SUPPORTING STATEMENT
FOR
10 CFR PART 26, FITNESS-FOR-DUTY PROGRAM,
Proposed 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 Part 26 requirements and standards apply to the following: licensees who are authorized to operate a nuclear power reactor; licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under 10 CFR Part 70; corporations, firms, partnerships, limited liability companies, associations, or other organizations that obtain a certificate of compliance or an approved compliance plan under 10 CFR Part 76, but only if the entity elects to engage in activities involving formula quantities of SSNM; and 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. Certain more limited information collection requirements apply to the following: holders of a combined operating license under 10 CFR Part 52, Subpart C, before the Commission has made the finding under §52.103, combined license applicants who have received authorization to construct under §50.10(e)(3), construction permit holders (under 10 CFR Part 50), construction permit applicants who have received authorization to construct under §50.10(e)(3), and holders of manufacturing licenses (under 10 CFR Part 52).

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 36 FFD programs, as follows: 31 FFD programs for 65 facilities with a total of 103 nuclear power reactors; 2 fuel-cycle facilities; 2 contractor/vendors; and 1 mixed-oxide fuel fabrication facility.

The proposed fatigue management provisions in Subpart I of Part 26 would apply to a smaller group of licensees and other entities, and be implemented through 33 programs (31 FFD programs covering nuclear power reactors and 2 programs covering contractor/vendors, who would be required to implement fatigue management provisions if their personnel provide services to nuclear power reactors in the appropriate job duty groups).

The recordkeeping and reporting requirements in the proposed 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 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 retain records related to employee assistance programs. Records and reports are also required under the proposed new fatigue management component of the FFD program. The recordkeeping and reporting requirements would be mandatory for licensees and

other entities subject to the rule. The NRC would use 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 proposed rule described in this clearance package constitutes a complete revision of Part 26.

The recordkeeping and reporting requirements of Part 26 are largely being centralized into Subpart I - Managing Fatigue (§26.197) and Subpart J - Recordkeeping and Reporting (§§26.211-26.219). Cross references to the recordkeeping and reporting requirements in Subpart J 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 §§26.213, 26.215, 26.217, and 26.219) to facilitate determining the burden impacts when a specific requirement is modified.

The estimated annual burden for the proposed rule of 545,942 hours for one-time recordkeeping (annualized), annual recordkeeping, and annual reporting of the proposed rule exceeds NRC's estimate for the current rule of 61,143 hours (as estimated in the draft clearance renewal published in the Federal Register on May 25, 2005 (70 FR 30148)) by 484,799 hours. Of this, 125,239 hours are for one-time recordkeeping requirements. The increase in burden is explained by several differences between the current rule and the proposed rule. In particular, the proposed rule creates 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 proposed 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 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 proposed 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 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. Finally, the proposed rule contains new fatigue management provisions that include reporting and recordkeeping burdens that were not part of previous estimates.

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, would provide 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, would provide 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) would require 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 would be the primary means by which a licensee or other entity would communicate 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) would require the current FFD policy statement to be readily available to all individuals subject to the policy and would specify 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 will ensure 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) would require 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 would specify 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 will be 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 proving "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) would specify 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) would be established by that section. Recordkeeping requirements for superseded procedures would be established by §26.215(b)(4).

Section 26.29, Training Content

> Paragaraph 26.29(a) would require 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) would require 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) would require 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) would require refresher training to be completed on a nominal 12-month frequency, and would allow individuals who pass a comprehensive annual examination to forgo refresher training.

The recurring burden of providing refresher training, which would include 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) would allow a licensee or other entity to accept the training of individuals who have been subject to another Part 26 program 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 that will be 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. These requirements would require licensees or other entities 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 would be established by §26.213(b)(1).

Section 26.31, Drug and alcohol testing

Paragraph 26.31(a) would require licensees and other entities to implement drug and alcohol testing programs for individuals who are subject to Part 26.

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 J.

Paragraph 26.31(b)(1)(i) would require 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] would be acceptable to meet the requirement. Section 26.31(b)(1)(i) would require the credit and criminal history checks and psychological assessments to be updated nominally every 5 years.

Paragraph 26.31(b)(1)(v) would require 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 would also be 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 would be part of the FFD program procedures required to be developed by §26.27.

Recordkeeping requirements for §26.31(b)(1)(i) would be established by §26.213(f). The proposed rule, by relaxing the current 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, would reduce the number of such records that would be created. However, the retention period for such records is not affected.

Paragraph 26.31(c) would require 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 would take 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 1907.4, 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 J of Part 26.

Paragraph 26.31(d)(1)(i)(A),(B) and (C) would allow 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 would be additions to the FFD procedures required to be developed under §26.27.

Paragraph 26.31(d)(1)(i)(D) would allow 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. 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 would allow licensees and other entities to add to the panel of drugs for which testing is required in proposed §26.31(d)(1). It would eliminate the reporting requirement in current Section 1.1(2) in Appendix A to Part 26 that requires licensees to obtain written approval from the Commission to test for additional drugs. However, the proposed rule would require 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 would be required to maintain a copy of each certification under §26.31(d)(1)(i)(D). Recordkeeping requirements for §26.31(d)(1)(i)(D) would be established by §26.213(g).

Paragraph 26.31(d)(1)(ii) would allow 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 secton 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).

This section would allow licensees and other entities to add to the panel of drugs for which testing is required in proposed §26.31(d)(1). It would ensure 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 would be required to maintain a copy of each certification under §26.31(d)(1)(ii). Recordkeeping requirements for §26.31(d)(1)(ii) would be established by §26.213(g).

Paragraph 26.31(d)(3)(ii) would provide 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) would require 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) would require 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 will be 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 will be made 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 would be 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) would be established by §26.213(g).

Paragraph 26.31(d)(6) would specify 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 for the third-party collection under §26.31(d)(6) would be established by this section.

Section 26.33, Behavioral observation, would require 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 third-party reports of FFD concerns would be prepared under this section. Actions in response to reports of FFD concerns would be taken under §26.31(c)(2) of the proposed rule, 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 §26.201(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 would be maintained as part of the records of for-cause tests under §§26.31 or 26.201.

Recordkeeping requirements, including the third-party burden for the initial behavioral observation reports, for §26.33 would be established by §§26.197(d)(4) or 26.213(a)(2).

Section 26.35, Employee assistance programs

> Paragraph 26.35(a) would require each licensee and other entity subject to Part 26 to maintain an employee assistance program (EAP) to offer confidential assessment, short term counseling, referral services, and treatment monitoring to its employees who have problems that could adversely affect the employees' 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 will form 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) would require 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 would be 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 would be 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 would be reportable under §26.219(b)(1) through (b)(3).

The EAP program will help 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 would be established by this section and by §26.27(a). Recordkeeping requirements for §26.35(c) third-party collections for the written waiver by the individual and the communications between the EAP and FFD program management would be established by this section.

Section 26.37, Protection of information

Paragraph 26.37(a) would require 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) would require 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 in performing assigned duties, 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) would require an individual to designate in writing his or her representative for specified FFD matters.

This third-party collection would be 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) would require 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) would require a 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 third-party 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) would be established by §26.213(a)(3).

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

Paragraph 26.39(a) would require each licensee and other entity subject to Part 26 to establish procedures for the review of a determination that an individual has violated FFD policy.

Paragraph 26.39(b) would require 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 will ensure 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.

Recordkeeping requirements for §§26.39(a) and (b) are established by §26.215(a).

Paragraph 26.39(d) would require 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 third-party 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 will help to ensure that incorrect information does not enter and proliferate throughout this information-sharing network.

Recordkeeping requirements for §26.39(d) are established by 26.213(a)(2).

Section 26.41, Audits and corrective action

Paragraph 26.41(a) would require 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, 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) would require 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) would require 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) would require licensees' contracts 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) would require 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) would allow licensees and other entities to jointly conduct audits or to accept audits conducted by other licensees, but would require 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 will help to ensure that necessary information is available for NRC inspections.

Third-party collection 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) would be established by §26.213(b)(2).

Section 26.55, Initial Authorization

Paragraph 26.55(a)(1) would require 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) would require 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) would be established by §§26.61 and 26.63 and by §§26.213(a)(1) and (a)(3).

Section 26.57, Authorization Update

Paragraph 26.57(a)(1) would require 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) would require 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) would be established by §§26.61 and 26.63 and by §§26.213(a)(1) and (a)(3).

Section 26.59, Authorization Reinstatement

Paragraph 26.59(a)(1) would require 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) would require 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) would provide 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) would require 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), would be captured by §§26.61 and 26.63 and by §§26.213(a)(1) and (a)(3).

Recordkeeping requirements for §26.59(c)(1) would be established by §26.61 and by §§26.213(a)(1) and (a)(3).

Section 26.61, Self-disclosure and employment history

Paragraph 26.61(a) would require 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) would specify 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) would specify 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 would relax the requirements in §§26.55, 26.57, and 26.59 when the specified conditions above would indicate that the self-disclosure and/or employment history are unnecessary and would 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 would be 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) would be established by §26.213(a)(1).

Paragraph 26.61(b) would specify 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) would require 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).

Paragraph 26.61(d) would specify that falsification of the self-disclosure statement or employment history is sufficient cause for denial of authorization.

This requirement is necessary to ensure that the information provided is true, accurate, and complete, and to ensure that the due process rights of individuals who are subject to the rule are protected by informing them with sufficient detail about the consequences of falsification. The requirement also partially meets the legal necessity of proving "prior notice" and having it documented for evidence in legal proceedings. As noted above in the discussion of §26.61(a), FFD programs require individuals to sign a statement included in the self-disclosure statement and employment history that the information provided by the individual is, as far as they are aware, correct.

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

Section 26.63, Suitable inquiry

Paragraph 26.63(a) would require the licensee or other entity to conduct a suitable inquiry 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) would specify 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 Part 26 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) would specify 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 of the proposed rule. 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) would be established by §26.213(a)(1).

Paragraph 26.63(c)(3) would specify 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.

This third-party 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 will also help 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) would be established by §26.213(a)(1).

> Paragraph 26.63(d) would require, 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.

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 will sign a release when first applying for authorization, and the release will be 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) would specify 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) would be specified by §§26.211 and 26.213(a), (b), and (c).

> Paragraph 26.63(f) would specify 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 contain information collections, 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) would provide that a licensee or other entity may reinstate authorization for an individual whose authorization has been interrupted for more than 30 days but less than 365 days, or for less than 30 days, respectively, if the

individual has negative results from alcohol testing and a specimen for drug testing is collected before authorization is reinstated. Paragraphs 26.65(d)(1)(ii) and (e)(2)(iii)(B) would 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) would be established by §26.213(a)(3).

Paragraph 26.65(g) would specify 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 tested individual'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(g) would be specified by §26.213(a)(2).

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

Paragraph 26.69(b) would specify 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 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)(3) would require, 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) would require 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) would require 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) would provide 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.

These requirements are necessary to ensure that the information upon which an authorization decision will be 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.

Recordkeeping requirements for §26.69(b) and (c)(3) would be specified by §26.213(a)(1).

Recordkeeping requirements for §§26.69(c)(4) and (5) and for §26.69(d) would be specified by §26.213(a)(3).

Section 26.75, Sanctions

Paragraphs 26.75(a), (b), (c), (d), (e) and (g) would specify 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) would specify 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, will be implemented through the creation of records of the sanction imposed. This will ensure 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) would be established by §26.213(c).

Paragraph 26.75(h) would specify that a licensee or other entity may not terminate an individual's authorization or take lesser administrative actions against the individual based solely on a positive initial drug test result, other than for marijuana and cocaine, from a testing performed at a licensee 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) would allow a licensee testing facility to inform licensee or entity management of initial, non-negative marijuana or cocaine test results where the specimen appears to be valid. 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) would require 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 would be established by §26.213(a)(2).

Paragraph 26.75(i)(4) would require 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 §§26.213 and 26.215 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 would be established by §26.213(a)(2).

Section 26.77, Management actions regarding possible impairment

Paragraph 26.77(c) would require 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) would be established by §26.219(a).

Section 26.85, Collector qualifications and responsibilities

> Paragraph 26.85(a) would require 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) would require 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 will be 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) would be established by §§26.215(a) and (b)(1).

> Paragraph 26.85(c)(4) would require 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 third-party 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) would be established by §26.215(a).

Section 26.87, Collection Sites

Paragraph 26.87(d)(3) would specify 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) would provide 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) would be established by §26.215(b)(3).

The paperwork burden for the posting required by §§26.87(d)(3) and (f)(1) would be established by those sections.

Paragraph 26.87(f)(3) would require 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) would require the collector to instruct the donor to participate with the collector in completing the chain-of-custody form.

Paragraph 26.87(f)(5) would require 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) would be established by §26.215(b)(2).

Section 26.89, Preparing to collect specimens for testing

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

Paragraph 26.89(b)(1) and (b)(2) would require that individuals show proper identification before testing, and, if they cannot produce acceptable identification the collector must notify FFD program management.

Paragraph 26.89(b)(3) would require 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) would require 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 would be required to report this to FFD management.

Paragraphs 26.89(a), (b)(1), and (b)(2) would create third-party collection requirements. Notice to FFD program management is necessary to ensure that appropriate actions are undertaken under the FFD procedures to determine of authorization of the person should be denied or other management actions taken. Paragraph 26.89(b)(3) would create a third-party collection requirement. Explanation of the testing procedure and obtaining a signed consent-to-test form 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. Paragraph 26.89(c) would create a third-party collection requirement. Informing the donor that the donor must remain present until the collection is complete protects 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 to determine of authorization of the person should be denied or other management actions taken.

The recordkeeping requirements for §§26.89(a), (b), and (c) would be established by §26.215(b)(6).

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

Paragraph 26.91(c)(1) - (3) would provide 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 will help to ensure that information is available for reviews of determination of fitness and legal proceedings, if any, addressing determinations of fitness. This requirement will also help 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) would be established by §26.215(b)(12).

Paragraph 26.91(e)(4) would require 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)(4) would create a third-party collection 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) would be established by §26.215(b)(14).

Section 26.93, Preparing for alcohol testing

> Paragraph 26.93(a)(6) would require 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 third-party collection 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) would be established by §26.215(b)(6).

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

> Paragraph 26.95(b)(5) would require 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) would be established by §26.215(b)(6).

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

> Paragraph 26.97(b)(2) would require 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) would require 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 will help 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) would be established by §26.215(b)(6).

Paragraph 26.97(d) would require 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 will be 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) would be established by 26.215(b)(6).

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

Paragraph 26.99(b) would require 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 proposed §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 proposed §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 proposed §26.101, no more than 30 minutes after the conclusion of the initial test.

Recordkeeping requirements for §26.99(b) would be established by §26.215(b)(6).

Section 26.101, Conducting a confirmatory test for alcohol

Paragraph 26.101(b)(7) would require 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 will 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 §26.101(b)(7) would be established by §26.215(b)(6).

Section 26.103, Determining a confirmed positive test result for alcohol

> Paragraph 26.103(b) would require 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 would inform FFD management and the licensee or other entity would prohibit 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) would be established by §26.215(b)(6).

Section 26.107, Collecting a urine sample

> Paragraph 26.107(b) would require 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 will 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) would be established by §26.215(b)(6).

Section 26.109, Urine specimen quantity

> Paragraph 26.109(b)(3) would require 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) would require 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 would be 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 third-party collection 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) would be established by §26.215(b)(6).

Section 26.111, Checking the validity of the urine specimen

Paragraph 26.111(c) would require 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 will not create a significant additional burden. However, the information provided could be useful to a laboratory conducting testing and would ensure 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(c) would be established by §26.215(b)(2).

Paragraph 26.111(d) would require 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 third-party collection requirement is necessary to ensure that the FFD program manager is informed of the possibility that a donor may have attempted to dilure, 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(d) would be established by §26.215(b)(6).

Section 26.113 Splitting the urine specimen

Paragraph 26.113 (b)(3) would require 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) would be established by §26.215(b)(2).

Section 26.115, Collecting a urine specimen under direct observation

Paragraph 26.115(b) would require 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) would be established by §26.215(a).

Paragraph 26.115(d) would require 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 third-party collection requirement in 25.115(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) would be established by §26.215(b)(2).

Paragraph 26.115(f)(3) would require 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) would be established by §26.215 (b)(2).

Section 26.117, Preparing urine specimens for storage and shipping

Paragraph 26.117(c) would require 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) would require 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) would require 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) would require 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) would be established by §26.215(b)(2).

Section 26.119, Determining "shy" bladder

> Paragraph 26.119(a) would require 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) would require 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) would require 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) would further require 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 will, in part, provide 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 will help 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) would be established by §26.215(b)(6).

Third-party recordkeeping requirements related to providing instructions and making a written determination for §§26.119(a), (b) (e), and (f) would be established by §26.119 itself.

Section 26.125, Licensee testing facility personnel

> Paragraph 26.125(b) would require 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) would require licensee testing facility files to include each individual technician'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; and appropriate data to support determinations of training and competency conducted in accordance with 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 will support 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) would be established by §26.215(a) and (b)(1).

Section 26.127, Procedures

Paragraph 26.127(a) would require 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) would require 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) would require 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 with non-instrumented devices, the facility would also be required to develop, implement, and maintain written standard operating procedures for each device. 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) would require 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) would require licensee testing facilities 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 would be required to maintain documentation that these procedures are followed and that all necessary corrective actions are taken. In addition, all facilities would be 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) would be established by §26.215(a).

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

> Paragraph 26.129(a) would require each licensee testing facility to limit access to secured areas only to specifically authorized individuals whose authorization is documented.

This requirement, which will involve 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) would require 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 would be 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 §26.219(b).

> Paragraph 26.129(d) would require licensee testing facilities's procedures for tracking custody and control of specimens to protect the identity of the donor. The facilities would be 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) would require 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.

Third-party recordkeeping requirements for §26.129(a) would be established by §26.215(b)(13).

Third-party recordkeeping requirements for §26.129(b) would be established by §26.215(b)(3).

Third-party recordkeeping requirements for §26.129(d) would be established by §26.215(b)(2).

Section 26.135, Split Specimens

> Paragraph 26.135(b) would allow, upon a non-negative 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 would provide his or her written permission 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.

Third-party recordkeeping requirements for §26.135(b) would be established by §26.215(b)(6).

Section 26.137, Quality assurance and quality control

> Paragraph 26.137(a) would require 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) would require a licensee testing facility that uses a non-instrumented device for validity screening tests that is not on the Substance Abuse and Mental Health Services Administration (SAMHSA) list of point-of-collection testing devices that are certified for use to document that the device meets the performance testing requirements specified in §26.137(b)(1)(ii)(A) - (C).
>
> Paragraph 26.137(b)(1)(iii) would require a licensing testing facility that has placed a device in service to either verify that the device remains on the SAMHSA-certified list or to conduct 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) would be established by §26.215(b)(3).

Recordkeeping requirements for §26.137(b)(1)(ii) and (iii) would be established by §26.215(b)(7).

> Paragraph 26.137(b)(2) would require licensee testing facilities to test at least 1 non-negative quality control specimen at the beginning of every 8-hour period in which the

facility will perform validity screening tests. If a result is incorrect and is a false negative, the licensee or other entity would be required to notify the NRC.

Paragraph 26.137(b)(3) would require licensee testing facilities to submit at least 1 specimen out of every 10 that test negative using a non-instrumented validity screening device to an HHS-certified laboratory. If results from the HHS-certified laboratory indicate an incorrect result and is a false negative result, the licensee or other entity would be required to notify the NRC.

These requirements are an integral part of the quality control/quality assurance process and protect donors from inaccurate test results as well as providing assurance that specimens of questionable validity are detected. The NRC notifications are necessary because false negative results from a validity screening device could mean that some attempts to subvert the testing process would not be detected. This could in turn result in a individual whose trustworthiness and reliability are questionable being granted or maintaining authorization. Notice to the NRC will ensure that both HHS and other licensees or other entities who also be using the device are notified of the device failure.

Reporting requirements for §26.137(b)(2) and 26.137(b)(3) would be established by §26.219(c)(3).

Paragraph 26.137(e)(8) would require 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) would require 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) would require 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) would be established by §26.215 (b)(3).

Recordkeeping requirements for §26.137(f) would be established by §26.215(b)(8).

Recordkeeping requirements for §26.137(h) would be established by §26.215(b)(5).

Section 26.139, Reporting initial validity and drug test results

Paragraph 26.139(d) would require licensee testing facilities to prepare information for annual reports to the NRC, as required in §26.217.

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 26.217 of the proposed rule would specify the program performance data to be included in the annual report.

Reporting requirements under §26.139(d) would be established by §26.217(b) and (e).

Section 26.153, Using certified laboratories for testing urine specimens

Paragraph 26.153(e) would require 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) would require licensees' and other entities' contracts with HHS-certified laboratories to implement all applicable obligations of Part 26 and would specify minimum requirements.

The third-party recordkeeping of the pre-award inspection and evaluation in the form of documentation of the inspection and evalution 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) would be established by §26.215(b)(9).

Recordkeeping requirements for §26.153(f) would be established by §26.213(e).

Paragraph 26.153(g) would require 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 custody-and-control form.

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 proposed paragraph would be necessary to prevent licensee's and other entity's specimens from being rejected.

Recordkeeping requirements for §26.153(g) would be established by §26.215(b)(2).

Section 26.155, Laboratory personnel

Paragraph 26.155(a)(1) would require 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) would require 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) would require 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) would require 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) would require that each HHS-certified laboratory have at least one certifying scientist to attest to the validity of test results. The paragraph would specify the requirements for the certifying scientist.

Paragraph 26.155(c) would require 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 would specify the requirements for the analysts' supervisor.

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

Paragraph 26.155(f) would require 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) would be established by §26.155(f).

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

Recordkeeping requirements for§26.155(a)(5) would be established by §26.215(b)(3).

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

Section 26.157, Procedures

Paragraph 26.157(a) would require 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) would require 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) would require HHS-certified laboratories 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 with non-instrumented devices, the facility would also be required to develop, implement, and maintain written standard operating procedures for each device.

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

Paragraph 26.157(e) would require 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 would be required to maintain documentation that these procedures are followed and that all necessary corrective actions are taken. In addition, all facilities would be 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) would be captured under HHS OMB control number 0930-0158 .

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

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

Paragraph 26.159(b) would require 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) would require 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) would require 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) would require 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 would be required to sign and complete custody-and-control forms for each specimen or aliquot as they are received.

Paragraph 26.159(f) would require 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) would require 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) would be captured under HHS OMB control number 0930-0158.

Recordkeeping requirements for §26.159(b) would be established by §26.215(b)(3).

Recordkeeping requirements for §26.159(c), (d), (e), (f), and (i) would be established by §26.215(b)(2).

Reporting requirements for reports of tampering to NRC under §26.159(b) would be established by §26.219(b)(3).

Section 26.163, Cutoff levels for drugs and drug metabolites

Paragraph 26.163(a)(2) would specify that if confirmatory validity testing indicates that a specimen is dilute, and if the results of additional analysis using FDA analytical kits indicate that the response is within 50 percent of the cutoff, then the HHS-certified laboratory would be required to inform the licensee's or other entity's MRO, and if requested by the MRO, test the specimen down to the confirmatory assay's limit of detection and report the results of the 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) would be established by §26.215(b)(6).

Section 26.165, Testing split specimens and retesting single specimens

Paragraph 26.165(a)(4) would require the HHS-certified laboratory to report to the MRO if initial and confirmatory test results from the specimen in Bottle A are positive for one

or more drugs or drug metabolites, or if validity testing at the HHS-certified laboratory shows that the specimen has been subject to adulteration, substitution, or other means of subversion. The paragraph also would require the MRO to notify the donor that the donor's specimen yielded a non-negative test result, and that the donor may request that the split specimen in Bottle B be tested by another HHS-certified laboratory. Paragraph 26.165(a)(4) also would provide that the donor, within three business days of being notified by the MRO that the specimen yielded a non-negative test result, may provide permission in writing for the testing of Bottle B.

Paragraph 26.165(a)(6) would require the HHS-certified laboratory that 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 26.165(b) would require the MRO to notify the donor of a single specimen that the donor's specimen yielded a drug-positive, adulterated, or substituted result, and that the donor may request that an aliquot from the single specimen be tested by another HHS-certified laboratory. It would also specify that the donor, within three business days of being notified by the MRO that the specimen yielded a drug-positive, adulterated, or substituted result, may provide permission in writing for the retesting of an aliquot of the specimen.

Paragraph 26.165(c)(4) would require the HHS-certified laboratory that retests the aliquot of the single specimen to provide all results to the other entity's MRO.

Paragraph 26.165(f)(1) would specify that a licensee or other entity may administratively withdraw an individual's authorization on the basis of a first confirmed non-negative 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) would require 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 §§26.213 and 26.215 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) would require 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) would require that the licensee or other entity provide the tested individual with a written statement that the records specified in §§26.213 and 26.215 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) would require 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. 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 non-negative test results or any temporary administrative action. If the original specimen was collected for random, for-cause, or post-event testing, the licensee or other entity shall document only that the test was performed and cancelled.

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(a)(4), (a)(6), and (c)(4) would be established by §26.215(b)(6).

Recordkeeping requirements for third-party collections for notifications to the donor, permissions by the donor, and access to records by the NRC inspectors under §26.165(a)(4), (a)(6), (b), (f)(1), (f)(1)(ii), (f)(1)(iv), and (f)(2) would be established in this section.

Section 26.167, Quality assurance and quality control

Paragraph 26.167(a) would require 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) would require 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 would be established by §26.215(b)(14).

Paragraph 26.167(f) would require each licensee or other entity to submit blind performance test samples to the HHS-certified laboratory. Under §26.167(f)(4) approximately 80 percent of the blind performance test samples must be blank (i.e., certified [by the preparer] to contain no drug).

This third-party collection requirement would involve the use of a simple standard form, and is a standard business practice of laboratories that prepare blind performance test samples.

Paragraph 26.167(g) would require the licensee or other entity to ensure that the HHS-certified laboratory investigates any testing errors or unsatisfactory performance. Paragraph 26.167(g)(1) would require 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 would be required to be documented and reported to appropriate levels of management Paragraph 26.167(g)(3) would require, 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(i) would require 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) would be established by §26.215(b)(7).

Recordkeeping requirements for §26.167(g)(3) would be established by §26.215(b)(8).

Section 26.169, Reporting results

Paragraph 26.169(a) would require 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(d) would require HHS-certified laboratories to contact the MRO by a secure electronic means to determine whether testing by another certified laboratory would be useful in the case of a specimen that has an invalid result to enable a determinatiion to be made about reporting either a positive or an adulterated result for that specimen.

Paragraph 26.169(e) would require HHS-certified laboratories to report all non-negative test results to the MRO.

Paragraph 26.169(f) would require HHS-certified laboratories to report numerical values for all non-negative test results to the MRO when requested by the MRO. This paragraph would also prohibit the MRO from disclosing quantitative test results to the licensee or other entity.

Paragraph 26.169(g) would require HHS-certified laboratories to report quantitative values for opiate test results for morphine or codeine that are greater than to equal to 15,000 ng/mL to the MRO.

Paragraph 26.169(h) would require 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 prohibit transmitting results verbally by telephone.

Paragraph 26.169(i) would require the HHS-certified laboratory, for negative test results, to transmit a computer-generated electronic report and/or a legible image or copy of the completed custody-and-control form to the MRO. For non-negative results, the laboratory would be required to transmit a legible image or copy of the completed custody-and-control form to the MRO.

Paragraph 26.169(j) would require the HHS-certified laboratory, for a specimen that has a non-negative result, to retain the original custody-and-control form and to transmit to the MRO a copy of the original custody-and-control form signed by a certifying scientist.

Paragraph 26.169(k) would require 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 would not be 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 would be required to be sent within 14 calendar days after the end of the one-year period covered by the report. Information that would be required to be included in the summary report is listed in §§26.169(k)(1) - (7).

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 would be 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 §26.215(b)(2), (b)(3), (b)(5), (b)(6), and (b)(8).

Section 26.183, Medical Review Officer

> Paragraph 26.183(a) would establish the required qualifications of the MRO and would require 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 subspeciality 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) would require the MRO to examine alternate causes of a non-negative result, including reviewing records made available by the donor, and documented medical conditions.
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> Paragraph 26.183(d)(1)(ii) would require 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) would allow 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) would require that the staff reviews of non-negative drug 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 third-party 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) would be established by this section or, for MROs no longer employed by the licensee, by §26.215(b)(1).

Recordkeeping requirements for §§26.183(c)(1), (d)(1)(ii), and (d)(2)(i) would be established by §26.213(a)(2).

Section 26.185, Determining a fitness-for-duty violation

Paragraph 26.185(a) would require the MRO to review all non-negative 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) would prohibit the MRO from determining that a non-negative test 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 non-negative result and, before reporting it as a violation, has discussed the result with the donor.

Paragraph 26.185(d) would allow the MRO to determine that a non-negative test result or other occurence is an FFD policy violation without having discussed the test result or other occurrence directly with the donor if the MRO had made and documented contact with the donor and the donor expressly declined the opportunity to discuss the test result or other occurrence that might constitute an FFD policy violation; or 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 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) would allow 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) would require 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) would require the MRO, if additional testing would not be 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) would require 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) would require 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) would require 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) would require 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 would be required to provide creditable medical evidence within 5 business days that he or she produced the adulterated result through normal human physiology.

Paragraph 26.185(i)(2) would require 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) would require 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) would require 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) would require, if the MRO determines that there is a legitimate medical explanation for a positive 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) would provide 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 non-negative 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) would provide that, if a second laboratory reconfirms any drug-positive test results or reconfirms any non-negative 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 non-negative validity test results, the MRO shall report that no FFD policy violation has occurred.

Paragraph 26.185(o) would require 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) would require the MRO to complete the MRO's review of non-negative 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 days of an initial non-negative 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 would be established by §26.213(a)(2).

Section 26.187, Substance Abuse Expert

Paragraph 26.187(d) would require 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) would require 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.

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) would be established by this section, or for SAEs no longer employed by the licensee by §215(b)(1).

Reporting requirements for §26.187(f) would be established by this section.

Section 26.189, Determination of Fitness

> Paragraph 26.189(a) would provide that a determination of fitness, the process whereby it is determined whether there are indications that an individual 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 would be prepared.
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> Paragraph 26.189(c) would provide 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 would be 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" would 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) would provide 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 would be established by §26.213(a)(4).

Section 26.197, General provisions

Paragraph 26.197(a) would require each licensee or other entity subject to Part 26, Subpart I, Managing Fatigue, to establish a policy for the management of fatigue and to incorporate it into the written policy required in §26.27(b).

Paragraph 26.197(b) would require each licensee or other entity subject to Part 26, Subpart I, Managing Fatigue, 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; describe the process for implementing work hour controls; describe the process for conducting fatigue assessments; and describe the sanctions, if any, that the licensee may impose on an individual following a fatigue assessment.

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 would be included in the overall policy and procedures for FFD. Therefore, the burden for the written policy and procedures required under §26.197 is included under §26.27(c) for the overall policy and procedures.

Paragraph 26.197(c) would require 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 26.197(d) would require 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 26.197(d)(1): Records of work hours for individuals subject to the work hour controls in §26.199;
- Paragraph 26.197(d)(2): Documentation of waivers that is required in §26.199(d)(3)(iv), including the basis for granting the waivers.
- Paragraph 26.197(d)(3): Documentation of work hour reviews that is required in §26.199(j)(3);
- Paragraph 26.197(d)(4): Documentation of fatigue assessments that is required in §26.201(f); and
- Paragraph 26.197(d)(5): Documentation of the collective work hours of each job duty group, as calculated in accordance with §26.199(b)(2).

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 26.197(e) would require the following information to be included in the annual FFD program performance report required under §26.217:

- Paragraph 26.197(e)(1): Summaries of the number of instances during the previous calendar year in which the licensee waived any of the work hour controls specified in §26.199(d)(1) and (d)(2) for individuals within each job duty group in §26.199(a). The report must include only those waivers under which work was performed, and each work hour control that was waived in §26.199(d)(1) and (d)(2), including all of the work hour controls that were waived for any single extended work period for which it was necessary to waive more than one work hour control.
- Paragraph 26.197(e)(2): The collective work hours of any job duty group listed in §26.199(a) that exceeded an average of 48 hours per person per week in any averaging period during the previous calendar year in accordance with §26.199(f)(3) and (f)(5). The report must include the dates that defined the averaging period(s) during which the collective work hours exceeded 48 hours per person per week; the job duty group that exceeded the collective work hours limit; the conditions that caused the job duty group collective work hours to exceed the collective work hours limit.

- Paragraph 26.197(e)(3): The number of fatigue assessments conducted during the previous calendar year, the conditions under which the fatigue assessment was conducted; and the management actions, if any, resulting from each fatigue assessment.

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 and events is necessary to permit self-assessments and internal reviews 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 §26.197 would be established by this section.

Reporting requirements for §§26.197(e)(1), (e)(2), and (e)(3) would be established by this section.

Section 26.199, Work hour controls

Paragraph 26.199(b)(2) would require licensees to calculate collective work hours as the average number of work hours worked among each group of individuals who perform the duties listed in paragraph (a) of this section, within an averaging period that may not exceed 13 weeks.

Paragraph 26.199(c) would require licensees to implement work hour controls for individuals to ensure that, except as permitted by the waiver provisions of §26.199(d)(3), 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 26.199(d)(1) would require licensees to implement work hour controls for individuals to ensure that, except as permitted by the waiver provisions in §26.199(d)(3), 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 26.199(d)(2) would require 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 shift turnover. At a minimum, licensees would be 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 accomodate a crew's scheduled transition between work schedules or shifts; a 24-hour break in any 7-day period; and a 48-hour break in any 14 day period, except during the first 14 days of any plant outage if the individual is performing the job duties listed in paragraphs 26.199(a)(1) through (a)(4).

Paragraph 26.199(d)(3) would require a licensee seeking a waiver of the individual work hour controls to demonstrate that an operations shift manager has determined that the waiver is necessary to mitigate or prevent a condition adverse to safety, or a security shift manager has determined that the waiver is necessary to maintain the security of the facility, or a senior-level manager with requisite signature authority has made either determination, and a supervisor who is qualified to direct the work to be performed by the individual has assessed the individual face-to-face and determined that there is a

reasonable assurance that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver will be granted. The licensee would be required to document the basis for an individual waiver of work hour controls, including 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 basis for the determination that the waiver is necessary and that there is a reasonable assurance that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver will be granted, as required by §26.199(d)(3)(i).

Paragraph 26.199(f)(5) would provide that licensees may exceed the collective work hour limits established in §26.199(f) if the licensee has received prior written approval from the NRC of a written request that includes a description of the specific circumstances that require the licensee to exceed the applicable collective work hour limit, the job duty group(s) affected, and the collective work hours limit(s) to be exceeded; a statement of the period of time during which it will be necessary to exceed the collective work hour limits; and a description of the fatigue mitigation strategies that the licensee will implement to ensure that the individuals affected will be fit to safely and competently perform their duties.

Paragraph 26.199(j)(1) and (2) would require licensees to review the control of work hours for individuals who are subject to Part 26, Subpart I within 30 days following the end of every averaging period to assess the effectiveness of the work hour controls and to assess staffing adequacy for all jobs subject to the work hour controls.

Paragraph 26.199(j)(3) would require licensees to document the methods used to conduct the reviews and the results of the reviews.

Paragraph 26.199(j)(4) would require 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 §26.199(b)(2) would be established by §26.197(d)(5).

Recordkeeping requirements for §§26.199(c) and (d)(1) would be established by §26.197(d)(1).

Recordkeeping requirements for §§26.199(d)(2) and (j)(3) would be established by §26.197(d)(3).

Recordkeeping requirements for §§26.199(d)(3) and (f)(5) would be established by §26.197(d)(2).

Recordkeeping requirements for §26.199(j)(4) would be established by this section.

Section 26.201, Fatigue assessments

Paragraph 26.201(f) would require 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.

Recordkeeping requirements for §26.201(f) would be established by §26.197(d)(4).

Section 26.211, General provisions [Recordkeeping and Reporting Requirements]

Paragraph 26.211(a) would provide that each licensee and other entity who is subject to Part 26 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.

Paragraph 26.211(b) would provide that each licensee and entity may store and archive records electronically, provided that the record is 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 this paragraph, this section influences 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.

Section 26.213, Recordkeeping requirements for licensees and other entities

Paragraph 26.213(a)(1) would require 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 26.213(a)(2) would require 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 26.213(a)(3) would require 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 26.213(a)(4) would require the retention of records of any determinations of fitness conducted under §26.189 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 26.213(b)(1) would require 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 26.213(b)(2) would require 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 26.213(c) would require 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 26.213(d) would require that licensees and other entities retain any superseded versions of the written FFD policy and procedures required under §26.27, 26.39, and 26.197(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 26.213(e) would require 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 26.213(f) would require 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 26.213(g) would require 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) and (d)(3)(iii)(C) respectively, for the period of time during which the FFD program follows those practices of 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 proposed 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 26.215, Recordkeeping requirements for collection sites, licensee testing facilities, and laboratories certified by the Department of Health and Human Services

Paragraph 26.215(a) would require 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 or until the completion of all legal proceedings related to the determination of an FFD violation, whichever is later, and would also provide 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 26.215(b) would specify that the records that must be retained pursuant to §26.215(a) include the following:

- Paragraph 26.215(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 26.215(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 approriate summary information has been recorded for program administration purposes);
- Paragraph 26.215(b)(3): Quality assurance and quality control records;
- Paragraph 26.215(b)(4): Superseded procedures;
- Paragraph 26.215(b)(5): All test data (including calibration curves and any calculations used in determining test results);
- Paragraph 26.215(b)(6): Test reports;
- Paragraph 26.215(b)(7): Records pertaining to performance testing;
- Paragraph 26.215(b)(8): Records pertaining to the investigation of testing errors or unsatisfactory performance discovered in 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 26.215(b)(9): Performance records on certification inspections;
- Paragraph 26.215(b)(10): Records of preventative maintenance on licensee testing of facility instruments;
- Paragraph 26.215(b)(11): Records that summarize any negative test results based on scientific insufficiency;
- Paragraph 26.215(b)(12): Printed or electronic copies of computer-generated data;
- Paragraph 26.215(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 26.215(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 proposed rule, in order to improve clarity in the organization of the rule and to respond to requests from stakeholders.

Section 26.217, Fitness-for-duty program performance data

Paragraph 26.217(a) would require licensees and other entities to collect and compile FFD program performance data.

Paragraph 26.217(b) would specify that the FFD program performance data must include the following information:

- Paragraph 26.217(b)(1): The random testing rate;
- Paragraph 26.217(b)(2): Drugs tested for and cutoff levels, including results of tests using lower cutoff levels and tests for drugs not included in the HHS panel;
- Paragraph 26.217(b)(3): Populations tested;
- Paragraph 26.217(b)(4): Number of tests administered and results of those tests sorted by population tested;
- Paragraph 26.217(b)(5): Conditions under which the tests were performed;
- Paragraph 26.217(b)(6): Substances identified;
- Paragraph 26.217(b)(7): Number of subversion attempts by type; and
- Paragraph 26.217(b)(8): Summary of management actions.

Paragraph 26.217(c) would require 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 26.217(d) would require 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 and to include the number of terminations and administrative actions taken against individuals in the reporting period.

Paragraph 26.217(e) would require 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 26.217(f) would permit 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 26.217(g) would specify that each C/V who maintains a licensee-approved drug and alcohol testing program is subject to the reporting requirements of §26.217 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 would be 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 proposed rule would require licensees and other entities to submit program performance data to the NRC every 12 months, rather than every 6 months as required by the current rule, to reduce reporting burden and to make the reporting time consistent with the NRC's need for the information.

Section 26.219, Reporting requirements

Paragraph 26.219(a) would require licensees and entities subject to Part 26 to report significant violations of the FFD policy, significant FFD program failures, and errors in drug and alcohol testing, and to report under §26.219 rather than §73.71.

Paragraph 26.219(b) would require 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 26.219(b)(1): The use, sale, distribution, possession, or presence of illegal drugs, or the consumption or presence of alcohol within a protected area or by an individual while performing duties within the scope of Part 26.
- Paragraph 26.219(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 activities within the scope of Part 26.
- Paragraph 26.219(b)(3): Any intentional act that casts doubt on the integrity of the FFD program; and
- Paragraph 26.219(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 activities within the scope of Part 26 while performing duties under Part 26.

Paragraph 26.219(c)(1) would require 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 blind performance testing at either a licensee testing facility or an HHS-certified laboratory, in the testing of 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 would be required to include a report of the incident and corrective action taken or planned.

Paragraph 26.219(c)(2) would require 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 26.219(c)(3) would require 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 devices required by §26.137(b)(2) and (3).

Paragraph 26.219(d) would require 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 would prohibit the tracking or trending of drug and alcohol test results in a manner that would permit 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 proposed rule would group 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 26.221, Inspections

Paragraph 26.221(a) would require 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 26.221(b) would require 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 §26.221(b) is established by §26.213(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 would 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 would be 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 none of the potential responses are filed electronically, because the licensees and other entities have concluded that they do not wish to do so.

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 would not be duplicated by other Federal information collection requirements and would not be 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 proposed 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 proposed 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) would require 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 would 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(a)(4) and (b) would require written permission from the donor before additional testing may occur if the initial sample had non-negative 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) would require 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(k) would require 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 would provide information from which the NRC can monitor the effectiveness of drug testing activities.

Section 26.185(p) would require an MRO to complete a review of non-negative test results and notify the licensee or other entity's designated representative within 10 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 26.197(d) would require 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 26.211(a) would require 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 would be subject to the rule require access to them in a legal or regulatory proceeding.

Section 26.213(a) would require 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 proposed 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 proposed requirement to retain records until the completion of all related legal proceedings would be added at the suggestion of stakeholders during public meetings. The stakeholders noted that some legal proceedings involving records of the type specified in the proposed paragraph have continued longer than the 5 years that the current rule requires these records to be retained and that adding a requirement to retain the records until all legal proceedings are complete would protect individuals' right to due process under the rule.

Sections 26.213(b)(1) and (b)(2) would require 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 proposed 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 26.213(c) would require 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 would be 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 would ensure that the records of the 5-year and permanent denials are available, should the individual seek authorization from another licensee or other entity.

Section 26.213(d) would require that licensees and other entities retain superseded FFD policies and procedures for at least 5 years or until they would no longer be needed to respond to a legal challenge. The period of time that superseded materials would be retained would be 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 proposed requirement to retain the policy and procedures related to any matter under legal challenge until the matter is resolved would be 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 26.213(e) would require 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 proposed requirement to retain the written agreements for any matter under legal challenge until the matter is resolved would be added to ensure that the materials remain available, should an individual, the NRC, a licensee, or another entity who would be subject to the rule require access to them in a legal or regulatory proceeding.

Section 26.213(f) would require 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 proposed §26.31(b)(1)(ii), 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 would be subject to this rule require access to them in a legal or regulatory proceeding. However, the proposed rule would establish 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 26.213(g) would require 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 proposed §26.31(d)(1)(i) and (d)(3)(iii)(C). The licensee or other entity would be 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 would be subject to this rule require access to them in a legal or regulatory proceeding.

Section 26.215(a) would require 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 would provide 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 proposed requirement would be 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 would be subject to this rule require access to them in a legal or regulatory proceeding.

Section 26.217(c) would require 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 would be subject to this rule require access to them in a legal or regulatory proceeding.

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 (SAMSHA) 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 this clearance package for the complete revision to Part 26 has been published in the Federal Register.

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, 26.115, 26.117, 26.119, 26.165, 26.183, 26.185, 26.189, 26.201, 26.213, and 26.219 would require each licensee or other entity to collect personal information for the purpose of complying with Part 26. Section 26.37(a) of the proposed rule would require 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) would permit 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) would provide 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) would provide 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 pertaininig to the subject individual.

Information identified as proprietary or confidential would be handled in accordance with 10 CFR 2.390 of the NRC regulations.

11. Justification for Sensitive Questions

Sections 26.31, 26.33, 26.35, 26.39, 26.61 through 26.70, 26.75, 26.77, 26.115, 26.117, 26.119, 26.165, 26.183, 26.185, 26.189, 26.201, 26.213, and 26.219 would 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 costs associated with information collection are given in Table 1 for one-time burden, Table 2 for annual recordkeeping burden, and Table 3 for annual reporting burden. Because the proposed rule constitutes a complete revision of Part 26, estimates are included for all sections that affect the information collection requirements. These estimates are based, in part, on discussions with nuclear utility employees, staff of the Nuclear Energy Institute, and on estimates made by NRC personnel who are familiar with the records and reports required by 10 CFR Part 26.

13. Estimates of Other Additional Costs

The quantity of records to be maintained is roughly proportional to the recordkeeping burden (excluding third-party communication requirements that are not specifically recordkeeping) 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 $26,953 (394,976 recordkeeping hours - 66,280 third-party hours = 328,696 recordkeeping hours x $205 per hour x .0004).

Approximately 50 percent of FFD programs, or 18 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 $108,000 (18 x 2 x $3,000).

14. Estimated Annualized Cost to the Federal Government

Table 4 describes the estimated annual cost to the NRC for administration of the reporting and recordkeeping requirements in the proposed Part 26. The cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Change in Burden or Cost

The estimated annual burden of 545,942 hours for one-time recordkeeping (annualized), annual recordkeeping, and annual reporting of the proposed rule exceeds NRC's estimate for

the current rule of 61,143 hours (as estimated in the draft clearance renewal published in the Federal Register on May 25, 2005 (70 FR 30148)) by 484,799 hours. Of this, 125,239 hours are for one-time recordkeeping requirements. Therefore, the proposed burden increase will be reduced by almost 25 percent once the one-time requirements are complete. The proposed 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 current rule to the proposed rule.

The factors that account for the increased estimate are the following: the proposed rule creates 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 proposed 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 proposed 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 proposed 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 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. Finally, the proposed rule contains new fatigue management provisions that include reporting and recordkeeping burdens that were not part of previous estimates.

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 would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

None.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical Methods are not used in this information collection.

Attachments:

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

Table 1
One-Time Recordkeeping Requirements
(Annualized)

Section	Number of Programs	Burden Hours per Recordkeeper (Annualized)	Total Annualized Burden Hours
26.27(a): Prepare FFD policy statement	36 programs	107	3,852
26.27(a): Prepare FFD procedures	36 programs	213	7,668
26.29(a): Prepare FFD training course	36 programs	83	2,988
26.29(b): Prepare FFD exam	36 programs	13.3	478
26.29(b): All current staff take FFD exam	36 programs	269.6	9,706
26.29(b): FFD staff mgmt grade FFD exam	36 programs	269.6	9,706
26.29(c)(1): FFD training for current staff	36 programs	2061.8	74,225
26.37(a): Confirm files and procedures protect personal information	36 programs	2.7	97
26.37(b): Obtain signed consent for release of information	36 programs	127.9	4,568
26.39(a) & (b): Prepare procedure for review of determination of FFD violation	36 programs	13.3	479
26.85(a): Prepare and deliver qualification training for urine collectors	36 programs	5.3	191
26.85(b): Prepare and deliver qualification training for alcohol collectors	36 programs	5.3	191
26.127(a): Prepare procedures for handling specimens at licensee testing facilities	36 programs	13.3	479
26.127(b): Prepare written chain-of-custody procedures for licensee testing facilities	36 programs	13.3	479
26.127(c): Prepare written procedures for assays performed by licensee testing facilities	36 programs	13.3	479
26.127(d): Prepare written procedures for instrument and device setup by licensee testing facilities	36 programs	13.3	479
26.127(e): Prepare written procedures for remedial actions for systems and testing devices at licensee testing facilities	36 programs	13.3	479

Section	Number of Programs	Burden Hours per Recordkeeper (Annualized)	Total Annualized Burden Hours
26.137(a): Develop QA/QC program and procedures for licensee testing facilities	36 programs	13.3	479
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
26.197(a): Prepare fatigue management policy (In addition to § 26.27 burden)	33 programs	13.3	439
26.197(b): Prepare fatigue management procedures (In addition to §26.27 burden)	33 programs	40	1,320
26.197(c): Prepare training on fatigue management.	33 programs	22.7	749
26.199(b): Develop group work hour tracking system	33 programs	133.3*	4,399
26.199(c): Develop individual work scheduling system	33 programs	33.3	1,099
Total			125,239

* Based on Regulatory Analysis estimate of $50,000 to develop revised timekeeping and tracking system.

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.	36 programs	2	72
26.27(c) Update policy & procedures	36 programs	2	72
26.27(d) Provide policy and procedures for NRC review	36 programs	2	72
26.29(b) FFD exams	36 programs	1	36
26.29(c)(2) Refresher FFD training or testing	36 programs	266	9,576
26.29(d) Accept FFD training from other licensees' programs	36 programs	16	576
26.31(b)(1)(i): Background checks for FFD personnel	36 programs	16	576
26.31(d)(1)(i)(D): Analysis and certification for unlisted drugs	9 programs	4	36
26.31(d)(1)(ii): Licensee additions to tested drugs	36 programs	8	288
26.31(d)(3)(iii)(A): Document more stringent cutoff levels	9 programs	8	72
26.31(d)(3)(iii)(C): Evaluation and certification of more stringent cutoff levels	9 programs	8	72
26.31(d)(6): Written permission of donor to conduct another analysis or test with specimen	9 programs	1	9
26.33: Records of behavioral observations	36 programs	400	14,400
26.35(a): Employee assistance program records	36 programs	16	576
26.35(c): Written waiver of right to privacy from individual given to EAP	36 programs	2	72
26.35(c): EAP disclosure to FFD mgmt.	18 programs	1	18
26.37(b)(1): Signed designation of personal representative for FFD matters	36 programs	108	3,888
26.37(c): Disclosure to other licensees	36 programs	99	3,564
26.37(d): Obtain lab results and provide result to individual	36 programs	30	1,080
26.39(a): Maintain procedures for review of determinations of FFD	36 programs	120	4,320

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.39(d): Update records to reflect outcome of review of determination of fitness	36 programs	40	1,440
26.41(a), (b), and (c): Conduct audits	36 programs	Burden shown under §26.41(f)	
26.41(d): Review C/V audit results	36 programs	40	1,440
26.41(f): Document and report audit results	36 programs	40	1,440
26.41(g): Share audit results with mgmt and with other FFD programs	35 programs	44	1,540
26.55(a)(1) & (a)(2): Obtain and review self-disclosure and empl. history and complete suitable inquiry	Burden shown under §§26.61 and 26.63		
26.57(a)(1) & (a)(2): Obtain and review self-disclosure and empl. history and complete suitable inquiry	Burden shown under §§26.61 and 26.63		
26.59(a)(1) & (a)(2): Obtain and review self-disclosure and empl. history and complete suitable inquiry	Burden shown under §§26.61 and 26.63		
26.59(c)(1): Obtain and review self-disclosure	Burden shown under §§26.61		
26.61(a): Written self-disclosure and employment history	36 programs	1,005	36,180
26.63(a) and (e): Suitable inquiry	36 programs	1,580	56,880
26.63(c)(2): Receive and file DD 214	36 programs	7	252
26.63(c)(3): Document refusal to supply employment information	36 programs	5	180
26.63(d) & (e): Obtain and maintain documentation of reinstated authorization from other FFD programs	36 programs	1	36
26.65(d)(1) and (e)(2): Prepare record of reinstatement or administrative withdrawal of authorization	36 programs	177	6,372
26.65(g): Adjust personnel records	36 programs	1	36
26.69(b) and (c)(3): Obtain and review employee records to confirm potentially disqualifying FFD situation resolved	36 programs	75	2,700
26.69(c)(4): Verify drug/alcohol treatment & testing completed	36 programs	3	108
26.69(c)(5): Verify pre-access drug/alcohol testing completed	36 programs	1	36

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.69(d): Verify reviewing officer's review completed	36 programs	24	864
26.75(a), (b), (c), (d), (e), and (g): Record of sanctions for FFD violation	36 programs	12	432
26.75(h):Record additional evidence indicating impairment	36 programs	18	648
26.75(i): Inform licensee of non-negative initial test result	36 programs	80	2880
26.75(i)(3) & (i)(4): Eliminate references to temporary administrative action and provide written statement that records expunged	36 programs	1	36
26.85(a), (b), & (c): Training collectors	36 programs	4	144
26.85(c)(4): Written instructions for alternate collectors	36 programs	16	576
26.87(d)(3) and (f)(1): Signage/security at test site	12 programs	0.3	4
26.87(f)(3) and (f)(5): Prepare custody-and-control form	12 programs	0.5	6
26.89(a): Report absence of donor	36 programs	1	36
26.89(b): Obtain ID and consent form or report failure to FFD mgmt.	36 programs	1.5	54
26.89(c): Report premature departure	36 programs	3	108
26.91(c)(1), (c)(2), and (c)(3): Record of EBT test results	Burden shown under §26.215(b)(12)		
26.91(e)(4): Prepare record of EBT maintenance	36 programs	6	216
26.93(a)(5) & (6): Document alcohol pre-test questions asked and answered	36 programs	296.	10,656
26.95(b)(5): Record donor identity for initial alcohol breath test	36 programs	296	10,656
26.97(b)(2): Record reason for new oral fluid alcohol test	36 programs	5	180
26.97(c)(1): Document reason for failure of 2nd collection attempt	36 programs	2.5	90
26.97(d): Record results and alcohol screening device used	36 programs	62	2,232
26.99(b): Record test time of initial test with 0.02% or higher BAC	36 programs	15.7	565

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.101(b)(7): Indicate time on EBT printout of alcohol test result	36 programs	15.7	565
26.103(b): Inform FFD mgmt of result between 0.01 and 0.02 when donor in work status 3 or more hours	36 programs	0.3	11
26.107(b): Document tampering attempt on c & c form	36 programs	1.3	47
26.109(b)(3): Notify FFD mgt.or MRO of “shy bladder” problem	36 programs	0.5	18
26.109(b)(4): Notify FFD mgmt. if observed collection required	36 programs	0.3	11
26.111(c): Note unusual findings on c & c form	36 programs	1.3	47
26.111(d):Report tampering attempts to FFD mgr.	36 programs	0.3	11
26.113(b)(3): Prepare c & c forms for both parts of split sample	36 programs	0.3	11
26.115(b): Obtain approval for collection under direct observation from FFD mgr. or MRO	36 programs	0.5	18
26.115(d): Prepare c & c form for directly observed collection	36 programs	0.3	11
26.115(f)(3): Record name of observer	36 programs	0.3	11
26.117(c), (d) & (e): Prepare ID labels and c & c forms for specimen shipment	36 programs	60	2,160
26.119(a), (e), & (f): Obtain evaluation from MRO or physician evaluating “shy bladder” claim	36 programs	5.5	198
26.119(b): MRO provides information to physician as background for evaluation of “shy bladder” claim	36 programs	2	72
26.125(b) & (c): Proficienty and qualifications records of testing facility personnel	36 programs	15	540
26.127(a): Procedures for handling specimens by licensee testing facilities	36 programs	40	1,440
26.127(b): Written chain-of-custody procedures for licensee testing facilities	36 programs	40	1,440
26.127(c): Written procedures for assays performed by licensee testing facilities	36 programs	40	1,440

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.127(d): Written procedures for instrument and device setup by licensee testing facilities	36 programs	40	1,440
26.127(e): Written procedures for remedial actions for systems and testing devices at licensee testing facilities	36 programs	40	1,440
26.129(a): Limit access to testing site	36 programs	2.5	90
26.129(b): Report to senior mgmt. attempts to tamper with specimens in transit	36 programs	1	36
26.129(d): Procedures for tracking c & c of specimens	36 programs	95	3,420
26.135(b): Donor's written permission for retest second part of split sample	36 programs	2	72
26.137(a): Maintain QA/QC program and procedures for licensee testing facility	36 programs	4	144
26.137(b)(1)(ii): Document performance of testing device not on SAMSHA list	2 programs	40	80
26.137(b)(1)(iii): Document results of annual test of device on on SAMSHA list	2 programs	20	40
26.137(e)(8): Document procedures to protect against carryover material	36 programs	2	72
26.137(f): Record finding of testing errors	36 programs	24	864
26.137(h): Label standards and controls	36 programs	65	2,340
26.139(d): Prepare information for FFD annual report on activities of licensee testing facility	36 programs	40	1,440
26.153(e): Inspect HHS-certified labs	36 programs	40	1,440
26.153(f): Include specified requirements in contracts with HHS labs	36 programs	40	1,440
26.153(g): Supply memo to HHS labs explaining use of non-federal c & c form	36 programs	0.5	18
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 lab personnel	Burden covered by HHS lab certification 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		

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
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 attests to validity of 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 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(b): Report evidence of tampering with specimens in transit to FFD program mgr. of licensee or other entity	36 programs	1	36
26.159(c), (d) and (e): Use and storage of c & c forms	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
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		

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.159(i): Obtain written authorization to store specimens other than 1 year	36 programs	0.5	18
26.163(a)(2): Inform licensee of dilute specimen and obtain MRO approval to test to limit of detection	36 programs	3	108
26.165(a)(4): Inform MRO when non-negative test result obtained	36 programs	6	216
26.165(a)(4): MRO informs donor of opportunity for test of Bottle B of split sample	36 programs	3	108
26.165(a)(4): Donor gives written permission for test of Bottle B of split sample	361 donors	1	361
26.165(a)(6): Provide results of test of Bottle B to MRO and to donor	36 programs	6	216
26.165(b): MRO informs donor of opportunity for retest of aliquot	36 programs	3	108
26.165(b): Donor gives written permission for retest of aliquot	361 donors	1	361
26.165(c)(4): HHS lab provides retest results to MRO	36 programs	8	288
26.165(f): Adjustments to personnel files and written notifications regarding test results, including temporary administrative actiion	36 programs	6	216
26.165(f)(1)(iv) and (f)(2): Written notice that records purged of references to temporary administrative action	36 programs	8	288
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): Preparer certifies contents of blind performance test samples submitted to HHS lab	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.167(g)(3): Certification by HHS lab that retesting requested by licensee or other entity has occurred	26 laboratories	1	26
26.167(i): Labeling of standards and controls	Burden covered by HHS lab certification requirements OMB Clearance # 0930-0158		
26.169(a): Reports of test results by HHS lab	Burden covered under §§26.169(e), (f), and (g)		
26.169(d): HHS contact with MRO to discuss whether testing by another HHS lab should be done	26 laboratories	2	52
26.169(e) & (f): HHS lab reports non-negative test results to the MRO	26 laboratories	350	9,100
26.169(g): HHS lab reports quantitative test results for opiates to MRO	1 laboratory	1	1
26.169(i): HHS lab transmits copy of the c & c form for negative results to the MRO	26 laboratories	0.25	7
26.169(j): HHS lab transmits original of c & c form for non-negative results to the MRO	26 laboratories	100	2,600
26.169(k): HHS lab prepares and submits annual statistical summary report of urinalysis testing results	26 laboratories	40	1,040
26.183(a): Documentation of MRO qualifications	36 programs	3.5	126
26.183(c)(1): MRO review of records for non-negative results	36 programs	24	864
26.183(d)(1)(ii): MRO report of drug test results to licensee's designated reviewing official	36 programs	24	864
26.183(d)(2)(i): MRO staff review and reporting of negative test results	36 programs	12	432
26.183(d)(2)(ii): MRO staff review c & c forms and forward changes to MRO	36 programs	12	432
26.185(a) MRO review of all non-negative test results and report to licensee or other entity	36 programs	50	1,800
26.185(c): MRO discussion of test results with the donor	36 programs	2	72
26.185(c): MRO report to licensee, following discussion with donor, of FFD violation	36 programs	2	72

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.185(d): Documentation that donor declined to discuss test results	36 programs	2	72
26.185(e): Documentation that donor was unavoidably prevented from discussing test results and request to reopen proceeding	36 programs	0.3	11
26.185(f)(1): MRO consultation with HHS lab to determine whether additional testing needed	36 programs	0.5	18
26.185(f)(2): MRO contact with donor regarding medical explanation for test result	36 programs	0.5	18
26.185(h)(1): MRO contact with donor to offer opportunity to provide medical evidence regarding substituted specimen	36 programs	1	36
26.185(h)(1): Donor presents medical explanation for substituted result	36 programs	1	36
26.185(h)(2): MRO notification to licensee that no valid medical explanation presented	36 programs	2	72
26.185(h)(3): MRO notification to licensee that valid medical explanation presented	36 programs	1	36
26.185(i)(1): MRO contact with donor to offer opportunity to provide medical evidence regarding adulterated specimen	36 programs	1	36
26.185(i)(1): Donor presents medical explanation for adulterated result	36 programs	1	36
26.185(i)(2): MRO notification to licensee that no valid medical explanation presented	36 programs	2	72
26.185(i)(3): MRO notification to licensee that valid medical explanation presented	36 programs	1	36
26.185(j)(3): MRO notification to licensee where evidence of drug abuse	36 programs	1	36
26.185(j)(3): MRO report to licensee that donor has violated FFD policy by use of another individual's prescription medication	36 programs	0.5	18
26.185(k): MRO report to licensee that no FFD policy violation has occurred	36 programs	1	36
26.185(m): MRO review of inspection and audit reports, quality control data, multiple specimens, and other data to determine if non-negative result is scientifically insufficient for determination of FFD policy violation	36 programs	1	36

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.185(n): MRO report to licensee on result of analysis by second laboratory	36 programs	2	72
26.185(o): MRO request for quantitation of test results	36 programs	0.5	18
26.185(o): Lab provides quantitation of test results	36 programs	1	36
26.185(p): MRO notice to licensee of determination of FFD policy violation	36 programs	8	288
26.187(d): SAE training requirements	36 programs	20	720
26.187(f): Documentation of SAE credentials and training	36 programs	1	36
26.189(a): Written record of determination of fitness	36 programs	68	2,448
26.189(c): Written record of "for cause" determination of fitness	36 programs	12	432
26.189(d): Modification of an initial determination of fitness	36 programs	1	36
26.197(d)(1): Records of work hours	Burden shown under §26.199(c), (d)(1), and (j)(4)		
26.197(d)(2): Documentation of waivers	Burden shown under §26.199(d)(3) and (f)(5)		
26.197(d)(3): Documentation of work hours	Burden shown under §26.199(d)(2) and (j)(3)		
26.197(d)(4): Documentation of fatigue assessment	Burden shown under §26.201(f)		
26.197(d)(5): Documentation of collective work hours	Burden shown under §26.199(b)(2)		
26.199(b)(2): Calculate collective work hours	33 programs	160	5,280
26.199(c): Schedule work hours	33 programs	2,080	68,640
26.199(d)(1): Implement work hour controls	33 programs	50	1,650
26.199(d)(2): Ensure adequate rest breaks	33 programs	50	1,650
26.199(d)(3): Document bases for waiver	3 programs	6	18
26.199(f)(5): Written approval from NRC for exceeding collective work hours	3 programs	6	18
26.199(j)(1) and (2): Review of control of work hours after each averaging period	33 programs	40	1,320
26.199(j)(3): Document methods for reviews	33 programs	20	660
26.199(j)(4): Record and trend problems regarding work hours	33 programs	20	660

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.201(f): Document results of fatigue assessments	33 programs	50	1,650
26.213(a)(1): Retain records of self-disclosure	36 programs	80	2,880
26.213(a)(2): Retain records on FFD violations	36 programs	80	2,880
26.213(a)(3): Retain records of authorization	36 programs	80	2,880
26.213(a)(4): Retain records of FFD determinations	36 programs	80	2,880
26.213(b)(1): Retain records of FFD training	36 programs	160	5,760
26.213(b)(2): Retain records of audits	36 programs	80	2,880
26.213(c): Retain records on 5-year authorization denial	36 programs	40	1,440
26.213(d): Retain superseded FFD policy	36 programs	80	2,880
26.213(e): Retain written agreements for services under Part 26	36 programs	16	576
26.213(f): Retain records of background investigations	36 programs	80	2,880
26.213(g): Retain documentation regarding additional drugs tested	36 programs	40	1,440
26.215(a): Maintain documentation of all aspect of testing process (not otherwise specified in 26.215(b))	36 programs	40	1,440
26.215(b)(1): Retain personal files	36 programs	20	720
26.215(b)(2): Retain chain-of-custody documents	36 programs	240	8,640
26.215(b)(3): Retain quality assurance records	36 programs	120	4,320
26.215(b)(4): Retain superseded procedures	36 programs	40	1,440
26.215(b)(5): Retain all test data	36 programs	240	8,640
26.215(b)(6): Retain test reports	36 programs	240	8,640
26.215(b)(7): Retain performance test records	36 programs	80	2,880
26.215(b)(8): Retain testing error investigation records	36 programs	40	1,440
26.215(b)(9): Retain certification inspection records	36 programs	40	1,440

Section	Number of Recordkeepers	Burden Hours per Recordkeeper	Total Annual Burden Hours
26.215(b)(10): Retain records on preventative maintenance	36 programs	40	1,440
26.215(b)(11): Retain records summarizing scientific insufficiency	36 programs	20	720
26.215(b)(12): Retain computer-generated data	36 programs	120	4,320
26.215(b)(13): Retain records on visitors	36 programs	20	720
26.215(b)(14): Retain records on EBT maintenance	36 programs	20	720
26.217(a) & (b): Collect FFD performance data	36 programs	200	7,200
26.217(c): Analyze FFD data annually	36 programs	80	2,880
26.217(d): Test results leading to termination	2 C/Vs	1	2
26.217(g): Sharing of required FFD information 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	240
26.219(d): Document non-reportable indicators of FFD program weaknesses	36 programs	20	720
26.221(a): Allow NRC to inspect and copy records	31 reactor programs	4	124
26.221(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	20
26.221(b): Allow NRC to inspect and copy records	5 C/V programs	4	20
Total			**394,976**

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	32
26.77(c) Report FFD-impaired NRC employee	36 programs	None	None	1	None
26.137(b)(2): Report incorrect false negative QC test result	Burden shown under §26.219(c)(3)				
26.137(b)(3): Report incorrect false negative QC lab result	Burden shown under §26.219(c)(3)				
26.139(d): Prepare information for annual report	Burden shown under §26.217(c)				
26.187(f): Provide SAE quals documentation to NRC	1 program	1	1	1	1
26.197(e)(1): Report work hour controls waivers to NRC	33 programs	1	33	3	99
26.197(e)(2): Report group work hours over limit to NRC	33 programs	1	33	2	66
26.197(e)(3): Report number of fatigue assess. to NRC	33 programs	1	33	14	462
26.217(e) and (f): Annual report of FFD program performance	36 programs	1	36	120	4,320
26.219(a): Reports of signif. FFD violations, program failurs, and errors in testing	Burden reported under 26.219(b) and (c)				
26.219(b): Report signif. FFD violations by phone w/in 24 hrs	36 programs	1	36	2.25	81
26.219(c)(1): Report results of testing error investigation to NRC w/in 30 days	2 programs	1	2	1	2

Section	Number of Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Total Burden Hours
26.219(c)(2): Notify NRC of false pos. on blind performance sample w/in 24 hrs	36 programs	142	5112	4	20,448
26.219(c)(3): Notify NRC of false neg. on QA check w/in 24 hrs	36 programs	6	216	1	216
Total			**5,504**		**25,727**

TOTAL PART 26 BURDEN: 545,942 hours (125,239 hours one-time recordkeeping annualized, 394,976 hours recordkeeping + 25,727 hours reporting)
TOTAL RESPONSES: 5,540 (5,504 responses + 36 recordkeepers)
NUMBER OF RESPONDENTS: 36 (31 reactor programs, 2 contractor/vendors, 2 fuel cycle facilities, and 1 mixed-oxide fuel fabrication facility)

Table 4
Annualized NRC Burden

NRC ACTION	No. Actions/Year	Burden Hours/Action	Total Hours
Review exemptions requests under §26.9	1	16 hours per review.	16
Review written FFD policies and procedures under §26.27(d)	12	8 hours. Reviews performed during periodic inspections.	96
Review records under §26.75(h) to ensure no inappropriate records are maintained	1	4 hours/review	4
Review reports under §26.77(c) that NRC employee or contractor is unfit for duty	0	No reports anticipated.	--
Review waiver requests submitted under §26.197(e).	2/yr	8 hours/request	16
Review annual reports submitted under §26.217	36	92 hours per report for 31 programs; 44 hours per report for 5 programs that do not include fatigue-related information	3,072
Review reports under §26.219 of significant violations of FFD policy, FFD program failures, and errors in testing	24	3 hours per report	72
Total			**3,276**