SUPPORTING STATEMENT1 FOR INFORMATION COLLECTIONS CONTAINED IN THE RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR ADVANCED REACTORS FINAL RULE

10 CFR PART 26
FITNESS-FOR-DUTY PROGRAMS

3150-0146

REVISION

DESCRIPTION OF INFORMATION COLLECTION

The U.S. Nuclear Regulatory Commission (NRC) is establishing an optional technology-inclusive regulatory framework for use by applicants for new commercial nuclear plant designs. The regulatory requirements developed in this rulemaking use methods of evaluation, including risk-informed and performance-based methods, that are flexible and practicable for application to a variety of new reactor technologies. The NRC's goals in amending these regulations are to continue to provide reasonable assurance of adequate protection of public health and safety and the common defense and security at sites at which new nuclear designs are deployed to at least the same degree of protection as required for current-generation light-water reactors; protect health and minimize danger to life or property to at least the same degree of protection as required for current-generation light-water reactors; provide greater operational flexibilities where supported by enhanced margins of safety that may be provided in new nuclear designs; and promote regulatory stability, predictability, and clarity.

The final rule covers a wide range of topics, including the following that result in recordkeeping and reporting requirements:

- Fitness for duty (FFD),
- Physical security,
- Cybersecurity,
- Access authorization,
- Plant design and analysis,
- Siting,
- Construction and manufacturing,
- Facility operations,
- Programs,
- Staffing,
- Decommissioning,
- Applications,
- Licensing basis information, and
- Quality assurance.

This supporting statement includes burden associated with information collection changes to 10 CFR Part 26 (3150-0146) (in particular, information collections associated with Subpart M to 10 CFR Part 26). The information collection changes to Part 26 associated with this final rule were submitted as a new clearance at the proposed rule stage, due to other submissions under this clearance number (3150-0273). Because the clearance number is available for submission

at the final rule stage, the information collections are being submitted under 3150-0146 for the final rule.

The rulemaking provides a tiered approach to FFD in Subpart M of Part 26 as an alternative to compliance with the FFD program requirements for facilities licensed under Parts 50, “Domestic Licensing of Production and Utilization Facilities,” and 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” In addition, the revisions to Part 26 introduce new technology-inclusive requirements (that were principally developed from existing FFD program requirements) in Subpart M.

This supporting statement describes how the final rule is establishes information collections in Subpart M to 10 CFR Part 26 (3150-0146) for facilities complying with this Subpart.

Affected Entities

For the purposes of this supporting statement, the NRC staff estimates that there will be five licensees during the three-year period covered by this clearance (2027-2029). During this period, the NRC staff assumes that of these five licensees, four will prepare and submit application materials for a construction permit and operating license and one will prepare and submit application materials for a combined license during the clearance period. In addition, there will be one applicant that will prepare and submit application materials for a combined license during the clearance period, but will not have a license issued during the clearance period. For the purposes of this supporting statement, the NRC assumes that all licensees and applicants during the clearance period will use Subpart M to 10 CFR Part 26.

Information Collections

This supporting statement covers recordkeeping, reporting, and third-party disclosure requirements that apply to the following types of information collections. A more detailed description of each provision is provided at the end of this supporting statement in “Description of Information Collection Requirements.”

- *Information documenting the policy for the management of fatigue.* Licensees and other entities are required to implement a policy for the management of fatigue for all individuals who are subject to the licensee’s or other entity’s FFD program.
- *Records on work hour controls.* Licensees and other entities are required to keep records of work hours, shift schedules, shift cycles, times and dates of all averaging periods, waivers and bases for granting waivers, work hour reviews, and fatigue assessments.
- *Reports on FFD program performance.* Licensees and other entities are required to submit annual FFD program performance reports and reports within 24 hours after the licensee or other entity discovers any intentional act that casts doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals who are subject to this subpart. Licensees and other entities are also required to submit reports on drug and alcohol testing errors.
- *Information about the FFD program to be submitted with the Final Safety Analysis Report.* Applicants are required to summarize the analysis that demonstrates compliance with 10 CFR 73.100(a)(1)(i) (if applicable), the applicability of the FFD program to individuals, the type of FFD program that will be implemented, its processes for drug and alcohol testing and fitness determinations, and sanctions.

- *Information describing changes.* Licensees and other entities are required to keep documentation that describes and analyzes changes made to the FFD program to ensure that such changes do not reduce the effectiveness of the FFD program.
- *Written policy statement.* Licensees and other entities are required to distribute a copy of the written policy statement to each individual subject to the FFD program before the individual is subject to drug and alcohol testing.
- *Written procedures.* Licensees and other entities are required to document procedures related to drug and alcohol testing, actions taken when individuals violate FFD policy or demonstrate they are not trustworthy and reliable, the process followed if behavior of an individual raises concern, operation and oversight of a collection facility, fatigue management requirements, and measures to prevent the subversion of drug and alcohol tests. If a licensee or other entity elects to use the information in an HHS Guideline, then that information must be included in the licensee's or other entity's procedures.
- *Records related to drug and alcohol testing.* Licensees and other entities are required to maintain records related to drug and alcohol testing. These records include: the processes and procedures for collecting, storing, and testing of biological specimens for drug and alcohol testing; drug and alcohol detection instrumentation and FFD program change warranting a forensic toxicologist review; and custody-and-control forms for biological specimens that are collected (excluding specimens collected and tested in instrumentation that passively collects, analyzes, and provides results).
- *Records related to the FFD training program.* Licensees and other entities are required to conduct periodic training on the FFD policy, procedures, and program responsibilities, which include content on fatigue management and behavioral observation. Individuals who collect specimens also need to be trained in specimen collector duties and responsibilities.
- *Information related to the behavioral observation program.* Licensees and other entities are required to maintain information gathered from behavioral observation that indicates a potential FFD policy violation.
- *Records of consent.* Licensees and other entities are required to prepare documentation of individuals' consent to be subject to the FFD program and authorization for the disclosure of information collected and maintained through the implementation of the FFD program.
- *Records related to appeals of FFD policy violations.* Licensees and other entities are required to document their procedures for an objective and impartial review of the facts leading to a determination that an individual violated the FFD policy and a schedule for the completion of the review.
- *Records related to the FFD program.* Licensees and other entities are required to collect FFD performance data and maintain records pertaining to the FFD program administration and FFD performance data required by existing 10 CFR 26.717 of the FFD program.
- *Records related to fitness determinations.* Licensees and other entities are required to document procedures for making suitability or fitness determinations to ensure that individuals are fit to perform the duties that make them subject to the FFD policy and maintain records that demonstrate the individual is fit for duty.

To satisfy the requirements of Subpart M, licensees are required to use unexpired NRC-provided forms to electronically report information required under 10 CFR 26.617(b)(2) and existing 10 CFR 26.717 for FFD and alcohol testing programs. A supporting statement describing the information collection requirements for the following forms, which may be used for these reports, will be submitted for approval under a new clearance (3150-0272):

- NRC Form 893, Single Positive Test Form, 10 CFR Part 26, Subpart M FFD Program, and
- NRC Form 894, Annual Reporting Form, 10 CFR Part 26, Subpart M FFD Program.

In addition, NRC Form 892, "Annual Fatigue Reporting Form," is available for licensees and other entities to annually report the information required under 10 CFR 26.202(e).

A. JUSTIFICATION

1. Need for the Collection of Information

The information collections contained in Subpart M of Part 26 requirements enable effective and efficient regulatory oversight of affected licensees and other entities through inspection and the assessment of FFD program performance to maintain public health and safety, promote the common defense and security, and to protect the environment. The NRC will use these information collections to assess licensee and other entity compliance with Part 26 through periodic NRC inspections, and to take corrective actions, as needed. The NRC also will use these information collections to evaluate the effectiveness of the regulations and to take additional actions, as needed, such as issuing guidance or amending Part 26 through rulemaking. The information collections also enable NRC to inspect the due process protections (e.g., appeals) that licensees and other entities are required to provide to each individual subject to an FFD program.

2. Agency Use and Practical Utility of Information

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

- To monitor licensee and other entity compliance with Part 26 requirements to ensure that each FFD program is adequate to protect public health and safety, promote the common defense and security, and protect the environment;
- To be informed of FFD-related performance issues in order to evaluate the need to implement timely regulatory actions to restore compliance, verify corrective actions, implement licensing actions, conduct public outreach, and/or inspect NRC-licensed activities;
- To evaluate the performance of drug and alcohol testing programs through the collection and analysis of annual program performance information to identify trends, lessons learned, and site-specific or industry-wide issues requiring NRC licensing or inspection response, generic communication, or rulemaking; and,
- To ensure that licensees and other entities can demonstrate compliance with the regulatory requirements for establishing and implementing a fatigue management program, through the collection and analysis of waivers from work-hour controls issued by the licensee or other entity.

3. Reduction of Burden Through Information Technology

The NRC has issued *Guidance for Electronic Submissions to the NRC*, which provides direction for the electronic transmission and submittal of documents to the NRC. Electronic transmission and submittal of documents can be accomplished via the following avenues: the Electronic Information Exchange (EIE) process, which is available from the NRC's "Electronic Submittals" Web page, by Optical Storage Media (OSM) (e.g. CD-ROM, DVD), by facsimile or by e-mail. The Electronic Submissions System ensures that information sent to the NRC is secure and unaltered during transmission. It operates 24 hours a day, except when it is taken down for scheduled maintenance. The application serves as a secure portal that respondents may use to transmit documents to the NRC. NRC staff estimates that approximately 99 percent of the potential responses to Part 26 are filed electronically.

The final rule does not impact the proportion of documents submitted to the NRC electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements.

5. Effort to Reduce Small Business Burden

The NRC is currently not aware of any known small entities as defined in 10 CFR 2.810 that are planning to apply for a commercial nuclear plant early site permit, construction permit, operating license, manufacturing license, or combined license under Part 53 that will be impacted by this final rule.

6. Consequences to Federal Program or Policy Activities if the Collection Is Not Conducted or Is Conducted Less Frequently

If the records and reports required by the final requirements in Part 26 are not collected or collected less frequently, then the NRC cannot adequately:

- independently monitor licensee and other entity compliance and ensure that each FFD program adequately protects public health and safety, promotes the common defense and security, and protects the environment;
- verify the scientific accuracy and validity of test results and ensure that the rights of individuals subject to testing are protected;
- complete a timely evaluation of FFD-related performance deficiencies and implement regulatory actions to restore compliance, assess corrective actions, inform the public, and propose changes to regulations or guidance, if necessary; and
- in a timely manner, inform the public and the licensees and other entities subject to Part 26 of FFD program performance trends, lessons learned, and site-specific or industry-wide issues.

7. Circumstances which Justify Variations from OMB Guidelines

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

- 10 CFR 26.617(b)(1) requires licensees and other entities that implement FFD programs under Subpart M to report to the NRC Operations Center by telephone within 24 hours of discovering any intentional act that casts doubt on the integrity of the program and any programmatic failure, degradation, or discovered vulnerability of the program that may permit undetected drug or alcohol use or abuse by individuals subject to testing. This requirement ensures that, in part, the NRC is timely informed so that appropriate regulatory actions can be initiated, as necessary.
- 10 CFR 26.617(b)(3) requires licensees and other entities to submit reports on drug and alcohol testing errors within 30 days of completing an investigation of any testing errors or unsatisfactory performance discovered at an HHS-certified laboratory or through the processing of appeals under 10 CFR 26.613, or errors or matters that could adversely reflect on the integrity of the random selection or random testing process. This requirement ensures that, in part, the NRC is timely informed so that appropriate regulatory actions can be initiated, as necessary.

Three requirements vary from the OMB guidelines described in 5 CFR 1320.5(d)(2)(iv) by requiring licensees and other entities to retain records for more than 3 years. Variations from OMB guidelines are necessary for the provisions listed below to ensure that information is available for the NRC to assess compliance with Part 26 and assure that each FFD program is adequate to protect public health and safety, promote the common defense and security, and protect the environment:

- 10 CFR 26.202(d)(1) through (d)(5) requires that records pertaining to the fatigue management program (including records of work hours of individuals, records of shift schedules and cycles or the beginning and end times and dates of all averaging periods, documentation of waivers issued, work hour reviews, and fatigue assessments) be retained for at least 3 years, which is consistent with OMB guidance, or until the completion of all related legal proceedings, whichever is later. The latter requirement ensures the availability of records for legal or regulatory proceedings and affords due process to individuals subject to the fatigue management program.
- 10 CFR 26.603(e)(4) requires licensees to retain a record of each change made to an FFD program implemented under Subpart M for a period of at least five years from the date the change was implemented. This retention period ensures that records are available as needed to confirm that changes to the FFD program are compliant with the provisions of Subpart M and do not diminish the effectiveness of the FFD program.
- 10 CFR 26.617(a) requires licensees and other entities that implement an FFD program under Subpart M to maintain records pertaining to the administration of the FFD program and FFD performance data until license termination. This retention period ensures that the NRC has access to these records for inspection purposes and for any legal proceedings resulting from the administration of the program.

8. Consultations Outside the NRC

The NRC published a proposed rule in the *Federal Register* for public comment on October 31, 2024 (89 FR 86918) as well as a draft OMB Supporting Statement for Part 26.

On November 19, 20, and 21, 2024, the NRC held a multi-day public meeting on the proposed rule. During this meeting, the NRC staff provided an overview of the proposed rule, addressed stakeholder questions, and communicated the methods available to submit public comments. The staff held a second public meeting on the proposed rule in early January 2025 with a focus on the topic of testing fueled manufactured reactors in the manufacturing facility and other technical topics of interest raised by stakeholders. In addition, the NRC staff hosted 24 public meetings with external stakeholders and participated in 16 Advisory Committee on Reactor Safeguards meetings on the draft proposed rule development before the rule was published for public comment.

The NRC prepared a summary and analysis of public comments received on the proposed rule, which totals two volumes (ML26042A229, ML26042A228). The public comment submissions are available from the Federal e-Rulemaking website at https://www.regulations.gov under Docket ID NRC-2019-0062.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

10 CFR 26.611 requires that each licensee or other entity that collects personal information about an individual for the purposes of complying with Part 26 establish and maintain a system of files and procedures that protects the privacy of each individual's information. Personal information collected under Part 26 is not submitted to the NRC. Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b).

11. Justification for Sensitive Questions

This final rule does not request sensitive information.

12. Estimated Burden and Burden Hour Cost

Detailed burden estimates are included in the supplemental burden spreadsheet titled, "Part 26 Burden Tables for the Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors Final Rule."

The estimated number of annual respondents is 6.

The overall estimated annual burden is 9,055 hours at an estimated annual cost of $1,394,470 (9,055 hours x $154/hour). This includes 82 hours for reporting, 8,382 hours for recordkeeping, and 592 hours for third party disclosures.

Total Burden Summary

Title	Responses	Hours	Cost
Reporting	8.9	81.6	$12,566.4
Recordkeeping	6.0	8,381.5	$1,290,751.0
Third-Party Disclosure	955.3	591.9	$91,152.6
TOTAL	970.2	9,055	$1,394,470.0

The NRC's average labor rate of $154 per hour for FY 2026 was used to calculate burden costs to the public because it aligns with 2024 Bureau of Labor Statistics data showing comparable hourly mean wages across five key occupational groups (executives, management, technical staff, licensing staff, and physicists) within the nuclear industry.

13. Estimate of Other Additional Costs

There are no additional costs associated with the final rule. Additional costs remain unchanged at $20,370.

14. Estimated Annualized Cost to the Federal Government

The following table identifies the anticipated burden hours per action for the NRC for entities be affected by the final rule during the clearance period.

Annualized NRC Cost

NRC Action	Rule Text Provision	No. Actions/Year	Burden Hours/Action	Total Hours	Total Cost
Review records	26.202(d) 26.603(e) 26.617	5	2	10	$1,540
Review applicant's description of its FFD program in the preliminary Final Safety Analysis Report	26.603(a)	5	24	120	$18,480
Review analysis demonstrating the facility meets the criterion in 73.100(a)(1)(i)	26.603(c)	5	80	400	$61,600
Review FFD policies and procedures	26.606	0	80	0	$0
Review, evaluate and respond to 24-	26.617(b) or 26.719(a), (b), and (c)	0	2	0	$0

hour and 30-day reports			
Total	15	530	$81,620

The staff has developed estimates of annualized costs to the Federal Government related to the conduct of this collection of information. These estimates are based on staff experience and subject matter expertise and include the burden needed to review, analyze, and process the collected information and any relevant operational expenses. The estimated cost to the government for the review of required reports and records is approximately $81,620 (530 hours at $154 per hour), based on the NRC's average labor rate of $154 per hour for FY 2026. The total cost to the Federal government for information collections associated with 10 CFR Part 26 is $445,545 ($363,925 + $81,620).

15. Reasons for Changes in Burden or Cost

As a result of the final rule, the estimated annual burden for information collection requirements for Part 26 increases by 9,055 hours, from 540,050 to 549,105 hours. The NRC staff anticipates that there will be five Part 53 licensees and one Part 53 applicant in the period covered by this clearance. 10 CFR 26.3(f) states that Part 53 applicants and licensees may elect to implement the alternate FFD program described in Subpart M of Part 26. Therefore, the estimated annual burden is expected to increase by 9,055 hours as a result of the reporting, recordkeeping, and third-party disclosure requirements that the five Part 53 licensees and one Part 53 applicant need to fulfill to comply with Part 26 during the period covered by this clearance (2027-2029).

16. Publication for Statistical Use

The information being collected is not expected to be published for statistical use.

17. Reason for Not Displaying the Expiration Date

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

18. Exceptions to the Certification Statement

None.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.

DESCRIPTION OF INFORMATION COLLECTION REQUIREMENTS CONTAINED IN THE RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR ADVANCED REACTORS FINAL RULE
10 CFR PART 26

3150-0146

The Part 26 requirements that impose information collections are discussed below:

Section 26.35 establishes requirements related to the employee assistance program (EAP). Section 26.35(a) requires licensees and other entities to maintain an EAP. Section 26.35(c) requires, in part, that EAP staff protect the privacy of each individual seeking assistance, which encourages use of the EAP. The EAP may release information to the licensee or other entity if the individual waives the right to privacy in writing, or if a determination is made that the individual's condition or actions pose or have posed an immediate hazard to himself or herself or others.

Section 26.202(a) through (e) establishes general provisions for fatigue-management programs and associated recordkeeping, disclosure, and reporting duties for facilities licensed under Part 53.

- Section 26.202(a) requires licensees and other entities to establish and incorporate into the written policy required by 10 CFR 26.606(a) a policy for the management of fatigue for all individuals subject to the licensee's FFD program.
- Section 26.202(b)(1) through (b)(4) describes the program elements that licensees and other entities must include in the development and implementation of written procedures for making a self-declaration of fatigue, implementing the work hour controls required by 10 CFR 26.205, conducting fatigue assessments, and imposing disciplinary actions.
- Section 26.202(c) specifies knowledge and abilities (KAs) on identifying and combatting symptoms of fatigue management to the content of the training and trainee assessments required by 10 CFR 26.608.
- Section 26.202(d) requires licensees and other entities to retain specific records for at least 3 years or until the completion of all related legal proceedings, whichever is later. These records include:
    - Records of work hours for individuals subject to work hours controls under 10 CFR 26.205,
    - For licensees implementing 10 CFR 26.205(d)(3), records of shift schedules and shift cycles, or, for licensees implementing 10 CFR 26.205(d)(7), records of shift schedules and records showing the beginning and end times and dates of all averaging periods, of individuals subject to work hours controls under 10 CFR 26.205,
    - Documentation of waivers required by 10 CFR 26.207(a)(4),
    - Documentation of work hour reviews required by 10 CFR 26.205(e)(3) and (e)(4), and
    - Documentation of fatigue assessments required by 10 CFR 26.211(g).
- Section 26.202(e) specifies the information licensees must include in the annual FFD program performance report required by 10 CFR 26.617. This reporting requirement ensures that licensees and other entities provide the NRC with the information needed to assess compliance with regulatory requirements for fatigue management and their effectiveness. The information to be included in the annual FFD program performance report can be contained in 10 CFR 26.202(e)(1) and (e)(2):

- Section 26.202(e)(1) requires a summary of all instances when the licensee waived work hour controls required by 10 CFR 26.205(d)(1) through (d)(5)(i) and (d)(7) for individuals described in 10 CFR 26.4(a). The summary should include only those waivers under which work was performed and specify the number of instances work hour controls were waived for individuals both working and not working on outage activities; and a summary showing the distribution of waiver use among the individuals applicable within each category of individuals in 10 CFR 26.4(a). NRC Form 892, “Annual Fatigue Reporting Form,” is available for licensees to log and submit the information included in the reporting requirements of 10 CFR 26.202(e).
- Section 26.202(e)(2) requires a summary of any corrective actions taken as a result of analyses of the above data, including fatigue assessments.

Section 26.603 establishes general FFD program provisions, with associated recordkeeping obligations, for licensees and other entities described in 10 CFR 26.3(f) that choose to establish, implement, and maintain a FFD program under Subpart M of Part 26.

- Section 26.603(a) establishes recordkeeping requirements for the following types of information, which must be included in the description of the FFD program that applicants are required to submit as part of the preliminary Final Safety Analysis Report required by Subpart H of Part 53:
  - Whether the applicant demonstrates compliance with 10 CFR 71.100(a)(1)(i),
  - A statement of whether the applicant has elected to implement an FFD program pursuant to 10 CFR 26.605(a), (b), or (a) and (b), or satisfy all Part 26 requirements except for those established in Subpart K and Subpart M,
  - A discussion of how the FFD program applies to the individuals described in 10 CFR 26.4 and how the program will be implemented offsite at an NRC-licensed facility authorized to assemble or test a manufactured reactor, if applicable,
  - A description of the process used for determining fitness and implementing drug and alcohol testing, including the collection and testing facilities to be used, biological specimens to be collected and tested, and sanctions for FFD policy violations,
- Section 26.603(e) governs FFD program change control and related recordkeeping requirements.
  - Section 26.603(e)(1)(i) establishes a recordkeeping requirement by requiring licensees and other entities that make changes to the FFD program to perform and retain an analysis demonstrating that the changes do not reduce the effectiveness of the FFD program.
  - Section 26.603(e)(4) requires licensees to retain a record of each change made under 10 CFR 26.603 for at least five years from the date the change was implemented, and to summarize each change in its annual FFD performance report.

Section 26.605(a) and (b) establishes FFD program elements and associated recordkeeping requirements for licensees or other entities implementing programs subject to this section. The program applies to the individuals, as applicable, described in 10 CFR 26.4.

Section 26.606 provides requirements for the written FFD policy and procedures, which are accompanied by certain disclosure and recordkeeping requirements. This section requires that a copy of the written FFD policy statement to each individual subject to the program before they

are subject to drug and alcohol testing. The written FFD policy statement must describe the performance objectives in 10 CFR 26.23 and the minimum days off requirements in 10 CFR 26.205(d)(3) or the maximum average work hours requirements in 10 CFR 26.205(d)(7), and information on what is expected of individuals subject to the FFD program and what consequences may result from a lack of adherence to the policy, including those elements described in 10 CFR 26.606(b), part 26-required sanctions, and required medical/clinical treatment and follow-up testing for FFD policy violations. This section also requires the policy statement to describe an individual's responsibilities to report for work in a physiological and psychological condition that enables the safe and competent performance of assigned duties and responsibilities and inform a designated representative when the individual determines that this cannot be accomplished. Furthermore, this section also requires the policy statement to prohibit the consumption of alcohol, at a minimum, within an abstinence period of 5 hours preceding the individual's arrival at the facility and to convey that abstinence from alcohol for the 5 hours preceding any scheduled tour of duty is considered to be a minimum that is necessary, but may not be sufficient, to ensure that the individual is fit for duty. 10 CFR 26.606(b) requires licensees and other entities to establish, implement and maintain written procedures on the following topics:

- Implementation of drug and alcohol testing, including the methods used for collecting, testing, shipping, and storing of biological specimens; the required urine specimen volumes, techniques for split specimen collections, and acceptability of urine specimens, protecting the privacy of individuals providing specimens, protecting integrity of specimens, and ensuring test results are valid and attributable to the correct individual; and the name and date of the specific final HHS Guidelines used and descriptions of the specific sections used,
- Immediate and follow-up actions that will be taken in cases when individuals violate the FFD policy and/or demonstrate they are not trustworthy and reliable,
- The process to be followed if an individual's behavior or condition raises concern regarding possible FFD policy violations,
- Operation and oversight of any onsite or offsite collection facility,
- Fatigue management requirements, and
- Measures to prevent subversion of drug and alcohol tests conducted onsite and offsite.

Section 26.607 establishes requirements for drug and alcohol testing and contain associated recordkeeping obligations.

- Section 26.607(i)(1) and (i)(2) establishes requirements for the use of hair as the biological matrix for drug testing. Paragraph (i)(1) requires that a licensee or other entity describe the process and procedures for hair testing, as applicable, within its written FFD policy. Paragraph (i)(2) requires that the initial and confirmatory testing cutoffs must be the cutoffs established by the HHS Guidelines for hair testing or, if not established by the HHS Guidelines or 10 CFR Part 26, as determined by a forensic toxicologist review conducted pursuant to 10 CFR 26.31(d)(1)(i)(D).
- Section 26.607(j)(2) requires licensees and other entities that elect to use a non-invasive testing instrument to screen individuals for drugs, drug metabolites, and alcohol before the individuals' entry into or exit from a protected or vital area to verify the accuracy of the portal area screening test for each substance with any positive results
- Section 26.607(l) requires the use of a Federal custody and control form for the collection and packaging of urine, oral fluid, and hair specimens..

Section 26.608 requires that individuals must be trained in the FFD policy, procedures, and their program responsibilities, including fatigue management and behavioral observation. Individuals who collect specimens also need to be trained in specimen collector duties and responsibilities.

The training program needs to use a systems approach to training as defined in 10 CFR 53.725 and described in 10 CFR 53.830 for those individuals in 10 CFR 26.4. FFD program training must include the consequences of an FFD policy violation and information disclosure and recordkeeping obligations. Licensees and other entities are required to periodically evaluate and revise the FFD training program.

Section 26.609(b) requires all individuals subject to the FFD program to conduct behavioral observation and report any information to the licensee or other entity if they believe that the onsite or offsite behaviors or activities of any individual covered by the FFD policy pose an unreasonable risk to the safety or security of the NRC-licensed facility or special nuclear material, may cause harm to others, or otherwise indicate that the individual cannot be relied upon to perform their duties or responsibilities or maintain access to NRC-licensed facilities, special nuclear material, or sensitive information that makes them subject to Part 26.

Section 26.611 requires the protection of information. Paragraph (a) requires licensees and other entities to establish and maintain a system of files and procedures to prevent unauthorized disclosure of personal information. Paragraph (b) requires licensees and other entities to obtain a signed consent form documenting the individual's agreement to participate in the FFD program and to authorize disclosure of personal information collected and maintained under Subpart M, prior to the individual becoming subject to FFD program requirements.

Section 26.613 establishes an appeals process and associated recordkeeping requirements. This section requires licensees and other entities to establish and implement procedures for an objective and impartial review of the facts related to a determination that an individual has violated the FFD policy. These procedures must include a schedule for the completion of the review.

Section 26.617 establishes recordkeeping and reporting requirements related to the administration of the FFD program.

- Section 26.617(a) requires licensees and other entities that implement FFD programs under Subpart M to maintain records, electronic or otherwise, pertaining to FFD program administration. These records must be available for NRC inspections and legal proceedings. Records pertaining to the administration of the FFD program and FFD performance data are retained until license termination.
- Section 26.617(b)(1) requires licensees and other entities to telephone the NRC Operations Center within 24 hours of discovering any intentional acts that jeopardize the integrity of the FFD program, or any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals who are subject to this subpart.
- Section 26.617(b)(2) requires licensees and other entities to submit FFD program performance data for January through December to the NRC annually by March 1 of each year, using unexpired NRC-provided forms:
    - NRC Form 893, Single Positive Test Form, 10 CFR Part 26, Subpart M FFD Program, and
    - NRC Form 894, Annual Reporting Form, 10 CFR Part 26, Subpart M FFD Program.

  The burden for reporting the information required by these forms is accounted for under OMB Clearance No. 3150-0272.
    - Licensees and other entities can voluntarily use NRC Form 892, Annual Fatigue Reporting Form, to report information required under 10 CFR 26.717(b)(9) for fatigue management programs.

- Section 26.617(b)(3) requires licensees and other entities to submit reports on drug and alcohol testing errors within 30 days of completing an investigation of any testing errors or unsatisfactory performance discovered at an HHS-certified laboratory or through the processing of appeals under 10 CFR 26.613, or errors or matters that could adversely reflect on the integrity of the random selection or random testing process.
- Section 26.617(c) requires licensees and other entities to provide detailed descriptions of individual FFD policy violations or FFD program weaknesses to the NRC, licensees, or other entities subject to part 26 when requested to support authorization determinations or performance monitoring. These descriptions must maintain compliance with the privacy requirements of 10 CFR 26.611.
- Section 26.617(e) requires licensees and other entities to document, trend, and correct non-reportable indicators of FFD programmatic weaknesses under the licensee's or other entity's corrective action program.

Section 26.619 requires licensees and other entities to develop, implement, and maintain procedures for making suitability or fitness determinations to ensure that individuals are fit to perform the duties and responsibilities that make them subject to the FFD policy.