

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

(OMB Clearance No. 3150-0146)

REVISION

DESCRIPTION OF THE INFORMATION COLLECTION

The U.S. Nuclear Regulatory Commission (NRC) regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 26 prescribes requirements for the establishment and maintenance of fitness-for-duty (FFD) programs for those licensees and other entities subject to the rule. These regulations are issued pursuant to the Atomic Energy Act of 1954, as amended, and Title II of the Energy Reorganization Act of 1974, as amended. Part 26 contains reporting and recordkeeping requirements that are necessary to provide, in part, reasonable assurance that persons subject to the rule are trustworthy, reliable, and not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, that in any way could adversely affect their ability to safely and competently perform their duties. These requirements also provide reasonable assurance that the effects of fatigue and degraded alertness on individual's abilities to safely and competently perform their duties are managed commensurate with maintaining public health and safety.

The Part 26 requirements apply, in whole or in part, to the following licensees and entities: (1) licensees authorized to operate a nuclear power reactor; (2) licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under 10 CFR Part 70; 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, if the entity engages in activities involving formula quantities of SSNM; (3) combined license applicants (10 CFR Part 52) who have been issued a limited work authorization (LWA, section 50.10(e)); combined license holders before the Commission has made the finding under of section 52.103(g)); construction permit applicants who have been issued a LWA (10 CFR 50.10) and construction permit holders (10 CFR Part 50); and, early site permit holders who have been issued an LWA, all under specific circumstances; and, (4) contractor/vendors (C/V) who implement FFD programs or program elements, to the extent that licensees and other entities rely upon those C/V FFD programs or program elements to meet the requirements of this part.

This clearance package includes recordkeeping and reporting requirements associated with the "Alternatives to Minimum Days Off Requirements" Final Rule, approved by U.S. Office of Management and Budget (OMB) by a nonsubstantive change request on April 10, 2012. Under the final rule, licensees and other entities subject to the requirements of Part 26, Subpart I, are required to state in their FFD policies and procedures which requirements they will comply with to mitigate cumulative fatigue of the applicable individuals at the nuclear power plant: the minimum days off requirements in section 26.205(d)(3) or the maximum average work hours requirements in section 26.205(d)(7). In addition, licensees that implement the maximum average work hours alternative (i.e., the 54-hours/week work control provision) must specify in their policies and procedures the work hour counting system they use.

This clearance also includes three electronic reporting forms (i.e., e-forms) that have been developed by the NRC, with input from the industry, to improve reporting efficiency:

- NRC Form 890, "Single Positive Test Form;"
- NRC Form 891, "Annual Reporting Form for Drug and Alcohol Tests;" and
- NRC Form 892, "Annual Fatigue Reporting Form."

This renewal represents the first submission of these forms to OMB. The e-forms facilitate consistency and accuracy through the use of a fill-in-the-blank format and drop-down menus. The forms provide a voluntary alternative means of reporting information required under 26.717 for drug and alcohol tests and 26.203(e) for fatigue and work hour controls. Licensees may still report this information in any format they choose; however, the forms provide a more efficient and standardized way of reporting should licensees choose to use them. The time to complete the forms is based on the estimates established for the associated requirements in the previous clearance package (2011-2014 clearance period).

## A. JUSTIFICATION

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

These information collections are necessary to enable effective and efficient regulatory oversight of affected licensee and other entities. Licensees and other entities must perform certain tasks, maintain records, and submit reports to comply with Part 26 drug and alcohol testing provisions and fatigue management requirements. These records and reports are necessary to enable regulatory inspection and evaluation of a licensee's or entity's compliance with NRC regulations, its FFD performance, and of any significant FFD-related events to help maintain public health and safety, promote the common defense and security, and protect the environment.

Part 26 recordkeeping and reporting requirements include provisions requiring licensees and other entities to develop and maintain policies and procedures; retain records of training, qualification, and authorization of individuals; retain records related to drug and alcohol specimen collections and tests; retain records related to specimen collection, testing, and review processes; report FFD program performance and significant violations, program failures, testing errors, and corrective actions; and, retain records related to audits, laboratories, and employee assistance programs. Records and reports are also required under the fatigue management component of the FFD program for evaluation of work schedules and actual hours worked, including minimum days off, licensee work hour reviews, waivers, self-declarations, and program requirements. Cross references to the recordkeeping and reporting requirements in Subpart N (e.g., sections 26.713, 26.715, 26.717, and 26.719) appear in other related portions of Part 26, but these cross references are not counted as an additional recordkeeping or reporting requirements. Therefore, the burden for recordkeeping and reporting is captured against the specific requirement rather than in the general sections to facilitate determining the burden impacts when a specific requirement is amended.

Part 26 recordkeeping and reporting requirements are mandatory for licensees and other entities subject to the rule. The NRC uses the reports to assess the effectiveness of FFD programs for those subject to the rule, determine whether the programs and its implementation are in compliance with regulations, and to take action to restore compliance, provide guidance, and implement rulemaking to enhance the Part 26 regulations when amendments are needed.

The reports also help improve regulatory efficiency, thereby reducing burden on affected licensees and entities, because NRC inspections can be more efficiently planned and conducted based on FFD performance at the sites and facilities subject to Part 26.

Section 26.4 requires training be provided to individuals to address the knowledge and abilities (KA) listed in section 26.29(a)(1) through (a)(10) who are subject to this part and who are also subject to a drug and alcohol testing program regulated by another Federal agency or State but who are not covered by these training elements of a Part 26 FFD program. Further, these State and Federal entities are required to ensure that the testing agency or organization notifies the licensee or other entity granting authorization of any FFD policy violation.

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 is necessary to ensure that licensees seeking exemptions from the requirements of Part 26 provide the information needed to enable the NRC to determine if the criteria for granting an exemption listed in section 50.12 or section 70.17 have been met.

10 CFR 26.27(a) requires each licensee or other entity subject to Part 26 to establish, implement, and maintain written policies and procedures designed to meet the section 26.23 performance objectives and specific requirements of Part 26. These performance objectives are: (a) provide reasonable assurance that individuals are trustworthy and reliable as demonstrated by the avoidance of substance abuse; (b) provide reasonable assurance that 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; (c) provide reasonable measures for the early detection of individuals who are not fit to perform the duties that require them to be subject to the FFD program; (d) provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs and alcohol; and, (e) provide reasonable assurance that 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. The written FFD policy and procedures are the primary means by which a licensee or other entity communicates its FFD policy and procedures to individuals who are subject to the policy and procedures. This requirement also ensures that the due process rights of individuals are protected by informing them in sufficient detail about licensee FFD rules, what is expected of them, and what consequences may result from a lack of adherence to the FFD policy.

10 CFR 26.27(b) requires the current FFD policy statement to be readily available to all individuals subject to the policy and specifies the minimum mandatory contents of the written policy statement, which include a description of the consequences of prohibited actions, reporting for testing requirements, alcohol abstinence requirements, the factors that could affect FFD, employee assistance programs, and responsibilities to report FFD violations or concerns. This requirement ensures that the FFD policy is included and maintained in the licensee's compendium of policies, where it can be reviewed by any individual who is subject to the FFD program.

10 CFR 26.27(c) requires each licensee or other entity to prepare, implement, and maintain written procedures that describe the methods to be used in implementing the FFD policy and requirements of Part 26. This requirement is necessary to ensure that individuals who manage and implement the FFD program and individuals subject to that FFD program are provided

specific detailed information about how testing for the use of drugs and alcohol are conducted, including the cutoff levels used in drug and alcohol testing and the time periods within which an individual who has been selected for random testing must report to the collection site; how and why behavioral observation is conducted; and how authorization is granted, maintained, reinstated, and withdrawn. This requirement also contributes to the protection of due process rights for individuals, who are subject to Part 26, provides for prior notice, and ensures documentation for evidence in legal proceedings.

10 CFR 26.27(d) specifies that the NRC may at any time review the written policy and procedures to ensure that they meet the performance objectives and requirements of Part 26. This requirement is necessary to ensure that the NRC can carry out timely evaluations of whether the policies or procedures of particular licensees or other entities fail to include necessary FFD program elements or include elements that are not consistent with the requirements of an effective FFD program.

Recordkeeping requirements for current policies and procedures under section 26.27(b), (c), and (d) are established by that section. Recordkeeping requirements for superseded procedures are established by section 26.715(b)(4).

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 training program must be maintained to meet Part 26 requirements. This requirement provides assurance that persons are adequately trained in KAs necessary to meet the section 26.23 performance objectives.

10 CFR 26.29(b) requires that all individuals subject to Part 26 demonstrate successful completion of training by passing a comprehensive examination about the KAs specified in section 26.29(a)(1) through (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)(1) requires training for all personnel to be completed before authorization (section 26.5) may be granted to an affected individual by a licensee or other entity. This is required to provide assurance that persons who have unescorted access to the protected area of the facility are trust worthy and reliable as demonstrated by their knowledge and adherence to Part 26 requirements.

10 CFR 26.29(c)(2) requires refresher training to be completed on a nominal 12-month frequency, and allows individuals who pass a comprehensive annual examination to forgo refresher training. This includes refresher training, training for new staff who are hired after the initial training, administration of the comprehensive annual examination, keeping FFD training updated, maintaining a question bank, and developing examinations to be given to new staff and to existing staff as an alternative to refresher training, is also accounted for under this section. This is required to provide assurance that persons who have unescorted access to the protected area of the facility are trust worthy and reliable 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 training of individuals who have been subject to another training program that meets the requirements of this section and who

have, within the previous 12 months, either had initial or refresher training or have successfully passed a comprehensive examination specified in section 26.29(b). The requirement is required because it reduces burden on licensees by enabling a receiving licensee to accept the Part 26 training provided to an individual by another licensee or entity who is subject to Part 26.

The above five recordkeeping requirements are established by section 26.713(b)(1).

10 CFR 26.31(a) requires licensees and other entities to implement drug and alcohol testing programs for individuals who are subject to Subpart B. The reporting and recordkeeping requirements associated with the drug and alcohol testing programs are described under subsequent subparts of Part 26, including Subparts E, F, G, H, and N.

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 conducted under a nuclear power plant's access authorization program (implemented pursuant to 10 CFR Part 73) are acceptable to meet the requirement. Paragraph 26.31(b)(1)(i) requires the credit and criminal history checks and psychological assessments to be updated nominally every 5 years. These recurring checks are required to demonstrate that persons who are subject to the rule are trustworthy and reliable and necessary for a licensee's determination whether to grant unescorted access to the protected area of its facility. Affected individuals must provide this information to a licensee or other entity subject to Part 26 so that a background investigation can be performed.

10 CFR 26.31(b)(1)(v) requires FFD program personnel to be subject to a behavioral observation program (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.

The above two requirements are necessary to ensure the honesty and integrity of persons who directly administer the FFD program. Assuring their FFD is important because the FFD program helps establish whether persons should maintain or be granted unescorted access to the protected areas at nuclear power plants or be allowed to possess, use, or transport formula quantities of SSNM. The written procedures for the BOP are part of the FFD program procedures required to be developed by section 26.27. Recordkeeping requirements for section 26.31(b)(1)(i) are established by section 26.713(f).

10 CFR 26.31(c) requires licensees and other entities to implement drug and alcohol testing programs that administer tests under the following conditions:

- (1) Pre-access. In order to grant initial, updated, or reinstated authorization to an individual.
- (2) For cause. In response to an individual's observed behavior or physical condition indicating possible substance abuse or after receiving credible information that an individual is engaging in substance abuse as defined in section 26.5.

(3) Post-event. The licensee takes action as soon as practical after an event involving a human error that was committed by an individual who is subject to Part 26, where the human error may have caused or contributed to the event.;

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

(5) Random. On a statistically random and unannounced basis such that all individuals in the population subject to testing have an equal probability of being selected and tested.

No records are required by this section. Records of the drug and alcohol testing programs are required in Part 26, Subparts C, D, E, F, G, and N.

10 CFR 26.31(d)(1)(i)(A), (B) and (C) allows licensees and other entities to add other drugs to the panel of substances for testing, but only if the additional drugs are listed in Schedules I-V of section 202 of the Controlled Substances Act [21 U.S.C. 812]; the licensee or other entity establishes appropriate cutoff limits for these substances; and the licensee or other entity establishes rigorous testing procedures for these substances, so that the MRO can evaluate the use of these substances. This requirement is necessary to ensure that adequate procedures are established for the testing of additional drugs. Those procedures are additions to the FFD procedures required to be developed under section 26.27.

10 CFR 26.31(d)(1)(i)(D) allows licensees and other entities to conduct an analysis 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 is necessary to ensure that the NRC can verify that the assays and cutoff levels are appropriate. The licensee or other entity is required to maintain a copy of each certification under section 26.31(d)(1)(i)(D). Recordkeeping requirements for section 26.31(d)(1)(i)(D) are established by section 26.713(g).

10 CFR 26.31(d)(1)(ii) allows licensees and other entities that are conducting post-event, follow-up, or for cause testing to test for drugs listed on Schedules I-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 or metabolites 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.

The above two requirements allow licensees and other entities to add to the panel of drugs for which testing is required in section 26.31(d)(1). This ensures that the NRC can verify that the assays and cutoff levels used in testing for the additional drugs are scientifically sound and legally defensible by requiring an independent forensic toxicologist to perform this evaluation and so certify in writing. The licensee or other entity is required to maintain a copy of each certification under section 26.31(d)(1)(ii). Recordkeeping requirements for section 26.31(d)(1)(ii) are established by section 26.713(g).

10 CFR 26.31(d)(3)(ii) provides that licensees and other entities may conduct validity screening and initial validity and drug tests of urine aliquots to determine which specimens are valid and negative and need no further testing, provided that the licensee's or other entity's staff possesses the necessary training and skills for the tasks assigned, the staff's qualifications are documented, and adequate quality controls for testing are implemented. This requirement is necessary to ensure that validity screening and initial validity and drug tests of urine aliquots are performed correctly. Documentation of the qualifications of the personnel of Licensee Testing Facilities (LTFs) and quality controls for testing are addressed under Subpart F, LTFs, sections 26.125, 26.127, 26.129, and 26.137.

10 CFR 26.31(d)(3)(iii)(A) requires a licensee or other entity that uses more stringent cutoff levels than the cutoff levels specified in section 26.163 to document the cutoff levels in any written policies and procedures in which cutoff levels for drug testing are described.

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

The above two requirements are necessary to 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 individuals subject to the FFD program through the written FFD program policies developed pursuant to section 26.27. Recordkeeping requirements for FFD policy and procedures are described under section 26.27. The licensee or other entity is required to maintain a copy of each certification under section 26.31(d)(3)(iii)(C). Recordkeeping requirements for section 26.31(d)(3)(iii)(A) and (C) are established by section 26.713(g).

10 CFR 26.31(d)(6) specifies that specimens collected under NRC regulations may only be designated or approved for testing as described in Part 26 and may not be used to conduct another analysis or test without the written permission of the donor. This requirement is necessary to ensure that specimens are not used for such testing as DNA testing, serological typing, or other forms of genetic or medical tests for diagnostic or specimen identification purposes without the express written permission of the donor. Recordkeeping requirements under section 26.31(d)(6) are established by this section.

Section 26.33 requires all individuals who are subject to Part 26 to report FFD concerns about other individuals subject to this part to the entity designated in the FFD policy. This section is necessary to increase the likelihood that if impairment from drugs, alcohol, fatigue or other

adverse behaviors are detected they will be brought to the attention of the licensees or other entities who are subject to the rule so that they can be appropriately addressed. This helps ensure that persons who are performing duties covered by Part 26 requirements are FFD, trustworthy, reliable, and can perform their duties safely and competently. The burden for reports of FFD concerns is covered under this section. Actions in response to reports of FFD concerns are taken under section 26.31(c)(2), which provides that licensees and other entities shall administer drug and alcohol tests for cause, in response to any observed behavior indicating possible substance abuse or after receiving credible information that an individual is abusing drugs or alcohol, and under section 26.211(a)(1), which provides for fatigue assessments in response to an observed condition of impaired alertness creating a reasonable suspicion that an individual is not fit to safely and competently perform his or her duties. Records of reports received pursuant to section 26.33 are maintained as part of for-cause testing records under sections 26.31 or 26.211. Recordkeeping requirements, including the burden for the initial behavioral observation reports, for section 26.33 are established by sections 26.203(d)(5) or 26.713(a)(2).

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 is necessary to define the scope and activities of the EAP and to provide assurance that person receive adequate treatment for conditions that could result in conditions adverse to safety. The written description of the EAP program forms part of the FFD program policy and procedures to be developed pursuant to section 26.27. The burden for the EAP program procedures is covered under this section.

10 CFR 26.35(c) requires, in part, the EAP staff to protect the privacy of any individual (including those who have self-referred) seeking assistance from the EAP, except if the individual waives the right to privacy in writing or 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 have problems that could adversely affect their ability to safely and competently perform assigned duties. This requirement is necessary to ensure confidentiality for individuals who seek EAP services, thus encouraging use of the EAP; except if the individual waives the right to privacy in writing or if EAP personnel determine that the individual poses or has posed an immediate hazard to him or herself or others. The requirement that the individual waive the right to privacy in writing is necessary to ensure that there is a clear record of the waiver in case of a legal proceeding. The requirement that the EAP staff informs the FFD program management, if the EAP personnel determine that the individual, in part, 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.

Recordkeeping requirements for section 26.35(a) policy and procedures are established by this section and by section 26.27(a). Recordkeeping requirements for section 26.35(c) collections for the written waiver by the individual and the communications between the EAP and FFD program management are established by this section.

10 CFR 26.37(a) requires each licensee or other entity subject to Part 26 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 that authorizes the disclosure of personal information to persons other than the subject or his or her representative, assigned MROs and MRO staff, NRC representatives, appropriate law enforcement officials under court order, licensee or other entity personnel who have a need to have access to the information to perform their assigned duties under the FFD program, the presiding officer in judicial or administrative proceedings initiated by the individual, persons deciding under review in section 26.39, and other persons pursuant to court order.

10 CFR 26.37(b)(1) requires an individual to designate in writing his or her representative for specified FFD matters. This collection is required if an individual desires representation by a union official, attorney, or other person with a need to review personal information about the individual.

10 CFR 26.37(c) requires disclosure to other licensees or entities who are legitimately seeking the information as required by Part 26 for authorization decisions and who have obtained a signed release from the subject individual.

10 CFR 26.37(d) requires the FFD program, including the collection site, HHS-certified laboratory, Substance Abuse Expert (SAE), or MRO, upon receipt of a written request by the subject individual or his or her designated representative, to promptly provide copies of all FFD records pertaining to the individual, including but not limited to records pertaining to a determination that the individual has violated the FFD policy, drug and alcohol test results, MRO reviews, determinations of fitness, and management actions pertaining to the subject individual. This paragraph also requires the licensee or other entity to obtain records related to the results of any relevant laboratory certification, review, or revocation-of-certification proceeding from the HHS-certified laboratory and provide them to the subject individual or his or her designated representative upon request.

The above five collection requirements are necessary to ensure the protection of personal information collected and maintained about individuals, and to ensure that such information is not disclosed to persons other than assigned MROs, other licensees legitimately seeking the information as required by Part 26 for employment decisions and who have obtained a release from current or prospective employees or C/V personnel, NRC representatives, appropriate law enforcement officials, the individual subject or his or her representative, or those licensee personnel who have a need to have access to the information in performing assigned duties. Recordkeeping requirements for section 26.37(c) and (d) are established in this section and those for section 26.37(b) are established by section 26.713(a)(3).

10 CFR 26.39(a) requires each licensee and other entity subject to Subpart B to establish procedures for the review of a determination that an individual has violated 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.

The above two requirements are necessary to ensure that there are written procedures that specify how each FFD program ensures that the criteria for determining that an individual has violated FFD policy have been met and provides individuals with a specified process for reviewing and appealing determinations that the individual has violated FFD policy. The requirements are necessary to ensure that the due process rights of individuals who are subject to the rule are protected by informing them with sufficient detail about licensee review procedures, what is expected of the individual, and what consequences may result from a lack of adherence to the policy. The requirements also partially meet the legal necessity of proving “prior notice” and having it documented for evidence in legal proceedings. Recordkeeping requirements for section 26.39(a) and (b) are established by section 26.715(a).

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 reflect the outcome of the review and delete or correct all information found to be inaccurate.

This collection requirement is necessary to ensure that the records of licensees and other entities do not contain incorrect information concerning FFD determinations pertaining to particular individuals. This requirement helps to ensure that incorrect information does not enter and proliferate throughout this information-sharing network. Recordkeeping requirements for section 26.39(d) are established by section 26.713(a)(2).

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 its FFD policy, the C/V shall ensure that the review procedure required by section 26.39 is provided to the individual. This requirement is necessary to ensure that individuals subject to the rule receive sufficient information about licensee review procedures, the responsibility of each individual under the policy, and the consequences of not adhering to the policy. The requirement also partially meets the legal necessity of proving prior notice and having the notice documented for evidence in legal proceedings. Recordkeeping requirements for section 26.39(e) are established by section 26.713(a)(2).

10 CFR 26.41(a) requires licensees and other entities to ensure that the FFD program elements provided by C/Vs, the FFD programs of any C/Vs that are accepted by the licensee or other entity, any FFD program services that are provided to the C/V by a subcontractor, and the programs of the HHS-certified laboratories upon whom the licensee or other entity and its C/Vs rely is audited and corrective actions are taken to resolve any problems identified.

10 CFR 26.41(b) requires licensees and other entities to ensure that the entire FFD program is audited as needed, and at least on a nominal 24-month frequency.

10 CFR 26.41(c)(1) requires licensees and other entities to ensure that FFD services that are 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-certified laboratories, are audited on a nominal 12-month frequency.

The burden for documenting audit records is accounted for under section 26.41(f).

10 CFR 26.41(d) requires contracts by licensees or other entities with C/Vs and HHS-certified laboratories to reserve the right of licensees to review all information and documentation that is reasonably relevant to audits of FFD program elements provided by C/Vs, the program elements of any C/Vs that are accepted by the licensee or other entity, and the programs of HHS-certified laboratories, and to obtain copies of and take away any documents and any other data that may be needed to assure that the C/V, its subcontractors, or the HHS-certified laboratory are performing their functions properly.

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.

These above requirements for audit documentation, maintenance of audit records, and access to audit information are necessary to help ensure identification and resolution of program weaknesses and to help licensees and other entities, including C/Vs and HHS-certified laboratories, determine what corrective actions are necessary and carry out necessary corrective actions. The requirements help to ensure that necessary information is available for NRC inspections. Requirements for obtaining copies of audit records under section 26.41(d) and distribution of audit records and reports to management under section 26.41(f) and (g) are established in these sections. Recordkeeping requirements for retention of audit records in section 26.41(f) and (g) are established by section 26.713(b)(2).

10 CFR 26.53(d) requires the FFD program of a licensee or other entity that is seeking to grant authorization to an individual who is maintaining authorization under another FFD program to ensure that the program elements to which the individual is subject under the transferring FFD program remain current. This section requires communications between the two FFD programs to ensure that the necessary information is transferred between them concerning the individual.

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) 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.

The above two requirements for the contents of the self-disclosure and employment history (i.e., suitable inquiry) are established by section 26.61. These requirements are necessary to help provide reasonable assurance that any individual who has never previously held authorization or whose authorization has been interrupted for a period of three years or more is trustworthy, reliable, and fit for duty, as demonstrated by avoiding substance abuse, as well as aspects of the individual's character and reputation other than substance abuse covered by the self-disclosure and suitable inquiry. Recordkeeping requirements for section 26.55(a)(1) and (a)(2) are established by sections 26.61 and 26.63 and by section 26.713(a)(1) and (3).

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.

The above two requirements are necessary to help provide reasonable assurance that any individual whose authorization has been interrupted for more than 365 days but less than 3 years and whose last period of authorization was terminated favorably who is granted reauthorization is trustworthy, reliable, and fit for duty, as demonstrated by avoiding substance abuse, as well as aspects of the individual's character and reputation other than

substance abuse covered by the self-disclosure and suitable inquiry. Recordkeeping requirements for section 25.57(a)(1) and (2) are established by sections 26.61 and 26.63 and by section 26.713(a)(1) and (3).

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 whose authorization has been interrupted for a period of more than 30 days but no more than 365 days and whose last period of authorization was terminated favorably before granting authorization to the individual.

10 CFR 26.59(a)(2) requires, in part, the licensee or other entity to complete a suitable inquiry for an individual whose authorization has been interrupted for a period of more than 30 days but no more than 365 days and whose last period of authorization was terminated favorably within 5 business days of reinstating authorization. These requirements are necessary to help provide reasonable assurance that any individual whose authorization has been interrupted for more than 30 days but no more than 365 days and whose last period of authorization was terminated favorably who is granted authorization reinstatement is trustworthy, reliable, and fit for duty, as demonstrated by avoiding substance abuse, as well as aspects of the individual's character and reputation other than substance abuse covered by the self-disclosure and suitable inquiry.

10 CFR 26.59(b) provides that if a licensee or other entity administratively withdraws an individual's authorization, and until the suitable inquiry is completed, the licensee or other entity may not record the administrative action to withdraw authorization as an unfavorable termination and may not disclose it in response to a suitable inquiry conducted under the provisions of section 26.63, a background investigation conducted under the provisions of this chapter, or any other inquiry or investigation. This requirement is necessary to ensure that information about an administrative withdrawal of authorization that is subsequently reversed does not become disseminated to licensees or other entities.

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. This requirement is necessary to help provide reasonable assurance that any individual whose authorization has been interrupted for no more than 30 days and whose last period of authorization was terminated favorably who is granted authorization reinstatement is trustworthy, reliable, and fit for duty, as demonstrated by avoiding substance abuse, as well as aspects of the individual's character and reputation other than substance abuse covered by the self-disclosure. Because the authorization has been interrupted for a period of no more than 30 days, no suitable inquiry is required.

Recordkeeping requirements for section 26.59(a)(1) and (2), including records of administrative withdrawal of authorization and subsequent termination of the withdrawal of authorization or unfavorable termination of authorization under section 26.59(b), are captured by sections 26.61 and 26.63 and by section 26.713(a)(1) and (3). Recordkeeping requirements for section 26.59(c)(1) are established by section 26.61 and by section 26.713(a)(1) and (3).

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 in specified circumstances.

10 CFR 26.61(a)(1) specifies that if the individual previously held authorization under Part 26, the licensee or other entity must verify that the individual's last period of authorization was terminated favorably, and that the individual has been subject to a behavioral observation and arrest-reporting program throughout the period since the individual's last authorization; if so, the licensee or other entity need not obtain the self-disclosure or employment history in order to grant authorization.

10 CFR 26.61(a)(2) specifies that if the individual's last period of authorization was terminated favorably within the past 30 days, the licensee or other entity need not obtain the employment history.

The above three requirements require, in part, submission of self-disclosures and employment histories by individuals seeking authorization. FFD programs require individuals to sign a statement at the conclusion of the self-disclosure statement and employment history that the information provided by the individual is, as far as they are aware, correct, and the burden for the self-disclosures, employment histories, and signed certification is included here. These paragraphs relax the requirements in sections 26.55, 26.57, and 26.59 when the specified conditions above indicate that the self-disclosure and/or employment history are unnecessary and reduce the number of situations in which a licensee or other entity must obtain and review the documents from those otherwise required by sections 26.55, 26.57, and 26.59. Verification that the last previous period of authorization was terminated favorably and that the licensee was subject to a BOP and arrest-reporting program is obtained from the nuclear reactor industry's Personnel Access Data System (PADS) to which industry representatives provide information concerning individuals who have had, have, or desire authorization (i.e., unescorted access) to enter the protected areas at nuclear power plants. Recordkeeping requirements for section 26.61(a) are established by section 26.713(a)(1).

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.

The above two requirements are necessary to ensure that the written self-disclosure and employment history are sufficiently complete and comprehensive to allow licensees and other entities to rely upon them for determinations concerning the trustworthiness, reliability, and fitness for duty of individuals, as demonstrated by avoiding substance abuse. They do not establish any information collection requirements in addition to those included in section 26.61(a), but they do specify the types of information that must be included in the self-disclosure and employment history required by section 26.61(a). These paragraphs specify the information to be reported or recorded in support of authorization determinations under sections 26.55, 26.57, and 26.59.

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) specifies that to meet the suitable inquiry requirement, licensees and other entities may rely upon the information that other licensees and entities who are subject to Subpart C have gathered for previous periods of authorization and specifies the information to be included, e.g., reasons for termination, eligibility for rehire, and other information that could reflect on the individual's fitness to be granted authorization.

10 CFR 26.63(c)(2) specifies that if a claimed period of employment was military service, the licensee or other entity may accept a copy of the DD 214 presented by the individual or provided by the custodian of military records.

The above three requirements specify the information to be reported or recorded in support of authorization determinations under sections 26.55, 26.57, and 26.59. In addition, they specify limitations on the scope of the reporting and recordkeeping necessary in support of the authorization determinations under sections 26.55, 26.57, and 26.59. 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 requirement. Paragraph 26.63(c)(2) creates an exception to the requirement for an employment history by allowing submission of an already existing record of military service. Recordkeeping requirements for section 26.63(a) and (c)(2) are established by section 26.713(a)(1).

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 is necessary to ensure that a record is created explaining gaps and absences in the information otherwise required by sections 26.55, 26.57, and 26.59, so that an individual is not charged with responsibility for such gaps and denied authorization on that basis. This requirement also helps to ensure that licensees and other entities can grant authorization, even if the information requested but not received from another company, previous employer, or educational institution, is not available. Recordkeeping requirements for section 26.63(c)(3) are established by section 26.713(a)(1).

10 CFR 26.63(d) requires, if a licensee or other entity presents to another licensee or other entity an individual's signed release authorizing the disclosure of information, that other licensee or entity shall disclose whether the individual's authorization was denied or terminated unfavorably as a result of a violation of an FFD policy and the information upon which the denial or unfavorable termination of authorization was based and any other information that is relevant to an authorization decision. This requirement is necessary to ensure 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. The individual signs a release when first applying for authorization and the release is placed in the licensee's record of the suitable inquiry. The owners and operators of nuclear power reactors have established and maintain a private system of

information known as PADS that contains data on personnel. Each participant is contractually obligated to supply updated information to PADS concerning individual authorizations, employment, and FFD violations.

10 CFR 26.63(e) specifies that in conducting a suitable inquiry, the licensee or other entity may obtain information and documents by electronic means, including but not limited to telephone, facsimile, or email. The licensee or other entity shall make a record of the contents of the telephone call and shall retain that record and any documents or electronic files obtained electronically. This requirement is necessary in light of the use of PADS and other electronic means of information transfer by licensees and other entities to ensure that a record is made and retained of the information secured by electronic means.

Recordkeeping requirements for section 26.63(d) and (e) are specified by sections 26.711 and 26.713(a), (b), and (c).

10 CFR 26.63(f) specifies the time periods that a suitable inquiry must cover for initial authorization, authorization update, and authorization reinstatement after an interruption of more than 30 days. While section 26.63(f) does not require information collection, it does affect the burden attributable to section 26.63. An average burden has been used for those estimates.

10 CFR 26.65(d)(1) and (e)(2) provides 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.

10 CFR 26.65(d)(1)(ii) and (e)(2)(iii)(B) further provide that unless the licensee or other entity verifies that the drug test results are negative within 5 business days of specimen collection, it must administratively withdraw authorization until the drug test results are received.

The above three requirements clarify the required testing where an individual's authorization is terminated less than a year, or less than 30 days. The paragraphs assure that an individual with reinstated authorization maintains the FFD requirements. Recordkeeping responsibilities for sections 26.65(d)(1) and 26.65(e)(2) are established by section 26.713(a)(3).

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 is necessary to 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. Recordkeeping requirements for section 26.65(f) are specified by section 26.713(a)(2).

10 CFR 26.67(a) specifies that when the licensee or other entity collects specimens from an individual for any pre-access testing that may be required under sections 26.65 or 26.69, the

licensee or other entity shall subject the individual to random testing under section 26.31(d)(2), except if the licensee or other entity does not grant authorization to the individual or the licensee or other entity relies on drug and alcohol tests that were conducted before the individual applied for authorization.

10 CFR 26.67(b) provides that if an individual is selected for one or more random tests after a requirement for pre-access testing under sections 26.65 or 26.69 has been met, 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 it has been granted, or grant authorization to the individual under section 26.69.

The above three collections involve notice to the individual regarding the status of their authorization (granted or not granted) and placement of information in PADS concerning the individual. Recordkeeping requirements for section 26.67 are specified by section 26.713(a)(2).

10 CFR 26.69(b) specifies that for an individual seeking authorization after a first confirmed positive drug or alcohol test result or a 5-year denial of authorization, a licensee or other entity must obtain and review a self-disclosure and employment history and complete a suitable inquiry with every employer by whom the individual claims to have been employed during the period addressed in the self-disclosure and must obtain and review any records that other licensees or entities who are subject to Part 26 may have developed related to the 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 shortest of the following periods: the past five years, since the individual's eighteenth 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 by whom the individual claims to have been employed during the period addressed in the employment history. If the individual held authorization within the past 5 years, the licensee or other entity must obtain and review any records that other licensees or entities who are subject to Part 26 may have developed with regard to potentially disqualifying FFD information about the individual within the past 5 years.

10 CFR 26.69(c)(3) requires, where potentially disqualifying FFD information is discovered that is not a first confirmed positive drug or alcohol test nor a 5-year denial of authorization, that the licensee verify that a professional qualified under section 26.187(a) has indicated the individual is fit for duty.

10 CFR 26.69(c)(4) requires the licensee to ensure the individual is in compliance with, or has completed, plans for treatment and drug and alcohol testing.

10 CFR 26.69(c)(5) requires the licensee to verify that results of pre-access drug and alcohol testing are negative before granting authorization, and that the individual is then subject to random testing.

10 CFR 26.69(d) provides that if an individual is authorized when other potentially disqualifying FFD information 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 potentially disqualifying FFD information; decide whether a determination of fitness is required; verify that if a determination of fitness is required that a professional with the appropriate qualifications has indicated that the individual is fit to safely and competently perform his or her duties; and implement any recommendations for treatment and follow-up drug and alcohol 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 meet the requirements of section 26.189 and were conducted under the FFD program of another licensee or entity subject to Part 26.

10 CFR 26.69(e)(1) requires licensees or other entities that imposed 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.

The above nine requirements are necessary to ensure that the information upon which an authorization decision is made about an individual who has had a first confirmed positive drug or alcohol test or a 5-year denial of authorization is fully complete and comprehensive for the period being covered. They require review of appropriate records, including the written treatment plan, records of drug and alcohol testing of the individual, and records of any potentially disqualifying FFD information that is disclosed or discovered. These collections involve notice to the individual regarding the status of their authorization (granted or not granted) and placement of information in PADS concerning the individual. Recordkeeping requirements for sections 26.69(b), (c)(1), (c)(2) and (c)(3) are specified by section 26.713(a)(1). Recordkeeping requirements for sections 26.69(c)(4) and (5) and for section 26.69(d) are specified by section 26.713(a)(3).

10 CFR 26.75(a), (b), (c), (d), (e) and (g) specifies the minimum sanctions that licensees and other entities must impose upon individuals who are determined to have violated the drug and alcohol provisions of an FFD policy. Paragraph 26.75(d) also specifies that if an individual resigns or withdraws his or her application for authorization before his or her authorization is terminated or denied for any violation of the FFD policy, the licensee or other entity shall record the resignation or withdrawal, the nature of the violation, and the minimum sanction that would have been required under Part 26 had the individual not resigned or withdrawn his or her application for authorization. These requirements, which establish a uniform set of sanctions for FFD violations, are implemented through the creation of records of the sanction imposed. This ensures that a record is created and maintained of the sanction that is available for later reference if the individual seeks authorization after the passage of time or at another facility. Records of sanctions are shared among FFD programs through the PADS to which the licensees send information concerning employment dates, approvals of access authorization, withdrawals of access authorization, violations of FFD policy, and other subjects. Recordkeeping requirements for sections 26.75(a), (b), (c), (d), (e)(2), and (g) are established by section 26.713(c).

10 CFR 26.75(h) specifies that a licensee or other entity may not terminate an individual's authorization and may not subject the individual to other administrative action based solely on a

positive test result from any initial drug test, other than positive initial test results for marijuana or cocaine metabolites from a specimen that is reported to be valid on the basis of either validity screening or initial validity testing performed at a LTF (LTF), unless 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 the following paragraphs.

10 CFR 26.75(i) allows a LTF to inform licensee or entity management of initial, non-negative marijuana or cocaine test results with a valid specimen. Licensees or other entities may administratively withdraw the donor's authorization or take lesser administrative actions against the donor, provided that certain conditions specified in section 26.75(i)(1) - (4) are met.

10 CFR 26.75(i)(3) requires that the licensee or other entity eliminate any matter from the individual's personnel record and other records that could link the individual to the temporary administrative action immediately upon receipt of a negative report from the HHS-certified laboratory or the MRO.

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

10 CFR 26.75(i)(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 potentially disqualifying FFD information. These requirements are necessary to ensure that any administrative action to withdraw authorization is not permanently recorded as an unfavorable termination of the individual, or communicated to another licensee or other entity as an unfavorable termination, unless and until such a record and such communication is correct and appropriate. This also ensures that an individual, the individual's personal representatives, and the NRC are allowed to review the records to ensure that no inappropriate records are retained, and that a written confirmation that the temporary administrative action will not be disclosed, and that the individual need not disclose the action, is provided to the individual. The recordkeeping requirements for this paragraph are established by section 26.713(a)(2).

10 CFR 26.77(c) requires a licensee or other entity that has a reasonable belief that an NRC employee or NRC contractor may be under the influence of any substance, or is otherwise unfit for duty, including when the observed behavior or physical condition is solely the result of

fatigue, the license must immediately notify the appropriate Regional Administrator by telephone, followed by written notification to document the verbal notification, or, if the Regional Administrator cannot be reached, to notify the NRC Operations Center. This requirement is necessary to ensure that the NRC receives immediate notification by telephone, followed by written notification, that an NRC employee or NRC contractor may be under the influence of a substance or is otherwise unfit for duty, so that the NRC can take action to remove the employee from duty and to take any other appropriate actions. Reporting requirements for section 26.77(c) are established by section 26.719(a).

10 CFR 26.85(a) requires qualification training for urine collectors on the requirements of Part 26, the FFD policy and procedures of the licensee or other entity for whom collections are performed, all steps necessary to complete a collection correctly and the proper completion and transmission of the custody-and-control form; methods to address problem collections, how to correct problems in collections, and the collector's responsibility for maintaining the integrity of the specimen collection and transfer process, ensuring the modesty and privacy of the donor, and avoiding conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

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

The above two requirements are necessary to ensure that individuals assigned to perform specimen collection activities under Part 26 are provided with appropriate training to complete the collection process consistent with the requirements in Subpart E. The burden for new collectors to complete one-time qualification training is accounted for under these paragraphs. Recordkeeping requirements for section 26.85(a) and (b) are established by section 26.715(a) and (b)(1).

10 CFR 26.85(c)(5) requires any medical professional, technologist or technician who serves as an alternative collector without meeting the training criteria otherwise required to be provided with detailed, clearly-illustrated, written instructions for collecting specimens in accordance in Subpart E.

This information collection requirement is necessary to ensure that alternative collectors have detailed instructions on how to perform the collections. Recordkeeping requirements for section 26.85(c)(4) are established by section 26.715(a).

10 CFR 26.85(e) requires collection site personnel files to include each individual's resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluations and advancement; incident reports, if any; results of tests that establish employee competency for the position he or she holds; and appropriate data to support determinations of honesty and integrity conducted in accordance with section 26.31(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. Records of training and competency of collection site personnel also helps justify the use of persons who perform FFD functions as part of another Part 26 program. Recordkeeping requirements for section 26.85(e) are established by section 26.715(a) and (b) (1).

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) provides that if a public rest room is used as a collection site, a sign must be posted, or an individual assigned, to ensure that no unauthorized personnel are present during the entire collection procedure.

The above two requirements are necessary in order to ensure that specimen collection sites are clearly identified to prevent unauthorized access to the collection site that could compromise the integrity of the collection process or the specimens, and to protect donor privacy. The recordkeeping requirements for section 26.87(c)(4) are established by section 26.715(b)(3). The paperwork burden for the posting required by section 26.87(d)(3) and (f)(1) is established by those sections.

10 CFR 26.87(f)(3) requires the person who accompanies the donor into the specimen collection area to be instructed on the collection procedures and his or her identity must be documented on the custody-and-control form.

10 CFR 26.87(f)(4) requires the collector to instruct the donor to participate with the collector in completing the chain-of-custody form.

10 CFR 26.87(f)(5) requires the authorized collector to maintain control of the specimen until the specimen is prepared for transfer, storage, or shipping, and to document his or her custody of the specimen on the custody and control form (CCF).

The above three requirements are necessary to ensure a chain-of-custody form is prepared that accurately identifies the origin of the specimen and links a particular specimen with a specific and correct donor. Recordkeeping requirements for section 26.87(f)(3) and (f)(5) are established by section 26.715(b)(2).

10 CFR 26.89(a) requires collectors to inform FFD program managers when an individual fails to appear for drug testing.

10 CFR 26.89(b)(1) and (b)(2) requires, in part, that individuals show proper identification before testing, and, if they cannot produce acceptable identification the collector must notify FFD program management.

10 CFR 26.89(b)(3) provides that if the donor is scheduled for pre-access testing and cannot produce acceptable identification, the collector may not proceed with the collection and shall inform FFD program management that the individual did not present acceptable identification.

10 CFR 26.89(b)(4) requires the collector to explain the testing procedure to the donor, show the donor the form(s) to be used, and ask the donor to sign a consent-to-testing form.

10 CFR 26.89(c) requires that the collector inform the donor that the donor must remain present at the collection site until the collection is complete. In the event the donor leaves the test site prematurely, the collector is required to report this to FFD management.

The above five requirements contribute to the assurance that the person providing a specimen is the person to be tested and if not, appropriate actions will be taken. For example, notice to FFD program management is necessary to ensure that appropriate corrective actions are undertaken under the FFD procedures to determine if authorization of the person should be denied or sanctions imposed. Paragraph 26.89(b)(4) requires an explanation to explain the testing procedure and to obtain a signed consent-to-test form, which are necessary to ensure that the due process rights of the individual are protected and there is a record that the individual understood the testing procedure and consented. The requirement in paragraph 26.89(c) informs the donor that he or she must remain present until the collection is complete to ensure the due process rights of the donor. Notice to FFD program management if the donor leaves or is uncooperative is necessary to ensure that appropriate actions are undertaken under the FFD procedures if authorization of the person should be denied or other management actions taken. The recordkeeping requirements for section 26.89(a), (b), and (c) are established by section 26.715(b)(6).

10 CFR 26.91(c)(1), (c)(2), and (c)(3) provides that an EBT device must provide a printed result of each breath test, assign a unique number to each completed test that is printed on each copy of the test result, and print on each copy of the test result the manufacturer's name for the device, its serial number, and the time of the test. This requirement is necessary to establish the specifications for EBT devices that may be used in FFD programs and to ensure that the results provided by EBT devices can be confirmed by the individual to whom the test is administered and that it is possible to confirm that no test results have been discarded or ignored. It may be necessary in some cases for licensees and other entities to obtain new EBTs with the capability of providing printed results, but most FFD programs are expected to already possess such devices. This requirement helps to ensure that adequate information is available for reviews necessary for a determination of fitness and in the conduct of legal proceedings, if any. This requirement also helps to ensure that information is available with which to track the performance (e.g., instrument calibration and linearity) of each EBT. This requirement does not directly create any records, but describes the types of records that must be created through the use of EBTs in FFD programs. Recordkeeping requirements for the records created using EBTs that meet the specifications of section 26.91(c)(1)-(3) are established by section 26.715(b)(12).

10 CFR 26.91(e)(4) requires, in part, the licensee or other entity to ensure that confirmed positive alcohol test results are derived from an EBT that is calibrated. The licensee or other entity shall implement one of the following procedures: if an EBT fails any external check of calibration, cancel every confirmed positive test result that was obtained using the EBT from any tests that were conducted after the EBT passed the last external calibration check; or after every confirmed positive test result obtained from using an EBT, conduct an external check of

calibration of the EBT in the presence of the donor. This contributes to accurate and reliable testing and protects the rights of the person being tested.

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 functioning properly and can provide reliable, accurate, and repeatable results within specified instrument parameters.

10 CFR 26.91(e)(5) requires that an internal record be maintained to document inspection, maintenance, and calibration activities. This record is necessary to ensure that inspection, maintenance, and calibration activities are being performed and can be reviewed and verified as being accurate; this helps protect the rights of the persons tested.

The recordkeeping requirements for section 26.91(e)(4) and (5) are established by section 26.715(b)(14).

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

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

10 CFR 26.97(b)(2) 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.

The above two requirements are necessary to ensure that if tests cannot be completed because the alcohol testing device cannot be used correctly, that fact must be provided as an explanation of the need for a new test. This helps to ensure that the need for a new test is not incorrectly attributed to the actions of the individual donor. These requirements also partially meet the legal necessity of protecting the due process rights of individuals who are subject to Part 26 and also proving "prior notice" and having it documented for evidence in legal proceedings. Recordkeeping requirements for section 26.97(b)(2) and (c)(1) are established by section 26.715(b)(6).

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

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 is necessary to ensure that the length of time the donor had been in work status when the initial test was conducted can be determined, in order to calculate the actual level while the individual was in work status, which is one factor under section 26.103 in determining whether to declare a confirmed positive test result. In addition, by recording the time of the initial test, the FFD program can demonstrate that the 15-minute waiting period required by section 26.93(a), if necessary, has occurred before the initial alcohol test was done. This requirement is also necessary to ensure that the confirmatory test is done, as required by section 26.101, no more than 30 minutes after the conclusion of the initial test. Recordkeeping requirements for section 26.99(b) are established by section 26.715(b)(6).

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. Recordkeeping requirements for section 26.101(b)(7) are established by section 26.715(b)(6).

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 at work status for 3 hours or more. The collector informs FFD management and the licensee or other entity prohibits the donor from duties subject to Part 26 until a determination of fitness is made. This third party collection requirement is necessary to ensure that FFD management is notified so that appropriate actions, including a determination of fitness, can be undertaken under the FFD procedures. Recordkeeping requirements for section 26.103(b) are established by section 26.715(b)(6).

10 CFR 26.107(b) requires the collector to document on the custody-and-control form any conduct that clearly indicates an attempt to tamper with a specimen. This requirement is an integral part of the collection procedure and is essential to documenting the chain of custody for

the specimens collected. The subversion of a Part 26 drug test is a relatively infrequent occurrence, however, it results in a burden on a licensee because the regulation requires the licensee to take certain actions to afford due process to the individual and verify the validity of the collection. Documentation is necessary to record any attempt to tamper with a specimen to support any subsequent appeals or reviews. Recordkeeping requirements for section 26.107(b) are established by section 26.715(b)(6).

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.

The above two requirements are necessary to ensure that the FFD program manager or MRO is informed of collection problems involving a particular donor so that the FFD program manager or MRO can initiate alternative procedures (or sanctions) for which their approval is required. Recordkeeping requirements for section 26.109(b)(4) are established by section 26.715(b)(6).

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

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

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

each testing result. Recordkeeping requirements for section 26.113(b)(3) are established by section 26.715(b)(2).

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

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

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

10 CFR 26.117(c) 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 custody-and-control form 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 custody-and-control form (or forms for both Bottle A and Bottle B, if split specimens procedures were followed) and certify proper completion of the collection.

10 CFR 26.117(k) requires that custody accountability of shipping containers during shipment by couriers, express carriers, and the postal service must be maintained by a tracking system provided by the courier, express carrier, or postal service.

The requirements in section 26.117(c), (d), and (e) are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The provision in section 26.117(k) is not intended to create a third-party recordkeeping requirement. Use of such tracking systems by couriers, express carriers, and the postal service is an ordinary business practice and relied upon for all shipments.

The provision enables licensees and other entities that they may rely upon the tracking system provided by the courier, express carrier, or postal service. Recordkeeping requirements for section 26.117(c), (d), and (e) are established by section 26.715(b)(2).

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 is necessary to ensure that a qualified MRO or licensed physician prepares an evaluation of whether the medical condition of the donor was or could have with a high probability been the basis for the donor's failure to provide a specimen.

10 CFR 26.119(b) requires the MRO, if the MRO is not performing the evaluation, to provide the physician who is performing the evaluation with information about the donor and the testing requirements, and instructions about the determination to be made by the physician.

10 CFR 26.119(e) requires a physician who performs an evaluation of the donor's failure to provide a sufficient specimen to prepare a written statement of his or her determination and the basis for it and to provide the statement to the MRO.

10 CFR 26.119(f) requires the physician, if he or she determines that the donor's medical condition is a serious and permanent or long-term disability that is highly likely to prevent the donor from providing a sufficient amount of urine for a very long or indefinite period of time, to set forth this determination and the reasons for it in the written statement to the MRO.

The above four requirements are necessary to ensure that if a donor does not provide a specimen within the specified time, then a medical evaluation, based on specified information and instructions, is prepared and provided in writing to the MRO. Recordkeeping requirements related to maintaining a record of the donor's testing results for section 26.119(a), (b), (e), and (f) are established by section 26.715(b)(6). Recordkeeping requirements related to providing instructions and making a written determination for sections 26.119(a), (b), (e), and (f) are established by section 26.119.

10 CFR 26.125(b) requires technicians who perform urine specimen testing to have documented proficiency in operating the testing instruments and devices used at the LTF.

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

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

10 CFR 26.127(a) requires LTFs 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 LTFs 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-certified laboratory, and continuing until final disposition of the specimens.

10 CFR 26.127(c) requires LTFs 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 LTFs 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 LTFs 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 maintain documentation that these procedures are followed and that all necessary corrective actions are taken. In addition, all facilities are required to have systems in place and to verify all stages of testing and reporting and to document the verification.

The above five requirements are an integral part of the quality assurance/quality control process for every testing facility and are essential to documenting the procedures to be followed to ensure that all steps in the testing and analysis process, including chain-of-custody for the specimens collected, are carried out in an appropriate manner by all personnel conducting the activities. Recordkeeping requirements for section 26.127(a), (b), (c), (d) and (e) are established by section 26.715(a).

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, is necessary to ensure that unauthorized persons do not gain access to testing areas where they might seek to subvert the testing process.

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 custody-and-control forms, 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 custody-and-control forms if the specimens must be transferred. This requirement is necessary to ensure 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.

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 custody-and-control forms. Such reports are required to be made as soon as practical and no later than 8 hours after the indications are identified. This requirement is necessary because confirmed reports of tampering must be reported to the NRC as required by section 26.719(b).

10 CFR 26.129(d) requires LTFs' procedures for tracking custody and control of specimens to protect the identity of the donor. The facilities are required to provide documentation of the testing process and each transfer of custody of the specimen, along with the date and purpose and every individual in the chain of custody.

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.

The above five requirements are an integral part of the quality assurance/quality control process for every testing facility and are essential to ensuring the security from tampering of the specimens collected and appropriate and timely actions if possible tampering is suspected. 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. Furthermore, section 26.129(h) is not intended to create a third-party recordkeeping requirement. Use of such tracking systems by couriers, express carriers, and the postal service is an ordinary business practice and relied upon for all shipments. The provision is intended to notify licensees and other entities that they may rely upon the tracking system provided by the courier, express carrier, or postal service. Recordkeeping requirements for section 26.129(a) are established by section 26.715(b)(13); section 26.129(b) established by section 26.715(b)(2); section 26.129(b)(1) established by section 26.715(b)(3); and, section 26.129(d) are established by section 26.715(b)(2).

10 CFR 26.135(b) allows, upon a positive, adulterated, or substituted result, the donor to request that a split specimen (if the FFD program follows split specimen procedures as described in section 26.113) be tested at another HHS-certified laboratory. The donor provides his or her written permission for the LTF to forward Bottle B from its secure storage to the HHS-certified laboratory for the testing of Bottle B. This requirement is necessary in order to ensure that a record exists of the donor's approval of a second test, in case of subsequent legal proceedings. Recordkeeping requirements for section 26.135(b) are established by section 26.715(b)(6).

10 CFR 26.137(a) requires each LTF to develop and implement a quality assurance program and procedures encompassing all aspects of the testing process. This requirement is an integral part of the quality assurance/quality control 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. Recordkeeping requirements for section 26.137(a) are established by section 26.715(b)(3).

10 CFR 26.137(b)(1)(ii) requires the licensee or other entity before using the test, to ensure that the validity screening test, by lot number, effectively identifies specimens of questionable validity by meeting the performance testing and quality control requirements listed in this section.

10 CFR 26.137(b)(1)(iii) requires a licensing testing facility 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.

The above two requirements are necessary to ensure that all point-of-collection testing devices used by a LTF meet certain minimum performance criteria. This will protect donors from inaccurate test results and provide assurance that specimens of questionable validity are detected. Recordkeeping requirements for section 26.137(b)(1)(ii) and (iii) are established by section 26.715(b)(7).

10 CFR 26.137(b)(3) requires LTFs to submit at least one specimen out of every 10 that test negative using each validity screening test to an HHS-certified laboratory as part of the LTF's quality assurance program. This requirement is an integral part of the quality control/quality assurance process and protects donors from inaccurate test results as well as providing assurance that specimens of questionable validity are detected. Recordkeeping requirements for section 26.137(b)(3) are established by section 26.715(b)(3). Reporting requirements for false negatives detected under section 26.137(b)(3) are established by section 26.719(c)(3).

10 CFR 26.137(e)(7) requires LTFs to document the implementation of 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 LTFs to prepare a record of findings and corrective actions taken, where applicable, for all investigations of any testing errors or unsatisfactory performance discovered in the testing of quality control samples, in the testing of actual specimens, or through the processing of management reviews or MRO reviews. The record must be signed and dated by the individuals who are responsible for the day-to-day management of the LTF and reported to appropriate levels of management.

10 CFR 26.137(h) requires standards and controls to be labeled with dates of when received, when prepared or opened, when placed in service, and when scheduled for expiration.

The above three requirements are an integral part of the quality assurance/quality control process for all testing and laboratory facilities. The requirements are necessary to protect donors from inaccurate results and to provide assurance that specimens of questionable validity are detected. Recordkeeping requirements for section 26.137(e)(8) are established by section 26.715(b)(3); section 26.137(f) established by section 26.715(b)(8); and, section 26.137(h) are established by section 26.715(b)(5).

10 CFR 26.139(d) requires LTFs to prepare information for annual reports to the NRC, as required in section 26.717. This requirement is necessary to ensure 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 program performance data is to be included in the annual report. Reporting requirements under section 26.139(d) are established by section 26.717(b) and (e).

10 CFR 26.153(e) requires a licensee or other entity, before awarding a contract to an HHS-certified laboratory, to conduct a pre-award inspection and evaluation of the procedural aspects of the laboratory's drug testing operations.

10 CFR 26.153(f) requires licensees' and other entities' contracts with HHS-certified laboratories to implement all applicable obligations of Part 26 and specifies minimum requirements.

The above three recordkeeping of the pre-award inspection and evaluation in the form of documentation of the inspection and evaluation ensures that FFD program personnel and managers not personally participating in the inspection and evaluation can review and assess the qualifications of the laboratory and make informed decisions about contracting with that laboratory. Recordkeeping requirements for section 26.153(e) are established by section 26.715(b)(9) and section 26.153(f) is established by section 26.713(e).

10 CFR 26.153(g) requires licensees or other entities who use a form other than the current Federal custody-and-control form to provide a memorandum to the HHS-certified laboratory 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 custody-and-control form unless the licensee or other entity provides a memorandum for the record. This paragraph is necessary to prevent licensee's and other entity's specimens from being rejected. Recordkeeping requirements for section 26.153(g) are established by section 26.715(b)(2).

10 CFR 26.155(a)(1) requires day-to-day management of the HHS-certified laboratory to be performed by an individual with documented scientific qualifications in analytic forensic toxicology.

10 CFR 26.155(a)(3) requires the individual to ensure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

10 CFR 26.155(a)(4) requires the day-to-day manager to review, sign, and date procedures to be followed by laboratory personnel whenever the procedures are first placed into use or changed or when a new individual assumes responsibility for management of the laboratory, and to ensure that copies of all procedures are maintained.

10 CFR 26.155(a)(5) requires the day-to-day manager to maintain a quality assurance program that, among other things, documents the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

10 CFR 26.155(b) requires that each HHS-certified laboratory have at least one certifying scientist to certify test results. The paragraph specifies the requirements for the certifying scientist.

10 CFR 26.155(c) requires that each HHS-certified laboratory assign at least one individual to be responsible for day-to-day operations and supervision of the technical analysts. The paragraph specifies the requirements for the analysts' supervisor.

10 CFR 26.155(e) requires that HHS-certified laboratories make available continuing education programs for personnel.

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

The above eight requirements are consistent with the HHS Guidelines, Sections 11.2 and 11.3 (73 FR 75122, December 10, 2008) and these requirements are necessary for a laboratory to conduct forensic drug testing and to ensure the scientific validity and supportability of the test results. As standard business practices, these records are not considered a burden for this analysis, because they are standard business practice. Recordkeeping requirements for section 26.155(a)(1), (a)(3), (b), and (c) are established by section 26.155(f); section 26.155(a)(4) established by section 26.157; and the section 26.155(a)(5) requirements are established by section 26.715(b)(3). The recordkeeping burden for section 26.155(e) and (f) is captured under OMB Control No. 0930-0158.

10 CFR 26.157(a) requires HHS-certified laboratories to develop, implement, and maintain clear and well-documented procedures for accession, receipt, shipment, and testing of urine specimens.

10 CFR 26.157(b) requires HHS-certified laboratories to have written chain-of-custody procedures describing the methods to be used to maintain control and accountability of specimens from receipt through completion of testing and reporting of results, during storage and shipping to another HHS-certified laboratory, if required, and continuing until final disposition of the specimens.

10 CFR 26.157(c) requires HHS-certified laboratories to develop, implement, and maintain a written standard operating procedures manual for each assay performed for drug and specimen validity testing. If the LTF performs validity screening tests with non-instrumented devices, the facility is also required to develop, implement, and maintain written standard operating procedures for each device.

10 CFR 26.157(d) requires HHS-certified laboratories to develop, implement, and maintain written procedures for instrument and device setup and normal operation.

10 CFR 26.157(e) requires HHS-certified laboratories to develop, implement, and maintain written procedures for remedial actions to be taken when systems and non-instrumented testing devices (if used for validity screening tests) are out of acceptable limits or errors are detected. Each facility is required to maintain documentation that these procedures are followed and that all necessary corrective actions are taken. In addition, all facilities are required to have systems in place and to verify all stages of testing and reporting and to document the verification.

The above five requirements are consistent with the HHS Guidelines, Section 11.1. These recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. As standard business practices, they are not considered a burden for this analysis. The recordkeeping burden for section 26.157(a), (b), (c), (d) and (e) is captured under OMB Control No. 0930-0158.

10 CFR 26.159(a) requires each HHS-certified laboratory to limit access to secured areas only to specifically authorized individuals whose authorization is documented.

10 CFR 26.159(b)(1) requires HHS-certified laboratories 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 custody-and-control forms. Any direct evidence of tampering or discrepancies in the information on the specimen bottles and the custody-and-control forms attached to the specimen bottles must be reported to the licensee or other entity within 24 hours of the discovery and must be noted on the custody-and-control forms for each specimen contained in the package.

10 CFR 26.159(c) requires laboratory personnel to use aliquots and laboratory internal custody-and-control forms when conducting initial and confirmatory tests, and that these forms remain in secure storage.

10 CFR 26.159(d) requires each HHS-certified laboratory's internal custody-and-control form 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 each HHS-certified laboratory's personnel to document the date and purpose each time a specimen is handled or transferred within the laboratory on the custody-and-control form, and to identify every individual in the chain. Authorized technicians are required to sign and complete custody-and-control forms for each specimen or aliquot as they are received.

10 CFR 26.159(f) requires that, when transferring a specimen to a second HHS-certified laboratory, the original custody-and-control form is packaged with its associated urine specimen bottle.

10 CFR 26.159(i) requires that, unless otherwise authorized in writing, specimens be retained in proper storage for 1 year.

The above eight requirements are consistent with the HHS Guidelines, Sections 11.7, 11.8, and 16.1. These requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. As standard business practices, they are not considered a burden for this analysis. The recordkeeping burden for section 26.159(a) is captured under OMB Control No. 0930-0158. Recordkeeping requirements for section 26.159(b) are established by section 26.715(b)(3) and section 26.159(c), (d), (e), (f), and (i) are established by section 26.715(b)(2). Reporting requirements for reports of tampering to NRC under section 26.159(b) are established by section 26.719(b)(3).

10 CFR 26.163(a)(2) specifies that if initial validity testing indicates that a specimen is dilute, and any response is equal to or greater than 50 percent of the cutoff, the HHS-certified laboratory shall test the specimen for those drugs and/or drug metabolites down to the confirmatory assay's limit of detection (LOD). The laboratory shall report the numerical values obtained from this special analysis to the MRO. This requirement is necessary to validate a dilute result to protect donors from inaccurate results, to provide assurance that specimens of questionable validity are detected, and to ensure the integrity of the testing process. The recordkeeping requirements for section 26.163(a)(2) are established by section 26.715(b)(6).

10 CFR 26.165(b)(1) requires that for a confirmed positive, adulterated, or substituted result reported on a single specimen of 30 ml or more, or a specimen in Bottle A of a split specimen which the donor submitted to the licensee or other entity, a donor may request (through the MRO) that an aliquot from the single specimen or the split (Bottle B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first laboratory. For an invalid test result, a donor may not request that an aliquot from the single specimen or the split specimen in Bottle B be tested by a second HHS-certified laboratory.

10 CFR 25.165(b)(2) requires the MRO to inform the donor that he or she may, within 3 business days of notification by the MRO of the confirmed positive, adulterated, or substituted test result, request the re-testing of an aliquot of the single specimen or the testing of the Bottle B split specimen. The MRO shall provide the donor with specific instructions for making this request (i.e., providing telephone numbers or other contact information). The MRO is required to have the ability to receive the donor's calls at all times during the 3-day period (e.g., by use of an answering machine with a time stamp feature when there is no one in the MRO's office to answer the phone). The donor's request may be oral or in writing.

10 CFR 25.165(b)(3) requires the donor to provide his or her permission for re-testing an aliquot of the single specimen or the testing of Bottle B.

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 that there was a legitimate reason for the donor's failure to contact the MRO within 3 business days, the MRO shall direct the retesting take place, as if the donor had made a timely request.

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

10 CFR 25.165(c)(4) provides that a second laboratory conducting retesting shall report all results to the licensee's or other entity's MRO.

10 CFR 26.165(f)(1) specifies that a licensee or other entity may administratively withdraw an individual's authorization on the basis of a first confirmed positive, adulterated, or substituted test result until the results of testing Bottle B or retesting an aliquot of a single specimen are available and have been reviewed by the MRO. Paragraph 26.165(f)(1) requires that licensees and other entities may not disclose the temporary administrative action against an individual whose initial drug test result is not subsequently confirmed by the MRO as a violation of FFD

policy in response to a suitable inquiry conducted under section 26.63, a background investigation conducted under Part 26, or to any other inquiry or investigation. The licensees or other entities must provide access to the system of files and records to personnel who are conducting reviews, inquiries into allegations, audits pursuant to section 26.41, and to NRC inspectors, to ensure that no records are retained. The licensees or other entities shall provide the tested individual with a written statement that the records specified in sections 26.713 and 26.715 have not been retained, and shall inform the individual in writing that the temporary administrative action that was taken will not be disclosed and need not be disclosed by the individual in response to requests for self-disclosure of potentially disqualifying FFD information.

10 CFR 26.165(f)(1)(ii) requires that the licensee or other entity eliminate any matter from the individual's FFD record and other records that could link the individual to the temporary administrative action immediately upon receipt of a negative report from the testing of Bottle B or retesting the aliquot of a single specimen.

10 CFR 26.165(f)(1)(iv) requires that the licensee or other entity provide the tested individual with a written statement that the records specified in sections 26.713 and 26.715 have not been retained and shall inform the individual in writing that the temporary administrative action that was taken will not be disclosed.

10 CFR 26.165(f)(2) requires that if the donor requests that either Bottle B be tested or an aliquot of a single specimen be retested and either is not available, the MRO shall cancel the test and inform the licensee or other entity that another collection is required under direct observation as soon as reasonably practical. The licensee or other entity shall eliminate from the donor's personnel and other records any matter that could link the donor to the original positive, adulterated or substituted test result(s) or any temporary administrative action.

The above ten requirements are necessary to provide donors with the opportunity to request that either Bottle B of a split specimen or an aliquot of a single specimen be tested if an initial non-negative test result is obtained, and to ensure that no records of a temporary administrative action taken as a result of an initial non-negative test result are retained if a negative report is received from the testing of Bottle B or retesting of an aliquot of a single specimen. These requirements are, in part, consistent with the HHS Guidelines, Section 15.1. 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.

Recordkeeping requirements for the test result collections in section 26.165(b)(1), (b)(6), and (c)(4) are established by section 26.715(b)(6). Recordkeeping requirements for collections for notifications to the donor, permissions by the donor, and access to records by the NRC inspectors under section 26.165(b)(1), (b)(2), (b)(3), (b)(4), (b)(6), (f)(1), (f)(1)(ii), (f)(1)(iv), and (f)(2).

10 CFR 26.167(a) requires each HHS-certified laboratory to have a quality assurance program encompassing 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. Quality assurance procedures must be designed, implemented, and reviewed to monitor the conduct of each step of the testing process. This requirement is consistent with the HHS Guidelines. These recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing, and to ensure the scientific legitimacy of test results. As standard business practices, these recordkeeping requirements are not considered a burden for this analysis.

10 CFR 26.167(c)(2)(i) requires that refractometers used by HHS-certified laboratories 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-certified laboratories that perform validity testing on urine specimens for FFD programs. The section does not create any separate records, but determines the types of records that will be created under other sections of Part 26. The section is consistent with the HHS Guidelines. This requirement also is necessary to protect donors from inaccurate results, and to ensure the integrity of the testing process. Recordkeeping requirements for the records created meeting the specifications of section 26.167(c)(2)(i) under other sections of Part 26 are established by section 26.715(b)(14).

10 CFR 26.167(f) requires the licensee or other entity to ensure that the HHS-certified laboratory investigates any testing errors or unsatisfactory performance. Paragraph 26.167(f)(1) requires sufficient records to be maintained to furnish evidence of activities affecting quality. The identification of the significant condition, the cause of the condition, and the corrective action taken are required to be documented and reported to appropriate levels of management. Paragraph 26.167(f)(3) requires, if a false positive error occurs on a blind performance test sample and the error is determined to be technical or methodological, that the licensee or other entity instruct the laboratory to provide all quality control data from the batch or analytical run of specimens that included the false positive sample. If retesting is required, the retesting must be documented by a statement signed by the laboratory's certifying scientist. These requirements are consistent with the HHS Guidelines and with Part 50, Appendix B, Quality Assurance Requirements for Nuclear Power Plants and Fuel Reprocessing Plants, Criterion XVI, Quality Assurance Records. These requirements are necessary to protect donors from inaccurate results, to provide assurance that specimens of questionable validity are detected, and to ensure the integrity of the testing process.

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.

Recordkeeping requirements for section 26.167(a), (c)(2)(i), and (f) are established by section 26.715(b)(7) and section 26.167(h) is established by section 26.715(b)(3).

10 CFR 26.168(a) requires each licensee or other entity to submit blind performance test samples to the HHS-certified laboratory. Sixty percent of the blind performance test samples

submitted to the laboratory must be positive for one or more drugs. This requirement involves the use of a simple standard form, and is a standard business practice of laboratories that prepare blind performance test samples.

10 CFR 26.168(h)(2) requires each licensee or other entity to ensure that the supplier of blind performance test samples provides the expiration date for each test sample. This requirement is a standard business practice of laboratories that prepare blind performance test samples.

10 CFR 26.168(i)(2) requires each licensee or other entity to use a custody-and-control form, place fictional initials on the specimen bottles' labels/seals, and indicate for the MRO on the MRO's copy that the specimen is a blind performance test sample. This requirement is a standard business practice for blind performance test samples.

10 CFR 26.169(a) requires HHS-certified laboratories to report test results to the licensee's or other entity's MRO within 5 business days after receiving the specimen. Before reporting any test result, the laboratory's certifying scientist must certify the result as 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 specimen identification number assigned by the licensee or other entity; and the specimen identification number assigned by the laboratory.

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

10 CFR 26.169(c)(2) requires HHS-certified laboratories to report to the MRO numerical values for all positive test results if the MRO requests them. The laboratory shall routinely provide quantitative values for confirmatory opiate test results for morphine or codeine that are greater than or equal to 15,000 ng/ml, even if the MRO has not requested quantitative values for the test result.

10 CFR 26.169(c)(3) requires HHS-certified laboratories to report to the MRO numerical values for all adulterated or substituted test results.

10 CFR 26.169(c)(4) requires the HHS-certified laboratory to contact the MRO and both will decide whether testing by another certified laboratory would be useful in being able to report a positive or adulterated result.

10 CFR 26.169(c)(5) an HHS-certified laboratory 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) requires the HHS-certified laboratory to transmit results by electronic means (e.g., teleprinter, facsimile, or computer) in a manner designed to ensure the confidentiality of the information, and would prohibits transmitting results verbally by telephone.

10 CFR 26.169(f) requires the HHS-certified laboratory to fax, courier, mail, or electronically transmit a computer-generated electronic report and/or a legible image or copy of the completed custody-and-control form 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 custody-and-control form to the MRO.

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

10 CFR 26.169(h) requires the HHS-certified laboratory to prepare an annual statistical summary report of urinalysis testing results for that year. To avoid sending data from which it is likely that information about an individual donor's test result can be inferred, the laboratory is not permitted to send a report if the licensee or other entity has fewer than 10 specimen test results in a one-year period. The summary report is required to be sent within 14 calendar days after the end of the one-year period covered by the report. Information that is required to be included in the statistical summary report is listed in section 26.169(h)(1) - (8).

The above ten requirements are necessary to ensure that licensees and other entities receive all necessary reports of test results and testing-related information from HHS-certified laboratories performing services for the licensees or other entities and are standard business practices for blind performance test samples. This information is necessary for implementation of the licensee or other entities' FFD programs and for submission in annual FFD program reports to the NRC. The recordkeeping and reporting requirements under section 26.169 are established by contract between licensees and other entities and HHS-certified laboratories. Such records and reports are generally consistent with the requirements for HHS-certified laboratories in the HHS Guidelines, as well as with usual and customary business practices for such laboratories. Recordkeeping requirements for section 26.169 are established by section 26.715(b)(2), (b)(3), (b)(5), (b)(6), and (b)(8).

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 is necessary to ensure that if questions are raised about the qualifications of the MRO a record is available that indicates that the MRO meets the requirements specified in Part 26 to serve as an MRO.

10 CFR 26.183(b)(2) establishes that the HHS-certified laboratory has a contract or retainer with the MRO for review of test results produced by the laboratory. This is standard business practice between two or more entities.

10 CFR 26.183(c)(1) requires the MRO to examine alternate causes of a positive, adulterated, substituted, invalid and, at the licensee's or other entity's discretion, the results of special analyses testing of dilute specimens, including reviewing records made available by the donor, and documented medical conditions.

10 CFR 26.183(d)(1)(ii)(D) requires the MRO to maintain the confidentiality of records and other donor personal information, except for those releases permitted under Part 26; to ensure the security of data transmission; and to ensure that drug test results are reported to the licensee's or other entity's designated reviewing official only in accordance with the requirements of Part 26.

The above four requirements and records are necessary to specify how the MRO performs certain duties such that reasonable assurance is provided in the medical review of drug testing results and protection of information.

10 CFR 26.183(d)(2)(i) allows MRO staff, under the direction of the MRO, to receive, review, and report negative test results to the designated representative of the licensee or other entity.

10 CFR 26.183(d)(2)(ii) requires that the staff reviews of positive, adulterated, substituted, invalid, or at the licensee's or other entity's discretion, dilute test results must be limited to reviewing the custody-and-control form to determine whether it contains any errors that may require corrective action and to ensure that it is consistent with the information on the MRO's copy. The staff may resolve errors in custody-and-control that require corrective action(s), but must forward the custody-and-control forms to the MRO for review and approval of the resolution.

The above two requirements are necessary to ensure the protection of personal information, except as necessary for the ongoing implementation of the FFD program. These requirements define the limits of the duties that the staff of the MRO may perform, and require the staff to make communications with the MRO to inform the MRO about actions proposed by the staff. Review of chain-of-custody errors and review of test results by an independent MRO is a key due process protection for individuals. These requirements therefore partially meet the legal necessity of protecting the due process rights of individuals who are subject to Part 26. Recordkeeping requirements for section 26.183(a) are established by this section or, for MROs no longer employed by the licensee, by section 26.715(b)(1). Recordkeeping requirements for section 26.183(c)(1), (d)(1)(ii), (d)(2)(i) and (d)(2)(ii) are established by section 26.713(a)(2).

10 CFR 26.185(a) requires the MRO to review all positive, adulterated, substituted, dilute, or invalid test results from the HHS-certified laboratory to determine whether the donor has violated the FFD policy before reporting the results to the licensee's or other entity's designated representative. This is required to ensure an appropriate medical review of drug results.

10 CFR 26.185(c) prohibits the MRO from determining that a positive, adulterated, substituted, dilute, or invalid result or other occurrence is a FFD policy violation and reporting it to the licensee or other entity without giving the donor an opportunity to discuss the test result or other occurrence with the MRO, if, after discussion, the MRO determines the result or occurrence is FFD violation, the MRO shall notify the licensee. These requirements are necessary to ensure that before the licensee or other entity is notified of a possible FFD violation the MRO has reviewed the positive, adulterated, substituted, dilute, or invalid result and, before reporting it as a violation, has discussed the result with the donor.

10 CFR 26.185(d) allows the MRO to determine that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is an FFD policy violation without having discussed the test result or other occurrence directly with the donor in three instances: (1) if the MRO has made and documented contact with the donor and the donor has expressly declined the opportunity to discuss the test result or other occurrence that might constitute an 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 and has instructed him or her to

contact the MRO; or (3) the MRO, after making all reasonable efforts and documenting the dates and time of those efforts, has been unable to contact the donor.

10 CFR 26.185(e) allows a donor, within 30 days of notification, to present to the MRO information documenting circumstances that unavoidably prevented the donor from being contacted by the MRO or a representative of the licensee or other entity, or from contacting the MRO in a timely manner to request that the MRO reopen the procedure for determining whether the donor's test result or other occurrence is an FFD policy violation.

The requirements in section 26.185(c), (d), and (e) help 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.

10 CFR 26.185(f)(1) requires the MRO to consult with an HHS-certified laboratory that reports an invalid result, to determine if additional testing by another HHS-certified laboratory 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 whether there is an acceptable medical explanation for the invalid result, and, if there is, to report to the licensee that the test result is not an FFD policy violation. The requirement ensures that the individual specific circumstances are evaluated.

10 CFR 26.185(h)(1) requires the MRO, if the HHS-certified laboratory reports a specimen as substituted, to contact the donor and offer the donor an opportunity to provide an acceptable medical explanation for the substituted result. The donor must provide credible medical evidence within 5 business days that he or she produced the specimen for which the HHS-certified laboratory reported a substituted result. Any medical evidence must be submitted through a referral physician who is experienced and qualified in the medical issues involved.

10 CFR 26.185(h)(2) requires the MRO, if the MRO determines there is no acceptable medical explanation for the substituted test result, to report to the licensee or other entity that the specimen was substituted.

10 CFR 26.185(h)(3) requires the MRO, if the MRO determines there is an acceptable medical explanation for the substituted test result, to report to the licensee or other entity that no FFD policy violation has occurred.

10 CFR 26.185(i)(1) requires the MRO, if the HHS-certified laboratory 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 that he or she produced the adulterated result through normal human physiology.

10 CFR 26.185(i)(2) requires that, if the MRO determines there is no acceptable medical explanation for the 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 there is an acceptable medical explanation for the adulterated test result, the MRO must report to the licensee or other entity that there was no FFD policy violation.

10 CFR 26.185(j)(3) requires that, if the MRO determines that the donor has used another individual's prescription medication and evidence of drug abuse is found, the MRO must report to the licensee that the donor has violated the FFD policy.

10 CFR 26.185(k) requires, if the MRO determines that there is a legitimate medical explanation for a positive confirmatory drug test result, and that the use of a drug identified through testing was in the manner and at the dosage prescribed and the results do not reflect a lack of reliability or trustworthiness, the MRO to report to the licensee or other entity that no FFD policy violation has occurred.

10 CFR 26.185(m) provides that, based on the review of inspection and audit reports, quality control data, multiple specimens, and other pertinent results, the MRO may determine that a positive, adulterated, substituted or invalid test result is scientifically insufficient for further action and may declare that a drug or validity test result is not an FFD policy violation.

10 CFR 26.185(n) provides that, if a second HHS-certified laboratory 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-certified laboratory does not reconfirm the drug-positive test result, the MRO shall report that no FFD policy violation has occurred; or if the second HHS-certified laboratory 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-certified laboratory and the laboratory shall provide, quantitation of the test results and other information necessary to make the determination.

10 CFR 26.185(p) requires the MRO to review positive, adulterated, substituted, and invalid test results and, in those instances in which the MRO determines that the donor has violated the FFD policy of the licensee or other entity, to notify the designated representative of the licensee or other entity in writing within 10 business days of receiving the positive, adulterated, or substituted test result from the HHS-certified laboratory.

The requirements in section 26.185(h)(1), (h)(2), (h)(3), (i)(1), (i)(2), (i)(3), (m), (n), (o) and (p) are necessary to meet, in part, the legal necessity of protecting the due process rights of individuals who are subject to Part 26, and also providing prior notice and having it documented for evidence in legal proceedings. These requirements also protect donors from inaccurate results, to provide assurance that specimens of questionable validity are detected, and to ensure the integrity of the testing process. Recordkeeping requirements for section 26.185 are established by section 26.713(a)(2).

10 CFR 26.187(d) requires the SAE to 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. This requirement is necessary to ensure that SAEs are aware of the special requirements associated with their position. Some aspects of the SAE training are covered in the FFD training given to all individuals who are subject to the FFD program. Additional training in topics specific to the SAE will also be prepared and given.

10 CFR 26.187(f) requires the SAE to maintain documentation showing that he or she currently meets all credentials, knowledge, and training requirements for a SAE established by section 26.187, and to provide this documentation upon request to NRC representatives, licensees, or other entities who are relying upon or contemplating relying upon the SAE's services and to other individuals and entities, in accordance with the requirements of section 26.37. This requirement is necessary to ensure 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.

Recordkeeping requirements for section 26.187(d) and (f) are established by this section, or for SAEs no longer employed by the licensee by section 26.715(b)(1). Reporting requirements for section 26.187(f) are established by this section.

10 CFR 26.189(a) provides that a determination of fitness, the process entered when there are indications that an individual in section 26.4(a) through (e), and, at the licensee's or other entity's discretion, section 26.4(f) and (g) may be in violation of the licensee's or other entity's FFD policy or is otherwise unable to safely and competently perform his or her duties, must be made by a licensed or certified professional who is appropriately qualified and has the necessary clinical expertise, as verified by the licensee or other entity, to evaluate the specific fitness issues presented by the individual. A written record of the determination of fitness must be prepared.

10 CFR 26.189(c) provides that a determination of fitness that is conducted for cause must be conducted through face-to-face interaction between the subject individual and the professional making the determination. If there is no conclusive evidence of an FFD policy violation but there is a significant basis for concern that the individual may be impaired while on duty, then the subject individual must be determined to be unfit for duty. This result does not constitute a violation of Part 26 nor of the licensee's or other entity's FFD policy, and no sanctions may be imposed. However, the professional who made the determination of fitness is required to consult with the licensee's or other entity's management personnel to identify the actions required 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 conducted for cause must be prepared.

The above two requirements are necessary to specify the procedures to be followed in making determinations of fitness of individuals under Part 26. Licensees must ensure that certain individuals whose job duties require them to have access to the protected areas of nuclear power plants or to perform certain specified duties are fit-for-duty and that such individuals are trustworthy and reliable, as demonstrated by the avoidance of substance abuse, are not under the influence of legal or illegal drugs or alcohol, or mentally or physically impaired from any cause that in any way adversely affects their ability to safely and competently perform their duties, and that the effects of fatigue and degraded alertness on individual's abilities to safely and competently perform their duties are managed commensurately with maintaining public health and safety, common defense, and security. 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.

10 CFR 26.189(d) provides that after the initial determination of fitness has been made, the professional making the determination may modify his or her evaluation and recommendations based on new or additional information from other sources. This requirement is necessary to ensure that if additional information is received that causes the determination of fitness to be modified, the determination is modified and records pertaining to the determination are changed to reflect the new determination.

Recordkeeping requirements for section 26.189 are established by section 26.713(a)(4).

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 subject to Subpart I, to develop, implement, and maintain written procedures that describe the process to be followed when an individual subject to Part 26 makes a self-declaration that he or she is not fit to safely and competently perform his or her duties for any part of a working tour as a result of fatigue. The procedure must describe the individual's and licensee's rights and responsibilities relating to self-declaration; describe requirements for establishing controls and conditions under which an individual may be permitted or required to perform work after that individual declared that he or she was not fit due to fatigue; and, describe the process to be followed if the individual disagreed 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.

The above two requirements are necessary to ensure that written policies and procedures are available to individuals that indicate how each FFD program subject to Subpart I meets the general objectives of Subpart I, and that describe any allowable variations in the program. The policy and procedures are necessary to ensure that individuals who are covered by Subpart I are aware of their responsibilities and rights by informing them with sufficient detail about licensee FFD rules, what is expected of them, and what consequences may result from a lack of adherence to the FFD policy. The requirements

also partially meet the legal necessity of proving prior notice and having it documented for evidence in legal proceedings.

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(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 is necessary to ensure 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) requires that the following information in a standard format is included in the annual FFD program performance report required by section 26.717.

10 CFR 26.203(e)(1) requires licensees to prepare a summary for each nuclear power plant site of all instances during the previous calendar year in which the licensee waived the work hour controls specified in section 26.205(d)(1) through (d)(5)(i) and (d)(7) for individuals described in

section 26.4(a). Each summary must include an accounting of only those waivers under which work was performed. If it was necessary to waive more than one work hour control during any single extended work period, the summary of instances must include each of the work hour controls that were waived during the period. For each category of individuals specified in section 26.4(a) the licensee shall report: the number of instances in which each work hour control specified in section 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), (d)(3)(i) through (d)(3)(v), and (d)(7) was waived for individuals not working on outage activities; the number of instances in which each work hour control specified in section 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), (d)(3)(i) through (d)(3)(v), (d)(4) and (d)(5)(i), and (d)(7) was waived for individuals working on outage activities; and a summary that shows the distribution of waiver use among the individuals within each category of individuals identified in section 26.4(a) (e.g., a table that shows the number of individuals that received only one waiver during the reporting period, the number of individuals that received a total of two waivers during the reporting period).

10 CFR 26.203(e)(2) requires licensees to include a summary of corrective actions, if any, resulting from the analyses of these data, including fatigue assessments.

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

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

10 CFR 26.205(b) requires licensees to calculate the work hours of individual's subject to this section as the amount of time the individuals perform duties for the licensee.

10 CFR 26.205(c) requires licensees to schedule the work hours of individuals who are 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 licensees to implement work hour controls for individuals to ensure that, except as permitted by the waiver provisions in section 26.207, 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 licensees to ensure that individuals have 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 licensees to ensure that individuals have, 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 licensees to ensure that individuals have, 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 licensees to ensure that individuals have, 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) provides 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 licensees with a voluntary alternative to the minimum days off requirements of section 26.205(d)(3) by permitting licensees to comply with the requirements for maximum average work hours.

10 CFR 26.205(d)(7)(i) establishes the alternative requirement to maintain individuals' 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 licensees, when the individual's work shift starts at the end of a calendar day and concludes during the next calendar day, to either consider all the work hours as if they were worked on the day the shift started or account for the work hours on the calendar days on which they were actually worked.

10 CFR 26.205(d)(7)(iii) requires licensees to state in their 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 within 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 licensees to evaluate the effectiveness of their 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 licensees to document the methods used to conduct the reviews and the results of the reviews.

10 CFR 26.205(e)(4) requires licensees 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.

The above eleven requirements are necessary to ensure that licensees and other entities are properly implementing 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 are necessary to enable licensees and other entities 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 programs, and to provide information for periodic audits. Recordkeeping requirements for section 26.205(c) and (d)(1) are established by section 26.203(d)(1); section 26.205(d)(2) through (d)(6) are established by section 26.203(d)(2); section 25.205(e)(1) through (e)(3) are established by section 26.203(d)(4); and, section 26.205(e)(4) are established by section 26.203(d)(4).

10 CFR 26.207(a)(4) requires licensees to document the bases for 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 is necessary to ensure that waivers and excepts 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 that documents the basis for the waiver and the identity of the person approving the waiver. Recordkeeping requirements for section 26.207 are established by section 26.203(d)(3).

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

10 CFR 26.211(f) requires licensees 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 is necessary to ensure that fatigue assessments of individuals are conducted in appropriate circumstances and in an appropriate manner. This requirement is necessary to ensure 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.

10 CFR 26.211(g) requires licensees to prepare an annual summary for each nuclear power plant site of instances of fatigue assessments that were conducted during the previous calendar year for any individual identified 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 is necessary to 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 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.

Recordkeeping requirements for section 26.211(f) and (g) are established by section 26.203(d)(5).

10 CFR 26.401(b) requires licensees and other entities who intend to implement an FFD program under Subpart K 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 is necessary to ensure licensees develop a FFD program to ensure worker fitness for duty prior for the start of construction of a nuclear reactor and that the document describing the FFD program is available for NRC review.

10 CFR 26.403(a) requires FFD programs under Subpart K to ensure that a clear, concise, written FFD policy statement is provided to individuals who are subject to the program. The policy statement must be written in sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy.

10 CFR 26.403(b) requires FFD programs under Subpart K to develop, implement, and maintain written procedures that address drug and alcohol testing program methods and techniques and procedures for ensuring valid results attributable to the correct individual, actions taken and procedures used for FFD violations, and the process to be followed for behavior that may raise concerns of possible FFD violations or impairment.

The written FFD policy and procedures required by Subpart K are the primary means by which a licensee or other entity communicates its FFD policy and procedures to individuals who are subject to the policy and procedures. These requirements are also necessary to ensure that individuals are protected by informing them in sufficient detail about licensee FFD rules, 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 very severe, including inability to perform certain functions in the industry, it is particularly important that all individuals who are potentially subject to them know their details.

10 CFR 26.405(a) requires licensees and other entities who implement a FFD program under subpart K to perform drug and alcohol 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.

10 CFR 26.405(c)(1) requires licensees 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 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) requires licensees to conduct post-accident testing as soon as practical after an event involving human error committed by individuals specified in section 26.4(f), where the human error may have caused or contributed to the accident. Licensees are required to test the individual(s) who committed the human error(s), but need not test individuals who were affected by the event but whose actions likely did not cause or contribute to the event, if the event resulted in: a significant illness or personal injury to the individual to be tested or another individual, which within 4 hours after the event is recordable under the Department of Labor standards contained in 29 CFR 1904.7 and subsequent amendments thereto, and results in death, days away from work, restricted work, transfer to another job, medical treatment beyond first aid, loss of consciousness, or other significant illness or injury as diagnosed by a physician or other licensed health care professional, if it does not result in death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness; or if it results in significant damage to any safety- or security-related SSC.

10 CFR 26.405(c)(4) requires licensees to conduct follow-up testing as part of a follow-up plan to verify an individual's continued abstinence from substance abuse.

10 CFR 26.405(d) requires licensees and other entities to test for specified drugs, adulterants, and alcohol at the cutoff levels specified in Part 26 and requires urine specimens collected for drug testing to be subject to validity testing.

10 CFR 26.405(e) requires the specimen collection and drug and alcohol testing procedures of FFD programs under Subpart K 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-certified laboratory. Any initial drug test performed by a licensee or other entity must use an immunoassay that meets U.S. Food and Drug Administration requirements for commercial distribution. Urine specimens that yield positive, adulterated, substituted, or invalid initial validity or drug test results must be subject to confirmatory testing by the HHS-certified laboratory, except for invalid specimens that cannot be tested. Other specimens that yield positive initial drug test results must be subject to confirmatory testing by a laboratory that meets stringent quality control requirements that are comparable to those required for certification by the HHS.

10 CFR 26.405(g) requires FFD programs under Subpart K to provide for an 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 individual designated by the licensee or other entity to perform the suitability and fitness evaluations required under section 26.419.

The above ten requirements are necessary to ensure testing occurs under all necessary circumstances. In order to ensure proper FFD is maintained testing must occur in pre-assignment, for cause, post-accident, follow-up, and random circumstances. These requirements also are necessary to ensure that specimens are tested for the specified drugs and that the testing is conducted properly.

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.

The above two requirements are necessary to ensure that fitness monitors know and understand the procedures established for the fitness monitoring program if the licensee or other entity elects to establish a fitness monitoring program. The preparation of the fitness monitoring policy and procedures is covered by section 26.403.

Section 26.407 requires that while the individuals specified in section 26.4(f) are constructing safety- or security-related SSCs, licensees and other entities shall ensure that these individuals are subject to behavioral observation, except if the licensee or other entity has implemented a fitness monitoring program under section 26.406. This requirement is necessary to ensure that if licensees and other entities elect to implement a random drug and alcohol testing program under section 26.405, they also implement behavioral observation under this section to deter substance abuse and detect indications of possible use, sale, or possession of illegal drugs, use or possession of alcohol on site, and impairment from any cause that if left unattended may result in a risk to public health and safety or the common defense and security.

10 CFR 26.411(a) requires licensees and other entities that collect personal information about an individual for the purpose of complying with Subpart K to establish and maintain a system of files and procedures to protect the personal information. FFD programs shall maintain and use such records with the highest regard for individual privacy.

10 CFR 26.411(b) requires licensees and other entities to obtain a signed consent that authorizes the disclosure of the personal information collected and maintained under Subpart K before disclosing the personal information, except for certain specified disclosures.

The above two information collection requirements are necessary to ensure the protection of personal information collected and maintained about individuals, and to ensure that such

information is not disclosed to persons other than assigned MROs, other licensees legitimately seeking the information as required by Part 26 for employment decisions and who have obtained a release from current or prospective employees or C/V personnel, NRC representatives, appropriate law enforcement officials, the individual subject or his or her representative, or those licensee personnel who have a need to have access to the information in performing assigned duties.

10 CFR 26.413 requires licensees and other entities that implement an FFD program to establish and implement procedures for the review of a determination that an individual in section 26.4(f) has violated the FFD policy. The procedure must provide for an objective and impartial review of the facts related to the determination that the individual has violated the FFD policy. These requirements are necessary to ensure that there are written procedures that specify how each FFD program ensures that the criteria for determining that an individual has violated FFD policy have been met and will provide individuals with a specified process for reviewing and appealing determinations that the individual has violated FFD policy. The requirements are necessary to ensure that the due process rights of individuals who are subject to the rule are protected by informing them with sufficient detail about licensee review procedures, what is expected of the individual, and what consequences may result from a lack of adherence to the policy. These requirements also partially meet the legal necessity of proving "prior notice" and having the review process documented for evidence in legal proceedings.

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

10 CFR 26.417(a) requires FFD programs under Subpart K to ensure that records pertaining to the administration of the program, which may be stored and archived electronically, are maintained so that they are available for NRC inspection purposes and for any legal proceedings resulting from the administration of the program.

10 CFR 26.417(b)(1) requires licensees and other entities who implement FFD programs to make reports to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers any intentional act that casts doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals who are subject to Subpart K. These events must be reported under Subpart K, rather than under the provisions of 10 CFR 73.71, because the events are associated with FFD programs at construction sites.

10 CFR 26.417(b)(2) requires licensees and other entities who implement FFD programs to make annual program performance reports for the FFD program.

The above three requirements are necessary to ensure that records are maintained by licensees and other entities that maintain collection sites and/or testing facilities, and by

laboratories certified by HHS that provide services to licensees and other entities, that demonstrate that drug and alcohol testing requirements are implemented properly. Such records are generally consistent with the requirements for HHS-certified laboratories in the HHS Guidelines, as well as with usual and customary business practices for such laboratories. These records are also necessary to enable licensees and other entities to review and correct any problems in implementing FFD drug and alcohol testing programs, and to enable the NRC to inspect the licensees' and other entities' drug and alcohol testing programs. This section groups recordkeeping requirements that apply to collection sites, testing facilities, and laboratories certified by HHS that provide services to licensees or other entities in one section in the rule, in order to improve clarity in the organization of the rule and to respond to requests from stakeholders.

These requirements are also necessary to ensure that licensees and other entities provide information about significant violations of FFD policy, testing errors, and other events affecting the performance of their FFD programs, including fatigue management, which will enable the NRC to ensure that those programs are adequately protecting public health and safety, common defense, and security. These reports are necessary to enable licensees and other entities to review and correct any problems in implementing FFD programs, and to enable the NRC to inspect the licensee's and other entities' FFD programs and to obtain information necessary to evaluate the effectiveness of the FFD programs. 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.

Section 26.419 provides that licensees and other entities who implement FFD programs under Subpart K shall 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) 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.

Although no records or reports are required by the above two paragraphs, they influence how the records and reports required by Part 26 will be made, 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 section 73.56, as supplemented by orders to nuclear power plants dated January 7, 2003, and subsequent rulemaking.

10 CFR 26.711(c) provides that licensees and other entities specified in section 26.3(a) and as applicable, section 26.3(c) and (d), shall inform each individual of his or her right to review information about the individual that is collected and maintained under Part 26 to assure its accuracy. Licensees and other entities are required to provide individuals with an opportunity to correct any inaccurate or incomplete information that is documented by licensees and other entities about the individual. This paragraph supplements the provisions in section 26.37 relating to protection of information and makes explicit that individuals can review and correct information about the individual collected and held by licensees or other entities.

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. The paragraph will ensure that information in the PADs system will be as correct and complete as possible.

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 ensure the retention and availability of 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.

The above eleven requirements are necessary to ensure that licensees and other entities collect and maintain records that demonstrate they are properly implementing FFD regulatory requirements in a manner adequate to protect public health and safety and the common defense and security. These records are also necessary to enable licensees and other entities to review and correct any problems in implementing FFD programs, including fatigue management, and to enable the NRC to review and audit the licensees' and other entities' FFD programs. This section groups recordkeeping requirements that apply to licensees and other entities in one section in the rule, in order to improve clarity in the organization of the rule and thereby to reduce the information collection burden associated with this recordkeeping.

10 CFR 26.715(a) requires collection sites providing services to licensees and other entities who are subject to Subpart N, LTFs, and HHS-certified laboratories to maintain and make available documentation of all aspects of the testing process for at least 2 two years or until the completion of all legal proceedings related to the determination of an FFD violation, whichever is later, and also provides that the 2-year period may be extended upon written notification by the NRC or by any licensee or other entity for whom services are being provided.

10 CFR 26.715(b) specifies that the documentation that must be retained pursuant to section 26.715(a) include the following:

- 10 CFR 26.715(b)(1): Personnel files, including training records, for all individuals who have been authorized to have access to specimens, but are no longer under contract to or employed by the collection site, LTF, or HHS-certified laboratory;
- 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): Quality assurance and quality control records;
- 10 CFR 26.715(b)(4): Superseded procedures;
- 10 CFR 26.715(b)(5): All test data (including calibration curves and any calculations used in determining test results);
- 10 CFR 26.715(b)(6): Test reports;
- 10 CFR 26.715(b)(7): Records pertaining to performance testing;
- 10 CFR 26.715(b)(8): Records pertaining to the investigation of testing errors or unsatisfactory performance discovered in quality control or blind performance testing, in the testing of actual specimens, or through the processing of appeals and MRO reviews, as well as any other errors or matters that could adversely reflect on the integrity of the testing process, investigation findings, and corrective actions taken, where applicable;
- 10 CFR 26.715(b)(9): Performance records on certification inspections;
- 10 CFR 26.715(b)(10): Records of preventative maintenance on licensee testing of facility 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-certified laboratories; and,
- 10 CFR 26.715(b)(14): Records of the inspection, maintenance, and calibration of EBTs.

The above requirements are necessary to ensure that records are maintained by licensees and other entities that maintain collection sites and/or testing facilities, and by laboratories certified by the HHSs that provide services to licensees and other entities, that demonstrate that drug and alcohol testing requirements are implemented properly. Such records are generally consistent with the requirements for HHS-certified laboratories in the HHS Guidelines, as well as with usual and customary business practices for such laboratories. These records are also necessary to enable licensees and other entities to review and correct any problems in implementing FFD drug and alcohol testing programs, and to enable the NRC to inspect the licensees' and other entities' drug and alcohol testing programs.

10 CFR 26.717(a) requires licensees and other entities to collect and compile FFD program performance data.

10 CFR 26.717(b) specifies that the FFD program performance data must include the following information:

- 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., individuals in applicant status, permanent licensee employees, C/Vs);
- 10 CFR 26.717(b)(4): Number of tests administered and results of those tests sorted by population tested (i.e., individuals in applicant status, permanent licensee employees, C/Vs);
- 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): The information on review of work hour controls required under section 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 the 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 any licensee or other entity who terminates an individual's authorization or takes administrative action on the basis of the results of a positive initial drug test for marijuana or cocaine to report those test results in the annual summary by processing stage (i.e., initial testing at the LTF, testing at the HHS-certified laboratory, and MRO determinations) and to include the number of terminations and administrative actions taken against individuals in the reporting period.

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 drug and alcohol 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.

These performance data reporting requirements are necessary to ensure that licensees and other entities provide information about the performance of their FFD programs that will enable the NRC to ensure that those programs are adequately protecting public health and safety. These reports also are necessary to enable licensees and other entities to review and correct any problems implementing FFD programs, and to enable the NRC to inspect these programs and to obtain information necessary to evaluate the effectiveness of the programs. Collection of information pertaining to significant FFD events is necessary to permit evaluations of events that might become problems and that may require actions (e.g., inspection or licensing actions) by the NRC staff to help ensure the health and safety of the public and the common defense and security.

10 CFR 26.719(a) requires licensees and entities subject to Part 26 to inform the NRC of significant violations of the FFD policy, significant FFD program failures, and errors in drug and alcohol testing, and to report under section 26.719 rather than section 73.71.

10 CFR 26.719(b) requires licensees and entities subject to Part 26 to 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 acts by any person who is licensed under 10 CFR Parts 52 and/or 55 to operate a power reactor, as well as any acts by SSNM transporters, FFD program personnel, or any supervisory personnel who are 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 the duties that require the individual to be subject to the FFD program.
- 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 the licensee or other entity to submit to the NRC a report within 30 days following completion of an investigation of any testing errors or unsatisfactory performance discovered in performance testing at either a LTF or an HHS-certified laboratory, in the testing of quality control or actual specimens, or through the processing of reviews under section 26.39 and MRO reviews under section 26.185, as well as 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 report of the incident and corrective action taken or planned. If the error involves an HHS-certified laboratory, the NRC shall ensure that HHS is notified of the finding.

10 CFR 26.719(c)(2) requires the licensee or other entity to notify the NRC within 24 hours following discovery of a false positive error on a blind performance test sample submitted to an HHS-certified laboratory.

10 CFR 26.719(c)(3) requires the licensee or other entity to notify the NRC within 24 hours following discovery of a false negative error on a quality assurance check of validity screening tests required by section 26.137(b).

10 CFR 26.719(d) requires the licensee or other entity to 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 drug and alcohol test results in a manner that permits the identification of any individuals.

The above six requirements are necessary to ensure that licensees and other entities provide information about significant violations of FFD policy, testing errors, and other events affecting the performance of their FFD programs that will enable the NRC to ensure that those programs are adequately protecting public health and safety, common defense, and security. These reports are necessary to enable licensees and other entities to review and correct any problems in implementing FFD programs, and to enable the NRC to inspect the licensee's and other entity's FFD program 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 help ensure the health and safety of the public and protection of the environment.

10 CFR 26.821(a) requires licensees and other entities to permit duly authorized NRC representatives to inspect, copy, or take away copies of its records as necessary to accomplish the purposes of Part 26. 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 licensees' and other entities' FFD programs, verify compliance, and to obtain information necessary to develop public policy.

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).

## 2. Agency Use of Information

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

- To monitor compliance with Part 26 requirements to ensure that the FFD Program for each licensee and other entities is adequate to protect public health and safety, promote the common defense and security, and protect the environment;
- To be informed of FFD-related problems and events 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 drug and alcohol testing and fatigue management performance information to analyze trends and lessons learned, and to identify site-specific or industry-wide issues requiring NRC licensing or inspection response, generic communication, or rulemaking.

## 3. Reduction of Burden through Information Technology

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

Approximately 95 percent of the reports that licensees and other entities submit to the NRC pursuant to sections 26.717 and 26.719 (drug and alcohol programs) and 26.203(e) (fatigue management programs) are electronically transmitted. Further, these licensees and other entities voluntarily use electronic forms, developed by the NRC in coordination with the industry, to report FFD program performance data. This has improved reporting efficiency, enhanced the consistency and accuracy of reported information, and enabled the use of information technology for data assessment and evaluation.

## 4. Efforts to Identify Duplication and Use Similar Information

Certain records referenced in Subpart G associated with HHS-certified laboratories are required to be kept, pursuant to the HHS Guidelines, to enable a records review under the standards of the National Laboratory Certification Program (a program administered by HHS). The development, maintenance, and storage of these records are also consistent with usual and customary business practices for forensic laboratories. 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 this rule 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 records required by Part 26 pertaining to drug and alcohol testing, including data about the performance of specimen collection sites, Licensee Test Facilities (LTFs), and HHS-certified laboratories; the chain of custody of specimens, laboratory test results, quality assurance and quality control procedures; the inspection, maintenance, and calibration of laboratory instruments; the training and qualifications of FFD program personnel; and, the security of specimen collection, storage, and testing facilities are standard components of all forensic specimen collection and testing programs. If these records are not developed, maintained, and stored in a timely and comprehensive manner, the scientific accuracy and validity of test results and the performance objectives of the FFD program cannot be assessed or verified nor can the rights of individuals subject to the program be protected and assured. Collection of information pertaining to individuals' past employment, past periods of authorization, if any, including authorization denial or unfavorable termination, past arrest record, and other potentially disqualifying FFD information also must be complete and must take place at the time that FFD authorization decisions are made, or inappropriate authorizations (i.e., inappropriate permission obtained to gain unescorted access to the protected area of a NRC-licensed facility) may be granted.

Records and reports associated with fatigue management are necessary to ensure that persons are capable of safely and competently performing their assigned tasks. If fatigue management records/reports are not collected or are obtained less frequently, persons who are fatigued and unable to safely and competently perform assigned duties could be assigned to operate or perform work at a nuclear power plant. This could result in conditions adverse to safety and/or security at nuclear power plants.

The annual report on the performance of licensees' and other entities' FFD programs provides data that is necessary for the NRC to assess whether FFD programs meet regulatory requirements, whether adverse trends are occurring that require regulatory action, and/or whether rulemaking is necessary to amend current requirements. Receiving FFD program performance data at least annually is necessary because a longer period of time could result in substantial program deterioration that could result in adverse conditions to public health and safety, common defense or security, or protection of the environment.

Overall, the Part 26 recordkeeping and reporting requirements contribute to the conduct of NRC inspection and licensing review to ascertain whether a licensee or other affected entity is in compliance with the requirements of Part 26.

7. Circumstances which Justify Variation from OMB Guidelines

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

10 CFR 26.77(c) requires a licensee or other entity that has a reasonable belief that an NRC employee or NRC contractor may be under the influence of any substance, or is otherwise unfit for duty, to immediately notify the appropriate Regional Administrator by telephone, followed by written notification (e.g., email or fax) to document the verbal notification. If the Regional Administrator cannot be reached, the licensee or other entity

must notify the NRC Operations Center. The immediate notification is necessary to inform the NRC of potential FFD violations by NRC staff, so that the NRC can address the situation immediately.

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

10 CFR 26.417(b)(1) requires licensees and other entities to report to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers any intentional act that casts doubt on the integrity of the Subpart K FFD program and any programmatic failure, degradation, or discovered vulnerability of the Subpart K FFD program that may permit undetected drug or alcohol use or abuse by individuals subject to Subpart K. This requirement is necessary to ensure, in part, that the NRC is timely informed so that appropriate regulatory actions can be initiated.

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

10 CFR 26.719(c)(2) requires licensees or other entities to report a false positive error that occurs on a blind performance test sample submitted to an HHS-certified laboratory within 24 hours of the discovery of the error. Because positive test results can result in significant actions taken by FFD programs, it is important that a false positive experienced by one FFD program be reported to the NRC immediately so that actions can be taken to provide notice to other FFD programs that a particular laboratory may be experiencing analytic problems.

10 CFR 26.719(c)(3) requires licensees or other entities to report a false negative error that occurs on a blind performance test sample submitted to an HHS-certified laboratory within 24 hours of the discovery of the error. Because negative test results can result in significant actions taken by FFD programs, it is important that a false negative experienced by one FFD program be reported to the NRC immediately so that actions can be taken to provide notice to other FFD programs that a particular laboratory may be experiencing analytic problems.

The following 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)(3) requires written permission from the donor before additional testing may be authorized by the MRO to proceed at a second HHS-certified laboratory for specimens with a confirmed positive, adulterated, or substituted test result. If a donor wants retesting of an aliquot of a single specimen or the testing of the bottle B (split specimen), he or she must request it in writing within 3 business days. The time

requirement is needed to ensure that the specimen(s) are retested quickly and do not deteriorate before retesting. The requirement protects the due process rights of donors.

10 CFR 26.169(a) requires the HHS-certified laboratory to report test results to the MRO of the licensee or other entity within 5 business days after receiving the specimen for testing. The requirement for reporting within 5 business days ensures that the FFD program can take prompt action if the test results indicate that the authorization of the individual should be withdrawn or that there is evidence of tampering, adulteration, or substitution that should be investigated that must be investigated promptly to ensure that the results of other tests are not affected in the same way.

10 CFR 26.169(h) requires the HHS-certified laboratory to provide to the licensee's or other entity's official responsible for coordination of the FFD program an annual statistical summary of urinalysis testing within 14 calendar days after the end of the 1-year period covered by the report. This requirement provides information from which the NRC can monitor the effectiveness of drug testing activities.

The following 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 specified records pertaining to the fatigue management program should be kept for at least 3 years, which is consistent with the OMB guidance, or until the completion of all related legal proceedings, whichever is later. The latter requirement is necessary to ensure that records pertaining either to a legal proceeding or NRC enforcement action against a licensee or other entity are available for review and use. The requirement protects the due process rights of licensees, other entities, and of individuals.

10 CFR 26.711(a) requires that if a retention period is not otherwise specified in the appropriate section of Part 26, records must be retained until the Commission terminates the facility license. This requirement is necessary to ensure that records are available should an individual, the NRC, a licensee, or another entity that is subject to the rule require access to them in a legal or regulatory proceeding.

10 CFR 26.713(a) requires that records of self-disclosures, employment histories, and suitable inquiries, records pertaining to the determination of a violation of the FFD policy and related management actions, documentation of the granting and termination of authorization, and records of any determinations of fitness conducted under section 26.189 must be retained for at least 5 years after the licensee or other entity terminates or denies an individual's authorization or until the completion of all related legal proceedings, whichever is later. The requirement to retain records for at least 5 years is necessary to ensure that licensees and other entities who may be considering granting authorization to an individual can obtain these records for review as part of the authorization decision-making process. The NRC considers that retention of these records for only 3 years will not be sufficient to ensure that individuals will be identified who seek reauthorization with a licensee or other entity after previously having violated an aspect of the FFD program. The requirement to retain records until the completion of all related legal proceedings was added at the suggestion of external stakeholders during public meetings. The stakeholders noted that some legal proceedings involving records of the type specified in the paragraph

have continued longer than the 5 years and that this recordkeeping protects an individual's right to due process under the rule.

10 CFR 26.713(b)(1) and (b)(2) requires that licensees and other entities retain records of FFD training and examinations, and of FFD audits, audit 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. The NRC again added the requirement to retain records until the completion of all related legal proceedings at the suggestion of stakeholders during public meetings to address the possibility of protracted legal proceedings.

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

10 CFR 26.713(d) requires that licensees and other entities retain superseded FFD policies and procedures for at least 5 years or until they no longer need to respond to a legal challenge. The 5 year time period ensures that the materials are available if subsequent licensees and other entities require the information in validating a determination of fitness made at the time the procedures were in effect. The requirement also requires that FFD policy and procedures related to any matter under legal challenge are maintained until the matter is resolved, should an individual, the NRC, a licensee, or another entity who is subject to this rule require access to them in a legal or regulatory proceeding.

10 CFR 26.713(e) requires licensees and other entities to retain the written agreement for the life of the agreement or until completion of all legal proceedings related to an FFD violation that involved the services, whichever is later. The requirement to retain the written agreements for any matter under legal challenge until the matter is resolved has been added to ensure that the materials remain available, should an individual, the NRC, a licensee, or another entity who is subject to the rule require access to them in a legal or regulatory proceeding.

10 CFR 26.713(f) requires licensees and other entities to retain records related to the background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel, conducted under section 26.31(b)(1)(i), for the length of the individual's employment by or contractual relationship with the licensee or other entity, or until the completion of all related legal proceedings, whichever is later. The

retention period is based on the NRC's need to have access to the records for inspection purposes and the potential need for the records to remain available should an individual, the NRC, a licensee, or another entity who is subject to this rule require access to them in a legal or regulatory proceeding. However, the rule establishes a limit on the period during which the records must be retained in order to reduce the burden associated with storing such records indefinitely.

10 CFR 26.713(g) requires licensees and other entities to retain records of the certification of the scientific and technical suitability of any assays and cutoff levels used for drug testing that are not addressed in Part 26, provided by a qualified forensic toxicologist, as required under section 26.31(d)(1)(i) and (d)(3)(iii)(C). The licensee or other entity is required to retain these records for the period of time during which the FFD program continued to test for drugs for which testing is not required under Part 26, uses more stringent cutoff levels than those specified in Part 26, or until the completion of all related legal proceedings, whichever is later. The retention period is necessary to ensure the NRC's access to the records for inspection purposes and that the records remain available should an individual, the NRC, a licensee, or another entity that is subject to this rule require access to them in a legal or regulatory proceeding.

10 CFR 26.715(a) requires collection sites providing services to licensees and other entities, LTFs, and HHS-certified laboratories to maintain and make available documentation of all aspects of the testing process for at least two years, which is consistent with OMB guidance, or until the completion of all legal proceedings related to the determination of an FFD violation, whichever is later. The section also provides that the 2-year period may be extended upon written notification by the NRC or by any licensee or other entity for which services are being provided. This requirement is necessary to ensure access to the records by the NRC or by a licensee or other entity securing services from the collection site or the HHS-certified laboratory for inspection purposes and that the records remain available should an individual, the NRC, a licensee, or another entity who is subject to this rule require access to them in a legal or regulatory proceeding.

10 CFR 26.717(c) requires a licensee and any other entity that has a licensee-approved FFD program to analyze the FFD program performance data at least annually and to retain records of the data, analyses, and corrective actions taken for at least three years, which is consistent with OMB guidelines, or until the completion of any related legal proceedings, whichever is later. This retention is necessary to ensure that the records remain available should an individual, the NRC, a licensee, or another entity that is subject to this rule require access to them in a legal or regulatory proceeding.

#### 8. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package was published in the *Federal Register* on February 19, 2014 (79 FR 9489).

The requirements of Part 26 are discussed on a continuing basis with representatives from affected stakeholders such as the Nuclear Energy Institute, nuclear power plants, fuel cycle fabrication facilities, HHS-certified laboratories, and other entities subject to the rule to help ensure that the rule is clear, effective, and does not represent an unnecessary burden. Furthermore, the NRC consults with the HHS, Office of National Drug Control Policy, National Institute on Drug Abuse, and U.S. Department of Transportation to ensure that the Part 26

requirements are consistent with other Federally-mandated drug and alcohol testing programs.

The NRC received one question from the Nuclear Energy Institute on February 22, 2014, seeking clarification about the use of the terms “respondent” and “3<sup>rd</sup> party respondent” in the clearance update.

*Question:*

Can you tell me what the term “respondent” and “3<sup>rd</sup> party respondent” refers to?

*NRC staff response:*

#### Respondent

For this collection, a “respondent” is any member of the public (i.e., someone who is not a Federal employee) who is responding to the information collection activities within 10 CFR Part 26. A respondent is anyone who is reporting to the NRC, keeping records, or disclosing information to a third party.

Typically, the respondent is the licensee submitting required information to the NRC (e.g. Section 26.719 – annual performance reports, 24-hour event reports) – see *Table 3 Annual Reporting Burden* in the supporting statement.

Due to the complexities of Part 26, a number of additional parties may need to provide information directly to the licensee (and not NRC). For example, a respondent can be an individual who provides a self-disclosure and employment history to the licensee per 26.61(a) so that an access authorization determination can be made – see *Table 4 Annual Third-Party Burden* in the supporting statement. Another example of a respondent is an HHS-certified laboratory that provides to each licensee on an annual basis a summary of drug testing results and also provides laboratory drug test results directly to the licensee MRO for review.

#### 3<sup>rd</sup> Party

A “third-party” disclosure is defined in 5 CFR 1350 as a requirement “for a person to obtain or compile information for the purpose of disclosure to members of the public... through posting, notification, labeling or similar disclosure requirements.” Again, “the public” refers to a person or organization other than a Federal employee or Federal entity.

An example of a disclosure of information to a third-party can be found in Section 26.53(h), in which the licensee must disclose information to the individual applying for authorization:

“The licensee or other entity to whom the individual has applied for authorization shall inform the individual that—

- (1) Withdrawal of his or her consent will withdraw the individual's current application for authorization under the licensee's or other entity's FFD program; and
- (2) Other licensees and entities will have access to information documenting the withdrawal as a result of the information sharing that is required under this part."

Further, a 3<sup>rd</sup> party can be the licensee if the rule requires individuals to report info to licensees (i.e., 2<sup>nd</sup> party is individual, 3<sup>rd</sup> party is licensee).

#### 9. Payment or Gift to Respondents

Not applicable.

#### 10. Confidentiality of the Information

Section 26.37 requires, in part, that each licensee or other entity who collects personal information about an individual for the purpose of complying with Part 26 to establish and maintain a system of files and procedures to protect the personal information, and to maintain and use such records with the highest regard for individual privacy. Personal information collected under Part 26 is maintained by the licensee and 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, 26.33, 26.35, 26.39, 26.61 through 26.70, 26.75, 26.77, 26.85, 26.115, 26.117, 26.119, 26.165, 26.183, 26.185, 26.189, 26.211, 26.411, 26.713, and 26.719 require each licensee or other entity to collect personal information (e.g., personally identifiable, medical, criminal, financial, etc., information) for the purpose of complying with Part 26. It is necessary to obtain this information to accomplish the performance objectives of Part 26, which include providing reasonable assurance that individuals who are subject to Part 26 are trustworthy and reliable as demonstrated by the avoidance of substance abuse and providing reasonable assurance that: individuals who are subject to Part 26 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 subject to Part 26 are free from the presence and effects of illegal drugs and alcohol 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; and to provide reasonable measures for the early detection of individuals who are not fit to perform the job duties that require them to be subject to Part 26.

#### 12. Estimate of Industry Burden and Costs

The estimated burden and costs associated with administering a drug and alcohol testing program that meets the requirements of 10 CFR Part 26, Subparts, A – H, M, N, and O (i.e., a full program) is based on the following 28 programs:

- operating commercial nuclear power reactors (24 programs)

- fuel-cycle facilities (2 programs)
- decommissioning commercial nuclear power reactor (1 program)
- C/V (1 program).

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

- commercial nuclear power reactor construction sites (2 programs).

The estimated burden and costs associated with administering the Subpart I, fatigue management program, is based on the following 23 programs:

- operating commercial nuclear power reactors (22 programs)
- C/V (1 program).

The previous collection period estimated “32 FFD Programs”, with each licensee and other entity managing the drug and alcohol testing and fatigue management elements of Part 26 as a single FFD program. However, based on information gained since the last clearance, NRC staff has separated the drug and alcohol and the fatigue programs because this is consistent with licensee and other entity management practice and more precisely reflects the burden and costs of the rule. This initiative enhances precision and clarity to the burden estimates represented in Tables 1 – 5. The NRC describes this initiative in more detail in Section 15.

The total number of respondents for this clearance period is estimated to be 98,630 and consists of 30 (28 + 2 = 30 from above) drug and alcohol programs, 23 fatigue management programs, 12 HHS-certified laboratories, and 98,565 third-party respondents<sup>1</sup>.

Multiplying the total number of burden hours by \$272 per hour (from 10 CFR 170.20) results in the following 2014 – 2017 clearance estimates:

<b>Table</b>	<b>Description</b>	<b>Burden Hours</b>	<b>Cost at \$272/hour</b>
1	One-Time Recordkeeping	41.4	\$11,261
2	Recordkeeping	314,177.4	\$85,456,253
3	Reporting	6,165.2	\$1,676,934
4	Third Party Disclosure	303,559.1	\$82,568,062
	<b>TOTAL</b>	<b>623,943.1</b>	<b>\$169,712,510</b>

<sup>1</sup> Third-party respondents include an estimated 98,565 persons (i.e., pre-access tests results for 2012 = 93,890 persons subject to full drug and alcohol programs plus 4,675 at Subpart K reactor construction sites).

13. Estimates of Other Additional Costs

One additional cost for the 2014 – 2017 clearance is for records storage. The quantity of records estimated to be maintained is roughly proportional to the recordkeeping burden and therefore can be used to calculate approximate records storage costs. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to 0.0004 times the recordkeeping burden cost. Therefore, the records storage cost for the current clearance is estimated to be \$67,214.2 (Tables 1+2+4 = 617,777.9 recordkeeping hours x \$272/hour x 0.0004).

14. Estimated Annualized Cost to the Federal Government

Table 5 presents the estimated annual cost to the NRC for administration 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 Parts 170. Using \$272/hour, the total estimated cost to government is:

Table	Burden Area	Hours	Cost (dollars)
5	NRC	3,107	\$845,104

15. Reasons for Change in Burden or Cost

The total burden for Part 26 changed from 667,080.6<sup>2</sup> hours to 623,943.1 hours, a decrease of 43,137.5 hours. The burden is summarized below and as detailed in Tables 1 – 4.

Table	Description	Clearance Period		Difference between the 2011-2014 and 2014-2017 Collections (hours)
		2011-2014 (hours)	2014-2017 (hours)	
1	One-Time Recordkeeping	6,720.4	41.4	-6,679.0
2	Recordkeeping	351,889.6	314,177.4	-37,712.2
3	Reporting	6,615.0	6,165.2	-449.8
4	Third Party Disclosure	301,855.6	303,559.1	1,703.5
<b>TOTAL</b>		<b>667,080.6</b>	<b>623,943.1</b>	<b>-43,137.5</b>

Changes to the total burden are based on the following 11 reasons:

(1) Separating Drug and Alcohol Programs from Fatigue Management Programs

For the previous collection period, the NRC assumed that licensees and other entities would manage the drug and alcohol program and the fatigue management program as a single FFD program (for that clearance 32 FFD programs were estimated). However, based on the review of licensee and other entity records and reports, the NRC determined that most licensees and other entities separately manage a drug and alcohol program and a fatigue management program. To add clarity to the burden estimate, the NRC more precisely presents the burden associated with each of these two programs throughout this clearance, referring to “drug and

<sup>2</sup> Note that burden totals for 2011-2014 include burden from the 2011 renewal as well as the Alternative to Minimum Days Off Requirements Final Rule.

alcohol” and “fatigue management” as separate programs rather than using the term “FFD program.” See paragraph (5) for additional discussion. For this current clearance period, NRC staff estimate 30 drug and alcohol programs and 23 fatigue programs. This change affects Tables 1 – 5.

## (2) Reactor Construction Sites – Subpart K Drug and Alcohol Programs

For the previous collection, the NRC assumed that only one Subpart K reactor construction site (i.e., 2 units at Vogtle electric generating plant) would be subject to Part 26 requirements. However, in fact, the industry commenced construction at an additional site (2 units at V.C. Summer nuclear station). In this current collection, these four commercial nuclear power reactors will remain under construction and NRC anticipates no new reactor construction at additional sites this clearance period.

The NRC elected to separate the drug and alcohol programs for the two Subpart K reactor construction sites from the operating reactor programs. This was done because the Part 26 recordkeeping and reporting requirements for operating reactors are more robust and result in a different burden than the Subpart K, requirements for a drug and alcohol program at a reactor construction site. Furthermore, the NRC staff review of electronically-reported site-specific FFD program performance data for drug and alcohol testing at operating reactors and reactor construction reactors determined differences in burden between operating and construction sites primarily due to differences in the number of tests conducted, percentage of positive test results, and other programmatic considerations. The separation of the Subpart K reactor construction site programs from operating reactor programs adds clarity and precision to the burden estimate.

In addition to the Subpart K requirements for a drug and alcohol program at a reactor construction site, Part 26 also requires reactor construction site entities to implement a drug and alcohol program equivalent to that of a full operating reactor program (10 CFR Part 26, Subparts A – H, M, N, and O) for higher-level supervisors, persons who perform specific activities, and FFD program personnel (such as the FFD manager, specimen collection personnel, and the MRO). As a result, the licensees for the power reactor units under construction (Vogtle and V.C. Summer), subject these employees and C/Vs to a full drug and alcohol testing program and have elected to include these personnel in the drug and alcohol program implemented at the co-located, operating power reactor(s). This assumption accounts for the burden associated with site personnel that may work on the reactor construction site as well as the operating reactor site. The third reactor construction site Watts Bar nuclear plant, unit 2, is discussed in paragraph (4) below. This change affects Tables 1 – 5.

## (3) Corporate-based FFD Programs for Multiple Facilities

For this collection period, the NRC reassessed the corporate ownership of each facility, because a corporate-based FFD program tends to result in lower per site burden and cost for some activities (e.g., a corporate-based FFD program would use the same policy statement to comply with section 26.27(b) for each of its sites instead of creating unique site-specific policy statements, as would be the case had each site been owned by a different corporate entity). A corporate-based FFD program may administer FFD activities at one or more of its facilities through a single drug and alcohol program and a single fatigue management program, with site-specific costs being passed on to the affected facilities. Furthermore, in order to reduce costs, multiple sites within a corporate structure may share computer-based technology systems,

MROs, SAEs, collection companies, and HHS-laboratories, and also may conduct joint audits. The difference in the number of drug and alcohol programs and the number of fatigue management programs in this collection period is primarily due to consolidation in the industry resulting in additional facilities now being managed by corporate-based FFD programs. The NRC learns of these changes after the acquisitions have been implemented; this makes precise and accurate estimates difficult. The change in the number of corporate programs affects the burden estimate in Tables 2 – 4.

#### (4) Status of Operating Commercial Nuclear Power Reactors

For this collection period, the collection assumes that there will be 100 operating commercial nuclear power reactors in the United States located at 61 facilities, with each facility consisting of one or more reactor units.

- In 2013, four commercial nuclear power reactors (Crystal River 3, Kewaunee, and San Onofre 2 & 3) permanently shutdown and are no longer subject to Part 26 requirements.
- In 2014, one commercial nuclear power reactor (Vermont Yankee) announced its intention to permanently shutdown and will no longer be subject to Part 26 requirements.
- The last collection did not account for the permanently shutdown facility (Zion 1 & 2) and for this collection period, Zion likely will no longer be subject to Part 26; however, the licensee has not yet announced when this will occur. As a result, NRC conservatively assumes that this facility will be subject to the Part 26 drug and alcohol testing provisions for the duration of this clearance period.
- As a voluntary option, one reactor construction entity (Watts Bar 2) elected to place all its reactor construction-related personnel in the full drug and alcohol program being implemented at the co-located operating power reactor. Therefore, the burden associated with this reactor construction entity is accounted for in the 28 operating reactor drug and alcohol programs.

The NRC does not collect actual costs associated with the Part 26 drug and alcohol programs and therefore cannot publish comparative burden values between a full drug and alcohol program for an operating power reactor and a Subpart K reactor construction site program. However, based on site-specific drug and alcohol testing data provided to the NRC, burden represented in this collection is more precise and accurate than the previous collection. The change in operating of affected entities affects the burden estimate in Tables 1 – 5.

#### (5) Fatigue Management Programs

For fatigue programs, burden estimates were adjusted for the current period due to a reduction in respondents from 29 FFD programs to 23 fatigue management programs. This resulted in a burden reduction associated with the fatigue management provisions.

Licensees and the one affected C/V have the option to implement the voluntary alternative to control work hours by limiting the maximum average hours worked to 54-hours per week. Based on industry information, the NRC estimates that 2 fatigue management programs will transition to the 54-hour work control provision every year for the next 3 years. The burden to make this transition is relatively small (Table 1). The burden is estimated to be equivalent to the minimum days off work-control provisions and affects (Tables 1 – 3).

#### (6) Two Newly Identified Third-Party Burdens

The NRC identified two additional burdens on third-party entities. The first is section 26.4 that requires training be provided to persons subject to a drug and alcohol testing program regulated by another Federal agency or State, but who are not covered by training elements described in Part 26. For the current collection period, the NRC conservatively estimates that half of the commercial nuclear power reactor industry has individuals subject to other State or Federal drug and alcohol testing programs and the other half to be subject to the licensee's FFD program. Further, these State and Federal entities are required to ensure that the licensee granting authorization is notified of any FFD policy violation. This requirement results in a relatively low third-party burden.

The second additional burden identified by the NRC is section 26.209 that requires individuals subject to the fatigue management provisions of 10 CFR Part 26, Subpart I, to self-declare whether they are fatigued prior to or during the conduct of work. All fatigue programs must implement the self-declaration provisions. Based on industry data, the NRC staff assumes that all fatigue programs have persons that will implement the self-declaration provision. This requirement results in a relatively low third-party (Table 4) burden estimate.

#### (7) Burden Consolidation

The requirements described in section 26.719(c)(1) – (3) were combined into a single item in Table 5 to more accurately account for the burden resulting from these requirements. . In addition, the NRC burden per review was reduced from 16 hours to 4 hours, based on staff experience conducting these reviews. These requirements are for the reporting of events and occurrences to the NRC involving testing errors at a licensee testing facility (LTF) and/or an HHS-certified laboratory.

#### (8) Mixed-Oxide (MOX) Fuel Fabrication Facility

The MOX facility is now expected to implement a drug and alcohol program after the 2014 – 2017 clearance period. The previous burden estimate also did not include the MOX facility.

#### (9) HHS-certified Laboratories

Based on site-specific drug and alcohol data obtained through NRC FFD program performance reports, the number of HHS-certified laboratories increased from 10 to 12. This change affects the burden estimate in Tables 2 and 3.

#### (10) Licensee Testing Facilities (LTFs)

Based on site-specific FFD program performance laboratory drug testing data, the number of LTFs decreased from 31 to 7. This change in the number of LTFs is based on improved information obtained from industry rather than a change in the number LTFs use by the industry since the previous clearance. Nonetheless, this reduction in the number of drug and alcohol programs using LTFs results in reduced burden estimates in Table 2 and 3.

#### (11) Voluntary Use of NRC's FFD Program Performance Electronic Reporting Forms

The current submission includes three electronic reporting forms (i.e., e-forms) that were developed by the NRC, with input from industry, to improve reporting efficiency:

- NRC Form 890, "Single Positive Test Form;"
- NRC Form 891, "Annual Reporting Form for Drug and Alcohol Tests;" and
- NRC Form 892, "Annual Fatigue Reporting Form."

The forms provide a voluntary alternative means of reporting information required under 26.717 for drug and alcohol tests and 26.203(e) for fatigue and work hour controls. Licensees may still report this information in any format they choose; however, the forms provide a more efficient and standardized way of reporting should licensees choose to use them. The time to complete the forms is based on the estimates established for the associated requirements in the previous clearance package (2011-2014 clearance period).

While the current submission is based on responses received from these three forms, the previous collection estimate was primarily informed by licensee-provided, hard-copy, FFD reports and records, information gained from discussions with industry representatives, and technical staff evaluation. This information was accurate, yet difficult to quantitatively evaluate. The NRC provided footnotes in the tables to describe what performance data was used in its burden estimate.

The information used in this current collection is more precise and accurate because: (1) program implementation costs have been qualitatively shared with the NRC over the last three years and (2) a majority of licensees and affected entities voluntarily use the NRC-provided e-forms for drug, alcohol, and fatigue performance data. The forms outline the specific information required to be submitted to the NRC, collect information in a uniform way, and enable more sophisticated data evaluation and assessment by the NRC.

Blank e-forms can be obtained from the following NRC website:

<http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/submit-ffd-reports.html>

E-forms completed by licensees and other entities, as well as the NRC's annual summary report for calendar year 2012, can be viewed at the following:

- a. Licensee and other entity specific FFD performance data submittals for drug and alcohol programs (sections 26.717 and 26.719) and fatigue management programs (section 26.203(e)) can be viewed in the NRC's Agencywide Documents Access and Management System located at: [www.nrc.gov/reading-rm/adams.html](http://www.nrc.gov/reading-rm/adams.html).
- b. The NRC annual report titled "Summary of Fitness for Duty Program Performance Reports for Calendar Year 2012," and past years, can be viewed at: [www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/performance-reports.html](http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/performance-reports.html).

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

Table 1, One-time Recordkeeping Burden (annualized)

The changes in Table 1 were primarily due to the change in the number of programs incurring one-time burden.

- For drug and alcohol programs, the previous clearance estimated that one (1) respondent would incur a one-time recordkeeping burden to develop and implement a program. For the current period, no new drug and alcohol programs are anticipated.
- For fatigue programs, the previous clearance was based on 27 fatigue programs implementing the Part 26 fatigue management requirements. For the current period, similar to the drug and alcohol testing programs, these fatigue management programs have already incurred a one-time burden.

The NRC estimates that two fatigue programs per year will voluntarily implement the 54-hour/week work control provision. Respondents will incur a one-time burden represented in section 26.203(a)-(c) and section 26.205(b)-(c) to transition to the alternative work-hour counting requirement.

#### Table 2, Annual Recordkeeping Burden

The burden estimate in Table 2 decreased by approximately 10.5 percent. This decrease was primarily due to changes in the number of recordkeepers based on whether the particular requirement is applicable to the program being implemented by the recordkeeper. Changes also resulted from the separation of the drug and alcohol program from the fatigue program, corporate restructuring, number of HHS-certified laboratories and LTFs, and quantitative data on the number of activities conducted (e.g., samples submitted, background checks conducted, consent forms completed, documents associated with medical officer reviews). Further, the NRC adjusted the burden-hour estimate per activity to correlate more precisely with the level of effort associated with the required record (i.e., documentation).

For fatigue-related requirements, the burden hours for section 26.203(a)-(c) were added due to the incorporation of the voluntary 54-hour/week work hour control provision found in section 26.205(d)(7). Two new provisions were added that were not previously identified in sections 26.4 and 26.9. The burden associated with these requirements is small.

#### Table 3, Annual Reporting Burden

The changes in the Table 3 burden estimate were primarily due to changes in the number of respondents which is based on whether the particular requirement is applicable to the program being implemented by the respondent. Changes also resulted from the separation of the drug and alcohol program from the fatigue program, corporate restructuring, number of HHS-certified laboratories and LTFs, and quantitative data on the number of activities conducted (e.g., samples submitted, background checks conducted, consent forms completed, documents associated with medical officer reviews). Further, the NRC adjusted the burden-hour estimate per activity to correlate more precisely with the level of effort associated with the required documentation.

For fatigue-related requirements, the burden hours for section 26.203(a)-(c) were added due to the incorporation of the voluntary 54-hour/week work hour control provision found in section 26.205(d)(7). The burden associated with these requirements is small.

#### Table 4, Annual Third-Party Burden

The primary reason for the increase of estimated burden in Table 4 was that the number of pre-access drug and alcohol tests increased throughout the commercial nuclear industry. This resulted in more costs associated with testing and evaluation of test results.

The estimated burden-hour cost for the current collection periods is \$272 (see 10 CFR 170.20, "Average Cost per Professional Staff Hour"). This represents a 5 percent increase from the previous collection period.

16. Publication for Statistical Use

None.

17. Reasons for Not Displaying the Expiration Date

NRC Forms 890, 891, and 892 will display the Part 26 expiration date. The remaining recordkeeping and reporting requirements for this information collection are associated with regulations and are not submitted on instruments such as forms or surveys. For this reason, there are no data instruments on which to display an OMB expiration date. Further, amending the regulatory text of the CFR to display information that, in an annual publication, could become obsolete would be unduly burdensome, and too difficult to keep current.

18. Exceptions to the Certification Statement

There are no exceptions to the certification statement. Small businesses are not affected and statistical use of the information was not made.

B. Collection of Information Employing Statistical Methods

Statistical methods are not used in this collection of information.

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

Section	Number of Programs	Burden Hours per Program (Annualized) <sup>3</sup>	Total Burden Hours (Annualized)
26.27(a): Prepare FFD policy statement	0 programs <sup>4</sup>	107.0	0
26.27(a): Prepare FFD procedures	0 programs	213.0	0
26.29(a): Prepare FFD training course	0 programs	83.0	0
26.29(b): Prepare FFD exam	0 programs	13.3	0
26.29(b): All current staff take FFD exam	0 programs	200.2 <sup>5</sup>	0
26.29(b): FFD management grades FFD exam	0 programs	200.2 <sup>6</sup>	0
26.29(c)(1): FFD training for current staff	0 programs	4,710.7 <sup>7</sup>	0
26.31(b)(1)(v): Prepare behavioral observation procedures for FFD program personnel	Burden accounted for under section 26.27(a) (0 programs)		
26.31(d)(1)(iii): Document additional drugs being tested	0 programs	0.3	0
26.37(a): Confirm files and procedures protect personal information	0 programs	2.7	0
26.37(b): Obtain signed consent for release of information	0 programs	98.1	0
26.39(a) and (b): Prepare procedure for review of determination of FFD violation	0 programs	13.3	0
26.85(a): Prepare and deliver qualification training for urine collectors	0 programs	5.3	0

<sup>3</sup> The “Burden Hours per Program (Annualized)” has been maintained in Table 1 for reference and future use.

<sup>4</sup> For this clearance period, no new drug and alcohol programs will be implemented and two (2) fatigue programs will voluntarily implement the 54-hour/week work control provision per year.

<sup>5</sup> Administering the exam and recording whether an individual passed the exam is estimated to take 10 minutes (0.17 hours) per employee. The estimated burden is based on the number of employees per new drug and alcohol testing program that complete an examination

<sup>6</sup> Recording whether an individual passed the exam is estimated to take 10 minutes (0.17 hours) per employee. The estimated burden is based on the number of employees per new drug and alcohol testing program that complete an examination.

<sup>7</sup> FFD training is estimated to take 4.0 hours per employee. The estimated burden is based on the number of employees per new drug and alcohol testing program that complete the employee training. \_\_\_\_\_

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

<b>Section</b>	<b>Number of Programs</b>	<b>Burden Hours per Program (Annualized)</b>	<b>Total Burden Hours (Annualized)</b>
26.85(b): Prepare and deliver qualification training for alcohol collectors	0 programs	5.3	0
26.127(a): Prepare procedures for handling specimens at LTF	0 programs	13.3	0
26.127(b): Prepare written chain-of-custody procedures for LTF	0 programs	13.3	0
26.127(c): Prepare written procedures for assays performed by LTF	0 programs	13.3	0
26.127(d): Prepare written procedures for instrument and test setup by LTF	0 programs	13.3	0
26.127(e): Prepare written procedures for remedial actions for systems and tests at LTF	0 programs	13.3	0
26.137(a): Develop QA/QC program and procedures for LTF	0 programs	13.3	0
26.155(a)(1), (3), (4), (5); (b),(c), (e), and (f): Confirm that HHS requirements for laboratory personnel qualifications and procedures already in place pursuant to HHS requirements also meet Part 26 requirements	0 HHS labs <sup>8</sup>	2.7	0
26.157(b), (c), (d), and (e): Confirm that laboratory procedures already in place pursuant to HHS requirements also meet Part 26 requirements	0 HHS Labs	2.7	0
26.159(a), (c), (e), (f): Confirm that specimen security, chain of custody, and preservation procedures already in place pursuant to HHS requirements also meet Part 26 requirements	0 HHS labs	2.7	0
26.203(a): Prepare fatigue management policy (in addition to 26.27 burden)	2 programs <sup>9</sup>	7.3	14.6

<sup>8</sup> The NRC estimates that no additional HHS-certified laboratories (referred to in this clearance as “HHS labs” or “HHS lab”) will take the steps necessary to provide services to NRC licensees under Part 26 during this clearance period.

<sup>9</sup> The NRC assumes that two existing fatigue programs each year will voluntarily implement the 54-hour/week work hour control provision. This footnote also applies to the estimates for section 26.203 (b) and (c), and section 26.205(b) and (c).

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

Section	Number of Programs	Burden Hours per Program (Annualized)	Total Burden Hours (Annualized)
26.203(b): Prepare fatigue management procedures (in addition to 26.27 burden)	2 programs	1.7	3.4
26.203(c): Prepare training on fatigue management.	2 programs	2.0	4
26.205(b): Develop work hour tracking system	2 programs	7.7	15.4
26.205(c): Develop individual work scheduling system	2 programs	2.0	4
26.401(b): Prepare Subpart K program plan	0 programs	60.0	0
26.403(a): Prepare written Subpart K FFD policy statement	0 programs	107.0	0
26.403(a): Distribute Subpart K FFD policy statement to all individuals	0 programs	5.0	0
26.403(b): Prepare written Subpart K FFD procedures	0 programs	213.0	0
26.406(a), (b), and (d): Establish a fitness monitoring program	0 programs	26.7	0
26.406(c): Establish procedures for fitness monitors	0 programs	40.0	0
26.407: Establish procedures for behavioral observation	0 programs	40.0	0
26.413: Develop procedures for review of determinations of FFD violations	0 programs	120.0	0
<b>TOTAL</b>			<b>41.4</b>

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.4: Requires training be provided to persons subject to a drug and alcohol testing program regulated by another Federal agency or State but who are not covered by these training elements of a Part 26 FFD program. Further, these State and Federal entities are required to ensure that the licensee granting authorization is notified of any FFD policy violation.	30.5 <sup>10</sup>	2	61
26.27(b): Make FFD policy statement available to staff subject to FFD requirements.	28 programs <sup>11</sup>	4.0	112
26.27(c): Record updates to policy and procedures	28 programs	8.0	224
26.27(d): Provide policy and procedures for NRC review	28 programs	4.0	112
26.29(b): Maintain records of FFD exams	28 programs	2.0	56
26.29(c)(2): Maintain records of refresher FFD training and testing	28 programs	2.0	56
26.29(d): Record acceptance of FFD training from other licensees' programs	28 programs	4.0	112
26.31(b)(1)(i): Record results of background checks for FFD personnel	28 programs	17.5	490
26.31(b)(1)(v): Record results of behavioral observation for FFD program personnel	28 programs	80.0	2,240
26.31(d)(1)(i)(D): Document analysis and certification for testing of drugs not included in the NRC minimum testing panel.	2.3 programs <sup>12</sup>	4.0	9.2
26.31(d)(1)(ii): Document licensee additions to tested drugs	2.3 programs	8.0	18.4

<sup>10</sup> Records are maintained at each site implementing a drug and alcohol testing program for personnel who have access to that site. The NRC assumes that half of these sites have offsite response personnel subject to an offsite drug and alcohol testing program.

<sup>11</sup> The previous clearance estimated 31 drug and alcohol testing programs. This clearance estimates 28 programs due to consolidation within the industry and as a result of facility decommissioning. The MOX facility is not expected to be licensed until after the period of the clearance.

<sup>12</sup> 2012 NRC FFD Program Performance Report (Section 4) reported that seven (7) drug and alcohol testing programs conducted testing for additional substances (7 programs / 3 years = 2.3 programs per year). This assumption also applies to the burden estimate for § 26.31(d)(1)(ii). The change in estimated burden is based on updated information detailed in the 2012 FFD Program Performance Report.

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.31(d)(3)(iii)(A): Document more stringent cutoff levels	2 programs <sup>13</sup>	8.0	16
26.31(d)(3)(iii)(C): Document evaluation and certification of more stringent cutoff levels	2 programs	8.0	16
26.31(d)(6): Document written permission of donor to conduct another analysis or test with specimen	0 programs <sup>14</sup>	1.0	0
26.33: Records of behavioral observations	28 programs	400.0	11,200
26.35(a): Employee assistance program records	28 programs	16.0	448
26.35(c): Maintain record of written waivers of right to privacy from individuals given to EAP	28 programs	2.0	56
26.35(c): Record of EAP disclosure to FFD program management	14 programs	1.0	14
26.37(b)(1): Record of signed designations of personal representative for FFD matters	28 programs	40.0	1,120
26.37(c): Record of disclosures to other licensees	28 programs	40.0	1,120
26.37(d): Record of HHS lab results and provide result to individual	28 programs	40.0	1,120
26.39(a): Maintain procedures for review of determinations of FFD	28 programs	40.0	1,120
26.39(d): Update records to reflect outcome of review of determination of fitness	28 programs	40.0	1,120
26.39(e): Record that a C/V administering a drug and alcohol program provides each individual that has violated an FFD policy with the review procedure	0 program	0.5	0 <sup>15</sup>
26.41(a), (b), and (c): Record of audits	Burden accounted for under section 26.41(f)		
26.41(d): Record of review of C/V audit results	28 programs	40.0	1,120

<sup>13</sup> 2012 FFD Program Performance Report (Section 4) reported that 6 drug and alcohol testing programs used more stringent testing cutoff levels. The NRC estimates that 2 new drug and alcohol programs per year will use more stringent cutoff levels. This assumption also applies to the burden estimate for section 26.31(d)(3)(iii)(C). The change in estimated burden is based on updated information detailed in the FFD Program Performance Report.

<sup>14</sup> Industry experience indicates that this provision has not been used by personnel subject to Part 26. The previous clearance estimated burden associated 8 drug and alcohol testing programs.

<sup>15</sup> The estimate is based on zero (0) positive, substituted, adulterated, and testing refusal results at the one C/V drug and alcohol program in 2012. One-half burden hour is estimated for each test. The previous clearance assumed that 31 C/V programs were subject to this requirement.

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.41(f): Document and report audit results	28 programs	40.0	1,120
26.41(g): Record that audit results shared with management and with other FFD programs	28 programs	40.0	1,120
26.53(e)(2): Record that C/Vs informed licensee of the termination of an individual's authorization	1 programs	120.0	120
26.53(g): Record that C/Vs and other licensees informed of Part 26 violations	7 programs	8.0	56
26.53(h): Record that written consent obtained from the subject individual before initiating any actions under Subpart C	28 programs	1,677	46,956 <sup>16</sup>
26.53(i): Record that all individuals applying for authorization informed, in writing, of the causes for denial or termination of authorization	28 programs	23.3	652 <sup>17</sup>
26.55(a)(1) and (a)(2): Record that obtained and reviewed self-disclosure & employment history and completed suitable inquiry	Burden accounted for under sections 26.61 and 26.63		
26.57(a)(1) and (a)(2): Record that obtained and reviewed self-disclosure & employment history & completed suitable inquiry	Burden accounted for under sections 26.61 and 26.63		
26.59(a)(1) and (a)(2): Record that obtained and reviewed self-disclosure & employment history & completed suitable inquiry	Burden accounted for under sections 26.61 and 26.63		
26.59(c)(1): Record that obtained and reviewed self-disclosure	Burden accounted for under section 26.61		
26.61(a): Record of written self-disclosure and employment history	28 programs	1,197.0	33,516
26.63(a), (c), and (e): Record of suitable inquiry	28 programs	1,197.0	33,516
26.63(c)(2): File DD 214	28 programs	4.0	112
26.63(c)(3): Document refusal of past employer to supply employment information	28 programs	2.7	75.6

<sup>16</sup> The estimate is based on 93,890 pre-access tests from the 2012 FFD program performance data. One-half burden hour is estimated for each written consent obtained prior to initiating a pre-access test.

<sup>17</sup> The estimate is based on 652 positive, adulterated, substituted and refusal to test results for pre-access testing (this includes both alcohol and drug test results) from the 2012 NRC FFD program performance data. One burden hour is estimated for each test result.

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.63(d) & (e): Maintain documentation of denial or unfavorable termination of authorization from other FFD programs	28 programs	1.0	28
26.65(d) and (e): Record of reinstatement or administrative withdrawal of authorization	28 programs	4.0	112
26.65(f): Administrative withdrawal of authorization	28 programs	1.0	28
26.67 Record of random drug and alcohol testing of persons who have applied for authorization	28 programs	5.5	154 <sup>18</sup>
26.69(b) and (c)(1): Record of written self-disclosure and employment history	Burden accounted for under section 26.713(a)(1)		
26.69(c)(2): Record that licensee confirmed potentially disqualifying FFD situation resolved	28 programs	40	1,120
26.69(c)(3): Record that licensee verified that qualified professional indicated individual is fit for duty.	28 programs	40	1,120
26.69(c)(4): Record of verification that drug/alcohol treatment and testing completed	28 programs	3.0	84
26.69(c)(5): Record of verification that pre-access drug/alcohol testing completed	28 programs	1.0	28
26.69(d): Record that reviewing officer's review completed	28 programs	24.0	672
26.69(e): Record of testing and treatment plans accepted from other FFD programs	28 programs	8.0	224
26.69(e)(1): Record that information transmitted on testing and treatment plans to other FFD programs	28 programs	8.0	224
26.75(a), (b), (c), (d), (e), and (g): Record of sanctions for FFD violation	28 programs	12.0	336
26.75(h): Record additional evidence indicating impairment	28 programs	18.0	504
26.75(i): Record of positive initial test result and temporary administrative action	28 programs	80.0	2,240

<sup>18</sup> This estimate is based on 2012 FFD program performance data which indicate that 61,722 random drug tests were conducted. Of these, this estimate assumes that approximately 0.5% of individuals that applied for authorization and received a pre-access test also were randomly tested. One-half burden hour is estimated for each test.

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.75(i)(3): Eliminate from record references to temporary administrative action	28 programs	1.0	28
26.85(a), (b), & (c): Training collectors	28 programs	4.0	112
26.85(e): Maintain personnel files	28 programs	4.0	112
26.87(d)(3) and (f)(1): Signage/security at test sites	28 programs	1.0	28
26.87(f)(3), (f)(4), and (f)(5): Record of custody-and-control forms	28 programs	2.0	56
26.89(a): Record of absence of donor reported	28 programs	1.0	28
26.89(b)(1), (b)(2), and (b)(4): Record that ID and consent-to-testing form obtained	28 programs	1.5	42
26.89(b)(3): Record that FFD program management informed that individual did not present identification	28 programs	1.0	28
26.89(c): Record of donor's refusal to cooperate in collection procedures	28 programs	1.0	28
26.91(c)(1), (c)(2), and (c)(3): Record of EBT test results	Burden accounted for under section 26.715(b)(2)		
26.91(e)(4): Record that results cancelled after EBT calibration check failure	0 programs <sup>19</sup>	6.0	0
26.91(e)(5): Prepare record of EBT maintenance	28 programs	6.0	168
26.93(a)(6): Document alcohol pre-test questions asked and answered	28 programs	80	2,240
26.95(b)(5): Record donor identity for initial alcohol breath test	28 programs	80	2,240
26.97(b)(2): Record reason for new oral fluid alcohol test	0 programs <sup>20</sup>	5.0	0
26.97(c)(1): Document reason for failure of second oral fluid collection attempt	0 programs	2.5	0
26.97(d): Record results and alcohol oral fluid screening device used	0 programs	0.25	0
26.99(b): Record test time of initial test with 0.02% or higher BAC	Burden accounted for under section 26.715(b)(2) <sup>21</sup>		

<sup>19</sup> The NRC inspection process has not identified any instances of EBT calibration check failures in the last three years resulting in the cancellation of prior positive test results. The previous clearance estimated that eight programs incurred burden to address this EBT equipment failure each year.

<sup>20</sup> Industry has not informed NRC that oral fluid testing for alcohol is utilized. The previous clearance estimated that all programs conducted oral fluid alcohol testing. This assumption also applies to section 26.97(c)(1) and (d).

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.101(b)(7): Record the result and document the time of the confirmatory alcohol test	0 programs	0	0
26.103(b): Record that FFD management informed of result between 0.01 and 0.02 when donor in work status 3 or more hours	8 programs	0.25	2
26.107(b): Document tampering attempt on CCF	28 programs	0.1	2.8
26.109(b)(3): Record that FFD mgt. or MRO notified of urination problem	28 programs	0.5	14
26.109(b)(4): Record that FFD management notified if observed collection required	28 programs	0.3	8.4
26.111(b): Note unusual findings regarding the color and clarity of a specimen on CCF (i.e., indication of specimen tampering)	4 programs	0.25 <sup>22</sup>	1.0
26.111(c): Record that unusual specimen temperature or other indications of tampering were reported to FFD manager.	28 programs	0.3	8.4
26.113(b)(3): Record of CCF (split sample)	28 programs	0.3	8.4
26.115(b): Record that approval obtained for collection under direct observation from FFD mgr. or MRO	28 programs	0.5	14
26.115(d): Record of CCF for directly observed collection	28 programs	0.3	8.4
26.115(f)(3): Record of name of observer	28 programs	0.3	8.4
26.117(c), (d), and (e): Prepare ID labels and CCF for specimen shipment	28 programs	60.0	1680
26.119(a), (e), and (f): Record that evaluation obtained from MRO or physician evaluating shy bladder claim	28 programs	6.0	168
26.119(b): Record that MRO provided information to physician as background for evaluation of shy bladder claim	28 programs	2.0	56

21 The standard alcohol testing equipment (i.e., EBT) utilized by industry automatically prints out the test result for each test conducted. The only burden associated with this requirement is to maintain records, which already is accounted for in section 26.715(b)(2). This assumption also applies to section 26.101(b)(7).

22 2012 FFD Program Performance Report data (Figure 1) indicate that four specimens collected during the year had unusual specimen characteristics indicating a possible subversion attempt.

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.125(b) and (c): Proficiency and qualifications records of LTF personnel	7 programs <sup>23</sup>	16.0	112
26.127(a): Procedures for handling specimens by LTFs	7 programs	40.0	280
26.127(b): Written chain-of-custody procedures for LTFs	7 programs	40.0	280
26.127(c): Written procedures for assays performed by LTFs	7 programs	40.0	280
26.127(d): Written procedures for instrument and device setup at LTFs	7 programs	40.0	280
26.127(e): Written procedures for remedial actions for systems and testing devices at LTFs	7 programs	40.0	280
26.129(a): Records associated with limiting access to LTF	7 programs	2.5	17.5
26.129(b): Inspect specimen packages, custody control forms, and obtain memorandum from specimen collector	7 programs	0.5	3.5
26.129(b)(1): Record of report to senior management of attempts to tamper with specimens in transit	7 programs	1.0	7.0
26.129(d): Procedures for tracking specimen CCFs	7 programs	80.0	560
26.135(b): Record of donor's written permission for retest second part of split sample	7 programs	2.2	15.4
26.137(a): Record of QA/QC program and procedures for LTF	7 programs	4.0	28
26.137(b)(1)(ii): Document performance of testing device not on SAMHSA list	2 programs	40.0	80
26.137(b)(1)(iii): Document results of annual test of device not on SAMHSA list	2 programs	20.0	40
26.137(b)(3): Record that 1 in 10 negative specimens submitted for validity screening	7 programs	40.0	280
26.137(e)(7): Document procedures to protect against carryover material	7 programs	2.0	14
26.137(f)(5): Record finding of testing errors	7 programs	24.0	168
26.137(h): Label standards and controls	7 programs	65.0	455
26.139(d): Record that information prepared for FFD annual report on activities of LTF	7 programs	40.0	280

<sup>23</sup> The previous clearance estimated that all drug and alcohol testing programs utilized LTFs. Data collected by the

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.153(e): Record of inspection of HHS labs	28 programs	40.0	1,120
26.153(f): Include specified requirements in contracts with HHS labs	28 programs	40.0	1,120
26.153(g): Record of memo to HHS labs explaining use of non-federal CCF	28 programs	0.5	14
26.159(b)(1): Record of report of evidence of tampering with specimens in transit to FFD program mgr. of licensee or other entity	28 programs	1.0	28
26.159(i): Record of written authorization to store specimens other than 1 year	28 programs	0.5	14
26.163(a)(2): Record that licensee informed of dilute specimen and report confirmatory validity test result to MRO	28 programs	1.0	28
26.165(b)(1): Record of donor request for the retest of an aliquot of a single specimen or testing of Bottle B of split specimen testing at a second HHS lab	28 programs	1	28
26.165(b)(2): Record that MRO informed donor of opportunity for re-test of an aliquot of a single specimen or testing of Bottle B of split specimen	28 programs	0.5	14
26.165(b)(3): Record that donor provided written permission for re-test of an aliquot of a single specimen or testing of Bottle B of the split specimen	Burden accounted for under section 26.165(b)(1)		
26.165(b)(4): Record that donor presented documentation for reason for inability to complete timely retest request	6 programs	0.2	1.2 <sup>24</sup>
26.165(b)(6): Record that results of re-test of an aliquot of a single specimen or testing of Bottle B of the split specimen was provided to the MRO and donor	28 programs	3.0	84
26.165(c)(4): Record that retesting results provided to MRO	12 laboratories <sup>25</sup>	2.5	30

<sup>24</sup> This estimate is based on 6 donors per year.

<sup>25</sup> The prior clearance estimated that 10 HHS-certified laboratories would provide services under Part 26. The current clearance uses updated information obtained from the NRC voluntary e-reporting system for FFD program performance data reporting.

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.165(f)(1): Adjustments to personnel files and written notifications regarding test results, including temporary administrative action	28 programs	6.0	168
26.165(f)(1)(iv) and (f)(2): Written record and notice that records purged of references to temporary administrative action	28 programs	8.0	224
26.167(f)(3): Record of certification by HHS lab that retesting requested by licensee or other entity has occurred	12 HHS labs	1.0	12
26.169(a): Records of reports of test results by HHS lab	Burden covered under section 26.169 (c)(1) through (c)(5)		
26.169(c)(1): Records of HHS lab reports of positive, adulterated, substituted, dilute, and invalid test results to the MRO	12 HHS labs	80.0	960
26.169(c)(2): Records of HHS lab reports of quantitative test results as requested by MRO	12 HHS labs	1.0	12
26.169(c)(2): Records of HHS lab reports of quantitative test results for opiates to MRO	12 HHS labs	0.5	6
26.169(c)(3): Records of HHS lab reports of quantitative test results for adulterated or substituted test results	12 HHS labs	2.5	30
26.169(c)(4): Record of HHS lab contact with MRO to discuss whether testing by another HHS lab should be done	12 HHS labs	2.0	24
26.169(c)(5): Record of HHS lab reports of concentrations exceeding linear range	2 HHS labs	1.0	2
26.169(f): Records of HHS lab transmittals of copies of the CCF for negative results to the MRO	12 HHS labs	109.5 <sup>26</sup>	1,314
26.169(g): Records of HHS lab transmittals of original CCF for positive, adulterated, substituted, dilute, and invalid test results to the MRO	12 HHS lab	44.7	536
26.169(h): Record that HHS lab prepared and submitted annual statistical summary report of urinalysis testing results	12 HHS lab	40.0	480

<sup>26</sup> All HHS-certified laboratories implementing Part 26 requirements electronically report and process drug test results. The 2012 FFD program performance data indicate that 164,270 drug tests were completed in 2012 (one record is generated for each test result). The burden-hour estimate per record is 30 seconds (0.008 hour).

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.183(a): Documentation of MRO qualifications	28 programs	3.5	98
26.183(c)(1): MRO review of records for positive, adulterated, substituted, invalid, or, at the licensee's or other entity's discretion, dilute test results	28 programs	19.1 <sup>27</sup>	535
26.183(d)(1)(ii)(D): Record of MRO report of drug test results to licensee's designated reviewing official	28 programs	19.1	535
26.183(d)(2)(i): Record of MRO staff review and reporting of negative test results	28 programs	292.2 <sup>28</sup>	8,182
26.183(d)(2)(ii): Record of MRO staff review of CCFs and forwarding changes to MRO	28 programs	1.9 <sup>29</sup>	53
26.185(a) Record of MRO review of all positive, adulterated, substituted, dilute, or invalid test results and report to licensee or other entity	28 programs	26.0	728
26.185(c): Record of MRO discussion of test results with the donor and report to licensee, following discussion with donor, of FFD violation	28 programs	26.0	728
26.185(d)(1): Documentation that donor declined to discuss test results	28 programs	2.0	56
26.185(e): Documentation that donor was unavoidably prevented from discussing test results and request to reopen proceeding	28 programs	0.3	8.4
26.185(f)(1): Record of MRO consultation with HHS lab to determine whether additional testing needed	28 programs	0.5	14

<sup>27</sup> 2012 FFD program performance data indicate that 536 positive, adulterated, and substituted drug test results were reported by 28 drug and alcohol programs. It is estimated that the MRO spends one burden hour to review each test result and communicate results. This represented an increase of 31 percent from the previous collection period. This assumption also applies to the burden estimate in section 26.183(d)(1)(ii)(D).

<sup>28</sup> The estimate assumes that 164,270 tests were conducted in 2012, minus 536 positive, adulterated, and substituted drug test results, minus 99 testing refusals not associated with a specimen test (equals the total number of negative drug test results reviewed by MROs and MRO staff = 163,635 tests). Of these, it is estimated that 90% are reviewed by MRO staff at 3 minutes (0.05 hour) per record. This represented an increase of 8.3 percent in tests results reviewed by MROs and MRO staff for this clearance period.

<sup>29</sup> The 2012 FFD program performance data indicate that 536 positive, adulterated, and substituted drug test results were reported by drug and alcohol programs. NRC estimates that the MRO spends 6 minutes (0.10 hour) to review each record. This represents a decrease of 36 percent in the number of records reviewed from the previous collection period.

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.185(f)(2): Record of MRO contact with donor regarding medical explanation for test result	28 programs	0.5	14
26.185(h)(1): Record of MRO contact with donor to offer opportunity to provide medical evidence regarding substituted specimen	28 programs	1.0	28
26.185(h)(1): Record that donor presented medical explanation for substituted result	28 programs	1.0	28
26.185(h)(2): Record of MRO notification to licensee that no valid medical explanation presented	28 programs	2.0	56
26.185(h)(3): Record of MRO notification to licensee that valid medical explanation presented	28 programs	1.0	28
26.185(i)(1): Record of MRO contact with donor to offer opportunity to provide medical evidence regarding adulterated specimen	28 programs	1.0	28
26.185(i)(1): Record that donor presented medical explanation for adulterated result	28 programs	1.0	28
26.185(i)(2): Record of MRO notification to licensee that no valid medical explanation presented	28 programs	2.0	56
26.185(i)(3): Record of MRO notification to licensee that valid medical explanation presented	28 programs	1.0	28
26.185(j)(3): Record of MRO notification to licensee where evidence of drug abuse	28 programs	1.0	28
26.185(j)(3): Record of MRO report to licensee that donor has violated FFD policy by use of another individual's prescription medication	28 programs	0.5	14
26.185(k): Record of MRO report to licensee that no FFD policy violation has occurred	28 programs	1.0	28
26.185(m): Record of MRO review of inspection and audit reports, quality control data, multiple specimens, and other data to determine if positive, adulterated, substituted, or invalid result is scientifically insufficient for determination of FFD policy violation	28 programs	1.0	28
26.185(n): Record of MRO report to licensee on result of analysis by second HHS lab	28 programs	2.0	56

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.185(o): Record of MRO request for quantitation of test results	28 programs	0.5	14
26.185(o): Record that lab provided quantitation of test results	28 programs	1.0	28
26.185(p): Record of MRO notice to licensee of determination of FFD policy violation	28 programs	8.0	224
26.187(d): SAE training requirements	28 programs	20.0	560
26.187(f): Documentation of SAE credentials and training	28 programs	1.0	28
26.189(a): Written record of determination of fitness	28 programs	80.2	2,246
26.189(c): Written record of a for cause determination of fitness	28 programs	16.3	456 <sup>30</sup>
26.189(d): Record of modification of an initial determination of fitness	28 programs	1.0	28
26.203(a): Prepare fatigue management policy (In addition to 26.27 burden)	2 programs	7.3	14.6
26.203(b): Prepare fatigue management procedures (in addition to 26.27 burden)	2 programs	1.7	3.4
26.203(c): Prepare training on fatigue management.	2 programs	2	4
26.203(d)(1): Records of work hours	Burden accounted for under section 26.205(c), (d)(1), and (e)(4)		
26.203(d)(2): Records of shift schedules and shift cycles	Burden accounted for under section 26.205(c), (d)(1), and (e)(4)		
26.203(d)(3): Documentation of waivers	Burden accounted for under section 26.207(a)(4)		
26.203(d)(4): Documentation of work hour reviews	Burden accounted for under section 26.205(d)(2), (e)(3) and (e)(4)		
26.203(d)(5): Documentation of fatigue assessment	Burden accounted for under section 26.211(f)		
26.205(b): Record of calculation of work hours	23 programs	160.0	3,680
26.205(c): Schedule work hours	23 programs	2,080.0	47,840
26.205(d)(1): Record of implementation of work hour controls	23 programs	50.0	1,150
26.205(d)(2): Record of adequate rest breaks	23 programs	50.0	1,150

<sup>30</sup> 2012 NRC FFD program performance data indicate that 457 for-cause tests were performed by drug and alcohol programs. NRC estimated one burden hour to prepare a record for each test. The previous clearance included both for-cause (797) and post-event tests (986) in the assumption on the annual number determinations of fitness performed (1,783). This assumption overstated the number of determinations of fitness performed.

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.205(e)(1) and (2): Record of review of control of work hours twice per calendar year	23 programs	40.0	920
26.205(e)(3): Document methods for reviews	23 programs	20.0	460
26.205(e)(4): Record and trend problems in regarding work hours	23 programs	20.0	460
26.207(a)(4): Document basis for waiver	3 programs	6.0	18
26.211(f): Document results of fatigue assessments	23 programs	50.0	1150
26.405(a): Record of random drug and alcohol testing	2 programs	705	1,410 <sup>31</sup>
26.405(c)(1): Document pre-assignment testing	2 programs	2,338	4,676 <sup>32</sup>
26.405(c)(2) and (c)(3): Document for-cause and post-event testing	2 programs	197	394 <sup>33</sup>
26.405(c)(4): Document follow-up testing	2 programs	34.5	69 <sup>34</sup>
26.405(d): Record of testing for specified drugs, adulterants, and alcohol, at Part 26 specified cutoff levels	Burden accounted for under section 26.405(a) - (c)(4)		
26.405(e): Record of methods to ensure privacy and quality control	2 programs	40.0	80
26.405(f): Record that testing conducted at an HHS lab	2 programs	40.0	80
26.405(g): Record of MRO review of positive, adulterated, substituted, and invalid drug and validity test results	2 programs	50.0	100
26.406(c): Record of fitness monitoring procedures (programs that do not adopt random testing and behavioral observation)	0 programs	80.0	0
26.411(a): Record of system of files and procedures to protect personal information	2 programs	4.0	8

<sup>31</sup> 2012 FFD program performance data indicate that Subpart K construction programs performed 2,819 random tests (2,819 tests / 2 programs = 1,410 per program). The estimate is based on one-half burden hour per test.

<sup>32</sup> 2012 FFD program performance data indicate that Subpart K construction programs performed 4,675 pre-access tests (4,675 tests / 2 programs = 2,338 tests per program). Estimate based on one burden hour per person to document pre-assignment testing.

<sup>33</sup> 2012 FFD program performance data indicate that Subpart K construction programs performed 237 for-cause and 157 post-event tests (237 + 157 = 394 tests / 2 programs = 197 tests per program). Estimate based on one burden hour per person to document for-cause and post-event testing determinations.

<sup>34</sup> 2012 FFD program performance data indicate that Subpart K construction programs performed 276 followup tests (276 tests / 2 programs = 138 tests per program). The estimate is based on one-quarter burden hour per test.

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.411(a): Collection of personal information	2 programs	2,189	4,378 <sup>35</sup>
26.411(b): Record that signed consent forms obtained	2 programs	1.5	3
26.413: Document results of review process	2 programs	80.0	160
26.415: Document and report audit results	2 programs	40.0	80
26.417(a): Retain program records	2 programs	20.0	40
26.417(b)(2): Collect FFD program performance data for Subpart K reactor construction site programs	2 programs	100.0	200.0
26.713(a)(1): Retain records of self-disclosure	28 programs	80.0	2,240
26.713(a)(2): Retain records on FFD violations	28 programs	80.0	2,240
26.713(a)(3): Retain records of authorization	28 programs	80.0	2,240
26.713(a)(4): Retain records of FFD determinations	28 programs	80.0	2,240
26.713(b)(1): Retain records of FFD training	28 programs	160.0	4,480
26.713(b)(2): Retain records of audits	28 programs	80.0	2,240
26.713(c): Retain records on 5-year authorization denial and permanent denial	28 programs	40.0	1,120
26.713(d): Retain superseded FFD policy	28 programs	80.0	2,240
26.713(e): Retain written agreements for services under Part 26	28 programs	16.0	448
26.713(f): Retain records of background investigations	28 programs	80.0	2,240
26.713(g): Retain documentation regarding additional drugs tested	28 programs	40.0	1,120
26.715(a): Maintain documentation of all aspect of testing process (not otherwise specified in 26.715(b))	28 programs	40.0	1,120
26.715(b)(1): Retain personal files	28 programs	20.0	560
26.715(b)(2): Retain chain-of-custody documents	28 programs	240.0	6,720
26.715(b)(3): Retain quality assurance records	28 programs	120.0	3,360
26.715(b)(4): Retain superseded procedures	28 programs	40.0	1,120
26.715(b)(5): Retain all test data	28 programs	240.0	6,720

<sup>35</sup> 2012 FFD program performance data indicate that an average of 4,378 workers were subject to drug and alcohol testing at Subpart K reactor construction site programs (4,378 workers / 2 programs = 2,189 workers per program). This estimate is based one burden hour per person to collect personal information from each worker. The previous clearance assumed 2,000 workers per construction site subject to a Subpart K program.

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.715(b)(6): Retain test reports	28 programs	240.0	6,720
26.715(b)(7): Retain performance test records	28 programs	80.0	2,240
26.715(b)(8): Retain testing error investigation records	28 programs	40.0	1,120
26.715(b)(9): Retain certification inspection records	28 programs	40.0	1,120
26.715(b)(10): Retain records on preventative maintenance	28 programs	40.0	1,120
26.715(b)(11): Retain records summarizing scientific insufficiency	28 programs	20.0	560
26.715(b)(12): Retain computer-generated data	28 programs	120.0	3,360
26.715(b)(13): Retain records on visitors	28 programs	20.0	560
26.715(b)(14): Retain records on EBT maintenance	28 programs	20.0	560
26.717(a) and (b): Collect FFD performance data for drug and alcohol testing programs	28 programs	100.0	2,800
26.717(a) and (b): Collect FFD performance data for fatigue management programs	23 programs	100.0	2,300
26.717(c): Analyze drug and alcohol testing program FFD data annually	28 programs	40.0	1,120
26.717(c): Analyze fatigue management program data annually	23 programs	40.0	920
26.717(d): Drug and alcohol test results leading to termination	1 C/V	1.0	1
26.717(g): Record that required FFD drug and alcohol testing information shared by C/V with licensee to ensure information is reported completely and is not duplicated in reports submitted to the NRC	1 C/V	120.0	120
26.719(b): Prepare 24-hour event report to submit to the NRC	1.2 <sup>36</sup>	1.0	1.2
26.719 (c): Prepare 30-day event report documentation	0.2 <sup>37</sup>	40.0	8.0

36 In the 2012 NRC FFD Program Performance Report, drug and alcohol testing programs reported 37 events (i.e., 24-hour event reports). The previous clearance did not account for this burden.

37 In the 2012 NRC FFD Program Performance Report, drug and alcohol testing programs reported 6 events (i.e., 30-day event reports). The previous clearance did not account for this burden.

**Table 2  
Annual Recordkeeping Burden**

<b>Section</b>	<b>Number of Recordkeepers</b>	<b>Burden Hours per Recordkeeper</b>	<b>Total Annual Burden Hours</b>
26.719(d): Document non-reportable indicators of FFD program weaknesses	30 programs	20.0	600
26.821(a): Allow NRC to inspect and copy records	30 programs	4.0	120
26.821(b): Written agreement between C/Vs and licensees to permit authorized NRC representatives to inspect, copy, or take away copies of C/Vs documents, records, and reports	1 C/V	4.0	4
<b>TOTAL</b>			<b>314,177.4</b>

**Table 3  
Annual Reporting Burden**

<b>Section</b>	<b>Number of Respondents</b>	<b>Responses per Respondent</b>	<b>Total Responses</b>	<b>Burden per Response (hours)</b>	<b>Total Burden Hours</b>
26.9: Application to NRC for exemption	0 programs <sup>38</sup>	1	0	0	0
26.77(c) Report FFD-impaired NRC employee	30 programs	0	0	1.0	0
26.137(b)(3): Report false negative QC test result from LTF	Burden accounted for under section 26.719(c)(3)				
26.139(d): Prepare information from LTF for annual FFD program performance report	Burden accounted for under section 26.717(e) and (f)				
26.187(f): Provide SAE qualifications documentation to NRC upon request	1 program	1	1	1.0	1
26.203(e)(1): Prepare information on waivers of work hour controls for inclusion in fatigue program performance report to NRC required by section 26.717(e) and (f)	23 programs	1	23	50.0 (Burden in addition to that accounted for under section 26.717)	1,150

<sup>38</sup> Based on the lack of previous NRC licensing actions, zero (0) exemptions for drug and alcohol programs are anticipated during the current clearance period.

**Table 3  
Annual Reporting Burden**

<b>Section</b>	<b>Number of Respondents</b>	<b>Responses per Respondent</b>	<b>Total Responses</b>	<b>Burden per Response (hours)</b>	<b>Total Burden Hours</b>
26.203(e)(2): Prepare summary of fatigue corrective actions for inclusion in fatigue program performance report to NRC required by section 26.717(e) and (f)	23 programs	1	23	6.0 (Burden in addition to that accounted for under sections 26.203(e)(1) and 26.717)	138
26.417(b)(1): Report to NRC by telephone within 24 hours of a programmatic failure under the Subpart K construction site drug and alcohol program	2 programs	1	2	4.0	8
26.417(b)(2): Prepare annual program performance report for Subpart K construction site drug and alcohol program	2 programs	1	2	80.0	160
26.717(d): Report termination drug and alcohol test results in the annual program performance summary by processing stage	Burden accounted for under section 26.717(e) and (f). NRC's 2012 FFD program performance data indicate 1,089 positive, adulterated, substituted, and refusal to test results.				

**Table 3  
Annual Reporting Burden**

<b>Section</b>	<b>Number of Respondents</b>	<b>Responses per Respondent</b>	<b>Total Responses</b>	<b>Burden per Response (hours)</b>	<b>Total Burden Hours</b>
26.717(e) and (f): Annual report of FFD program performance for fatigue management programs	62 sites <sup>39</sup>	1	62	8	496
26.717(e) and (f): Annual report of FFD program performance for drug and alcohol testing programs	65 sites <sup>40</sup>	1	65	60	3,900
26.719(a): Reports of significant drug and alcohol program violations, program failures, and errors in testing	Burden accounted for under sections 26.719(b) and (c)				

<sup>39</sup> In 2012, 23 fatigue management programs submitted one FFD program performance report for each of the 62 sites (61 operating reactor sites and 1 C/V). NRC staff anticipated in the previous clearance that a fatigue management program would submit one consolidated report for all of its sites. However, the majority of sites used the NRC voluntary electronic reporting form for fatigue management information and it is not possible to consolidate these forms into a single submission. Therefore, burden is now reflected by site instead of by program. Reporting burden to develop the content for the fatigue management reports is presented in sections 26.203(e)(1) and (e)(2). This line item only pertains to burden to produce the report and send it to the NRC.

<sup>40</sup> In 2012, 28 drug and alcohol programs submitted one FFD program performance report for each of the 65 sites (61 operator reactor sites, 1 decommissioning reactor site (Zion), 1 C/V, and 2 fuel cycle facilities). In the experience of NRC staff, licensees no longer submit a consolidated report for all sites because most programs use the NRC voluntary electronic reporting forms for drug and alcohol information reporting and it is not possible to consolidate these forms into a single submission. As a result, the number of respondents has been modified from the last clearance to the individual sites that are submitting the reports.

**Table 3  
Annual Reporting Burden**

<b>Section</b>	<b>Number of Respondents</b>	<b>Responses per Respondent</b>	<b>Total Responses</b>	<b>Burden per Response (hours)</b>	<b>Total Burden Hours</b>
26.719(b): Report significant drug and alcohol program violations by phone within 24 hours	15 programs	2.47 <sup>41</sup>	37	4.0	148
26.719(c)(1): Report the results of testing error investigation to NRC within 30 days	6 programs	1	6	24.0 <sup>42</sup>	144
26.719(c)(2): Notify NRC of false positive test result on blind performance test sample within 24 hours	1 program	1	1	4.0	4
26.719(c)(3): Notify NRC of false negative test result on QA check within 24 hours	4 programs	1	4	4.0	16
<b>TOTAL</b>					<b>6,165.0</b>

<sup>41</sup> The 2012 FFD program performance report data indicate that drug and alcohol testing programs reported 37 events (i.e., 24-hour event reports). The number of responses per respondent is calculated as follows: 37 events / 15 programs = 2.47 responses.

<sup>42</sup> NRC staff experience in reviewing licensee and other entity reports indicates that most errors are associated with false negative results from blind performance sample testing that requires investigation and coordination between the specimen supplier and the LTF and/or HHS-certified testing laboratory.

**Table 4  
Annual Third-Party Burden**

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.4: Requires that training be provided to persons subject to a drug and alcohol testing program regulated by another Federal agency or State but who are not covered by these training elements of a Part 26 FFD program. Further, these State and Federal entities are required to ensure that the licensee granting authorization is notified of any FFD policy violation.	14 <sup>43</sup>	2	28
26.31(b)(1)(i): Individuals provide responses to background checks for FFD personnel	93,890 <sup>44</sup>	1.0	93,890
26.31(d)(6): Donors provide written permission to conduct another analysis or test with specimen	8	1.0	8
26.35(a): Employee assistance program records (independent non-licensee EAP programs)	14 <sup>45</sup>	32.0	448
26.35(c): Individuals give written waiver of right to privacy to EAP	5,636 <sup>46</sup>	0.3	1,691
26.35(c): Record of disclosure by independent EAP to FFD management.	15	1.0	15
26.37(b): Individuals provide signed consent for release of information	1,127 <sup>47</sup>	0.3	338
26.37(b)(1): Individuals provide signed designation of personal representative for FFD matters	961	1.0	961

<sup>43</sup> Estimate is based on one half the number of drug and alcohol programs utilizing offsite response personnel subject to an offsite drug and alcohol testing program.

<sup>44</sup> Estimate is based on 93,890 pre-access tests from NRC's 2012 FFD program performance data. This represents an increase of approximately 11 percent in the annual number of pre-access tests conducted in the previous collection period (these data do not include personnel at decommissioning reactors or the Subpart K construction sites because the requirement is not applicable to these entities).

<sup>45</sup> Estimate assumes that 50 percent of the EAP programs at the 28 drug and alcohol programs are non-licensee programs.

<sup>46</sup> Estimate assumes 5 percent of 112,732 persons subject to random testing provide written consent. The total number of drug and alcohol testing programs subject to this requirement is 28 (these data do not include personnel at decommissioning reactors or the Subpart K construction sites).

<sup>47</sup> Estimate assumes that 1 percent of persons subject to drug and alcohol testing programs (1 percent of 112,732 persons) provide written consent to release information to parties not authorized to access this information under Part 26. The previous clearance overestimated the number of individuals that provide consent to release information.

**Table 4  
Annual Third-Party Burden**

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.37(d): Record that FFD program personnel provided records to individual	961	1.0	961
26.53(h): Individuals provide written consent before any actions are initiated under Subpart C	93,890	0.3	28,167
26.55(a)(1) and (a)(2): Individual applicants for initial authorization prepare self-disclosure and employment history	Burden accounted for under sections 26.61 and 26.63		
26.57(a)(1) and (a)(2): Individual applicants for authorization update prepare self-disclosure and employment history	Burden accounted for under sections 26.61 and 26.63		
26.59(a)(1) and (a)(2): Individual applicants for authorization reinstatement prepare self-disclosure and employment history	Burden accounted for under sections 26.61 and 26.63		
26.59(c)(1): Individual applicants for authorization reinstatement after period of interruption of no more than 30 days prepare self-disclosure	Burden accounted for under section 26.61		
26.61(a): Individuals prepare written self-disclosure and employment history	93,890	1.0	93,890
26.63(a), (c), and (e): Verification from former employers through suitable inquiry that information provided by individual on previous authorization(s) is accurate and complete	93,890	0.8	75,112
26.63(c)(2): Receive form DD 214 regarding previous military service	Burden of supplying DD 214 affects DOD		
26.63(c)(3): Past employer refuses to supply employment information	180	0.5	90
26.67: Records of random drug and alcohol testing of persons who have applied for authorization	335 <sup>48</sup>	0.5	168
26.69(b) and (c)(1): Applicant provides written self-disclosure and employment history	Burden accounted for under section 26.63		
26.69(c)(2): Record that licensee confirmed potentially disqualifying FFD situation resolved	939 <sup>49</sup>	2.0	1,878

<sup>48</sup> The 2012 FFD program performance data indicate that drug and alcohol programs performed 61,722 random drug and alcohol tests. This burden estimate assumes that approximately 0.5 percent of individuals that apply for authorization and who receive a pre-access test also will receive a random test prior to the granting of authorization. The number of random tests conducted in 2012 increased by 23 percent in comparison to the random testing total used in the previous clearance.

<sup>49</sup> Estimate assumes that licensees identify potentially disqualifying information in the applications of 1 percent of the 93,890 persons seeking pre-access authorization that requires further examination. The previous clearance

**Table 4  
Annual Third-Party Burden**

<b>Section</b>	<b>Number of Responses</b>	<b>Burden Hours per Response</b>	<b>Total Annual Burden Hours</b>
26.85(c): Alternative collectors not employed by licensee provide proof of qualification	22	1.0	22
26.85(e): Maintain personnel files for alternative collectors	22	4.0	88
26.87(f)(3), (f)(4), and (f)(5): Record of information from non-designated (emergency) test site	2	1.0	2
26.89(a): Record that absence of donor reported by non-licensee collection site	2	1.0	2
26.89(b)(3): Record that non-licensee collection site informed FFD program management that individual did not present identification	2	1.0	2
26.89(c): Record that non-licensee collection site reported donor's refusal to cooperate in the collection procedures.	2	1.0	2
26.91(e)(4): Record that results cancelled after EBT calibration check failure (non-licensee collection site)	1	1.0	1
26.91(e)(5): Prepare record of EBT maintenance (non-licensee collection site)	22	4.0	88
26.93(a)(6): Document alcohol pre-test questions asked and answered (non-licensee collection site)	280 <sup>50</sup>	0.3	84
26.95(b)(5): Record donor identity for initial alcohol breath test (non-licensee collection site)	280	0.3	84
26.97(b)(2): Record reason for new oral fluid alcohol test (non-licensee collection site)	8	0.5	4
26.97(c)(1): Document reason for failure of second collection attempt (non-licensee collection site)	1	1.0	1
26.97(d): Record results and alcohol screening device used (non-licensee collection site)	8	0.3	2
26.99(b): Record test time of initial test with 0.02% or higher BAC (non-licensee collection site)	1	0.3	0

underestimated licensee burden by assuming 6 individuals per drug and alcohol program required such a review.

<sup>50</sup> Estimate assumes that 10 persons per drug and alcohol program, who are FFD program personnel not located at the reactor site, fuel cycle facility, or C/V site where collections are typically made, will be tested at a U.S. Department of Transportation compliant collection site per section 26.31(b)(2).

**Table 4  
Annual Third-Party Burden**

<b>Section</b>	<b>Number of Responses</b>	<b>Burden Hours per Response</b>	<b>Total Annual Burden Hours</b>
26.101(b)(7): Indicate time on EBT printout of confirmatory alcohol test result (non-licensee collection site)	1	0.3	0
26.103(b): Non-licensee collector informs FFD management of result between 0.01 and 0.02 when donor in work status 3 or more hours	0	0.5	0
26.107(b): Document tampering attempt on CCF form (non-licensee collection site)	0	1.0	0
26.109(b)(3): Record that non-licensee collector notified FFD management or MRO notified of shy bladder problem	0	0.5	0
26.109(b)(4): Record that non-licensee collector notified FFD management if observed collection required	0	0.3	0
26.111(b): Non-licensee collector notes unusual findings on CCF	2	0.5	1
26.111(c): Record that non-licensee collector notified FFD manager of tampering attempts	0	0.4	0
26.113(b)(3): Record of CCF for both parts of split urine sample (non-licensee collection site)	0	0.3	0
26.115(b): Record that approval obtained for collection under direct observation from FFD manager or MRO (non-licensee collection site)	0	0.3	0
26.115(d): Record of CCF for directly observed collection (non-licensee collection site)	0	0.3	0
26.115(f)(3): Record of name of observer (non-licensee collection site)	0	0.3	0
26.117(c), (d), and (e): Prepare ID labels and CCF for specimen shipment (non-licensee collection site)	280 <sup>51</sup>	0.3	84
26.119(a), (e), and (f): Record that evaluation obtained from MRO or physician evaluating shy bladder claim (non-licensee collection site)	0	6.0	0
26.119(b): MRO provides information to physician as background for evaluation of shy bladder claim	0	2.0	0
26.129(b): Non-licensee specimen collector prepares memorandum to LTF personnel documenting investigation of discrepancies between specimen bottles and CCFs	0	1.0	0

<sup>51</sup> This estimate of 10 persons per drug and alcohol program is consistent with the previous clearance estimate.

**Table 4  
Annual Third-Party Burden**

<b>Section</b>	<b>Number of Responses</b>	<b>Burden Hours per Response</b>	<b>Total Annual Burden Hours</b>
26.135(b): Donor prepares written permission for retest second part of split sample	1	0.5	1
26.137(b)(3): Submit 1 in 10 negative specimens for validity screening to HHS lab	0	40.0	0
26.153(g): Supply memorandum to HHS lab explaining use of non-federal CCF	2	0.5	1
26.155(a)(1): Document qualifications of lab manager at HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(a)(3): Lab manager documents training of lab personnel	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(a)(4): Lab manager reviews and signs lab procedures	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(a)(5): Lab manager maintains QA program	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(b): Certifying scientist to certify test results from HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(c): Supervise technical analysts at HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(e): Continuing education for staff at HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.155(f): Lab personnel records	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.157(a): Written procedures for accession, receipt, shipment, and testing of urine specimens at HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.157(b): Written chain-of-custody procedures for HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.157(c): Written procedures manual for each assay performed by HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.157(d): Written procedures for device set-up and operation	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		

**Table 4  
Annual Third-Party Burden**

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.157(e): Written procedures for remedial actions to address systems and instrument errors	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.159(a): Documented restriction to access to HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.159(c), (d), and (e): Use and storage of CCFs	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.159(f): Use of CCF when shipping specimen to another HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.165(b)(1): Donor requests aliquot or split specimen to be tested by a second HHS lab	1	1.0	1
26.165(b)(2): Record that non-licensee MRO informed donor of opportunity for re-test of aliquot or test of Bottle B of split sample	1	0.3	0
26.165(b)(3): Written permission by donor for re-test of aliquot or test of Bottle B of split sample	1	1.0	1
26.165(b)(4): Donor presents documentation for reason unable to complete timely retest request	0	1.0	0
26.165(b)(6): HHS lab provides results of re-test of aliquot or test of Bottle B to MRO and to donor	1	0.5	1
26.167(a): Document quality assurance program of HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.167(c)(2)(i): Refractometer at the HHS lab must display specific gravity to 4 decimals and be interfaced with laboratory information management system or computer and/or document result by hard copy or electronic display	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.167(f)(3): Certification by HHS lab that retesting requested by licensee or other entity has occurred	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.167(h): Labeling of standards and controls	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		

**Table 4  
Annual Third-Party Burden**

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.168(a): Certification of contents of blind performance test samples submitted to HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.168(h)(2): Ensure supplier provides expiration date for test sample	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.168(i)(2): Use CCF, place fictional initials on specimen labels, and indicate blind performance test samples	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.169(a): Reports of test results by HHS lab	Burden covered under section 26.169(c)(1) through (c)(5)		
26.169(c)(1): HHS lab record of reports of positive, adulterated, substituted, dilute, and invalid test results to the MRO	686 <sup>52</sup>	0.25	172
26.169(c)(2): HHS lab record of quantitative test results as requested by MRO	5	1.0	5
26.169(c)(2): HHS lab record of quantitative test results for opiates to MRO	16 <sup>53</sup>	1.0	16
26.169(c)(3): HHS lab record of quantitative test results for adulterated or substituted test results	5 <sup>54</sup>	1.0	5
26.169(c)(4): HHS lab record of contact with MRO to discuss whether testing by another HHS lab should be done	10	0.5	5
26.169(f): HHS lab transmits copy of CCF for negative results to the MRO	Electronic transmission		
26.169(g): HHS lab transmits original CCF for positive, adulterated, substituted, dilute and invalid results to the MRO	686	0.5	343
26.169(h): HHS lab prepares and submits annual statistical summary report of urinalysis testing results	10	40.0	400
26.183(a): Documentation of MRO qualifications	28 <sup>55</sup>	1.0	28

<sup>52</sup> This estimate presents the total number of drug positive, adulterated, and substituted test results (536) reported to the MRO by HHS-certified laboratories in 2012 for all drug and alcohol testing programs (28).

<sup>53</sup> This estimate is based on a total of 16 opiate positive drug test results reported in the 2012 FFD program performance data. This is the same total of opiate positive drug tests reported in the previous collection period.

<sup>54</sup> This estimate is based on one (1) adulterated and four (4) substituted validity test results reported in 2012 FFD program performance data. The revised estimate represents a burden decrease of 90percent from the previous collection period. The change is based on improved data obtained through the voluntary e-reporting system.

**Table 4  
Annual Third-Party Burden**

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.183(c)(1): MRO review of records for positive, adulterated, substituted, invalid, or, at the licensee's or other entity's discretion, dilute test results	Burden accounted for under section 26.185(a)		
26.183(d)(2)(i): Record of MRO staff review and reporting of negative test results	16,373 <sup>56</sup>	0.05	819
26.183(d)(2)(ii): Record of MRO staff review of CCFs and forward changes to MRO	54 <sup>57</sup>	0.1	5
26.185(a) Record of MRO review of all positive, adulterated, substituted, or invalid test results and report to licensee or other entity	635	1.0	635
26.185(c): Record of MRO discussion of test results with the donor and record of report to licensee, following discussion with donor, of FFD violation	635	1.0	635
26.185(d)(1): Documentation that donor declined to discuss test results	81	1.0	81
26.185(e): Documentation that donor was unavoidably prevented from discussing test results and request to reopen proceeding	8	1.0	8
26.185(f)(1): MRO consultation with HHS lab to determine whether additional testing needed	Burden accounted for under section 26.185(c)		
26.185(f)(2): MRO contact with donor regarding medical explanation for test result	Burden accounted for under section 26.185(c)		
26.185(h)(1): MRO contact with donor to provide medical evidence regarding substituted specimen	Burden accounted for under section 26.185(c)		
26.185(h)(2): MRO notification to licensee that no valid medical explanation presented	Burden accounted for under section 26.185(c)		
26.185(h)(3): MRO notification to licensee that valid medical explanation presented	Burden accounted for under section 26.185(c)		

<sup>55</sup> NRC staff assumes in the revised estimate that each drug and alcohol testing program employs one MRO. The previous clearance underestimated the number of MROs employed by licensees.

<sup>56</sup> This estimate assumes that 164,270 tests conducted in 2012, minus 536 positive, adulterated, and substituted drug test results, minus 99 testing refusals not associated with a specimen test (equals the total number of negative drug test results reviewed by MROs and MRO staff = 163,635 tests). It is estimated that 10 percent of negative drug test results are reviewed by MROs and MRO staff who are non-licensee employees.

<sup>57</sup> The 2012 FFD program performance data indicate that 536 drug positive, adulterated, and substituted drug test results were reported. This estimate assumes that 10 percent of the reported drug test results are reviewed by MROs who are non-licensee employees.

**Table 4  
Annual Third-Party Burden**

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.185(i)(1): MRO contact with donor to provide medical evidence regarding adulterated specimen	Burden accounted for under section 26.185(c)		
26.185(i)(2): MRO notification to licensee that no valid medical explanation presented	Burden accounted for under section 26.185(c)		
26.185(i)(3): MRO notification to licensee that valid medical explanation presented	Burden accounted for under section 26.185(c)		
26.185(j)(3): MRO notification to licensee where evidence of drug abuse	Burden accounted for under section 26.185(c)		
26.185(j)(3): MRO report to licensee that donor has violated FFD policy by use of another individual's prescription medication	Burden accounted for under section 26.185(c)		
26.185(k): MRO report to licensee that no FFD policy violation has occurred	24	1.0	24
26.185(m): MRO review of inspection and audit reports, quality control data, multiple specimens, and other data to determine if positive, adulterated, substituted, or invalid result is scientifically insufficient for determination of FFD policy violation	24	1.0	24
26.185(n): Record of MRO report to licensee on result of analysis by second HHS lab	54 <sup>58</sup>	1.0	54
26.185(o): Record of MRO request for quantitation of test results	8	0.5	4
26.185(o): Lab provides quantitation of test results	8	1.0	8
26.185(p): MRO notice to licensee of determination of FFD policy violation	Burden covered by section 26.185(c)		
26.187(d): SAE training requirements	24	20.0	480
26.187(f): Documentation of SAE credentials and training	24	1.0	24
26.189(a): Written record of determination of fitness	69 <sup>59</sup>	1	54

58 NRC staff assumes in this estimate that 10 percent of the 536 positive, adulterated, and substituted drug test results are challenged by the donor and a retest of a single aliquot of the original specimen or the Bottle B (split) specimen is tested at a second HHS-certified laboratory. Of these tests, 10 percent are estimated to be reviewed by non-licensee MROs.

59 Of these, 10 percent are reviewed by non-licensee MROs.

**Table 4  
Annual Third-Party Burden**

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.189(c): Written record of for-cause determination of fitness	6.9 <sup>60</sup>	1.0	6.9
26.189(d): Modification of an initial determination of fitness based on information from other sources	24	1.0	24
26.209(a): Persons must self declare whether they are fatigued	23	0.3	6.9
26.405(g): MRO report of positive, adulterated, substituted, and invalid drug test results	90 <sup>61</sup>	1.0	90
26.411(b): Obtain signed consent form	4,675 <sup>62</sup>	0.3	1,403
26.719(c): Respond to a request for information associated with a 30-day event report due to a LTF or HHS lab testing error	6	8	48
26.821(b): Written agreement between C/Vs and licensees to permit authorized NRC representatives to inspect, copy, and/or retain copies of a C/V's documents, records, and reports	5	4.0	20
<b>TOTAL</b>			<b>303,559.1</b>

TOTAL PART 26 BURDEN: 623,943.1 hours, as viewed in table provided below.

TOTAL RESPONSES: 411,291 responses. This is equal to 129 total annual reporting responses from Table 3 plus 65 recordkeepers (30 drug and alcohol programs + 23 fatigue management programs + 12 HHS-certified laboratories) plus 410,999.9 third-party responses from Table 4.

NUMBER OF RESPONDENTS: 98,630 respondents. This is equal to 30 drug and alcohol programs plus 23 fatigue management programs plus 12 HHS-certified laboratories plus 98,565 third-party respondents<sup>63</sup>).

<sup>60</sup> 2012 FFD program performance data included 69 for-cause positive test results. Ten (10) percent are assumed

<sup>61</sup> 2012 FFD program performance data indicated that 90 positive tests results for all drug testing performed at the two Subpart K reactor construction sites (additional violations were noted, but these were associated with testing refusals where no specimens were tested).

<sup>62</sup> 2012 FFD program performance data indicated that 4,675 pre-access tests were performed at the two Subpart K reactor construction sites.

<sup>63</sup> Third-party respondents include an estimated 98,565 persons (i.e., pre-access tests results for 2012 = 93,890 persons subject to full drug and alcohol programs plus 4,675 at Subpart K reactor construction sites. This does not

THIRD-PARTY BURDEN: 303,559 hours, as viewed in table provided below.

Table	Description	Clearance Period		Difference between the 2011-2014 and 2014-2017 Collections (hours)
		2011-2014 (hours)	2014-2017 (hours)	
1	One-Time Recordkeeping	6,720.4	41.4	-6,679.0
2	Recordkeeping	351,889.6	314,177.4	-37,712.2
3	Reporting	6,615.0	6,165	-449.8
4	Third Party Disclosure	301,855.6	303,559.1	1,703.5
<b>TOTAL</b>		<b>667,080.6</b>	<b>623,943.1</b>	<b>-43,137.5</b>

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include MROs because they are within the program and already counted.

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

<b>NRC ACTION</b>	<b>No. Actions/ Year</b>	<b>Burden Hours/ Action</b>	<b>Total Hours</b>
Review exemption requests under section 26.9	2	16 hours per review	32
Review written FFD policies and procedures under section 26.27(d)	12	8 hours per review. Reviews performed during periodic inspections.	96
Review records under section 26.75(h) to ensure no inappropriate records are maintained	12	4 hours per review. Reviews performed during periodic inspections.	48
Review reports under section 26.77(c) that NRC employee or contractor is unfit for duty	0	No reports anticipated	0
Review documentation provided by SAE upon request by NRC under section 26.187(f)	1	4 hours per review	4
Review telephone reports to NRC Operations Center of significant FFD program failures for FFD programs under Subpart K submitted under section 26.417(b)(1)	1	16 hours per review	16
Review, analyze, and summarize annual FFD program performance reports for drug and alcohol programs under Subpart K submitted under section 26.417(b)(2)	2	25 hours per report	50
Review, analyze, and summarize annual fatigue management data specified in section 26.201(e) that is required to be included in the annual FFD program performance reports submitted under section 26.717(e) and (f)	62	10 hours per report <sup>64</sup>	620

<sup>64</sup> In calendar year 2012, 23 fatigue management programs submitted an annual FFD program performance report for each of the 61 operating reactor sites and 1 C/V. In the previous clearance, the estimated burden for NRC to fatigue management report and drug and alcohol program report was included collectively for 26.717(e) and (f). However, to more precisely allocate burden based on activity, NRC staff have separated the burden to review fatigue management reports and drug and alcohol reports into two separate items for 26.717(e) and (f). This is necessary because the number of fatigue and drug and alcohol reports submitted each year is different, and because the time spent by NRC staff to review, analyze, and summarize the data in each report is different.

<b>NRC ACTION</b>	<b>No. Actions/ Year</b>	<b>Burden Hours/ Action</b>	<b>Total Hours</b>
Review, analyze, and summarize annual FFD program performance report for the drug and alcohol testing program at each operating nuclear power reactor site, fuel cycle facility, and C/V submitted under section 26.717(e) and (f)	65	25 hours per report <sup>65</sup>	1,625
Review reports under section 26.719(a) of significant violations of FFD policy, drug and alcohol program failures, and errors in laboratory testing	Burden reported under section 26.719(b) and (c)		
Review 24-hour event reports by telephone to NRC Operations Center of significant FFD violations required by section 26.719(b)	37 <sup>66</sup>	16 hours per review	592
Review 30-day reports to the NRC of investigations involving testing errors required by section 26.719(c)	6 <sup>67</sup>	4 hours per review	24
<b>TOTAL</b>			<b>3,107</b>

<sup>65</sup> One annual FFD program performance report for drug and alcohol testing must be submitted for each licensee or other entity site. In calendar year 2012, the 28 drug and alcohol testing programs submitted one FFD program performance report for each of the 65 sites (61 operator reactor sites, 1 decommissioning reactor site (Zion), 1 C/V, and 2 fuel cycle facilities).

<sup>66</sup> The number of 24-hour reportable events is presented in the 2012 NRC FFD Program Performance Report, Table 1, Reportable Events Resulting from Individual Employee Violations.

<sup>67</sup> The number of 30-day event reports is presented in the 2012 NRC FFD Program Performance Report, Table 2, Laboratory Testing Performance Issues.