DRAFT 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[1] 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 their 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.

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 (HHS labs)*. 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),

[1] Entities that must have a 10 CFR Part 26 FFD program include: (1) 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;" (2) holders of, and certain applicants for, a combined license for a nuclear power plant under the provisions of 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants;" (3) 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; and (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 Part 26.

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, and records on fitness determinations and 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):

- 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. All sites have been using fillable-fileable PDFs since the calendar year 2015 reporting cycle.

This clearance extension includes information collection and reporting requirements included in a “Fitness for Duty Drug Testing Requirements” final rule, which was preapproved by OMB on October 18, 2022, and published in the Federal Register on November 22, 2022 (87 FR 71422).

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 test results, 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 more precisely and transparently estimate the burden associated with each information collection, the burden of each activity generating 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 (e.g., CD-ROM, DVD), by facsimile or by e-mail. NRC staff estimates that approximately 99 percent of the potential responses are filed electronically.

Since 2015, all annual FFD program performance reports submitted by licensees and other entities to the NRC pursuant to 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. Only one type of report, required under 10 CFR 26.719(b) and 10 CFR 26.417(b)(1), cannot be submitted electronically to the NRC (i.e., the licensee or other entity must 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, "Laboratories Certified by the Department of Health and Human Services" of Part 26 are required to be maintained pursuant to the 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). An HHS-certified laboratory[2] maintaining the same records would meet the requirements of both programs. 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:

- 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.

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

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 each individual safety and competently perform their duties. 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 the 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 NRC Regional Administrator by telephone, followed by written notification (e.g., email or fax) to document the oral notification. If the NRC Regional Administrator cannot be reached, the licensee or other entity must notify the NRC Operations Center. This immediate notification is necessary to enable prompt NRC action to address this situation.

- 10 CFR 26.185(p) requires an MRO to complete the review of each drug positive, adulterated, substituted, and invalid test result, and if no legitimate medical explanation exists for the result, to notify the licensee or other entity's designated representative within 10 business days of receiving the HHS lab test result. This 10-business day notification 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 FFD program that may permit undetected drug or alcohol use or abuse by individuals subject to testing under Subpart K of Part 26. This 24-hour notification ensures that the NRC can take prompt regulatory action, 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 lab. 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 action 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 that utilizes an LTF to make a report to the NRC Operations Center by telephone within 24 hours of discovering a false negative testing error on a quality assurance check of validity screening tests, as required under section 26.137(b). A false negative test result is a significant programmatic error warranting immediate action by the licensee to ensure that the accuracy of LTF testing of specimens is consistent with the requirements of Part 26. Timely reporting ensures that the NRC can take immediate action, if necessary, when a licensee reports this testing error.

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 a confirmed 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 lab. If the donor wishes to request this additional testing, the request must be provided by oral or written means within 3 business days. This 3-business day requirement ensures that the specimen(s) are promptly processed and sent for retesting at a second HHS lab, which is a donor protection, and also ensures to the timely identification of any unsatisfactory performance of the initial HHS lab based on testing performed by the second HHS lab (section 26.719 reportability may also apply).

- 10 CFR 26.169(a) requires the HHS lab 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 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 lab 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 year end. This reporting timeframe is necessary because each licensee or other entity is required to submit annual FFD program performance information to the NRC within 2 months of the end of the previous calendar year, as required under section 26.717(e). Receipt of the HHS lab statistical summary in a timely manner is necessary to ensure that accurate information is included in the FFD program performance report.

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 and 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, certificate, or other regulatory approval. This retention requirement ensures to records availability for legal and 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 later. 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 determinations of fitness. 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. This retention requirement also ensures to records availability for legal and regulatory proceedings and affords due process to individuals subject to a D&A testing program.

- 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 each denial period is based on the regulatory significance of the violation. A 5-year denial of authorization is the minimum sanction for 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 the most severe sanction imposed on an individual and applies to attempts to subvert a required drug or alcohol test and a third confirmed positive drug or alcohol test result under Part 26. 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 denials 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 ensures that the NRC has access to records during inspection to evaluate regulatory compliance and ensures to the availability of records for legal and 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 records during inspection to evaluate regulatory compliance and ensures to the availability of records for legal and 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 lab) 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, if 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 3 years (consistent with OMB guidelines), or until the completion of any related legal proceedings (ensures records access to affected parties). This retention period ensures to records availability for NRC inspection, and for legal and regulatory proceedings.

8. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package has been published in the *Federal Register*.

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, Category I special nuclear material (SNM) licensees, and C/Vs; and third-party entities such as HHS labs. For example, staff attends periodically held Nuclear Energy Institute meetings and industry conferences. The NRC staff also consults with HHS and the U.S. Department of Transportation to ensure that the requirements in Part 26 are 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 and 26.411 require that each licensee or other entity that collects personal information about an individual for the purposes 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, 26.403, 26.413, 26.419, 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, N, and O (i.e., a D&A testing program) is based on the following 24 programs:

- operating nuclear power reactor sites (21 programs),[3]
- Category I SNM (2 programs) sites, and
- C/Vs (1 program).

The estimated burden hours and costs associated with administering reactor construction site D&A testing programs meeting the requirements under Subpart K of Part 26, is based on anticipated construction activities beginning at four small modular reactor (SMRs) construction sites in the final year of the clearance period.

- reactor construction sites (4 programs).

The estimated burden hours and costs associated with administering 21 fatigue management programs meeting the requirements under Subpart I of Part 26, is based on 53 operating nuclear power reactor sites. A licensee with multiple power reactor sites will maintain a single fatigue management program covering all its sites.

The estimated number of respondents per year for this clearance period is 64,392 and consists of 28 D&A testing programs (24 + 4 = 28 from above), 21 fatigue management programs, and 64,343 third-party respondents.[4]

Multiplying the total number of burden hours by $300 per hour results in the following estimates for the 2024–2027 clearance:

Table	Description	Burden Hours	Cost
1	One-Time Recordkeeping	2,192.0	$ 657,600
2	Annual Recordkeeping	167,554.1	$ 50,266,226
3	Annual Reporting	5,307.7	$ 1,590,200
4	Annual Third-Party Disclosure	365,003.0	$ 109,500,900
	TOTAL	**540,049.8**	**$ 162,014,926**

[3] This clearance period covers 94 operating nuclear power reactors located at 53 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 with multiple power reactor sites will maintain a single FFD program that covers all its sites. As a result, the number of FFD programs for operating nuclear power reactors is less than the number of sites.

[4] The NRC staff estimates 64,343 third-party respondents for this clearance period (i.e., 60,257 individuals subject to pre-access testing at D&A testing programs + 4,028 individuals subject to pre-access testing at reactor construction site D&A testing programs (only in the third year of this clearance period) + 9 HHS labs + 1 BPTS supplier + 24 EAPs + 24 non-licensee collection sites). The previous clearance reported 70,514 third-party respondents.

The estimated number of individuals subject to pre-access testing per year is the average number of pre-access tests performed from calendar year (CY) 2019 through CY 2021.

The $300 hourly rate used in the burden estimates is based on the NRC's fee for hourly rates as noted in 10 CFR 170.20 "Average cost per professional staff-hour." For more information on the hourly rate, see the "Revision of Fee Schedules, Fee Recovery for Fiscal Year 2023" final rule (88 FR 39120, June 15, 2023).

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. The records storage cost has been determined to be equal to 0.0004 times the recordkeeping burden cost. Therefore, the storage cost for the FFD records accounted for in Tables 1 and 2 of the current clearance is estimated to be $20,370 (0.0004 x 169,746 hours x $300 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 $300 per hour, the total estimated annualized cost to the Federal government is:

Table	Burden Area	Hours	Cost
5	NRC	1,213.1	$ 363,925

15. Reasons for Change in Burden or Cost

As summarized below, the total burden for Part 26 changed from 599,647.9 hours to 540,049.8 hours, a decrease of 59,598.2 hours. The responses decreased from 368,702.6 to 324,646.3, a decrease of 44,056.3 responses.

Table	Description	Clearance Period		Change in Burden Hours
		Previous ROCIS Total	Current Request	
1	One-Time Recordkeeping	466.7	2,192.0	1,725.3
2	Annual Recordkeeping	181,815.5	167,554.1	-14,261.4
3	Annual Reporting	5,409.7	5,300.7	-109.0
4	Annual Third-Party Disclosure	411,956.1	365,003.0	-46,953.1
	TOTAL	**599,647.9**	**540,049.8**	**-59,598.2**

Four reasons account for the changes to the total estimated burden from the previous clearance period.

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

The NRC anticipates that construction activities will commence at four SMR sites in 2027, the third year of this clearance period. Each SMR site is anticipated to be owned by a different licensee and therefore, each licensee will maintain one reactor construction site D&A testing program.

The NRC is estimating an increase in the burden associated with the new reactor construction site D&A testing programs for this clearance period as follows:

- One-time burden increase of 2,112 hours annually (Table 1), and
- Annual burden increase of 1,980 hours (Tables 2 – 4).

(2) Operating Nuclear Power Reactors

The NRC estimates that 94 nuclear power reactors located at 53 sites (i.e., a site has one or more power reactors) will operate for the duration of this clearance period.

The previous clearance included 90 operating nuclear power reactors at 51 sites. These previous clearance totals assumed that five operating nuclear power reactors at three sites would permanently cease operating and begin decommissioning in 2019, the first year of that clearance period (i.e., Byron Units 1 and 2; Dresden Units 2 and 3; Palisades[5]). However, the licensees for the Byron and Dresden nuclear power reactors decided to continue plant operations and these four reactors at two sites have been included in the current clearance. A decommissioning site is not subject to Part 26.

For D&A testing programs, even though the number of operating nuclear power reactors increased for this clearance, the annual burden estimates in Tables 2 – 4 decreased by 57,550 hours. The decrease in estimated annual burden is due to fewer individuals subject to a D&A testing program each year (e.g., fewer individuals applying for access, specimens collected and tested, initial and annual refresher trainings completed).

For fatigue management programs, the annual burden estimates in Tables 2 – 4 increased by 806 hours and is the result of the additional two power reactor sites included in this clearance period.

(3) D&A Testing Programs

For the current clearance period, the number of D&A testing programs for operating nuclear power reactor sites, Category I SNM sites, and C/Vs is estimated to remain the same as in the prior clearance period at 24 programs.

No changes to the number of D&A testing programs resulted from the Byron and Dresden reactor sites that were assumed to enter decommissioning under the previous clearance but subsequently continued operating because each site is part of a corporate fleet with multiple sites that continue to operate (i.e., Constellation). (4) Fatigue Management Programs (Part 26, Subpart I)

In the previous clearance period, the estimated burden for Part 26 activities included the submission and review of COVID-19 health emergency exemption requests. The COVID-19 public health emergency declaration ended on May 11, 2023. As a result, the annual burden associated with these fatigue management COVID-19 exemption requests has been eliminated from the current clearance period, which resulted in a decrease in estimated annual reporting burden in Table 3 of 80 hours. This submission requests the discontinuance of the COVID-19 related fatigue forms. The forms will be removed from the NRC website upon approval of this clearance.

[5] Palisades shutdown on May 20, 2022.

(5) Drug Testing Laboratories

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

Since the last clearance period, the three remaining sites that utilized LTFs have transitioned to only conducting drug testing at HHS labs. As a result, the number of sites using an LTF has decreased from 3 to 0. NRC staff knowledge of current industry practice does not suggest any change in the number of LTFs during the current clearance period.

The transition to only using HHS labs to conduct drug and validity testing of specimens has eliminated the estimated annual burden for licensees using LTFs as reflected in Table 2 from 3,339 hours to 0 hours. The burden incurred by the 3 licensee sites that transitioned from using LTFs to only conducting testing at HHS labs for these licensees is now solely captured by the applicable requirements in Table 2 for sites only using HHS labs for specimen testing.

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

Table 1, One-time Recordkeeping Burden (annualized)

The burden estimate total in Table 1 increased by approximately 370 percent (from 467 hours to 2,192 hours).

The majority of the change in estimated burden for this clearance period pertains to the information collections for four anticipated new reactor construction site D&A testing programs (i.e., developing FFD program policies and procedures).

Table 2, Annual Recordkeeping Burden

The burden estimate total in Table 2 decreased by approximately 8 percent (from 181,816 hours to 167,554 hours).

Changes resulted from the number of LTFs used for testing (decreased to 0), and the decrease in the number of activities conducted by D&A testing programs (e.g., fewer individuals applying for access, background checks performed, specimens collected and tested, MRO test result reviews).

Table 3, Annual Reporting Burden

The burden estimate total in Table 3 decreased by approximately 2 percent (from 5,410 hours to 5,301 hours).

Table 4, Annual Third-Party Burden

The burden estimate total in Table 4 decreased by approximately 11 percent (from 411,956 hours to 365,003 hours). The change in burden resulted from the decrease in the number of activities completed by individuals (e.g., fewer individuals applying for access, consent forms completed, specimens collected, initial and annual trainings completed) and HHS labs (fewer specimens tested).

Calculation of Some Burden Estimates in Table 2, Annual Recordkeeping Burden

The estimated burden for each annual recordkeeping requirement in Table 2 is calculated by multiplying the "Number of Recordkeepers" by the "Burden Hours per Recordkeeper." For some requirements in Table 2, the reported "Burden Hours per Recordkeeper" changes in each clearance. In these instances, while the burden per record is consistent (e.g., 2 minutes to print and retain a record detailing training completion and examination results), the number of records completed in a given year is variable (i.e., the number of individuals that complete training and an examination). To reflect the "Burden Hours per Recordkeeper" for the requirements with variability in the number of records retained, the burden per record is multiplied by the number records created annually (i.e., Total Annual Burden Hours), which is then divided by the "Number of Recordkeepers" to result in the "Burden Hours per Recordkeeper). When a calculation is performed in this manner, the "Notes" field associated with the requirement in the burden spreadsheet table includes information on the estimated burden per record, and the number of records estimated to be generated on an annual basis.

Calculation of Burden for NRC Form 891
The burden for the NRC Form 891, "Annual Reporting Form for Drug and Alcohol Tests" is estimated to be 110 hours annually for the upcoming clearance cycle. The burden for this form may change from one clearance period to the next, depending on the number of anticipated positive test results.Finally, the NRC's fee rate changed since the last clearance period, increasing from $279 to $300 per hour.

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.

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.

TOTAL PART 26 BURDEN: 540,049.8 hours (see table below)

TOTAL RESPONSES: 324,646 responses. This is equal to 254 total annual reporting responses from Table 3 + 49 recordkeepers (24 D&A testing programs + 4 reactor construction site D&A testing programs + 21 fatigue management programs) + 324,343 third-party responses from Table 4.

NUMBER OF RESPONDENTS: 64,392 respondents. This is equal to 24 D&A testing programs + 4 reactor construction site D&A testing programs + 21 fatigue management programs + 64,343 third-party respondents[6]).

THIRD-PARTY BURDEN: 365,003 hours (see table below)

Table	Description	Clearance Period		Change in Burden Hours
		Previous ROCIS Total	Current Request	
1	One-Time Recordkeeping	466.7	2,192.0	1,725.3
2	Annual Recordkeeping	181,815.5	167,554.1	-14,261.4
3	Annual Reporting	5,409.7	5,300.7	-109.0
4	Annual Third-Party Disclosure	411,956.1	365,003.0	-46,953.1
	TOTAL	**599,647.9**	**540,049.8**	**-59,598.2**

The estimated burden by Part 26 requirement for one-time and annual recordkeeping, annual reporting, annual third-party disclosures, and annual NRC burden is provided in a separate spreadsheet attachment to this supporting statement.

[6] The NRC estimates 64,343 third-party respondents for this clearance period (i.e., 60,257 individuals subject to pre-access testing at D&A testing programs + 4,028 individuals subject to pre-access testing at reactor construction site D&A testing programs (only in the third year of this clearance period) + 9 HHS labs + 1 BPTS supplier + 24 EAPs + 24 non-licensee collection sites). The previous clearance estimated 70,514 third-party respondents 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 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 by which a licensee or other entity communicates 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. 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 to the licensee or other entity. 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 they 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 for 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 through G, and N.

- Pre-access (to grant initial, updated, or reinstated authorization to an individual)

- 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)

- Post-event (after an event involving human error that may have caused or contributed to the event)

- Follow-up (as part of a follow-up plan to verify continued abstinence of substance abuse)

- 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). Section 26.713(g) establishes the recordkeeping requirements for section 26.31(d)(1)(i)(D).

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). Section 26.713(g) establishes the recordkeeping requirements for 26.31(d)(1)(ii).

- 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 April 30, 2008.

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 their 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 their 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 their assigned duties under 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 a 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, "Program Elements" 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. License 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 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. Section 26.713(a)(1) establishes the recordkeeping requirements for section 26.63(c)(3).

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 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) – (c).

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 requirements 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 for 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).

- 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 their 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. Section 26.713(a)(2) establishes the recordkeeping requirements for section 26.75(i) and (i)(3).

- 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. Section 26.713(a)(2) establishes the recordkeeping requirements for section 26.75(i)(4).

10 CFR 26.77(c) requires the 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, including when the observed behavior or physical condition is solely the result of fatigue, must immediately notify the appropriate NRC Regional Administrator by telephone, followed by written notification (e.g., email, fax) to document the oral notification, or, if the NRC Regional Administrator cannot be reached, to notify the NRC Operations Center. This requirement ensures that the NRC receives immediate so that the NRC can take action to remove the employee or contractor from duty and to take appropriate actions.

10 CFR 26.85(a) requires qualification collector training: on each specimen the collector is to collect under 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 Federal custody and control form (Federal CCF); methods to address problem collections; operation of the particular specimen collection or alcohol testing device(s); how to correct problems in collections; and the collector's responsibility for maintaining the integrity of the specimen collection 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. Each collector must receive qualification training and demonstrate proficiency to serve as a collection consistent with the requirements in Subpart E, "Collecting Specimens for Testing" of Part 26. Section 26.715(a) and (b)(1) establish the recordkeeping requirements for section 26.85(a).

10 CFR 26.85(b) 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(b).

10 CFR 26.85(d) 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. Section 26.715(a) and (b)(1) establishes the recordkeeping requirements for section 26.85(d).

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 Federal 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. Section 26.715(b)(2) establishes the recordkeeping requirements for section 26.87(f)(3) through (f)(5).

- 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 that will be used for a urine specimen collection, 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 observer on the Federal CCF.

- 10 CFR 26.87(f)(4) requires that after the collector has possession of the specimen, the collector must 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 for drug testing until the specimen is prepared for transfer, storage, or shipping, and to document the collector's custody of the specimen on the Federal 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 they 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 does not 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 program 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. Section 26.715(b)(12) establishes the recordkeeping requirements for records created by EBTs that meet the specifications of section 26.91(c)(1)-(3).

10 CFR 26.91(e)(4) requires, in part, that each licensee or other entity use a calibrated EBT to perform 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 questions about substances 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. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.93(a)(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. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.95(b)(5).

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. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.97(b)(2) and (c)(1).

- 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, for alcohol testing of oral fluids, to show the device and its reading to the donor, record the result, and record that an alcohol screening device (ASD) was used. This documentation requirement is a donor protection, supports FFD management action, if needed, and preserves records to enable internal audits, NRC inspection, and legal and regulatory 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 can be evaluated 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 a description of any donor conduct that indicates an attempt to tamper with a specimen, on the Federal CCF or through another documentation method consistent with the collection procedures of the licensee or other entity. Documentation of a collector's contemporaneous observations about a potential subversion attempt is critical information to provide to the MRO or FFD program manager to support a determination on whether a second collection is necessary under direct observation, is a donor protection, and preserves information to inform a possible subversion determination. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.107(b).

10 CFR 26.107(d) describes the actions that a specimen collector must take if a refusal to test is determined during the specimen collection process. The collector must: (1) inform the donor that a refusal to test has been determined; (2) document a description of the refusal to test on the Federal CCF or through another documentation method consistent with the collection procedures of the licensee or other entity; and (3) immediately inform the FFD program manager. These required actions improve the consistency and effectiveness of Part 26 by ensuring that uniform action is taken by a collector when a subversion attempt is identified during the specimen collection process. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.107(d).

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 Federal CCF or through another documentation method consistent with the collection procedures of the licensee or other entity. Documentation of a collector's contemporaneous observations about a potential subversion attempt is critical information to provide to the MRO or FFD program manager to support a determination on whether a second collection is necessary under direct observation, is a donor protection, and preserves information to inform a possible subversion determination. Section 26.715(b)(2) establishes the recordkeeping requirements for section 26.111(b).

10 CFR 26.111(c) requires the collector to contact the FFD program 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 MRO or FFD program manager is informed of contemporaneous information on a possible subversion attempt, serves as critical input to support appropriate management actions, and also is a donor protection. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.111(c).

10 CFR 26.113(b)(3) requires the collector to prepare a Federal 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. Section 26.715(b)(2) establishes the recordkeeping requirements for section 26.113(b)(3).

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 and because of the limited circumstances when a collection of this type is permitted. This determination must be documented. Section 26.715(a) establishes the recordkeeping requirements for section 26.115(b).

10 CFR 26.115(d) requires the collector to complete a new Federal 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 proper chain of custody is established for the collection of a separate specimen, that the testing laboratory, the MRO, and the licensee or other entity is informed of the specific circumstance(s)

warranting the collection of a specimen under direct observation, and ensures that a record of the testing event is maintained to enable review during internal audits, NRC inspection, and at legal or regulatory proceedings. Section 26.715(b)(2) establishes the recordkeeping requirements for section 26.115(d).

10 CFR 26.115(f)(4) requires, in instances when a same-gender collector is not available and an observer is chosen to watch a donor provide a specimen under direct observation, that the collector record the name of the observer on the Federal CCF. This requirement is a donor protection, enables internal licensee or other entity audits, NRC inspection of regulatory compliance, and preserves a record of the collection process in case of legal or regulatory proceedings. Section 26.715(b)(2) establishes the recordkeeping requirements for section 26.115(f)(4)

10 CFR 26.117(c) – (e), and (k) specify the documentation procedures to ensure chain of custody of a 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 Federal 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 Federal CCF and certify proper completion of each specimen collected.

- 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 detailing the physician's determination and the basis for it and to provide that statement to the MRO.

- 10 CFR 26.119(f) requires the physician, if it is determined 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. Section 26.715(a) and (b)(1) establish the recordkeeping requirements for section 26.125(b) and (c).

- 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 they hold, 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 Federal 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 Federal 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 Federal 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 confirmed positive drug test result or adulterated or substituted validity test result, to request that either Bottle B of a split specimen or an aliquot of a single specimen be tested at a second HHS lab under section 26.165(b). This requirement ensures that a record exists of the donor's approval for the MRO to direct the LTF to send the donor's specimen to a second HHS lab for testing, which is a donor protection and enables review during internal audits, NRC inspection, and at legal or regulatory proceedings. Section 26.715(b)(6) establishes the recordkeeping requirements for section 26.135(b).

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 QC 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. Section 26.715(b)(3) establishes the recordkeeping requirements for section 26.137(d)(6).

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 licensor 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 a specimen from being rejected for testing. Section 26.715(b)(2) establishes the recordkeeping requirements for section 26.153(g).

10 CFR 26.157(a) requires the HHS lab to develop, implement, and maintain procedures specific to Part 26 that document the accession, receipt, shipment, and testing of specimens. The creation and maintenance of these records enables the licensee or other entity to conduct audits under section 26.41(c) and the NRC to evaluate regulatory compliance through inspection. The preservation of these records also is a donor protection and ensures to the availability of records for legal and regulatory proceedings. Section 26.715(b) establishes the recordkeeping requirements for section 26.157(a).

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. Section 26.715(b)(3) establishes the recordkeeping requirements for section 26.159(b) and section 26.715(b)(2) establishes the recordkeeping requirements for section 26.159(c), (d), (e), (f), and (i). Section 26.719(b)(3) establishes the reporting requirements for section 26.159(b)(1).

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

- 10 CFR 26.159(c) requires HHS lab personnel to use laboratory internal chain of custody forms when conducting initial and confirmatory tests, and to retain the original Federal CCFs in secure storage.

- 10 CFR 26.159(d) requires the internal chain of custody form 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, the HHS lab personnel must document on the chain of custody form the date and purpose. Authorized technicians are required to sign and complete a chain of custody form for each specimen or aliquot they receive.

- 10 CFR 26.159(f) requires that, when transferring a specimen to a second HHS lab, a copy of the Federal 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 OR a specimen is collected under direct observation for any of the conditions specified in 10 CFR 26.115(a)(1) through (3) and (a)(5), AND the immunoassay response of any drug or drug metabolite test (i.e., the initial drug test) is equal to or greater than 40 percent of the cutoff, THEN the HHS lab must test the specimen for that drug or drug metabolite to the limit of quantitation(LOQ) for the confirmatory drug test assay. The laboratory shall report the numerical values (i.e., the quantitative test result) obtained from this special analysis to the MRO. This testing requirement enables the licensee or other entity to ensure that a donor is not attempting to subvert the testing process by consuming large amounts of fluid just before providing a urine specimen for testing to avoid detection of drug use by reducing the detectible amount of drug or drug metabolites below the testing cutoff level. Providing the numerical values for the test result is a donor protection and provides information to the MRO regarding the drug concentration detected in the donor's specimen. 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 at a second HHS lab for a confirmed positive drug test result or adulterated or substituted validity test result. If testing at a second HHS lab fails to confirm the test result reported by the initial HHS lab, the licensee or other entity must ensure that no records of the temporary administrative action taken as a result of the initial HHS lab result are retained. The incidence for testing at a second HHS lab failing to confirm the initial HHS lab test result is exceedingly rare. 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 HHS lab 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 they may, within 3 business days of notification by the MRO of the confirmed drug positive, adulterated, or substituted test result, request the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen to be performed at a second HHS lab. 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) specifies that no entity, other than the MRO as permitted in 10 CFR 26.185(I), may order the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen.

- 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 shall administratively withdraw an individual's authorization on the basis of a first confirmed positive, adulterated, or substituted test result until the results of testing Bottle B or retesting an aliquot of a single specimen are available and have been reviewed by the MRO. Section 26.165(f)(1) prohibits licensees and other entities from disclosing the temporary administrative action against an individual who's first confirmed positive drug or adulterated or substituted validity test result is not confirmed by the second HHS lab (in this case a cancelled test result would be reported by the MRO). In addition, the licensee or other entity may not disclose the temporary administrative action 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 licensee or other entity 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 report a cancelled test result and inform the licensee or other entity that another

collection is required under direct observation as soon as reasonably practical. The donor shall receive no notice of the collection requirement before they are instructed to proceed to the collection site. 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. Section 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. Section 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 QC 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 Responsible Person. 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(g) specifies that each licensee or other entity must use BPTSs that have been certified by the BPTS supplier to meet the various formulation criteria (e.g., drug positive, adulterated, dilute, substituted). The BPTS supplier will provide documentation to the licensee or other entity that demonstrates 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 Federal CCF, place fictional initials on the specimen bottles' labels/seals and indicate on the MRO's copy of the Federal CCF that the specimen is a BPTS.

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 contract between the licensee or other entity and their HHS lab under section 26.169 and 26.183(f) establish the recordkeeping and reporting requirements for the HHS lab. 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 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 Federal 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 Federal CCF and transmit to the MRO a copy of the original Federal 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 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 drug positive, adulterated, substituted, and invalid test results, as well the review of special analyses testing conducted under section 26.163(a)(2) for dilute specimens and specimens collected under any of the direct observation conditions specified in section 26.115(a)(1) through (3) and (a)(5). This examination includes reviewing records provided by the donor (e.g., prescription bottle information, dispensing pharmacy, prescribing physician, 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 Federal 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 exits 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 an 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(f)(3) requires the MRO to perform an additional review for specimens with an invalid test result due to a pH value in the range of 9.0 to 9.5. The MRO is to consider if elapsed time and/or high temperature might have caused the test result by evaluating specimen handling conditions. If the MRO obtains sufficient information from the licensee or other entity, collection site, LTF, or HHS lab that specimen handling conditions (from collection, receipt, transportation, or storage) could have resulted in the invalid test result, then the MRO would direct the licensee or other entity to collect a second urine specimen from the donor as soon as reasonably practicable. The second specimen would not be collected under direct observation, because sufficient evidence was obtained to conclude that donor action likely was not the cause of the invalid test result. The MRO would document information on the review of specimen handling conditions. Documenting the basis for collecting a second specimen under non-observed conditions ensures that a supportable basis exists for the decision, is a donor protection, and enables the licensee, other entity, and the NRC to evaluate regulatory compliance. Section 10 CFR 26.713(a)(2) establishes the recordkeeping requirements for 10 CFR 26.185(f)(3).

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 of when the donor provided the specimen for testing. 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 creditable medical evidence within 5 business days of when they provided the specimen for testing.

- 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, QC 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 complete the review of each drug positive, adulterated, substituted, and invalid test result, and if no legitimate medical explanation exists for the result, to notify the designated representative of the licensee or other entity within 10 business days of receiving the HHS lab test result.

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 they currently meet all credentials, knowledge, and training requirements as specified in 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 their 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 their 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 professional 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. Section 26.713(a)(4) establishes the recordkeeping requirements for section 26.189.

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 they are not fit to safely and competently perform their 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 they were 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. This section establishes the recordkeeping requirements for section 26.203(e) and the reporting requirements for section 26.203(e)(1) and (e)(2).

- 10 CFR 26.203(e) requires that the following information in a standard format in the annual FFD program performance report required under 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. Section 26.41(f) and (g) establish the recordkeeping and reporting and recordkeeping for section 26.203(f).

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 individual 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 individual 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. Section 26.203(d)(3) establishes the recordkeeping requirements for section 26.207

10 CFR 26.209 requires each individual subject to the rule to self-declare that they are unable to safely and competently perform their 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. Section 26.203(d)(5) establishes the recordkeeping requirements for section 26.211(f).

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. Section 26.203(d)(5) establishes the recordkeeping requirements for section 26.211(g).

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 QC 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 safely and competently perform their 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 testing 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 testing under Subpart K of Part 26. This 24-hour notification ensures that the NRC can take prompt regulatory action, if needed.

- 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 the licensees and other entities specified in section 26.3(a) and as applicable, section 26.3(c) and (d), shall inform each individual of their 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) requires the retention of records pertaining to licensees and other entities that maintain collection sites and/or LTFs, and for HHS labs that conduct testing for licensees and other entities under Part 26. These records enable licensees, other entities, and the NRC to evaluation compliance with Part 26 requirements. The retention of these records is a donor protection, enables licensees and other entities to review and correct problems in implementing FFD D&A testing programs, and ensures to the availability of records for legal and regulatory proceedings.

- 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 or LTF;

- 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 QC 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 publicly 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:

    - 10 CFR 26.717(b)(1): The random testing rate;

- 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;

- 10 CFR 26.717(b)(3): Populations tested (i.e., licensee or other entity employees, C/Vs);

- 10 CFR 26.717(b)(4): Number of tests administered, and the results of those tests sorted by population tested (i.e., licensee or other entity employees, C/Vs);

- 10 CFR 26.717(b)(5): Conditions under which the tests were performed;

- 10 CFR 26.717(b)(6): Substances identified;

- 10 CFR 26.717(b)(7): Number of subversion attempts by type;

- 10 CFR 26.717(b)(8): Summary of management actions; and

- 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(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.

- 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:

    - 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.

    - 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.

    - 10 CFR 26.719(b)(3): Any intentional act that casts doubt on the integrity of the FFD program; and

    - 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 of discovering of a false positive testing error on a BPTS tested by an HHS lab.

- 10 CFR 26.719(c)(3) requires that a licensee or other entity that utilizes an LTF for testing to notify the NRC within 24 hours of discovering 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 (e-forms) (i.e., fillable-fileable PDFs).

- 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

OMB approved NRC Forms 890 and 891 with its approval of the information collections in the 10 CFR Part 26 final rule published in the Federal Register on November 22, 2022 (87 FR 71422). OMB approved NRC Form 892 on September 29, 2021 (with the extension of Part 26 under ICR Reference No. 202103-3150-002).

No changes have been made to the e-forms for this clearance extension.

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. All licensees and other entities use e-forms, which 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 2024-2027 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.

NUREG/CR-7183 “Best Practices for Behavioral Observation Programs at Operating Power Reactors and Power Reactor Construction Sites” (available through the NRC’s Agencywide Document Access and Management System (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 (RG) 5.84, “Fitness-For-Duty Programs at New Reactor Constructions Sites,” July 2015 (ML15083A412). RG 5.84 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 Constructions Sites,” revision 6, April 2013 (ML13093A340). This guidance applies to licensees, applicants, and C/Vs who implement a reactor construction site D&A testing program.

RG 5.89, “Fitness-For-Duty Programs for Commercial Power Reactor and Category I Special Nuclear Material Licensees,” November 2022 (ML20143A034). This guidance describes methods that the NRC staff considers acceptable for complying with the urine specimen collection and test results review requirements in 10 CFR Part 26. The intent of this RG is to assist the licensees and other entities implementing 10 CFR Part 26 by describing processes and procedures that the NRC finds acceptable for the collection of urine specimens and test result reviews by the MRO. Specifically, the RG provides guidance on (1) the monitoring of a donor during the 3-hour hydration period, (2) the optional use of mirrors to assist in conducting observed collections, and (3) the conduct of an additional review by the MRO for urine specimens with invalid test results due to high pH values (in the range of 9.0 to 9.5).