

SUPPORTING STATEMENT
FOR
10 CFR PART 26, FITNESS-FOR-DUTY PROGRAM,
Final Rule
(OMB Clearance No. 3150-0146)

COMPLETE REVISION OF 10 CFR PART 26

DESCRIPTION OF THE INFORMATION COLLECTION

Part 26 of Title 10 of the Code of Federal Regulations contains the Nuclear Regulatory Commission's requirements and standards for the establishment, implementation, and maintenance of fitness-for-duty (FFD) programs. The proposed rule was published in the Federal Register on August 26, 2005 (70 FR 50441), and was submitted to OMB. On September 26, 2005, OMB withheld approval of the proposed rule and filed a comment and continue, which requires NRC to submit the final rule to OMB for approval prior to publication of the final rule.

The Part 26 requirements and standards, except for Subpart K, apply to the following: licensees who are authorized to operate a nuclear power reactor under 10 CFR 50.57 and holders of a combined license under 10 CFR Part 52 after the Commission has made the finding under 10 CFR 52.103(g). Licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under 10 CFR Part 70 and any corporations, firms, partnerships, limited liability company, association, or other organization that obtains a certificate of compliance or an approved compliance plan under 10 CFR Part 76, but only if the entity elects to engage in activities involving formula quantities of SSNM, are required to comply with all the requirements except for Subparts I and K. Contractor/vendors (C/Vs) who implement FFD programs or FFD 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 10 CFR Part 26, are required to comply with all the requirements of 10 CFR Part 26. The following licensees and other entities are required to comply with all the requirements of 10 CFR Part 26 except for Subpart I: combined license applicants under 10 CFR Part 52 who have been issued a limited work authorization under § 50.10(e), if the limited work authorization authorizes the applicant to install the foundations, including the placement of concrete, for safety- or security related structures, systems, and components (SSCs) under the limited work authorization; combined license holders under 10 CFR Part 52 before the Commission has made the finding under § 52.103(g); construction permit applicants under 10 CFR Part 50 who have been issued a limited work authorization under § 50.10(e), the limited work authorization authorizes the applicant to install the foundations, including the placement of concrete, for safety- or security-related SSCs under the limited work authorization; construction permit holders under 10 CFR Part 50; and early site permit holders who have been issued a limited work authorization under § 50.10(e), if the limited work authorization authorizes the early site permit holder to install the foundations, including the placement of concrete, for safety- or security-related SSCs under the limited work authorization.

The 103 operating nuclear power reactors in the United States are 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. A licensee may administer the FFD activities at one or more facilities through a single FFD program (i.e., the same FFD policy and procedures apply, a single FFD staff administers the drug and alcohol testing program, one medical review officer performs the MRO functions, etc.) This information collection supporting statement estimates the burden associated with reporting and recordkeeping activities for 52 FFD programs, as follows: 28 FFD

programs for 65 facilities with a total of 103 nuclear power reactors; 2 fuel-cycle facilities; 2 contractor/vendors; 1 mixed-oxide fuel fabrication facility; and 19 construction FFD programs (with 10 programs covering single units and 9 programs covering double units).

The fatigue management provisions in Subpart I of Part 26 apply to a smaller group of licensees and other entities, and are estimated to be implemented through 30 programs (28 FFD programs covering nuclear power reactors and 2 programs covering contractor/vendors, who are required to implement fatigue management provisions if their personnel provide services to nuclear power reactors in the appropriate job duty groups). The NRC plans to withdraw Order EA-03-038, "Issuance of Order for Compensatory Measures Related to Fitness-for-Duty Enhancements Applicable to Nuclear Facility Security Force Personnel," April 29, 2003 once the fatigue management provisions in Subpart I for security force personnel take effect.

At operating nuclear power reactors FFD programs meeting all of the requirements of Part 26 except Subpart K are required to apply to those categories of individuals who are granted unescorted access to the nuclear power plant protected areas and who perform the following duties: operating or on-site directing of the operation of systems and components that a risk-informed evaluation process has shown to be significant to public health or safety; performing health physics or chemistry duties required as a member of the on-site emergency response organization minimum shift component; performing the duties of a fire brigade member who is responsible for understanding the effects of fire and fire suppressants on safe shutdown capability; performing maintenance or on-site directing of the maintenance of SSCs that a risk-informed evaluation process has shown to be significant to public health and safety; and performing security duties as an armed security force officer, alarm station operator, response team leader, or watchperson.

Operating nuclear power reactors FFD programs meeting all of the requirements of Part 26, except the fatigue management requirements in §§ 205-209 of Subpart I and Subpart K, apply to those individuals who are granted unescorted access to the nuclear power plant protected areas but who do not perform the duties listed in the preceding paragraph, and to all persons who are required to physically report to the licensee's Technical Support Center or Emergency Operations Facility by licensee emergency plans and procedures.

Licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) and entities who obtain a certificate of compliance or an approved compliance plan under Part 76, FFD programs meeting all of the requirements of Part 26, except Subparts I and K, are required to apply these requirements to those individuals whose duties for the licensees or other entities require them to be granted unescorted access to Category IA material, who create or have access to procedures or records for safeguarding SSNM, who measure Category IA material, who transport or escort Category IA material, or who guard Category IA material.

With respect to nuclear power plant construction, Part 26 requires that when construction activities begin, any individual whose duties for the licensees and other entities listed in § 26.3(c) require him or her to have the following types of access or to perform the following activities at the location where the nuclear power plant will be constructed and operated, shall be subject to an FFD program that meets all of the requirements of 10 CFR Part 26 except Subparts I and K: serves as a security officer under NRC requirements; performs quality assurance activities; is designated by a licensee or other entity to perform fitness monitoring under Subpart K; determines that inspections, tests, and analyses, or parts thereof, required under 10 CFR Part 52 have been successfully completed, supervises or manages the construction of safety- or security-related SSCs, or directs or implements the access authorization (AA) program, including

having access to the information used by the licensee or other entity to make AA determinations, making AA determinations, issuing entry-control picture badges, conducting background investigations or psychological assessments, adjudicating reviews or appeals of AA determinations, auditing the AA program, or performing any of these AA activities for any C/V upon whom the licensee's or other entity's AA program will rely.

Any individual who is constructing or directing the construction of safety- or security-related structures, systems, and components (SSCs), must either be subject to an FFD program that meets the requirements of Subpart K or an FFD program that meets all of the requirements of 10 CFR Part 26 except Subparts I and K. Licensees and other entities may either subject these individuals to random drug and alcohol testing and behavioral observation, or they may subject them to a fitness monitoring program. This analysis assumes 2 of the 19 FFD programs at nuclear power plant construction sites will be active within the period of this clearance. These programs will be closely associated with FFD programs at existing nuclear power reactors and will adopt random testing and behavioral observation. Within the 3-year period of this clearance, NRC estimates that neither of the two Subpart K FFD programs will adopt fitness monitoring.

All FFD program personnel who are involved in the day-to-day operations of the program and whose duties require them to have the following types of access or to perform the following duties are subject to an FFD program that meets all of the requirements of Part 26 except Subparts I and K and, at the licensee's or other entity's discretion, Subpart C: persons who can link test results with the individual who was tested before an FFD policy violation determination is made, including but not limited to the MRO, all persons who can make determinations of fitness, all persons who can make authorization decisions, all persons involved in selecting or notifying individuals for testing, and all persons involved in the collection or on-site testing of specimens.

The rule described in this clearance package constitutes a complete revision of Part 26.

The recordkeeping and reporting requirements in the rule 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 other records related to the collection, testing and review processes; report FFD program performance and significant violations, program failures and testing errors; and corrective actions; and retain records related to employee assistance programs. Records and reports are also required under the fatigue management component of the FFD program. The 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, and whether the provisions are implemented as the NRC intends.

The recordkeeping and reporting requirements of Part 26 are largely centralized into Subpart I - Managing Fatigue (§26.203) and Subpart N - Recordkeeping and Reporting Requirements (§§26.711-26.719), and Subpart K - FFD Programs for Construction (§§26.405, 26.411, and 26.417). Cross references to the recordkeeping and reporting requirements in Subpart N appear in other related portions of the Part 26 rule, but these cross references do not constitute additional recordkeeping or reporting requirements.

The burden for the recordkeeping and reporting requirements is captured against the specific requirement rather than in the general sections for recordkeeping and reporting (primarily §§26.713, 26.715, 26.717, and 26.719) to facilitate determining the burden impacts when a specific requirement is modified.

The estimated annual burden for the final rule of 871,200 hours, including one-time

recordkeeping (annualized), annual recordkeeping, annual reporting, and third-party responses, exceeds NRC's estimate for the previous rule of 61,143 hours (as estimated in the final clearance renewal published in the Federal Register on October 3, 2005 (70 FR 57625)) by 810,057 hours. Of this, 114,597 hours are for one-time recordkeeping requirements. The increase in burden is explained by several differences between the former rule and the final rule. In particular, the final rule creates significantly more detailed requirements pertaining to the FFD authorization process for individuals to ensure consistency with the NRC's access authorization requirements for nuclear power plants established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003. The final rule includes more detailed requirements pertaining to the specimen collection and testing process, to increase consistency with other relevant Federal rules and guidelines, including the U.S. Department of Health and Human Services (DHHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines). The final rule also includes a new subpart addressing requirements for HHS-certified laboratories, adds requirements for confirmatory drug and alcohol testing and verification testing, and expands and makes more explicit the requirements for licensee testing facilities. The burden estimate for the final rule captures significant third-party collections associated with the reporting and recordkeeping for the drug and alcohol testing activities that were not captured in the previous rule. Experience from the implementation of the current FFD rule, information obtained from stakeholders, and information obtained from sources such as the DHHS National Laboratory Certification Program has led the NRC to revise its estimates of the burden of certain activities. The final rule also contains a new Subpart I adding new fatigue management provisions that include reporting and recordkeeping burdens that were not part of previous estimates. The final rule also contains a new Subpart K adding new requirements for an FFD program for construction that includes reporting and recordkeeping burdens, some of which were not part of previous estimates, for an estimated 19 new FFD programs involving individuals constructing new nuclear power reactors.

A. JUSTIFICATION

As provided by the Atomic Energy Act (AEA), as amended, and the Energy Reorganization Act of 1974, in order to provide for the protection of public health and safety, including the radiation safety of workers and the general public, and the common defense and security, the NRC licenses and regulates the owners and operators of nuclear power plants, entities that are authorized to construct nuclear power plants, entities that are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM), and holders of combined licenses and manufacturing licenses under 10 CFR Part 52. NRC provides in 10 CFR Part 26 that the owners and operators of nuclear power plants, entities that are authorized to construct nuclear power plants, entities that are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM), and holders of combined licenses and manufacturing licenses under 10 CFR Part 52 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 subject to fitness-for-duty programs.

The fitness-for-duty programs must provide reasonable assurance that such individuals are trustworthy, reliable, and fit for duty, 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 commensurate with maintaining public health and safety. The fitness-for-duty programs must also 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 the program and provide reasonable assurance that the workplaces subject to Part 26 are free

from the presence and effects of illegal drugs and alcohol.

The reporting and recordkeeping provisions of 10 CFR Part 26 (listed below) support the following important functions of the fitness-for-duty program: (1) they provide a record of the authorization process through which individuals become authorized to have or maintain access to the protected areas of nuclear power plants or to perform certain specified duties; (2) they provide a record of the drug and alcohol testing procedures and the chain of custody of samples to be available in case a determination of fitness is necessary and/or if a determination of fitness is challenged under either the procedures specified by Part 26 or through litigation; and (3) they provide records for both self-assessments by licensees and other entities and audits and inspections by the NRC of FFD programs. Because fitness-for-duty programs are required for key functions at nuclear power reactors, and because FFD programs can impose significant consequences on individuals who violate the FFD requirements, access to detailed records concerning the individuals covered by the programs is particularly important.

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

These information collections are necessary to properly manage fitness-for-duty programs. Licensees must perform certain tasks, maintain records, and prepare reports to demonstrate their fulfillment of regulatory requirements. Certain events are of such significance that they must be reported to the NRC. Collection of this information pertaining to significant fitness-for-duty events is necessary to permit timely evaluation of events that might become problems and that may require a timely response by the NRC staff to ensure that the health and safety of the public is not endangered.

Section 26.9, Specific Exemptions, 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 10 CFR 50.12 or 10 CFR 70.17.

This reporting requirement is necessary to ensure that licensees seeking exemptions from the requirements of 10 CFR 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.

Section 26.11, Communications, provides that all communications, applications, and reports may, except where otherwise specified, be sent to the Commission either by mail or, where practicable, by electronic submission.

This section contains no information collections and merely specifies acceptable means for submitting information under Part 26.

Section 26.27, Written Policy and Procedures

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 general performance objectives and specific requirements of Part 26.

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. These requirements are also necessary to ensure 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. 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. The one-time burden for the initial development of the policy is shown under this paragraph.

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. The burden for incorporating and maintaining the policy statement in the policy compendium is shown under this paragraph.

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. It specifies the mandatory contents of the procedures, including procedures to be used in testing for drugs and alcohol; procedures for protecting the employee and the integrity of the specimen; procedures to ensure that the test results are valid and attributable to the correct individual; procedures to describe the immediate and follow-up actions that will be taken in those cases when individuals are determined to have been involved in the use, sale, or possession of illegal drugs, consumed alcohol to excess as determined by a test that measures blood alcohol content (BAC), attempted to subvert the testing process, refused to provide a specimen, or had a legal action taken relating to drug or alcohol consumption; procedures to ensure that individuals who are called in to perform an unscheduled working tour are fit to perform the task assigned; and procedures to describe the process to be followed if an individual's behavior raises a FFD concern.

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. They also provide a description of programs that are available to personnel desiring assistance in dealing with drug, alcohol, or other problems that could adversely affect their performance. These requirements also partially meet the legal necessity of protecting the due process rights of individuals who are subject to Part 26, and also providing "prior notice" and having it documented for evidence in legal proceedings. The one-time burden for initial preparation of the procedures and the recurring burden for updating and amending the FFD procedures are shown under this paragraph.

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 do include elements that are not consistent with the requirements of an effective FFD program. The recurring burden for providing the policy or procedure to the NRC, when it is reviewed as part of the inspection process or when it is otherwise requested, is shown under this paragraph.

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).

Section 26.29, Training

Paragraph 26.29(a) requires licensees and other entities to ensure that individuals who are subject to Part 26 have specified knowledge and abilities.

The one-time burden for developing a training course, including the development of an initial question bank that reflects the requirements of Part 26, including both drug and alcohol testing and fatigue management provisions, is shown under this paragraph.

Paragraph 26.29(b) requires all individuals subject to Part 26 to demonstrate successful completion of training by passing a comprehensive examination about the knowledge and abilities specified in §26.29(a)(1) through (10).

The one-time burden of testing all personnel subject to the FFD program when the Part 26 rule becomes effective is shown under this paragraph, and includes the burden of FFD management personnel to prepare the computerized examination from the question bank, to grade the examinations, to notify individuals of results, and to maintain records of the examination results.

In addition, the recurring burden of testing individuals who become subject to the FFD programs of licensees or other entities at a later time is shown under this paragraph. The recurring burden includes the time required for preparation of the computerized examination, to grade the examinations, to notify individuals of results, and to maintain records of the examination results.

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.

The one-time burden of providing training to those staff of licensees and other entities when the Part 26 rules become effective is shown under this paragraph.

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.

The recurring burden of providing refresher training, which includes training for new staff who are hired after the initial training, and administering a comprehensive annual examination, is shown under this paragraph. The burden of 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 paragraph.

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 requirements in §26.29 are necessary to ensure that individuals assigned to activities within the scope of Part 26 are provided with appropriate training so that they understand the methods used to implement the FFD policy, the personal and public health and safety hazards associated with abuse of drugs or alcohol, the effects of prescription and over-the-counter drugs and dietary conditions on drug test results, their roles and responsibilities in the implementation of the fitness-for-duty program, the role of the Medical Review Officer (MRO), and the Employee Assistance Program (EAP) services available; that they are sufficiently skilled to detect conditions that arise from abuse or presence of drugs or alcohol, and that they know the proper action to be initiated. Licensees or other entities are required to prepare appropriate examination questions and maintain a question bank, develop and administer examinations, assess whether individuals pass or fail the examinations, and communicate examination results to the individuals and to the FFD program managers. FFD programs are expected to administer and grade examinations and communicate results by means of their computer networks. These requirements also partially meet the legal necessity of providing “prior notice” and having it documented (by training and examination records) for evidence in legal proceedings.

Recordkeeping requirements for §26.29 are established by §26.713(b)(1).

Section 26.31, Drug and alcohol testing

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 [10 CFR Part 25] are acceptable to meet the requirement. Section 26.31(b)(1)(i) requires the credit and criminal history checks and psychological assessments to be updated nominally every 5 years.

Paragraph 26.31(b)(1)(v) requires FFD program personnel to be subject to a behavioral observation program designed to assure that they continue to meet the highest standards of honesty and integrity. When an 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.

These requirements are necessary to ensure the honesty and integrity of persons who directly administer the FFD program. Assuring their fitness for duty 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 behavioral observation program 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). The current rule, by relaxing the previous requirement in Section 2.3(2) of Appendix A to Part 26 that requires background checks and psychological evaluations of FFD program personnel to be conducted at least once every three years and providing instead that credit and criminal history checks and updated psychological assessments must be conducted nominally every 5 years, reduces the number of such records that are created. However, the retention period for such records is not affected.

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. The licensee or other entity shall test the individual(s) who committed the error(s), and need not test individuals who were affected by the event but whose actions likely did not cause or contribute to the event. The individual(s) who committed the human error(s) shall be tested if the event resulted in: (i) 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, even 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; (ii) a radiation exposure or release of radioactivity in excess of regulatory limits; or (iii) actual or potential substantial degradations of the level of safety and security of the plant;

(4) Followup. As part of a followup plan to verify continued abstention from the use of 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 paragraph. Records of the drug and alcohol testing programs are required in Subparts C, D, E, F, G, and N of Part 26.

Paragraph 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; 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 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 section allows licensees and other entities to add to the panel of drugs for which testing is required in §26.31(d)(1). It eliminates the reporting requirement in the previous Section 1.1(2) in Appendix A to Part 26 that required licensees to obtain written approval from the Commission to test for additional drugs. However, the current rule requires that the assay and cutoff levels to be used in testing for the additional drugs 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 paragraph §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.

This section allows licensees and other entities to add to the panel of drugs for which testing is required in §26.31(d)(1). It 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.

These 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 26.31(d)(3)(iii)(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, Behavioral observation

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 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. 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).

Section 26.35, Employee assistance programs

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. 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 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. Licensees and other entities are prohibited from requiring the EAP to routinely report the names of individuals who self-refer to the EAP or the nature of the assistance the individuals sought. However, if EAP personnel determine that an individual poses or has posed an immediate hazard to himself or herself or others, EAP personnel are required to so inform FFD program management, and need not obtain a written waiver of the right to privacy from the individual. The individual conditions or actions that EAP personnel shall report to FFD program management include, but are not limited to, substantive reasons to believe that the individual (i) is likely to commit self-harm or harm to others; (ii) has been impaired from using drugs or alcohol while in a work status and has a continuing substance abuse disorder that makes it likely he or she will be impaired while in a work status in the future; or (iii) has ever engaged in any acts that are reportable under §26.719(b)(1) through (b)(3).

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 himself 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. 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.

Section 26.37, Protection of information

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 and maintain a system of files and procedures to protect the personal information.

The one-time burden to confirm that the FFD files and procedures are adequate to protect personal information is covered under this section.

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. The one-time burden to confirm that the signed consent and designation of a personal representative have been obtained is covered under this section.

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, 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.

These 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.

Recordkeeping requirements for §26.37(b) are established by §26.713(a)(3).

Section 26.39, Review process for fitness-for-duty policy violations

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.

These one-time 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. An increase in the number of transient personnel who work solely in the nuclear industry but who travel from site to site and work at several different sites has led to increased information sharing among licensees and C/Vs about individuals in the workforce. 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.

The requirements are 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).

Section 26.41. Audits and corrective action

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 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 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).

Section 26.53, General Provisions

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 individual may withdraw consent at any time. If consent is withdrawn, the licensee or other entity may not initiate any elements of the authorization process that were not in process at the time the consent was withdrawn but may complete and document any elements in progress at the time consent is withdrawn. 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. The licensee or other entity shall inform the individual that withdrawal of consent will withdraw the individual's current application for authorization; and other licensees and entities will have access to information documenting the withdrawal.

This requirement requires the licensee or other entity to obtain and retain a written consent from the individual before initiating actions to grant or maintain authorization or to withdraw authorization. Because actions relating to authorization become part of a record that can affect the individual's ability to be employed in the nuclear power industry, their consent to the actions is necessary to protect them 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.

Section 26.55, Initial Authorization

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.

Requirements for the contents of the self-disclosure and employment history 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 §§25.55(a)(1) and (a)(2) are established by §§26.61 and 26.63 and by §§26.713(a)(1) and (a)(3).

Section 26.57, Authorization Update

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.

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

Section 26.59, Authorization Reinstatement

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 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. If the suitable inquiry is not completed within 5 business days due to circumstances that are outside of the licensee's or other entity's control and the licensee or other entity is not aware of any potentially disqualifying

information regarding the individual within the past 5 years, the licensee or other entity may maintain the individual's authorization for another 5 business days. If the suitable inquiry is not completed within 10 business days of reinstating authorization, the licensee or other entity shall administratively withdraw the individual's authorization until the suitable inquiry is completed.

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 Chapter 10 of the Code of Federal Regulations, or any other inquiry or investigation. The individual may not be required to disclose the administrative action in response to requests for self-disclosure of potentially disqualifying FFD information.

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 (a)(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 (a)(3).

Recordkeeping requirements for §26.59(c)(1) are established by §26.61 and by §§26.713(a)(1) and (a)(3).

Section 26.61, Self-disclosure and employment history

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.

These sections create the requirement for 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 sections 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 behavioral observation and arrest-reporting program is obtained from the nuclear reactor industry's Personnel Access Data System (PADS), to which plants send information concerning individuals.

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.

These 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 sections specify the information to be reported or recorded in support of authorization determinations under §§26.55, 26.57, and 26.59.

Section 26.63, Suitable inquiry

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.

These sections 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. Sections 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 the Personnel Access Data System (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 paragraph 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.

Section 26.65 Pre-access drug and alcohol testing

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.

These sections clarify the required testing where an individual's authorization is terminated less than a year, or less than 30 days. The sections 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).

Section 26.67, Random drug and alcohol testing of individuals who have applied for authorization

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 section, 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.

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

Section 26.69, Authorization with potentially disqualifying fitness-for-duty information

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 followup testing for an individual to ensure that information documenting the treatment and/or followup plan is identified to any subsequent licensee or other entity who seeks to grant authorization to the individual.

These 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).

Section 26.75, Sanctions

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) 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 industry's Personnel Access Database System (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 triggers 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 Medical Review Officer.

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.

The recordkeeping requirements for this section are established by §26.713(a)(2).

Paragraph 26.75(i)(4) 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 under §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.

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. This provision, in addition, 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 section are established by §26.713(a)(2).

Section 26.77, Management actions regarding possible impairment

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, to 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).

Section 26.85, Collector qualifications and responsibilities

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.

This requirement is 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 sections.

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 Subpart E of Part 26.

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).

These requirements are necessary to ensure that the training, competency of the collection site personnel 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 collection site personnel also will supports reliance by licensees and other entities on test results from testing that was performed by another Part 26 program.

Recordkeeping requirements for §26.85(e) are established by §26.715(a) and (b)(1).

Section 26.87, Collection Sites

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.

These 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 requirements in §§26.87(f)(3), (f)(4), and (f)(5) are necessary to ensure a chain-of-custody form is prepared that identifies the origin of the specimen and associates the specimen with the correct donor.

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

Section 26.89. Preparing to collect specimens for testing

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

Paragraph 26.89(b)(1) and (b)(2) requires that individuals show proper identification before testing, and, if they cannot produce acceptable identification the collector must notify FFD program management. When so informed, FFD program management shall contact the individual's supervisor to verify in-person the individual's identity, or, if the supervisor is not available, take other steps to establish the individual's identity and determine whether the lack of identification was an attempt to subvert the testing process.

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.

Notice to FFD program management is necessary to ensure that appropriate actions are undertaken under the FFD procedures to determine if authorization of the person should be

denied or other management actions taken. Paragraph 26.89(b)(4) creates a requirement to explain the testing procedure and 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).

Section 26.91, Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use

Paragraph 26.91(c)(1), (c)(2), and (c)(3) provides that an evidential breath testing 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 evidential breath testing 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 evidential breath testing devices (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 information is available for reviews of determination of fitness and legal proceedings, if any, addressing determinations of fitness. This requirement also helps to ensure that information is available with which to track the performance 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 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. If the EBT fails the external calibration check, cancel the donor's test result and conduct another initial and confirmatory test on a different EBT as soon as practicable.

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.

Paragraph 26.91(e)(5) creates a requirement to create an internal record of the inspection, maintenance, and calibration. This requirement is necessary to ensure that past inspection, maintenance, and calibration activities can be reviewed and confirmed.

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

Section 26.93, Preparing for alcohol testing

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) - (a)(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).

Section 26.95, Conducting an initial test for alcohol using a breath specimen

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).

Section 26.97, Conducting an initial test for alcohol using a specimen of oral fluids

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.

These 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 a 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 help to 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 §26.97(d) are established by 26.715(b)(6).

Section 26.99, Determining the need for a confirmatory test for alcohol

Paragraph 26.99(b) requires the collector to ensure that the time when an initial test whose result is 0.02 percent Blood Alcohol Content (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 also is 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).

Section 26.101, Conducting a confirmatory test for alcohol

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 help to 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).

Section 26.103, Determining a confirmed positive test result for alcohol

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).

Section 26.107, Collecting a urine sample

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 accompanies the specimen, such as an attempt to bring an adulterant or urine substitute into the room or stall used for urination.

Recordkeeping requirements for §26.107(b) are established by §26.715(b)(6).

Section 26.109, Urine specimen quantity

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 30mL, 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 15mL and less than 30mL, 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.

These requirements are necessary to ensure that the FFD program manager or MRO is informed to collection problems involving a particular donor so that the FFD program manager or MRO can initiate alternative procedures for which their approval is required.

Recordkeeping requirements for §26.109(b)(4) are established by §26.715(b)(6).

Section 26.111, Checking the validity of the urine specimen

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 it 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 and/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 supervision.

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).

Section 26.113 Splitting the urine specimen

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 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).

Section 26.115, Collecting a urine specimen under direct observation

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 should be used must make that decision and document it.

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.

The requirement in §26.115(b) 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 duty 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).

Section 26.117, Preparing urine specimens for storage and shipping

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

Section 26.119, Determining "shy" bladder

Paragraph 26.119(a) requires a donor who has not provided a specimen of at least 30 ml within the 3 hours permitted for urine collection to obtain, within 5 business days, an evaluation from a licensed physician, or from the MRO if the MRO has the appropriate expertise.

This requirement is necessary to ensure that a qualified MRO or licensed physician prepares an evaluation of whether the medical condition of the donor was or could have with a high

probability been the basis for the donor's failure to provide a specimen.

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.

These 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. The medical evaluation, in part, provides an opportunity to the donor to demonstrate that the failure to provide the specimen is not an attempt to subvert the testing process but is, instead, the result of a valid medical condition, and helps to ensure that the licensee or other entity does not inappropriately impose sanctions on the individual.

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 itself.

Section 26.125, Licensee testing facility personnel

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.

These 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).

Section 26.127, Procedures

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.

These 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).

Section 26.129, Assuring specimen security, chain of custody, and preservation

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, which involves 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.

These 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.

The provision in §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).

Recordkeeping requirements for §26.129(b) are established by §26.715(b)(2).

Recordkeeping requirements for §26.129(b)(1) are established by §26.715(b)(3).

Recordkeeping requirements for §26.129(d) are established by §26.715(b)(2).

Section 26.135, Split Specimens

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).

Section 26.137, Quality assurance and quality control

Paragraph 26.137(a) requires each licensee testing facility to develop and implement a quality assurance program and quality assurance procedures encompassing all aspects of the testing process.

These 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.

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.

These 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(a) are established by §26.715(b)(3).

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.

These 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).

Recordkeeping requirements for §26.137(f) are established by §26.715(b)(8).

Recordkeeping requirements for §26.137(h) are established by §26.715(b)(5).

Section 26.139, Reporting initial validity and drug test results

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 of the rule specifies the program performance data to be included in the annual report.

Reporting requirements under §26.139(d) are established by §26.717(b) and (e).

Section 26.153, Using certified laboratories for testing urine specimens

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 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).

Recordkeeping requirements for §26.153(f) are 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 # 0930-0158).

This requirement is consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. Under the HHS Guidelines, 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. The 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).

Section 26.155, Laboratory personnel

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.

These requirements are consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, Sections 11.2 and 11.3. HHS explains (69 FR 19691, April 13, 2004), that 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.

Recordkeeping requirements for §§26.155(a)(1), (a)(3), (b), and (c) are established by §26.155(f).

Recordkeeping requirements for §26.155(a)(4) are established by §26.157.

Recordkeeping requirements for §26.155(a)(5) are established by §26.715(b)(3).

The recordkeeping burden for §26.155(e) and (f) is captured under HHS OMB control number 0930-0158.

Section 26.157. Procedures

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.

These requirements are consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, 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 HHS OMB control number 0930-0158 .

Section 26.159, Assuring specimen security, chain of custody, and preservation

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.

These requirements are consistent with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, 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 HHS OMB control number 0930-

0158.

Recordkeeping requirements for §26.159(b) are established by §26.715(b)(3).

Recordkeeping requirements for §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).

Section 26.163. Cutoff levels for drugs and drug metabolites

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).

Section 26.165. Testing split specimens and retesting single specimens

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 26.165(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 26.165(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 26.165(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 under §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.

These 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 Mandatory Guidelines for Federal Workplace Drug Testing Programs, Section 15.1. The 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) are established in this section.

Section 26.167, Quality assurance and quality control

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 Mandatory Guidelines for Federal Workplace Drug Testing Programs. 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, they 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 Mandatory Guidelines for Federal Workplace Drug Testing Programs. 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 Mandatory Guidelines for Federal Workplace Drug Testing Programs and with 10 CFR 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 Mandatory Guidelines for Federal Workplace Drug Testing Programs 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).

Recordkeeping requirements for §26.167(h) are established by §26.715(b)(3).

Section 26.168, Blind performance testing

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.

Section 26.169, Reporting results

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 summary report is listed in §§26.169(k)(1) - (8).

These 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. 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 Mandatory Guidelines for Federal Workplace Drug Testing Programs, 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).

Section 26.183, Medical Review Officer

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 subspecialty 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(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.

These requirements and records are necessary to specify how the MRO performs certain duties.

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.

These 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).

Section 26.185. Determining a fitness-for-duty violation

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.

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) 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 26.185(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.

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. The 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).

Section 26.187, Substance Abuse Expert

Paragraph 26.187(d) requires the Substance Abuse Expert (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 followup evaluation, continuing treatment recommendations, and the followup 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 Substance Abuse Expert to maintain documentation showing that he or she currently meets all credentials, knowledge, and training requirements

for a Substance Abuse Expert 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 substance abuse expert'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 Substance Abuse Expert 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 Substance Abuse Experts 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.

Section 26.189, Determination of Fitness

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.

These 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. The determinations of fitness-for-duty must provide reasonable assurance 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. The fitness-for-duty determinations must also 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 the program and provide reasonable assurance that the workplaces subject to Part 26 are free from the presence and effects of illegal drugs and alcohol. 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).

Section 26.203. General provisions

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.

These requirements are necessary to ensure that written policies and procedures are available to individuals that indicate how each FFD program subject to Subtitle 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 policy and procedures for fatigue management are included in the overall 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 Medical Review Officer (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 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 under §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.

These 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 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).

Section 26.205, Work hours

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. Except as permitted by paragraphs (b)(1) through (b)(5) of this section, the calculated work hours must include all time performing duties for the licensee, including all within-shift break times and rest periods during which there are no reasonable opportunities or accommodations appropriate for restorative sleep.

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. Except as permitted in § 26.207, at a minimum, licensees are required to ensure that individuals subject to Subpart I have a 10-hour break between successive work periods or an 8-hour break when a break of less than 10 hours is necessary to accommodate a crew's scheduled transition between work schedules or shifts; and a 34-hour break in any 9-day period.

Paragraph 26.205(d)(3) requires licensees to ensure that individuals have, at a minimum, the number of days off specified in this paragraph. For the purposes of this subpart, a day off is defined as a calendar day in which an individual does not start a work shift. For the purposes of calculating the average number of days off required in this paragraph, the duration of the shift cycle may not exceed 6 weeks. Individuals who are working 8-hour shift schedules shall have at least 1 day off per week, averaged over the shift cycle; individuals who are working 10-hour shift schedules shall have at least 2 days off per week, averaged over the shift cycle; individuals who are working 12-hour shift schedules while performing the duties described in § 26.4(a)(1) through (a)(3) shall have at least 2.5 days off per week, averaged over the shift cycle; individuals who are working 12-hour shift schedules while performing the duties described in § 26.4(a)(4), shall have at least 2 days off per week, averaged over the shift cycle, and individuals who are working 12-hour shift schedules while performing the duties described in § 26.4(a)(5) shall have at least 3 days off per week, averaged over the shift cycle.

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 unit outage activities. However, the licensee is required to ensure that the individuals specified in § 26.4(a)(1) through (a)(3) have at least 3 days off in each successive (i.e., non-rolling) 15-day period and that the individuals specified in § 26.4(a)(4) have at least 1 day off in any 7-day period.

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. However, licensees shall ensure that these individuals have at least 4 days off in each successive (i.e., non-rolling) 15-day period; and during the first 60 days of an unplanned security system outage or increased threat condition, licensees need not meet the requirements of either paragraph (d)(3) or (d)(5)(i) of this section.

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.

These 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).

Recordkeeping requirements for §26.205(d)(2) through (d)(7) are established by §26.203(d)(2).

Recordkeeping requirements for §25.205(e)(1) through (e)(3) are established by §26.203(d)(4).

Recordkeeping requirements for §26.205(e)(4) are established by this section.

Section 26.207, Waivers and exceptions

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 necessitate the waiver, a statement of the scope of work and time period for which the waiver is approved, and the bases for the determinations. The waiver should be signed by the person with requisite signature authority, as specified in §26.207(a)(1).

This requirement is necessary to ensure that waivers and exceptions 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).

Section 26.211, Fatigue assessments

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 will enable the 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).

Section 26.401, General

Paragraph 26.401(b) requires licensees and other entities who intend to implement an FFD program under Subpart K to submit an descriptions 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.

Section 26.403, Written Policy and Procedures

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. The one-time burden for the initial development of the policy is shown under this paragraph.

Section 26.405, Drug and alcohol testing

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 followup testing as part of a followup 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 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.

These 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.

Section 26.406, Fitness Monitoring Program

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 §24.4(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.

These 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 under § 26.403.

Section 26.407, Behavioral Observation

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.

Section 26.411, Protection of Information

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.

These 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, Review Process

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 one-time 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. The requirements also partially meet the legal necessity of proving “prior notice” and having it documented for evidence in legal proceedings.

Section 26.415, Audits

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.

These 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.

Section 26.417, Recordkeeping and Reporting

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.

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

These 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 Department of Health and Human Services 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 Mandatory Guidelines for Federal Workplace Drug Testing Programs, 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 the Department of Health and Human Services 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 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, Suitability and fitness evaluations

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.

Section 26.711, General provisions [Recordkeeping and Reporting Requirements]

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 these 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 10 CFR 73.56, as supplemented by orders to nuclear power plants dated January 7, 2003.

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 individuals 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.

Section 26.713, Recordkeeping requirements for licensees and other entities

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 followup 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.

These 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, and to enable the NRC to review and audit the licensee's 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.

Section 26.715, Recordkeeping requirements for collection sites, licensee testing facilities, and laboratories certified by the Department of Health and Human Services

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.

These 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 Department of Health and Human Services 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 Mandatory Guidelines for Federal Workplace Drug Testing Programs, 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 the Department of Health and Human Services 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.

Section 26.717, Fitness-for-duty program performance data

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; and
- 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 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 by the NRC staff to ensure that the health and safety of the public and the common defense and security are not endangered. The rule requires licensees and other entities to submit program performance data to the NRC every 12 months, rather than every 6 months as required by the previous rule, to reduce reporting burden and to make the reporting time consistent with the NRC's need for the information.

Section 26.719, Reporting requirements

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.

These 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. The rule groups these reporting requirements into one section in order to improve clarity in the organization of the rule and to respond to requests of stakeholders.

Section 26.821, Inspections

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 licensee's and other entities' FFD programs 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 entities' FFD program or may have their 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).

2. Agency Use of Information

The NRC will use the information included in the records and reports required in this part for one or more of the following purposes:

- to monitor compliance with Part 26 and ensure that licensees' and other entities' FFD programs are adequate to protect public health and safety and minimize danger to life and property, common defense, and security;
- to determine if there are problems requiring timely response by the NRC staff (NRC actions might vary depending on the circumstances, but include immediate telephone contact with the licensee or other entity to discuss the event or followup at the site);
- to perform empirical evaluations of drug and alcohol testing and fatigue management in support of any future considerations, including analysis of trends and lessons learned.

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 is beneficial to them. Most licensees collect, store, and format fitness-for-duty data electronically. The NRC issued a regulation on October 10, 2003 (68 FR 58792), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. It is estimated that approximately 70% of the potential responses are filed

electronically. Most licensees collect and store fitness-for-duty 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 under the standards for a National Laboratory Certification Program established by the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, and also are consistent with usual and customary business practices for forensic laboratories. Licensees for nuclear power reactors maintain a system of records on individuals subject to access authorization requirements called the Personnel Access Database System (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. 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 NRC has determined that the affected entities are not small entities or businesses as those terms are used in the Regulatory Flexibility Act.

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

The records required by the rule 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, training and qualifications of FFD program personnel, and security of specimen collection, storage, and testing facilities, are standard components of all forensic specimen collection and testing programs. If these records are not made in a comprehensive manner at the time that specimen collection and testing occurs, the scientific accuracy of test results cannot be assessed or verified and neither the performance objectives of the FFD program nor the protection of the rights of individuals subject to the program can be attained. 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 may be granted. The annual report on the performance of licensees' and other entities' programs provides data that is necessary for the NRC to assess whether the FFD programs are meeting the program requirements. The rule reduces the frequency of the current FFD performance report from semi-annually to annually. Receiving FFD program performance data at least annually is necessary because any longer period of time could result in substantial program deterioration that would result in potential threats to public health and safety and danger to common defense and security.

7. Circumstances which Justify Variation from OMB Guidelines

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 26.165 (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.

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 26.203(d) requires that specified records pertaining to fatigue management should be kept for at least three 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 an enforcement action against a licensee or other entity for failure to comply with the fatigue management requirements of Subpart I of Part 26 or to an individual are available. The requirement protects the due process rights of licensees and other entities and of individuals.

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 that the NRC is informed promptly so that the appropriate NRC managers can address the situation immediately.

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 five years, which is consistent with the previous rule, 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 three 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 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 that the previous rule requires these records to be retained and that adding a requirement to retain the records until all legal proceedings are complete protects individuals' 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 three 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. Because of the extremely serious nature of the actions that cause an individual to receive either a 5-year denial of authorization or a permanent denial of authorization, the 40-year retention requirement is intended to cover the longest expected working life of an individual, so that the record is available over the individual's entire working life. Requiring the record to continue to be available, even if the license is terminated of the licensee or other entity that had denied the individual's authorization, is necessary because the individual whose authorization was denied for 5 years or permanently denied under that licensee's FFD program would not necessarily leave the industry. Requiring retention and availability of the records pertaining to those individuals ensures that the records of the 5-year and permanent denials are available, should the individual seek authorization from another licensee or other entity.

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 period of time that superseded materials are retained has been increased from 3 to 5 years to ensure 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 to retain the policy and procedures related to 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 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 (as in the current rule) 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 who 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 whom 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 who is subject to this rule require access to them in a legal or regulatory proceeding.

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.

8. Consultations Outside the NRC

The requirements of 10 CFR Part 26 are discussed on a continuing basis with the Nuclear Energy Institute (NEI), the Substance Abuse and Mental Health Services Administration (SAMHSA) of the Department of Health and Human Services (HHS), and licensees individually and at industry-wide meetings.

In 2000, the Office of Management and Budget commented on the information collection clearance document submitted by the NRC in support of a proposed revision of the FFD rule. The NRC has prepared responses to those comments, the majority of which dealt with issues aside from reporting and recordkeeping. The NRC's responses are presented in Section V.A. of the Federal Register notice announcing the proposed rule and the availability of this supporting statement for public comment. Between 2001 and 2004, the NRC staff conducted 11 stakeholder meetings on the drug and alcohol testing portions of Part 26 and held 13 stakeholder meetings on a proposed draft rule to incorporate provisions to manage worker fatigue. Subsequent to the Commission's decision in May 2004 to combine the two rulemaking efforts, the staff held one stakeholder meeting on the combined rule in July 2004, and two meetings on the fatigue portions of the combined rule in August and September 2004. During the meetings the staff discussed with the stakeholders the proposed reporting and recordkeeping requirements along with other topics pertaining to the proposed FFD requirements. At the July 2004 stakeholders meeting, the stakeholders received a detailed description of the estimated reporting and recordkeeping burdens associated with the proposed rule provisions as they existed at that time. Stakeholders provided verbal commentary on a few sections, but in general the stakeholders stated that they preferred to comment on the reporting and recordkeeping burden estimates when the proposed rule was published. The NRC offered to review and, consistent with the rulemaking schedule outlined to stakeholders at the public meetings, consider comments sent in following the meeting and received prior to September 15, 2004. However, no comments were received. Subsequent to the July 2004 stakeholders meeting, the NRC also requested and received data from six nuclear power plants pertaining to certain fatigue management provisions in the proposed Subpart I. Throughout this period of time, the staff made the draft proposed rule language available to the public through the agency's internet-based interactive rulemaking website at <http://ruleforum.llnl.gov>. All comments received between 2001 and September 15, 2004, were considered in developing this burden estimate.

An opportunity for public comment on the information collection requirements contained in the proposed rule published in the Federal Register on August 26, 2005, (70 FR 50442) elicited comments from several commenters. Stakeholders objected to the proposed annual reporting

requirements that would have required licensees to report, as part of their annual FFD program performance report, information concerning implementation of their fatigue management program. Several commenters asserted that the NRC should delete the reporting requirements from the rule because they would not provide new or unique information, are unnecessary to protect public health and safety, are unnecessary to facilitate NRC oversight of implementation of the revised rule, and are unduly burdensome. Commenters also stated that the NRC has not met its obligation under the Paperwork Reduction Act with respect to the information collection requirements in the proposed reporting requirement. They argued that the NRC failed to adequately justify the need for these provisions to achieve the objectives of the proposed FFD rule and to objectively support the agency's estimate of the burden created for affected licensees. The commenters asserted that the annual report would require at least 30 clerical hours to develop and 20 management hours to review.

In response to public comments on the reporting requirements, the NRC revised certain requirements for the inclusion of fatigue management information in the annual FFD program report. The NRC also made conforming changes to the reporting requirements as part of changes to other provisions of the rule.

Section 26.203(e) [Reporting] of the final rule presents the reporting requirements associated with licensee implementation of Subpart I. This section does not retain the requirements in proposed § 26.197(e)(2) for the reporting of information pertaining to the control of collective work hours because the final rule does not include collective work hour controls. In addition, the agency revised the requirements in proposed § 26.197(e)(1) and (e)(2) in response to comments that the required information would not provide a meaningful indication of licensee performance in managing work hours because a number of valid conditions may warrant waivers of work hour controls. Through its review of authorized waivers from the work hour limits in plant technical specifications, the NRC has found that waivers are most frequently associated with outage activities. Accordingly, the NRC has revised the final rule to require licensees to report whether a waiver of the work hour requirements in § 26.205 was associated with an outage activity.

As a result of these revisions, the NRC will be better able to interpret a licensee's changes in waiver use over time and understand why certain annual reports for a given licensee may indicate a heightened level of waiver use relative to the licensee's previous reports. The NRC recognizes that outages are not the only cause of waivers; however, the agency expects that most other causes of waiver use will be for substantially shorter periods of time or involve smaller groups of workers and that these other conditions would not have a substantive effect on overall waiver use. For unique causes that may have more substantive effects (e.g., licensee response to hurricanes), the NRC is likely to be aware of or able to identify these conditions if they were to significantly affect waiver use. The NRC notes that the frequency of waiver use (i.e., how often individuals exceed the work hour limits while performing functions important to safety and security) indicates the potential for worker fatigue to affect the performance of these functions, regardless of whether a waiver is the result of an activity associated with an outage or a cause that is beyond the licensee's control.

In addition to requiring an indication of whether a waiver was associated with an outage activity, the NRC revised the annual report requirement to require a frequency distribution of waivers for each of the five duty groups described in § 26.4(a) of the final rule. As a result, the annual report would include, for example, a table that shows the number of operators who received just one waiver during the year, the number of operators who received two waivers during the year, and so on. The NRC incorporated this requirement in the final rule in response to comments that the rule should also require licensees to report the number of workers covered under § 26.199(a) of the proposed rule to provide an appropriate context for the annual reporting of waivers. The

NRC understood that the intent of this comment was to provide a basis for evaluating the number of waivers from the work hour controls relative to the number of individuals subject to those controls. The NRC chose not to require licensees to report the number of individuals covered under § 26.4(a) of the final rule because that number will vary throughout the course of the reporting period, particularly when the reporting period includes a unit outage. In addition, the NRC believes that the required distribution of waivers more effectively provides context to the waiver use information by indicating whether the waivers were concentrated among individuals performing a certain duty and whether the waiver use in a duty group was associated with relatively few individuals or distributed among many individuals.

The NRC does not agree with comments that the requirements for including fatigue management information should be deleted from the rule because they would not provide new or unique information to the NRC, would be unnecessary to protect public health and safety, would be unnecessary to facilitate NRC oversight of the revised rule, and would be unduly burdensome. In choosing to retain reporting requirements for waiver use, the NRC considered several aspects of the work hour requirements in the final rule. First, the NRC established the work hour limits in the final rule at levels such that the potential for fatigue is substantive for individuals working in excess of those limits. Second, the rule permits licensees to authorize waivers of the limits only for circumstances in which the additional work hours are necessary to prevent or mitigate a condition adverse to safety or security. Finally, the rule only requires a waiver if the individual is operating or maintaining an SSC that a risk-informed evaluation process has shown to be important to the protection of public health and safety or if the individual is performing specified functions that are essential to an effective response to a fire, plant emergency, or implementation of the site security plan. As a result, information concerning licensee use of waivers indicates (1) the number of hours worked on risk-significant activities by individuals who are at increased potential for impairment, and (2) how often a licensee must mitigate or prevent a condition adverse to safety while relying on individuals who are at increased potential for impairment. The NRC considers this unique information, not otherwise reported, to be relevant to the agency's mission.

In response to public comments suggesting that the requirement to include fatigue assessment information and any management actions in response to the fatigue assessments, the NRC concluded that the fatigue assessment information that would have been reported under the requirements of the proposed rule is more the purview of a licensee's corrective action program, and would have been more detailed than the program performance data for drug and alcohol testing required under § 26.717(c) of the final rule. Accordingly, the final rule requires licensees to report a summary of corrective actions, if any, resulting from the licensee's analysis of waiver and fatigue assessment data. As a consequence, the required reports will provide information that will focus more on licensee performance in managing worker fatigue and will enable NRC to review licensee reporting of waivers in the context of associated corrective actions.

The NRC expects that the information provided by licensees in response to the annual reporting requirements in Subpart I will facilitate NRC oversight of the implementation of the requirements through the following means and that the industry-estimated 50 hours of licensee staff effort to include fatigue management information in the annual report is justified for the following reasons:

- Consistency, efficiency, and continuity of NRC oversight—Information provided through the annual FFD program performance reports concerning fatigue management will enable the NRC to achieve a higher level of consistency and efficiency in the oversight of the implementation of the requirements in Subpart I and in the enforcement of those requirements. Without the reporting requirements, the NRC's inspection of licensee FFD programs would likely be limited to individual inspectors evaluating licensee fatigue

management for a sample of workers at a site for a limited time period. These assessments would necessarily be conducted without the benefit of broader contextual information from the site or the industry normative information that would be available through the annual reports. In contrast, the annual reports will help ensure a common perspective and maintain consistency among inspectors conducting the oversight process. In addition, the annual reports can enhance the efficiency of the NRC inspection process by providing information necessary to allow the agency to focus inspection resources on duty groups (e.g., security or maintenance) that may warrant review. The reports will enable the NRC to be better focused in preparing for the inspection, reduce the burden of onsite inspection hours, and potentially reduce the total number of hours required for a baseline inspection. Further, the annual reporting will also help to achieve a more complete and continuous assessment of licensee performance because the NRC intends to conduct the baseline inspection of FFD programs only once every 2 years.

- Evaluation of rule implementation for lessons learned—Although the NRC and stakeholders have made extensive efforts to ensure clear and enforceable requirements that are effective and practical for the management of worker fatigue, the rule introduces the potential for unintended consequences and lessons learned. In addition, changes in the size and composition of the nuclear industry may have unforeseen implications for site staffing and fatigue management. The NRC expects that the site-specific and normative information obtained through the annual reports can provide important insights regarding opportunities to amend the rule to improve its effectiveness or reduce unnecessary burden. The NRC notes that information provided by the FFD program performance reports was the basis for reducing the random testing rate for drugs and alcohol required in a previous amendment to Part 26.
- Consistent interpretation of waiver criterion—The final rule provides licensees the discretion to use waivers to exceed the work hour limits, thereby allowing levels of work hours that could adversely affect worker FFD. The principal basis for allowing waivers is to reduce the additional staffing burden that licensees would otherwise incur if waivers were not available to address exigent circumstances. The annual reporting of waiver use in conjunction with the corrective action summaries will enable the NRC to ensure that licensees use this discretion in a manner consistent with the objectives of the rule and not as a means to compensate for a lack of adequate staffing. Further, although the use of waivers is limited to conditions when the work hours are “necessary to prevent or mitigate a condition adverse to safety or security,” the NRC recognizes the potential for licensees to develop different interpretations regarding this criterion. Some industry commenters on the proposed rule took exception to the NRC’s characterization of high levels of waiver use at some sites as abuse. These commenters suggested that differences in licensee waiver practices could be attributed to the policy being subject to a number of interpretations during the many years that it has been in effect. Regardless of the cause of the differences in licensee use of work hour control waivers, the NRC considers it prudent to address, through rulemaking, the lessons learned from past implementation of the policy and provide a level of oversight through the annual reporting requirement that will ensure consistent implementation of the waiver criteria in the future.

In addition to the reasons cited in the preceding paragraphs explaining the need for reporting requirements to ensure the effective and efficient oversight of the implementation of the rule, the NRC considers the reporting requirements to be justified and beneficial for the following additional reasons:

- Consistency with other Part 26 requirements and performance objective—The final rule

retains the requirement of the former rule that licensees must report the results of drug and alcohol testing and the performance objective for reasonable assurance that individuals are not impaired from any cause (§§ 26.719 [Reporting requirements] and 26.23(b) of the final rule). In addition, several studies discussed in detail in the Statement of Considerations for the final rule have demonstrated that worker fatigue can produce levels of impairment that are comparable to blood alcohol concentrations above the levels permitted by this rule. Further, given the frequency of worker concerns regarding fatigue and the work scheduling practices that are common during outages, the incidence of impairment from fatigue is likely to be greater than the very low incidence of drug and alcohol use that is detected through testing. Therefore, the NRC considers the reporting of information pertaining to licensee management of worker fatigue to be consistent with the requirements for reporting information pertaining to drug and alcohol testing, the performance objective of this rulemaking for licensees to implement a comprehensive FFD program, and the NRC's belief that the management of worker fatigue is no less important to worker FFD than the effective detection and deterrence of drug and alcohol use.

- Public confidence—Public interest groups such as the UCS and the Project on Government Oversight have commented at public meetings that relevant information regarding worker fatigue is withheld to either protect alleged identity or, in the case of security personnel, plant security. In addition, several public media articles have been published during the past 2 years reporting instances of guards sleeping and guards fearing repercussions for refusing forced and excessive overtime. Information submitted by licensees in the annual reports will be publicly available and will reassure public stakeholders that the NRC is appropriately cognizant of licensee actions regarding fatigue management and that the NRC's oversight of these activities is transparent to all stakeholders.
- The burden is limited and justified—Section 26.203(e) of the final rule requires licensees to report information concerning fatigue management as part of the annual FFD program report. As a result, the burden associated with this reporting requirement is an incremental change to the reporting requirement for drug and alcohol testing. In addition, the fatigue management information required by § 26.203(e) of the final rule is largely information that licensees will have already generated to demonstrate compliance with other provisions of Subpart I. As a result, the burden associated with the report will be largely associated with compiling the information in an appropriate form and reviewing that compilation. The NRC has reviewed the public comments suggesting that the agency underestimated the number of clerical and management hours associated with this requirement and has taken these comments into consideration in estimating the burden of the reporting requirements in § 26.203(e) of the final rule. Nevertheless, the NRC considers the burden associated with the annual reporting requirements to be justified for the reasons described in this and the preceding paragraphs.

The NRC also considered comments that the reporting requirement ignores significant duplication in licensee efforts. The NRC agrees that § 26.205(e) of the final rule requires licensees to periodically review and assess the effectiveness of the work hour controls and that the licensee's corrective action program, which is routinely inspected by the NRC, will document and trend these reviews. However, as noted previously, the NRC considers the annual reports to be a limited burden that will enable the NRC to provide more effective and consistent oversight and achieve other objectives for the effective implementation of the requirements in Subpart I.

NRC also offered significant opportunities to stakeholders to provide their views on the reporting and recordkeeping requirements in subpart K of the rule. On March 29, 2006, NRC conducted a public meeting in which stakeholders provided their views on the conceptual

framework for the subpart K requirements, and a similar meeting was held on November 7, 2006 in which the staff described concepts for subpart K to stakeholders and obtained verbal and written comments from the stakeholders, including discussions of potential reporting and recordkeeping requirements.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

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 for the purpose of complying with Part 26. Section 26.37(a) of the rule requires 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. Section 26.37(b) permits disclosure of personal information concerning an individual only pursuant to a signed consent from the individual, except for disclosures to the following: the subject individual or his or her representative, when the individual has designated the representative in writing for specified FFD matters; assigned MROs and MRO staff; NRC representatives; appropriate law enforcement officials under court order; a licensee's or other entity's representatives who have a need to have access to the information in performing assigned duties, including determinations of fitness, audits of FFD programs, and human resources functions; the presiding officer in a judicial or administrative proceeding that is initiated by the subject individual; persons deciding matters under review for FFD policy violations under §26.39; and other persons pursuant to court order. Section 26.37(c) provides that personal information that is collected under Part 26 must be disclosed to other licensees or other entities, including C/Vs, or their authorized representatives, who are legitimately seeking the information for authorization decisions as required by Part 26 and who have obtained a signed release from the subject individual. Section 26.37(d) provides that upon receipt of a written request by the subject individual or his or her designated representative, the licensee, other entity, HHS-certified laboratory, or MRO possessing such records shall promptly provide copies of all records pertaining to the determination of a violation of the FFD policy, including test results, MRO reviews, and management actions pertaining to the subject individual.

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

11. Justification for Sensitive Questions

Sections 26.31, 26.33, 26.35, 26.39, 26.61 through 26.70, 26.75, 26.77, 26.85, 26.115, 26.117, 26.119, 26.165, 26.183, 26.185, 26.189, 26.211, 26.411, 26.713, and 26.719 require each licensee or other entity to collect personal information for the purpose of complying with Part 26. It is necessary to obtain sensitive personal 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; 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, that the workplaces subject to Part 26 are free from the presence and effects of illegal drugs and alcohol,

and 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; 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 burden associated with the information collections are given in Table 1 for one-time burden, Table 2 for annual recordkeeping burden, Table 3 for annual reporting burden, and Table 4 for third-party collections. Because the new rule constitutes a complete revision of Part 26, estimates are included for all sections that affect the information collection requirements and establish a new baseline. These estimates are based, in part, on discussions with nuclear utility employees, staff of the Nuclear Energy Institute, staff of the Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMSHA), and on estimates made by NRC personnel who are familiar with the records and reports required by 10 CFR Part 26. The overall estimated burden is 871,261 hours at an estimated cost of \$224,785,338 (871,261 hours x \$258 per hour).

13. Estimates of Other Additional Costs

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 .0004 times the recordkeeping burden cost. Therefore, the storage cost for this clearance is estimated to be \$89,186 (864,207 recordkeeping hours x \$258 per hour x .0004).

Approximately 50 percent of FFD programs, or 20 programs, are expected to purchase an average of 2 evidentiary breath testing (EBT) devices per program at a cost of approximately \$3,000 per device for a total of \$120,000 (20 x 2 x \$3,000).

The overall additional cost of this collection is estimated at \$209,186 (\$89,186 + \$120,000).

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 is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and/or 171. The total estimated cost to government is estimated as \$1,044,384 (4,048 hours x \$258 per hour).

15. Reasons for Change in Burden or Cost

The overall estimated burden has increased by 810,118 hours from 61,143 hours (as estimated in the renewal published in the Federal Register on October 3, 2005 (70 FR 57625) to 871,261 hours. The revised estimate incorporates annual reporting and recordkeeping burden, one-time recordkeeping (annualized), and annual third-party burden for this rulemaking. The one-time recordkeeping (annualized) totals 114,598 hours. Therefore, the burden increase will be reduced by about 14 percent once the one-time requirements are complete. The final rule is a complete revision of Part 26, and as such the burden increase or decrease cannot be associated with changes in the estimate for particular rule sections from the former rule to the final rule.

The factors that account for the increased estimate are the following: the rule creates significantly more detailed requirements pertaining to the FFD authorization process for individuals to ensure consistency with the NRC's access authorization requirements for nuclear power plants established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003. The rule includes more detailed requirements pertaining to the specimen collection and testing process, to increase consistency with other relevant Federal rules and guidelines, including the U.S. Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines). The rule adds requirements for confirmatory drug and alcohol testing and verification testing, and makes more explicit the requirements for licensee testing facilities. The burden estimate for the rule captures significant third-party collections associated with the reporting and recordkeeping associated with the drug and alcohol testing activities that were not captured in the previous rule. Experience from the implementation of the previous FFD rule, information obtained from stakeholders, and information obtained from sources such as the DHHS National Laboratory Certification Program has led the NRC to revise its estimates of the burden of certain activities. Finally, the rule contains new fatigue management provisions that include reporting and recordkeeping burdens that were not part of previous estimates, and it contains new requirements for FFD programs for individuals involved in the construction of new nuclear power reactors. The fatigue management requirements pertain to 30 programs; the FFD requirements for individuals involved in the construction of new reactors are expected to apply to FFD programs at 19 new nuclear power reactor construction sites.

16. Publication for Statistical Use

Not applicable.

17. Reasons for Not Displaying the Expiration Date

The requirement will be contained in a regulation. 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

None. No small businesses are affected. No statistical use of the information is made.

Attachments:

1. Table 1 – One-Time Recordkeeping Burden
2. Table 2 – Annual Recordkeeping Burden
3. Table 3 – Annual Reporting Burden
4. Table 4 – Annual Third-Party Burden
5. Table 5 – Annualized NRC Reporting and Recordkeeping Burden

Table 1
One-Time Recordkeeping Requirements
(Annualized)

Section	Number of Programs	Burden Hours per Program (Annualized)	Total Burden Hours (Annualized)
26.27(a): Prepare FFD policy statement	33 programs	107.0	3,531
26.27(a): Prepare FFD procedures	33 programs	213.0	7,029
26.29(a): Prepare FFD training course	33 programs	83.0	2,739
26.29(b): Prepare FFD exam	33 programs	13.3	439
26.29(b): All current staff take FFD exam	33 programs	96.3 ¹	3,178
26.29(b): FFD staff mgmt grade FFD exam	33 programs	96.3 ²	3,178
26.29(c)(1): FFD training for current staff	33 programs	2,266.7 ³	74,801
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	33 programs	0.3	10
26.37(a): Confirm files and procedures protect personal information	33 programs	2.7	89
26.37(b): Obtain signed consent for release of information	33 programs	5.6 ⁴	185
26.39(a) and (b): Prepare procedure for review of determination of FFD violation	33 programs	13.3	439
26.85(a): Prepare and deliver qualification training for urine collectors	33 programs	5.3	175
26.85(b): Prepare and deliver qualification training for alcohol collectors	33 programs	5.3	175
26.127(a): Prepare procedures for handling specimens at licensee testing facilities	33 programs	13.3	439
26.127(b): Prepare written chain-of-custody procedures for licensee testing	33 programs	13.3	439

¹Estimate assumes 1,700 employees per program take the FFD exam. 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 289 hours per program (96.3 hours annualized).

²Estimate assumes 1,700 employees per program take the FFD exam. Recording whether the individual passed the exam is estimated to take 10 minutes (0.17 hours) per employee or 289 hours per program (96.3 hours annualized).

³Estimate assumes 1,700 employees per program that require FFD training. The FFD training is estimated to take 4.0 hours per employee or 6,800 hours per program (2,266.7 hours annualized).

⁴Estimate assumes 1,700 employees per program that must consent to the release of information. The collection is estimated to take 5 minutes (0.01 hours per employee) or 17 hours per program (5.6 hours annualized).

Section	Number of Programs	Burden Hours per Program (Annualized)	Total Burden Hours (Annualized)
facilities			
26.127(c): Prepare written procedures for assays performed by licensee testing facilities	33 programs	13.3	439
26.127(d): Prepare written procedures for instrument and test setup by licensee testing facilities	33 programs	13.3	439
26.127(e): Prepare written procedures for remedial actions for systems and tests at licensee testing facilities	33 programs	13.3	439
26.137(a): Develop QA/QC program and procedures for licensee testing facilities	33 programs	13.3	439
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	26 HHS labs	2.7	70
26.157(b), (c), (d), and (e): Confirm that laboratory procedures already in place pursuant to HHS requirements also meet Part 26 requirements	26 HHS labs	2.7	70
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	26 HHS labs	2.7	70
26.203(a): Prepare fatigue management policy (In addition to §§26.27 burden)	30 programs	13.3	399
26.203(b): Prepare fatigue management procedures (in addition to §26.27 burden)	30 programs	26.6	798
26.203(c): Prepare training on fatigue management.	30 programs	22.7	681
26.205(b): Develop work hour tracking system	30 programs	133.3 ⁵	3,999
26.205(c): Develop individual work scheduling system	30 programs	33.3	999
26.401(b): Prepare Subpart K program	19 programs	60.0	1,140

⁵Based on estimate by NEI of \$50,000 for contractor to develop model revised timekeeping and tracking system, and estimate of 400 hours per program to approve and adopt the revised timekeeping system.

Section	Number of Programs	Burden Hours per Program (Annualized)	Total Burden Hours (Annualized)
plan			
26.403(a): Prepare written Subpart K FFD policy statement	19 programs	107.0	2,033
26.403(a): Distribute Subpart K FFD policy statement to all individuals	2 programs ⁶	5.0	10
26.403(b): Prepare written Subpart K FFD procedures	19 programs	213.0	4,047
26.406(a), (b), and (d): Establish a fitness monitoring program	0 programs ⁷	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	14 programs	120.0	1,680
Table 1: Total			114,598

⁶Based on estimate that 19 programs will begin development of Subpart K FFD programs by preparing the program plan and procedures, but that within the clearance period only 2 will begin construction and implement their programs.

⁷Based on estimate that no programs will adopt fitness monitoring during this 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.	33 programs	4.0	132
26.27(c): Record updates to policy & procedures	33 programs	8.0	264
26.27(d): Provide policy and procedures for NRC review	33 programs	4.0	132
26.29(b): Maintain records of FFD exams	33 programs	2.0	66
26.29(c)(2): Maintain records of refresher FFD training and testing	33 programs	2.0	66
26.29(d): Record acceptance of FFD training from other licensees' programs	33 programs	4.0	132
26.31(b)(1)(i): Record results of background checks for FFD personnel	33 programs	17.5	578
26.31(b)(1)(v): Record results of behavioral observation for FFD program personnel	33 programs	80.0	2,640
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	33 programs	8.0	264
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	33 programs	400.0	13,200
26.35(a): Employee assistance program records	33 programs	16.0	528
26.35(c): Maintain record of written waivers of right to privacy from individuals given to EAP	33 programs	2.0	66
26.35(c): Record of EAP disclosure to FFD mgmt.	16 programs	1.0	16
26.37(b)(1): Record of signed designations of personal representative for FFD matters	33 programs	40.0	1,320
26.37(c): Record of disclosures to other	33 programs	40.0	1,320

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
licensees			
26.37(d): Record of lab results and provide result to individual	33 programs	40.0	1,320
26.39(a): Maintain procedures for review of determinations of FFD	33 programs	40.0	1,320
26.39(d): Update records to reflect outcome of review of determination of fitness	33 programs	40.0	1,320
26.39(e): Record that review procedure provided to individual	33 programs	14.8	488 ⁸
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	33 programs	40.0	1,320
26.41(f): Document and report audit results	33 programs	40.0	1,320
26.41(g): Record that audit results shared with mgmt and with other FFD programs	33 programs	40.0	1,320
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
26.53(h): Record that written consent obtained from the subject individual before initiating any actions under Subpart C	33 programs	1,197.0	39,501 ⁹
26.53(i): Record that all individuals applying for authorization informed, in writing, of the causes for denial or termination of authorization	33 programs	19.6	647 ¹⁰
26.55(a)(1) and (a)(2): Record that obtained and reviewed self-disclosure and empl. 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 and empl. history and completed suitable inquiry	Burden shown under §§26.61 and 26.63		

⁸Estimate is based on 0.5 hours/test record and 979 positive test results from NRC's "Summary of Fitness-for-Duty Program Performance Reports for 2005," (henceforth, "2005 FFD program performance data"). <http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/performance-reports.html>

⁹Estimate is based on 79,005 pre-access tests from NRC's 2005 FFD program performance data. One-half burden hour is estimated for each test.

¹⁰Estimate is based on 648 positive pre-access test results from NRC's 2005 FFD program performance data. One hour is estimated for each positive test result.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.59(a)(1) and (a)(2): Record that obtained and reviewed self-disclosure and empl. history and 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	33 programs	1,197.0	39,501
26.63(a), (c), and (e): Record of suitable inquiry	33 programs	1,197.0	39,501
26.63(c)(2): File DD 214	33 programs	4.0	132
26.63(c)(3): Document refusal of past employer to supply employment information	33 programs	2.7	89
26.63(d) & (e): Maintain documentation of denial or unfavorable termination of authorization from other FFD programs	33 programs	1.0	33
26.65(d) and (e): Record of reinstatement or administrative withdrawal of authorization	33 programs	4.0	132
26.65(f): Administrative withdrawal of authorization	33 programs	1.0	33
26.67 Record of random drug and alcohol testing of persons who have applied for authorization	33 programs	757.6	25,001 ¹¹
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	33 programs	40	1,320
26.69(c)(3): Record that licensee verified that qualified professional indicated individual is fit for duty.	33 programs	40	1,320
26.69(c)(4): Record of verification that drug/alcohol treatment & testing completed	33 programs	3.0	99
26.69(c)(5): Record of verification that pre-access drug/alcohol testing completed	33 programs	1.0	33
26.69(d): Record that reviewing officer's review completed	33 programs	24.0	792
26.69(e): Record of testing and treatment plans accepted from other FFD programs	33 programs	8.0	264

¹¹NRC's 2005 FFD program performance data reported approximately 50,000 total random drug tests at 0.5 hours per test.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.69(e)(1): Record that information transmitted on testing and treatment plans to other FFD programs	33 programs	8.0	264
26.75(a), (b), (c), (d), (e), and (g): Record of sanctions for FFD violation	33 programs	12.0	396
26.75(h): Record additional evidence indicating impairment	33 programs	18.0	594
26.75(i): Record of positive initial test result and temporary administrative action	33 programs	80.0	2,640
26.75(i)(3): Eliminate from record references to temporary administrative action	33 programs	1.0	33
26.85(a), (b), & (c): Training collectors	33 programs	4.0	132
26.85(e): Maintain personnel files	33 programs	4.0	132
26.87(d)(3) and (f)(1): Signage/security at test site	11 programs	0.3	3
26.87(f)(3), (f)(4), and (f)(5): Record of custody-and-control forms	11 programs	2.0	22
26.89(a): Record of absence of donor reported	33 programs	1.0	33
26.89(b)(1), (b)(2), and (b)(4): Record that ID and consent-to-testing form obtained	33 programs	1.5	50
26.89(b)(3): Record that FFD program management informed that individual did not present identification	33 programs	1.0	33
26.89(c): Record of donor's refusal to cooperate in collection procedures	33 programs	1.0	33
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	33 programs	6.0	198
26.93(a)(6): Document alcohol pre-test questions asked and answered	33 programs	322.9	10,656
26.95(b)(5): Record donor identity for initial alcohol breath test	33 programs	322.9	10,656
26.97(b)(2): Record reason for new oral fluid alcohol test	33 programs	5.0	165
26.97(c)(1): Document reason for failure of	33 programs	2.5	83

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
2 nd collection attempt			
26.97(d): Record results and alcohol screening device used	33 programs	62.0	2,046
26.99(b): Record test time of initial test with 0.02% or higher BAC	33 programs	17.1	564
26.101(b)(7): Record time on EBT printout of alcohol test result	33 programs	17.1	564
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	33 programs	0.3	10
26.107(b): Document tampering attempt on c & c form	33 programs	1.4	46
26.109(b)(3): Record that FFD mgt. or MRO notified of "shy bladder" problem	33 programs	0.5	17
26.109(b)(4): Record that FFD management notified if observed collection required	33 programs	0.3	10
26.111(b): Note unusual findings on c & c form	33 programs	1.4	46
26.111(c): Record that tampering attempts reported to FFD mgr.	33 programs	0.3	10
26.113(b)(3): Record of c & c forms for both parts of split sample	33 programs	0.3	10
26.115(b): Record that approval obtained for collection under direct observation from FFD mgr. or MRO	33 programs	0.5	17
26.115(d): Record of c & c form for directly observed collection	33 programs	0.3	10
26.115(f)(3): Record of name of observer	33 programs	0.3	10
26.117(c), (d), and (e): Prepare ID labels and c & c forms for specimen shipment	33 programs	60.0	1,980
26.119(a), (e), and (f): Record that evaluation obtained from MRO or physician evaluating "shy bladder" claim	33 programs	6.0	198
26.119(b): Record that MRO provided information to physician as background for evaluation of "shy bladder" claim	33 programs	2.0	66
26.125(b) and (c): Proficiency and qualifications records of testing facility personnel	33 programs	16.0	528
26.127(a): Procedures for handling	33 programs	40.0	1,320

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
specimens by licensee testing facilities			
26.127(b): Written chain-of-custody procedures for licensee testing facilities	33 programs	40.0	1,320
26.127(c): Written procedures for assays performed by licensee testing facilities	33 programs	40.0	1,320
26.127(d): Written procedures for instrument and device setup by licensee testing facilities	33 programs	40.0	1,320
26.127(e): Written procedures for remedial actions for systems and testing devices at licensee testing facilities	33 programs	40.0	1,320
26.129(a): Records associated with limiting access to testing site	33 programs	2.5	83
26.129(b): Inspect specimen packages, custody control forms, and obtain memorandum from specimen collector	33 programs	0.5	17
26.129(b)(1): Record of report to senior management of attempts to tamper with specimens in transit	33 programs	1.0	33
26.129(d): Procedures for tracking c & c of specimens	33 programs	80.0	2,640
26.135(b): Record of donor's written permission for retest second part of split sample	33 programs	2.2	73
26.137(a): Record of QA/QC program and procedures for licensee testing facility	33 programs	4.0	132
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	33 programs	40.0	1,320
26.137(e)(7): Document procedures to protect against carryover material	33 programs	2.0	66
26.137(f)(5): Record finding of testing errors	33 programs	24.0	792
26.137(h): Label standards and controls	33 programs	65.0	2,145
26.139(d): Record that information prepared for FFD annual report on activities of licensee testing facility	33 programs	40.0	1,320
26.153(e): Record of inspection of HHS-certified labs	33 programs	40.0	1,320

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.153(f): Include specified requirements in contracts with HHS labs	33 programs	40.0	1,320
26.153(g): Record of memo to HHS labs explaining use of non-federal c & c form	33 programs	0.5	17
26.159(b)(1): Record of report of evidence of tampering with specimens in transit to FFD program mgr. of licensee or other entity	33 programs	1.0	33
26.159(i): Record of written authorization to store specimens other than 1 year	33 programs	0.5	17
26.163(a)(2): Record that licensee informed of dilute specimen and report confirmatory validity test result to MRO	33 programs	3.0	99
26.165(b)(1): Record of donor requests for aliquot or split specimen to be tested by a second HHS-certified laboratory	33 programs	10.0	330 ¹²
26.165(b)(2): Record that MRO informed donor of opportunity for re-test of aliquot or test of Bottle B of split sample	33 programs	3.0	99
26.165(b)(3): Record that donor gave written permission for re-test of aliquot or test of Bottle B of split sample	33 programs	10.0	330
26.165(b)(4): Record that donor presented documentation for reason for inability to complete timely retest request	33 programs	0.2	7 ¹³
26.165(b)(6): Record that results of re-test of aliquot or test of Bottle B provided to MRO and to donor	33 programs	6.0	198
26.165(c)(4): Record that retesting results provided to MRO	26 laboratories	12.7	330
26.165(f)(1): Adjustments to personnel files and written notifications regarding test results, including temporary administrative action	33 programs	6.0	198
26.165(f)(1)(iv) and (f)(2): Written record and notice that records purged of references to temporary administrative action	33 programs	8.0	264
26.167(f)(3): Record of certification by HHS lab that retesting requested by licensee or other entity has occurred	26 laboratories	1.0	26

¹²Estimate is based on 361 donors (NRC's 2005 total positive test results minus pre-access test results) and one burden hour per donor.

¹³Based on 6 estimated donors and one burden hour per donor.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
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	26 laboratories	80.0	2,080
26.169(c)(2): Records of HHS lab reports of quantitative test results as requested by MRO	5 laboratories	1.0	5
26.169(c)(2): Records of HHS lab reports of quantitative test results for opiates to MRO	16 laboratories ¹⁴	1.0	16
26.169(c)(3): Records of HHS lab reports of quantitative test results for adulterated or substituted test results	26 laboratories	20.0	520
26.169(c)(4): Record of HHS contact with MRO to discuss whether testing by another HHS lab should be done	26 laboratories	2.0	52
26.169(c)(5): Record of HHS lab reports of concentrations exceeding linear range	5 laboratories	1.0	5
26.169(f): Records of HHS lab transmittals of copies of the c & c form for negative results to the MRO	26 laboratories	80.0	2,080
26.169(g): Records of HHS lab transmittals of original of c & c form for positive, adulterated, substituted, dilute or invalid results to the MRO	26 laboratories	80.0	2,080
26.169(h): Record that HHS lab prepared and submitted annual statistical summary report of urinalysis testing results	26 laboratories	40.0	1,040
26.183(a): Documentation of MRO qualifications	33 programs	3.5	116
26.183(c)(1): MRO review of records for positive, adulterated, substituted, invalid, or, at the licensees or other entity's discretion,	33 programs	24.0	792

¹⁴Estimate based on 16 total positive opiate drug tests listed in NRC's 2005 FFD program performance data.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
dilute test results			
26.183(d)(1)(ii)(D): Record of MRO report of drug test results to licensee's designated reviewing official	33 programs	24.0	792
26.183(d)(2)(i): Record of MRO staff review and reporting of negative test results	33 programs	12.0	396
26.183(d)(2)(ii): Record of MRO staff review of c & c forms and forwarding of changes to MRO	33 programs	12.0	396
26.185(a) Record of MRO review of all positive, adulterated, substituted, dilute, or invalid test results and report to licensee or other entity	33 programs	48.0	1,584
26.185(c): Record of MRO discussion of test results with the donor	33 programs	2.0	66
26.185(c): Record of MRO report to licensee, following discussion with donor, of FFD violation	33 programs	2.0	66
26.185(d)(1): Documentation that donor declined to discuss test results	33 programs	2.0	66
26.185(e): Documentation that donor was unavoidably prevented from discussing test results and request to reopen proceeding	33 programs	0.3	10
26.185(f)(1): Record of MRO consultation with HHS lab to determine whether additional testing needed	33 programs	0.5	17
26.185(f)(2): Record of MRO contact with donor regarding medical explanation for test result	33 programs	0.5	17
26.185(h)(1): Record of MRO contact with donor to offer opportunity to provide medical evidence regarding substituted specimen	33 programs	1.0	33
26.185(h)(1): Record that donor presented medical explanation for substituted result	33 programs	1.0	33

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.185(h)(2): Record of MRO notification to licensee that no valid medical explanation presented	33 programs	2.0	66
26.185(h)(3): Record of MRO notification to licensee that valid medical explanation presented	33 programs	1.0	33
26.185(i)(1): Record of MRO contact with donor to offer opportunity to provide medical evidence regarding adulterated specimen	33 programs	1.0	33
26.185(i)(1): Record that donor presented medical explanation for adulterated result	33 programs	1.0	33
26.185(i)(2): Record of MRO notification to licensee that no valid medical explanation presented	33 programs	2.0	66
26.185(i)(3): Record of MRO notification to licensee that valid medical explanation presented	33 programs	1.0	33
26.185(j)(3): Record of MRO notification to licensee where evidence of drug abuse	33 programs	1.0	33
26.185(j)(3): Record of MRO report to licensee that donor has violated FFD policy by use of another individual's prescription medication	33 programs	0.5	17
26.185(k): Record of MRO report to licensee that no FFD policy violation has occurred	33 programs	1.0	33
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	33 programs	1.0	33
26.185(n): Record of MRO report to licensee on result of analysis by second laboratory	33 programs	2.0	66
26.185(o): Record of MRO request for	33 programs	0.5	17

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
quantitation of test results			
26.185(o): Record that lab provided quantitation of test results	33 programs	1.0	33
26.185(p): Record of MRO notice to licensee of determination of FFD policy violation	33 programs	8.0	264
26.187(d): SAE training requirements	33 programs	20.0	660
26.187(f): Documentation of SAE credentials and training	33 programs	1.0	33
26.189(a): Written record of determination of fitness	33 programs	80.2	2,647
26.189(c): Written record of "for cause" determination of fitness	33 programs	35.2	1,162 ¹⁵
26.189(d): Record of modification of an initial determination of fitness	33 programs	1.0	33
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)		
26.205(b): Record of calculation of work hours	30 programs	160.0	4,800
26.205(c): Schedule work hours	30 programs	2,080.0	62,400
26.205(d)(1): Record of implementation of work hour controls	30 programs	50.0	1,500
26.205(d)(2): Record of adequate rest breaks	30 programs	50.0	1,500
26.205(e)(1) and (2): Record of review of control of work hours twice per calendar year	30 programs	40.0	1,200

¹⁵Based on 1,161 for-cause tests in 2005 and 1 hour to prepare record.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.205(e)(3): Document methods for reviews	30 programs	20.0	600
26.205(e)(4): Record and trend problems in regarding work hours	30 programs	20.0	600
26.207(a)(4): Document bases for waiver	3 programs	6.0	18
26.211(f): Document results of fatigue assessments	30 programs	50.0	1,500
26.405(a): Record of random drug and alcohol testing	2 programs	875.0	1,750 ¹⁶
26.405(c)(1): Document pre-assignment testing	2 programs	1,750.0	3,500 ¹⁷
26.405(c)(2) and (c)(3): Document for-cause and post accident testing	2 programs	38.0	76
26.405(c)(4): Document follow up testing	2 programs	190.0	380
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	2 programs	40.0	80
26.405(f): Record that testing conducted at an HHS-certified laboratory	2 programs	40.0	80
26.405(g): Record of MRO review of positive, adulterated, substituted, and invalid drug and validity test results	2 programs	50.0	100
26.406(c): Record of fitness monitoring procedures (programs that do not adopt random testing and behavioral observation)	0 programs	80.0	0
26.411(a): Record of system of files and procedures to protect personal information	2 programs	4.0	8
26.411(a): Collection of personal information	2 programs	1,750.0	3,500 ¹⁸
26.411(b): Record that signed consent forms obtained	2 programs	1.5	3
26.413: Document results of review process	2 programs	80.0	160
26.415: Document and report audit results	2 programs	40.0	80

¹⁶Value based on estimate of 2 construction programs choosing to conduct random testing (rather than fitness monitoring), 1,750 workers per construction site subject to the FFD program, a 100% test rate, and one/half hour of burden per test.

¹⁷Estimate based on one hour per person to document pre-assignment testing for 1,750 workers at the construction site subject to the FFD program.

¹⁸Estimate based on one hour per person to collect personal information for 1,750 workers at the construction site subject to the FFD program.

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.417(a): Retain program records	2 programs	20.0	40
26.713(a)(1): Retain records of self-disclosure	33 programs	80.0	2,640
26.713(a)(2): Retain records on FFD violations	33 programs	80.0	2,640
26.713(a)(3): Retain records of authorization	33 programs	80.0	2,640
26.713(a)(4): Retain records of FFD determinations	33 programs	80.0	2,640
26.713(b)(1): Retain records of FFD training	33 programs	160.0	5,280
26.713(b)(2): Retain records of audits	33 programs	80.0	2,640
26.713(c): Retain records on 5-year authorization denial and permanent denial	33 programs	40.0	1,320
26.713(d): Retain superseded FFD policy	33 programs	80.0	2,640
26.713(e): Retain written agreements for services under Part 26	33 programs	16.0	528
26.713(f): Retain records of background investigations	33 programs	80.0	2,640
26.713(g): Retain documentation regarding additional drugs tested	33 programs	40.0	1,320
26.715(a): Maintain documentation of all aspect of testing process (not otherwise specified in 26.715(b))	33 programs	40.0	1,320
26.715(b)(1): Retain personal files	33 programs	20.0	660
26.715(b)(2): Retain chain-of-custody documents	33 programs	240.0	7,920
26.715(b)(3): Retain quality assurance records	33 programs	120.0	3,960
26.715(b)(4): Retain superseded procedures	33 programs	40.0	1,320
26.715(b)(5): Retain all test data	33 programs	240.0	7,920
26.715(b)(6): Retain test reports	33 programs	240.0	7,920
26.715(b)(7): Retain performance test records	33 programs	80.0	2,640
26.715(b)(8): Retain testing error investigation records	33 programs	40.0	1,320
26.715(b)(9): Retain certification inspection records	33 programs	40.0	1,320
26.715(b)(10): Retain records on preventative maintenance	33 programs	40.0	1,320

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.715(b)(11): Retain records summarizing scientific insufficiency	33 programs	20.0	660
26.715(b)(12): Retain computer-generated data	33 programs	120.0	3,960
26.715(b)(13): Retain records on visitors	33 programs	20.0	660
26.715(b)(14): Retain records on EBT maintenance	33 programs	20.0	660
26.717(a) and (b): Collect FFD performance data	33 programs	200.0	6,600
26.717(c): Analyze FFD data annually	33 programs	80.0	2,640
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
26.719(d): Document non-reportable indicators of FFD program weaknesses	33 programs	20.0	660
26.821(a): Allow NRC to inspect and copy records	33 programs	4.0	132
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	5 C/Vs	4.0	20
Table 2 Total			412,448

**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	33 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	Burden shown under §26.717(e) and (f)				

Section	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Total Burden Hours
information for annual FFD program performance report					
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)	30 programs	1	30	50.0 (Burden in addition to that shown for §26.717)	1,500
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)	30 programs	1	30	6.0 (Burden in addition to that shown for 26.203(e)(1) and 26.717)	180
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	2 programs	1	2	80.0	160
26.717(d): Report termination test results in the annual summary by processing stage	Burden shown under § 26.717(e) and (f). NRC's 2005 FFD program performance data indicates 979 positive test results.				
26.717(e) and (f): Annual report of FFD program performance	33 programs	1	33	150.0	4,950
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	24 programs	1	24	4.0	96

Section	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Total Burden Hours
by phone w/in 24 hrs					
26.719(c)(1): Report results of testing error investigation to NRC w/in 30 days	2 programs	1	2	1.0	2
26.719(c)(2): Notify NRC of false positives on blind performance sample w/in 24 hrs	16 programs	1	16	4.0	64
26.719(c)(3): Notify NRC of false negative on QA check w/in 24 hrs	16 programs	1	16	4.0	64
Table 3 Total			157		7,053

**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	79,005 ¹⁹	1.0	79,005
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 ²⁰	32.0	512
26.35(c): Individuals give written waiver of right to privacy to EAP	56,100 ²¹	0.3	16,830
26.35(c): Record of disclosure by independent EAP to FFD mgmt.	16	1.0	16
26.37(b): Individuals provide MROs with signed consent for release of information	56,100	0.3	16,830
26.37(b)(1): Individuals provide signed designation of personal representative for FFD matters	979	1.0	979
26.37(d): Record that FFD program personnel provided records to individual	979	1.0	979
26.53(h): Individuals provide written consent before any actions are initiated under Subpart C	79,005	0.3	23,702
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		
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		

¹⁹Estimate based on 79,005 pre-access tests from NRC's 2005 FFD program performance data.

²⁰Estimate assumes that 50 percent of 33 EAP programs are non-licensee EAP programs.

²¹Estimate assumes 1,700 employees in 33 programs take the FFD exam.

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.61(a): Individuals prepare written self-disclosure and employment history	79,005	1.0	79,005
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	79,005	0.8	63,204
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	25,000 ²²	0.5	12,500
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	198 ²³	2	396
26.85(c): Alternative collectors not employed by licensee provide proof of qualification	16	1.0	16
26.85(e): Maintain personnel files for non-licensee collection sites	16	4.0	64
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	16	1.0	16
26.89(b)(3): Record that non-licensee collection site informed FFD program management that individual did not present identification	16	1.0	16
26.89(c): Record that non-licensee collection site reported donor's refusal to cooperate in the collection procedures.	16	1.0	16

²²NRC's 2005 FFD program performance data reported approximately 50,000 total random drug tests. Half are estimated to be performed by non-licensee testing facilities with results provided to the licensees.

²³ Each of the 33 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
26.91(e)(4): Record that results cancelled after EBT calibration check failure (non-licensee collection site)	4	1.0	4
26.91(e)(5): Prepare record of EBT maintenance (non-licensee collection site)	16	4.0	64
26.93(a)(6): Document alcohol pre-test questions asked and answered (non-licensee collection site)	28,348 ²⁴	0.3	8,504
26.95(b)(5): Record donor identity for initial alcohol breath test (non-licensee collection site)	28,348	0.3	8,504
26.97(b)(2): Record reason for new oral fluid alcohol test (non-licensee collection site)	283	0.5	142
26.97(c)(1): Document reason for failure of 2 nd collection attempt (non-licensee collection site)	8	1.0	8
26.97(d): Record results and alcohol screening device used (non-licensee collection site)	28,348	0.3	8,504
26.99(b): Record test time of initial test with 0.02% or higher BAC (non-licensee collection site)	142 ²⁵	0.3	43
26.101(b)(7): Indicate time on EBT printout of confirmatory alcohol test result (non-licensee collection site)	142	0.3	43
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	20	0.5	10
26.107(b): Document tampering attempt on c & c form (non-licensee collection site)	2	1.0	2
26.109(b)(3): Record that non-licensee collector notified FFD management or MRO notified of "shy bladder" problem	16	0.5	8
26.109(b)(4): Record that non-licensee collector notified FFD management if observed collection required	16	0.3	5

²⁴Based on 56,696 random, for-cause, follow-up, and other tests from NRC's 2005 FFD program performance data. Half of the donor identities from these tests are estimated to be performed by non-licensee collection sites.

²⁵Based on 284 positive test results from random, for-cause, follow-up, and other tests from NRC's 2005 FFD program performance data. Half of the test times are estimated to be performed by non-licensee collection sites.

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.111(b): Non-licensee collector notes unusual findings on c & c form	16	0.5	8
26.111(c): Record that non-licensee collector notified FFD mgr. of tampering attempts	16	0.4	6
26.113(b)(3): Record of c & c forms for both parts of split urine sample (non-licensee collection site)	284	0.3	85
26.115(b): Record that approval obtained for collection under direct observation from FFD mgr. or MRO (non-licensee collection site)	16	0.3	5
26.115(d): Record of c & c form for directly observed collection (non-licensee collection site)	16	0.3	5
26.115(f)(3): Record of name of observer (non-licensee collection site)	16	0.3	5
26.117(c), (d), and (e): Prepare ID labels and c & c forms for specimen shipment (non-licensee collection site)	28,348	0.3	8,504
26.119(a), (e), and (f): Record that evaluation obtained from MRO or physician evaluating "shy bladder" claim (non-licensee collection site)	16	6.0	96
26.119(b): MRO provides information to physician as background for evaluation of "shy bladder" claim	16	2.0	32
26.129(b): Non-licensee specimen collector prepares memorandum to licensee testing facility personnel documenting investigation of discrepancies between bottles and c & c forms	8	1.0	8
26.135(b): Donor prepares written permission for retest second part of split sample	284	0.5	142
26.137(b)(3): Submit 1 in 10 negative specimens for validity screening to HHS lab	16	40.0	640
26.153(g): Supply memo to HHS labs explaining use of non-federal c & c 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 mgr. documents training of	Burden covered by HHS lab certification		

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
lab personnel		requirements OMB Clearance # 0930-0158	
26.155(a)(4): Lab mgr. reviews and signs lab procedures		Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158	
26.155(a)(5): Lab mgr. 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	
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 c & c forms		Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158	

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.159(f): Use of c & c 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	331	1.0	331
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	331	0.3	99
26.165(b)(3): Written permission by donor for re-test of aliquot or test of Bottle B of split sample	331	1.0	331
26.165(b)(4): Donor presents documentation for reason unable to complete timely retest request	6	1.0	6
26.165(b)(6): HHS lab provides results of re-test of aliquot or test of Bottle B to MRO and to donor	331	0.5	166
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		
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 c & c form, place fictional initials on specimen labels, and indicate blind performance test samples	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
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	979	1.0	979
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 ²⁶	1.0	16
26.169(c)(3): HHS lab record of quantitative test results for adulterated or substituted test results	29 ²⁷	1.0	29
26.169(c)(4): HHS lab record of contact with MRO to discuss whether testing by another HHS lab should be done	26	2.0	52
26.169(f): HHS lab transmits copy of the c & c form for negative results to the MRO	26	8.0	208
26.169(g): HHS lab transmits original of c & c form for positive, adulterated, substituted, dilute or invalid results to the MRO	979	0.5	490
26.169(h): HHS lab prepares and submits annual statistical summary report of urinalysis testing results	26	40.0	1,040
26.183(a): Documentation of MRO qualifications	24 ²⁸	5.0	120
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	Burden covered by §26.185(a)		
26.183(d)(2)(i): Record of MRO staff review and reporting of negative test results	576 ²⁹	0.3	173
26.183(d)(2)(ii): Record of MRO staff review of c & c forms and forward changes to MRO	756 ³⁰	0.1	76

²⁶Estimate based on 16 total positive opiate drug tests listed in NRC's 2005 FFD program performance data.

²⁷Estimate based on 29 adulterated specimens detected as listed in NRC's 2005 FFD program performance data.

²⁸Estimate assumes that 75 percent of 33 programs use MROs who are non-licensee employees.

²⁹Estimate assumes 12 responses processed annually from 2 laboratories for 24 programs.

³⁰NRC's 2005 FFD program performance data reported 979 positive tests and 29 adulterated tests in 2005, for a total of 1,008. Estimate assumes 75 percent of the 1,008 reported positive and adulterated tests are reviewed by MROs who are non-licensee employees.

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
26.185(a) Record of MRO review of all positive, adulterated, substituted, dilute, or invalid test results and report to licensee or other entity	756	1.0	756
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	756	1.0	756
26.185(d)(1): Documentation that donor declined to discuss test results	76	1.0	76
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)		
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	24	1.0	24

Section	Number of Responses	Burden Hours per Response	Total Annual Burden Hours
specimens, and other data to determine if positive, adulterated, substituted, or invalid result is scientifically insufficient for determination of FFD policy violation			
26.185(n): Record of MRO report to licensee on result of analysis by second laboratory	24	1.0	24
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)		
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	241 ³¹	0.5	121
26.189(c): Written record of “for-cause” determination of fitness	77 ³²	1.0	77
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 and validity test results	1	1.0	1
26.411(b): Obtain signed consent form	3,500 ³³	0.3	1,050
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,	5	4.0	20

³¹Based on proportion of 331 random, for-cause, follow-up, and other positive test results from NRC's 2005 FFD program performance data pertaining to all 33 programs, attributable to 24 non-licensure programs.

³² Based on proportion of 106 for-cause positive test results from NRC's 2005 FFD program performance data pertaining to all 33 programs, attributable to 24 non-licensure programs.

³³ Estimate is based on 1,750 employees at 2 programs.

and reports			
Table 4 Total	580,777		337,162

TOTAL PART 26 BURDEN: 871,261 hours (114,598 hours one-time recordkeeping annualized, 412,448 hours annual recordkeeping + 7,053 annual hours reporting + 337,162 hours annual 3rd party burden.)

TOTAL RESPONSES: 580,986 (157 annual reporting responses + 52 recordkeepers + 580,777 third party responses)

NUMBER OF RESPONDENTS: 63,152 (Each FFD program is one respondent, with 28 reactor FFD programs, 2 contractor/vendor FFD programs, 2 fuel cycle facility FFD programs, and 1 mixed-oxide fuel fabrication facility FFD program, for a total of 33 FFD program respondents, plus 19 Subpart K construction FFD program respondents, plus 63,100 third party respondents).³⁴

THIRD PARTY BURDEN: 337,162 hours annual 3rd party burden

³⁴ Third party respondents include an estimated 59,600 individuals subject to FFD requirements at operating nuclear power reactors; 25,000 applicants for employment; 79,000 applicants for access authorization; 56,000 employees providing waivers to FFD programs; varying numbers of employees providing FFD-related information, and during this clearance period 3,500 individuals under Subpart K FFD programs. However, these categories are not mutually exclusive because applicants for employment may become employees, and if employed may apply for access authorization (to the extent possible the FFD and access authorization programs are seeking to combine the background information that they each seek into a single request). If authorized, individuals will be subject to an FFD program and will be required to provide waivers and to provide information to the program. To calculate average burden the estimated number of individuals subject to FFD programs, 63,100 (59,600 + 3,500) is used.

**Table 5
Annualized NRC Burden**

NRC ACTION	No. Actions/Year	Burden Hours/Action	Total Hours
Review exemptions 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)	2	24 hours per review (in addition to burden shown under § 26.717 for review of balance of annual FFD program performance report)	48
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)	2	40 hours per report	80
Review annual program performance reports for FFD at operating nuclear power reactors, C/Vs, and other entities submitted under §26.717(e) and (f)	33	92 hours per report for 28 programs; 44 hours per report for 5 programs that do not include fatigue-related information	2,796
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)		

Review reports by telephone to NRC Operations Center of significant FFD violations required by § 26.719(b)	24	16 hours per review	384
Review reports to NRC of investigations of testing errors by licensee testing facilities or HHS laboratories required by § 26.719(c)(1)	2	16 hours per review	32
Review reports to NRC of false positive errors on blind performance samples required by § 26.719(c)(2)	16	16 hours per review	256
Review reports to NRC Operations Center of false negative errors on QA checks of validity screening tests required by § 26.719(c)(3)	16	16 hours per review	256
Table 5 Total			4,048