

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

(OMB Clearance No. 3150-0146)

EXTENSION WITH BURDEN REVISION

DESCRIPTION OF THE INFORMATION COLLECTION

The U.S. Nuclear Regulatory Commission (NRC) regulations in 10 CFR Part 26 (Part 26) prescribe 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 which 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, which 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 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, § 50.10(e)); combined license holders before the Commission has made the finding under of § 52.103(g)); construction permit holders who have been issued a LWA; 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.

A. JUSTIFICATION

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

These information collections are necessary to properly manage FFD programs and 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 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., §§ 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.

These 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.

Section 26.9 provides that the Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 26, and specifies that exemption requests must meet the provisions of § 50.12 or § 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 §§ 50.12 or 70.17 have been met.

Paragraph 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 § 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.

Paragraph 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 fitness-for-duty, 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.

Paragraph 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.

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 Recordkeeping requirements for superseded procedures are established by § 26.715(b)(4).

Paragraph 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 knowledge and abilities. This training program must be maintained to meet Part 26 requirements. This requirement provides assurance that persons are adequately trained in knowledge and abilities necessary to meet the § 26.23 performance objectives.

Paragraph 26.29(b) requires that all individuals subject to Part 26 demonstrate successful completion of training by passing a comprehensive examination about the knowledge and abilities specified in § 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.

Paragraph 26.29(c)(1) requires training for all personnel to be completed before FFD program authorization may be granted to 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.

Paragraph 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 shown 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.

Paragraph 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 § 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 § 26.713(b)(1).

Paragraph 26.31(a) requires licensees and other entities to implement drug and alcohol testing programs for individuals who are subject to this subpart. 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.

Paragraph 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 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.

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 a Medical Review Officer (MRO) and MRO staff are on site at a licensee's or other entity's facility, 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 determines those persons who are granted unescorted access to protected areas in nuclear power plants or who 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 § 26.27. Recordkeeping requirements for § 26.31(b)(1)(i) are established by § 26.713(f).

Paragraph 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 evidence that an individual is engaging in substance abuse as defined in § 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) Followup. As part of a follow-up plan to verify continued abstinence from the abuse of legal drugs or use of illegal substances covered under Part 26.

(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.

Paragraphs 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 § 26.27.

Paragraph 26.31(d)(1)(i)(D) allows licensees and other entities to conduct an analysis for a drug or drug metabolite not listed in § 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 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 § 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 § 26.31(d)(1)(i)(D). Recordkeeping requirements for § 26.31(d)(1)(i)(D) are established by § 26.713(g).

Paragraph 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 § 26.31(d)(1)(i)(D).

Paragraph 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 § 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 § 26.31(d)(1)(ii). Recordkeeping requirements for § 26.31(d)(1)(ii) are established by § 26.713(g).

Paragraph 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 and quality controls for testing are addressed under Subpart F, "Licensee Testing Facilities," §§ 26.125, 26.127, 26.129, and 26.137.

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

Paragraph 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 § 26.27. Recordkeeping requirements for FFD policy and procedures are described under § 26.27. The licensee or other entity is required to maintain a copy of each certification under § 26.31(d)(3)(iii)(C). Recordkeeping requirements for § 26.31(d)(3)(iii)(A) and (C) are established by § 26.713(g).

Paragraph 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 § 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 in a competent manner. The burden for reports of FFD concerns is covered under this section. Actions in response to reports of FFD concerns are taken under § 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 § 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 § 26.33 are maintained as part of the records of for-cause tests under §§ 26.31 or 26.211. Recordkeeping requirements, including the burden for the initial behavioral observation reports, for § 26.33 are established by §§ 26.203(d)(5) or 26.713(a)(2).

Paragraph 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 § 26.27. The burden for the EAP program procedures is covered under this section.

Paragraph 26.35(c) requires, in part, the EAP staff to protect the identity and 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 program helps to prevent harm through early intervention. 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 inform the FFD program management if the EAP personnel determine that the individual poses or has posed an immediate hazard to himself or others is necessary to increase the likelihood that impairment and other adverse behaviors are appropriately addressed by the licensees and other entities who are subject to the rule.

Recordkeeping requirements for § 26.35(a) policy and procedures are established by this section and by § 26.27(a). Recordkeeping requirements for § 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.

Paragraph 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 personal information.

Paragraph 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 § 26.39, and other persons pursuant to court order.

Paragraph 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.

Paragraph 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.

Paragraph 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 §§ 26.37(c) and (d) are established in this section and those for § 26.37(b) are established by § 26.713(a)(3).

Paragraph 26.39(a) requires each licensee and other entity subject to this subpart to establish procedures for the review of a determination that an individual has violated FFD policy.

Paragraph 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 §§ 26.39(a) and (b) are established by § 26.715(a).

Paragraph 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 § 26.39(d) are established by § 26.713(a)(2).

Paragraph 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 § 26.39 is provided to the individual. This requirement is necessary to ensure that 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 requirement also partially meets the legal necessity of proving “prior notice” and having it documented for evidence in legal proceedings. Recordkeeping requirements for § 26.39(e) are established by § 26.713(a)(2).

Paragraph 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.

Paragraph 26.41(b) requires licensees and other entities to ensure that the entire FFD program is audited as needed, and at least nominally every 24 months.

Paragraph 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 shown under § 26.41(f).

Paragraph 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.

Paragraph 26.41(f) requires the results of any audits required by § 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.

Paragraph 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 § 26.41(d) and distribution of audit records and reports to management under § 26.41(f) and (g) are established in these sections. Recordkeeping requirements for retention of audit records in § 26.41(f) and (g) are established by § 26.713(b)(2).

Paragraph 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 requirement requires communications between the two FFD programs to ensure that the necessary information is transferred between them concerning the individual.

Paragraph 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 § 26.4(a) through (e) and (g), or, at the licensee's or other entity's discretion, § 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 § 26.69 to maintain the individual's authorization. This requirement 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.

Paragraph 26.53(g) requires the licensees and C/Vs specified in § 26.4(a) and, as applicable, (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 requirement 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.

Paragraph 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.

Paragraph 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 § 26.5. This requirement 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.

Paragraph 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.

Paragraph 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 § 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 §§ 26.55(a)(1) and (a)(2) are established by §§ 26.61 and 26.63 and by § 26.713(a)(1) and (3).

Paragraph 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.

Paragraph 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 § 25.57(a)(1) and (2) are established by §§ 26.61 and 26.63 and by § 26.713(a)(1) and (3).

Paragraph 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.

Paragraph 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.

Paragraph 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 § 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.

Paragraph 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 § 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 § 26.59(b), are captured by §§ 26.61 and 26.63 and by § 26.713(a)(1) and (3). Recordkeeping requirements for § 26.59(c)(1) are established by § 26.61 and by § 26.713(a)(1) and (3).

Paragraph 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.

Paragraph 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.

Paragraph 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 §§ 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 §§ 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 of commercial nuclear power plants. Recordkeeping requirements for § 26.61(a) are established by § 26.713(a)(1).

Paragraph 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.

Paragraph 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 § 26.61(a), but they do specify the types of information that must be included in the self-disclosure and employment history required by § 26.61(a). These paragraphs specify the information to be reported or recorded in support of authorization determinations under §§ 26.55, 26.57, and 26.59.

Paragraph 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.

Paragraphs 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 this subpart 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.

Paragraph 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 §§ 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 §§ 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 § 26.63(a) and (c)(2) are established by § 26.713(a)(1).

Paragraph 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 §§ 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 § 26.63(c)(3) are established by § 26.713(a)(1).

Paragraph 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.

Paragraph 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 § 26.63(d) and (e) are specified by §§ 26.711 and 26.713(a), (b), and (c).

Paragraph 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 § 26.63(f) does not require information collection, it does affect the burden attributable to §26.63. An average burden has been used for those estimates.

Paragraphs 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.

Paragraphs 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 §§ 26.65(d)(1) and 26.65(e)(2) are established by § 26.713(a)(3).

Paragraph 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 § 26.65(f) are specified by § 26.713(a)(2).

Paragraph 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 §§26.65 or 26.69, the licensee or other entity shall subject the individual to random testing under §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.

Paragraph 26.67(b) provides that if an individual is selected for one or more random tests after a requirement for pre-access testing under §§26.65 or 26.69 has been met, the licensee may grant authorization before the random testing is completed.

Paragraph 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 §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 §26.67 are specified by §26.713(a)(2).

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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 §26.187(a) has indicated the individual is fit for duty.

Paragraph 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.

Paragraph 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.

Paragraph 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 followup drug and alcohol testing from the determination of fitness.

Paragraph 26.69(e) allows licensees and other entities to rely on followup testing, treatment plans, and determinations of fitness that meet the requirements of §26.189 and were conducted under the FFD program of another licensee or entity subject to Part 26.

Paragraph 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 §§ 26.69(b), (c)(1), (c)(2) and (c)(3) are specified by § 26.713(a)(1). Recordkeeping requirements for §§ 26.69(c)(4) and (5) and for § 26.69(d) are specified by § 26.713(a)(3).

Paragraphs 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 §§ 26.75(a), (b), (c), (d), (e)(2), and (g) are established by § 26.713(c).

Paragraph 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 licensee testing facility, 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.

Paragraph 26.75(i) allows a licensee testing facility 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 § 26.75(i)(1) - (4) are met.

Paragraph 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 § 26.713(a)(2).

Paragraph 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 § 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 § 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

§§ 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 § 26.713(a)(2).

Paragraph 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 § 26.77(c) are established by § 26.719(a).

Paragraph 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.

Paragraph 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 collection activities under Part 26 are provided with appropriate training so that they understand the methods that are used to implement the FFD policy. The burden for one-time training for collectors and the ongoing burden for training new collectors are both shown under these paragraphs. Recordkeeping requirements for § 26.85(a) and (b) are established by § 26.715(a) and (b)(1).

Paragraph 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 10 CFR Part 26, 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 § 26.85(c)(4) are established by § 26.715(a).

Paragraph 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 § 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 § 26.85(e) are established by § 26.715(a) and (b)(1).

Paragraph 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.

Paragraph 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 § 26.87(c)(4) are established by § 26.715(b)(3). The paperwork burden for the posting required by §§ 26.87(d)(3) and (f)(1) is established by those sections.

Paragraph 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.

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

Paragraph 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.

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 § 26.87(f)(3) and (f)(5) are established by § 26.715(b)(2).

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

Paragraphs 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.

Paragraph 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.

Paragraph 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.

Paragraph 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 § 26.89(a), (b), and (c) are established by § 26.715(b)(6).

Paragraphs 26.91(c)(1), (c)(2), and (c)(3) provides that an evidential breath testing (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 evidential breath testing 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 § 26.91(c)(1)-(3) are established by § 26.715(b)(12).

Paragraph 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.

Paragraph 26.91(e)(5) requires that the inspection, maintenance, and calibration of the EBT be performed by the manufacturer or a certified representative of the manufacturer. This helps ensure that the instrument is accurate and can provide reliable and repeatable results within specified instrument parameters.

Paragraph 26.91(e)(5) results in the creation of an internal record of the inspection, maintenance, and calibration activities. This is necessary to ensure that inspection, maintenance, and calibration activities can be reviewed and verified as being accurate; this helps protect the rights of the persons tested.

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

Paragraph 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 § 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 § 26.93(a)(6) are established by § 26.715(b)(6).

Paragraph 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 § 26.95(b)(5) are established by § 26.715(b)(6).

Paragraph 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.

Paragraph 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 § 26.97(b)(2) and (c)(1) are established by § 26.715(b)(6).

Paragraph 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 § 26.97(d) are established by § 26.715(b)(6).

Paragraph 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 § 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 § 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 § 26.101, no more than 30 minutes after the conclusion of the initial test. Recordkeeping requirements for § 26.99(b) are established by § 26.715(b)(6).

Paragraph 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 § 26.101(b)(7) are established by § 26.715(b)(6).

Paragraph 26.103(b) requires the collector to declare test results as negative where the results show BAC below .02 but at or above .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 § 26.103(b) are established by § 26.715(b)(6).

Paragraph 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. Because it is expected to be an infrequent occurrence, it does not create a significant additional burden. However, it is necessary to ensure that an immediate record of any attempt to tamper with a specimen is prepared and that it accompanies the specimen. Recordkeeping requirements for § 26.107(b) are established by § 26.715(b)(6).

Paragraph 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, the collector shall discontinue the collection and notify the FFD program manager or MRO to initiate the “shy bladder” procedures in § 26.119.

Paragraph 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 § 26.109(b)(4) are established by § 26.715(b)(6).

Paragraph 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 a 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 § 26.111(b) are established by § 26.715(b)(2).

Paragraph 26.111(c) requires the collector to contact the designated FFD manager if the collector has the reasonable belief, based on observation, that the donor may have attempted to dilute, substitute, or adulterate the specimen. The FFD manager may require the donor to provide a second specimen under observation. This requirement is necessary to ensure that the FFD program manager is informed of the possibility that a donor may have attempted to dilute, substitute, or adulterate a specimen, so that the FFD program manager can examine the circumstances and determine whether to initiate appropriate management actions, including notification to the NRC if the facts of attempted dilution, substitution, or adulteration of a specimen are confirmed. Recordkeeping requirements for § 26.111(c) are established by § 26.715(b)(6).

Paragraph 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 § 26.113(b)(3) are established by § 26.715(b)(2).

Paragraph 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 collection of 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 § 26.115(b) are established by § 26.715(a).

Paragraph 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 § 26.115(d) are established by § 26.715(b)(2).

Paragraph 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 § 26.115(f)(3) are established by § 26.715 (b)(2).

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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 §§ 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 § 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 § 26.117(c), (d), and (e) are established by § 26.715(b)(2).

Paragraph 26.119(a) requires a donor who has not provided a specimen (i.e., shy bladder) 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.

Paragraph 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.

Paragraph 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.

Paragraph 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 § 26.119(a), (b), (e), and (f) are established by § 26.715(b)(6). Recordkeeping requirements related to providing instructions and making a written determination for §§ 26.119(a), (b), (e), and (f) are established by § 26.119.

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

Paragraph 26.125(c) requires licensee testing facility 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 licensee testing facility to correctly use the instruments and devices that the licensee testing facility 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 licensee testing facility 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 § 26.125(b) and (c) are established by § 26.715(a) and (b)(1).

Paragraph 26.127(a) requires licensee testing facilities to develop, implement, and maintain clear and well-documented procedures for accession, receipt, shipment, and testing of urine specimens.

Paragraph 26.127(b) requires licensee testing facilities 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.

Paragraph 26.127(c) requires licensee testing facilities to develop, implement, and maintain written standard operating procedures for each assay performed for drug and specimen validity testing. If the licensee testing facility performs validity screening tests, the licensee testing facility 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.

Paragraph 26.127(d) requires licensee testing facilities 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.

Paragraph 26.127(e) requires licensee testing facilities 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 § 26.127(a), (b), (c), (d) and (e) are established by § 26.715(a).

Paragraph 26.129(a) requires each licensee testing facility 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.

Paragraph 26.129(b) requires licensee testing facility 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, licensee testing facility 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.

Paragraph 26.129(b)(1) requires licensee testing facilities 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 § 26.719(b).

Paragraph 26.129(d) requires licensee testing facilities's 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.

Paragraph 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, § 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 § 26.129(a) are established by § 26.715(b)(13); § 26.129(b) established by § 26.715(b)(2); § 26.129(b)(1) established by § 26.715(b)(3); and, § 26.129(d) are established by § 26.715(b)(2).

Paragraph 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 §26.113) be tested at another HHS-certified laboratory. The donor provides his or her written permission for the licensee testing facility 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 § 26.135(b) are established by § 26.715(b)(6).

Paragraph 26.137(a) requires each licensee testing facility 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 § 26.137(a) are established by § 26.715(b)(3).

Paragraph 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.

Paragraph 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 licensee testing facility 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 § 26.137(b)(1)(ii) and (iii) are established by § 26.715(b)(7).

Paragraph 26.137(b)(3) requires licensee testing facilities 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 licensee testing facility'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 § 26.137(b)(3) are established by § 26.715(b)(3). Reporting requirements for false negatives detected under § 26.137(b)(3) are established by § 26.719(c)(3).

Paragraph 26.137(e)(7) requires licensee testing facilities 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.

Paragraph 26.137(f)(5) requires licensee testing facilities 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 licensee testing facility and reported to appropriate levels of management.

Paragraph 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 § 26.137(e)(8) are established by § 26.715(b)(3); § 26.137(f) established by § 26.715(b)(8); and, § 26.137(h) are established by § 26.715(b)(5).

Paragraph 26.139(d) requires licensee testing facilities to prepare information for annual reports to the NRC, as required in § 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 § 26.139(d) are established by § 26.717(b) and (e).

Paragraph 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.

Paragraph 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 § 26.153(e) are established by § 26.715(b)(9) and § 26.153(f) is established by § 26.713(e).

Paragraph 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 Custody and Control Form (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 § 26.153(g) are established by § 26.715(b)(2).

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

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

Paragraph 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 §§ 26.155(a)(1), (a)(3), (b), and (c) are established by § 26.155(f); § 26.155(a)(4) established by § 26.157; and the § 26.155(a)(5) requirements are established by § 26.715(b)(3). The recordkeeping burden for § 26.155(e) and (f) is captured under OMB Control No. 0930-0158.

Paragraph 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.

Paragraph 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.

Paragraph 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 licensee testing facility 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.

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

Paragraph 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 § 26.157(a), (b), (c), (d) and (e) is captured under OMB Control No. 0930-0158.

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

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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 § 26.159(a) is captured under OMB Control No. 0930-0158. Recordkeeping requirements for § 26.159(b) are established by § 26.715(b)(3) and § 26.159(c), (d), (e), (f), and (i) are established by § 26.715(b)(2). Reporting requirements for reports of tampering to NRC under § 26.159(b) are established by § 26.719(b)(3).

Paragraph 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 § 26.163(a)(2) are established by § 26.715(b)(6).

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

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

Paragraph 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 § 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 § 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 §§ 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.

Paragraph 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.

Paragraph 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 §§ 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.

Paragraph 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 § 26.165(b)(1), (b)(6), and (c)(4) are established by § 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 § 26.165(b)(1), (b)(2), (b)(3), (b)(4), (b)(6), (f)(1), (f)(1)(ii), (f)(1)(iv), and (f)(2).

Paragraph 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, limit of detection (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.

Paragraph 26.167(c)(2)(i) requires a refractometer used by an HHS-certified laboratory to 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 in HHS-certified laboratories to perform tests 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, to allow donors to see the result, and to ensure the integrity of the testing process. Recordkeeping requirements for the records created meeting the specifications of § 26.167(c)(2)(i) under other sections of Part 26 are established by § 26.715(b)(14).

Paragraph 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.

Paragraph 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 § 26.167(a), (c)(2)(i), and (f) are established by § 26.715(b)(7) and § 26.167(h) is established by § 26.715(b)(3).

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

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

Paragraph 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.

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

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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 § 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 § 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 § 26.169 are established by § 26.715(b)(2), (b)(3), (b)(5), (b)(6), and (b)(8).

Paragraph 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.

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

Paragraph 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, dilute result, including reviewing records made available by the donor, and documented medical conditions.

Paragraph 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.

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

Paragraph 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 § 26.183(a) are established by this section or, for MROs no longer employed by the licensee, by § 26.715(b)(1). Recordkeeping requirements for § 26.183(c)(1), (d)(1)(ii), (d)(2)(i) and (d)(2)(ii) are established by § 26.713(a)(2).

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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 § 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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 credible medical evidence within 5 business days that he or she produced the adulterated result through normal human physiology.

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

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

Paragraph 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.

Paragraph 26.185(p) requires the MRO to complete the MRO's review of positive, adulterated, substituted, and invalid test results and, in those instances in which the MRO determines that the donor has violated the licensee's or other entity's FFD policy, to notify the licensee or other entity's designated representative in writing within 10 business days of an initial positive, adulterated, or substituted test result.

The requirements in § 26.185(h)(1), (h)(2), (h)(3), (i)(1), (i)(2), (i)(3), (m), (n), (o) and (p) are necessary to 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. 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 § 26.185 are established by § 26.713(a)(2).

Paragraph 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.

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

Paragraph 26.189(a) provides that a determination of fitness, the process entered when there are indications that an individual in § 26.4(a) through (e), and, at the licensee's or other entity's discretion, § 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.

Paragraph 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.

Paragraph 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 § 26.189 are established by § 26.713(a)(4).

Paragraph 26.203(a) requires each licensee or other entity subject to Part 26, 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 § 26.27(b).

Paragraph 26.203(b) requires each licensee or other entity subject to Part 26, 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 under § 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 Part 26, 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 § 26.203 are included under § 26.27(b) and (c) for the overall policy and procedures.

Paragraph 26.203(c) requires licensees to add specific knowledge and abilities (KAs) to the content of the training that is required in § 26.29(a) and the comprehensive examination required in § 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 Part 26 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 fitness-for-duty 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.

Paragraph 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:

- Paragraph 26.203(d)(1): Records of work hours for individuals subject to the work hour controls in § 26.205;
- Paragraph 26.203(d)(2): Records of shift schedules and shift cycles of individuals who are subject to the work hour controls in § 26.205;

- Paragraph 26.203(d)(3): Documentation of waivers that is required in § 26.207(a)(4), including the basis for granting the waivers.
- Paragraph 26.203(d)(4): Documentation of work hour reviews that is required in § 26.205(e)(3) and (e)(4); and,
- Paragraph 26.203(d)(5): Documentation of fatigue assessments that is required in § 26.211(g).

These § 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.

Paragraph 26.203(e) requires that the following information in a standard format is included in the annual FFD program performance report required by § 26.717.

Paragraph 26.203(e)(1): Summaries 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 §26.205(d)(1) through (d)(5)(i) for individuals described in § 26.4(a). The summary must include 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 § 26.4(a) the licensee shall report: the number of instances in which each work hour control specified in § 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), and (d)(3)(i) through (d)(3)(iv) was waived for individuals not working on outage activities; the number of instances in which each work hour control specified in § 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)(4) and (d)(5)(i) 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 § 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).

Paragraph 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 § 26.203(e) are established by this section. Reporting requirements for § 26.203(e)(1), and (e)(2) are established by this section.

Paragraph 26.203(f) requires licensees to audit the management of worker fatigue as required by § 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 § 26.203(f) are established by § 26.41(f) and (g).

Paragraph 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.

Paragraph 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.

Paragraph 26.205(d)(1) requires licensees to implement work hour controls for individuals to ensure that, except as permitted by the waiver provisions in §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.

Paragraph 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.

Paragraph 26.205(d)(3) requires licensees to ensure that individuals have, at a minimum, the number of days off specified in this paragraph.

Paragraph 26.205(d)(4) exempts licensees from the requirements of paragraph (d)(3) of this section for individuals specified in § 26.4(a)(1) through (a)(4) for the first 60 days of an outage, while the individuals are working on outage activities.

Paragraph 26.205(d)(5) exempts licensees from the requirements of paragraph (d)(3) of this section for individuals specified in § 26.4(a)(5) for the first 60 days of a unit outage, security system outage, or increased threat condition.

Paragraph 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.

Paragraph 26.205(e) requires licensees to evaluate the effectiveness of their control of work hours for individuals who are subject to Part 26, 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.

Paragraph 26.205(e)(3) requires licensees to document the methods used to conduct the reviews and the results of the reviews.

Paragraph 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 § 26.205(c) and (d)(1) are established by § 26.203(d)(1); § 26.205(d)(2) through (d)(6) are established by § 26.203(d)(2); § 25.205(e)(1) through (e)(3) are established by § 26.203(d)(4); and, § 26.205(e)(4) are established by § 26.203(d)(4).

Paragraph 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 § 26.207 are established by § 26.203(d)(3).

Paragraph 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.

Paragraph 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 § 26.4(a) through (c). Each summary must include: the conditions under which each fatigue assessment was conducted (i.e., self-declaration, for cause, post-event, followup); 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 § 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 § 26.211(f) and (g) are established by § 26.203(d)(5).

Paragraph 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.

Paragraph 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.

Paragraph 26.403(b) requires FFD programs under this 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.

Paragraph 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 § 26.405.

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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 §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.

Paragraph 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.

Paragraph 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.

Paragraph 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.

Paragraph 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 licensee testing facilities, 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 FDA (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.

Paragraph 26.405(g) requires FFD programs under this subpart 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 § 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, followup, 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.

Paragraphs 26.406(a), (b), and (d) require licensees and other entities that do not implement random testing under §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 § 26.4(f), and the frequency with which observations must be conducted.

Paragraph 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 § 26.403.

Section 26.407 requires that while the individuals specified in § 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 § 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 §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.

Paragraph 26.411(a) requires licensees and other entities that collect personal information about an individual for the purpose of complying with this subpart 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.

Paragraph 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 this subpart 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.

Section 26.413 requires licensees and other entities that implement a FFD program to establish and implement procedures for the review of a determination that an individual in §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.

Paragraph 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.

Paragraph 26.417(a) requires FFD programs under this subpart 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.

Paragraph 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 this subpart. These events must be reported under this subpart, rather than under the provisions of 10 CFR 73.71, because the events are associated with FFD programs at construction sites.

Paragraph 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, 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 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 of Part 26 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.

Paragraph 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.

Paragraph 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 § 73.56, as supplemented by orders to nuclear power plants dated January 7, 2003, and subsequent rulemaking.

Paragraph 26.711(c) provides that licensees and other entities specified in § 26.4(a) 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 § 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.

Paragraph 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.

Paragraph 26.713(a)(1) requires the retention of records of self-disclosures and suitable inquiries conducted under §§ 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.

Paragraph 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.

Paragraph 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.

Paragraph 26.713(a)(4) requires the retention of records of any determinations of fitness conducted under § 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.

Paragraph 26.713(b)(1) requires that licensees and other entities retain records of FFD training and examinations conducted under § 26.29 for at least 3 years or until the completion of all related legal proceedings, whichever is later.

Paragraph 26.713(b)(2) requires that licensees and other entities retain records of FFD audits, audit findings, and corrective actions taken under § 26.41 for at least 3 years or until the completion of all related legal proceedings, whichever is later.

Paragraph 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 § 26.75(c), (d), or (e)(2) and any permanent denials of authorization under § 26.75(b) and (g) for at least 40 years or until, upon application, the NRC determines that the records are no longer needed.

Paragraph 26.713(d) requires that licensees and other entities retain any superseded versions of the written FFD policy and procedures required under §§ 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.

Paragraph 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.

Paragraph 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 § 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.

Paragraph 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 § 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.

Paragraph 26.715(a) requires collection sites providing services to licensees and other entities who are subject to this subpart, licensee testing facilities, and HHS-certified laboratories to maintain and make available documentation of all aspects of the testing process for at least 2 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.

Paragraph 26.715(b) specifies that the documentation that must be retained pursuant to § 26.715(a) include the following:

- Paragraph 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, licensee testing facility, or HHS-certified laboratory;
- Paragraph 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);
- Paragraph 26.715(b)(3): Quality assurance and quality control records;
- Paragraph 26.715(b)(4): Superseded procedures;
- Paragraph 26.715(b)(5): All test data (including calibration curves and any calculations used in determining test results);
- Paragraph 26.715(b)(6): Test reports;
- Paragraph 26.715(b)(7): Records pertaining to performance testing;
- Paragraph 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;
- Paragraph 26.715(b)(9): Performance records on certification inspections;
- Paragraph 26.715(b)(10): Records of preventative maintenance on licensee testing of facility instruments;
- Paragraph 26.715(b)(11): Records that summarize any test results that the MRO determined to be scientifically insufficient for further action;

- Paragraph 26.715(b)(12): Printed or electronic copies of computer-generated data;
- Paragraph 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 licensee testing facilities and HHS-certified laboratories; and,
- Paragraph 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.

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

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

- Paragraph 26.717(b)(1): The random testing rate;
- Paragraph 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 level of detection (LOD);
- Paragraph 26.717(b)(3): Populations tested (i.e., individuals in applicant status, permanent licensee employees, C/Vs);
- Paragraph 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);
- Paragraph 26.717(b)(5): Conditions under which the tests were performed;
- Paragraph 26.717(b)(6): Substances identified;
- Paragraph 26.717(b)(7): Number of subversion attempts by type;
- Paragraph 26.717(b)(8): Summary of management actions; and,
- Paragraph 26.717(b)(9): The information on review of work hour controls required under § 203(e)(1) and (e)(2).

Paragraph 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.

Paragraph 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 licensee testing facility, 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.

Paragraph 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.

Paragraph 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.

Paragraph 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 § 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 in implementing FFD programs, and to enable the NRC to inspect the licensees' and other entities' FFD 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 ensure that the health and safety of the public and the common defense and security are not endangered.

Paragraph 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 § 26.719 rather than § 73.71.

Paragraph 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:

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

- Paragraph 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.

Paragraph 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 licensee testing facility or an HHS-certified laboratory, in the testing of quality control or actual specimens, or through the processing of reviews under § 26.39 and MRO reviews under § 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.

Paragraph 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.

Paragraph 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 § 26.137(b).

Paragraph 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 four 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 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.

Paragraph 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.

Paragraph 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 programs 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 § 26.821(b) is established by § 26.713(e).

Commission Order

In addition to the requirements in Part 26, the NRC issued an order on April 29, 2003, related to the work-hour provisions of Part 26, Subpart I, "Fatigue management." The order prescribed criteria such that nuclear facility security force personnel are not assigned to duty while in a fatigued condition that could reduced their alertness or ability to perform functions necessary to identify and promptly respond to plants security threats. At that time, 65 power reactor sites were required to comply with 10 CFR Part 26 and the order. The burden for this order was estimated in the Part 26 (prior rule) clearance dated October 3, 2005, 70 FR 57625.

As described in the Federal Register summary for the March 31, 2008, amendment of 10 CFR Part 26 (70 FR 16967), the provisions required in Part 26, Subpart I, replaced the requirements imposed by the order. As a result, the requirements of the order were relaxed for all affected entities (see NRC letter dated June 8, 2009, accessible at the NRC's Agencywide Documents Access and Management System at accession number ML091060582) and the burden was included in the 2007-2010 clearance estimate. The NRC assumed that the burden associated with the order was approximately equivalent to the corresponding requirements in Part 26, Subpart I.

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 the requirements of Part 26 to ensure that licensees' and other entities' FFD programs and the implementation of such programs are 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). It is estimated that approximately 70% of all responses are filed electronically. Most all licensees and other entities subject to Part 26 collect and store FFD data electronically.

4. Efforts to Identify Duplication and Use Similar Information

Certain records referenced in Subpart G of Part 26 belonging to 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 the U.S. Department of Health and Human Services). 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 licensees are not duplicated by other Federal information collection requirements and are not available from any other source. NRC has in place an on-going program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

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 testing facilities, 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 obtained less frequently, persons could be assigned to operate or perform

work in a nuclear power plant who are fatigued and unable to safely and competently perform assigned duties. This could result in conditions adverse to safety and/or security.

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 sections 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:

Section 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 appropriate NRC managers can address the situation immediately.

Section 26.185(p) requires an MRO to complete a review of positive, adulterated, substituted, and invalid test results and notify the licensee or other entity's designated representative within 10 business days of the an initial non-negative test result. Notification within 10 days is necessary so that the licensee or other entity can take prompt action concerning the non-negative result.

Section 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 of Part 26. This requirement is necessary to ensure, in part, that the NRC is timely informed so that appropriate regulatory actions can be initiated.

Section 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.

Section 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.

Section 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 sections 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:

Section 26.165 (b)(3) requires written permission from the donor before additional testing may occur if the initial sample had positive, adulterated, or substituted results. If a donor wants retesting, 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.

Section 26.169(a) requires HHS-certified laboratory to report test results to the licensee's or other entity's MRO within 5 business days after receiving the specimen. 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.

Section 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 sections 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:

Section 26.203(d) requires that specified records pertaining to fatigue management should be kept for at least 3 years, which is consistent with the OMB Guidelines, "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.

Section 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 who is subject to the rule require access to them in a legal or regulatory proceeding.

Section 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 § 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.

Sections 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.

Section 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 not 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 shutdown) is necessary because the individual may attempt to re-enter the industry at a different facility. Requiring retention and availability of the records pertaining to those individuals subject to 5-year and permanent denial of authorization ensures that that these records are available for NRC and licensee review.

Section 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.

Section 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.

Section 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 § 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.

Section 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 § 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.

Section 26.715(a) requires collection sites providing services to licensees and other entities, licensee testing facilities, 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.

Section 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 has been published in the Federal Register.

The requirements of Part 26 are discussed on a continuing basis with representatives from the NEI, licensees, 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.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

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

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.

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 drug and alcohol portion of the estimated burden and costs are based on:

- 27 FFD programs for commercial nuclear power reactors
- 2 fuel-cycle facilities
- 2 C/Vs

- 1 reactor plant construction site

The fatigue management portion of the estimated burden and cost is based on:

- 27 FFD programs for commercial nuclear power reactors
- 2 C/Vs, if they provide services to nuclear power reactors in the appropriate job duty groups

Regarding commercial nuclear power plants, there are 104 operating reactors in the United States located at 65 facilities, with each facility consisting of one or more reactor units. Several facilities may be owned and operated by the same licensee (i.e., the same corporate entity). A licensee may therefore administer the FFD activities at one or more of its facilities through a single FFD program (e.g., the same FFD policy and procedures apply to multiple reactor plants, with a single FFD staff administering the drug and alcohol testing program). Furthermore, multiple sites may share MROs, Substance Abuse Experts, a particular specimen collection company, or HHS-laboratory and conduct joint audits to achieve cost savings and burden reduction.

Regarding power reactor construction, the burden and cost of recordkeeping and reporting requirements depends on the type of FFD program implemented by, and at the discretion of, the construction entity. For example, a construction entity could implement a Subpart K FFD program for its personnel who construct or direct the construction of safety- or security-related SSCs. This would be a program specifically focused on the workers and first-line supervisors, the majority of personnel on the construction site. The Subpart K requirements are designed to help lower the cost for FFD program development and implementation while still providing reasonable assurance that the Part 26 performance objectives can still be met. For higher-level supervisors, other persons who perform key activities, and FFD program personnel (such as the FFD manager, specimen collection personnel, and the MRO), these personnel would be subject to a so-called “full FFD program,” one that meets all of the requirements of Part 26, except Subparts I and K, in order to provide reasonable assurance. Then, as this construction site completes certain construction milestones and approaches reactor operation, the construction entity will start transitioning all affected persons to its full FFD program. As an option, a construction entity could elect to place all affected personnel in a full FFD program throughout construction and maintain this one program into the period of reactor operation (i.e., implement a full program for all affected persons and not implement a Subpart K program). Historically, the power reactor industry and NRC have assumed that this latter option would be more expensive than implementing the Subpart K program option; as of September 2010, insufficient quantitative information exists to publish comparative burden values. There are pros and cons to both options. The burden associated with the one construction site that recently implemented an FFD program was captured in the 19 construction entities used for the 2007-2010 clearance. For the current 2010-2013 clearance, the NRC re-baselines this estimate to one (1) entity that will incur costs associated with implementing an FFD program at its construction site. This re-baselining is more accurate of actual costs estimated to be incurred over the next 3 years.

The NRC staff utilized insights gained from discussions with representatives from five commercial nuclear power entities, NEI, HHS’s Substance Abuse and Mental Health Services Administration, and one HHS-certified laboratory. This external information was supplemented by internal estimates made by NRC staff familiar with the records and reports required by the rule and the lessons learned from rule implementation.

As a result, using burden hours x \$259/hour from 10 CFR 170.20, the 2010-2013 clearance estimate for industry is:

Table	Burden Area	Hours	Cost (dollars)
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1	One-Time	6,463	1,673,917
2	Recordkeeping	351,889	91,139,251
3	Reporting	6,615	1,713,285
4	3 rd Party	301,857	78,180,963
TOTAL		666,824	172,707,416

13. Estimates of Other Additional Costs

There are two additional costs for the 2010-2013 clearance: records storage costs and evidentiary breath testing (EBT) device costs. This cost aggregation was also used in the 2007-2010 clearance. Note that the “additional cost” burden in the current 2010-2013 clearance, as reflected below, is less than the previous clearance primarily due to the re-estimation of one-time costs, see Table 1 and paragraph 15, “Reasons for Change in Burden or Cost.”

The quantity of records to be maintained is roughly proportional to the recordkeeping burden and therefore can be used to calculate approximate records storage costs. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined to be equal to 0.0004 times the recordkeeping burden cost. Therefore, the records storage cost for the 2010-2013 clearance is estimated to be \$68,398 (Tables 1+2+4 = 660,209 recordkeeping hours x \$259/hour x 0.0004).

Three FFD programs are expected to purchase 2 EBT devices at a cost of approximately \$3,000 per device for a total of \$12,000 (3 x 2 x \$3,000).

The estimate of additional costs is estimated at \$80,398 (\$68,398 + \$12,000).

14. Estimated Annualized Cost to the Federal Government

Table 5 describes 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 and 171. Using \$259/hour, the total estimated cost to government is:

Table	Burden Area	Hours	Cost (dollars)
5	NRC	3,004	778,036

15. Reasons for Change in Burden or Cost

The total burden for Part 26 changed from 871,261 hours to 666,824 hours, a decrease of 204,437 hours. The burden is summarized below and as detailed in Tables 1-4.

Table	Table Description	Clearance Period		Difference between the 2007-2010 and 2010-2013 Collections (hours)
		2007-2010 (hours)	2010-2013 (hours)	
1	One-Time	114,598	6,463	↓ 108,135 or 94%
2	Records	412,448	351,889	↓ 60,559 or 15%
3	Reports	7,053	6,615	↓ 438 or 6.2%
4	3 rd Party	337,162	301,857	↓ 35,305 or 11%

TOTAL	Clearance Period		Difference between the
	871,261	666,824	↓ 204,437 or 24%

Burden estimates changed for three main reasons:

- 1) The number of respondents or responses was adjusted for a number of requirements. Many requirements which were previously estimated to affect 33 recordkeepers now are estimated to affect 31 recordkeepers. The number of FFD programs has been reduced from 33 to 31 because two FFD programs were combined into one and because an FFD program is not required for the MOX facility until after it receives its NRC license, which is expected to occur after the 2010-2013 clearance period. In addition, some requirements previously were estimated to affect 26 laboratories and are now estimated to affect 10 laboratories, this is based on 2009 industry information that indicated that only 10 laboratories support all Part 26 programs.
- 2) Based on external input and staff experience, the burden estimates for a number of requirements were adjusted. The burden estimates in the current package represent the NRC's best estimates based on staff knowledge and experience in administering the FFD program, discussions with representatives from the commercial nuclear power industry, NEI, and HHS's Substance Abuse and Mental Health Services Administration. This period, the staff also included information from discussions with one HHS-certified laboratory, the conduct of public meetings to hear comment on the Commission's drug, alcohol, and fatigue management provisions, and from the American Association of Medical Review Officers. No more than 9 external entities were contacted.
- 3) For the 2007-2010 clearance, the NRC used the CY 2005 FFD program performance data and for the 2010-2013 clearance, the staff used the CY 2009 FFD program performance data. The data from these annual performance reports informs the clearance estimates and results in fact-of-life changes to the burden estimate. These data are affected by actual numbers of persons on each NRC-licensed facility, or affected entity, subject to Part 26.

Following is a summary of the changes, by table:

Table 1, Annualized one-time recordkeeping requirements

The previous clearance was based on 33 respondents incurring one-time recordkeeping burdens to implement FFD programs. Because these entities have already incurred this one-time burden, they are no longer included as respondents for these requirements. For the current clearance period, the NRC estimates that a single respondent will incur one-time implementation burdens.

The burden hours per program for the requirements in § 26.29(b) and § 26.29(c)(1) are based on the number of employees per new FFD program who take the FFD exam. Program data shows that more employees per program are taking the exam than previously estimated. As a result, the NRC has increased the burden hours per program for these requirements.

These two changes resulted in a decrease in burden on Table 1 of 108,135 hours (from 114,598 to 6,463).

Table 2, Annual recordkeeping requirements:

For some requirements, the number of hours per recordkeeper is based on the on the number of activities conducted (e.g., samples submitted, background checks conducted, consent forms

completed, documents associated with medical officer reviews). For the following requirements, although the burden hour estimate per activity remained the same, the burden hours per recordkeeper were adjusted based on the number of activities conducted (informed by CY2008 FFD program performance data): § 26.39(e); § 26.53(h) and (i); § 26.97(d); § 26.103(b); § 26.163(a)(2); and § 26.189(c).

For some requirements, the NRC adjusted the burden hour estimate per activity to correlate more precisely with the level of effort associated with the required documentation. The burden hour estimates for the following requirements were reduced for this reason: § 26.93(a)(6); § 26.95(b)(5); § 26.99(b); § 26.101(b)(7); § 26.107(b); § 26.165(b)(1)&(2); § 26.165(b)(6); § 26.165(c)(4); § 26.169(c)(2)&(3); § 26.169(f)&(g) (see footnote 20); § 26.183(d)(2)(ii); and § 26.185(a). The burden estimates for the following requirements were increased for this reason: § 26.183(c)(1); § 26.183(d)(1)(ii)(D); § 26.183(d)(2)(i); and § 26.185(c).

The burden hour estimates for three requirements were adjusted based on updated estimates of the number of construction workers per construction site who would be subject to the FFD program. This adjustment affected the burden hours per recordkeeper for the following requirements: § 26.405(a) and (c)(1); and, § 26.411(a).

The assumptions underlying the burden estimate for § 26.67 were updated and the burden estimate decreased. Previously the estimate assumed that all persons with pre-access testing would also have a random drug test; however, CY08 data indicates that only 0.5% of those with pre-access testing will also have a random drug test. This reduced the burden for this requirement from 25,001 to 133 hours (see footnote 15).

The assumptions underlying the burden estimate for § 26.87(d)(3) and § 26.87(f)(1), (3), (4)&(5) were updated. It is now assumed that the requirement applies to all programs, rather than one-third of programs. This resulted in a minor increase in burden (<100 hours).

The burden hours for § 26.165(b)(3) were eliminated. These hours are accounted for in the burden estimate for § 26.165(b)(1).

Table 3, Annual reporting requirements

The burden estimate for § 26.719(c)(1) was increased from 1 hour to 24 hours per response based on NRC staff experience in evaluating errors in the testing program. The NRC believes that an estimate of 3 days (24 hours) is a more accurate representation of the burden necessary to investigate and report an error.

Table 4, Annual 3rd party disclosure requirements:

Based on NRC's 2008 FFD program performance data, the number of estimated responses was updated for a number of requirements. The most significant changes in the burden resulting from these changes were:

- § 26.31(b)(1)(i), § 26.53(h), § 26.61(a), and § 26.63(a)(c)&(e). The estimated number of respondents for these requirements changed from 79,005 to 87,468 based on actual data from CY08 on the number of pre-access tests. This resulted in a combined increase in burden of 23,696 hours.
- § 26.35(c). The estimated number of responses decreased from 56,100 responses and 16,830 hours to 5,476 responses and 1,643 hours, resulting in a reduction of 15,187 hours. This change is due to a change in the assumptions underlying the estimates. Previously, it was assumed that that 100% of those subject to the FFD programs would waive their right to

privacy. Based upon data and experience, NRC now estimates that 5% of employees will waive their right to privacy.

- § 26.93(a)(6), § 26.95(b)(5), and § 26.117(c),(d),&(e). The estimated number of responses decreased from 28,248 to 310 for these requirements, due to a change in the assumptions underlying the estimates. The previous estimate assumed that all pre-access tests were conducted off-site. The current estimate more accurately assumes that 10 persons per program are tested off-site. This change resulted in a combined decrease in burden of 25,233 hours.
- § 26.97(d). The estimated number of responses decreased from 28,248 to 8 based on a change in the assumptions underlying the estimate. The previous estimate was based on an assumption that all pre-access tests utilized oral fluid testing being accomplished by a third party. This was adjusted to reflect industry practices, in which oral fluid testing is more uncommon than previously estimated. This resulted in a decrease in burden of 8,502 hours.
- Minor adjustments were made to the burden estimates for § 26.169(c)(1)&(c)(4), and § 26.183(a), and § 26.183(d)(2)(i) based on improved knowledge of the testing process.
- The burden for § 26.169(f) was eliminated because the data are transmitted electronically via automated processes requiring no user time burden. Time to record test results is captured in the estimates for other requirements.

In addition, the estimated burden hour cost increased from \$257 to \$259 due to a change in the agency's fee rate.

16. Publication for Statistical Use

The NRC develops an annual report summarizing the previous year commercial power reactor industry drug and alcohol FFD performance. These reports are accessible at <http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty.html>.

17. Reasons for Not Displaying the Expiration Date

The information collection requirements are contained in Part 26. Amending the *Code of Federal Regulations* to display information that, in an annual publication, could become obsolete is 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.

Attachments:

Table 1 – One-Time Recordkeeping Burden

Table 2 – Annual Recordkeeping Burden

Table 3 – Annual Reporting Burden

Table 4 – Annual Third-Party Burden

Table 5 – Annualized NRC Reporting and Recordkeeping Burden

Table 1
One-Time Recordkeeping Burden
(Annualized)

Section	Number of Programs	Burden Hours per Program (Annualized)	Total Burden Hours (Annualized)
26.27(a): Prepare FFD policy statement	1 program ¹	107.0	107
26.27(a): Prepare FFD procedures	1 program	213.0	213
26.29(a): Prepare FFD training course	1 program	83.0	83
26.29(b): Prepare FFD exam	1 program	13.3	13
26.29(b): All current staff take FFD exam	1 program	200.2 ²	200
26.29(b): FFD staff mgmt grade FFD exam	1 program	200.2 ³	200
26.29(c)(1): FFD training for current staff	1 program	4,710.7 ⁴	4,711
26.31(b)(1)(v): Prepare behavioral observation procedures for FFD program personnel	Burden shown under § 26.27		
26.31(d)(1)(iii): Document additional drugs being tested	1 program	0.3	0
26.37(a): Confirm files and procedures protect personal information	1 program	2.7	3

¹ The 2007-2010 clearance estimated 33 FFD programs (all FFD programs subject to Part 26) would incur one-time burden associated with implementing the amended Part 26 rule (March 31, 2008). For the 2010-2013 clearance period, the NRC estimates that one new FFD program will be created.

² The estimate assumes that 3,533 employees per new FFD program will take the FFD exam. This estimate is based on the number of employees subject to an FFD program, as estimated by taking the number of random tests conducted in a year (at 50% random testing rate) and doubling the number of tests. This information was obtained from the NRC Information Notice 2009-28, "Summary of Fitness-for-Duty Program Performance Reports for Calendar Year 2008" (i.e., "CY 2008 FFD program performance data") which can be viewed at <http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/performance-reports.html>. Administering the examination and recording the fact that the individual took the examination is estimated to take 10 minutes (0.17 hours) to complete per employee or 600 hours per program (200 hours annualized).

³ The estimate assumes that 3,533 employees per new FFD program will take the FFD exam. Recording whether the individual passed the exam is estimated to take 10 minutes (0.17 hours) per employee or 600 hours per program (200 hours annualized).

⁴ The estimate assumes that 3,533 employees per new FFD program will take the FFD training. The FFD training is estimated to take 4.0 hours per employee or 14,132 hours per program (4,711 hours annualized).

Section	Number of Programs	Burden Hours per Program (Annualized)	Total Burden Hours (Annualized)
26.37(b): Obtain signed consent for release of information	1 program	98.1 ⁵	98
26.39(a) and (b): Prepare procedure for review of determination of FFD violation	1 program	13.3	13
26.85(a): Prepare and deliver qualification training for urine collectors	1 program	5.3	5
26.85(b): Prepare and deliver qualification training for alcohol collectors	1 program	5.3	5
26.127(a): Prepare procedures for handling specimens at licensee testing facility	1 program	13.3	13
26.127(b): Prepare written chain-of-custody procedures for licensee testing facility	1 program	13.3	13
26.127(c): Prepare written procedures for assays performed by licensee testing facility	1 program	13.3	13
26.127(d): Prepare written procedures for instrument and test setup by licensee testing facility	1 program	13.3	13
26.127(e): Prepare written procedures for remedial actions for systems and tests at licensee testing facility	1 program	13.3	13
26.137(a): Develop QA/QC program and procedures for licensee testing facility	1 program	13.3	13
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 ⁶	2.7	0

⁵ The estimate assumes 3,533 employees per FFD program that must consent to the release of information. The collection is estimated to take 5 minutes (0.083 hours per employee) or 294 hours per program (98 hours annualized).

⁶ The NRC estimates that no additional HHS-certified laboratories will take the steps necessary to provide services to NRC licensees under Part 26 during the 2010-2013 clearance period.

Section	Number of Programs	Burden Hours per Program (Annualized)	Total Burden Hours (Annualized)
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)	1 program	13.3	13
26.203(b): Prepare fatigue management procedures (in addition to §26.27 burden)	1 program	26.6	27
26.203(c): Prepare training on fatigue management.	1 program	22.7	23
26.205(b): Develop work hour tracking system	1 program	133.3 ⁷	133
26.205(c): Develop individual work scheduling system	1 program	33.3	33
26.401(b): Prepare Subpart K program plan	1 program	60.0	60
26.403(a): Prepare written Subpart K FFD policy statement	1 program ⁸	107.0	107
26.403(a): Distribute Subpart K FFD policy statement to all individuals	1 program ⁹	5.0	5
26.403(b): Prepare written Subpart K FFD procedures	1 program	213.0	213

⁷ Based on an estimate by the Nuclear Energy Institute (NEI), \$50,000 is needed for a contractor to develop a revised timekeeping and tracking system and that approximately 400 hours per program is necessary to approve and adopt the revised timekeeping system.

⁸ The 2007-2010 clearance estimated that 2 programs would implement a Subpart K program. During that previous period, one of the two programs implemented a Subpart K FFD program.

⁹ For the 2010-2013 clearance period, the NRC estimates that one program will develop its Subpart K FFD program plan and procedures. This program will be developed approximately one year prior to the conduct of safety- or security-related construction activities.

Section	Number of Programs	Burden Hours per Program (Annualized)	Total Burden Hours (Annualized)
26.406(a), (b), and (d): Establish a fitness monitoring program	0 programs ¹⁰	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	1 program	120.0	120
Table 1: Total			6,463

¹⁰ This estimate is based on the NRC assumption that no FFD programs will adopt fitness monitoring during the 2010-2013 clearance period.

**Table 2
Annual Recordkeeping Burden**

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.27(b): Make FFD policy statement available to staff subject to FFD reqs.	31 programs ¹¹	4.0	124
26.27(c): Record updates to policy & procedures	31 programs	8.0	248
26.27(d): Provide policy and procedures for NRC review	31 programs	4.0	124
26.29(b): Maintain records of FFD exams	31 programs	2.0	62
26.29(c)(2): Maintain records of refresher FFD training and testing	31 programs	2.0	62
26.29(d): Record acceptance of FFD training from other licensees' programs	31 programs	4.0	124
26.31(b)(1)(i): Record results of background checks for FFD personnel	31 programs	17.5	543
26.31(b)(1)(v): Record results of behavioral observation for FFD program personnel	31 programs	80.0	2,480
26.31(d)(1)(i)(D): Document analysis and certification for unlisted drugs	8 programs	4.0	32
26.31(d)(1)(ii): Document licensee additions to tested drugs	31 programs	8.0	248
26.31(d)(3)(iii)(A): Document more stringent cutoff levels	8 programs	8.0	64
26.31(d)(3)(iii)(C): Document evaluation and certification of more stringent cutoff levels	8 programs	8.0	64
26.31(d)(6): Document written permission of donor to conduct another analysis or test with specimen	8 programs	1.0	8
26.33: Records of behavioral observations	31 programs	400.0	12,400

¹¹ The 2007-2010 clearance estimated 33 FFD programs, which included one mixed-oxide (MOX) fuel fabrication facility. The 2010-2013 clearance estimates 31 FFD programs. The number of FFD programs has been reduced from 33 to 31 because one FFD program was combined with an existing FFD program (28 to 27 FFD programs) and because an FFD program is not required for the MOX facility until after it receives its NRC license. The MOX facility not expected to be licensed until after the period of the clearance.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.35(a): Employee assistance program records	31 programs	16.0	496
26.35(c): Maintain record of written waivers of right to privacy from individuals given to EAP	31 programs	2.0	62
26.35(c): Record of EAP disclosure to FFD mgt.	16 programs	1.0	16
26.37(b)(1): Record of signed designations of personal representative for FFD matters	31 programs	40.0	1,240
26.37(c): Record of disclosures to other licensees	31 programs	40.0	1,240
26.37(d): Record of lab results and provide result to individual	31 programs	40.0	1,240
26.39(a): Maintain procedures for review of determinations of FFD	31 programs	40.0	1,240
26.39(d): Update records to reflect outcome of review of determination of fitness	31 programs	40.0	1,240
26.39(e): Record that review procedure provided to individual	31 programs	15.5	481 ¹²
26.41(a), (b), and (c): Record of audits	Burden shown under § 26.41(f)		
26.41(d): Record of review of C/V audit results	31 programs	40.0	1,240
26.41(f): Document and report audit results	31 programs	40.0	1,240
26.41(g): Record that audit results shared with mgmt and with other FFD programs	31 programs	40.0	1,240
26.53(e)(2): Record that C/Vs informed licensee of the termination of an individual's authorization	2 programs	120.0	240
26.53(g): Record that CVs and other licensees informed of Part 26 violations	8 programs	8.0	64

¹² The estimate is based on 991 positive, adulterated, and substituted test results (this includes both alcohol and drug test results) from NRC's CY 2008 FFD program performance data. One-half burden hour is estimated for each test.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.53(h): Record that written consent obtained from the subject individual before initiating any actions under Subpart C	31 programs	1,411	43,734 ¹³
26.53(i): Record that all individuals applying for authorization informed, in writing, of the causes for denial or termination of authorization	31 programs	21.4	664 ¹⁴
26.55(a)(1) and (a)(2): Record that obtained and reviewed self-disclosure & employment history and completed suitable inquiry	Burden shown under §§ 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 shown under §§ 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 shown under §§ 26.61 and 26.63		
26.59(c)(1): Record that obtained and reviewed self-disclosure	Burden shown under § 26.61		
26.61(a): Record of written self-disclosure and employment history	31 programs	1,197.0	37,107
26.63(a), (c), and (e): Record of suitable inquiry	31 programs	1,197.0	37,107
26.63(c)(2): File DD 214	31 programs	4.0	124
26.63(c)(3): Document refusal of past employer to supply employment information	31 programs	2.7	84
26.63(d) & (e): Maintain documentation of denial or unfavorable termination of authorization from other FFD programs	31 programs	1.0	31
26.65(d) and (e): Record of reinstatement or administrative withdrawal of authorization	31 programs	4.0	124
26.65(f): Administrative withdrawal of authorization	31 programs	1.0	31

¹³ The estimate is based on 87,468 pre-access tests from NRC's CY 2008 FFD program performance data. One-half burden hour is estimated for each test.

¹⁴ The estimate is based on 664 positive, adulterated, and substituted pre-access test results (this includes both alcohol and drug test results) from NRC's CY 2008 FFD program performance data. One burden hour is estimated for each test result.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.67 Record of random drug and alcohol testing of persons who have applied for authorization	31 programs	4.3	133 ¹⁵
26.69(b) and (c)(1): Record of written self-disclosure and employment history	Burden shown under § 26.713(a)(1)		
26.69(c)(2): Record that licensee confirmed potentially disqualifying FFD situation resolved	31 programs	40	1,240
26.69(c)(3): Record that licensee verified that qualified professional indicated individual is fit for duty.	31 programs	40	1,240
26.69(c)(4): Record of verification that drug/alcohol treatment & testing completed	31 programs	3.0	93
26.69(c)(5): Record of verification that pre-access drug/alcohol testing completed	31 programs	1.0	31
26.69(d): Record that reviewing officer's review completed	31 programs	24.0	744
26.69(e): Record of testing and treatment plans accepted from other FFD programs	31 programs	8.0	248
26.69(e)(1): Record that information transmitted on testing and treatment plans to other FFD programs	31 programs	8.0	248
26.75(a), (b), (c), (d), (e), and (g): Record of sanctions for FFD violation	31 programs	12.0	372
26.75(h): Record additional evidence indicating impairment	31 programs	18.0	558
26.75(i): Record of positive initial test result and temporary administrative action	31 programs	80.0	2,480
26.75(i)(3): Eliminate from record references to temporary administrative action	31 programs	1.0	31

¹⁵ NRC's CY 2008 FFD program performance data reported 54,759 total random drug tests. Of these, this estimate assumes that approximately 0.5% of individuals who have applied for authorization and who have received a pre-access test also will be randomly tested. One-half burden hour is estimated for each test. The 2007-2010 clearance reported that all persons received random drug and alcohol testing during the period prior to clearance being approved; that estimate therefore was conservatively high.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.85(a), (b), & (c): Training collectors	31 programs	4.0	124
26.85(e): Maintain personnel files	31 programs	4.0	124
26.87(d)(3) and (f)(1): Signage/security at test sites	31 programs	1.0	31
26.87(f)(3), (f)(4), and (f)(5): Record of custody-and-control forms	31 programs	2.0	62
26.89(a): Record of absence of donor reported	31 programs	1.0	31
26.89(b)(1), (b)(2), and (b)(4): Record that ID and consent-to-testing form obtained	31 programs	1.5	47
26.89(b)(3): Record that FFD program management informed that individual did not present identification	31 programs	1.0	31
26.89(c): Record of donor's refusal to cooperate in collection procedures	31 programs	1.0	31
26.91(c)(1), (c)(2), and (c)(3): Record of EBT test results	Burden shown under § 26.715(b)(12)		
26.91(e)(4): Record that results cancelled after EBT calibration check failure	8 programs	6.0	48
26.91(e)(5): Prepare record of EBT maintenance	31 programs	6.0	186
26.93(a)(6): Document alcohol pre-test questions asked and answered	31 programs	80	2,480
26.95(b)(5): Record donor identity for initial alcohol breath test	31 programs	80	2,480
26.97(b)(2): Record reason for new oral fluid alcohol test	31 programs	5.0	155
26.97(c)(1): Document reason for failure of 2 nd collection attempt	31 programs	2.5	78
26.97(d): Record results and alcohol screening device used	31 programs	0.25	8
26.99(b): Record test time of initial test with 0.02% or higher BAC	31 programs	0.25	8
26.101(b)(7): Record time on EBT printout of alcohol test result	31 programs	0.25	8

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.103(b): Record that FFD mgmt 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 form	31 programs	0.1	3
26.109(b)(3): Record that FFD mgt. or MRO notified of "shy bladder" problem	31 programs	0.5	16
26.109(b)(4): Record that FFD management notified if observed collection required	31 programs	0.3	9
26.111(b): Note unusual findings on CCF form	31 programs	1.4	43
26.111(c): Record that tampering attempts reported to FFD mgr.	31 programs	0.3	9
26.113(b)(3): Record of CCF forms for both parts of split sample	31 programs	0.3	9
26.115(b): Record that approval obtained for collection under direct observation from FFD mgr. or MRO	31 programs	0.5	16
26.115(d): Record of CCF form for directly observed collection	31 programs	0.3	9
26.115(f)(3): Record of name of observer	31 programs	0.3	9
26.117(c), (d), and (e): Prepare ID labels and CCF forms for specimen shipment	31 programs	60.0	1,860
26.119(a), (e), and (f): Record that evaluation obtained from MRO or physician evaluating "shy bladder" claim	31 programs	6.0	186
26.119(b): Record that MRO provided information to physician as background for evaluation of "shy bladder" claim	31 programs	2.0	62
26.125(b) and (c): Proficiency and qualifications records of testing facility personnel	31 programs	16.0	496
26.127(a): Procedures for handling specimens by licensee testing facilities	31 programs	40.0	1,240
26.127(b): Written chain-of-custody procedures for licensee testing facilities	31 programs	40.0	1,240
26.127(c): Written procedures for assays performed by licensee testing facilities	31 programs	40.0	1,240

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.127(d): Written procedures for instrument and device setup by licensee testing facilities	31 programs	40.0	1,240
26.127(e): Written procedures for remedial actions for systems and testing devices at licensee testing facilities	31 programs	40.0	1,240
26.129(a): Records associated with limiting access to testing site	31 programs	2.5	78
26.129(b): Inspect specimen packages, custody control forms, and obtain memorandum from specimen collector	31 programs	0.5	16
26.129(b)(1): Record of report to senior management of attempts to tamper with specimens in transit	31 programs	1.0	31
26.129(d): Procedures for tracking CCF of specimens	31 programs	80.0	2,480
26.135(b): Record of donor's written permission for retest second part of split sample	31 programs	2.2	68
26.137(a): Record of QA/QC program and procedures for licensee testing facility	31 programs	4.0	124
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	31 programs	40.0	1,240
26.137(e)(7): Document procedures to protect against carryover material	31 programs	2.0	62
26.137(f)(5): Record finding of testing errors	31 programs	24.0	744
26.137(h): Label standards and controls	31 programs	65.0	2,015
26.139(d): Record that information prepared for FFD annual report on activities of licensee testing facility	31 programs	40.0	1,240
26.153(e): Record of inspection of HHS-certified labs	31 programs	40.0	1,240

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.153(f): Include specified requirements in contracts with HHS labs	31 programs	40.0	1,240
26.153(g): Record of memo to HHS labs explaining use of non-federal CCF form	31 programs	0.5	16
26.159(b)(1): Record of report of evidence of tampering with specimens in transit to FFD program mgr. of licensee or other entity	31 programs	1.0	31
26.159(i): Record of written authorization to store specimens other than 1 year	31 programs	0.5	16
26.163(a)(2): Record that licensee informed of dilute specimen and report confirmatory validity test result to MRO	31 programs	1.0	31
26.165(b)(1): Record of donor requests for aliquot or split specimen to be tested by a second HHS-certified laboratory	31 programs	1.4	42 ¹⁶
26.165(b)(2): Record that MRO informed donor of opportunity for re-test of aliquot or test of Bottle B of split sample	31 programs	0.5	16
26.165(b)(3): Record that donor gave written permission for re-test of aliquot or test of Bottle B of split sample	Burden shown under § 26.165(b)(1)		
26.165(b)(4): Record that donor presented documentation for reason for inability to complete timely retest request	31 programs	0.2	6 ¹⁷
26.165(b)(6): Record that results of re-test of aliquot or test of Bottle B provided to MRO and to donor	31 programs	3.0	93
26.165(c)(4): Record that retesting results provided to MRO	10 laboratories ¹⁸	2.5	25

¹⁶ The estimate is based on 846 positive, adulterated, and substituted drug test results from NRC's CY 2008 FFD program performance report data. The assumption is that 10% of all donors will request a retest/split specimen test be performed at a second HHS-certified laboratory. The burden is estimated at one-half burden hour per event.

¹⁷ This estimate is based on 6 donors and one-burden hour per donor.

¹⁸ The 2007-2010 clearance estimated that 26 HHS-certified laboratories would provide services under Part 26. The clearance uses updated information obtained from a 2009 industry survey that reported that only 10 laboratories support all Part 26 programs.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.165(f)(1): Adjustments to personnel files and written notifications regarding test results, including temporary administrative action	31 programs	6.0	186
26.165(f)(1)(iv) and (f)(2): Written record and notice that records purged of references to temporary administrative action	31 programs	8.0	248
26.167(f)(3): Record of certification by HHS lab that retesting requested by licensee or other entity has occurred	10 laboratories	1.0	10
26.169(a): Records of reports of test results by HHS lab	Burden covered under §§ 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	10 laboratories	80.0	800
26.169(c)(2): Records of HHS lab reports of quantitative test results as requested by MRO	2 laboratories	1.0	2
26.169(c)(2): Records of HHS lab reports of quantitative test results for opiates to MRO	10 laboratories	0.5	5
26.169(c)(3): Records of HHS lab reports of quantitative test results for adulterated or substituted test results	10 laboratories	2.5	25
26.169(c)(4): Record of HHS lab contact with MRO to discuss whether testing by another HHS lab should be done	10 laboratories	2.0	20
26.169(c)(5): Record of HHS lab reports of concentrations exceeding linear range	2 laboratories	1.0	2
26.169(f): Records of HHS lab transmittals of copies of the CCF form for negative results to the MRO	10 laboratories	125.8 ¹⁹	1258
26.169(g): Records of HHS lab transmittals of original of CCF form for positive, adulterated, substituted, dilute or invalid results to the MRO	10 laboratories	42.3	423

¹⁹ Electronic reporting is allowed by the regulations and assumed for all laboratories. Each laboratory would process a record into their electronic reporting system at 15,095 records per year at a burden-hour estimate of 30 seconds per record.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.169(h): Record that HHS lab prepared and submitted annual statistical summary report of urinalysis testing results	10 laboratories	40.0	400
26.183(a): Documentation of MRO qualifications	31 programs	3.5	109
26.183(c)(1): MRO review of records for positive, adulterated, substituted, invalid, or, at the licensees or other entity's discretion, dilute test results	31 programs	26 ²⁰	806
26.183(d)(1)(ii)(D): Record of MRO report of drug test results to licensee's designated reviewing official	31 programs	26 ²⁰	806
26.183(d)(2)(i): Record of MRO staff review and reporting of negative test results	31 programs	213 ²¹	6,603
26.183(d)(2)(ii): Record of MRO staff review of CCF forms and forwarding of changes to MRO	31 programs	2.6 ²²	81
26.185(a) Record of MRO review of all positive, adulterated, substituted, dilute, or invalid test results and report to licensee or other entity	31 programs	26.0	806
26.185(c): Record of MRO discussion of test results with the donor and report to licensee, following discussion with donor, of FFD violation	31 programs	26.0	806
26.185(d)(1): Documentation that donor declined to discuss test results	31 programs	2.0	62
26.185(e): Documentation that donor was unavoidably prevented from discussing test results and request to reopen proceeding	31 programs	0.3	9

²⁰ NRC's CY 2008 FFD program performance data reported 846 positive, adulterated, and substituted drug test results. It is estimated that an MRO staff spend one burden hour to review each test result and communicate results.

²¹ The estimate assumes that 151,937 tests were conducted in 2008, minus 846 positive, adulterated, and substituted drug tests, equals the total number of negative drug test results reviewed by MROs and MRO staff. Of these, it is estimated that 90% are reviewed by MRO staff at 3 minutes per record.

²² NRC's CY 2008 FFD program performance data reported 846 positive, adulterated, and substituted drug test results. It is estimated that MRO staff spend 6 minutes to review each record.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.185(f)(1): Record of MRO consultation with HHS lab to determine whether additional testing needed	31 programs	0.5	16
26.185(f)(2): Record of MRO contact with donor regarding medical explanation for test result	31 programs	0.5	16
26.185(h)(1): Record of MRO contact with donor to offer opportunity to provide medical evidence regarding substituted specimen	31 programs	1.0	31
26.185(h)(1): Record that donor presented medical explanation for substituted result	31 programs	1.0	31
26.185(h)(2): Record of MRO notification to licensee that no valid medical explanation presented	31 programs	2.0	62
26.185(h)(3): Record of MRO notification to licensee that valid medical explanation presented	31 programs	1.0	31
26.185(i)(1): Record of MRO contact with donor to offer opportunity to provide medical evidence regarding adulterated specimen	31 programs	1.0	31
26.185(i)(1): Record that donor presented medical explanation for adulterated result	31 programs	1.0	31
26.185(i)(2): Record of MRO notification to licensee that no valid medical explanation presented	31 programs	2.0	62
26.185(i)(3): Record of MRO notification to licensee that valid medical explanation presented	31 programs	1.0	31
26.185(j)(3): Record of MRO notification to licensee where evidence of drug abuse	31 programs	1.0	31
26.185(j)(3): Record of MRO report to licensee that donor has violated FFD policy by use of another individual's prescription medication	31 programs	0.5	16
26.185(k): Record of MRO report to licensee that no FFD policy violation has occurred	31 programs	1.0	31

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
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	31 programs	1.0	31
26.185(n): Record of MRO report to licensee on result of analysis by second laboratory	31 programs	2.0	62
26.185(o): Record of MRO request for quantitation of test results	31 programs	0.5	16
26.185(o): Record that lab provided quantitation of test results	31 programs	1.0	31
26.185(p): Record of MRO notice to licensee of determination of FFD policy violation	31 programs	8.0	248
26.187(d): SAE training requirements	31 programs	20.0	620
26.187(f): Documentation of SAE credentials and training	31 programs	1.0	31
26.189(a): Written record of determination of fitness	31 programs	80.2	2,486
26.189(c): Written record of "for cause" determination of fitness	31 programs	57.5	1,783 ²³
26.189(d): Record of modification of an initial determination of fitness	31 programs	1.0	31
26.203(d)(1): Records of work hours	Burden shown under § 26.205(c), (d)(1), and (e)(4)		
26.203(d)(2): Records of shift schedules and shift cycles	Burden shown under § 26.205(c), (d)(1), and (e)(4)		
26.203(d)(3): Documentation of waivers	Burden shown under § 26.207(a)(4)		
26.203(d)(4): Documentation of work hour reviews	Burden shown under § 26.205(d)(2), (e)(3) and (e)(4)		
26.203(d)(5): Documentation of fatigue assessment	Burden shown under § 26.211(f)		

²³ Based on 1,783 for-cause tests from NRC's CY 2008 FFD program performance report and one burden hour to prepare a record.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.205(b): Record of calculation of work hours	29 programs	160.0	4,640
26.205(c): Schedule work hours	29 programs	2,080.0	60,320
26.205(d)(1): Record of implementation of work hour controls	29 programs	50.0	1,450
26.205(d)(2): Record of adequate rest breaks	29 programs	50.0	1,450
26.205(e)(1) and (2): Record of review of control of work hours twice per calendar year	29 programs	40.0	1,160
26.205(e)(3): Document methods for reviews	29 programs	20.0	580
26.205(e)(4): Record and trend problems in regarding work hours	29 programs	20.0	580
26.207(a)(4): Document bases for waiver	3 programs	6.0	18
26.211(f): Document results of fatigue assessments	29 programs	50.0	1,450
26.405(a): Record of random drug and alcohol testing	1 program	500.0	500 ²⁴
26.405(c)(1): Document pre-assignment testing	1 program	2,000	2,000 ²⁵
26.405(c)(2) and (c)(3): Document for-cause and post accident testing	1 program	38.0	38
26.405(c)(4): Document follow up testing	1 program	190.0	190
26.405(d): Record of testing for specified drugs, adulterants, and alcohol, at Part 26 specified cutoff levels	Burden shown under § 26.405(a) - (c)(4)		
26.405(e): Record of methods to ensure privacy and quality control	1 program	40.0	40
26.405(f): Record that testing conducted at an HHS-certified laboratory	1 program	40.0	40

²⁴ This quantity is based on an estimate of one construction program choosing to conduct random testing (rather than fitness monitoring), 2,000 workers per construction site subject to the FFD program (based on a 2009 NRC site visit and information presented by the site construction contractor), a 50% test rate, and one-half burden hour per test.

²⁵ Estimate based on one burden hour per person to document pre-assignment testing for 2,000 workers at the construction site subject to the FFD program.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.405(g): Record of MRO review of positive, adulterated, substituted, and invalid drug and validity test results	1 program	50.0	50
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	1 program	4.0	4
26.411(a): Collection of personal information	1 program	2,000.0	2,000 ²⁶
26.411(b): Record that signed consent forms obtained	1 program	1.5	2
26.413: Document results of review process	1 program	80.0	80
26.415: Document and report audit results	1 program	40.0	40
26.417(a): Retain program records	1 program	20.0	20
26.713(a)(1): Retain records of self-disclosure	31 programs	80.0	2,480
26.713(a)(2): Retain records on FFD violations	31 programs	80.0	2,480
26.713(a)(3): Retain records of authorization	31 programs	80.0	2,480
26.713(a)(4): Retain records of FFD determinations	31 programs	80.0	2,480
26.713(b)(1): Retain records of FFD training	31 programs	160.0	4,960
26.713(b)(2): Retain records of audits	31 programs	80.0	2,480
26.713(c): Retain records on 5-year authorization denial and permanent denial	31 programs	40.0	1,240
26.713(d): Retain superseded FFD policy	31 programs	80.0	2,480
26.713(e): Retain written agreements for services under Part 26	31 programs	16.0	496
26.713(f): Retain records of background investigations	31 programs	80.0	2,480
26.713(g): Retain documentation regarding additional drugs tested	31 programs	40.0	1,240

²⁶ Estimate based on one burden hour per person to collect personal information for 2,000 workers at the construction site subject to the FFD program.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.715(a): Maintain documentation of all aspect of testing process (not otherwise specified in 26.715(b))	31 programs	40.0	1,240
26.715(b)(1): Retain personal files	31 programs	20.0	620
26.715(b)(2): Retain chain-of-custody documents	31 programs	240.0	7,440
26.715(b)(3): Retain quality assurance records	31 programs	120.0	3,720
26.715(b)(4): Retain superseded procedures	31 programs	40.0	1,240
26.715(b)(5): Retain all test data	31 programs	240.0	7,440
26.715(b)(6): Retain test reports	31 programs	240.0	7,440
26.715(b)(7): Retain performance test records	31 programs	80.0	2,480
26.715(b)(8): Retain testing error investigation records	31 programs	40.0	1,240
26.715(b)(9): Retain certification inspection records	31 programs	40.0	1,240
26.715(b)(10): Retain records on preventative maintenance	31 programs	40.0	1,240
26.715(b)(11): Retain records summarizing scientific insufficiency	31 programs	20.0	620
26.715(b)(12): Retain computer-generated data	31 programs	120.0	3,720
26.715(b)(13): Retain records on visitors	31 programs	20.0	620
26.715(b)(14): Retain records on EBT maintenance	31 programs	20.0	620
26.717(a) and (b): Collect FFD performance data	31 programs	200.0	6,200
26.717(c): Analyze FFD data annually	31 programs	80.0	2,480
26.717(d): Test results leading to termination	2 C/Vs	1.0	2
26.717(g): Record that required FFD information shared by C/V with licensee to ensure information is reported completely and is not duplicated in reports submitted to the NRC	2 C/Vs	120.0	240

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.719(d): Document non-reportable indicators of FFD program weaknesses	31 programs	20.0	620
26.821(a): Allow NRC to inspect and copy records	31 programs	4.0	124
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	2 C/Vs	4.0	8
Table 2 Total			351,889

**Table 3
Annual Reporting Burden**

Section	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Total Burden Hours
26.9: Application to NRC for exemption	2 programs	1	2	16.0	32
26.77(c) Report FFD-impaired NRC employee	31 programs	None	None	1.0	None
26.137(b)(3): Report false negative QC lab result	Burden shown under § 26.719(c)(3)				
26.139(d): Prepare information for annual FFD program performance report	Burden shown under § 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 FFD program performance report to NRC required by § 26.717(e) and (f)	29 programs	1	29	50.0 (Burden in addition to that shown for § 26.717)	1,450
26.203(e)(2): Prepare summary of fatigue corrective actions for inclusion in FFD program performance report to NRC required by § 26.717(e) and (f)	29 programs	1	29	6.0 (Burden in addition to that shown for §§ 26.203(e)(1) and 26.717)	174
26.417(b)(1): Report to NRC by telephone within 24 hours programmatic failures under Subpart K FFD program	1 program	1	1	4.0	4
26.417(b)(2): Prepare annual program performance report for Subpart K FFD program	1 program	1	1	80.0	80

Section	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Total Burden Hours
26.717(d): Report termination test results in the annual summary by processing stage	Burden shown under § 26.717(e) and (f). NRC's 2008 FFD program performance data indicates 991 positive test results.				
26.717(e) and (f): Annual report of FFD program performance	31 programs ²⁷	1	31	150.0	4,650
26.719(a): Reports of significant FFD violations, program failures, and errors in testing	Burden reported under §§ 26.719(b) and (c)				
26.719(b): Report significant FFD violations by phone w/in 24 hrs	15 programs	1	15	4.0	60
26.719(c)(1): Report results of testing error investigation to NRC w/in 30 days	6 programs	1	6	24.0 ²⁸	144
26.719(c)(2): Notify NRC of false positives on blind performance sample w/in 24 hrs	1 program	1	1	4.0	4
26.719(c)(3): Notify NRC of false negative on QA check w/in 24 hrs	4 programs	1	4	4.0	16
Table 3 Total			120		6,615

²⁷ Based on an assumption that programs submit consolidated reports, but that the reports summarize data by site as required by § 26.717(f).

²⁸ Experience in reviewing licensee reports indicates that most errors reported are associated with false negative results from blind performance sample testing that requires investigation and coordination between the specimen suppliers and the testing laboratories.

**Table 4
Annual Third-Party Burden**

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.31(b)(1)(i): Individuals provide responses to background checks for FFD personnel	87,468 ²⁹	1.0	87,468
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)	16 ³⁰	32.0	512
26.35(c): Individuals give written waiver of right to privacy to EAP	5,476 ³¹	0.3	1,643
26.35(c): Record of disclosure by independent EAP to FFD mgt.	16	1.0	16
26.37(b): Individuals provide signed consent for release of information	54,400	0.3	16,320
26.37(b)(1): Individuals provide signed designation of personal representative for FFD matters	991	1.0	991
26.37(d): Record that FFD program personnel provided records to individual	991	1.0	991
26.53(h): Individuals provide written consent before any actions are initiated under Subpart C	87,468	0.3	26,240
26.55(a)(1) and (a)(2): Individual applicants for initial authorization prepare self-disclosure and employment history	Burden shown under §§ 26.61 and 26.63		
26.57(a)(1) and (a)(2): Individual applicants for authorization update prepare self-disclosure and employment history	Burden shown under §§ 26.61 and 26.63		
26.59(a)(1) and (a)(2): Individual applicants for authorization reinstatement prepare self-disclosure and employment history	Burden shown under §§ 26.61 and 26.63		

²⁹ Estimate based on 87,468 pre-access tests from NRC's CY 2008 FFD program performance data.

³⁰ Estimate assumes that 50% of 31 EAP programs are non-licensee EAP programs.

³¹ Estimate assumes 5% of 3,533 employees per FFD program provide consent. The total number of FFD programs subject to this requirement is 31.

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.59(c)(1): Individual applicants for authorization reinstatement after period of interruption of no more than 30 days prepare self-disclosure	Burden shown under §§ 26.61		
26.61(a): Individuals prepare written self-disclosure and employment history	87,468	1.0	87,468
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	87,468	0.8	69,974
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	274 ³²	0.5	137
26.69(b) and (c)(1): Applicant provides written self-disclosure and employment history	Burden shown under § 26.63		
26.69(c)(2): Record that licensee confirmed potentially disqualifying FFD situation resolved	186 ³³	2.0	372
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

³² NRC's CY 2008 FFD program performance data reported 54,759 total random drug tests. Of these, this estimate assumes that only approximately 0.5% represent individuals who have applied for authorization and who have received a pre-access test who also will be randomly tested.

³³ Each of the 31 programs is estimated to have 6 applications in which potentially disqualifying FFD information must be further examined by obtaining additional information from non-licensee sources.

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
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)	310 ³⁴	0.3	93
26.95(b)(5): Record donor identity for initial alcohol breath test (non-licensee collection site)	310	0.3	93
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 2 nd 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
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 mgmt 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

³⁴ This assumes an estimated 10 persons per program, who are FFD program personnel not located at the reactor site where collections are typically made, who may be tested at a U. S. Department of Transportation-compliant collection site per § 26.31(b)(2).

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
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 form	2	0.5	1
26.111(c): Record that non-licensee collector notified FFD mgr. of tampering attempts	0	0.4	0
26.113(b)(3): Record of CCF forms 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 mgr. or MRO (non-licensee collection site)	0	0.3	0
26.115(d): Record of CCF form 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 forms for specimen shipment (non-licensee collection site)	310	0.3	93
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 licensee testing facility personnel documenting investigation of discrepancies between bottles and CCF forms	0	1.0	0
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

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.153(g): Supply memo to HHS labs explaining use of non-federal CCF form	2	0.5	1
26.155(a)(1): Document qualifications for lab mgr of HHS-certified 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 of 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 by 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		

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 CCF forms	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.159(f): Use of CCF form 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-certified laboratory	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): HHS-certified laboratory's refractometer 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		

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.167(h): Labeling of standards and controls	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
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 form, 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 §§ 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	846	0.25	212
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 ³⁵	1.0	16
26.169(c)(3): HHS lab record of quantitative test results for adulterated or substituted test results	51 ³⁶	1.0	51
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 the CCF form for negative results to the MRO	Electronic transmission		
26.169(g): HHS lab transmits original of CCF form for positive, adulterated, substituted, dilute or invalid results to the MRO	846	0.5	423

³⁵ This estimate is based on 16 total positive opiate drug tests listed in NRC's CY 2008 FFD program performance data.

³⁶ This estimate is based on 51 adulterated specimens detected as listed in NRC's CY 2008 FFD program performance data.

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
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	23 ³⁷	1.0	23
26.183(c)(1): MRO review of records for positive, adulterated, substituted, invalid, or, at the licensee or other entity's discretion, dilute test results	Burden covered by § 26.185(a)		
26.183(d)(2)(i): Record of MRO staff review and reporting of negative test results	101,986 ³⁸	0.05	5,099
26.183(d)(2)(ii): Record of MRO staff review of CCF forms and forward changes to MRO	635 ³⁹	0.1	64
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 covered by § 26.185(c)		
26.185(f)(2): MRO contact with donor regarding medical explanation for test result	Burden covered by § 26.185(c)		

³⁷ This estimate assumes that 75% of the 31 programs use MROs who are non-licensee employees.

³⁸ This estimate assumes that 151,937 tests conducted in 2008, minus 846 positive drug tests, equals the total number of negative drug test results reviewed by MROs and MRO staff. Of these, it is estimated that 90% are reviewed by MRO staff, 75% of whom are non-licensee employees.

³⁹ NRC's CY 2008 FFD program performance data reported 846 positive, adulterated, and substituted drug test results. Estimate assumes 75% of the 846 reported tests are reviewed by MROs who are non-licensee employees.

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.185(h)(1): MRO contact with donor to provide medical evidence regarding substituted specimen	Burden covered by § 26.185(c)		
26.185(h)(2): MRO notification to licensee that no valid medical explanation presented	Burden covered by § 26.185(c)		
26.185(h)(3): MRO notification to licensee that valid medical explanation presented	Burden covered by § 26.185(c)		
26.185(i)(1): MRO contact with donor to provide medical evidence regarding adulterated specimen	Burden covered by § 26.185(c)		
26.185(i)(2): MRO notification to licensee that no valid medical explanation presented	Burden covered by § 26.185(c)		
26.185(i)(3): MRO notification to licensee that valid medical explanation presented	Burden covered by § 26.185(c)		
26.185(j)(3): MRO notification to licensee where evidence of drug abuse	Burden covered by § 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 covered by § 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 laboratory	64 ⁴⁰	1.0	64
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 § 26.185(c)		

⁴⁰ This estimate assumes 10% of 846 positive, adulterated, and substituted drug test results are challenged by the donor and a retest/split specimen test is conducted. Of these, 75% are reviewed by non-licensee MROs.

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
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	245 ⁴¹	0.5	123
26.189(c): Written record of “for-cause” determination of fitness	76 ⁴²	1.0	76
26.189(d): Modification of an initial determination of fitness based on information from other sources	24	1.0	24
26.405(g): MRO report of positive, adulterated, substituted, and invalid drug test results	0	1.0	0
26.411(b): Obtain signed consent form	2,000	0.3	600
26.821(b): Written agreement between C/Vs and licensees to permit authorized NRC representatives to inspect, copy, or take away copies of C/V’s documents, records, and reports	5	4.0	20
Table 4 Total	521,757		301,857

⁴¹ Based on proportion of 327 random, for-cause, follow-up, and other test positive results from NRC’s CY 2008 FFD program performance data pertaining to all 31 programs, of which 75% assumed to be performed by a non-licensee MRO or SAE.

⁴² Based on proportion of 101 for-cause positive test results from NRC’s CY 2008 FFD program performance data pertaining to all 31 programs, of which 75% are assumed to be performed by a non-licensee MRO or SAE.

TOTAL PART 26 BURDEN: 666,824 hours (6,463 hours one-time recordkeeping annualized + 351,889 hours annual recordkeeping + 6,615 annual hours reporting + 301,857 hours annual third party burden).

TOTAL RESPONSES: 521,919 (120 total annual reporting responses from Table 3 + 42 recordkeepers (31 FFD programs + 10 laboratories + 1 Subpart K program) + 521,757 third-party responses from Table 4).

NUMBER OF RESPONDENTS: 89,510 is equal to 31 FFD program responses (each FFD program is one respondent: 27 reactor programs + 2 contractor/vendors + 2 fuel cycle facilities) plus 1 Subpart K construction FFD program respondent plus 10 HHS-certified laboratories plus 89,468 third-party respondents⁴³).

THIRD-PARTY BURDEN: 301,857 hours annual third party burden.

⁴³ Third-party respondents include an estimated 87,468 (pre-access tests conducted) individuals subject to FFD requirements at operating nuclear power reactors and 2,000 individuals at one Subpart K construction site.

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

NRC ACTION	No. Actions/Year	Burden Hours/Action	Total Hours
Review exemption requests under § 26.9	2	16 hours per review.	32
Review written FFD policies and procedures under § 26.27(d)	12	8 hours per review. Reviews performed during periodic inspections.	96
Review records under § 26.75(h) to ensure no inappropriate records are maintained	12	4 hours per review. Reviews performed during periodic inspections.	48
Review reports under § 26.77(c) that NRC employee or contractor is unfit for duty	0	No reports anticipated.	
Review documentation provided by SAE upon request by NRC under § 26.187(f)	1	4 hours per review.	4
Review summary of data on work hour waiver requests required under §26.203(e)(1) to be included in annual FFD program performance report required by § 26.717(e) and (f)	Burden reported below under § 26.717(e) and (f)		
Review telephone reports to NRC Operations Center of significant FFD program failures for FFD programs under Subpart K submitted under § 26.417(b)(1)	1	16 hours per review	16
Review annual program performance reports for FFD programs under Subpart K submitted under § 26.417(b)(2)	1	40 hours per report	40
Review annual program performance reports for FFD at operating nuclear power reactors, C/Vs, and other entities submitted under § 26.717(e) and (f)	31	80 hours per report for 29 programs; 40 hours per report for 2 programs that do not include fatigue-related information	2,400
Review reports under § 26.719(a) of significant violations of FFD policy, FFD program failures, and errors in testing	Burden reported under §§ 26.719(b) and (c)		

NRC ACTION	No. Actions/Year	Burden Hours/Action	Total Hours
Review reports by telephone to NRC Operations Center of significant FFD violations required by § 26.719(b)	15 ⁴⁴	16 hours per review	240
Review reports to NRC of investigations of testing errors by licensee testing facilities or HHS laboratories required by § 26.719(c)(1)	6	16 hours per review	96
Review reports to NRC of false positive errors on blind performance samples required by § 26.719(c)(2)	1	16 hours per review	16
Review reports to NRC Operations Center of false negative errors on QA checks of validity screening tests required by § 26.719(c)(3)	1	16 hours per review	16
Table 5 Total			3,004

⁴⁴ Average annual number of reportable events involving reactor operators, supervisors, and FFD program personnel from CY 2006 through CY 2008 as reported in NRC's CY 2008 FFD program performance report, Table 5.