under Subpart K of Part 26 | 0 programs | 40 ¹¹ | 0 |
| 26.413: Develop procedures for the review of determinations of FFD violations (reactor construction site D&A testing program) | 0 programs | 120 | 0 |
| 26.713(g): Documentation on testing for additional drugs as permitted under section 26.31(d)(1), use of more stringent testing cutoff levels as permitted under section 26.31(d)(3), or both. | Burden accounted for under section 26.31(d)(1)(i)(D) and (d)(1)(ii), and section 26.31(d)(3)(iii)(A) and (d)(3)(iii)(c) | | |
| | | TOTAL | 112 |

¹¹ The previous clearance mistakenly excluded this burden.

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|--------------------------------|--------------------------------------|----------------------------------|
| 26.4(j): For personnel granted authorization by a licensee, who are covered by the D&A testing program regulated by a State or Federal agency – (1) record of training that demonstrates section 26.29(a) training requirements met (if not already covered by the program); (2) record of notice of any FFD policy violation | 33.5 ¹² | 2.0 | 67 |
| 26.27(b): Make FFD policy statement readily available to subject personnel | 26 programs ¹³ | 16.0 | 416 |
| 26.27(c): Updates to FFD policy and procedures | 26 programs | 80.0 ¹⁴ | 2,080 |
| 26.27(d): Provide FFD policy and procedures to NRC for review (performed during periodic inspections) | 26 programs | 4.0 | 104 |
| 26.29(b): Record of training completion (initial training on FFD policy) and results of comprehensive examination | 26 programs | 104.1 ¹⁵ | 2,707 |
| 26.29(c)(2): Record of training completion (annual refresher training on FFD policy) | 26 programs | 133.2 ¹⁶ | 3,464 |

12 The NRC staff estimates that 50 percent of the 67 sites implementing a D&A testing program grant authorization to offsite response personnel subject to a State or Federal agency D&A testing program (e.g., emergency fire and medical response personnel, SSNM transporters). The previous clearance underestimated the burden for this activity because it calculated burden on a D&A testing program basis rather than on a site-specific basis.

13 The NRC staff estimates 26 D&A testing programs for this clearance period. The previous clearance estimated 28 D&A testing programs.

14 The NRC staff estimates that each D&A testing program will spend 80 hours per year updating the FFD policy and procedures. The previous clearance estimated 8.0 hours in annual burden per program. The majority of burden for FFD policy and procedures updates was imprecisely included under section 26.713(d) "Retain superseded FFD policies and procedures," which estimated 80 hours in annual burden per program. For this clearance, 80 hours of annual burden per program is accounted for under section 26.27(c) for policy and procedures updates, with 8.0 hours of annual burden per program accounted for under section 26.713(d) for retaining superseded FFD policies and procedures.

15 The NRC staff estimates that a D&A testing program will spend 2 minutes (0.033 hour) per individual for the licensee or other entity to print and retain a record detailing training completion and examination results. The NRC staff estimates that 81,219 individuals will complete training each year. This 81,219 value is the average number of individuals pre-access tested from CY 2013 through CY 2015 (i.e., 80,763 in CY 2013; 82,711 in CY 2014; and 80,184 in CY 2015). The previous clearance under estimated burden for the recordkeeping requirements associated with initial training and examination completion. The NRC staff estimated per D&A testing program, 2.0 hours in annual burden under section 26.29(b) and 160 hours in annual burden under section 26.713(b)(1) for "records of FFD training and examinations under section 26.29." Note, the estimated burden for section 26.713(b)(1) also accounted for recordkeeping burden for section 26.29(c)(2).

16 The NRC staff estimates the same 2 minute (0.033 hour) burden per individual for the licensee or other entity to print and retain a record detailing training completion. The NRC staff estimates that 103,933 individuals subject to a

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|--|--|--------------------------------------|----------------------------------|
| 26.29(d): Record acceptance of FFD training from other licensees' programs | 26 programs | 4.0 | 104 |
| 26.31(b)(1)(i): Records of background investigations, credit and criminal history checks, and psychological assessments performed on individuals designated as FFD personnel | 26 programs | 16.0 ¹⁷ | 416 |
| 26.31(b)(1)(v): Record results of behavioral observation for FFD program personnel | Burden accounted for under section 26.189(c) | | |
| 26.31(d)(3)(ii): Document LTF technician qualifications to perform validity and drug tests | Burden accounted for under section 26.125(b) and (c) | | |
| 26.33: Behavioral observation records | Burden accounted for under section 26.189(c) ¹⁸ | | |
| 26.35(c): Record of written waiver of right to privacy from individuals given to the Employee Assistance Program (EAP) | 13 programs | 2.0 | 26 |
| 26.35(c): Record of EAP disclosure to a licensee or other entity that an individual poses an immediate hazard, or who has waived in writing the right to privacy | 13 programs | 1.0 | 13 |
| 26.37(b)(1): Record of signed consent from individual to disclose information collected under Part 26 to the individual's representative on an FFD matter | 26 programs | 2.5 ¹⁹ | 65 |

D&A testing program (i.e., individuals subject to random testing) will complete annual refresher training. The 103,933 value is the annual average number of individuals subject to a random testing program from CY 2013 through CY 2015 (i.e., 104,728 in CY 2013; 104,037 in CY 2014; and 103,033 in CY 2015). The previous clearance underestimated burden for the recordkeeping requirements associated with annual refresher training. The NRC estimated per D&A testing program, 2.0 hours in annual burden under section 26.29(c)(2) and 160 hours in annual burden under section 26.713(b)(1) for "records of FFD training and examinations under section 26.29." Note, the estimated burden for section 26.713(b)(1) also accounted for recordkeeping burden for section 26.29(b).

17 The NRC staff estimates that five (5) individuals per D&A testing program per year apply for authorization as FFD program personnel. A D&A testing program is estimated to spend 1.0 hour to review an applicant's records. The previous clearance overestimated burden for this activity by assuming that all individuals applying for access in a year would provide information under this requirement. This inaccurate assumption resulted in an overestimate of 93,555 hours in annual burden.

18 A record is created under the BOP when an FFD concern is identified by an individual and reported to FFD management so that action can be taken to assess the situation (e.g., a fitness determination, for-cause testing). The previous clearance overestimated annual burden for this activity at 400 hours per D&A testing program.

19 The NRC staff estimates that an individual will spend 15 minutes (0.25 hour) reviewing and signing a consent form to provide access to a representative to assist with an FFD violation. The NRC staff estimates that 258 individuals that test positive on random, for-cause, post-event, and follow-up testing would request assistance from a

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|--|--------------------------------|--------------------------------------|----------------------------------|
| 26.37(c): Record of signed release from subject individual to disclose personal information collected under Part 26 to other licensees or other entities | 26 programs | 40.0 | 1,040 |

representative. The 258 value is the average number of testing violations reported by D&A testing programs from CY 2013 through CY 2015. The previous clearance overestimated burden at 40 burden hours per FFD program per year.

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|---|-------------------------------|---------------------------|
| 26.37(d): FFD management provides records to individual on an FFD violation | 26 programs | 40.0 | 1,040 |
| 26.39(a): Maintain procedures for the review of FFD violation determinations | Burden accounted for under section 26.27(c) | | |
| 26.39(b): D&A testing program provides notice to an individual of the grounds of an FFD policy violation determination and review procedures | 26 programs | 87.3 ²⁰ | 2,271 |
| 26.39(d): If a review of an FFD violation finds in favor of the individual, the licensee or other entity updates records (delete or correct all inaccurate information) | 6 programs ²¹ | 16.0 | 96 |
| 26.39(e): C/V with a D&A testing program provides review procedures to each individual that has violated the FFD policy | 1 program ²² | 0.5 | 1 |
| 26.41(a), (b), and (c): Record of audits | Burden accounted for under section 26.41(f) and (g) | | |
| 26.41(d): Record of review of C/V audit results | 26 programs | 40.0 | 1,040 |
| 26.41(f): Document and report audit results | 26 programs | 40.0 | 1,040 |

²⁰ The previous clearance did not include this requirement. Instead, recordkeeping burden for violations of the FFD policy were accounted for under sections 26.75(a) – (e) and (g); 26.713(a)(2), and 26.713(c), with annual burden per D&A testing program estimated at 132 hours (12 hours + 80 hours + 40 hours). This 132-hour value overestimated burden per FFD policy violation.

In this clearance, the NRC staff consolidated all burden associated with FFD policy sanctions under section 26.39(b) and estimates 2.75 hours per individual with an FFD policy violation (i.e., 2.0 hours of FFD manager time + 0.75 hours of FFD staff time). The average number of individuals with a positive (drug and/or alcohol), adulterated, substituted, and refusal to test result from CY 2013 through CY 2015 is 826 (770 in CY 2013; 819 in CY 2014; and 888 in CY 2015).

²¹ NRC estimates that following a review that finds in favor of the individual, six (6) D&A testing programs per year will update relevant records for an individual to address inaccurate information on an FFD violation. The previous clearance estimated that all D&A testing program incurred this burden. The estimated burden per D&A testing program also has been reduced from 40 hours to 16 hours per event.

²² Only one C/V, the Institute of Nuclear Power Operations (INPO), maintains an independent D&A testing program under Part 26. All other C/Vs fall under the licensee or other entity D&A testing program and would not be subject to this recordkeeping requirement. INPO averages less than one positive test result per year (i.e., a total of two (2) individuals tested positive from CY 2013 through CY 2015). The previous clearance overestimated annual burden at 120 hours.

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|--|-------------------------|-------------------------------|---------------------------|
| 26.41(g): Sharing of audit reports – D&A testing programs may jointly conduct audits or accept audits of C/Vs and HHS labs conducted by other D&A testing programs (if the audit addresses the same services utilized by each D&A testing program) | 26 programs | 40.0 | 1,040 |
| 26.53(e)(2): Record that C/V informed licensee of the denial or termination of an individual's authorization | 1 program | 13.0 ²³ | 13 |
| 26.53(g): Record that C/Vs and other licensees informed of Part 26 violations | 0 programs | 8.0 | 0 |
| 26.53(h): Obtain and retain written consent from each individual before initiating any actions under Subpart C of Part 26 | 26 programs | 156.2 | 4,061 ²⁴ |
| 26.53(i): Individual applying for authorization is informed in writing of the reason(s) for the denial or termination of authorization | 26 programs | 21.8 | 568 ²⁵ |

²³ See previous footnote discussion on INPO. The previous clearance overestimated burden at 120 hours per year. This estimate is inconsistent with FFD program performance data. The estimated burden for a C/V to notify a D&A testing program of the termination of an individual's authorization is 30 minutes (0.5 hour) per program (26 D&A testing programs would be notified of each event).

²⁴ The NRC staff estimates that D&A testing programs will obtain written consent from 81,219 individuals per year. This value is the average number of individuals with pre-access tests from CY 2013 through CY 2015 (i.e., 80,763 in CY 2013; 82,711 in CY 2014; and 80,184 in CY 2015). Three minutes (0.05 hour) is the estimated burden for the licensee or other entity to file a signed consent form received from an individual before initiating a pre-access test (the previous clearance overestimated burden at 30 minutes (0.5 hour) per individual for this activity). The majority of burden for reading and signing the consent form is accounted for as third-party burden in Table 4. The previous clearance estimated 93,890 pre-access tests per year.

²⁵ The NRC staff estimates that 568 individuals per year who apply for authorization at D&A testing programs will have a pre-access testing violation (i.e., a positive test result for drug(s) and/or alcohol, an adulterated or substituted validity test result, or a refusal to test). The 568 value is the average number of pre-access testing violations reported in CY 2013 through CY 2015 (492 in 2013, 567 in 2014, and 644 in 2015). One hour is estimated per pre-access D&A testing violation. The previous clearance estimated 652 individuals per year had a pre-access testing violation.

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|---|--------------------------------------|----------------------------------|
| 26.55(a)(1) – (a)(2): Initial authorization 26.57(a)(1) – (a)(2): Authorization update 26.59(a)(1) – (a)(2): Authorization reinstatement For each individual applying for authorization, a record of a completed self-disclosure, employment history, and suitable inquiry is maintained | Burden accounted for under sections 26.61(a), (a)(1), and (a)(2), and 26.63(a), (c) and (e) | | |
| 26.59(c)(1): Obtain, review, and retain an applicant's self-disclosure | Burden accounted for under section 26.61(a), (a)(1), and (a)(2) | | |
| 26.61(a), (a)(1), and (a)(2): Obtain, review, and retain an applicant's written self-disclosure and employment history | 26 programs | 1,561.9 | 40,610 ²⁶ |
| 26.61(b) and (c): Specify the information to be collected in the self-disclosure and employment history | Burden accounted for under section 26.61(a), (a)(1), and (a)(2) | | |
| 26.63(a), (c), and (e): Obtain, review, and retain an applicant's suitable inquiry | 26 programs | 1,516.9 | 40,610 ²⁷ |
| 26.63(c)(2): Obtain, review, and retain information on an applicant's U.S. military service (i.e., form DD 214) | 26 programs | 4.0 | 104 |
| 26.63(c)(3): Document inability to obtain information from an applicant's past employer(s) | 26 programs | 3.0 | 78 |
| 26.63(d) and (e): Maintain documentation of denial or unfavorable termination of authorization from other FFD programs | 26 programs | 1.0 | 26 |
| 26.63(f): Specifies the time periods that a suitable inquiry must cover (for initial authorization, authorization update, and authorization reinstatement) | Burden accounted for under section 26.63(a), (c), and (e) | | |

26 The NRC staff estimates that a licensee or other entity will spend an average of 30 minutes (0.5 hour) to review, verify, and file information provided in an applicant's self-disclosure and employment history. This activity is completed for each of the 81,219 individuals per year that apply for authorization at D&A testing programs (i.e., the average number of pre-access tests performed from CY 2013 through CY 2015). The previous clearance estimated 33,516 hours of burden for this activity.

27 The NRC staff estimates that a D&A testing program will spend an average of 30 minutes (0.5 hour) to review, verify, and retain information provided in an applicant's suitable inquiry. This activity is completed for each of the 81,219 individuals estimated to apply for authorization at D&A testing programs per year (i.e., individuals pre-access tested).

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|--|--------------------------------------|----------------------------------|
| 26.65(d) and (e): Record of reinstatement or administrative withdrawal of authorization | 26 programs | 4.0 | 104 |
| 26.65(f): Authorization reinstatement after an interruption – record of administrative withdrawal of authorization under section 26.65(d)(1)(ii) or (e)(2)(iii)(B) | 26 programs | 1.0 | 26 |
| 26.67 Record of random D&A testing of persons who have applied for authorization and who have received a pre-access test, but who have yet to be granted authorization | Burden accounted for under section 26.183(d)(2)(i) | | |
| 26.69(b) and (c)(1): Authorization following a 1 st or 2 nd positive drug or alcohol test result, or if other PDI is identified – obtain, review, and retain an applicant’s self-disclosure and employment history | Burden accounted for under section 26.61(a) | | |
| 26.69(c)(2): Record that the licensee or other entity identified and resolved PDI (not reviewed and favorably resolved by a previous licensee or other entity) | 26 programs | 62.5 ²⁸ | 1,624 |
| 26.69(c)(3): Record that the licensee or other entity verified that an applicant with a prior FFD testing violation (i.e., a 5-year denial for a 2 nd positive result) has abstained from substance abuse for at least 5 years | Burden accounted for under section 26.69(c)(4) | | |

²⁸ The NRC staff estimates that potentially disqualifying FFD information (PDI) is identified in the applications of 812 individuals each year (i.e., 1 percent of the 81,219 individuals that annually apply for authorization at D&A testing programs) and that a D&A testing program will spend 2.0 hours per application to resolve identified PDI.

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|---|--------------------------------------|----------------------------------|
| 26.69(c)(4): Record that an SAE conducted a determination of fitness and concluded that an applicant with PDI is fit to safely and competently perform duties (i.e., evaluated clinically appropriate treatment and follow-up testing plans were developed by an SAE – for an applicant with a prior 1 st positive result; ensured treatment recommendations and follow-up testing from an SAE's determination of fitness are initiated – for an applicant with a prior 2 nd positive result; or verified the applicant is in compliance with and successfully completed any follow-up testing and treatment plans) | 26 programs | 40.0 | 1,040 |
| 26.69(c)(5): Record of negative results for pre-access D&A testing (needed prior to granting authorization) | 26 programs | 52.1 ²⁹ | 1,354 |
| 26.69(d): Record of reviewing official's determination on an applicant's request for access authorization | 26 programs | 24.0 | 624 |
| 26.69(e): Record that follow-up testing and treatment plan for an applicant from the D&A testing program of another licensee or other entity has been verified (that is treatment and follow-up testing successfully completed) | 26 programs | 8.0 | 208 |
| 26.69(e)(1): Record that information transmitted on testing and treatment plans to other FFD programs (at donor request) | 26 programs | 8.0 | 208 |
| 26.75(a) – (e), and (g): Records of sanctions for FFD violations | Burden accounted for under section 26.39(b) ³⁰ | | |

²⁹ The NRC staff estimates that the licensee's reviewing official will spend 1 minute (0.017 hour) per person to confirm that negative pre-access testing results have been received. An average of 81,219 individuals were pre-access tested from CY 2013 through CY 2015 (80,763 in CY 2013, 82,711 in CY 2014, and 80,184 in CY 2015). The previous clearance underestimated burden at 1.0 hour per D&A testing program per year.

³⁰ The previous clearance estimated 12.0 hours of annual burden per D&A testing program to account for records on FFD policy violations. In this clearance, the NRC staff accounts for this burden under section 26.39(b) "D&A testing program provides notice to an individual of the grounds of an FFD policy violation determination and review procedures."

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|--------------------------------|--------------------------------------|----------------------------------|
| 26.75(h): Record that an individual's authorization was administratively withdrawn due to impairment confirmed under section 26.189, or because the individual posed a safety hazard | 26 programs | 15.6 ³¹ | 405 |
| 26.75(j): Record of temporary administrative withdrawal of an individual's authorization due to an initial positive test result for marijuana and/or cocaine at an LTF | 0 programs ³² | 80.0 | 0 |
| 26.75(i)(3): Eliminate from an individual's record any references to a temporary administrative withdrawal of authorization due to an initial positive marijuana and/or cocaine test result at an LTF that did not confirm positive after testing at an HHS lab | 0 programs | 1.0 | 0 |
| 26.85(a) and (b): Training of urine and alcohol collectors and maintain training records in personnel files | 26 programs | 80.0 | 208 |
| 26.87(d)(3): If a collection site cannot be dedicated solely to collecting specimens, secure the portion of the facility when a specimen collection is in process and post a sign indicating access permitted only to authorized personnel | 26 programs | 1.0 | 26 |

³¹ A review of FFD program performance data from CY 2013 through CY 2015 indicates that an average of 405 for-cause tests were performed by D&A testing programs each year (424 in CY 2013, 418 in CY 2014, and 374 in CY 2015). The NRC staff estimates burden at 1.0 hour per for-cause testing instance. The previous clearance estimated 18.0 hours per D&A testing program.

³² Based on FFD program performance data, no D&A testing program with an LTF takes administrative action against an individual for an initial marijuana and/or cocaine positive test result. The previous estimate was incorrect in that it assumed that all 28 D&A testing programs took administrative action against an individual (only one D&A testing program using LTFs implemented this policy). Thus, the previous clearance overestimated burden by 2,160 hours. This assumption also applies to section 26.75(i)(3).

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|--|---|--------------------------------------|----------------------------------|
| 26.87(f)(1) and (f)(3) – (f)(5): Post a sign outside the collection area (if a public restroom used) and document on the custody-and-control form (CCF) the name of a same gender observer (in the exceptional event that a designated collection site is inaccessible, the collector is not the same gender as the donor, and a urine specimen must be immediately collected) | 2 programs ³³ | 0.5 | 1 |
| 26.89(a): Collector notifies FFD management that a donor failed to report to the collection site | 4 programs | 0.25 | 1 |
| 26.89(b)(1), (b)(2), and (b)(4): Record that ID and consent-to-testing form obtained | 26 programs | 1.5 | 39 |
| 26.89(b)(3): Record that FFD management informed that an individual did not present identification (pre-access testing) | 26 programs | 1.0 | 26 |
| 26.89(c): Collector documents on CCF a donor's refusal to cooperate with the collection process | Burden accounted for under section 26.107(b) | | |
| 26.91(c)(1) – (c)(3): Record of evidential breath testing (EBT) device test results | Burden accounted for under section 26.715(b)(2) | | |
| 26.91(e)(4): Record that results cancelled after EBT calibration check failure | 0 programs ³⁴ | 6.0 | 0 |
| 26.91(e)(5): EBT maintenance records | 26 programs | 6.0 | 156 |
| 26.93(a)(6): Document that alcohol pre-test questions communicated to the donor | 26 programs | 47.1 ³⁵ | 1,224 |
| 26.95(b)(5): Record donor identity for initial alcohol breath test | 26 programs | 47.1 ³⁶ | 1,224 |

³³ The NRC staff estimates that two (2) D&A testing programs per year will encounter this rare event. The previous clearance estimated that all D&A testing programs would encounter such an event each year.

³⁴ In the last 3 years, the NRC inspection process has not identified any instances of EBT calibration check failures that resulted in the cancellation of prior positive test results.

³⁵ The NRC staff estimates that 146,831 individuals will be alcohol tested each year by D&A testing programs. This value is the average number of tests conducted per from CY 2013 through CY 2015 (146,249 in CY 2013, 148,634 in CY 2014, and 145,610 in CY 2015). Prior to initiating an alcohol test, the collector is estimated to take 30 seconds (0.008 hour) to ask and document the communication of the pre-test questions. The previous clearance estimated 80 hours per D&A testing program.

³⁶ The NRC staff estimates that 146,831 individuals will be alcohol tested each year. Prior to initiating an alcohol

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|---|--------------------------------------|----------------------------------|
| 26.97(b)(2): Record reason for new oral fluid alcohol test | 0 programs ³⁷ | 0.25 | 0 |
| 26.97(c)(1): Document reason for failure of second oral fluid collection attempt | 0 programs | 0.25 | 0 |
| 26.97(d): Record results and alcohol oral fluid screening device used | 0 programs | 0.25 | 0 |
| 26.99(b): Record time of initial alcohol test of 0.02 percent or higher blood alcohol concentration (BAC) | Burden accounted for under section 26.715(b)(2) ³⁸ | | |
| 26.101(b)(7): Record time and BAC result of confirmatory alcohol test | | | |
| 26.103(b): Record that FFD management notified of a confirmatory alcohol test result of 0.01 to 0.02 percent BAC | 8 programs | 0.25 | 2 |
| 26.107(b): Collector documents on CCF any donor conduct during collection process indicating an attempt to tamper with a specimen, and notifies FFD management | 26 programs | 0.25 | 7 |
| 26.109(b)(3): Collector documents on CCF that donor was unable to provide a specimen in the 3-hour time allotted (i.e., a shy bladder), and notifies FFD management | 26 programs | 0.25 | 7 |
| 26.109(b)(4): Collector documents on CCF if a specimen (less than 30 mL) appears to be tampered with and/or donor behavior during collection indicated a possible subversion attempt, and notifies FFD management | Burden accounted for under section 26.107(b) | | |

test, the collector will positively identify the donor and document the donor's name – this activity is estimated to take 30 seconds (0.008 hour). The previous clearance overestimated burden at 80 hours per D&A testing program.

37 The NRC staff is not aware of any D&A testing program that conducts oral fluid alcohol screening testing. This assumption also applies to section 26.97(c)(1) and (d).

38 The EBT devices used by regulated entities automatically print the test result for each test completed. The only burden associated with this requirement is to maintain records, which already is accounted for under section 26.715(b)(2). This assumption also applies to section 26.101(b)(7).

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|--|--------------------------------------|----------------------------------|
| 26.111(b): Collector documents on CCF if specimen characteristics (color, clarity) indicate possible tampering by the donor | Burden accounted for under section 26.107(b) | | |
| 26.111(c): Collector documents on CCF unusual specimen temperature and/or observations during the collection indicating possible tampering, and notifies FFD management. | | | |
| 26.113(b)(3): Collector completes CCF for split-specimen collection | Burden accounted for under section 26.117(c) – (e) | | |
| 26.115(b): Collector documents on CCF approval from FFD manager or MRO to collect a specimen under direct observation | 26 programs | 0.5 | 13 |
| 26.115(d): Collector documents on CCF that observed collection performed and reason for the observed collection | Burden accounted for under section 26.115(b) | | |
| 26.115(f)(3): Collector documents on CCF the name of observer of directly observed collection | | | |
| 26.117(c) – (e): Collector prepares ID labels and CCF for specimen shipment | 26 programs | 188.2 ³⁹ | 4,894 |
| 26.119(a), (e), and (f): Written evaluation from the physician who performed a medical evaluation of a donor with a shy bladder (i.e., unable to provide a specimen of adequate volume in the allotted 3-hours) | 13 programs | 2.0 | 26 |
| 26.119(b): Record that MRO provided information and instructions to the physician who is to perform the examination of a donor with a shy bladder | 13 programs | 1.0 | 13 |
| 26.125(b) and (c): Records on the proficiency and qualifications of LTF personnel | 6 programs ⁴⁰ | 16.0 | 96 |

³⁹ The NRC staff estimates that a collector spends 2 minutes (0.033 hour) per specimen collection to prepare the specimen ID labels, CCF, and specimen packaging for shipment. The average number of specimen collections completed in a year, from CY 2013 through CY 2015, is 146,831. The previous clearance underestimated burden at 60 hours per D&A testing program.

⁴⁰ In 2015, one D&A testing program ceased using LTFs. The previous clearance reported that seven (7) D&A testing programs used an LTF for drug and validity testing.

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|--------------------------------|--------------------------------------|----------------------------------|
| 26.127(a) – (e): Maintaining LTF written procedures on the handling of specimens, chain-of-custody procedures, testing assays, instrument and device setup, and remedial actions for systems and testing devices. | 6 programs | 40.0 ⁴¹ | 240 |
| 26.129(a): Maintain documentation of access to secure areas of an LTF by all authorized individuals (i.e., an access log) | 6 programs | 4.0 | 24 |
| 26.129(b): LTF inspects specimen packages, CCFs, and obtains memorandum from specimen collectors to correct identified discrepancies | 6 programs | 0.5 | 3 |
| 26.129(b)(1): LTF record of report to senior licensee or other entity management of attempts to tamper with specimens in transit | 0 programs ⁴² | 1.0 | 0 |
| 26.129(d): LTF procedures for tracking specimen CCFs | 6 programs | 80.0 | 480 |
| 26.135(b): LTF record of direction from MRO to send the Bottle B of a split specimen to a second HHS lab for testing | 6 programs | 0.5 | 3 |
| 26.137(a): Record of QA/QC program and procedures for LTF | 6 programs | 4.0 | 24 |
| 26.137(b)(1)(ii): LTF documentation of performance testing of a device not approved by SAMHSA for point-of-collection testing | 0 programs ⁴³ | 40.0 | 0 |
| 26.137(b)(1)(iii): LTF documentation of annual test results for a device not approved by SAMHSA for point-of-collection testing | 0 programs | 20.0 | 0 |
| 26.137(b)(3): LTF records that 1 in 10 specimens that test negative on validity screening testing are sent to an HHS lab for testing as part of the LTF's QA program | 0 programs | 40.0 | 0 |

41 Based on improved knowledge of LTF testing practices, the NRC staff estimates that D&A testing program with an LTF spends an average of 40 hours each year maintaining testing procedures. The previous clearance estimated 200 hours per D&A testing program. These procedural revisions most likely would be associated with lessons learned, process improvements, and in response to internal audits of the LTF.

42 The NRC staff is not aware of any instances specimen tampering in route to the LTF from the collection site. These events would be reportable under section 26.719. The prior clearance estimated that six (6) D&A testing programs with an LTF incurred this burden.

43 The NRC staff is not aware of any LTF conducting point-of-collection validity screening tests. The previous clearance estimated two (2) programs performed validity screening tests that were not on the SAMHSA point-of-collection testing list. This assumption also applies to section 26.137(b)(1)(iii).

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|--|--------------------------------------|----------------------------------|
| 26.137(d)(6): LTF records that 1 in 10 specimens that test negative on initial validity testing are sent to an HHS lab for testing as part of the LTF's QA program | 6 programs ⁴⁴ | 40.0 | 240 |
| 26.137(e)(7): LTF documented procedures to protect against carryover material | Burden accounted for under section 26.127(a) – (e) | | |
| 26.137(f)(5): LTF records on testing errors | 6 programs | 8.0 | 48 |
| 26.137(h): LTF labeling of standards and controls | 6 programs | 40.0 | 240 |
| 26.139(d): Record that the LTF prepared a summary of test results for inclusion in the FFD annual program performance report submitted under section 26.717 | 6 programs | 40.0 | 240 |
| 26.153(g): Record of memorandum sent to the HHS lab explaining the use of non-Federal CCF | 26 programs | 0.5 | 13 |
| 26.159(b)(1): Record that the licensee or other entity received notice from the HHS lab within 24 hours of the lab identifying evidence of tampering of a specimen | 0 programs ⁴⁵ | 1.0 | 0 |
| 26.159(i): Record of written authorization to store specimens other than 1 year | 26 programs | 0.5 | 13 |
| 26.163(a)(2): Record that special analyses testing conducted on a dilute specimen and report of the test results | Burden accounted for under section 26.169(c)(1) | | |
| 26.165(b)(1): Record of a 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 lab | Burden accounted for under section 26.165(b)(6) | | |
| 26.165(b)(2): Record that MRO informed the donor of the opportunity to request the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen at a second HHS lab | Burden accounted for under section 26.185(c) | | |

44 The previous clearance did not include this burden. Instead, this burden was accounted for under section 26.137(b)(3). Because no LTFs conduct validity screening testing, the burden for this QA activity has been correctly accounted for under section 26.137(d)(6) for initial validity testing.

45 NRC has not received any section 26.719 reports on specimen tampering events during transportation of specimens from the collection site to the testing laboratory. These events would be reportable to the NRC staff under section 26.719. The previous clearance overestimated burden by assuming that all 28 D&A testing programs incurred this burden.

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|---|-------------------------------|---------------------------|
| 26.165(b)(3): Donor's written permission provided to the MRO for the retesting of an aliquot of a single specimen or testing of the Bottle B split specimen at a second HHS lab | Burden accounted for under section 26.165(b)(6) | | |
| 26.165(b)(4): Record that the donor presented documentation to the MRO on the inability to submit a timely request to initiate specimen retesting at a second HHS lab | Burden accounted for under section 26.185(c) | | |
| 26.165(b)(6): MRO reviews HHS lab results on the retesting of an aliquot of a single specimen or testing of the Bottle B split specimen, informs the donor of the results, and notifies FFD management | 26 programs | 1.2 ⁴⁶ | 31 |
| 26.165(c)(4): Results report received from the second HHS lab that performed retesting an aliquot of a single specimen or the testing of the Bottle B split specimen | Burden accounted for under section 26.165(b)(6) | | |
| 26.165(f)(1): Adjustments to personnel files and written notifications regarding the results of retesting an aliquot of a single specimen or testing of the Bottle B split specimen, including temporary administrative actions | 0 programs | 6.0 | 0 |
| 26.165(f)(1)(iv) and (f)(2): Written record and notice that records purged of references to temporary administrative action | 0 programs | 8.0 | 0 |

46 The NRC staff estimates that 31 individuals each year will request a retest of a specimen that is drug positive, adulterated, or substituted. The 31 value is 5 percent of the 621 test results that meet this category from CY 2013 through CY 2015. An MRO is estimated to spend 1.0 hour to contact the initial laboratory (LTF or HHS lab) that conducted testing to process the request to send the donor's specimen 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. The previous clearance estimated 3.0 burden hours per program for this activity.

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|---|-------------------------------|---------------------------|
| 26.167(f)(3): Record received from the Responsible Person of an HHS lab on a false positive BPTS testing error (determined to be technical or methodological), demonstrating that retesting of all positive, adulterated, substituted, and invalid specimens from the time of final resolution of the error back to the time of the last satisfactory performance test cycle has been completed | 0 programs ⁴⁷ | 1.0 | 0 |
| 26.168(a): Maintain documentation of HHS lab certification of BPTS formulation | 26 programs | 2.6 | 67 ⁴⁸ |
| 26.168(i)(2): Licensee or other entity completes 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 | 26 programs | 34.4 | 893 ⁴⁹ |
| 26.169(a): Records of reports of test results by HHS lab | Burden accounted for under section 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(c)(3): Records of HHS lab reports of quantitative test results for adulterated or substituted test results | | | |

47 No section 26.719 reportable events were received from CY 2013 through CY 2015 on a false positive test result for BPTS testing. Therefore, the NRC staff estimates that no programs would incur burden under this requirement.

48 This burden was not included in the previous clearance. The NRC staff estimates that each FFD program will spend 2.6 hours to maintain documentation on the HHS lab certification of the BPTS formulation for each specimen received. [67 sites with a D&A testing program x 1.0 hour per site = 67 hours]

49 The previous clearance incorrectly listed this activity under Table 4 as third-party burden incurred by HHS labs and indicated that the OMB Clearance No. 0930-0158 for HHS lab certification covered this burden (it did not). The licensee or other entity only incurs this burden when preparing a BPTS for shipment to an HHS lab for testing. The NRC staff estimates that preparing one BPTS takes 20 minutes (0.333 hour), with 40 BPTS prepared per year per site with a D&A testing program (i.e., 10 BPTSs prepared per quarter per site). [67 sites x 0.333 hour per BPTS x 40 BPTSs per site = 893 hours]

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|--|---|-------------------------------|---------------------------|
| 26.169(c)(4): MRO discusses with HHS lab whether additional testing at a second HHS lab on a specimen with an invalid result is warranted, and documents the determination | Burden accounted for under section 26.185(f)(1) | | |
| 26.169(c)(5): Records of HHS lab reports of concentrations exceeding linear range | Burden accounted for under section 26.183(c)(1) | | |
| 26.169(f): Records of HHS lab transmittals of CCF copies for negative test results to the MRO | 26 programs | 47.1 ⁵⁰ | 1,224 |
| 26.169(g): HHS lab copy of the original CCF for each positive, adulterated, substituted, dilute, and invalid test results to the MRO | Burden accounted for under section 26.169(c)(1) | | |
| 26.169(h): Record of HHS lab statistical summary report of urinalysis testing results (for the calendar year) | 26 programs | 2.0 | 52 |
| 26.183(a): Documentation of MRO qualifications | 26 programs | 4.0 | 104 |
| 26.183(c)(1): MRO review of HHS lab test result record for a positive, adulterated, substituted, invalid, or at the licensee's or other entity's discretion, dilute specimen | 26 programs | 2.0 ⁵¹ | 52 |
| 26.183(d)(1)(ii)(D): Record of MRO report of confirmed drug positive, adulterated, substituted, or refusal to test result to the licensee's designated reviewing official | 26 programs | 2.0 ⁵² | 52 |

⁵⁰ All HHS labs electronically report the results of drug and validity testing of specimens to the MRO. A review of FFD program performance data from D&A testing programs from CY 2013 through CY 2015 indicates that an average of 146,831 drug tests were completed each year (146,249 in CY 2013, 148,634 in CY 2014, and 145,610 in CY 2015). The NRC staff estimates burden at 30 seconds (0.0083 hour) per record reviewed. The prior clearance estimated a 164,270 drug tests conducted each year.

⁵¹ An average of 621 drug positive, adulterated, substituted, and refusal to test results were reported by 26 D&A testing programs each year (566 in CY 2013, 618 in CY 2014, and 679 in CY 2015). The NRC staff estimates burden at 5 minutes (0.083 hour) per MRO review of an individual's test results. The previous clearance overestimated the burden for this activity at 1.0 hour per test result review. This assumption also applies to the burden estimate in section 26.183(d)(1)(ii)(D).

⁵² The NRC staff estimates that the MRO or MRO staff will spend 5 minutes (0.083 hour) per test result to communicate the determination to the licensee's designated reviewing official. The previous clearance overestimated burden at 1.0 hour per test result review.

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|--|--|--------------------------------------|----------------------------------|
| 26.183(d)(2)(i): Record of MRO staff review and report of negative test results to FFD management | 26 programs | 282.4 ⁵³ | 7,342 |
| 26.183(d)(2)(ii): Record of MRO staff review of CCFs for positive, adulterated, substituted and invalid results and forwards changes to MRO for review | 26 programs | 2.4 ⁵⁴ | 62 |
| 26.185(a) Record of MRO review of a drug positive, adulterated, substituted, dilute, or invalid HHS lab test result | Burden accounted for under section 26.183(c)(1) | | |
| 26.185(c): Record of MRO discussion of positive, adulterated, substituted, dilute, or invalid test result with donor | 26 programs | 11.9 ⁵⁵ | 311 |
| 26.185(d)(1): Documentation that donor declined to discuss test results with MRO | Burden accounted for under section 26.185(c) | | |
| 26.185(e): Documentation reviewed by the MRO on a donor's inability to discuss test results and a request to reopen proceeding | 26 programs | 0.5 | 13 |
| 26.185(f)(1): Record of MRO consultation with HHS lab to determine whether additional testing at another HHS lab is needed for a specimen with an invalid result | 26 programs | 0.5 | 13 |
| 26.185(f)(2): Record of MRO contact with donor about an invalid test result, and medical information received | Burden accounted for under section 26.185(c) | | |
| 26.185(h)(1): Record of MRO contact with donor about a substituted test result, and medical information received | | | |
| 26.185(h)(2): Record of MRO confirmation of a substituted test result (no legitimate medical explanation) | Burden accounted for under section 26.183(d)(1)(ii)(D) | | |

⁵³ The NRC staff estimates that MRO staff will spend 3 minutes (0.05 hour) to review each HHS lab result (an average of 146,831 tests were performed from CY 2013 through CY 2015 by D&A testing programs).

⁵⁴ The NRC staff estimates that MRO staff spend 6 minutes (0.10 hour) to review each positive, adulterated, substituted, and invalid test result record. The number of records reviewed (621) is discussed under section 26.183(c)(1).

⁵⁵ The NRC staff estimates that an MRO will spend an average of 30 minutes (0.5 hour) to contact the donor, discuss the HHS lab test results, and document the discussion and determination. The average number of drug positive, adulterated, and substituted specimens in CY 2013 through CY 2015 is 621 results (566 in CY 2013, 618 in CY 2014, and 679 in CY 2015). The previous clearance overestimated burden at 1.0 hour per result (i.e., this estimate included duplicative burdens already accounted for under other provisions).

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|--|---|-------------------------------|---------------------------|
| 26.185(h)(3): MRO record of determination of a legitimate medical explanation for a substituted test result | Burden accounted for under section 26.183(d)(2)(i) | | |
| 26.185(i)(1): Record of MRO contact with donor about an adulterated test result, and medical information received | Burden accounted for under section 26.185(c) | | |
| 26.185(i)(2): Record of MRO confirmation of an adulterated test result (no legitimate medical explanation) | Burden accounted for under section 26.183(d)(1)(ii)(D) | | |
| 26.185(i)(3): MRO record of determination of a legitimate medical explanation for an adulterated test result | Burden accounted for under section 26.183(d)(2)(i) | | |
| 26.185(j): Prescription medication drug positives (applies to amphetamine, morphine, and codeine results) – records of MRO review of HHS lab result, discussion of positive result with donor, and review of medication information from the donor | 26 programs | 2.3 ⁵⁶ | 60 |
| 26.185(k): Record of MRO report to 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 sections 26.183(d)(2)(i) and 26.185(c) | | |
| 26.185(m): Record of MRO review of inspection and audit reports, QC data, multiple specimens, and other data to determine if positive, adulterated, substituted, or invalid result is scientifically insufficient for determination of FFD policy violation | 26 programs | 1.0 | 26 |

⁵⁶ The NRC staff estimates that an MRO will spend, on average, 1.0 hour reviewing a positive test result associated with the use of a prescription medication. These activities consist of obtaining information from the donor and confirming this information with a prescribing physician or pharmacy. The NRC staff estimates 60 positive results each year associated with legitimate medical use.

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|--|--------------------------------------|----------------------------------|
| 26.185(n): Record of MRO review of a positive, adulterated or substituted test result from a second HHS lab (results of retesting a single specimen or testing of a Bottle B split specimen), and MRO communication of the test result to the donor, and report results to FFD management | 26 programs | 0.6 | 16 |
| 26.185(o): Record of MRO request and HHS lab report of quantitation test results for testing performed on a specimen from a donor applying for reauthorization following a 1 st positive drug test result | 26 programs | 0.5 | 13 |
| 26.185(p): MRO written notice to licensee or other entity of a positive, adulterated, substituted, or invalid test result | Burden accounted for under section 26.185(c) | | |
| 26.187(d): SAE training requirements | 26 programs | 20.0 | 520 |
| 26.187(f): Documentation of SAE credentials and training | 26 programs | 1.0 | 26 |
| 26.189(b): Determination of fitness record | 26 programs | 80.0 | 2,080 |
| 26.189(c): Record of for cause determination of fitness | 26 programs | 15.6 | 405 ⁵⁷ |
| 26.189(d): Record of modification of an initial determination of fitness | 1 programs | 1.0 | 1 |
| 26.203(a): Prepare fatigue management policy (in addition to 26.27 burden) | 0 programs | 7.3 | 0 |
| 26.203(b): Prepare fatigue management procedures (in addition to 26.27 burden) | 0 programs | 1.7 | 0 |
| 26.203(c): Prepare training on fatigue management. | 0 programs | 2.0 | 0 |
| 26.203(d)(1) and (d)(2): Records of work hours, shift schedules, and shift cycles | Burden accounted for under section 26.205(c), (d)(1), and (e)(4) | | |
| 26.203(d)(3): Documentation of waivers | Burden accounted for under section 26.207(a)(4) | | |
| 26.203(d)(4): Documentation of work hour reviews | Burden accounted for under section 26.205(d)(2), (e)(3) and (e)(4) | | |

⁵⁷ A review of FFD program performance data from CY 2013 through CY 2015 indicates that an average of 405 for-cause tests were performed by D&A testing programs each year (424 in CY 2013, 418 in CY 2014, and 374 in CY 2015). NRC estimates burden at 1.0 hour to evaluate an individual and document the criteria met to conduct for-cause testing. The previous clearance estimated 457 for-cause tests performed each year.

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|--|--------------------------------------|----------------------------------|
| 26.203(d)(5): Documentation of fatigue assessment | Burden accounted for under section 26.211(f) | | |
| 26.205(b): Record of calculation of work hours | 21 programs | 160.0 | 3,360 |
| 26.205(c): Schedule work hours | 21 programs | 2,080.0 | 43,680 |
| 26.205(d)(1): Record of implementation of work hour controls | 21 programs | 50.0 | 1,050 |
| 26.205(d)(2): Record of adequate rest breaks | 21 programs | 50.0 | 1,050 |
| 26.205(e)(1) and (2): Record of review of control of work hours twice per calendar year | 21 programs | 40.0 | 840 |
| 26.205(e)(3): Document methods for reviews | 21 programs | 20.0 | 420 |
| 26.205(e)(4): Record and trend problems in regarding work hours | 21 programs | 20.0 | 420 |
| 26.207(a)(4): Document basis for waiver | 21 programs | 6.0 | 126 |
| 26.211(f): Document results of fatigue assessments | 21 programs | 50.0 | 1,050 |
| 26.403(a): Updates to FFD policy and procedures (reactor construction site D&A testing program) | 2 programs | 16.0 | 32 ⁵⁸ |
| 26.403(a): Provide FFD policy to individuals subject to a reactor construction site D&A testing program | 2 programs | 8.0 | 16 |
| 26.405(b): Records of random D&A tests | 2 programs | 193.9 | 388 ⁵⁹ |
| 26.405(c)(1): Records of pre-assignment D&A tests | 2 programs | 287.4 | 575 ⁶⁰ |
| 26.405(c)(2) and (c)(3): Records of for-cause and post-event D&A tests | 2 programs | 308.8 | 618 ⁶¹ |

⁵⁸ The previous clearance did not account for annual recordkeeping burden. While the previous clearance did include one-time recordkeeping burden for creating the FFD policy and procedures in Table 1, "One-Time Recordkeeping Burden," the burden associated with updating the policy and procedures was not included.

⁵⁹ FFD program performance data from CY 2013 through CY 2015 indicate that reactor construction site D&A testing programs conducted an average of 4,653 random tests per year (2,822 in CY 2013; 4,957 in CY 2014; 6,179 in CY 2015). The previous clearance reported 2,819 random tests per year. The NRC staff estimates burden at 5 minutes (0.083 hour) to document a random test result. The previous clearance overestimated burden for this activity at 30 minutes (0.5 hour) per test.

⁶⁰ FFD program performance data from CY 2013 through CY 2015 indicate that reactor construction site D&A testing programs conducted an average of 6,898 pre-access tests per year (5,886 in CY 2013; 8,414 in CY 2014; 6,395 in CY 2015). The previous clearance reported 4,675 pre-access tests per year. The NRC staff estimates burden at 5 minutes (0.083 hour) to document a pre-assignment test result. The previous clearance overestimated burden for this activity at 1.0 hour per test.

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|--|--------------------------------|--------------------------------------|----------------------------------|
| 26.405(c)(4): Records of follow-up D&A tests | 2 programs | 21.1 | 42 ⁶² |
| 26.405(e): Updates to specimen collection and D&A testing procedures to protect the donor's privacy, integrity of the specimen, and stringent quality controls to ensure accurate test results | 2 programs | 40.0 | 80 |
| 26.405(f): Record that testing conducted at an HHS lab | 2 programs | 40.0 | 80 |
| 26.405(g): MRO review of positive, adulterated, substituted, and invalid drug and validity test results (reactor construction site D&A testing program) | 2 programs | 81.3 | 163 ⁶³ |
| 26.406(c): Updates to fitness monitoring procedures (programs that do not adopt random testing and behavioral observation) | 0 programs | 80.0 | 0 |
| 26.411(a): Updates to procedures for maintaining a system of files to protect personal information collected under Subpart K of Part 26 | 2 programs | 40.0 | 80 |
| 26.411(a) and (b): Collection of personal information under Subpart K of Part 26 | 2 programs | 3,817 | 7,634 ⁶⁴ |
| 26.413: Document results of review process | 2 programs | 80.0 | 160 |

61 FFD program performance data from CY 2013 through CY 2015 indicate that reactor construction site D&A testing programs conducted an average of 618 for-cause and post-event tests per year (383 in CY 2013; 658 in CY 2014; 811 in CY 2015). The previous clearance reported at total of 394 for-cause and post-event tests per year. The NRC staff estimates 1.0 hour per person to document a for-cause or post-event testing event (determination for testing and test result) – this the same per activity burden estimate used in the previous clearance.

62 FFD program performance data from CY 2013 through CY 2015 indicate that reactor construction site D&A testing programs conducted an average of 505 follow-up tests per year (303 in CY 2013; 510 in CY 2014; 703 in CY 2015). The previous clearance reported 276 follow-up tests per year. The NRC staff estimates 5 minutes (0.083 hour) to document a follow-up test result. The previous clearance overestimated burden for this activity at 1.0 hour per test.

63 FFD program performance data from CY 2013 through CY 2015 indicated that reactor construction site D&A testing programs averaged 253 drug and alcohol positive, adulterated, substituted and refusal to test results per year (178 in CY 2013, 295 in CY 2014, and 287 in CY 2015). Alcohol test results were eliminated from these reviews to result in an average of 217 results for MRO review each year. The NRC staff estimates 45 minutes (0.75 hour) per test to review the HHS lab result, discuss the result with the donor and communicate with FFD management about the confirmed result. The previous clearance estimated that each reactor construction site would incur 50 hours of annual burden for these MRO reviews per program.

64 NRC estimates that an average of 3,817 individuals will be subject to testing each year at a reactor construction site D&A testing program, with a burden of 1.0 hour per person to collection personal information. This value is the average number of random tests performed from CY 2013 through CY 2015 (2,524 in CY 2013; 4,051 in CY 2014; and 4,876 in CY 2015). The previous clearance estimated 2,189 individuals per D&A testing program per year.

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|--|---|--------------------------------------|----------------------------------|
| 26.415: Document and report audit results | 2 programs | 40.0 | 80 |
| 26.417(a): Records pertaining to the administration of a reactor construction site D&A testing program | 2 programs | 20.0 | 40 |
| 26.417(b)(1): Maintain documentation on a 24-hour event report to the NRC | Burden accounted for under section 26.719(b) | | |
| 26.417(b)(2): Collect FFD program performance data for reactor construction D&A testing program | 2 programs | 100.0 | 200 |
| 26.713(a)(1): Records of self-disclosures, employment histories, and suitable inquiries (under sections 26.55, 26.57, 26.59, and 26.69) that result in the granting of authorization | Burden accounted for under section 26.61(a), and section 26.63(a), (c), and (e) | | |
| 26.713(a)(2): Records pertaining to the determination of a violation of FFD policy and related management actions | Burden accounted for under section 26.39(b) | | |
| 26.713(a)(3): Documentation of the granting and termination of authorization | 26 programs | 80.0 | 2,080 |
| 26.713(a)(4): Records of determinations of fitness performed under section 26.189 (including recommendations for treatment and follow-up testing plans) | 26 programs | 80.0 | 2,080 |
| 26.713(b)(1): Records of FFD training and examinations conducted under section 26.29 | Burden accounted for under section 26.29(a) and (b) | | |
| 26.713(b)(2): Records of audits, audit findings, and corrective actions taken under section 26.41 | Burden accounted for under sections 26.41(a) – (d), (f) and (g) | | |
| 26.713(c): Records on 5-year and permanent denials of authorization | Burden accounted for under section 26.39(b) | | |
| 26.713(d): Records of superseded versions of FFD policies and procedures | 26 programs | 8.0 ⁶⁵ | 208 |
| 26.713(e): Records of written agreements for services under Part 26 | 26 programs | 16.0 | 416 |

⁶⁵ The NRC staff estimates that each D&A testing program will spend an average of 8 hours per year maintaining records of superseded FFD policies and procedures. The previous clearance estimated 80 hours per program per year. In this clearance, those 80 hours of annual burden per program have been reallocated to section 26.27(c) to more precisely align effort with activity (i.e., section 26.27(c) accounts for “Updates to the FFD policy and procedures”).

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|--|---|--------------------------------------|----------------------------------|
| 26.713(f): Records of background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel conducted under section 26.31(b)(1)(i) | Burden accounted for under section 26.31(b)(1)(i) | | |
| 26.715(a): Documentation of all aspects of testing process at LTFs and collection sites (not otherwise specified in section 26.715(b)) | 26 programs | 40.0 | 1,040 |
| 26.715(b)(1): Retain personnel files on staff at collection sites and LTFs | 26 programs | 20.0 | 520 |
| 26.715(b)(2): Retain collection site and LTF lab chain-of-custody documents | 26 programs | 240.0 | 6,240 |
| 26.715(b)(3): Retain LTF QA/QC records | 6 programs ⁶⁶ | 120.0 | 720 |
| 26.715(b)(4): Retain superseded procedures (LTFs and collection sites) | 26 programs | 40.0 | 1,040 |
| 26.715(b)(5): Retain all test data from LTF (including calibration curves and any calculations used in determining test results) | 6 programs | 240.0 | 1,440 |
| 26.715(b)(6): LTF test reports | 6 programs | 240.0 | 1,440 |
| 26.715(b)(7): LTF performance testing records | 6 programs | 80.0 | 480 |
| 26.715(b)(8): Records from LTF and HHS lab on the investigation of testing errors or unsatisfactory performance, and any corrective actions taken | 8 programs ⁶⁷ | 40.0 | 320 |
| 26.715(b)(10): Records of preventative maintenance on LTF instruments | 6 programs | 40.0 | 240 |

⁶⁶ This requirement only applies to D&A testing programs that utilize an LTF. The previous clearance incorrectly estimated that it applied to all D&A testing programs. This assumption change also applies to section 26.715(b)(5), (b)(6), (b)(7), (b)(10), and (b)(12). The associated third-party disclosure burden for each of these requirements is accounted for in Table 4.

⁶⁷ The previous clearance overestimated burden for this recordkeeping activity (it assumed that all D&A testing programs incurred this burden). However, based on section 26.719(c) reports, from CY 2013 through CY 2015, and average of eight reports on testing errors or unsatisfactory performance at an LTF or HHS lab were reported.

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|---|--|--------------------------------------|----------------------------------|
| 26.715(b)(11): Retain records that summarize any test results the MRO determined to be scientifically insufficient for further action | 1 program | 3.0 ⁶⁸ | 3 |
| 26.715(b)(12): LTF retains computer-generated data | 6 programs | 120.0 | 720 |
| 26.715(b)(13): Retain records (e.g., an access log) of authorized visitors, maintenance personnel, and service personnel who accessed secure areas at the LTF | Burden accounted for under section 26.129(a) ⁶⁹ | | |
| 26.715(b)(14): Retain records of the inspection, maintenance and calibration of EBTs (collection sites) | 26 programs | 20.0 | 520 |
| 26.717(a) and (b): Collect FFD performance data for D&A testing program | 26 programs | 100.0 | 2,600 |
| 26.717(a) and (b): Collect FFD performance data for fatigue management program | 21 programs | 100.0 | 2,100 |
| 26.717(c): Analyze D&A testing program FFD data annually | 26 programs | 40.0 | 1,040 |
| 26.717(c): Analyze fatigue management program data annually | 21 programs | 40.0 | 840 |
| 26.717(d): D&A test results leading to termination | 1 C/V | 1.0 | 1 |
| 26.717(g): Collect and report D&A testing program data to the NRC (for C/V with a testing program) | Burden already accounted for under section 26.717(a) and (b) | | |

⁶⁸ The NRC staff estimates that a scientifically insufficient test result is a rare event and would be reported to the NRC under a section 26.719. The previous clearance overestimated that this rare event would be encountered by each D&A testing program at an annual burden of 20 hours per program. FFD program performance data do not support the assumption used in the previous clearance.

⁶⁹ The previous clearance overestimated burden for this activity by assuming that it applied to all D&A testing programs. It only applies to LTFs (already covered under section 26.129(a), and HHS labs (burden already covered under section 26.159(a) in Table 4 – Third-Party Burden).

**Table 2
Annual Recordkeeping Burden**

| Section | Number of Recordkeepers | Burden Hours per Recordkeeper | Total Annual Burden Hours |
|--|--------------------------------|--------------------------------------|----------------------------------|
| 26.719(b): Maintain documentation developed to make a 24-hour event report to the NRC | 37 sites ⁷⁰ | 1.0 | 37 |
| 26.719 (c): Prepare 30-day event report documentation | 8 sites ⁷¹ | 40.0 | 320 |
| 26.719(d): Document non-reportable indicators of FFD program weaknesses | 28 programs | 20.0 | 560 |
| 26.821(a): Provide NRC with access to records (to inspect, copy, or take away records) | 28 programs | 4.0 | 112 |
| 26.821(b): Written agreement between C/Vs and licensees to permit authorized NRC representatives to inspect, copy, or take away copies of C/Vs documents, records, and reports | 1 C/V | 4.0 | 4 |
| TOTAL | | | 220,887 |

70 NRC estimates that licensee and other entities will submit 37 reports per year under section 26.719(b). This value is the average number of section 26.719(b) reports received from CY 2013 through CY 2015 (40 reports in 2013, 38 reports in 2014, and 33 reports in 2015). The previous clearance estimated 37 reports per year.

71 The NRC staff estimates that eight (8) reports will be received per year under 26.719(c). This value is the average number of reports received per year from CY 2013 through CY 2015 (16 reports in 2013, 5 reports in 2014, 3 reports in 2015). The previous clearance estimated six (6) reports per year.

**Table 3
Annual Reporting Burden**

| Section | Number of Respondents | Responses per Respondent | Total Responses | Burden per Response (hours) | Total Burden Hours |
|--|--|---------------------------------|------------------------|------------------------------------|---------------------------|
| 26.9: Application to NRC for exemption | 0 programs ⁷² | 1 | 0 | 0 | 0 |
| 26.77(c): Report impaired NRC employee | 0 programs | 0 | 0 | 1.0 | 0 |
| 26.137(b)(3): Report false negative LTF validity screening result | No LTF conducts validity screening testing (if any did, burden would be accounted for under section 26.719(c)(3)) | | | | |
| 26.203(e)(1): Prepare information on waivers of work hour controls for inclusion in fatigue program performance report to NRC required by section 26.717 | 21 programs | 1 | 21 | 50.0 | 1,050 |
| 26.203(e)(2): Prepare summary of fatigue corrective actions for inclusion in fatigue program performance report to NRC required by section 26.717 | 21 programs | 1 | 21 | 6.0 | 126 |

⁷² The NRC staff does not anticipate receiving any licensing exemption requests during the current clearance period. The prior clearance also anticipated zero exemption requests.

**Table 3
Annual Reporting Burden**

| Section | Number of Respondents | Responses per Respondent | Total Responses | Burden per Response (hours) | Total Burden Hours |
|---|--|---------------------------------|------------------------|------------------------------------|---------------------------|
| 26.417(b)(1): Report to NRC by telephone within 24 hours of identifying a programmatic failure in a reactor construction site D&A testing program | Burden accounted for under section 26.719(b) | | | | |
| 26.417(b)(2): Prepare annual FFD program performance report for a reactor construction site D&A testing program | 2 programs | 1 | 2 | 80.0 | 160 |
| 26.717: Annual FFD program performance report for fatigue management programs | 59 sites ⁷³ | 1 | 59 | 8.0 | 472 |
| 26.717: Annual FFD program performance report for D&A testing programs | 67 sites ⁷⁴ | 1 | 67 | 60.0 | 4,020 |

⁷³ Each year, 59 operating nuclear power reactor sites each will submit one FFD program performance report on fatigue management (NRC Form 892). The reporting burden to develop the content for the fatigue management reports is presented in section 26.203(e)(1) and (e)(2). This line item only pertains to the burden hours to produce the report and submit it to the NRC.

⁷⁴ Each year, 67 sites (59 operating nuclear power reactor sites, 2 fuel cycle facilities, 5 corporate FFD programs, and 1 C/V) will submit annual FFD program performance report information on D&A test results (NRC Forms 890 and 891) to the NRC. The previous clearance estimated that 65 sites (61 operator reactor sites, 1 decommissioning reactor site, 2 fuel cycle facilities, and 1 C/V) submitted D&A test results information each year.

**Table 3
Annual Reporting Burden**

| Section | Number of Respondents | Responses per Respondent | Total Responses | Burden per Response (hours) | Total Burden Hours |
|--|--|---------------------------------|------------------------|------------------------------------|---------------------------|
| 26.719(a): Report a significant FFD program violation, programmatic failure, or D&A testing error | Burden accounted for under sections 26.719(b), and (c)(1) – (c)(3) | | | | |
| 26.719(b): Report to the NRC by telephone within 24 hours of identifying a significant D&A testing program violation | 37 sites ⁷⁵ | 1 | 37 | 4.0 | 148 |
| 26.719(c)(1): Submit a report to the NRC within 30 days of completing an investigation into an LTF or HHS lab testing error | 8 sites ⁷⁶ | 1 | 8 | 24.0 | 192 |
| 26.719(c)(2): Notify the NRC by telephone within 24 hours of receiving notice of a false positive on a BPTS test result | 0 program | 1 | 0 | 4.0 | 0 |

⁷⁵ NRC estimates that licensee and other entities will submit 37 reports per year under section 26.719(b). This value is the average number of section 26.719(b) reports received from CY 2013 through CY 2015 (40 reports in 2013, 38 reports in 2014, and 33 reports in 2015). The previous clearance estimated 37 reports per year (but reported the number of responses per respondent as 37 events / 15 program, or 2.47 responses per respondent).

⁷⁶ NRC estimates that licensee and other entities will submit 8 reports per year under section 26.719(c)(1). This value is the average number of section 26.719(c)(1) reports received from CY 2013 through CY 2015 (16 reports in 2013, 5 reports in 2014, and 3 reports in 2015). The previous clearance estimated 6 reports year.

**Table 3
Annual Reporting Burden**

| Section | Number of Respondents | Responses per Respondent | Total Responses | Burden per Response (hours) | Total Burden Hours |
|---|------------------------------|---------------------------------|------------------------|------------------------------------|---------------------------|
| 26.719(c)(3): Notify the NRC by telephone within 24 hours of receiving a false negative test result on a QA check of a validity screening test from an LTF | 0 programs ⁷⁷ | 1 | 0 | 4.0 | 0 |
| TOTAL | | | | | 6,168 |

⁷⁷ The previous clearance estimated 4 FFD programs per year each reported a section 26.719(c)(3) report to the NRC. However, based on additional information obtained by the NRC, no LTF performs validity screening testing. Therefore, this reporting requirement does not apply.

**Table 4
Annual Third-Party Disclosure Burden**

| Section | Number of Responses | Burden Hours per Response | Total Annual Burden Hours |
|---|---------------------|---------------------------|---------------------------|
| 26.4(j): For personnel granted authorization by a licensee, who are covered by a D&A testing program regulated by a State or Federal agency – (1) provision of training record to the licensee to demonstrate section 26.29(a) training requirements met (if not already covered in the existing program); (2) notification of any FFD policy violations by those granted authorization by the licensee or other entity | 33.5 ⁷⁸ | 2.0 | 67 |
| 26.29(b): Complete initial training on FFD policy and take comprehensive examination | 81,219 | 2.0 ⁷⁹ | 162,439 |
| 26.29(c)(2): Complete annual refresher training on FFD policy | 103,933 | 1.5 ⁸⁰ | 155,899 |
| 26.31(b)(1)(i): Individual applying for access to serve as FFD program personnel provides background check information for the background investigation, credit and criminal history checks, and psychological assessment) | 335 ⁸¹ | 1.0 | 335 |

⁷⁸ The NRC estimates that 50 percent of the 67 sites with a D&A testing program grant authorization to offsite response personnel subject to a State or Federal agency D&A testing program (e.g., emergency fire and medical response personnel, SSNM transporters). The previous clearance underestimated burden for this activity because it calculated burden on a D&A testing program basis rather than on a site-specific basis.

⁷⁹ The NRC estimates 1.5 burden hours per individual to complete the standard web-based training used by industry (National Academy for Nuclear Training e-Learning (NANTeL) Generic FFD and Behavioral Observation training or equivalent) + 0.5 hours per individual to complete the comprehensive examination). The previous clearance did not include this burden hour estimate (it was included as a one-time burden for a new D&A testing program under Table 1 and no new programs were accounted for in that clearance). While this activity is completed one time for each individual applying for access, the licensee or other entity of a D&A testing program hires new individuals each year (thus this is an annual burden). The NRC estimates that 81,219 individuals will complete initial training each year (this value is the average number of individuals receiving a pre-access test in CY 2013, CY 2014, and CY 2015).

⁸⁰ The NRC estimates 1.5 burden hours per individual to complete annual refresher training (i.e., completing the NANTeL Generic FFD and Behavioral Observation training, or equivalent). The previous clearance did not include this burden hour estimate (it was included as a one-time burden for a new D&A testing program under Table 1 and no new programs were accounted for in that clearance). The NRC estimates that 103,933 individuals will complete annual refresher training each year (this value is the average number of individuals subject to a random testing program from CY 2013 through CY 2015 (104,728 in CY 2013; 104,037 in CY 2014; and 103,033 in CY 2015). This assumption overestimates the burden for annual refresher training because some individuals in the random testing program will have received initial training each year. However, no data were available to address this issue.

⁸¹ The NRC estimates that an average of five (5) individuals per D&A testing program each year will apply for authorization to serve as FFD program personnel. The previous clearance overestimated burden for this activity by assuming that it applied to all individuals applying for access (i.e., 93,890 pre-access tests completed per year). This correction reduced the estimated annual burden from 93,890 hours to 335 hours.

**Table 4
Annual Third-Party Disclosure Burden**

| Section | Number of Responses | Burden Hours per Response | Total Annual Burden Hours |
|--|----------------------|---------------------------|---------------------------|
| 26.35(a): Employee assistance program (EAP) records | 26 ⁸² | 32.0 | 832 |
| 26.35(c): Individual completes and provides the EAP with a written waiver of right to privacy to share information with FFD management | 1,039 ⁸³ | 0.25 | 260 |
| 26.35(c): Record of EAP disclosure to FFD management about an individual that poses an immediate hazard | 13 | 1.0 | 13 |
| 26.37(b): Individual provides signed consent for release of information | 258 ⁸⁴ | 0.25 | 65 |
| 26.37(b)(1): Individual provides signed designation of personal representative for an FFD matter | 258 ⁸⁵ | 0.25 | 65 |
| 26.37(d): Request by donor or donor's presentative to the licensee or other entity to provide personal records collected under Part 26 | 26 ⁸⁶ | 0.25 | 7 |
| 26.53(h): Applicant provides written consent before any actions are initiated under Subpart C of Part 26 | 81,219 ⁸⁷ | 0.25 | 20,305 |

82 The NRC estimates that each EAP is a service provider under contract with a D&A testing program. The previous clearance estimated that 50 percent of EAPs programs were contracted services and 50 percent were licensee or other entity programs accounted for in Table 2.

83 The NRC estimates that 1,039 individuals per year (1 percent of 103,933 individuals subject to a D&A testing program – i.e., individuals subject to a random testing program) will provide written consent to the EAP to release information to FFD management. The 103,933 value is the average number of individuals per year from CY 2013 through CY 2015 (104,728 in CY 2013; 104,037 in CY 2014; and 103,033 in CY 2015). The previous clearance estimated 5,636 individuals per year (i.e., 5 percent of 112,732 individuals subject to random testing under D&A testing programs).

84 The NRC estimates that 258 individuals per year would provide written consent to release information to entities or individuals not authorized to access this information under Part 26. See the footnote for section 26.37(b)(1) for a description on the 258 value. The previous clearance overestimated burden by assuming that 1 percent of the total number of individuals subject to a D&A testing program each year would provide consent to release information. This activity is more likely to result because of a D&A testing violation.

85 The NRC estimates that only those individuals that have been granted access would seek representation for an FFD related matter (i.e., for a testing violation on a random, for-cause, post-event, or follow-up test). The average number of individuals with a non-pre-access testing violation from CY 2013 through CY 2015 is 258 per year. The previous clearance estimated that all 961 individuals with an FFD D&A testing violation in a year would request representation on an FFD related matter. This assumption also applies to section 26.37(b)(1) and (d).

86 The NRC estimates that of the 258 individuals per year that seek representation for an FFD related matter (see section 26.37(b)(1) discussion), 10 percent would request access to personal records maintained under Part 26.

87 The NRC estimates that 81,219 individuals will apply for authorization each year at D&A testing programs. The

**Table 4
Annual Third-Party Disclosure Burden**

| Section | Number of Responses | Burden Hours per Response | Total Annual Burden Hours |
|--|---|---------------------------|---------------------------|
| 26.55(a)(1) – (a)(2): Initial authorization 26.57(a)(1) – (a)(2): Authorization update 26.59(a)(1) – (a)(2): Authorization reinstatement Each individual applying for authorization must complete a self-disclosure, employment history, and suitable inquiry | Burden accounted for under sections 26.61(a), and 26.63(a), (c) and (e) | | |
| 26.59(c)(1): Applicant prepares self-disclosure (for authorization reinstatement period of interruption of no more than 30 days) | Burden accounted for under section 26.61(a) | | |
| 26.61(a): Applicant prepares self-disclosure and employment history | 81,219 | 1.0 | 81,219 |
| 26.63(a), (c), and (e): Former employer(s) provide information to the licensee or other entity to verify an applicant's suitable inquiry information on previous authorization(s) | 81,219 | 0.75 | 60,915 |
| 26.63(c)(2): U.S. Department of Defense (DOD) provides licensee or other entity with form DD 214 which details an applicant's military service record | Burden of supplying DD 214 affects DOD, or is accounted for under section 26.61(a) (if supplied by the applicant) | | |
| 26.63(c)(3): Former employer refuses to provide information to the licensee or other entity about an applicant's prior employment history | 180 | 0.1 | 15 |
| 26.67: Records of random D&A testing of persons who have applied for authorization, but who have not been granted unescorted access authorization | 406 ⁸⁸ | 0.5 | 203 |
| 26.69(b) and (c)(1): Applicant provides written self-disclosure and employment history to the licensee or other entity (for authorization following a 1 st or 2 nd positive drug or alcohol test result, or if other PDI is identified) | Burden accounted for under section 26.61(a) | | |

81,219 value is the average number of individuals that were pre-access tested at a D&A testing program from CY 2013 through CY 2015 (80,763 in CY 2013, 82,711 in CY 2014, and 80,184 in CY 2015). The NRC estimates that each applicant spends 15 minutes (0.25 hour) reviewing and signing a written consent form.

⁸⁸ The NRC estimates that licensees and other entities will randomly D&A test 406 individuals per year that have applied for authorization, but before authorization had been granted (i.e., 0.5 percent of the 81,219 individuals that apply for authorization at a D&A testing program each year). The previous clearance estimated 335 individuals per year (i.e., 0.5 percent of 61,722 random D&A tests – this was an incorrect calculation as pre-access tests results should have been used).

**Table 4
Annual Third-Party Disclosure Burden**

| Section | Number of Responses | Burden Hours per Response | Total Annual Burden Hours |
|--|---------------------|---------------------------|---------------------------|
| 26.69(c)(2): Former employer(s) of an applicant provide response to licensee or other entity request to confirm suitable inquiry information for an applicant with PDI | 812 ⁸⁹ | 2.0 | 1,624 |
| 26.85(c): Alternative collectors not employed by licensee provide proof of qualification | 26 | 1.0 | 26 |
| 26.85(e): Maintain personnel files for alternative collectors | 26 | 4.0 | 104 |
| 26.89(a): Record that a donor did not appear for testing (non-licensee collection site) | 2 | 1.0 | 2 |
| 26.89(b)(3): Record that FFD management informed that an individual did not present identification (non-licensee collection site) | 2 | 1.0 | 2 |
| 26.89(c): Record that FFD management informed that a donor refused to cooperate with the collection procedures (non-licensee collection site) | 0 | 0.25 | 0 |
| 26.91(e)(4): Record that results cancelled after EBT calibration check failure (non-licensee collection site) | 0 | 1.0 | 0 |
| 26.91(e)(5): Prepare record of EBT maintenance (non-licensee collection site) | 26 | 4.0 | 104 |
| 26.93(a)(6): Document alcohol pre-test questions asked and answered (non-licensee collection site) | 260 ⁹⁰ | 0.25 | 65 |
| 26.95(b)(5): Record donor identity for initial alcohol breath test (non-licensee collection site) | 260 | 0.25 | 65 |
| 26.97(b)(2): Record reason for new oral fluid alcohol test (non-licensee collection site) | 0 ⁹¹ | 0.5 | 0 |
| 26.97(c)(1): Document reason for failure of second collection attempt (non-licensee collection site) | 0 | 1.0 | 0 |
| 26.97(d): Record results and alcohol screening device used (non-licensee collection site) | 0 | 0.25 | 0 |

⁸⁹ The NRC estimates that licensees and other entities will identify potentially disqualifying FFD information (PDI) in the applications of 812 individuals per year (i.e., 1 percent of the 81,219 individuals that apply for authorization at a D&A testing program each year). The previous clearance estimated 939 individuals per year (i.e., 1 percent of 93,890 individuals).

⁹⁰ The NRC estimates that 10 individuals per D&A testing program (26 programs x 10 individuals = 260) are FFD program personnel not located at the reactor site, fuel cycle facility, or C/V site where collections are typically made and will be tested at a U.S. Department of Transportation compliant collection site per section 26.31(b)(2). This assumption also applies to section 26.95(b)(5), and 26.117(c), (d), and (e).

⁹¹ The NRC is not aware of any license or other entity that performs oral fluid alcohol screening tests. The previous collection included an estimate of eight (8) responses per year. This assumption also applies to sections 26.97(d)

**Table 4
Annual Third-Party Disclosure Burden**

| Section | Number of Responses | Burden Hours per Response | Total Annual Burden Hours |
|--|---------------------|---------------------------|---------------------------|
| 26.99(b): Record test time of initial test with 0.02 percent BAC or higher (non-licensee collection site) | | | |
| 26.101(b)(7): EBT printout of confirmatory alcohol test result includes time of test (non-licensee collection site) | | | |
| Burden accounted for under section 26.715(b)(2) ⁹² | | | |
| 26.103(b): Collector informs FFD management of result between 0.01 and 0.02 percent BAC when donor in work status 3 or more hours (non-licensee collection site) | 0 | 0.25 | 0 |
| 26.107(b): Collector documents tampering attempt on CCF form (non-licensee collection site) | | | |
| Burden accounted for under section 26.111(b) | | | |
| 26.109(b)(3): Collector documents on CCF shy-bladder situation and notifies FFD management (non-licensee collection site) | 0 | 0.25 | 0 |
| 26.109(b)(4): Collector documents on CCF confirmation from FFD management to conduct a an observed collection (non-licensee collection site) | 0 | 0.25 | 0 |
| 26.111(b): Collector documents on CCF if specimen characteristics (color, clarity) indicate possible tampering by the donor (non-licensee collection site) | 0 | 0.25 | 0 |
| 26.111(c): Collector documents on CCF unusual specimen temperature and/or other observations made during the collection of possible tampering attempt and notifies FFD management (non-licensee collection site) | 0 | 0.25 | 0 |
| 26.113(b)(3): Collector completes CCF for split-specimen collection (non-licensee collection site) | | | |
| Burden accounted for under section 26.117(c) – (e) | | | |
| 26.115(b): Collector documents on CCF approval from FFD manager or MRO to collect a specimen under direct observation (non-licensee collection site) | 0 | 0.25 | 0 |
| 26.115(d): Collector documents on CCF directly observed collection performed and the reason for the observed collection (non-licensee collection site) | | | |
| Burden accounted for under section 26.115(b) | | | |
| 26.115(f)(3): Record of name of observer (non-licensee collection site) | 0 | 0.25 | 0 |

⁹² The EBT devices used by regulated entities automatically print the test result for each test completed. The only burden associated with this requirement is to maintain records, which already is accounted for in section 26.715(b)(2).

**Table 4
Annual Third-Party Disclosure Burden**

| Section | Number of Responses | Burden Hours per Response | Total Annual Burden Hours | | | |
|---|--|---------------------------|---------------------------|--|--|--|
| 26.117(c) – (e): Collector prepares ID labels and CCF for specimen shipment (non-licensee collection site) | 260 ⁹³ | 0.25 | 65 | | | |
| 26.119(a), (e), and (f): Physician evaluating shy-bladder claim prepares report of medical examination of donor and provides this information to the MRO | 13 | 2.0 | 26 | | | |
| 26.129(b): Collector prepares memorandum and sends to LTF documenting investigation of discrepancies between specimen bottle and CCF (non-licensee collection site) | 0 | 1.0 | 0 | | | |
| 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) | | | | | |
| 26.153(g): Supply memorandum to HHS lab explaining use of non-federal CCF (non-licensee collection site) | 2 | 0.5 | 1 | | | |
| 26.155(a)(1): Documentation of HHS lab manager qualifications | Burdens covered by HHS lab certification requirements OMB Clearance No. 0930-0158 | | | | | |
| 26.155(a)(3): HHS lab personnel training documentation | | | | | | |
| 26.155(a)(4): HHS lab manager reviews and signs lab procedures | | | | | | |
| 26.155(a)(5): HHS lab manager maintains QA program | | | | | | |
| 26.155(b): Certifying scientist at HHS lab certified test results | | | | | | |
| 26.155(c): Supervise technical analysts at HHS lab | | | | | | |
| 26.155(e): Continuing education of HHS lab staff | | | | | | |
| 26.155(f): HHS lab personnel records | | | | | | |
| 26.157(a): Written HHS lab procedures for accession, receipt, shipment, and testing of urine specimens | | | | Burdens covered by HHS lab certification requirements OMB Clearance No. 0930-0158 | | |
| 26.157(b): Written HHS lab chain-of-custody procedures | | | | | | |
| 26.157(c): Written HHS lab procedures for each testing assay performed | | | | | | |
| 26.157(d): Written HHS lab procedures for device set-up and operation | | | | | | |

⁹³ This estimate of 10 persons per D&A testing program is consistent with the previous clearance.

**Table 4
Annual Third-Party Disclosure Burden**

| Section | Number of Responses | Burden Hours per Response | Total Annual Burden Hours |
|--|---|---------------------------|---------------------------|
| 26.157(e): Written HHS lab procedures for remedial actions to address systems and instrument errors | | | |
| 26.159(a): Retain records (e.g., an access log) of authorized visitors, maintenance personnel, and service personnel who accessed secure areas of HHS lab | | | |
| 26.159(b)(1): Record that the HHS lab notified the licensee or other entity within 24 hours of identifying evidence of specimen tampering | 0 | 1.0 | 0 ⁹⁴ |
| 26.159(c) – (e): Use and storage of CCFs at HHS lab | Burden accounted for under section 26.715(b)(2) | | |
| 26.159(f): Use of CCF by HHS lab when shipping a specimen to another HHS lab | 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 | 31 | 1.0 | 31 |
| 26.165(b)(3): Donor provides written request to the MRO for the retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen | 31 | 1.0 | 31 |
| 26.165(b)(4): Donor presents documentation to the MRO on the reason for not being able to make a timely retest request | Burden accounted for under section 26.185(e) | | |
| 26.165(b)(6): HHS lab provides report to the MRO of the quantitative test results of the retesting of aliquot of a single specimen or the testing of the Bottle B split specimen | Burden accounted for under section 26.185(n) | | |

⁹⁴ The previous clearance did not include this third-party burden for the HHS lab, but did include a burden estimate in Table 2, “Annual Recordkeeping Burden,” for the licensee or other entity to retain reports received from the HHS lab under this requirement.

**Table 4
Annual Third-Party Disclosure Burden**

| Section | Number of Responses | Burden Hours per Response | Total Annual Burden Hours |
|---|--|---------------------------|---------------------------|
| 26.167(a): HHS lab documents QA program (encompasses all aspects of the testing process) | Burdens covered by HHS lab certification requirements OMB Clearance No. 0930-0158 | | |
| 26.167(c)(2)(i): Refractometer at the HHS lab must display specific gravity to 4 decimals and be interfaced with laboratory information management system or computer and/or document result by hard copy or electronic display | | | |
| 26.167(f)(3): False positive error on BPTS test and the error is technical or methodological, the HHS lab Responsible Person must document that retesting of all positive, adulterated, substituted, and invalid specimens from the time of final resolution of the error back to the time of the last satisfactory performance test cycle has been completed, as requested by the licensee or other entity | 0 ⁹⁵ | 8.0 | 0 |
| 26.167(h): HHS lab labels standards and controls | Burden covered by HHS lab certification requirements OMB Clearance No. 0930-0158 | | |
| 26.168(a): Blind performance test sample (BPTS) supplier provides HHS lab certification letter of BPTS formulation to licensee or other entity | 2 ⁹⁶ | 8.0 | 16 |
| 26.168(h)(2): BPTS sample supplier provides expiration date on each BPTS | 2 | 8.0 | 16 |
| 26.169(a): HHS lab reports test results to the MRO of the licensee or other entity MRO | Burden covered under section 26.169(c)(1) | | |

95 The previous clearance incorrectly reported that the burden to comply with this requirement was covered by the HHS lab certification requirements under OMB Clearance No. 0930-0158. This activity is a Part 26 third-party disclosure requirement applicable to HHS labs. A review of 30-day event reports indicated no false positives from CY 2013 through CY 2015.

96 The previous clearance incorrectly reported that burden to comply with section 26.168(a) was covered under by the HHS laboratory certification requirements (OMB Clearance No. 0930-0158). However, this burden is incurred by BPTS suppliers that provide services to licensees and other entities. FFD program performance data from CY 2013 through CY 2015 indicated that only two BPTS suppliers provide services to Part 26 regulated entities. This assumption also applies to section 26.168(h)(2).

**Table 4
Annual Third-Party Disclosure Burden**

| Section | Number of Responses | Burden Hours per Response | Total Annual Burden Hours |
|---|---------------------|---------------------------|---|
| 26.169(c)(1): HHS lab provides record to the MRO for each positive, adulterated, substituted, dilute, and invalid test result | 621 ⁹⁷ | 0.25 | 155 |
| 26.169(c)(2): HHS lab provides quantitative test result record for positive drug test (at the request of the MRO) | | | Burden accounted for under section 26.169(c)(1) |
| 26.169(c)(3): HHS lab provides quantitative test result record for adulterated or substituted test results (at the request of the MRO) | | | |
| 26.169(c)(4): HHS lab record of contact with MRO to discuss if additional testing by another HHS lab should be conducted on a specimen with an invalid test result | 10 | 0.5 | 5 |
| 26.169(f): HHS lab transmits to the MRO a copy of CCF for specimens with negative test results | | | Burden accounted for under section 26.715(b)(2) |
| 26.169(g): HHS lab transmits a copy of the original CCF signed by the certifying scientist (for positive, adulterated, substituted, dilute and invalid test result) | | | |
| 26.169(h): HHS lab prepares and submits annual statistical summary report of urinalysis testing results | 67 ⁹⁸ | 2.0 | 134 |
| 26.185(c): Donor discussion with MRO of positive, adulterated, substituted, dilute, or invalid test result | 621 | 0.5 ⁹⁹ | 311 |
| 26.185(e): Donor provides documentation to the MRO demonstrating an inability to discuss test results and requesting the test result determination be reopened | 8 | 1.0 | 8 |
| 26.185(f)(1): HHS lab consultation with MRO on whether additional testing of a specimen with an invalid test result should be performed at a second HHS lab | 26 | 0.5 | 13 |

97 This estimate presents the total number of drug positive, adulterated, and substituted test results (621) reported to the MRO by HHS labs from CY 2013 through CY 2015 for all D&A testing programs (566 in CY 2013, 618 in CY 2014, and 679 in CY 2015).

98 The previous clearance incorrectly estimated the number of responses as one for each HHS lab. Instead, the number of responses are the number of reports developed by HHS labs that perform testing for FFD programs (67 reports). The NRC estimates that it takes an HHS lab 2.0 hours to prepare and send an annual summary report of test results to a licensee or other entity.

99 The NRC estimates that the donor spends an average of 30 minutes (0.5 hour) in discussion with the MRO regarding an HHS lab test result. The average number of drug positive, adulterated, and substituted specimens in CY 2013 through CY 2015 is 621 results (566 in CY 2013, 618 in CY 2014, and 679 in CY 2015). The previous clearance overestimated the burden per discussion at 1.0 hour.

**Table 4
Annual Third-Party Disclosure Burden**

| Section | Number of Responses | Burden Hours per Response | Total Annual Burden Hours |
|--|---|---------------------------|---------------------------|
| 26.185(f)(2): Donor discussion with MRO regarding an invalid test result | Burden accounted for under section 26.185(c) | | |
| 26.185(h)(1): Donor discussion with MRO regarding a substituted test result | | | |
| 26.185(i)(1): Donor discussion with MRO regarding an adulterated test result | Burden accounted for under section 26.185(c) | | |
| 26.185(j): Donor discussion with MRO regarding a positive test result from use of a prescription medication (amphetamine, morphine, codeine), and donor provides documentation on medication use to the MRO (e.g., prescription information and pharmacy, prescribing physician information) | 60 | 1 ¹⁰⁰ | 60 |
| 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) | 31 ¹⁰¹ | 0.25 | 8 |
| 26.185(o): HHS lab provides report with quantitative test results for a specimen from a donor applying for reauthorization following a 1 st positive drug test result (at MRO request) | Burden accounted for under section 26.169(c)(1) | | |
| 26.189(b): If a qualified treatment professional other than the MRO or SAE performs a determination of fitness on an individual, that treatment professional completes and provides a written determination to the MRO | 26 | 1 | 26 |
| 26.209(a): Individual declares that due to fatigue, he or she is unable to safely and competently perform his or her duties | 21 | 0.3 | 6 |
| 26.411(b): Applicant provides written consent to the reactor construction site D&A testing program | 6,898 ¹⁰² | 0.25 | 1,725 |

100 The NRC estimates that an MRO will spend 1.0 hour reviewing a positive test result associated with the use of a prescription medication. These activities consist of obtaining information from the donor and confirming this information with a prescribing physician, pharmacy, or both. The NRC estimates that 60 positive results are consistent with a legitimate medical use each year.

101 NRC estimates that 5 percent of the 621 positive, adulterated, and substituted specimens will be retested at a second HHS lab at the request of the donor. The previous clearance estimated that 10 percent of these specimens would be retested.

102 The NRC estimates 6,898 individuals per year provide a signed consent form (i.e., the average number of pre-assignment tests performed by the reactor construction site D&A testing programs from CY 2013 through CY 2015 – 5,886 in CY 2013, 8,414 in CY 2014, and 6,395 in CY 2015). The NRC estimates that each applicant will spend 15 minutes (0.25 hour) reviewing and then signing a written consent. The previous clearance estimated 4,675 individuals per year.

**Table 4
Annual Third-Party Disclosure Burden**

| Section | Number of Responses | Burden Hours per Response | Total Annual Burden Hours |
|---|---|---------------------------|---------------------------|
| 26.715(a): Documentation of all aspects of HHS lab testing process, not specified elsewhere in section 26.715(b) | Burden covered by HHS lab certification requirements OMB Clearance No. 0930-0158 | | |
| 26.715(b)(1): Retain personnel files on HHS lab staff | | | |
| 26.715(b)(2): Retain HHS lab chain-of-custody documents | 9 | 240 | 2,160 |
| 26.715(b)(3): Retain HHS lab QA/QC records | Burden covered by HHS lab certification requirements OMB Clearance No. 0930-0158 | | |
| 26.715(b)(4): Retain HHS lab superseded procedures | 9 | 40 | 360 |
| 26.715(b)(5) Retain all test data from HHS lab (including calibration curves and any calculations used in determining test results) | Burden covered by HHS lab certification requirements OMB Clearance No. 0930-0158 | | |
| 26.715(b)(6): HHS lab test reports | 9 | 240 | 2,160 |
| 26.715(b)(7): HHS lab performance testing records | Burden covered by HHS lab certification requirements OMB Clearance No. 0930-0158 | | |
| 26.719(c): HHS lab provides information to the licensee or other entity on investigation completed on a testing error (information for 30-day event report to NRC) | 8 | 8 | 64 |
| 26.821(b): Written agreement between C/Vs and licensees to retain Part 26 records and to permit authorized NRC representatives access to those records for inspection | 5 | 4.0 | 20 |
| TOTAL | | | 492,029 |

TOTAL PART 26 BURDEN: 719,195.9 hours (see table below)

TOTAL RESPONSES: 441,833 responses. This is equal to 215 total annual reporting responses from Table 3 + 49 recordkeepers (26 D&A testing programs + 2 reactor construction site D&A testing programs + 21 fatigue management programs) + 441,569 third-party responses from Table 4.

NUMBER OF RESPONDENTS: 88,229 respondents. This is equal to 26 D&A testing programs + 2 reactor construction site D&A testing programs + 21 fatigue management programs + 88,180 third-party respondents¹⁰³).

THIRD-PARTY BURDEN: 492,029 hours (see table below)

| Table | Description | Clearance Period | | Change in Burden Hours |
|--------------|-------------------------------|-------------------|-------------------|------------------------|
| | | 2014-2017 (hours) | 2017-2020 (hours) | |
| 1 | One-Time Recordkeeping | 41.4 | 112.0 | + 70.6 |
| 2 | Annual Recordkeeping | 314,177.4 | 220,886.5 | - 93,290.9 |
| 3 | Annual Reporting | 6,165.2 | 6,168.0 | + 2.8 |
| 4 | Annual Third-Party Disclosure | 303,559.1 | 492,029.4 | + 188,470.3 |
| TOTAL | | 623,943.1 | 719,195.9 | + 95,252.8 |

¹⁰³ The NRC estimates 88,180 third-party respondents for this clearance period (i.e., 81,219 persons subject to pre-access testing at D&A testing programs + 6,898 individuals subject to pre-access testing at reactor construction site D&A testing programs + 9 HHS labs + 2 BPTS suppliers + 26 EAPs + 26 non-licensee collection sites). The previous clearance estimated 98,565 third-party respondents per year.

**Table 5
Annualized NRC Reporting and Recordkeeping Burden**

| NRC ACTION | No. Actions/ Year | Burden Hours/ Action | Total Hours |
|---|--|-------------------------|----------------|
| Review exemption request under section 26.9 | 0 ¹⁰⁴ | 16 hours | 0 |
| Review FFD policies and procedures under section 26.27(d) (performed during periodic inspections) | 12 | 8 hours | 96 |
| Review records under section 26.75(h) to ensure only appropriate records maintained for a licensee or other entity who administratively withdraws access for initial positive drug tests for marijuana or cocaine at an LTF (performed during periodic inspections) | 0 ¹⁰⁵ | 4 hours | 0 |
| Review and evaluate report made under section 26.77(c) regarding an NRC employee or contractor being unfit for duty | 0 | 4 hours | 0 |
| Review documentation provided by SAE upon request by NRC under section 26.187(f) | 1 | 4 hours | 4 |
| Review and evaluate a 24-hour report made under section 26.417(b)(1) to the NRC Operations Center on a significant FFD program failure | Burden accounted for under section 26.719(b) | | |
| Annual FFD program performance report – Review, analyze, and summarize information received under 26.417(b)(2) from a reactor construction site D&A testing program. | 2 | 25 hours | 50 |
| Annual fatigue management performance report – Review, analyze, and summarize fatigue management data specified in section 26.201(e) that is submitted under section 26.717 | 59 ¹⁰⁶ | 10 hours | 590 |

104 The NRC does not anticipate receiving any exemption requests in the current clearance period. The previous clearance estimated two (2) exemption requests per year, none were received.

105 A review of CY 2015 FFD program performance data indicated that no licensee or other entity utilizing an LTF administratively withdraws access based on an initial positive drug test for marijuana or cocaine. The previous clearance overestimated this burden at 12 reviews per year.

106 In CY 2015, 21 fatigue management programs submitted an annual FFD program performance report for each of the 59 operating nuclear power reactor sites.

| NRC ACTION | No. Actions/ Year | Burden Hours/ Action | Total Hours |
|--|----------------------|-------------------------|----------------|
| Annual FFD program performance report – Review, analyze, and summarize information received under 26.717 from a D&A testing program | 67 ¹⁰⁷ | 12 hours | 804 |
| 24-hour report – Review, evaluate, and respond to a report made under section 26.719(b) to the NRC Operations Center regarding a significant FFD policy violation or programmatic failure | 37 ¹⁰⁸ | 8 hours ¹⁰⁹ | 296 |
| 30-day report – Review, evaluate, and respond to a report made under section 26.719(c) to the NRC detailing the investigation of any testing errors or unsatisfactory performance discovered at an LTF or HHS lab. | 8 ¹¹⁰ | 4 hours | 32 |
| TOTAL | | | 1,872 |

107 Each operating nuclear power reactor site (59 sites), fuel cycle facility (2 sites), corporate FFD program (5 sites), and C/V (1 site) submits annual FFD Program Performance report information to the NRC. The previous clearance estimated that NRC staff spent an average of 25 hours per site to review, analyze, and summarize FFD program performance report information. Based on full industry use of the electronic reporting forms (i.e., NRC Forms 890 and 890) and upgrades to the NRC information processing system, NRC estimates this activity will take 12 hours per FFD performance report.

108 FFD program performance data from CY 2013 through CY 2015 indicate that NRC received an average of 37 reports per year under section 26.719(b). The previous clearance also estimated 37 reports per year.

109 The previous clearance estimated that NRC staff spent 16 hours to review and evaluate each section 26.719(b) report. Based on improved knowledge of the review process, this activity is estimated to take 8 hours per report.

110 FFD program performance data from CY 2013 through CY 2015 indicate that NRC received an average of eight (8) reports per year under section 26.719(c). The previous clearance estimated six (6) reports per year.

APPENDIX A

DESCRIPTION OF INFORMATION COLLECTION REQUIREMENTS CONTAINED IN 10 CFR PART 26

10 CFR 26.4(j) requires that a licensee or other entity provide training to each individual subject to Part 26 on the knowledge and abilities (KAs) listed in section 26.29(a)(1) through (a)(10). In addition, individuals subject to the D&A testing program of another Federal or State agency, who have been granted authorization by a licensee or other entity under Part 26, must complete training on any KA in section 26.29(a) not included in the training provided by the Federal or State agency. State and Federal agencies also must notify the licensee granting authorization of any FFD policy violations by these individuals.

10 CFR 26.9 provides that the Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the requirements of Part 26, and specifies that exemption requests must meet the provisions of 10 CFR 50.12 or 10 CFR 70.17. This reporting requirement ensures that licensees seeking an exemption from any Part 26 requirement provide the NRC with information to determine if the criteria for granting an exemption listed in sections 50.12 or 70.17 have been met.

10 CFR 26.27(a) requires each licensee or other entity subject to Part 26 to establish, implement, and maintain written policies and procedures designed to meet the performance objectives in section 26.23 and other requirements in Part 26. The written FFD policy is the primary means of communicating information on the FFD program to individuals subject to Part 26, and the FFD procedures are the primary means of documenting how the FFD program is administered by the licensee or other entity. This requirement also ensures that the due process rights of individuals are protected by providing information on the FFD policy and consequences of not adhering to the policy.

10 CFR 26.27(b) requires each licensee or other entity to make a clear and concise FFD policy statement readily available to all subject individuals specifies the minimum contents that must be included in the policy statement. For example, the FFD policy must include a description of the consequences of prohibited actions (abuse of legal drugs and alcohol, misuse of prescriptions), alcohol abstinence requirements, factors that can affect the fitness-for-duty of an individual, employee assistance programs, and responsibilities to report FFD concerns. This requirement ensures that the current, specific, and concise information on the FFD policy is available for review by all individuals subject to the FFD program. Section 26.713(d) also ensures that superseded versions of the FFD policy are maintained.

10 CFR 26.27(c) requires that each licensee or other entity prepare and maintain written procedures that describe the methods used to implement the FFD policy that meets the requirements in Part 26. This requirement ensures that individuals that administer the FFD program have detailed and specific information on the methods for testing drugs and alcohol (e.g., the drug testing panel and testing cutoff levels); the conditions under which testing is permitted (e.g., when an individual is selected for random testing he or she must report to the collection site); how and why behavioral observation is conducted; and how authorization is granted, maintained, reinstated, and withdrawn. This requirement contributes to the protection of due process rights of individuals subject to Part 26, provides for prior notice, and ensures that

documentation is maintained in support of legal proceedings. Section 26.713(d) also ensures that the licensee or other entity maintains superseded versions of the FFD procedures.

10 CFR 26.27(d) specifies that the NRC may, at any time, review the written FFD policy and procedures of a licensee's or other entity's FFD program. This requirement ensures that NRC has timely access to records, which is necessary to support inspection and the evaluation of compliance with Part 26 requirements.

10 CFR 26.29(a) requires that the licensee-developed training program contain specific content to ensure that individuals who are subject to Part 26 have specified KAs. This requirement provides assurance that persons receive sufficient training in the KAs necessary to meet the performance objectives in section 26.23.

10 CFR 26.29(b) requires that all individuals subject to Part 26 successfully complete training and pass a comprehensive examination on the KAs specified in section 26.29(a)(1) through (a)(10). The examination must be developed, maintained, and executed to provide assurance that persons are adequately knowledgeable of Part 26 requirements.

10 CFR 26.29(c)(2) requires those individuals who already have completed the comprehensive examination under 26.29(b), to complete refresher training on a nominal 12-month frequency (or more frequently if a need is indicated). Refresher training provides assurance that persons subject to Part 26 continue to be trustworthy, reliable, and fit for duty as demonstrated by their knowledge and adherence to Part 26 requirements.

10 CFR 26.29(d) allows a licensee or other entity to accept the initial or annual refresher training completed by an individual subject to Part 26 under another the FFD program of another license or other entity, if the section 26.26(b) training was successfully completed within the previous 12 months. The provision may reduce training burden on licensees and other entities that use personnel that work for multiple regulated entities in a single year (e.g., short-term outage workers that travel between licensee sites on a frequent basis).

Section 26.713(b)(1) establishes the recordkeeping requirements for section 26.29(a), (b), (c)(1) and (c)(2), and (d).

10 CFR 26.31(b)(1)(i) requires licensees and other entities to complete background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel before their assignment to tasks directly associated with administration of the FFD program. The background investigations, credit and criminal history checks, and psychological investigations would be conducted under a nuclear power plant's access authorization program (implemented pursuant to 10 CFR Part 73). Section 26.31(b)(1)(i) requires updates to the credit and criminal history checks, and psychological assessments every 5 years, which ensure that FFD program personnel continue to be trustworthy and reliable. This information ensures that a licensee can make an informed determination of whether an individual is trustworthy and reliable and able to service as a member of the FFD program personnel staff. Affected individuals must provide this information to a licensee or other entity to enable the completion of these evaluations. Section 26.713(f) establishes the recordkeeping requirements of section 26.31(b)(1)(i).

10 CFR 26.31(b)(1)(v) requires FFD program personnel to be subject to a BOP designed to assure that they continue to meet the highest standards of honesty and integrity. When the Medical Review Officer (MRO) and MRO staff are located on site at the facility of a licensee or other entity, the MRO and MRO staff are also subject to behavioral observation. Section 26.189(c) accounts for the burden of records generated under the BOP.

10 CFR 26.31(c) requires licensees and other entities to implement D&A testing programs that administer tests under five conditions. No records are required by this section, but are required under Subparts C – G, and N.

- (1) Pre-access (to grant initial, updated, or reinstated authorization to an individual)
- (2) For cause (in response to an individual's observed behavior or physical condition indicating possible substance abuse, or after receiving credible information of substance abuse)
- (3) Post-event (after an event involving human error that may have caused or contributed to the event)
- (4) Follow-up (as part of a follow-up plan to verify continued abstinence of substance abuse)
- (5) Random (on a statistically random and unannounced basis such that all individuals in the population subject to testing have an equal probability of being selected and tested)

10 CFR 26.31(d)(1)(i)(C) permits a licensee or other entity to test for additional substances not included in the NRC-required testing panel. To do so, the substance(s) must be listed in Schedules I through V of section 202 of the Controlled Substances Act [21 U.S.C. 812] and the licensee or other entity must establish rigorous testing procedures so that the MRO can evaluate the use of these substances. The development of rigorous testing procedures ensures to the accuracy of test results and is a donor protection. The burden for this activity is accounted for under section 26.27.

10 CFR 26.31(d)(1)(i)(D) permits a licensee or other entity to test for a drug or drug metabolite not listed in section 26.31, if the assay and cutoff levels to be used are certified in writing as scientifically sound and legally defensible by an independent qualified forensic toxicologist who has no relationships with manufacturers of the assays or instruments to be used or the HHS Certified Laboratory that will conduct the testing for the licensee or other entity, which could be construed as a potential conflict of interest. Certification is not required if the U.S. Department of Health and Human Services' (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines) are revised to authorize use of the assay in testing for the additional drug or drug metabolites and the licensee or other entity uses the cutoff levels established in the HHS Guidelines. This paragraph allows licensees and other entities to add to the panel of drugs for which testing is required in section 26.31(d)(1) and to assign cutoff levels that shall be certified in writing as scientifically sound and legally defensible by an independent forensic toxicologist. This requirement ensures that the NRC can verify that the assays and cutoff levels are appropriate. The licensee or other entity is required to maintain a copy of each certification under section 26.31(d)(1)(i)(D). Recordkeeping requirements for section 26.31(d)(1)(i)(D) are established by section 26.713(g).

10 CFR 26.31(d)(1)(ii) and (d)(1)(ii) permit licensees and other entities to test for additional drugs beyond the minimum testing panel in section 26.31(d)(1). These requirements detail the process that a licensee or other entity must complete to verify that the assays and cutoff levels used in testing are scientifically sound and legally defensible (i.e., independent forensic toxicologist evaluation and written certification). The licensee or other entity is required to maintain a copy of each certification under section 26.31(d)(1)(ii). Recordkeeping requirements for section 26.31(d)(1)(ii) are established by section 26.713(g).

- 10 CFR 26.31(d)(1)(ii) allows licensees and other entities that are conducting post-event, follow-up, or for cause testing to test for any drugs listed on Schedules I through V of section 202 of the Controlled Substances Act [21 U.S.C. 812] that an individual is suspected of having abused. If the drug(s) or drug metabolite(s) tested are not included in the FFD program's drug panel, the assay and cutoff levels to be used must be certified in writing by an independent qualified forensic toxicologist in accordance with section 26.31(d)(1)(i)(D).
- 10 CFR 26.31(d)(1)(iii) requires licensees or other entities to document and describe the additional drugs for which testing will be performed in written policies and procedures.

10 CFR 26.31(d)(3)(ii) describes the training and skills that LTF technicians must possess to perform validity and drug testing of urine specimens and requires the retention of documentation of these qualifications. These requirements ensure that LTF technicians perform drug and validity tests correctly. The burden for documenting the qualifications of LTF personnel is accounted for under section 26.125(b) and (c).

10 CFR 26.31(d)(3)(iii)(A) and (d)(3)(iii)(C) ensure that individuals receive prior notice of the cutoff levels that are used, and that those cutoff levels are certified by an appropriate expert as meeting the criteria of scientific and technical suitability. The cutoff levels used in a licensee or other entity's testing program are available to subject individuals through the FFD policy or procedures developed pursuant to section 26.27. The licensee or other entity must maintain a copy of each certification under section 26.31(d)(3)(iii)(C). Section 26.713 establishes the recordkeeping requirements for section 26.31(d)(3)(iii)(A) and (C).

- 10 CFR 26.31(d)(3)(iii)(A) requires a licensee or other entity that uses more stringent cutoff levels than the cutoff levels specified in section 26.163 to document the cutoff levels in any written policies and procedures in which cutoff levels for drug testing are described.
- 10 CFR 26.31(d)(3)(iii)(C) requires the scientific and technical suitability of more stringent cutoff levels to be evaluated and certified, in writing, by a forensic toxicologist, unless the HHS Guidelines are revised to lower the cutoff levels used for the drug or drug metabolites in Federal workplace testing programs and the licensee or other entity implements the cutoff levels published in the HHS Guidelines, or if the licensee or other entity received written approval of the NRC to test for lower cutoff levels before the implementation of the final rule.

10 CFR 26.33 requires all individuals subject to an FFD program be subject to behavioral observation by trained personnel who can detect impairment from drugs, alcohol, fatigue or

other adverse behaviors and can notify specified personnel identified in the FFD policy to take appropriate action. The burden for records of FFD concerns based on possible impairment from drugs or alcohol is covered under section 26.31(c)(2), which describes for-cause D&A testing actions to be conducted when any observed behavior or credible information received indicates possible substance abuse. The burden for records of FFD concerns related to fatigue is covered under section 26.211(a)(1), which describes the requirement to perform a fatigue assessment in response to an observed condition of impaired alertness creating a reasonable suspicion that an individual is not fit to safely and competently perform his or her duties. Records generated pursuant to section 26.33 are maintained as part of for-cause testing records under section 26.31 or fatigue assessment records under section 26.211.

10 CFR 26.35(a) requires each licensee and other entity to maintain an employee assistance program (EAP) to offer confidential assessment, short term counseling, referral services, and treatment monitoring to individuals who have problems that could adversely affect the individuals' abilities to safely and competently perform their duties. This requirement defines the scope and activities of the EAP and provides assurance that personnel have access to adequate treatment options for conditions that could result in conditions adverse to safety. A written description of the EAP program is included in the FFD policy and procedures developed under section 26.27.

10 CFR 26.35(c) requires, in part, that EAP staff protect the privacy each individual seeking assistance, which encourages use of the EAP. The EAP may release information to the licensee or other entity if the individual waives the right to privacy in writing, or if a determination is made that the individual's condition or actions pose or have posed an immediate hazard to himself or herself or others. The EAP offers confidential assessment, short-term counseling, referral services, and treatment monitoring to individuals who self-identify problems that could potentially affect their ability to safely and competently perform assigned duties, and may also include those who have violated the FFD and are receiving treatment for substance abuse. The requirement that the individual waive the right to privacy in writing is a donor protection. The requirement that the EAP staff informs the FFD program management if an individual poses or has posed an immediate hazard to him or herself or others, is necessary to enable early intervention to prevent self-harm, harm to others, a reportable occurrence, or condition adverse to safety or security.

10 CFR 26.37(a), (b) and (b)(1), (c), and (d) ensure that personal information collected under Part 26 is protected, and only disclosed to persons permitted to access such information under Part 26 or specifically authorized by the donor through written consent.

- 10 CFR 26.37(a) requires each licensee or other entity that collects personal information on an individual for the purpose of complying with Part 26, to establish, use, and maintain a system of files and procedures to protect the individual's privacy.
- 10 CFR 26.37(b) requires each licensee or other entity to obtain a signed consent from an individual that authorizes the disclosure of personal information collected under Part 26. No consent is needed if information sharing is authorized by Part 26 (e.g., MRO and MRO staff; NRC representatives; law enforcement officials under court order; licensee or other entity personnel with a need for access to perform assigned duties in the FFD program; presiding officer in judicial or administrative proceeding initiated by the individual).

- 10 CFR 26.37(b)(1) specifies that if an individual requests the licensee or other entity disclose personal information collected under Part 26 to the individual's designated representative for specified FFD matters (e.g., a union official, attorney), the individual must designate this request in writing. This collection is a donor protection that ensures that personal information collected under Part 26 is not disclosed without the donor's permission, and also provides the licensee or other entity with documentation to demonstrate evidence of receipt of this request.
- 10 CFR 26.37(c) requires that an FFD program disclose, after receiving a signed release form a subject individual, information collected under Part 26 to other licensees or entities making authorization decisions under Part 26. Section 26.713(a) establishes the recordkeeping requirements for section 26.37(c).
- 10 CFR 26.37(d) requires the FFD program (including the collection site, HHS lab, Substance Abuse Expert (SAE), or MRO), after receiving a written request from a subject individual or designated representative, to promptly provide copies of all FFD records pertaining to the individual (e.g., records on the determination of an FFD policy violation, D&A test results, MRO reviews, determinations of fitness, HHS lab certification). This section is a donor protection by providing access to records created under Part 26. Sections 26.713 and 26.715 establish the recordkeeping requirements for section 26.37(d).

10 CFR 26.39(a) and (b) ensure that a licensee or other entity establish procedures for the determination of FFD policy violations, notification of those determinations to subject individuals, and afford individuals with an objective and impartial review of such determinations, if requested. These requirements afford due process to individuals subject to the rule by providing specific information on the FFD policy violation, and the procedures to follow if a review of that determination is sought. Section 26.715(a) establishes the recordkeeping requirements for sections 26.39(a) and (b)

- 10 CFR 26.39(a) requires each licensee and other entity subject to Subpart B to establish procedures for the review of a determination that an individual has violated the FFD policy.
- 10 CFR 26.39(b) requires that the procedures for the review of a determination that an individual has violated FFD policy provide for giving notice to the individual of the grounds for the determination that the individual has violated the FFD policy and provide for an opportunity for the individual to respond and submit additional information.

10 CFR 26.39(d) requires that if a review of a determination that an individual has violated FFD policy finds in favor of the individual, the licensee or other entity must update the relevant records to delete or correct all information found to be inaccurate. This requirement is a donor protection and ensure that a licensee's and other entity's records do not contain incorrect information concerning FFD determinations. Section 26.713(a)(2) establishes the recordkeeping requirements for section 26.39(d).

10 CFR 26.39(e) requires that when a C/V is administering an FFD program on which licensees and other entities rely, and the C/V determines that its employee, subcontractor, or applicant

has violated the FFD policy, the C/V provides the individual with the review procedure required by section 26.39(b). This requirement affords due process by ensuring that each individual with an FFD policy violation is provided specific information on the FFD policy violation determination, and the procedures to follow if a review of that determination is sought. Section 26.713(a)(2) establishes the recordkeeping requirements for section 26.39(e).

10 CFR 26.41(a), (b), (c)(1), (d), (f), and (g) specify the licensee and other entity auditing requirements, including audit documentation, records maintenance, and records access. These requirements ensure that a licensee or other entity documents oversight of C/Vs and service providers. These records would be evaluated during NRC inspections. Section 26.713(b)(2) establishes the recordkeeping requirements for retaining audit records.

- 10 CFR 26.41(a) requires licensees and other entities to audit the FFD program elements provided by any C/V, the FFD program of any C/V accepted by the licensee or other entity, any FFD program service provided to the C/V by a subcontractor, and any HHS lab used by the licensee or other entity and its C/Vs. This section also requires that corrective actions be taken for any problems identified during an audit. Licensee or other entity audits of service providers and C/Vs ensure to the continuing effectiveness of the FFD program.
- 10 CFR 26.41(b) requires that licensees and other entities audit the entire FFD program on a nominal 24-month frequency, or sooner if needed.
- 10 CFR 26.41(c)(1) requires that licensees and other entities to audit on a nominal 12-month frequency the FFD services provided to a licensee or other entity by C/V personnel who are off site or are not under the direct daily supervision or observation of the licensee's or other entity's personnel, and HHS labs.
- 10 CFR 26.41(d) requires that a licensee's or other entity's contract with a C/V or HHS lab include two records access provisions. The right to access and review information that is reasonably relevant to audits of FFD program elements provided by C/Vs, the program elements of any C/Vs accepted by the licensee or other entity, and the HHS lab. The right to obtain and take away copies any documents and data that may be needed to assure that the C/V, its subcontractors, or the HHS lab properly perform functions.
- 10 CFR 26.41(f) requires the results of any audits required by section 26.41(a), (b), and (c) to be documented and reported to senior corporate and site management. C/Vs who have licensee-approved FFD programs must provide the licensees to whom they provide services with copies of the audit report.
- 10 CFR 26.41(g) allows licensees and other entities to jointly conduct audits or to accept audits conducted by other licensees, but requires them to review audit records and reports to identify any areas that were not covered by the shared or accepted audit and to maintain a copy of the shared audit and inspection records, including findings, recommendations, and corrective actions.

10 CFR 26.53(e)(2) requires a C/V to inform a licensee or other entity if the C/V's FFD program denies or unfavorably terminates an individual's authorization and the individual is performing

any duties for the licensee or other entity that are specified in section 26.4(a) through (e) and (g), or, at the licensee's or other entity's discretion, section 26.4(f). The licensee or other entity is required to deny or unfavorably terminate the individual's authorization to perform those duties on the day that it receives information from the C/V, or to implement the process in section 26.69 to maintain the individual's authorization. This section requires communications between the C/V and the licensee or other entity to ensure that the necessary information is transferred between them concerning the individual.

10 CFR 26.53(g) requires the licensee and C/V personnel specified in section 26.4(a) and, as applicable, section 26.4(d) to identify any violation of any requirement of Part 26 to any licensee who has relied on or intends to rely on the FFD program element that is determined to be in violation of Part 26. This section requires communications between the C/V and the licensee or other entity to ensure that the necessary information is transferred between them concerning the violation.

10 CFR 26.53(h) requires licensees and other entities to obtain the knowledge and written consent of the subject individual before initiating any actions under Subpart C, Granting and Maintaining Authorization. The licensee or other entity is required to record the individual's application for authorization; withdrawal of consent; the reason given for the withdrawal, if any; and any pertinent information gathered from the elements that were completed. Actions relating to authorization become part of a record that can affect the individual's ability to be employed in the nuclear power industry. An individual's consent to actions is necessary to protect the person from actions taken without their knowledge or approval.

10 CFR 26.53(i) requires licensees and other entities to inform, in writing, any individual who is applying for authorization that the following actions are sufficient cause for denial or unfavorable termination of authorization: refusal to provide written consent for the suitable inquiry; refusal to provide or falsification of any personal information required under Subpart C of Part 26; refusal to provide written consent for the sharing of personal information with other licensees or C/Vs; and failure to report any legal actions, as defined by section 26.5. This section requires the licensee or other entity to provide a written notice to the individual of the actions that are sufficient cause for denial or unfavorable termination. This notice is necessary in advance to allow individuals to determine whether the application process may lead to an unfavorable record that could preclude their future employment in the nuclear power industry.

10 CFR 26.55(a)(1) and (a)(2) require that a self-disclosure (section 26.61) and suitable inquiry (section 26.63) be completed by each applicant who has never held authorization or whose authorization has been interrupted for more than 3 years. Information provided in the self-disclosure, employment history, and suitable inquiry enables the licensee or other entity to make an access determination (i.e., is the applicant trustworthy, reliable, and fit for duty). Sections 26.61, 26.63, and 26.713(a)(1) and (3) establish the recordkeeping requirements for section 26.55(a)(1) and (a)(2).

- 10 CFR 26.55(a)(1) requires the licensee or other entity to obtain and review a self-disclosure and employment history from an individual before granting authorization to the individual.
- 10 CFR 26.55(a)(2) requires the licensee or other entity to complete a suitable inquiry before granting authorization to the individual.

10 CFR 26.57(a)(1) and (a)(2) require that a self-disclosure (section 26.61) and suitable inquiry (section 26.63) be completed by each applicant who is applying for authorization after an interruption of more than 365 days but less than 3 years, and whose last period of authorization was terminated favorably. Information provided in the self-disclosure, employment history, and suitable inquiry enables the licensee or other entity to make an access determination (i.e., is the applicant trustworthy, reliable, and fit for duty). Sections 26.61, 26.63, and 26.713(a)(1) and (a)(3) establish the recordkeeping requirements for section 26.57(a)(1) and (a)(2).

- 10 CFR 26.57(a)(1) requires the licensee or other entity to obtain and review a self-disclosure and employment history from an individual before granting authorization to the individual.
- 10 CFR 26.57(a)(2) requires the licensee or other entity to complete a suitable inquiry before granting authorization to the individual.

10 CFR 26.59(a)(1) and (a)(2) require that a self-disclosure (section 26.61) and suitable inquiry (section 26.63) be completed by each applicant who is applying for authorization after an interruption of more than 30 days but no more than 365 days, and whose last period of authorization was terminated favorably. Information provided in the self-disclosure, employment history, and suitable inquiry enables the licensee or other entity to make an access determination (i.e., is the applicant trustworthy, reliable, and fit for duty). Sections 26.61, 26.63, and 26.713(a)(1) and (a)(3) establish the recordkeeping requirements for section 26.59(a)(1) and (a)(2).

- 10 CFR 26.59(a)(1) requires the licensee or other entity to obtain and review a self-disclosure and employment history from an individual before granting authorization to the individual.
- 10 CFR 26.59(a)(2) requires the licensee or other entity to complete a suitable inquiry before granting authorization to the individual.

10 CFR 26.59(c)(1) requires the licensee or other entity to obtain and review a self-disclosure from an individual whose authorization has been interrupted for a period of no more than 30 days and whose last period of authorization was terminated favorably before granting authorization to the individual. In this instance, because authorization was interrupted for a short time period (30 days or less), a suitable inquiry would not be completed. The self-disclosure information enables the licensee or other entity to provide reasonable assurance that an individual is trustworthy, reliable, and fit for duty, as demonstrated by avoiding substance abuse, and information on the individual's character and reputation covered in the self-disclosure. Information provided in the self-disclosure enables the licensee or other entity to make an access determination (i.e., is the applicant trustworthy, reliable, and fit for duty). Sections 26.61, and 26.713(a)(1) and (a)(3) establish the recordkeeping requirements for section 26.59(c)(1).

10 CFR 26.61(a), (a)(1) and (a)(2) specify when a self-disclosure and employment history must be completed for an individual seeking authorization. The burdens for an applicant to complete and review a self-disclosure and an employment history, and the licensee or other entity to review this information are accounted for under section 26.61(a). Paragraph 26.61(a)(1) and (a)

(2) relax the self-disclosure and employment history reporting requirements in sections 26.55, 26.57, and 26.59. Section 26.713(a)(1) establishes the recordkeeping requirements for section 26.61(a).

- 10 CFR 26.61(a) requires a licensee or other entity to obtain a written self-disclosure and employment history from an individual who is applying for authorization, except under two circumstances described in section 26.61(a)(1) and (a)(2).
- 10 CFR 26.61(a)(1) specifies that a self-disclosure and employment history are not needed, if the individual previously held authorization under Part 26, the licensee or other entity verifies the individual's last authorization was terminated favorably, and the individual was subject to a behavioral observation and an arrest-reporting program throughout the time since the last authorization.
- 10 CFR 26.61(a)(2) specifies that an the individual's last period of authorization was terminated favorably within the past 30 days, the licensee or other entity need not obtain the individual's employment history.

10 CFR 26.61(b) and (c) specify the information to be collected in the self-disclosure and employment history from an applicant and ensures that necessary information on trustworthiness, reliability, and fitness for duty is available to support a licensee's or other entity's authorization determination under sections 26.55, 26.57, or 26.59. The burden for this information collection is accounted for under section 26.61(a), (a)(1), and (a)(2).

- 10 CFR 26.61(b) specifies the information to be included in the written self-disclosure, and includes information on FFD policy violations; authorization denials; unfavorable terminations of authorization; use, sale, or possession of illegal drugs; abuse of legal drugs or alcohol; subversion or attempted subversion of a drug or alcohol testing program; refusal to take a drug or alcohol test; substance abuse treatment (except for self-referral); and, legal or employment action taken for alcohol or drug use.
- 10 CFR 26.61(c) requires the individual to provide an employment history listing employers and dates of employment.

10 CFR 26.63(a), (b), (c) and (c)(2), and (f) describe information to be reported or recorded in support of authorization determinations under sections 26.55, 26.57, and 26.59, and also describe limitations on use of this information. Paragraphs 26.63(b), (c), and (f) specify that licensees and other entities may rely on third-party communications, but do not create any additional recordkeeping requirements. Paragraph 26.63(c)(2) creates an additional information collect if an applicant's employment history included military service. Section 26.713(a)(1) establishes the recordkeeping requirements for section 26.63(a) and (c)(2).

- 10 CFR 26.63(a) requires the licensees or other entities to ensure a suitable inquiry has been conducted unless the individual was previously authorized, the licensee has verified that the last authorization was terminated favorably, and the individual was subject to a behavioral observation and arrest-reporting program throughout the period of interruption.

- 10 CFR 26.63(b), (c), and (f) specify that for the suitable inquiry requirement, a licensee or other entity may rely upon information gathered by other entities subject to Subpart C of Part 26 regarding an applicant's previous period(s) of authorization (e.g., reasons for termination, eligibility for rehire, determinations of fitness conducted under section 26.189, reviews and resolutions of PDI).
- 10 CFR 26.63(c)(2) specifies that if an applicant employment history includes military service, the licensee or other entity must request a characterization of service, reason for separation, and any disciplinary actions related to PDI. If the applicant's last duty post cannot provide this information, a copy of the DD 214 from the custodian of military records or from the applicant is acceptable.

10 CFR 26.63(c)(3) specifies that if a company, previous employer, or educational institution to whom the licensee or other entity has directed a request for information refuses to provide information within 3 business days of the request, the licensee or other entity shall document this refusal, inability, or unwillingness in the record of the investigation and obtain a confirmation of employment or educational enrollment and attendance from at least one alternate source. If the licensee or other entity uses an alternate source but the response is received after 3 business days, the response should be evaluated and documented. This requirement ensures that a record is created that documents any gaps or absences in the information otherwise required by sections 26.55, 26.57, and 26.59. This requirement also helps to ensure that licensees and other entities can grant authorization, even if the information requested but not received from another company, previous employer, or educational institution, is not available. Recordkeeping requirements for section 26.63(c)(3) are established by section 26.713(a)(1).

10 CFR 26.63(d) requires, if a licensee or other entity presents to another licensee or other entity an individual's signed release authorizing the disclosure of information, that other licensee or entity shall disclose whether the individual's authorization was denied or terminated unfavorably as a result of a violation of an FFD policy and the information upon which the denial or unfavorable termination of authorization was based and any other information that is relevant to an authorization decision. This requirement ensures that information about individuals can be transferred from one licensee or other entity to another licensee or other entity for FFD determinations, because individuals who belong to the much more transient workforce that is currently employed in the nuclear industry frequently move from one licensee or other entity to another. Sections 26.711 and 26.713(a), (b), and (c) establish the recordkeeping requirements in section 26.63(d)

10 CFR 26.63(e) specifies that a the licensee or other entity may obtain, when verifying information provided by an applicant in a suitable inquiry, information and documents by electronic means (including but not limited to telephone, facsimile, or email). The licensee or other entity shall document information obtained by telephone, and retain any records, documents, and files obtained, as required by sections 26.711 and 26.713(a),(b), and (c).

10 CFR 26.63(f) specifies the time periods that a suitable inquiry must cover for initial authorization, authorization update, and authorization reinstatement after an interruption of more than 30 days. While this section does not contain an information collection, it specifies when information is to be collected under section 26.63(a), (c) and (e).

10 CFR 26.65(d)(1) and (e)(2) provide that a licensee or other entity may reinstate authorization for an individual whose authorization has been interrupted for more than 30 days but less than 365 days, or for less than 30 days, respectively, if the individual has negative results from alcohol testing and a specimen for drug testing is collected before authorization is reinstated. Section 26.713(a)(3) establishes the recordkeeping responsibilities for sections 26.65(d)(1) and 26.65(e)(2).

10 CFR 26.65(d)(1)(ii) and (e)(2)(iii)(B) specify that if a licensee or other entity does not receive negative drug test results within 5 business days of specimen collection for an individual seeking authorization reinstatement after an interruption of more than 30 days, authorization must be administratively withdrawn until the test results are received.

10 CFR 26.65(f) specifies that if a licensee or other entity administratively withdraws an individual's authorization under paragraphs (d)(1)(ii) or (e)(2)(iii)(B), and until the drug results are known, the licensee or other entity may not record the administrative action to withdraw authorization as an unfavorable termination. Immediately upon receipt of negative test results, the licensee or other entity shall ensure that any matter that could link the individual to the temporary administrative action is eliminated from the donor's personnel record and other records. This requirement ensures that the personnel records for each individual only contain accurate information. Section 26.713(a)(2) establishes the recordkeeping requirements for section 26.65(f).

10 CFR 26.67(a), (b), and (c) specifies that an individual must be subject to random testing if the individual has applied for authorization under sections 26.65 or 26.29, has been pre-access tested, but has yet to be granted authorization. Section 26.713(a)(2) and (a)(3) establishes the recordkeeping requirements of section 26.67.

- 10 CFR 26.67(a) specifies that an individual that has applied for authorization shall be subject to random testing under section 26.31(d)(2), except if authorization has not been granted, or the licensee or other entity relies on D&A tests that were conducted before the individual applied for authorization (in which case the individual would be subject to random testing upon arrival at the licensee or other entity's facility for inprocessing and thereafter).
- 10 CFR 26.67(b) provides that if an individual is selected for one or more random tests after completing pre-access testing under sections 26.65 or 26.69, the licensee may grant authorization before the random testing is completed.
- 10 CFR 26.67(c) provides that if an individual has a confirmed positive, adulterated, or substituted test result from any drug, validity, or alcohol test required under this paragraph, the licensee or other entity may deny authorization, terminate the individual's authorization if already granted, or grant authorization to the individual under section 26.69.

10 CFR 26.69(b), (c)(1) – (c)(5), (d), and (e) and (e)(1) specify the information upon which a licensee or other entity is to base an authorization decision on when evaluating individuals that have disclosed PDI (i.e., FFD policy violation for a first or second drug or alcohol positive, a violation of FFD policy not based on D&A testing). Section 26.713(a)(1) establishes the recordkeeping requirements for sections 26.69(b), (c)(1), (c)(2) and (c)(3); and section

26.713(a)(3) establishes the recordkeeping requirements for sections 26.69(c)(4) and (c)(5), and 26.69(d).

- 10 CFR 26.69(b) specifies that for an individual seeking authorization after a first or second confirmed positive drug or alcohol test result, the licensee or other entity must: (1) obtain and review a self-disclosure and employment history; (2) complete a suitable inquiry with each employer that the individual claims to have been employed by during the period addressed in the self-disclosure; and (3) obtain and review any records from other Part 26 regulated entities developed on the individual related to unfavorable termination or denial of authorization.

10 CFR 26.69(c)(1) requires the licensee or other entity to obtain and review a self-disclosure and employment history for the past 5 years (for whichever time period is shorter – since the individual's 18th birthday, or since the individual's last period of authorization was terminated).

- 10 CFR 26.69(c)(2) requires the licensee or other entity to complete a suitable inquiry with every employer listed in the applicant's employment history. If the individual held authorization within the past 5 years, the licensee or other entity also must obtain and review any records that other Part 26 regulated entities developed regarding PDI obtained within the past 5 years.
- 10 CFR 26.69(c)(3) requires, where PDI is discovered that is not a first or second confirmed positive drug or alcohol test, that the licensee or other entity verify that a professional qualified under section 26.187(a) has determined that the individual is fit for duty.
- 10 CFR 26.69(c)(4) requires the licensee or other entity to ensure the individual is in compliance with, or has completed, plans for treatment and D&A testing from the determination of fitness.
- 10 CFR 26.69(c)(5) requires the licensee to verify that results of pre-access D&A testing are negative before granting authorization, and that the individual then is subject to random testing.
- 10 CFR 26.69(d) provides that if an individual is authorized when other PDI is disclosed or discovered, in order to maintain the individual's authorization the licensee or other entity shall ensure that a reviewing official completes a review of the circumstances associated with the PDI; decide whether a determination of fitness is required; verify that if a determination of fitness is required that a professional with the appropriate qualifications has indicated that the individual is fit to safely and competently perform his or her duties; and implement any recommendations for treatment and follow-up D&A testing from the determination of fitness.
- 10 CFR 26.69(e) allows licensees and other entities to rely on follow-up testing, treatment plans, and determinations of fitness that were completed by the FFD program of another licensee or other entity under 26.189.

- 10 CFR 26.69(e)(1) requires licensees or other entities that administered treatment and/or follow-up testing for an individual to ensure that information documenting the treatment and/or follow-up plan is identified to any subsequent licensee or other entity who seeks to grant authorization to the individual.

10 CFR 26.75(a) – (e), and (g) specify the minimum sanctions that licensees and other entities must impose for violations of the FFD policy (e.g., a first positive drug test result, attempting to subvert a test, possession of illegal drugs or consumption of alcohol on site). The licensee or other entity must maintain a record of the sanction imposed on each individual, which is necessary in case the individual applies for authorization at a later date (at the same or another facility subject to Part 26). Section 26.713(c) establishes the recordkeeping requirements for section 26.75(a) – (e) and g.

10 CFR 26.75(h) specifies that a licensee or other entity performing initial drug and validity testing of specimens at an LTF may not terminate an individual's authorization or subject an individual to other administrative action based solely on a positive initial drug test, except if the test is positive for marijuana or cocaine metabolites. This provision does not prohibit a licensee from taking additional action if other evidence indicates the individual is impaired or might otherwise pose a safety hazard. This requirement does not create any reporting or recordkeeping requirements; however, it initiates the requirements in sections 26.75(i).

10 CFR 26.75(i) and (i)(3) ensure that any administrative action to withdraw authorization is not permanently recorded as an unfavorable termination of the individual, or communicated to another licensee or other entity as an unfavorable termination, unless and until such a record and such communication is correct and appropriate. The recordkeeping requirements for these requirements are established by section 26.713(a)(2).

- 10 CFR 26.75(i) allows an LTF to inform the licensee or entity of a positive initial drug test result for marijuana or cocaine metabolite and for the licensee or other entity to administratively withdraw an individual's authorization (or take lesser administrative action against the individual), provided that certain conditions specified in section 26.75(i)(1) – (i)(4) are met.
- 10 CFR 26.75(i)(3) requires that a licensee or other entity immediately eliminate any matter from an individual's personnel files that could link that individual to the temporary administrative action taken in response to an initial positive drug test result from an LTF for marijuana or cocaine metabolite that confirmed negative after additional testing at an HHS lab.

10 CFR 26.75(i)(4) requires, in part, that licensees and other entities may not disclose the temporary administrative action against an individual whose initial drug test result is not subsequently confirmed by the MRO as a violation of FFD policy in response to a suitable inquiry conducted under section 26.63, a background investigation conducted under Part 26, or to any other inquiry or investigation. The licensees or other entities must provide access to the system of files and records to personnel who are conducting reviews, inquiries into allegations, audits conducted pursuant to section 26.41, and to NRC inspectors, to enable reviews and to verify the adequacy of record requirements (for this case, to verify that the record was not retained). The licensees or other entities shall provide the tested individual with a written statement that the records specified in sections 26.713 and 26.715 have not been retained, and

shall inform the individual in writing that the temporary administrative action that was taken will not be disclosed and need not be disclosed by the individual in response to requests for self-disclosure of PDI. These requirements ensure that any administrative action to withdraw authorization is not permanently recorded as an unfavorable termination of the individual, or communicated to another licensee or other entity as an unfavorable termination, unless and until such a record and such communication is correct and appropriate. This also ensures that an individual, the individual's personal representatives, and the NRC are allowed to review the records to ensure that no inappropriate records are retained, and that a written confirmation that the temporary administrative action will not be disclosed, and that the individual need not disclose the action, is provided to the individual. The recordkeeping requirements for this paragraph are established by section 26.713(a)(2).

10 CFR 26.77(c) requires a licensee or other entity that has a reasonable belief that an NRC employee or NRC contractor may be under the influence of any substance, or is otherwise unfit for duty, including when the observed behavior or physical condition is solely the result of fatigue, must immediately notify the appropriate Regional Administrator by telephone, followed by written notification to document the verbal notification, or, if the Regional Administrator cannot be reached, to notify the NRC Operations Center. This requirement ensures that the NRC receives immediate notification by telephone, followed by written notification, that an NRC employee or NRC contractor may be under the influence of a substance or is otherwise unfit for duty, so that the NRC can take action to remove the employee from duty and to take any other appropriate actions. Reporting requirements for section 26.77(c) are established by section 26.719(a).

10 CFR 26.85(a) and (b) ensure that individuals performing specimen collections under Part 26 received appropriate training to complete the collection process consistent with the requirements in Subpart E of Part 26. Section 26.715(a) and (b)(1) establishes the recordkeeping requirements for section 26.85(a) and (b).

- 10 CFR 26.85(a) requires qualification training for urine collectors on the requirements of Part 26, the FFD policy and procedures of the licensee or other entity for whom collections are performed, all steps necessary to complete a collection correctly and the proper completion and transmission of the custody-and-control form (CCF); methods to address problem collections, how to correct problems in collections, and the collector's responsibility for maintaining the integrity of the specimen collection and transfer process, ensuring the modesty and privacy of the donor, and avoiding conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.
- 10 CFR 26.85(b) requires qualification training for alcohol collectors on the requirements of Part 26, the FFD policy and procedures of the licensee or other entity for whom collections are performed, and any changes to alcohol collection procedures, the alcohol testing requirements of Part 26, operation of the particular alcohol testing device(s) or evidential breath testing devices (EBTs) to be used, consistent with the most recent version of the manufacturer's instructions, methods to address problem collections, how to correct problems in collections, and the collector's responsibility for maintaining the integrity of the specimen collection and transfer process, ensuring the modesty and privacy of the donor, and avoiding conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

10 CFR 26.85(c)(5) requires that an alternative collector that does not meet the training criteria in Part 26 be provided with detailed, clearly-illustrated, written instructions for collecting specimens in accordance with Subpart E. This information ensures that an alternative collector is able to perform a collection consistent with Part 26 requirements and also is a donor protection. Section 26.715(a) establishes the recordkeeping requirements for section 26.85(c) (4).

10 CFR 26.85(e) describes the types of records to be included in the personnel file of a specimen collector (e.g., job description, resume, references, certifications or licenses, references, performance evaluations, incident reports, results of competency tests, any PDI from background investigations performed under section 23.31(b)). This requirement is necessary to provide assurance that the education, training, and competency of these personnel are adequate to correctly understand processes and procedures, and can use the instruments and devices necessary to implement specimen collection and analysis. This assurance is vital for the determinations of fitness. In addition, records of training and competency are important evidence in any litigation that may occur with respect to test results. Sections 26.715(a) and (b)(1) establish the recordkeeping requirements for section 26.85(e) are established by.

10 CFR 26.87(d)(3) and (f)(1) ensure that collection sites are clearly identified to prevent unauthorized access that could compromise the integrity of the collection process and privacy of the donor.

- 10 CFR 26.87(d)(3) specifies that if a collection site cannot be dedicated solely to collecting specimens, the portion of the facility that is used for specimen collection must be secured and, during the time period during which a specimen is being collected, a sign must be posted to indicate that access is allowed only for authorized personnel.
- 10 CFR 26.87(f)(1) requires that in the exceptional event when a designated collection site is inaccessible and a specimen must be immediately collected (e.g., an event investigation), that a sign be posted or an individual assigned to ensure that no unauthorized personnel are present during the collection procedure (this requirement applies if a public restroom is used).

10 CFR 26.87(f)(3) – (f)(5) ensure that in the exceptional event that a designated collection site is inaccessible and there is an immediate requirement to collect a urine specimen, that a chain-of-custody form (CCF) is prepared that accurately identifies the origin of the specimen and links that specimen to the donor. The information collection requirements also protect the donor. Recordkeeping requirements for section 26.87(f)(3) and (f)(5) are established by section 26.715(b)(2).

- 10 CFR 26.87(f)(3) requires that if a same gender collector is not available to accompany the donor into the specimen collection area, then the collector must select a same-gender person to accompany the donor, provide instruction on the collection procedures to that person, and the collector must document the identity of the person on the CCF.

- 10 CFR 26.87(f)(4) requires that after the collector has possession of the specimen, that he or she instruct the donor to participate in completing the remaining steps in chain-of-custody procedures.
- 10 CFR 26.87(f)(5) requires that the authorized collector maintain control of the specimen until the specimen is prepared for transfer, storage, or shipping, and to document his or her custody of the specimen on the CCF.

10 CFR 26.89(a), (b)(1) – (b)(4), and (c) specify specimen collection procedures to follow and communications to complete based on specific circumstances that may arise during a collection. For example, paragraph 26.89(b)(4) requires the collector to explain of the collection procedure and obtaining a signed consent-to-test form, which is a donor protection and ensures to the due process rights of the individual. Paragraph 26.89(c) requires the collector to inform the donor that he or she must remain present until the collection is complete, and ensures that the donor is aware of the consequences of leaving before the process is complete. Notice to FFD program management if the donor leaves or is uncooperative ensures that appropriate actions are undertaken under the FFD procedures. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.89(a), (b), and (c).

- 10 CFR 26.89(a) requires collectors to inform FFD program managers when an individual fails to appear for drug testing.
- 10 CFR 26.89(b)(1) and (b)(2) requires, in part, that individuals show proper identification before testing, and, if they cannot produce acceptable identification the collector must notify FFD program management.
- 10 CFR 26.89(b)(3) provides that if the donor is scheduled for pre-access testing and cannot produce acceptable identification, the collector may not proceed with the collection and shall inform FFD program management that the individual did not present acceptable identification.
- 10 CFR 26.89(b)(4) requires the collector to explain the testing procedure to the donor, show the donor the form(s) to be used, and ask the donor to sign a consent-to-testing form.
- 10 CFR 26.89(c) requires that the collector inform the donor that the donor must remain present at the collection site until the collection is complete. In the event the donor leaves the test site prematurely, the collector is required to report this to FFD management.

10 CFR 26.91(c)(1), (c)(2), and (c)(3) specifies that an EBT device may be used for initial testing for alcohol, and must be used for confirmatory testing, and specify the contents of each printed test result (i.e., time of the test, a unique number is assigned and printed on the result along with the manufacturer's device name and serial number). This requirement establishes the specifications of EBT devices to be used for alcohol testing and ensures that the results provided by EBT devices can be attributable to the tested individual and the equipment used for testing. This requirement helps to ensure that adequate information is available for reviews necessary for a determination of fitness and in the conduct of legal proceedings, if any. This requirement also helps to ensure that information is available with which to track the

performance (e.g., instrument calibration and linearity) of each EBT. This requirement does not directly create any records, but describes the types of records that must be created through the use of EBTs in FFD programs. Recordkeeping requirements for the records created using EBTs that meet the specifications of section 26.91(c)(1)-(3) are established by section 26.715(b)(12).

10 CFR 26.91(e)(4) requires, in part, that each licensee or other entity use a calibrated EBT to performed confirmatory alcohol testing. The licensee or other entity can verify that an EBT is calibrated by following one of two procedures. Conduct an external check of calibration of the EBT in the presence of the donor after every confirmed positive test result; or as specified by the equipment manufacturer (e.g., after a specified number of tests are performed). If the later process is followed and the EBT fails the external calibration check, the licensee or other entity would have to cancel every confirmed positive test result that was obtained using that EBT from the point after the EBT passed the last external calibration check. This process ensures to accurate and reliable test results, and is a donor protection. Section 26.715(b)(14) establishes the recordkeeping requirements for section 26.91(e)(4).

10 CFR 26.91(e)(5) requires that the inspection, maintenance, and calibration of each EBT be performed by the manufacturer or a certified representative of the manufacturer. This helps ensure that each instrument is producing reliable, accurate, and repeatable results within specified instrument parameters. Section 26.715(b)(14) establishes the recordkeeping requirements for section 26.91(e)(5).

10 CFR 26.91(e)(5) requires that records be maintained document the inspection, maintenance, and calibration activities performed on EBTs. These records ensure that the licensee or other entity and the NRC can perform oversight on alcohol testing activities. These records also are a donor protection, ensuring to the accuracy of test results.

10 CFR 26.93(a)(6) requires that, prior to collecting a specimen for alcohol testing, the collector must document that certain questions about substance ingested and instructions about the testing process as specified in section 26.93(a)(1)-(5) were communicated to the donor. This requirement ensures that the donor understands how the test will be conducted and what the donor must and must not do in order to ensure that the test result is valid and that the testing process is not subverted. This requirement also partially meets the legal necessity of protecting the due process rights of individuals who are subject to Part 26 and also proving prior notice and having it documented for evidence in legal proceedings. Recordkeeping requirements for section 26.93(a)(6) are established by section 26.715(b)(6).

10 CFR 26.95(b)(5) requires a collector conducting an initial breath test for alcohol to ensure that the test result can be associated with the donor and is maintained secure. This requirement is necessary to help ensure that the test result is an accurate and correct record with respect to the individual who is being tested. This requirement also partially meets the legal necessity of protecting the due process rights of individuals who are subject to Part 26 and also proving and documenting prior notice for evidence in legal proceedings. Recordkeeping requirements for section 26.95(b)(5) are established by section 26.715(b)(6).

10 CFR 26.97(b)(2) and (c)(1) ensures that if tests cannot be completed because the alcohol testing device cannot be used correctly, that fact must be provided as an explanation of the need for a new test. This helps to ensure that the need for a new test is not incorrectly

attributed to the actions of the individual donor. These requirements also partially meet the legal necessity of protecting the due process rights of individuals who are subject to Part 26 and also proving “prior notice” and having it documented for evidence in legal proceedings. Recordkeeping requirements for section 26.97(b)(2) and (c)(1) are established by section 26.715(b)(6).

- 10 CFR 26.97(b)(2) requires that, if the steps required to use the device correctly could not be completed successfully, the collector must record the reason for a new test.
- 10 CFR 26.97(c)(1) requires that, if a second attempt at collection fails following the failure of the initial attempt, the collector must document the reasons the collection could not be completed.

10 CFR 26.97(d) requires the collector, when using a testing device, to show the device and its reading to the donor, record the result, and record that an alcohol screening device (ASD) was used. This requirement is necessary so that the donor can verify that a particular device was used and confirm the result and the fact that the result was recorded correctly. This record is important for due process rights of the tested individual and in the determination of fitness, if any. The record of the use of the ASD and the result of the test also provide important information for tracking the activities of the FFD program and helps ensure that information is available for audits and NRC inspections. This requirement also partially meets the legal necessity of proving and documenting prior notice for evidence in legal proceedings. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.97(d).

10 CFR 26.99(b) requires the collector to ensure that the time when an initial test whose result is 0.02 percent blood alcohol concentration (BAC) or higher was concluded (i.e., the time at which the test result was known) is recorded. This requirement ensures that the length of time the donor had been in work status when the initial test was conducted can be determined, in order to calculate the actual level while the individual was in work status, which is one factor under section 26.103 in determining whether to declare a confirmed positive test result. In addition, by recording the time of the initial test, the FFD program can demonstrate that the 15-minute waiting period required by section 26.93(a), if necessary, has occurred before the initial alcohol test was done. This requirement is also necessary to ensure that the confirmatory test is done, as required by section 26.101, no more than 30 minutes after the conclusion of the initial test. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.99(b).

10 CFR 26.101(b)(7) requires the collector to show the donor the result displayed upon or printed by the EBT, record the result, and document the time at which the confirmatory test result was known. This requirement is necessary so that the donor can personally know that a particular device was used for the confirmatory test, the indicated confirmatory test result, and the fact that the confirmatory test result was recorded correctly. The record of the result of the confirmatory test and the time at which the result was known also provide important information for determining whether or not a confirmed positive test result for alcohol must be declared. This requirement also provides important information for tracking the activities of the FFD program, and helps ensure that information is available for audits and NRC inspections. This requirement also partially meets the legal necessity of protecting the due process rights of individuals who are subject to Part 26 and also proving prior notice and having it documented

for evidence in legal proceedings. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.101(b)(7).

10 CFR 26.103(b) requires the collector to declare test results as negative where the results show BAC below 0.02 but at or above 0.01, if the donor has been in work status for 3 hours or more. The collector informs FFD management, and the licensee or other entity prohibits the donor from performing duties until a determination of fitness is made. This third party collection requirement ensures that FFD management is notified so that appropriate actions, including a determination of fitness, can be undertaken under the FFD procedures. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.103(b).

10 CFR 26.107(b) requires the collector to document on the CCF any conduct that clearly indicates an attempt to tamper with a specimen. This requirement is an integral part of the collection procedure and is essential to documenting the chain of custody for the specimens collected. The subversion of a Part 26 drug test is a relatively infrequent occurrence, however, it results in a burden on a licensee because the regulation requires the licensee to take certain actions to afford due process to the individual and verify the validity of the collection. Documentation is necessary to record any attempt to tamper with a specimen to support any subsequent appeals or reviews. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.107(b).

10 CFR 26.109(b)(3) and (b)(4) ensure that the specimen collector notifies the FFD program manager or MRO if a donor is unable to provide a urine specimen of sufficient quantity within the allotted timeframe permitted by Part 26. This notification ensures that additional procedures can be initiated by the licensee or other entity to address this collection event.

- 10 CFR 26.109(b)(3) requires that, if the donor has not provided a specimen of at least 30 mL within 3 hours of the first unsuccessful attempt to urinate the required volume of fluid, the collector shall discontinue the collection and notify the FFD program manager or MRO to initiate the evaluation procedures in section 26.119.
- 10 CFR 26.109(b)(4) requires the collector to discard specimens less than 30 mL, unless the collector has reason to believe that the donor had diluted, adulterated, substituted, or otherwise tampered with the specimen. In that event, if the sample is greater than 15 mL and less than 30 mL, the collector is required to prepare the specimen for shipping to the HHS-certified lab and contact FFD management to determine whether a directly observed collection is required. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.109(b)(4)

10 CFR 26.111(b) requires the collector to inspect the urine specimen and to note any unusual findings on the CCF. This requirement is an integral part of the collection procedure and is essential to documenting the chain of custody for the specimens collected. Because this is expected to be an infrequent occurrence, it does not create a significant additional burden. However, the information provided could be useful to the laboratory conducting testing and ensures the scientific supportability of the test results in case of a review in support of a determination of fitness or legal proceedings. Recordkeeping requirements for section 26.111(b) are established by section 26.715(b)(2).

10 CFR 26.111(c) requires the collector to contact the designated FFD manager if there is a reasonable belief, based on observation, that the donor may have attempted to subvert the testing process through specimen dilution, substitution, or adulteration. The FFD manager may require the donor to provide a second specimen under direct observation. This requirement ensures that the FFD program manager is informed of the possibility that a donor may have attempted to subvert the testing process and to receive direction regarding appropriate management actions to take. Recordkeeping requirements for section 26.111(c) are established by section 26.715(b)(6).

10 CFR 26.113(b)(3) requires the collector to prepare a CCF for both specimens when the urine specimen is split into two specimen bottles. This requirement is an integral part of the collection procedure and is essential to documenting the chain of custody for the specimens collected. Chain of custody, in turn, is a fundamental procedure for sample analysis, because it provides an equivalently-obtained sample for testing and ensures that there is a record demonstrating that the specimens analyzed by the laboratory are the same specimens that were obtained from the donor. When the sample is split into two specimen bottles, a chain-of-custody form must be prepared to accompany each bottle to properly identify each testing result. Recordkeeping requirements for section 26.113(b)(3) are established by section 26.715(b)(2).

10 CFR 26.115(b) requires that, before collecting a urine specimen under direct observation, the collector must obtain the agreement of the FFD program manager or MRO. This requirement is necessary because of the intrusive nature of collecting a urine specimen under direct observation. Therefore, a person qualified in making the determination that direct collection must be used must make that decision; this determination must be documented. Recordkeeping requirements for section 26.115(b) are established by section 26.715(a).

10 CFR 26.115(d) requires the collector to complete a new CCF for a specimen obtained from a directly observed collection, and to record on the form that the collection was observed and the reason(s) for the observed collection. This requirement ensures that the FFD program manager or MRO is informed of the need for a collection under direct observation, so that the FFD program manager or MRO can examine the circumstances and approve or deny the request for a collection under direct observation; the FFD program manager or MRO, not the collector, are qualified and assigned the responsibility of making the determination. The requirement to complete a new CCF, and record the basis for the collection, is an integral part of the collection procedure and is essential to documenting circumstances of collection in case of subsequent legal proceedings. Recordkeeping requirements for section 26.115(d) are established by section 26.715(b)(2).

10 CFR 26.115(f)(3) requires that, if someone other than the collector observed the collection, the collector must record the observer's name on the CCF. This requirement is an integral part of the collection procedure and is essential to documenting the identity of the observer in case of subsequent legal proceedings. Recordkeeping requirements for section 26.115(f)(3) are established by section 26.715 (b)(2).

10 CFR 26.117(c) – (e), and (k) specify the documentation procedures to ensure chain of custody of urine specimen. These procedures ensure the integrity of the collection process and shipment of specimens to the testing laboratory, and protect the donor. Section 26.715(b)(2) establishes the recordkeeping requirements for section 26.117(c), (d), and (e). No recordkeeping requirement is established under section 26.117(k), but the procedures

described in the section ensure that the licensee or other entity uses a shipping service that tracks custody of each package.

- 10 CFR 26.117(c) requires the collector to place an identification label containing the date, the donor's specimen number, and any other identifying information provided or required by the FFD program securely on each specimen container.
- 10 CFR 26.117(d) requires the donor to initial the identification label(s) on the specimen bottle(s) and to read and sign a statement on the CCF certifying that the specimen(s) identified as having been collected from the donor is, in fact, the specimen(s) that the donor provided.
- 10 CFR 26.117(e) requires the collector to complete the CCF (or CCFs for both Bottle A and Bottle B, if split specimens procedures were followed) and certify proper completion of the collection.
- 10 CFR 26.117(k) requires that custody accountability of shipping containers during shipment by couriers, express carriers, and the postal service must be maintained by a tracking system provided by the courier, express carrier, or postal service. Use of such tracking systems by couriers, express carriers, and the postal service is an ordinary business practice. This is not a third-party disclosure requirement, but ensures that the licensee or other entity utilizes shipping services that can afford this level of package tracking.

10 CFR 26.119(a), (b), (e), and (f) ensure that if a donor cannot provide a specimen within the 3-hours allocated for collection, then a medical evaluation, based on specified information and instructions, is prepared and provided in writing to the MRO. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.119(a), (b), (e), and (f).

- 10 CFR 26.119(a) requires a donor who has not provided a specimen of at least 30 mL within the 3 hours permitted for urine collection to obtain, within 5 business days, an evaluation from a licensed physician, or from the MRO if the MRO has the appropriate expertise. This requirement ensures that a qualified MRO or licensed physician prepares an evaluation of whether the medical condition of the donor was or could have with a high probability been the basis for the donor's failure to provide a specimen.
- 10 CFR 26.119(b) requires the MRO, if the MRO is not performing the evaluation, to provide the physician who is performing the evaluation with information about the donor and the testing requirements, and instructions about the determination to be made by the physician.
- 10 CFR 26.119(e) requires a physician who performs an evaluation of the donor's failure to provide a sufficient specimen to prepare a written statement of his or her determination and the basis for it and to provide the statement to the MRO.
- 10 CFR 26.119(f) requires the physician, if he or she determines that the donor's medical condition is a serious and permanent or long-term disability that is highly likely to prevent the donor from providing a sufficient amount of urine for a very long or

indefinite period of time, to set forth this determination and the reasons for it in the written statement to the MRO.

10 CFR 26.125(b) and (c) ensure that the training, competency of the technicians and staff of a LTF to correctly use the instruments and devices that the LTF has selected can be verified. This is an important support for the review process underlying determinations of fitness. In addition, records of training and competency may be important evidence in any litigation that may occur with respect to test results. Records of training and competency of LTF personnel also supports reliance by licensees and other entities on test results from testing that was performed by another Part 26 program. Recordkeeping requirements for section 26.125(b) and (c) are established by section 26.715(a) and (b)(1).

- 10 CFR 26.125(b) requires technicians who perform urine specimen testing to have documented proficiency in operating the testing instruments and devices used at the LTF.
- 10 CFR 26.125(c) requires LTF files to include each individual's resume of training and experience, certification of license, if any; references; job descriptions; records of performance evaluations and advancement; incident reports, if any; results of tests that establish the employee's competency for the position he or she holds, including certification that personnel are proficient in conducting testing; and appropriate data to support determinations of honesty and integrity required by Part 26.

10 CFR 26.127(a) – (e) describe the QA/QC processes that each LTF conducting testing must utilize. These processes ensure to the accuracy and integrity of the specimen testing and chain-of-custody. Section 26.715(a) establishes the recordkeeping requirements for section 26.127(a) – (e).

- 10 CFR 26.127(a) requires the LTF to develop, implement, and maintain clear and well-documented procedures for accession, receipt, shipment, and testing of urine specimens.
- 10 CFR 26.127(b) requires the LTF to have written chain-of-custody procedures describing the methods to be used to maintain control and accountability of specimens from receipt through completion of testing and reporting of results, during storage and shipping to the HHS lab, and continuing until final disposition of the specimens.
- 10 CFR 26.127(c) requires the LTF to develop, implement, and maintain written standard operating procedures for each assay performed for drug and specimen validity testing. If the LTF performs validity screening tests, the LTF is also required to develop, implement, and maintain written standard operating procedures for each test. 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 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 26.127(e) requires the LTF to develop, implement, and maintain written procedures for remedial actions to be taken when systems and instrumented and non-instrumented testing devices (if used for validity screening tests) are out of acceptable limits or errors are detected. Each facility is required to document adherence to established procedures and to take corrective action when necessary. In addition, all facilities are required to have systems in place and to verify all stages of testing and reporting and to document the verification.

10 CFR 26.129(a), (b) and (b)(1), (d) and (h) specify the QA/QC processes used at an LTF ensure to the security of specimens, to identify tampering events, and to take appropriate and timely actions if necessary. These requirements protect donors from inaccurate results, provide assurance that specimens of questionable validity are identified, and ensure to the integrity of the testing process. Section 26.129(h) is not a third-party disclosure requirement, but ensures that the licensee or other entity utilizes shipping services that afford package specific tracking.

- 10 CFR 26.129(a) requires each LTF to limit access to secured areas only to specifically authorized individuals whose authorization is documented. This requirement, involving the collection of signatures of persons visiting the secured areas of testing facilities and a check of their credentials or other authorization for such entry, ensures that unauthorized persons do not gain access to testing areas where they might seek to subvert the testing process. Section 26.715(b)(13) establishes the recordkeeping requirements for section 26.129(a).
- 10 CFR 26.129(b) requires LTF personnel to inspect each package when specimens are received for evidence of possible tampering and to compare the information on the specimen containers within each package to the information on the accompanying CCFs, and to attempt to resolve any discrepancies. When resolving any discrepancies, LTF personnel are required to obtain a memorandum for the record from the specimen collector to document correction of the discrepancy. The memorandum must accompany the specimens and CCFs if the specimens must be transferred. This requirement ensures that a record of the resolution of any discrepancies involving information about specimens is prepared and accompanies the specimens following the resolution of the discrepancy. This will avoid duplicative efforts to resolve discrepancies and will ensure that the information accompanying the specimen is correct. Section 26.715(b)(2) establishes the recordkeeping requirements for section 26.129(b).
- 10 CFR 26.129(b)(1) requires LTFs to report to licensee senior management any indications of tampering with specimens in transit from the collection site or at a testing facility, or discrepancies in the information on specimen bottles or on the accompanying CCFs. Such reports must be made as soon as practical, but no later than 8 hours after identification of the tampering event. The timeliness of this requirement is necessary so that the licensee or other entity can make a 24-hour notification to the NRC under section 26.719(b). Section 26.715(b)(3) establishes the recordkeeping requirements for section 26.129(b)(1).

- 10 CFR 26.129(d) requires that the procedures used by the LTF for tracking custody and control of specimens protect the identity of the donor. The LTF must provide documentation of the testing process and each transfer of custody of the specimen, including the date, purpose, and individual receiving the specimen.
- 10 CFR 26.129(h) requires that custody accountability of shipping containers during shipment by couriers, express carriers, and the postal service must be maintained by a tracking system provided by the courier, express carrier, or postal service.

10 CFR 26.135(b) allows the donor, upon notification of a positive, adulterated, or substituted test result, to request that Bottle B of a split specimen (as described in section 26.113) be tested at a second HHS lab under the procedures in section 26.165(b). This requirement ensures that a record exists of the donor's approval for the MRO to request the additional specimen testing at a second HHS certified laboratory, in case of subsequent legal proceedings. Recordkeeping requirements for section 26.135(b) are established by section 26.715(b)(6).

10 CFR 26.137(a) requires each LTF to develop and implement a QA program and procedures encompassing all aspects of the testing process. This requirement is an integral part of the QA/QC process for all testing and laboratory facilities. The requirement is necessary to help ensure accurate and repeatable results, protect donors from inappropriate sanctions, and to provide assurance that specimens of questionable validity are detected. Section 26.715(b)(3) establishes the recordkeeping requirements for section 26.137(a).

10 CFR 26.137(b)(1)(ii) and (b)(1)(iii) establish the performance testing criteria an LTF must meet if point-of-collection testing devices are used to perform validity screening testing. These requirements protect donors from inaccurate drug and validity test results. Section 26.715(b)(7) establishes the recordkeeping requirements for section 26.137(b)(1)(ii) and (b)(1)(iii).

- 10 CFR 26.137(b)(1)(ii) requires the licensee or other entity before using the test, to ensure that the validity screening test, by lot number, effectively identifies specimens of questionable validity by meeting the performance testing and quality control requirements listed in this section.
- 10 CFR 26.137(b)(1)(iii) requires an LTF that has placed a validity screening test in service to either verify that the device remains on the SAMHSA-approved list or if the list is unavailable, ensure the manufacturer's documentation documents the test's validity and that the licensee conducts performance testing at a nominal annual frequency.

10 CFR 26.137(b)(3) requires that each LTF performing validity screening testing must submit at least one donor specimen out of every 10 that test negative to an HHS lab as part of the LTF's QA program. This requirement is an integral part of the QA/QC process, protects donors from inaccurate test results, and provides assurance that validity test performed by an LTF is accurate. Section 26.715(b)(3) establishes the recordkeeping requirements for section 26.137(b)(3).

10 CFR 26.137(d)(6) requires that each LTF performing initial validity testing must submit at least one donor specimen out of every 10 that test negative to an HHS lab as part of the LTF's QA program. This requirement is an integral part of the QA/QC process, protects donors from inaccurate test results, and provides assurance of the accuracy of validity tests performed by

LTFs. Recordkeeping requirements for section 26.137(d)(6) are established by section 26.715(b)(3).

10 CFR 26.137(e)(7), (f)(5), and (h) specify the QA/QC processes to be used at an LTF to protect donors from inaccurate test results.

- 10 CFR 26.137(e)(7) requires each LTF to document procedures to ensure that carryover (i.e., materials from a previous test that have not been adequately purged from the apparatus) does not contaminate the testing of a donor's specimen.
- 10 CFR 26.137(f)(5) requires each LTF to record findings and corrective actions taken, when applicable, for the investigation of any errors or unsatisfactory performance discovered in the testing of QC samples, donor specimens, or through the processing of management reviews or MRO reviews. The records of each investigation must be signed and dated by the individual(s) responsible for the day-to-day management of the LTF, and reported to appropriate management. Section 26.715(b)(8) establishes the recordkeeping requirement for section 26.137(f)(5).
- 10 CFR 26.137(h) requires the LTF to label the standards and controls with the date of receipt, when prepared or opened, when placed in service, and when scheduled for expiration. Section 26.715(b)(5) establishes the recordkeeping requirements for section 26.137(h).

10 CFR 26.139(d) requires LTFs to prepare information on drug and validity tests performed, for inclusion in the annual FFD program performance report submitted by the licensee or other entity to the NRC under sections 26.417(b)(2) or 26.717. This requirement ensures that the NRC can monitor testing program effectiveness. The NRC has concluded that annual reporting creates the appropriate balance between reporting burden and the NRC's need for information. Section 26.717 specifies the D&A testing information to be included in each FFD program performance report. Section 26.717(b) and (e) establish the reporting requirements for section 26.139(d).

10 CFR 26.153(e) and (f) establish the pre-award inspection and evaluation that a licensee or other entity must complete prior to using a new HHS lab for testing, and details the minimum requirements that a licensee or other entity must include in the contract with the HHS lab.

- 10 CFR 26.153(e) requires a licensee or other entity, before awarding a contract to an HHS lab, to conduct a pre-award inspection and evaluation of the procedural aspects of the laboratory's drug testing operations. This review ensures that the HHS lab meets the requirements in Part 26 specified to conduct drug and validity testing. Section 26.715(b)(9) establishes the recordkeeping requirements for section 26.153(e).
- 10 CFR 26.153(f) establishes the minimum requirements that must be included in each contract between a licensee or other entity and the HHS lab that is to perform drug and validity testing under Part 26. The minimum requirements include complying with applicable State licensure requirements, making qualified laboratory personnel available to testify in proceedings, maintaining records in accordance with section 26.37, providing access to records, conflict of interest provisions, and laboratory access for inspections. Section 26.713(e) establishes the recordkeeping requirements for section 26.153(f).

10 CFR 26.153(g) requires licensees or other entities who use a form other than the current Federal CCF to provide a memorandum to the HHS lab explaining why a non-Federal form was used, and to ensure that the form used contains all the required information on the Federal Drug Testing CCF (OMB Control No. 0930-0158). This requirement is consistent with the HHS Guidelines stating that laboratories may reject any specimen that is submitted for testing with a non-Federal CCF unless the licensee or other entity provides a memorandum for the record. This paragraph is necessary to prevent licensee's and other entity's specimens from being rejected. Section 26.715(b)(2) establishes the recordkeeping requirements for section 26.153(g).

10 CFR 26.155(a)(1), (a)(3) – (a)(5), (b), (c), (e) and (f) align with the HHS laboratory certification requirements under the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines). These requirements ensure the scientific validity and supportability of test results. Recordkeeping requirements for section 26.155(a)(1), (a)(3), (b), and (c) are established by section 26.155(f); section 26.155(a)(4) established by section 26.157; and the section 26.155(a)(5) requirements are established by section 26.715(b)(3). The recordkeeping burden for section 26.155(e) and (f) is captured under OMB Control No. 0930-0158.

- 10 CFR 26.155(a)(1) requires day-to-day management of the HHS lab to be performed by an individual with documented scientific qualifications in analytic forensic toxicology.
- 10 CFR 26.155(a)(3) requires the individual to ensure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.
- 10 CFR 26.155(a)(4) requires the day-to-day manager to review, sign, and date procedures to be followed by laboratory personnel whenever the procedures are first placed into use or changed or when a new individual assumes responsibility for management of the laboratory, and to ensure that copies of all procedures are maintained.
- 10 CFR 26.155(a)(5) requires the day-to-day manager to maintain a QA program that, among other things, documents the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.
- 10 CFR 26.155(b) requires that each HHS lab have at least one certifying scientist to certify test results. The paragraph specifies the requirements for the certifying scientist.
- 10 CFR 26.155(c) requires that each HHS lab assign at least one individual to be responsible for day-to-day operations and supervision of the technical analysts. The paragraph specifies the requirements for the analysts' supervisor.
- 10 CFR 26.155(e) requires that HHS labs make available continuing education programs for personnel.

- 10 CFR 26.155(f) requires each laboratory personnel file to include a resume, any professional certifications or licenses, a job description, and documentation to show that the individual has been properly trained to perform his or her job function(s).

10 CFR 26.157(a) – (e) align with the HHS laboratory procedures requirements in the HHS Guidelines. These recordkeeping requirements ensure to the chain of custody of specimens and the integrity of the testing process. The recordkeeping burden for section 26.157(a), (b), (c), (d) and (e) is captured under OMB Control No. 0930-0158.

- 10 CFR 26.157(a) requires HHS labs to develop, implement, and maintain clear and well-documented procedures for accession, receipt, shipment, and testing of urine specimens.
- 10 CFR 26.157(b) requires HHS labs to have written chain-of-custody procedures describing the methods to be used to maintain control and accountability of specimens from receipt through completion of testing and reporting of results, during storage and shipping to another HHS lab, if required, and continuing until final disposition of the specimens.
- 10 CFR 26.157(c) requires HHS labs to develop, implement, and maintain a written standard operating procedures manual for each assay performed for drug and specimen validity testing. If an LTF uses non-instrumented devices to perform validity screening tests, the LTF must develop, implement, and maintain written standard operating procedures for each device.
- 10 CFR 26.157(d) requires HHS labs to develop, implement, and maintain written procedures for instrument and device setup and normal operation.
- 10 CFR 26.157(e) requires HHS labs to develop, implement, and maintain written procedures for remedial actions to be taken when systems and non-instrumented testing devices (if used for validity screening tests) are out of acceptable limits or errors are detected. Each facility is required to maintain documentation that these procedures are followed and that all necessary corrective actions are taken. In addition, all facilities are required to have systems in place and to verify all stages of testing and reporting and to document the verification.

10 CFR 26.159(a), (b)(1), (c) – (f), and (i) align with the HHS lab certification requirements under the HHS Guidelines for specimen chain of custody at the laboratory. The recordkeeping burden for section 26.159(a) is captured under OMB Control No. 0930-0158. Recordkeeping requirements for section 26.159(b) are established by section 26.715(b)(3) and section 26.159(c), (d), (e), (f), and (i) are established by section 26.715(b)(2). Reporting requirements for reports of tampering to NRC under section 26.159(b) are established by section 26.719(b)(3).

- 10 CFR 26.159(a) requires each HHS lab to limit access to secured areas and only to those individuals whose authorization is documented.
- 10 CFR 26.159(b)(1) requires HHS labs to inspect each shipment of specimens for evidence of possible tampering and to compare information on specimen bottles within

each package to the information on the accompanying CCFs. Any direct evidence of tampering or discrepancies in the information on the specimen bottles and the CCFs attached to the specimen bottles must be reported to the licensee or other entity within 24 hours of the discovery and must be noted on the CCF for each specimen contained in the package.

- 10 CFR 26.159(c) requires HHS lab personnel to use laboratory internal CCFs when conducting initial and confirmatory tests, and to retain these forms in secure storage.
- 10 CFR 26.159(d) requires the internal CCF used by an HHS lab to allow for identification of the donor, and documentation of the testing process and transfers of custody of the specimen.
- 10 CFR 26.159(e) requires that each time a specimen is handled or transferred within the HHS lab, that the HHS lab personnel document on the CCF the date and purpose. Authorized technicians are required to sign and complete CCFs for each specimen or aliquot received.
- 10 CFR 26.159(f) requires that, when transferring a specimen to a second HHS lab, the original CCF is packaged with the urine specimen bottle.
- 10 CFR 26.159(i) requires that, unless otherwise authorized in writing, specimens be retained in storage for 1 year.

10 CFR 26.163(a)(2) specifies that if initial validity testing indicates that a specimen is dilute, and the immunoassay response of any drug or drug metabolite test is equal to or greater than 50 percent of the cutoff, the licensee or other entity may require the HHS lab to test the specimen for that drug or drug metabolite to the limit of detection (LOD) for the confirmatory assay. The laboratory shall report the numerical values (i.e., the quantitative test result) obtained from this special analysis to the MRO. This requirement enables the licensee or other entity to validate a dilute result to protect the donor from an inaccurate test result, to provide assurance that a specimen of questionable validity is detected, and to ensure the integrity of the testing process. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.163(a)(2)

10 CFR 26.165(b)(1) – (b)(4), (b)(6), (c)(4), (f)(1), (f)(1)(ii), (f)(1)(iv), and (f)(2) 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 an initial non-negative test result is obtained, and to ensure that no records of a temporary administrative action taken as a result of an initial non-negative test result are retained if a negative report is received from the testing of Bottle B or retesting of an aliquot of a single specimen. These requirements are necessary to protect donors from inaccurate results and to provide assurance that specimens of questionable validity are detected. They also assure to the donor the confidential nature of temporary administrative actions.

- 10 CFR 26.165(b)(1) specifies that for a confirmed positive, adulterated, or substituted test result reported on a single specimen (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. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.165(b)(1).

- 10 CFR 25.165(b)(2) requires the MRO to inform the donor that he or she may, within 3 business days of notification by the MRO of the confirmed positive, adulterated, or substituted test result, request the re-testing of an aliquot of the single specimen or the testing of the Bottle B split specimen. 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 the donor's calls at all times during the 3-day period (e.g., by use of an answering machine with a time stamp feature when there is no one in the MRO's office to answer the phone). The donor's request may be oral or in writing.
- 10 CFR 25.165(b)(3) requires the donor to provide his or her permission to the MRO to initiate the retesting of an aliquot from a single specimen or the testing of the Bottle B split specimen.
- 10 CFR 25.165(b)(4) provides that if the donor has not requested a retest of an aliquot of a single specimen or a test of the split specimen within 3 business days, the donor may present to the MRO information documenting that serious injury, illness, lack of actual notice of the confirmed test result, inability to contact the MRO, or other circumstances unavoidably prevented the donor from making a timely request. If the MRO concludes a legitimate reason existed for the donor's inability to make contact within 3 business days, the MRO shall direct that specimen retesting take place.
- 10 CFR 26.165(b)(6) requires the second HHS lab that re-tests an aliquot of a single specimen or tests the Bottle B split specimen to provide the quantitative test results to the MRO, and then directs the MRO to provide the test results to the donor. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.165(b)(6).
- 10 CFR 25.165(c)(4) requires the second HHS lab conducting retesting of an aliquot of a single specimen or the testing of the Bottle B split specimen to report test results to the licensee's or other entity's MRO. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.165(c)(4).
- 10 CFR 26.165(f)(1) specifies that a licensee or other entity may 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. Paragraph 26.165(f)(1) requires that licensees and other entities may not disclose the temporary administrative action against an individual whose initial drug test result is not subsequently confirmed by the MRO as a violation of FFD policy in response to a suitable inquiry conducted under section 26.63, a background investigation conducted under Part 26, or to any other inquiry or investigation. The licensees or other entities must provide access to the system of files and records to personnel who are conducting reviews, inquiries into allegations, audits pursuant to section 26.41, and to NRC inspectors, to ensure that no records are retained. The licensees or other entities shall provide the tested individual with a written statement that the records specified in sections 26.713 and 26.715 have not been retained, and shall inform the individual in

writing that the temporary administrative action that was taken will not be disclosed and need not be disclosed by the individual in response to requests for a self-disclosure of PDI.

- 10 CFR 26.165(f)(1)(ii) requires that the licensee or other entity eliminate any matter from the individual's FFD record and other records that could link the individual to the temporary administrative action immediately upon receipt of a negative report from the testing of Bottle B or retesting the aliquot of a single specimen.
- 10 CFR 26.165(f)(1)(iv) requires that the licensee or other entity provide the tested individual with a written statement that the records specified in sections 26.713 and 26.715 have not been retained and shall inform the individual in writing that the temporary administrative action that was taken will not be disclosed.
- 10 CFR 26.165(f)(2) requires that if the donor requests that either Bottle B be tested or an aliquot of a single specimen be retested and either is not available, the MRO shall cancel the test and inform the licensee or other entity that another collection is required under direct observation as soon as reasonably practical. The licensee or other entity shall eliminate from the donor's personnel and other records any matter that could link the donor to the original positive, adulterated or substituted test result(s) or any temporary administrative action.

10 CFR 26.167(a) specifies that the QA program of each HHS lab must encompass all aspects of the testing process (including, but not limited to, specimen accessioning, chain of custody, security and reporting of results, initial and confirmatory testing, certification of calibrators and controls, and validation of analytical procedures). The performance characteristics (e.g., accuracy, precision, LOD, limit of quantitation (LOQ), specificity) of each test must be validated and documented for each test. Validation procedures must document that carryover does not affect the donor's specimen results. Periodic re-verification of analytical procedures is required. The QA procedures must ensure that the HHS lab monitors the conduct of each step in the testing process. These recordkeeping requirements ensure to the scientific legitimacy and accuracy of test results. Section 26.715(b)(7) establishes the recordkeeping requirements for section 26.167(a).

10 CFR 26.167(c)(2)(i) requires that refractometers used by HHS labs must report and display the specific gravity to 4 decimal places and to be interfaced with a laboratory information management system or computer and/or to generate a hard copy or digital electronic display to document the numerical result. This requirement is necessary to establish the specifications for refractometers used by HHS labs that perform validity testing on urine specimens. The section does not create any separate records, but determines the types of records that will be reported under section 26.161(d), (e) and (f).

10 CFR 26.167(f) requires the licensee or other entity to ensure that the HHS lab investigates any testing errors or unsatisfactory performance. Paragraph 26.167(f)(1) requires sufficient records to be maintained to furnish evidence of activities affecting quality. The identification of the significant condition, the cause of the condition, and the corrective action taken are required to be documented and reported to appropriate levels of management. Paragraph 26.167(f)(3) requires, if a false positive error occurs when testing a BPTS and the error is determined to be technical or methodological, that the licensee or other entity instruct the laboratory to provide all

quality control data from the batch or analytical run of specimens that included the false positive sample. If retesting is required, the retesting must be documented by a statement signed by the laboratory's certifying scientist. These requirements are consistent with the HHS Guidelines and with Part 50, Appendix B, Quality Assurance Requirements for Nuclear Power Plants and Fuel Reprocessing Plants, Criterion XVI, Quality Assurance Records. These requirements are necessary to protect donors from inaccurate results, to provide assurance that specimens of questionable validity are detected, and to ensure the integrity of the testing process. Section 26.715(b)(7) establishes the recordkeeping requirements for section 26.167(f).

10 CFR 26.167(h) requires laboratory calibrators and controls to be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions that are obtained from commercial manufacturers and that are properly labeled as to content and concentration. The standards and controls must be labeled with the dates when they are received, when prepared or opened, when placed in service, and when scheduled for expiration. These requirements are consistent with the HHS Guidelines and are standard business and laboratory practices necessary for any laboratory to conduct forensic drug testing, and to ensure the scientific legitimacy of test results. As standard business practices, they are not considered a burden for this analysis. Section 26.75(b)(3) establishes the recordkeeping requirements for section 26.167(h).

10 CFR 26.168(a) requires each licensee or other entity to submit BPTSs to the HHS lab, and describes the number of specimens to be submitted each quarter of the calendar year. No, recordkeeping requirements are contained in this section, but the burden for submitting BPTS is accounted for under section 26.168(g).

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 will provide documentation that the specimens provided meet the formulation criteria

10 CFR 26.168(h)(2) requires each licensee or other entity to ensure that the BPTS supplier provides an expiration date on each sample.

10 CFR 26.168(i)(2) requires each licensee or other entity to use a complete a CCF, place fictional initials on the specimen bottles' labels/seals, and indicate on the MRO's copy of the CCF that the specimen is a BPTS.

10 CFR 26.169(a), (c), (c)(1) – (c)(5), and (e) – (h) ensure that licensees and other entities receive test result reports and testing-related information from HHS labs performing specimen testing. The recordkeeping and reporting requirements under section 26.169 are established by contract between licensees and other entities and HHS labs. Section 26.715(b)(2), (b)(3), (b)(5), (b)(6), and (b)(8) establishes the recordkeeping requirements for section 26.169.

- 10 CFR 26.169(a) requires HHS labs to report test results to the MRO within 5 business days after receiving the specimen. Before reporting any test result, a certifying scientist must certify that 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; any indications of tampering, adulteration, or substitution that may be present; the

identification number assigned to the specimen by the licensee or other entity; and the specimen identification number assigned by the HHS lab.

- 10 CFR 26.169(c) requires HHS labs to report to the MRO of a licensee or other entity the test results for all specimens tested (both negative and positive).
- 10 CFR 26.169(c)(1) requires HHS labs to report all positive, adulterated, substituted, dilute, and invalid test results to the MRO.
- 10 CFR 26.169(c)(2) requires, if request by the MRO, that the HHS lab report the numerical values (i.e., quantitative values) for all positive drug test results. The HHS lab is required to provide the quantitative values for confirmatory positive opiate test results for morphine or codeine with a concentration greater than or equal to 15,000 ng/mL (even if not requested by the MRO).
- 10 CFR 26.169(c)(3) requires HHS labs to report to the MRO the numerical test result values for adulterated and substituted specimens.
- 10 CFR 26.169(c)(4) requires the HHS lab to contact the MRO and both will decide whether testing by another HHS lab would be useful in being able to report a positive or adulterated test result. This contact may occur through any secure electronic means (e.g., telephone, fax, e-mail). If no further testing is necessary, the HHS lab must report an invalid test result for the specimen.
- 10 CFR 26.169(c)(5) an HHS lab may report to the MRO that the quantitative value "exceeds the linear range of the test," that the quantitative value is "equal to or greater than <insert the value for the upper limit of the linear range>," or may report an accurate quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen.
- 10 CFR 26.169(e) specifies that an HHS lab may transmit results by electronic means (e.g., teleprinters, facsimile, or computer) in a manner designed to ensure the confidentiality of the information, and prohibits transmitting results verbally by telephone.
- 10 CFR 26.169(f) specifies that for negative results, the HHS lab may fax, courier, mail, or electronically transmit a computer-generated electronic report and/or a legible image or copy of the completed CCF to the MRO. However, for positive, adulterated, substituted, dilute, and invalid results, the laboratory shall fax, courier, mail, or electronically transmit a legible image or copy of the completed CCF to the MRO.
- 10 CFR 26.169(g) requires the HHS lab for a specimen that has a positive, adulterated, substituted, dilute, or invalid result, to retain the original CCF and transmit to the MRO a copy of the original CCF signed by a certifying scientist.
- 10 CFR 26.169(h) requires the HHS lab performing tests for a licensee or other entity to prepare an annual statistical summary report of urinalysis testing results for that year. To avoid sending data from which it is likely that information about an individual donor's test result can be inferred, the laboratory is not permitted to send a report if the licensee or other entity has fewer than 10 specimen test results in a one-year period. The

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 sections 26.417(b)(2) and 26.717. Information that is required to be included in the statistical summary report is listed in section 26.169(h)(1) – (h)(8).

10 CFR 26.183(a), (c)(1), and (d)(1)(ii)(D) specifies MRO qualifications, responsibilities, and procedures to maintain confidentiality of donor information collected as part of the test result review process.

- 10 CFR 26.183(a) establishes the required qualifications of the MRO and requires a record of the degree held by the MRO and the results of the MRO examination administered by a nationally-recognized MRO certification board or sub-specialty board. This requirement ensures that a record is available that demonstrates that the MRO meets the qualification requirements in Part 26.
- 10 CFR 26.183(c)(1) requires the MRO to examine alternate causes of a positive, adulterated, substituted, invalid, and, at the licensee's or other entity's discretion, special analyses test results of dilute specimens, including reviewing records provided by the donor (e.g., prescription medication use, information on medical treatment).
- 10 CFR 26.183(d)(1)(ii)(D) requires the MRO to maintain the confidentiality of records and donor personal information, except as permitted under Part 26, to ensure the security of data transmission and communication of test results to the licensee's or other entity's designated reviewing official.

10 CFR 26.183(d)(2)(i) and (d)(2)(ii) describe the procedures that MRO staff must follow to protect donor information collected as part of the testing process. These requirements define the duties that MRO staff may perform (e.g., receive test results from the HHS lab, review test result reports, schedule interviews with donors). These requirements protect donor due process rights, ensure to the confidentiality of collected information, and define the activities that MRO staff may perform. Section 26.713(a)(2) establishes the recordkeeping requirements for section 26.183(d)(2)(i) and (d)(2)(ii).

- 10 CFR 26.183(d)(2)(i) allows MRO staff, under the direction of the MRO, to receive and review HHS lab reports of negative test results, and to notify the licensee or other entity of these test results.
- 10 CFR 26.183(d)(2)(ii) specifies limitations on MRO staff reviews of positive, adulterated, substituted, invalid, and at the licensee's or other entity's discretion, dilute test results. MRO staff can review the HHS lab result and MRO copy of the CCF to identify errors requiring correction, but must forward any changes to the MRO for review and approval.

10 CFR 26.185(a), and (c) – (e) provide procedures for the review of drug test results by a qualified and trained MRO, the MRO discussion of test results with a donor to evaluate if a legitimate medical explanation exists for a test result, and the process to follow if the MRO is unable to discuss test results with the donor. These provisions provide due process rights to individuals tested under Part 26.

- 10 CFR 26.185(a) requires the MRO to review all positive, adulterated, substituted, dilute, and invalid test results from the HHS lab to determine whether the donor has violated the FFD policy before reporting the results to the licensee or other entity. The MRO review assesses if any legitimate medical reason exists that may explain a test result (e.g., use of a legally prescribed medication).
- 10 CFR 26.185(c) prohibits the MRO from determining that a positive, adulterated, substituted, dilute, or invalid result or other occurrence is a FFD policy violation without first giving the donor an opportunity to discuss the test result or occurrence and to provide a legitimate medical explanation. If the MRO determines the result or occurrence is an FFD violation after discussion with the donor, the MRO must notify the licensee or other entity of this determination.
- 10 CFR 26.185(d) permits the MRO to confirm a positive, adulterated, substituted, dilute, or invalid test result or other FFD policy violation without discussing the test result or other occurrence with the donor under any of the following circumstances: (1) the MRO has made and documented contact with the donor and the donor declined the opportunity to discuss the test result or other FFD policy violation; (2) a representative of the licensee or other entity, or a MRO staff member, has successfully made and documented contact with the donor, has instructed the donor to contact the MRO, and more than 1 business day has elapsed; or (3) the MRO is unable to contact the donor after making all reasonable efforts and documenting the date and time of each attempt.
- 10 CFR 26.185(e) allows a donor, within 30 days of notification of an FFD violation, to present the MRO with information documenting circumstances that unavoidably prevented the donor from contacting the MRO or a representative of the licensee or other entity in a timely manner. The MRO then would consider the request and whether to reopen the procedure to discuss the test result with the donor.

10 CFR 26.185(f)(1) requires the MRO to consult with an HHS lab that reports an invalid result, to determine if additional testing by another HHS lab would be useful. This requirement is necessary to protect donors from inaccurate results, to provide assurance that specimens of questionable validity are detected, and to ensure the integrity of the testing process.

10 CFR 26.185(f)(2) requires the MRO, if additional testing is not useful, to contact the donor to determine if an acceptable medical explanation exists for the invalid result, and, if there is, to report to the licensee that the test result is not an FFD policy violation, but that a negative test result was not obtained. The licensee or other entity would then take additional actions (i.e., collect a second specimen from the individual).

10 CFR 26.185(h)(1) – (h)(3), (i)(1) – (i)(3), (j), (k), and (m) – (p) meet, in part, the legal necessity of protecting the due process rights of individuals subject to Part 26, and provide prior notice and documentation of that notice if needed in a legal proceeding. These requirements afford donor protections against inaccurate results, provide assurance that attempts to subvert the testing process are evaluated, and ensure to the integrity of the testing process. Section 26.713(a)(2) establishes recordkeeping requirements for section 26.185.

- 10 CFR 26.185(h)(1) requires the MRO, if the HHS lab reports a specimen as substituted, to contact the donor and offer the donor an opportunity to provide an acceptable medical explanation for the substituted result. The donor must provide credible medical evidence within 5 business days that he or she produced the specimen for which the HHS lab reported a substituted result. Any medical evidence must be submitted through a referral physician who is experienced and qualified in the medical issues involved.
- 10 CFR 26.185(h)(2) requires the MRO, if the MRO determines there is no acceptable medical explanation for the substituted test result, to report to the licensee or other entity that the specimen was substituted.
- 10 CFR 26.185(h)(3) requires that if the MRO determines that an acceptable medical explanation exists for a substituted test result, the MRO must report to the licensee or other entity that the donor has not violated the FFD policy.
- 10 CFR 26.185(i)(1) requires the MRO, if the HHS lab reports a specimen as adulterated, to contact the donor and offer the donor an opportunity to provide an acceptable medical explanation for the adulterated result. The donor is required to provide credible medical evidence within 5 business days that he or she produced the adulterated result through normal human physiology.
- 10 CFR 26.185(i)(2) requires that if the MRO determines that no acceptable medical explanation exists for an adulterated test result, the MRO must report to the licensee or other entity that the specimen is adulterated.
- 10 CFR 26.185(i)(3) requires that if the MRO determines that an acceptable medical explanation exists for an adulterated test result, the MRO must report to the licensee or other entity that the donor has not violated the FFD policy.
- 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 that the donor has violated the FFD policy.
- 10 CFR 26.185(k) requires that if the MRO determines that a legitimate medical explanation exists for a confirmatory positive drug test result (i.e., a prescription medication identified by testing was used in the manner and at the dosage prescribed and the results do not reflect a lack of reliability or trustworthiness), the MRO must report to the licensee or other entity that there was no FFD policy violation.
- 10 CFR 26.185(m) provides that, based on the review of inspection and audit reports, quality control data, multiple specimens, and other pertinent results, the MRO may determine that a positive, adulterated, substituted or invalid test result is scientifically insufficient for further action and may declare that a drug or validity test result is not an FFD policy violation.
- 10 CFR 26.185(n) provides that, if a second HHS lab reconfirms the drug-positive test result or reconfirms the 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 lab

does not reconfirm the drug-positive test result, 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(o) requires the MRO to review drug test results from an individual whose authorization was terminated or denied following a first violation of FFD policy. In order to determine whether subsequent positive confirmatory drug test results represent new drug use or remaining metabolites from the drug use that initially resulted in the FFD policy violation, the MRO shall request from the HHS lab and the laboratory shall provide, quantitation of the test results and other information necessary to make the determination.
- 10 CFR 26.185(p) requires the MRO to review positive, adulterated, substituted, and invalid test results 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 receiving the positive, adulterated, or substituted test result from the HHS lab.

10 CFR 26.187(d) requires that an SAE receive qualification training on: the background, rationale, and scope of Part 26; key drug testing requirements of Part 26 (including specimen collection, laboratory testing, MRO review, and problems in drug testing); key alcohol testing requirements of Part 26 (including specimen collection, laboratory testing, MRO review, and problems in alcohol tests); SAE qualifications and prohibitions; the role of the SAE in making determinations of fitness and the return-to-duty process (including the initial evaluation, referrals for education and/or treatment, the follow-up evaluation, continuing treatment recommendations, and the follow-up testing plan); procedures for SAE consultation and communication with licensees or other entities, MROs, and treatment providers; reporting and recordkeeping requirements of Part 26; and issues that SAEs confront in carrying out their duties under Part 26. Qualification training ensures that each SAE can perform required functions under Part 26. Section 26.187(f) establishes the recordkeeping requirements for section 26.187(d).

10 CFR 26.187(f) requires the SAE to maintain documentation showing that he or she currently meets all credentials, knowledge, and training requirements for a SAE established by section 26.187, and to provide this documentation upon request to NRC representatives, licensees, or other entities who are relying upon or contemplating relying upon the SAE's services and to other individuals and entities, in accordance with the requirements of section 26.37. This requirement ensures that the training and competency of the SAE can be verified by NRC inspectors, license auditors, or other staff of the licensee or other entity conducting self-assessments or other activities. Records of training and competency may be important evidence in any litigation that may occur with respect to test results and/or FFD program management actions or sanctions. In addition, records of training and competency of SAE will support reliance by licensees and other entities on FFD program results from other Part 26 programs.

10 CFR 26.189(a) and (c) specify the procedures to make determinations of fitness under Part 26 and ensure that each individual subject to an FFD program is fit-for-duty and not impaired in any way that could affect their ability to safely and competently perform assigned

duties. These requirements also ensure that only qualified professionals complete a determination of fitness and that records are maintained on the assessment — protecting the due process rights of the individual and ensure that records on the determination are available if needed in a legal proceeding.

- 10 CFR 26.189(a) provides that a determination of fitness must be performed on an individual subject to an FFD program that may be in violation of the FFD policy, or otherwise unable to safely and competently perform his or her assigned duties. A determination of fitness must be made by a licensed or certified professional appropriately qualified and with the necessary clinical expertise, as verified by the licensee or other entity, to evaluate the fitness issues presented by an individual. A written record of the determination of fitness must be prepared.
- 10 CFR 26.189(c) requires that a for cause determination of fitness be conducted through a face-to-face interaction between the subject individual and the professional making the assessment. If a determination concludes that an individual may be impaired while on duty, then the subject individual would be determined to be unfit for duty and the professional then would consult with FFD management to identify actions to ensure that any possible limiting condition does not represent a threat to workplace or public health and safety. A written record of the determination of fitness must be prepared.

10 CFR 26.189(d) permits the profession who completed a fitness determination, to modify the evaluation and recommendations if new or additional information is obtained. This requirement ensures that relevant information regarding an individual's fitness is incorporated into the determination of fitness. Any updates to the fitness determination would be documented and maintained. Recordkeeping requirements for section 26.189 are established by section 26.713(a)(4).

10 CFR 26.203(a) and (b) ensure that written policies and procedures of a fatigue management program are available to subject individuals. The policy and procedures inform subject individuals of rights and responsibilities under the program, and the consequences of not complying with the fatigue management policy. The requirements also partially meet the legal necessity of providing prior notice and documentation of that notice as evidence in a legal proceeding. The provisions for policy and procedures for fatigue management are included in the overall requirement regarding policy and procedures for FFD. Therefore, the burdens for the written policy and procedures required under section 26.203 are included under section 26.27(b) and (c) for the overall policy and procedures.

- 10 CFR 26.203(a) requires each licensee or other entity subject to Subpart I, to establish a policy for the management of fatigue for all individuals who are subject to the licensee's FFD program and to incorporate it into the written policy required in section 26.27(b).
- 10 CFR 26.203(b) requires each licensee or other entity with a fatigue management program under Subpart I, to develop, implement, and maintain written procedures that describe the process to be followed when an individual makes a self-declaration that he or she is not fit to safely and competently perform his or her duties for any part of a working tour as a result of fatigue. The procedure must describe the individual's and

licensee's rights and responsibilities relating to self-declaration; describe requirements for establishing controls and conditions under which an individual may be permitted or required to perform work after that individual declared that he or she was not fit due to fatigue; and, describe the process to be followed if the individual disagrees with the results of a fatigue assessment. The procedures must also describe the process for implementing the controls required by section 26.205, describe the process for conducting fatigue assessments, and describe the disciplinary actions, if any, that the licensee may impose on an individual following a fatigue assessment and the conditions and considerations for taking those disciplinary actions.

10 CFR 26.203(c) requires licensees to add specific KAs to the content of the training that is required in section 26.29(a) and the comprehensive examination required in section 26.29(b) relating to knowledge of and ability to identify symptoms of work fatigue and contributors to decreased alertness in the workplace. This requirement ensures that individuals assigned to activities within the scope of Subpart I are provided with appropriate training with respect to fatigue so that they are sufficiently skilled to detect conditions that arise from fatigue, they know the proper action to be initiated, and that they understand the methods that will be used to implement the FFD policy, the personal and public health and safety hazards associated with fatigue, their roles and responsibilities in the implementation of the FFD program as it addresses fatigue, the role of the MRO, and the EAP services available. The requirement also partially meets the legal necessity of providing prior notice and having it documented for evidence in legal proceedings.

10 CFR 26.203(d) requires all licensees and other entities to retain the following records for at least 3 years or until the completion of all related legal proceedings, whichever is later:

- 10 CFR 26.203(d)(1): Records of work hours for individuals subject to the work hour controls in section 26.205;
- 10 CFR 26.203(d)(2): Records of shift schedules and shift cycles of individuals who are subject to the work hour controls in section 26.205(d)(3), in addition to records showing the beginning and end times and dates of all 6-week or shorter averaging periods if applying the maximum average work hour requirements of section 26.205(d)(7);
- 10 CFR 26.203(d)(3): Documentation of waivers that is required in section 26.207(a)(4), including the basis for granting the waivers.
- 10 CFR 26.203(d)(4): Documentation of work hour reviews that is required in section 26.205(e)(3) and (e)(4); and,
- 10 CFR 26.203(d)(5): Documentation of fatigue assessments that is required in section 26.211(g).

These section 26.203 requirements are necessary to ensure that licensees and other entities establish and properly implement fatigue management programs. Licensees and other entities must maintain records to demonstrate the fulfillment of regulatory requirements for self-assessments and to support the preparation of annual reports, and to provide information to the NRC to be used in evaluating the effectiveness of the fatigue management programs required by Part 26.

10 CFR 26.203(e), (e)(1), and (e)(2) ensure that licensees and other entities provide information to the NRC to demonstrate their fulfillment of regulatory requirements for fatigue management and to allow the NRC to assess the effectiveness of the fatigue management requirements. Collection of this information pertaining to significant fatigue-management topics, events, and corrective actions is necessary to permit self-assessments and internal reviews and audits by licensees and to permit timely evaluation of events that might become problems and that may require action by the NRC staff to ensure that the health and safety of the public is not endangered. Recordkeeping requirements for section 26.203(e) are established by this section. Reporting requirements for section 26.203(e)(1), and (e)(2) are established by this section.

- 10 CFR 26.203(e) requires that the following information in a standard format is included in the annual FFD program performance report required by section 26.717.
- 10 CFR 26.203(e)(1) requires licensees to prepare a summary for each nuclear power plant site of all instances during the previous calendar year in which the licensee waived the work hour controls specified in section 26.205(d)(1) through (d)(5)(i) and (d)(7) for individuals described in section 26.4(a). Each summary must include an accounting of only those waivers under which work was performed. If it was necessary to waive more than one work hour control during any single extended work period, the summary of instances must include each of the work hour controls that were waived during the period. For each category of individuals specified in section 26.4(a) the licensee shall report: the number of instances in which each work hour control specified in section 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), (d)(3)(i) through (d)(3)(v), and (d)(7) was waived for individuals not working on outage activities; the number of instances in which each work hour control specified in section 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), (d)(3)(i) through (d)(3)(v), (d)(4) and (d)(5)(i), and (d)(7) was waived for individuals working on outage activities; and a summary that shows the distribution of waiver use among the individuals within each category of individuals identified in section 26.4(a) (e.g., a table that shows the number of individuals that received only one waiver during the reporting period, the number of individuals that received a total of two waivers during the reporting period).
- 10 CFR 26.203(e)(2) requires licensees to include a summary of corrective actions, if any, resulting from the analyses of these data, including fatigue assessments.

10 CFR 26.203(f) requires licensees to audit the management of worker fatigue as required by section 26.41. This requirement ensures that licensees audit FFD program elements provided by C/Vs and the FFD programs of any C/Vs that are accepted by the licensee. Reporting and recordkeeping requirements for section 26.203(f) are established by section 26.41(f) and (g).

10 CFR 26.205(b), (c), (d)(1) – (d)(7), (d)(7)(i) – (d)(7)(iii), (d)(8), (e), and (e)(3) – (e)(4) ensure that licensees and other entities properly implement work hour controls, including waivers of those controls, for personnel performing activities on systems, structures, and components that a risk-informed evaluation process has shown to be significant to public health and safety. These records enable each licensee and other entity to review and correct any problems in maintaining control of work hours, to enable the NRC to inspect the licensee's and other entities' fatigue management program, and to provide information for periodic audits. Section 26.203(d)(1) establishes the recordkeeping requirements for section 26.205(c) and (d)(1); section 26.203(d)(2) establishes the recordkeeping requirements for 26.205(d)(2) through (d)(6);

section 26.203(d)(4) establishes the recordkeeping requirements for section 25.205(e)(1) through (e)(3); and section 26.203(d)(4) establishes the recordkeeping requirements for section 26.205(e)(4).

- 10 CFR 26.205(b) requires each licensee to calculate the work hours of each individual subject to this section as the amount of time each individuals performs duties for the licensee.
- 10 CFR 26.205(c) requires each licensee to schedule the work hours of each individual who is subject to this section consistent with the objective of preventing impairment from fatigue due to the duration, frequency, or sequencing of successive shifts.
- 10 CFR 26.205(d)(1) requires each licensee to implement work hour controls for each individual to ensure that, except as permitted by the waiver provisions in section 26.207, the individual's work hours do not exceed 16 work hours in any 24-hour period, 26 work hours in any 48-hour period, and 72 work hours in any 7-day period.
- 10 CFR 26.205(d)(2) requires each licensee to ensure that each individual has adequate rest breaks between successive work periods, during which the individual does not perform any duties for the licensee other than one shift turnover, either at the beginning or the end of a shift, but not both.
- 10 CFR 26.205(d)(3) requires each licensee to ensure that each individuals has, at a minimum, the number of days off specified in this paragraph or comply with the requirements for maximum average work hours in section 26.205(d)(7).
- 10 CFR 26.205(d)(4) requires each licensee to ensure that each individuals has, at a minimum, the number of days off specified in this paragraph and exempts licensees from the requirements of paragraph (d)(3) or (d)(7) of this section for individuals specified in section 26.4(a)(1) through (a)(4) for the first 60 days of an outage, while the individuals are working on outage activities.
- 10 CFR 26.205(d)(5) requires each licensee to ensure that each individual has, at a minimum, the number of days off specified in this paragraph and exempts licensees from the requirements of paragraph (d)(3) or (d)(7) of this section for individuals specified in section 26.4(a)(5) for the first 60 days of a unit outage, security system outage, or increased threat condition.
- 10 CFR 26.205(d)(6) specifies that the 60-day periods in paragraphs (d)(4) and (d)(5) of this section may be extended for each individual in 7-day increments for each non-overlapping 7-day period in which the individual has worked not more than 48 hours during the unit or security system outage or increased threat condition, as applicable.
- 10 CFR 26.205(d)(7) provides each licensee with a voluntary alternative to the minimum days off requirements of section 26.205(d)(3), by permitting the licensee to comply with the requirements for maximum average work hours.
- 10 CFR 26.205(d)(7)(i) establishes the alternative requirement to maintain each individual's weekly average of work hours at less than 54, calculated using an averaging

period of up to 6 weeks, which advances by 7 consecutive calendar days at the finish of every averaging period.

- 10 CFR 26.205(d)(7)(ii) requires each licensee, when an individual's work shift starts at the end of a calendar day and concludes during the next calendar day, to either account for all of an individual's work hours as worked on the day the shift started or work hours on the calendar days on which they were actually worked.
- 10 CFR 26.205(d)(7)(iii) requires each licensee to state in its FFD policies and procedures the work hour counting system in section 26.205(d)(7)(ii) the licensee is using.
- 10 CFR 26.205(d)(8) requires each licensee to explicitly state in its FFD policies and procedures the work hour control requirements with which it is complying: minimum days off provisions of section 26.205(d)(3) or maximum average work hour provisions of section 26.205(d)(7).
- 10 CFR 26.205(e) requires each licensee to evaluate the effectiveness of its control of work hours for individuals who are subject to Subpart I, at a minimum of once per calendar year. If any plant or security system outages or increased threat conditions occurred since the licensee completed the most recent review, the licensee must include in the review an evaluation of the control of work hours during the outages or the increased threat conditions. The review must be completed within 30 days of the end of the review period. Paragraphs 26.205(e)(1) and (e)(2) describe the topics that must be included in the reviews.
- 10 CFR 26.205(e)(3) requires each licensee to document the methods used to conduct reviews and the results of those reviews.
- 10 CFR 26.205(e)(4) requires each licensee to record, trend, and correct, under the licensee's corrective action program, any problems identified in maintaining control of work hours consistent with the specific requirements and performance objectives of Part 26.

10 CFR 26.207(a)(4) requires each licensee to document the bases for the issuance of individual waivers. The documented basis for a waiver must include a description of the circumstances that necessitated the waiver, a statement of the scope of work and time period for which the waiver is approved, and the bases for the determinations. This requirement ensures that waivers to the work hours controls are approved only by those supervisors and shift managers authorized to determine if a waiver is necessary and that a record is created to document the basis for the waiver and the identity of the person approving the waiver. Recordkeeping requirements for section 26.207 are established by section 26.203(d)(3).

10 CFR 26.209 requires each individual subject to the rule to self-declare that he or she is unable to safely and competently perform his or her duties due to fatigue, and for the licensee to take certain actions if such a declaration is made.

10 CFR 26.211(f) requires each licensee to document the results of any fatigue assessments conducted, the circumstances that necessitated the fatigue assessment, and any controls and

conditions that were implemented. This requirement ensures that fatigue assessments of individuals are conducted in appropriate circumstances and in an appropriate manner. This requirement ensures that the due process rights of individuals who are subject to the fatigue management requirements are protected. It will support internal licensee self-assessments of fatigue-management programs. This requirement also enables NRC to review and audit the licensees' and other entities' fatigue management programs. Recordkeeping requirements for section 26.211(f) is established by section 26.203(d)(5).

10 CFR 26.211(g) requires the licensee or other entity of each operating nuclear power reactor site to prepare an annual summary detailing instances of fatigue assessments conducted during the previous calendar year for individuals described in section 26.4(a) through (c). Each summary must include: the conditions under which each fatigue assessment was conducted (e.g., self-declaration, for cause, post-event, or follow-up); a statement of whether or not the individual was working on outage activities at the time of the self-declaration or condition resulting in the fatigue assessment; the category of duties the individual was performing, if the individual was performing the duties described in section 26.4(a)(1) through (a)(5) at the time of the self-declaration or condition resulting in the fatigue assessment; and the management actions, if any, resulting from each fatigue assessment. This requirement ensures that licensees and other entities provide information to the NRC to demonstrate their fulfillment of regulatory requirements for fatigue management and to allow the NRC to assess the effectiveness of the fatigue management requirements. Collection of this information pertaining to fatigue assessments and the management actions, if any, resulting from fatigue assessments is necessary to permit internal reviews and audits by licensees and to permit evaluation of events and trends that might become problems and that may require action by the NRC staff to ensure that the health and safety of the public is not endangered. The recordkeeping requirements for section 26.211(g) is established by section 26.203(d)(5).

10 CFR 26.401(b), and 26.403(a) and (b), establish the FFD policy and procedures required by Subpart K and are the primary means by which a licensee or other entity communicates its FFD policy and procedures to individuals who are subject to an FFD program under Part 26. These requirements ensure that each individual is informed in sufficient detail about the licensee or other entity's FFD policy and procedures, what is expected of them, and what consequences may result from a lack of adherence to the FFD policy. Because the consequences of lack of adherence to the FFD policy can be severe (up to a permanent denial of authorization), it is critical that all subject individuals understand the FFD policy. Maintaining FFD procedures ensures that the licensee or other entity of the reactor construction site D&A testing program uniformly implements the program, and ensures that program oversight by the NRC during inspection is possible.

- 10 CFR 26.401(b) requires the licensee or other entity of a reactor construction site D&A testing program to submit a description of the FFD program and its implementation to the NRC as part of the license, permit, or limited work authorization application. This requirement ensures that NRC receives sufficient information to ensure that the licensee's or other entity's FFD program will meet the requirements in Subpart K prior to the start of construction activities.
- 10 CFR 26.403(a) requires the licensee or other entity of each reactor construction site D&A testing program to provide a clear, concise, written FFD policy statement to individuals subject to the FFD program. The policy statement must be written in

sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy.

- 10 CFR 26.403(b) requires the license or other entity of each reactor construction site D&A testing program to develop, implement, and maintain written procedures. These procedures must address drug and alcohol testing methods and techniques; protect donor privacy, specimen integrity, and test result accuracy; specify actions to be taken for FFD violations; and the process to follow if behavior is identified in an individual that raise concerns of possible FFD violations or impairment.

10 CFR 26.405(a), (b), (c)(1) – (c)(4), and (d) – (g) describes the conditions when testing is to be performed by a reactor construction site D&A testing program. Testing must occur on pre-assignment, for cause, post-accident, follow-up, and random (unless a fitness monitoring program is maintained under section 26.406). These requirements provide assurance that individuals subject to an FFD program are fit for duty. These requirements also ensure that each specimen is tested for the specified drugs, and MRO review of test results is performed.

- 10 CFR 26.405(a) requires licensees and other entities who implement a FFD program under subpart K to perform D&A testing that complies with the requirements of section 26.405.
- 10 CFR 26.405(b) provides that if a licensee or other entity elects to impose random testing for drugs and alcohol, the random testing must meet certain specified criteria (address predictability in testing, report for testing in a timely manner after notification of testing).
- 10 CFR 26.405(c)(1) requires licensees and other entities to conduct pre-assignment testing before employees are assigned to construct safety- or security-related structures, systems, and components (SSCs) of nuclear power reactors.
- 10 CFR 26.405(c)(2) requires licensees and other entities to conduct for-cause testing in response to an individual's observed behavior or physical condition indicating possible substance abuse or after receiving credible information that an individual is engaging in substance abuse.
- 10 CFR 26.405(c)(3) specifies the conditions when licensees and other entities must conduct post-accident testing after an event involving human error committed by individuals specified in section 26.4(f).
- 10 CFR 26.405(c)(4) requires licensees and other entities to conduct follow-up testing to verify an individual's continued abstinence from substance abuse.
- 10 CFR 26.405(d) specifies the substances (and cutoff levels) to be tested in the specimens collected from subject individuals by a reactor construction site D&A testing program (drugs, adulterants, and alcohol).
- 10 CFR 26.405(e) requires the specimen collection and D&A testing procedures to protect the donor's privacy and the integrity of the specimen, and to implement stringent quality controls to ensure that test results are valid and attributable to the correct

individual. At the licensee's or other entity's discretion, specimen collections and alcohol testing may be conducted at a local hospital or other facility under the specimen collection and alcohol testing requirements of 49 CFR Part 40 and subsequent amendments thereto.

- 10 CFR 26.405(f) requires testing of urine specimens for drugs and validity, except validity screening and initial drug and validity tests that may be performed by LTFs, must be performed in an HHS lab. Urine specimens that yield positive, adulterated, substituted, or invalid initial validity or drug test results must be subject to confirmatory testing by the HHS lab, except for invalid specimens that cannot be tested. Other specimens that yield positive initial drug test results must be subject to confirmatory testing by a laboratory that meets stringent quality control requirements that are comparable to those required for certification by the HHS.
- 10 CFR 26.405(g) requires the MRO review of positive, adulterated, substituted, and invalid confirmatory drug and validity test results to determine whether the donor has violated the FFD policy, before reporting the results to the licensee or other entity to perform the suitability and fitness evaluations required under section 26.419.

10 CFR 26.406(a) – (d) ensure that fitness monitors, if a reactor construction site implements a fitness monitoring program, know and understand the procedures to perform fitness monitoring. The preparation of the fitness monitoring policy and procedures is covered by section 26.403.

- 10 CFR 26.406(a), (b), and (d) require licensees and other entities that do not implement random testing under section 26.405(b) to establish a fitness monitoring program to deter substance abuse and detect indications of possible use, sale, or possession of illegal drugs; use or possession of alcohol on site or while on duty; or impairment from any cause that if left unattended may result in a risk to public health and safety or the common defense and security. To ensure that the fitness of individuals is monitored effectively, licensees and other entities must consider the number and placement of monitors required, the necessary ratio of monitors to individuals specified in section 26.4(f), and the frequency with which observations must be conducted.
- 10 CFR 26.406(c) requires licensees and other entities that do not elect to establish a random testing program to establish instead a fitness monitoring program and to establish procedures that fitness monitors shall follow and to train the monitors to implement the program.

10 CFR 26.407 requires that individuals constructing safety- or security-related SSCs, as described in section 26.4(f), be subject to behavioral observation by the licensee or other entity of a reactor construction site D&A testing program (except if the program implements a fitness monitoring program under section 26.406). This requirement ensures that if licensees and other entities elect to implement a random D&A testing program under section 26.405, they also implement a BOP to identify possible impairment from the use of drugs, alcohol, or from any other cause that may affect an individual's ability to safety and competently perform assigned duties.

10 CFR 26.411(a) and (b) establish protections for the personal information collected by the licensee or other entity of a reactor construction site D&A testing program under Part 26.

- 10 CFR 26.411(a) requires licensees and other entities that collect personal information about an individual to comply with Subpart K and to establish and maintain a system of files and procedures to protect this information.
- 10 CFR 26.411(b) requires licensees and other entities to obtain a signed consent from the donor that authorizes the disclosure of personal information collected and maintained under Subpart K before disclosing the personal information, except as specified in Part 26.

10 CFR 26.413 requires the licensee or other entity of a reactor construction site D&A testing program to establish and implement procedures for the review of a determination that a subject individual violated the FFD policy. These procedures must provide for an objective and impartial review of the facts on the FFD policy violation determination. These requirements ensure that written procedures specify the criteria for determining that an individual has violated the FFD policy and provide individuals with a specified process for reviewing and appealing these determinations. The requirements also provide due process to individuals subject to Part 26 by providing sufficient detail on the review procedures for FFD policy violation determinations, acceptable behavior, and the consequences of FFD policy violations.

10 CFR 26.415(a) requires the licensee or other entity of a reactor construction site D&A testing program to ensure that audits are performed to assure the effectiveness of the FFD program, including FFD program elements provided by C/Vs, and the FFD programs of C/Vs accepted by the licensee or other entity. The requirements for audit documentation, maintenance of audit records, and access to audit information ensure to the identification and resolution of program weaknesses and help licensees and other entities, including C/Vs and HHS labs, determine what corrective actions are necessary and carry out necessary corrective actions. These requirements ensure that information is available for NRC review during inspections.

10 CFR 26.417(a), (b)(1) and (b)(2), and 26.419 require the licensee or other entity of each reactor construction site D&A testing program to ensure that the collection site(s), LTF (if used), and HHS labs maintain records, which enables verification of compliance with Part 26 specimen collection and testing requirements. These records also enable licensees and other entities to review and correct problems in implementing D&A testing programs, and enable NRC evaluation of these records through inspection.

These requirements also ensure that information about significant violations of FFD policy, testing errors, and other events affecting the performance of a reactor construction site D&A testing program is provided to the NRC in a timely manner so that staff action can be taken, if necessary. These reports enable licensees and other entities to review and correct any problems in implementing FFD programs, and enable the NRC to inspect the licensee's and other entities' FFD programs and to obtain information necessary to evaluate the effectiveness of the FFD programs. Collection of information pertaining to significant FFD events is necessary to permit evaluations of events that might become problems and that may require timely response by the NRC staff to ensure that the health and safety of the public is not endangered.

- 10 CFR 26.417(a) requires reactor construction site D&A testing programs to maintain records on FFD program administration, which enables NRC review during inspection and availability is necessary for legal and regulatory proceedings.
- 10 CFR 26.417(b)(1) requires reactor construction site D&A testing programs to make reports to the NRC Operations Center by telephone within 24 hours of discovering an intentional act that casts doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals who are subject to Subpart K. These events must be reported under Part 26, rather than under 10 CFR 73.71, because the events are associated with FFD programs at reactor construction sites.
- 10 CFR 26.417(b)(2) requires the licensee or other entity of each reactor construction site D&A testing program to submit an annual FFD program performance report to the NRC.
- Section 26.419 requires that the licensee or other entity of each reactor construction site D&A testing program develop, implement, and maintain procedures for evaluating whether to assign individuals to construct safety- and security-related SSCs. The procedures must provide reasonable assurance that the individuals are fit to safely and competently perform their duties and are trustworthy and reliable, as demonstrated by the avoidance of substance abuse. This section establishes the overall performance objective for Subpart K and specifies that licensees and other entities are required to prepare and maintain procedures for ensuring that the performance objective will be met through the evaluation of the suitability and fitness of individuals assigned to construct safety-related and security-related SSCs.

10 CFR 26.711(a) and (b). Although no records or reports are required by these two paragraphs, they influence how the records and reports required by Part 26 will be created, stored, and archived. This section provides licensees and other entities with the opportunity to use electronic records and makes the requirements in Part 26 consistent with access authorization requirements established in 10 CFR 73.56, orders issued to the licensees of nuclear power plants on January 7, 2003, and subsequent rulemaking.

- 10 CFR 26.711(a) provides that each licensee and other entity shall maintain records and submit certain reports to the NRC. Records that are required by the regulations in Part 26 must be retained for the period specified by the appropriate regulation. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the facility license, certificate, or other regulatory approval.
- 10 CFR 26.711(b) provides that each licensee and entity may store and archive records electronically, provided that the record provides an accurate representation of the original, cannot be altered once it has been committed to storage, and can be easily retrieved and recreated.

10 CFR 26.711(c) provides that licensees and other entities specified in section 26.3(a) and as applicable, section 26.3(c) and (d), shall inform each individual of his or her right to review information about the individual that is collected and maintained under Part 26 to assure its

accuracy. Licensees and other entities are required to provide individuals with an opportunity to correct inaccurate or incomplete information that is maintained under Part 26. This paragraph supplements the provisions in section 26.37 relating to protection of information and makes explicit that individuals can review and request that the licensee or other entity to correct any inaccurate information identified.

10 CFR 26.711(d) provides that licensees and other entities shall ensure that only correct and complete information about individuals is retained and shared with other licensees and entities. If shared information changes or new information is developed, licensees and other entities are required to correct or augment the shared information contained in the records. If the changed or developed information has implications for adversely affecting an individual's eligibility for authorization, the licensee or other entity shall inform the reviewing official of any FFD program under which the individual is maintaining authorization of the updated information on the day of discovery. The reviewing official shall take appropriate actions, which may include denial or unfavorable termination of the individual's authorization. This paragraph ensures that incorrect or incomplete information about individuals is corrected and that newly obtained information relevant to the individual's eligibility for authorization is shared with other FFD programs.

10 CFR 26.713(a)(1) – (a)(4), (b)(1) and (b)(2), and (c) – (g) ensure that licensees and other entities collect and maintain records that demonstrate compliance with Part 26. These records ensure that licensees and other entities can review and correct problems identified in implementing FFD programs, and enables NRC inspection of FFD programs. This section contains the majority of recordkeeping requirements in Part 26; however, the activities that generate the records maintained under these requirements are located elsewhere.

- 10 CFR 26.713(a)(1) requires the retention of records of self-disclosures and suitable inquiries conducted under sections 26.55, 26.57, 26.59, and 26.69 that result in the granting of authorization 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.
- 10 CFR 26.713(a)(2) requires the retention of records pertaining to any 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.
- 10 CFR 26.713(a)(3) requires the retention of records of documentation of the granting and termination of authorization 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.
- 10 CFR 26.713(a)(4) requires the retention of records of any determinations of fitness conducted under section 26.189, including recommendations for treatment and follow-up testing plans, 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.

- 10 CFR 26.713(b)(1) requires that licensees and other entities retain records of FFD training and examinations conducted under section 26.29 for at least 3 years or until the completion of all related legal proceedings, whichever is later.
- 10 CFR 26.713(b)(2) requires that licensees and other entities retain records of FFD audits, audit findings, and corrective actions taken under section 26.41 for at least 3 years or until the completion of all related legal proceedings, whichever is later.
- 10 CFR 26.713(c) requires that licensees and other entities to retain and make available records pertaining to any 5-year denial of authorization under section 26.75(c), (d), or (e) (2), and any permanent denials of authorization under section 26.75(b) and (g) for at least 40 years or until, upon application, the NRC determines that the records are no longer needed.
- 10 CFR 26.713(d) requires that licensees and other entities retain any superseded versions of the written FFD policy and procedures required under sections 26.27, 26.39, and 26.203(b) for at least 5 years or until completion of all legal proceedings related to an FFD violation that may have occurred under the policy and procedures, whichever is later.
- 10 CFR 26.713(e) requires that licensees and other entities retain written agreements for the provision of services under Part 26 for the life of the agreement or until completion of all legal proceedings related to an FFD policy violation that involved those services, whichever is later.
- 10 CFR 26.713(f) requires that licensees and other entities retain records of the background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel, conducted under section 26.31(b)(1), for the length of the individual's employment by or contractual relationship with the licensee or other entity, or until the completion of all related legal proceedings, whichever is later.
- 10 CFR 26.713(g) requires that if a licensee's and other entity's FFD program includes tests for drugs in addition to those specified in Part 26, the licensee or other entity shall retain the documentation certifying the scientific and technical suitability of the assays and cutoff levels used, as required under section 26.31(d)(1)(i) and (d)(3)(iii)(C) respectively, for the period of time during which the FFD program follows those practices or until the completion of all related legal proceedings, whichever is later.

10 CFR 26.715(a) establishes a 2 year retention period (or longer if related to a legal proceeding) for the records generated by collection sites, LTFs and HHS labs that provide services to a licensee's or other entity's D&A testing program. The retention period also may be extended upon written notice from the NRC, or by the licensee or other entity for whom services are provided.

10 CFR 26.715(b)(1) – (b)(14) describe the records that must be maintained pursuant to the retention period in section 26.715(a). These requirements ensure that records are maintained by licensees and other entities that maintain collection sites and/or testing facilities, and by laboratories certified by the HHS that provide services to licensees and other entities, that demonstrate that D&A testing requirements are implemented properly. Such records are

generally consistent with the requirements for HHS labs in the HHS Guidelines, as well as with usual and customary business practices for such laboratories. These records are also necessary to enable licensees and other entities to review and correct any problems in implementing FFD D&A testing programs, and to enable the NRC to inspect the licensees' and other entities' D&A testing programs.

- 10 CFR 26.715(b)(1): 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 lab;
- 10 CFR 26.715(b)(2): Chain of custody documents (other than forms recording specimens with negative test results and no FFD violations or anomalies, which may be destroyed after appropriate summary information has been recorded for program administration purposes);
- 10 CFR 26.715(b)(3): QA/QC records;
- 10 CFR 26.715(b)(4): Superseded procedures;
- 10 CFR 26.715(b)(5): All test data (including calibration curves and any calculations used in determining test results);
- 10 CFR 26.715(b)(6): Test reports;
- 10 CFR 26.715(b)(7): Records pertaining to performance testing;
- 10 CFR 26.715(b)(8): Records pertaining to the investigation of testing errors or unsatisfactory performance discovered in quality control or blind performance testing, in the testing of actual specimens, or through the processing of appeals and MRO reviews, as well as any other errors or matters that could adversely reflect on the integrity of the testing process, investigation findings, and corrective actions taken, where applicable;
- 10 CFR 26.715(b)(9): Performance records on certification inspections;
- 10 CFR 26.715(b)(10): Records of preventative maintenance on LTF instruments;
- 10 CFR 26.715(b)(11): Records that summarize any test results that the MRO determined to be scientifically insufficient for further action;
- 10 CFR 26.715(b)(12): Printed or electronic copies of computer-generated data;
- 10 CFR 26.715(b)(13): Records that document the dates, times of entry and exit, escorts, and purposes of entry of authorized visitors, maintenance personnel, and service personnel who have accessed secured areas of LTFs and HHS labs; and,
- 10 CFR 26.715(b)(14): Records of the inspection, maintenance, and calibration of EBTs.

10 CFR 26.717 (a), (b), (b)(1) – (b)(9), (c) – (g) establish the FFD program performance data reporting requirements that each licensee or other entity must maintain and report to the NRC on an annual basis. Preparation of the annual FFD program performance report enables each

licensee and other entity to review site performance and address issues, if noted. FFD program performance reports provide the NRC with timely information on site-specific D&A testing program performance to assess compliance with regulatory requirements. The NRC also aggregates and evaluates FFD program performance data to identify adverse trends in substance use that may require regulatory action, additional NRC evaluation through inspection, or other oversight activities. NRC summarizes information from annual FFD program performance reports and publishes a publically available report that informs the public and regulated entities on performance trends. These site-specific annual reports also support NRC evaluation of FFD programs through inspection. The information provided in annual performance reports enables effective oversight of D&A testing programs to protect public health and safety.

- 10 CFR 26.717(a) requires licensees and other entities to collect and compile FFD program performance data.
- 10 CFR 26.717(b) describes the required data to be provided in each FFD program performance report:
 - o 10 CFR 26.717(b)(1): The random testing rate;
 - o 10 CFR 26.717(b)(2): Drugs tested for and cutoff levels, including results of tests using lower cutoff levels, tests for drugs not included in the HHS panel, and tests of dilute specimens tested at the LOD;
 - o 10 CFR 26.717(b)(3): Populations tested (i.e., individuals in applicant status, permanent licensee employees, C/Vs);
 - o 10 CFR 26.717(b)(4): Number of tests administered and results of those tests sorted by population tested (i.e., individuals in applicant status, permanent licensee employees, C/Vs);
 - o 10 CFR 26.717(b)(5): Conditions under which the tests were performed;
 - o 10 CFR 26.717(b)(6): Substances identified;
 - o 10 CFR 26.717(b)(7): Number of subversion attempts by type;
 - o 10 CFR 26.717(b)(8): Summary of management actions; and
 - o 10 CFR 26.717(b)(9): Information on fatigue management programs required under section 26.203(e)(1) and (e)(2).
- 10 CFR 26.717(c) requires any licensee or other entity who has a licensee-approved FFD program to analyze FFD program performance data at least annually and to retain records of the data, analyses, and corrective actions taken for at least 3 years or until the completion of any related legal proceedings, whichever is later.
- 10 CFR 26.717(d) requires that if a licensee or other entity terminates an individual's authorization or takes administrative action on the basis of initial drug testing positive

results for marijuana or cocaine at an LTF, it must report those test results in the annual FFD program performance report. Test results must be provided by processing stage (i.e., initial testing at the LTF, testing at the HHS lab, and MRO determinations), and include the number of terminations and administrative actions taken.

- 10 CFR 26.717(e) requires licensees and other entities to submit the FFD program performance data (for January through December) to the Commission annually, before March 1 of the following year.
- 10 CFR 26.717(f) permits licensees and other entities to submit FFD program performance data in a consolidated report, if the report presents the data separately for each site.
- 10 CFR 26.717(g) specifies that each C/V who maintains a licensee-approved D&A testing program is subject to the reporting requirements of section 26.717 and shall submit the required information either directly to the NRC or through the licensee(s) or entities to whom the C/V provided services during the year. Licensees, C/Vs, and other entities are required to share information to ensure that the information is reported completely and is not duplicated in reports submitted to the NRC.

10 CFR 26.719(a), (b), (b)(1) – (b)(4), (c)(1) – (c)(3), and (d) ensure that licensees and other entities subject to Part 26 to provide timely information on significant violations of FFD policy, testing errors, and other events affecting FFD program performance to the NRC. These reports ensure that licensees and other entities review and correct any problems in implementing FFD programs, and enables NRC action to assess these events prior to periodic inspections, and to take appropriate action, as needed, to protect public health and safety, and the common defense and security.

- 10 CFR 26.719(a) requires licensees and entities to inform the NRC of significant violations of the FFD policy, significant FFD program failures, and errors in D&A testing, and to report under section 26.719 rather than section 73.71.
- 10 CFR 26.719(b) requires licensees and other entities report the following 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:
 - o 10 CFR 26.719(b)(1): The use, sale, distribution, possession, or presence of illegal drugs, or the consumption or presence of alcohol within a protected area.
 - o 10 CFR 26.719(b)(2): Any act by a person licensed under 10 CFR Parts 52 to operate a nuclear power reactor, SSNM transporters, FFD program personnel, or supervisory personnel authorized under Part 26 if such acts: (i) involve the use, sale, or possession of a controlled substance; (ii) result in a determination that the individual has violated the licensee's or other entity's FFD policy; or (iii) involve the consumption of alcohol within a protected area or while performing required duties.

- o 10 CFR 26.719(b)(3): Any intentional act that casts doubt on the integrity of the FFD program; and,
 - o 10 CFR 26.719(b)(4): Any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals within a protected area, or by individuals assigned to perform duties that require them to be subject to the FFD program.
- 10 CFR 26.719(c)(1) requires that a licensee or other entity submit to the NRC a report within 30 days of completing an investigation of any LTF or HHS lab testing error or unsatisfactory performance issue. These performance issues could be discovered during performance testing, testing of specimens (quality control or donor), or through the reviews completed under sections 26.39 and 26.185, and can include any other errors or matters that could adversely reflect on the integrity of the random selection or testing process. The report is required to include a description of the incident and corrective actions taken or planned. If the error involves an HHS lab, the NRC shall ensure that HHS is notified of the finding.
 - 10 CFR 26.719(c)(2) requires that a licensee or other entity notify the NRC within 24 hours following discovery of a false positive error for the testing of a BPTS at an HHS-certified laboratory.
 - 10 CFR 26.719(c)(3) requires that a licensee or other entity notify the NRC within 24 hours following discovery of a false negative error on a QA check of validity screening tests required by section 26.137(b).
 - 10 CFR 26.719(d) requires that a licensee or other entity document, trend, and correct non-reportable indicators of FFD programmatic weaknesses under the licensee's or other entity's corrective action program, but prohibits the tracking or trending of D&A test results in a manner that permits the identification of any individuals.

10 CFR 26.821(a) requires licensees and other entities to permit NRC-authorized representatives to inspect, copy, or take away copies of its records and to inspect its premises, activities, and personnel as may be necessary to accomplish the purposes of Part 26. This requirement enables the NRC to obtain copies of documents for additional review and analysis at NRC offices. Copies of records enable the NRC to evaluate FFD program performance and to verify compliance with Part 26 requirements.

10 CFR 26.821(b) requires licensees and other entities to enter into written agreements with their C/Vs that permit duly authorized NRC representatives to inspect, copy, or take away copies of the C/V's documents, records, and reports related to implementation of the licensee's or other entity's FFD program under the scope of the contracted activities. This requirement is necessary because C/Vs may administer components of the licensee's or other entity's FFD program or may have its own FFD program pertaining to their employees who work under contract to licensees or other entities in situations in which they are subject to FFD requirements. This requirement is necessary to enable the NRC to obtain copies of documents for additional review and analysis at the offices of the NRC and for the development of a written record on topics involving Part 26. Such copies of records may be necessary to enable the NRC to evaluate the C/Vs' FFD programs and to obtain information necessary to develop public

policy. The recordkeeping requirement for section 26.821(b) is established by section 26.713(e).

This clearance also includes three PDF electronic reporting forms (i.e., fillable-fileable PDFs) approved by OMB under ICR No. 3150-0146 on November 13, 2014:

- NRC Form 890 – Single Positive Test Form
- NRC Form 891 – Annual Reporting Form for Drug and Alcohol Tests
- NRC Form 892 – Annual Fatigue Reporting Form

No changes have been made to the e-forms for this clearance extension. OMB approved a non-substantive change request for updates to NRC Forms 890 and 891, on December 29, 2016 (OMB ICR No. 201612-3150-005).

NRC Forms 890, 891 and 892 provide a voluntary means of reporting information required under sections 26.417(b)(2) and 26.717 for D&A testing programs and section 26.203(e) for fatigue management programs. As of the CY 2015 FFD program performance reporting cycle, all licensees and other entities use e-forms (over 90 percent used e-forms in 2013 and 2014). Full use of e-forms enabled more precise and robust data comparisons in this clearance on burden estimates. Advantages of using these fillable-fileable PDFs include:

- Adaptive form functionalities (e.g., fields appear, disappear, or auto-populate based on other form entries — these functions simplify the data reporting user experience)
- In form guidance (when the user holds the mouse over a form field a text box appears that contains the field name and associated guidance, as applicable)
- Built in validations that improve data quality and completeness (e.g., drop-down menu selections, check box fields, a “Validation & Lock” function that reviews form entries and identifies incomplete and inaccurate data entries in red highlighted color)
- Technology enhances data reporting and facilitates analysis by the NRC

The estimated burden to complete each form is based on the 2017-2020 clearance period.

- Blank fillable-fileable PDFs can be downloaded from the following NRC website: <http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/submit-ffd-reports.html>.
- Each fillable-fileable PDF submitted by a licensee or other entity to meet the annual FFD program performance reporting requirements in sections 26.417(b)(2), 26.717, and 26.203(e) can be viewed in the NRC’s Agencywide Documents Access and Management System which is available at the website: www.nrc.gov/reading-rm/adams.html. Reports can be located by searching for the property “Document Type: “License-Fitness for Duty (FFD) Performance Report).
- The NRC published a summary of D&A testing results for 2013 in the report titled “Summary of Fitness for Duty Program Performance Reports for Calendar Year 2013.” This report is available for download at: www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/performance-reports.html. The NRC has yet to publish

summary reports for calendar year 2014 and 2015 D&A test results, but data from these reporting years are included in the burden estimates in this clearance.

Guidance for Information Collections Contained in 10 CFR Part 26

NUREG/CR-7183 “Best Practices for Behavioral Observation Programs at Operating Power Reactors and Power Reactor Construction Sites” (ADAMS Accession No. ML14189A355). Identifies best practices associated with BOPs used by a cross section of Federal agencies and private entities. The document also discusses the need for effective BOPs at operating power reactors and power reactors under construction, and presents insights and recommendations on how to improve BOP performance.

Regulatory Guide 5.84, “Fitness-For-Duty Programs At New Reactor Construction Sites” (ADAMS Accession No. ML15083A412). Endorses the methods to develop an FFD program at new power reactor construction site as described in the industry guidance document Nuclear Energy Institute (NEI) 06-06, “Fitness-for-Duty Guidance for New Nuclear Power Plant Construction Sites” (ADAMS Accession No. ML15083A412). This guidance applies to licensees, applicants, and C/Vs who implement a reactor construction site D&A testing program.