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

10 CFR PART 26
FITNESS-FOR-DUTY PROGRAMS

3150-XXXX

NEW

DESCRIPTION OF INFORMATION COLLECTION

The U.S. Nuclear Regulatory Commission (NRC) is proposing to establish an optional technology-inclusive regulatory framework for use by applicants for new commercial nuclear plant designs. The regulatory requirements developed in this rulemaking would 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 proposed rule covers a wide range of topics, including the following that would 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). Due to the recent submission of the Part 26 renewal, the information collection changes to Part 26 associated with this final rule are being submitted as a new clearance. The NRC staff intends submit under the 3150-0146 clearance number at the final rule stage.

The rulemaking would provide a tiered approach to FFD in proposed 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 proposed revisions to Part 26 introduce new requirements (that were principally developed from existing FFD program requirements) and terminology associated with the technology-inclusive requirements in proposed Subpart M. The principal changes to Part 26 would include proposed 10 CFR 26.3(f) that would require holders of a Part 53 manufacturing license to implement an FFD program, new and revised definitions, use of alternative biological specimens (such as oral fluid or hair), use of point of collection testing and assessment (POCTA) devices, change control and FFD program performance monitoring requirements, and use of the instructions in the U.S. Department of Health and Human Service’s Mandatory Guidelines for Federal Workplace Drug Testing (HHS Guidelines) to conduct drug testing.

The supporting statements describing recordkeeping and reporting requirements in 10 CFR Part 53 (3150- XXXX), 10 CFR Part 73 (3150-0002), NRC Forms 893 and 894 (3150-XXXX), NRC Forms 366, 366A, and 366B (3150-0104), and NRC Form 361 (3150-0238) have been submitted under the respective clearances. Burden associated with 10 CFR Part 50 (3150-0011) has been submitted as a new clearance due to the submission of the Part 50 renewal.

Affected Entities

For the purposes of this supporting statement, the NRC staff estimates that there would be 2 applicants during the three-year period covered by this clearance (2025-2027). During this period, the NRC staff assumes that of these 2 applicants, 1 would prepare and submit application materials for a construction permit and 1 would prepare application materials for a combined license.

The information collection requirements under proposed 10 CFR Part 26 would be triggered when Part 53 licensees and other entities covered by proposed 10 CFR 26.3(f) are required to implement an FFD program. Under the proposed rulemaking, holders of manufacturing licenses would be required to implement an FFD program before commencing activities involving the assembly of a manufactured reactor. For other Part 53 licensees and entities, the FFD program would need to be implemented no later than the start of construction activities. During the period covered by this clearance (2025-2027), the information collection requirements associated with proposed 10 CFR 26.603(a) would require applicants to submit a description of the FFD program as part of a Part 53 license application.

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 would be 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 would be 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 would be required to submit annual FFD program performance reports (including a summary of when the licensee waives work hour controls and any corrective actions resulting from analysis of that data, including fatigue assessments, and a summary of changes made under proposed 10 CFR 26.603(e) and reports telephoned to the NRC Operations Center 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.
- *Information demonstrating the licensee qualifies for implementing an FFD program under 10 CFR 26.604.* Licensees would be required to prepare and maintain a site-specific analysis demonstrating the licensee satisfies the proposed criterion in 10 CFR 53.860(a)(2). These criteria require that the radiological consequences from a design-basis threat initiated event do not result in offsite doses in excess of 25 rem (250 mSv) total effective dose equivalent for an individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of a postulated fission product release or for an individual located at any point on the outer boundary of the low population zone who is exposed to the radioactive cloud resulting from the postulated fission product release during the entire period of its passage.

- *Information about the FFD program to be submitted with the Final Safety Analysis Report.* Applicants would be required to summarize the site-specific analysis, 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, sanctions, and a summary of its performance monitoring and review program (PMRP), including its measures and thresholds.
- *Information relating to the PMRP.* Licensees and other entities would be required to document its performance measures, thresholds, monitoring program, biennial reviews, and quantitative and qualitative reviews.
- *Annual reports and biennial reviews under the PMRP.* Licensees and other entities would be required to perform a biennial review of performance measures and weaknesses, and submit an annual program performance report describing, in part, program weaknesses, corrective actions, and data obtained from its fatigue management and drug and alcohol testing programs.
- *Information describing changes.* Licensees and other entities would be 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 would be required to distribute a copy of the written policy statement to each individual subject to the FFD program before the individual is subject to behavioral observation and/or drug and alcohol testing.
- *Written procedures.* Licensees and other entities would be 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 would be required to maintain records related to drug and alcohol testing. These records would include: the processes and procedures for collecting, storing, and testing of biological specimens for drug and alcohol testing; documentation of forensic toxicologist reviews of POCTA devices, 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 would be required to conduct periodic training on the FFD policy, procedures, and program responsibilities, which would include content on fatigue management and behavioral observation. Individuals who collect specimens would also need to be trained in specimen collector duties and responsibilities.
- *Information related to the behavioral observation program.* Licensees and other entities would be required to maintain information gathered from behavioral observation that indicates a potential FFD policy violation.
- *Records of consent.* Licensees and other entities would be 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 would be 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 would be 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 would be 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 proposed Subpart M, licensees would be required to use two new Portable Document Form (PDF) electronic reporting forms (i.e., fillable-fileable PDFs) to report information required under proposed 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 will be submitted for approval under a new clearance (3150-XXXX):

- NRC Form 893, 10 CFR Part 26, Subpart M, Single FFD Policy Violation Form, and
- NRC Form 894, 10 CFR Part 26, Subpart M, Annual Reporting Form for FFD Information.

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

A. JUSTIFICATION

1. Need for the Collection of Information

The information collections contained in the proposed Part 26 requirements would 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 would 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 would 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 would enable NRC to inspect the due process protections (e.g., appeals) that licensees and other entities would be required to provide to each individual subject to an FFD program.

2. Agency Use and Practical Utility of Information

The NRC would use the information included in the records and reports required by 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 proposed rule would 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 would be impacted by this proposed 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 proposed requirements in Part 26 are not collected or collected less frequently, then the NRC would not be able to 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

One requirement would 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) would require 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 would ensure that, in part, the NRC is timely informed so that appropriate regulatory actions can be initiated, as necessary.

Four requirements would 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) would require 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 would ensure 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(c) would require licensees and other entities that implement an FFD program under 10 CFR 26.604 to perform a site-specific analysis demonstrating that the facility and its operation satisfy the proposed criterion in 10 CFR 53.860(a)(2), which ensure that the radiological consequences for a design-basis threat initiated event do not exceed the specified offsite doses. This analysis would be maintained until the permanent cessation of operations. This retention period would ensure that licensees and other entities that elect to implement an FFD program under 10 CFR 26.604 continue to meet the necessary entry criterion.
- 10 CFR 26.603(e)(4) would require licensees to retain a record of each change made to an FFD program implemented under proposed Subpart M for a period of at least five years from the date the change was implemented. This retention period would ensure 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) would require 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 would ensure 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

Opportunity for public comment on the information collection requirements for this clearance package has been published in the *Federal Register*.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Proposed 10 CFR 26.611 would require 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 proposed 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 Proposed Rule."

The estimated number of annual respondents is 2.

The overall estimated annual burden is 656 hours at an estimated annual cost of $196,800 (656 hours x $300/hour). This includes 0 hours for reporting, 656 hours for recordkeeping, and 0 hours for third party disclosures.

Total Burden Summary

Title	Responses	Hours	Cost
Reporting	0	0	$0
Recordkeeping	2	656	$196,800
Third-Party Disclosure	0	0	$0
TOTAL	2	656	$196,800

The $300 hourly rate used in the burden estimates is based on the Nuclear Regulatory Commission's fee for hourly rates as noted in 10 CFR 170.20, "Average cost per professional staff-hour." For more information on the basis of this rate, see the "Revision of Fee Schedules; Fee Recovery for Fiscal Year 2023" (88 FR 39120, Aug. 14, 2023).

13. Estimate of Other Additional Costs

There are no additional costs.

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 proposed 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(d)(1) 26.603(e)(5) 26.617(a)	0	2	0	$0
Review applicant's description of its FFD program in the preliminary Final Safety Analysis Report	26.603(a)	2	24	48	$14,400
Review analysis demonstrating the facility meets the criterion in 53.860(a)(2)	26.603(c)	0	80	0	$0
Review FFD policies and procedures	26.606	0	80	0	$0
Review and analyze annual FFD program performance report	26.617(b) or 26.717(e)	0	16	0	$0
Review, evaluate and respond to 24-hour and 30-	26.617(b) or 26.719(a), (b), and (c)	0	2	0	$0

NRC Action	Rule Text Provision	No. Actions/Year	Burden Hours/Action	Total Hours	Total Cost
day reports					
Total		2		48	$14,400

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 $14,400 (48 hours at $300 per hour), based on the NRC fee rate.

15. Reasons for Changes in Burden or Cost

As a result of the proposed rule, the estimated annual burden for information collection requirements for Part 26 would increase by 656 hours. The NRC staff anticipates that there will be two Part 53 applicants in the period covered by this clearance. Proposed 10 CFR 26.3(f) states that Part 53 applicants and licensees may elect to implement the alternate FFD program described in proposed Subpart M of Part 26. Therefore, the estimated annual burden is expected to increase by 656 hours as a result of the recordkeeping requirements that the two Part 53 applicants would need to fulfill to comply with proposed Part 26 during the period covered by this clearance (2025-2027).

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 PROPOSED RULE
10 CFR PART 26

3150-0146

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

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

- Section 26.202(a) would require 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) would describe 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) would specify 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) would require 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) would specify the information licensees must include in the annual FFD program performance report required by 10 CFR 26.617. This reporting requirement would ensure 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 would be contained in 10 CFR 26.202(e)(1) and (e)(2):
    - Section 26.202(e)(1) would require 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,” would be 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) would require a summary of any corrective actions taken as a result of analyses of the above data, including fatigue assessments.

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

- Section 26.603(a) would establish recordkeeping requirements for the following types of information, which must be included in the description of the FFD program that applicants would be required to submit as part of the preliminary Final Safety Analysis Report required by proposed Subpart Hof Part 53:
  - A summary of the assumptions, methodology, conclusion, and references contained in the site-specific analysis, if the applicant performed the analysis under 10 CFR 26.603(c),
  - A statement of whether the applicant has elected to implement an FFD program pursuant to 10 CFR 26.604 or 10 CFR 26.605, or satisfy all Part 26 requirements except for those established in Subpart K and proposed 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 sanctions for FFD policy violations,
  - A summary of the FFD performance monitoring and review program, including the measures and thresholds required by 10 CFR 26.603(d)(1).
- Section 26.603(c) would require licensees and other entities that choose to implement an FFD program under 10 CFR 26.604 to perform and maintain, until permanent cessation of operations, a site-specific analysis demonstrating the facility and its operation satisfy the criterion in 10 CFR 53.860(a)(2). Maintenance of the analysis would be required to include updates to reflect changes made to the staffing, FFD programs, or offsite support resources described in the analysis, to show that the facility and its operation continue to satisfy the criterion.
- Section 26.603(d) would govern the FFD PMRP and associated recordkeeping requirements.
  - Section 26.603(d)(1) would require licensees to document and maintain the PMRP. The documentation would include: performance measures, thresholds for performance measures, monitoring program, biennial review, and various quantitative and qualitative reviews.
  - Section 26.603(d)(2) would require licensees to implement corrective actions to remediate FFD performance deficiencies, as indicated by performance thresholds, qualitative reviews, or audits.

- Section 26.603(d)(3) would require licensees to perform the documented review described in 10 CFR 26.603(d)(1)(iv) on a biennial basis. The review must demonstrate the suitability of performance measures and thresholds and describe program weaknesses and corrective actions which would be reported to the NRC.

- Section 26.603(e) would govern FFD program change control and related recordkeeping requirements.
  - Section 26.603(e)(1)(i) would establish 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) would require 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 26.604(a) would establish FFD program elements and associated recordkeeping requirements for licensees or other entities that satisfy the criterion in 10 CFR 53.860(a)(2)(i), which ensure that the radiological consequences from a design-basis threat initiated event do not result in offsite doses that exceed the specified values. The program would apply to the individuals, as applicable, described in 10 CFR 26.4.

Section 26.605(a) and (b) would establish FFD program elements and associated recordkeeping requirements for licensees or other entities that do not implement 10 CFR 26.604. The program would apply to the individuals, as applicable, described in 10 CFR 26.4.

Section 26.606 would provide requirements for the written FFD policy and procedures, which are accompanied by certain disclosure and recordkeeping requirements. This section would require that a copy of the written FFD policy statement to each individual subject to the program before they are subject to behavioral observation, drug and alcohol testing, or both. 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 proposed 10 CFR 26.606(b), part 26-required sanctions, and required medical/clinical treatment and follow-up testing for FFD policy violations. This section would also require 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. Proposed 10 CFR 26.606(b) would require 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 an 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 would establish requirements for drug and alcohol testing and contain associated recordkeeping obligations.

- Section 26.607(h)(1) and (h)(3) would govern the use of a POCTA device. Paragraph (h)(1) would contain a recordkeeping obligation associated with the requirement for a forensic toxicologist to review and document their evaluation that the validity and accuracy of the device for alcohol and/or all the drugs and drug metabolites listed in 10 CFR 26.31(d) are comparable to the performance achieved by initial testing conducted using a similar technology at an HHS-certified laboratory. For initial testing of drugs and drug metabolites using a POCTA device, this review must include a documented evaluation of POCTA device performance against the requirements in 10 CFR 26.161(b) for a urine specimen or the procedures in the HHS Guidelines for urine or oral fluid, as implemented by the licensee or other entities through its procedures. Paragraph (h)(3) would require the licensee or other entity to implement procedures that ensure a POCTA device is used to effectively collect and screen results and prevent subversion attempts.
- Section 26.607(i)(1) and (i)(2) would establish requirements for the use of hair as the biological matrix for drug testing. Paragraph (i)(1) would require that a licensee or other entity describe the process and procedures for hair testing, as applicable, within its written FFD policy. Paragraph (i)(2) would require that the initial and confirmatory testing cutoffs must be the cutoffs established by HHS for hair testing or, if not established by HHS or the NRC, as determined by a forensic toxicologist review conducted pursuant to 10 CFR 26.31(d)(1)(i)(D).
- Section 26.607(j)(1) would require licensees and other entities that elect to use a POCTA instrument to screen individuals for drugs, drug metabolites, and alcohol before entering or exiting a protected or vital area to obtain a documented evaluation from a forensic toxicologist who has reviewed the POCTA instrument and determined that the instrument and its setpoints are acceptable for detecting and screening the relevant substances.
- Section 26.607(l) would require the use of a U.S. Office of Management and Budget-approved custody-and-control form for the collection and packaging of urine, oral fluid, and hair specimens. This section would establish a recordkeeping requirement by requiring that licensees and other entities that elect to use a POCTA device implement and maintain a procedure for ensuring that specimens collected with a POCTA device are accurately tracked, handled, stored, disposed of, and uniquely associated with their donor.

Section 26.608 would require that individuals must be trained in the FFD policy, procedures, and their program responsibilities, including fatigue management and behavioral observation. Individuals who collect specimens would also need to be trained in specimen collector duties and responsibilities. The training program would need 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 would be required to periodically evaluate and revise the FFD training program.

Section 26.609(b) would require 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 would require the protection of information. Paragraph (a) would require licensees and other entities to establish and maintain a system of files and procedures to prevent unauthorized disclosure of personal information. Paragraph (b) would require 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 proposed Subpart M, prior to the individual becoming subject to FFD program requirements.

Section 26.613 would establish an appeals process and associated recordkeeping requirements. This section would require 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 would establish recordkeeping and reporting requirements related to the administration of the FFD program.

- Section 26.617(a) would require licensees and other entities that implement FFD programs under proposed 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 would be retained until license termination.
- Section 26.617(b)(1) would require 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) would require 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 the appropriate NRC-provided forms:
    - NRC Form 893, 10 CFR Part 26, Subpart M, Single FFD Policy Violation Form, and
    - NRC Form 894, 10 CFR Part 26, Subpart M, Annual Reporting Form for FFD Information .

  The burden for reporting the information required by these forms is accounted for under OMB Clearance No. 3150-XXXX.
    - 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(c) would require 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 26.619 would require 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.