THIS PRELIMINARY RULE LANGUAGE AND ACCOMPANYING DISCUSSION IS BEING RELEASED TO SUPPORT INTERACTIONS WITH STAKEHOLDERS AND THE ADVISORY COMMITTEE ON REACTOR SAFEGUARDS (ACRS). THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS DOCUMENT AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

THE STAFF IS PRIMARILY SEEKING INSIGHTS REGARDING THE CONCEPTS IN THIS PRELIMINARY LANGUAGE AND SECONDARILY SEEKING INSIGHTS RELATED TO DETAILS SUCH AS NUMERICAL VALUES FOR VARIOUS CRITERIA. WHILE THE NRC WILL CONSIDER ALL COMMENTS RECEIVED IN FURTHER DEVELOPING THE PRELIMINARY LANGUAGE, IT WILL NOT PROVIDE WRITTEN RESPONSES TO THOSE COMMENTS. ONCE THE PROPOSED RULE IS ISSUED IN THE *FEDERAL REGISTER*, THE PUBLIC WILL HAVE AN ADDITIONAL OPPORTUNITY TO PROVIDE COMMENTS AND THE AGENCY WILL RESPOND IN WRITING TO ALL PUBLIC COMMENTS ON THE PROPOSED RULE WHEN ISSUING A FINAL RULE.

10 CFR Part 26, FITNESS FOR DUTY PROGRAMS

Summary Statements

The staff is proposing a risk-informed, performance-based approach for the application of drug and alcohol testing and fatigue management requirements for facilities licensed under Part 53.

Applicants that meet the criterion in § 53.830(a)(2)(i) of the preliminary proposed rule text would be able to implement a fitness for duty (FFD) program described in proposed new Part 26, subpart M, “Fitness for Duty Programs for Facilities Licensed Under Part 53,” that is similar to the requirements applied to research and test reactors. For example, drug and alcohol testing would not be required; however, other Part 26 requirements like behavioral observation and a performance monitoring program would be required.

Applicants that do not meet the criterion would be subject to an alternate FFD program that is also prescribed in subpart M, or an FFD program that implements all Part 26 requirements, except for those requirements in 10 CFR Part 26, subparts K, “FFD Program for Construction,” or M.

With regards to fatigue management requirements, work hour controls would be required for personnel at operating facilities in accordance with the existing scoping criteria (10 CFR 26.4). The applicability of these scoping criteria for certain individuals (such as operators and maintenance personnel) would rely on the risk evaluation performed by a given applicant, and the determined risk significance of the work being performed by a given individual.

The NRC proposes that the new subpart M apply FFD requirements to facilities licensed under Part 53, in lieu of just including Part 53 licensees in the category of licensees with facilities licensed under 10 CFR Part 50 or 52, for four principal reasons. First, subpart M would apply FFD requirements in a risk-informed, performance-based manner commensurate with the radiological risk

consequences presented by facilities licensed under Part 53. This regulatory strategy is consistent with that already in Part 26; however, the proposal accounts for advanced reactor designs that may present very low radiological risk when compared to that of a traditional light water reactor licensed under Part 50 or 52. Second, subpart M would enable a Part 53 licensee to implement innovative drug testing technologies while continuing to provide reasonable assurance that individuals can safely and competently perform assigned duties and responsibilities. Third, subpart M would consolidate the applicable FFD requirements. This should help stakeholders understand the proposed framework and facilitate early involvement and comment on preliminary proposed rule text. This approach also could help licensees implement the requirements. Lastly, the framework is performance-based. FFD performance monitoring is proposed where the licensee must assess its FFD performance against site-specific, FFD program, and generic industry performance. Also, a change control process is proposed to allow a licensee to change its FFD program while ensuring that FFD program effectiveness is maintained. These four reasons are consistent with the NRC white paper, "Risk-Informed and Performance-Based Human-System Considerations for Advanced Reactors," and the Commission's "Policy Statement on the Regulation of Advanced Reactors."

Preliminary Proposed Language Black text is existing language in Part 26 Red text is preliminary proposed rule language	**Discussion**
Subpart A – Administrative Provisions	
§ 26.3 Scope ….. (f) Before construction, licensees and other entities that have applied for or have been issued a license under Part 53, "Licensing and Regulation of Advanced Nuclear Reactors," shall implement the requirements in subpart M or all the requirements of this part except subparts K and M. Licensees and other entities who have received a manufacturing license under Part 53 must implement the requirements in subpart M or all the requirements of this part, except subparts K and M, before the loading of nuclear fuel in a reactor vessel module.	Proposed § 26.3(f) places Part 53 licensees or other entities within the scope of Part 26. Note that Part 26 uses the terminology licensees and "other entities" as defined in § 26.5. The FFD framework for facilities licensed under Part 53 does not allow Part 53 licensees to implement the requirements in subpart K, FFD program for construction. The principal reasons are that subpart K (1) would not apply to manufacturing licensees who fabricate and fuel a reactor vessel module; (2) only applies during construction, whereas subpart M applies during construction and operation; (3) does not address training, authorization, and Medical Review Officer performance; (4) has less rigor in the protection of worker rights and sensitive information; and (5) is not consistent with recent Commission position on the use of performance-based regulations.
§ 26.4 FFD program applicability to categories of individuals (a) All persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and, as applicable, (c) and perform the following duties shall be subject to an FFD program that meets all of the requirements of this part, except subpart K of this part, and those persons who are granted unescorted access to nuclear power reactor protected areas by the licensees and other entities in § 26.3(f) and perform the following duties shall be subject to an FFD program that meets the requirements in subpart M, unless the licensee or other entity subjects these individuals to an FFD program that meets all of the requirements of this part except for those requirements in subparts K and M.	Section 26.4 is very specific as to its applicability to individuals who perform certain duties and responsibilities or who are afforded certain types of access to protected areas, materials, or information. This section would be revised to account for the types of individuals working at a facility licensed under Part 53 who must be subject to an FFD program. The NRC expects that not all categories of individuals described in this section would be applicable to all Part 53 facilities, but the proposed changes cover all individuals currently within the scope of consideration. Paragraph (a) - This is the applicability paragraph for certain individuals during reactor operation. This

	paragraph is an example of how a licensee makes a risk-informed determination whether to apply its FFD program to the categories of individuals in this paragraph.
(1) Operating or onsite directing of the operation of systems and components that a risk-informed evaluation process has shown to be significant to public health and safety;	Paragraph (1) - For Part 53 applicants, this existing scoping criterion will ensure that *Certified Operators*, as defined in § 26.5 below, and NRC-licensed reactor operators are subject to fatigue management controls, including work hour controls, when the actions they are performing are risk-significant. In the accompanying NRC guidance under development, the staff is considering offering flexibility in the application of current work hour controls for reactor operators at Part 53 sites in cases where those licensees can demonstrate, through their risk-informed evaluation process, that operator actions are not relied upon to protect the public health and safety or the environment. The NRC plans to ensure that its guidance will be informed by the criteria listed in § 53.755(a). Additionally, in some instances, work hour controls may only be applicable during certain operations evolutions that are determined to be "significant to public health and safety." For example, a plant's risk-informed evaluation could determine that plant safety during the startup of a facility relies on manual action, while periods of normal operation do not. In such instances, operators would need to be subject to work hour controls during the startup period; however, during periods of normal operation, where plant safety can be achieved via automated safety systems and other design features of the plant, operators would not be subject to work hours restrictions. Applicants that intend to not apply work hour controls to operators during any period while the plant is operating

	would need to provide sufficient justification in their risk-informed evaluations. Additionally, for facilities licensed under Part 53 that perform operations activities from a remote facility (for example, a remote control room/station/console), such a remote facility would be considered to be an extension of the "site" for the purposes of considering "onsite directing" throughout § 26.4(a).
(2) Performing health physics or chemistry duties required as a member of the onsite emergency response organization minimum shift complement; (3) Performing the duties of a fire brigade member who is responsible for understanding the effects of fire and fire suppressants on safe shutdown capability;	Paragraphs (2) and (3) - For certain advanced reactor designs, it may be the case that there will be no individuals who perform these duties.
(4) Performing maintenance or onsite directing of the maintenance of SSCs that a risk-informed evaluation process has shown to be significant to public health and safety; and	Paragraph (4) - This duty, as written, scopes in personnel performing work on equipment non-safety-related but safety significant or relied upon to meet certain criteria (including maintenance work on automated instrumentation and controls, passive systems, etc.). For instance, workers responsible for conducting surveillance tests required by plant Technical Specifications would need to be under work hours controls. It should be noted that the current Part 26 guidance pertaining to the interpretation of "maintenance" limits the applicability of this criterion to maintenance activities that change the state or condition of the SSC. This guidance may need to be revised to incorporate other maintenance activities (for example, non-destructive examination) that will be relied upon to provide a basis for operability of SSCs important to safety.

	In instances where applicants intend to not apply work hour controls to individuals performing maintenance activities, those applicants would need to provide sufficient justification in their risk-informed evaluations. Additionally, for facilities licensed under Part 53 that maintain or control equipment that is important to safety at a remote facility (for example, a remote control room or control station/console), such a remote facility would be considered to be an extension of the "site" for the purposes of considering "onsite direction".
(5) Performing security duties as an armed security force officer, alarm station operator, response team leader, or watchman, hereinafter referred to as security personnel.	Paragraph (5) - Part 53 sites that require security personnel would need to ensure that work hour controls are administered for those personnel.
(b) All persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and, as applicable, (c) and who do not perform the duties described in paragraph (a) of this section shall be subject to an FFD program that meets all of the requirements of this part, except §§ 26.205 through 26.209 and subpart K of this part. All persons who are granted unescorted access to a facility licensed under Part 53, and who do not perform the duties described in § 26.4(a), shall be subject to the requirements in subpart M of this part, unless the licensee or other entity implements an FFD program that meets all of the requirements of this part, except §§ 26.205 through 26.209 and subparts K and M.	Paragraph (b) - This is the applicability paragraph for individuals who have access to the protected area. This requirement helps ensure the defense-in-depth regulatory framework that provides reasonable assurance that individuals who have unescorted access are trustworthy and reliable. For example, this requirement helps mitigate the insider threat.
(c) All persons who are required by a licensee in § 26.3(a) and, as applicable, (c) to physically report to the licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) by licensee emergency plans and procedures shall be subject to an FFD program that meets all of the requirement of this part, except §§ 26.205 through 26.209 and subpart K of this part. For licensees in § 26.3(f), all persons who are assigned by the licensee to participate remotely and make decisions or direct actions regarding plant safety	Paragraph (c) - This is the applicability paragraph for those individuals who are assigned to the EOF or TSC and those that direct or conduct activities remotely. Note that Part 53 facilities may be remotely operated or rely on other facilities to fulfill the traditional role of a TSC or EOF; therefore, new text is proposed to account for other facilities or remotely performed activities. Further, the use of personnel to operate, maintain, surveil, and respond to

and security, and all persons who are assigned by the licensee to participate remotely in emergency response activities or physically report to the TSC or EOF (or an equivalent facility), shall be subject to an FFD program that meets all of the requirements described in subpart M of this part, unless the licensee or other entity implements an FFD program that meets all of the requirements of this part, except §§ 26.205 through 26.209 and subparts K and M. (d) […]	adverse plant conditions and/or security events may be different than those traditionally included in the TSC or EOF team.
(e) When construction activities, as defined in § 26.5, begin, any individual whose duties for the licensees and other entities in § 26.3(c) require him or her to have the following types of access or perform the following activities at the location where the nuclear power plant will be constructed and operated shall be subject to an FFD program that meets all of the requirements of this part, except subparts I, K, and M of this part, and for any individual whose duties for the licensees and other entities in § 26.3(f) require him or her to the have the following types of access, perform construction activities as defined in § 26.5, or perform the following activities shall be subject to an FFD program as described in subpart M of this part or an FFD program that meets all of the requirements of this part, except subparts I, K, and M:	Paragraph (e) - This is the applicability paragraph for construction. Note that Part 26 already defines "construction." The NRC will assess and align this definition, if necessary, with the Part 53 definition of "construction."
(1) Serves as security personnel […]	
(2) Performs quality assurance, quality control, or quality verification activities related to safety- or security-related construction activities;	Paragraph (e)(2) - The NRC is proposing a revision to the term "safety-related" as provided in § 26.5 below.
(3) Based on a designation under § 26.406 by a licensee or other entity, monitors the fitness of the individuals specified in paragraph (f) of this section;	
(4) Witnesses or determines inspections, tests, and analyses certification required under Parts 52 or 53 of this chapter;	Paragraph (e)(4) - Applicability statement.
(5) Supervises or manages the construction of ~~safety- or~~ security-related SSCs or the construction of SSCs that a risk-informed	Paragraph (e)(5) - The reference to "safety-related SSCs" is being removed to more generalize this scoping language. This terminology may change for Part 53

evaluation process has shown to be significant to public health and safety; or (6) Directs, as defined in § 26.5, or implements the access authorization program, including— […]	licensed facilities; this may cause a conforming change to this paragraph.
(f) Any individual who is constructing or directing ~~the~~ construction ~~of safety- or security-related SSCs~~ activities as defined in § 26.5 shall be subject to an FFD program that meets the requirements of subpart K, or, if applicable, subpart M of this part, unless the licensee or other entity subjects these individuals to an FFD program that meets all of the requirements of this part, except for subparts I, K, and M.	Paragraph (f) - This is the applicability paragraph for those individuals who construct or direct the construction of commercial power reactors licensed under Part 50 or 52 in the current Part 26 rule. Since the definition of construction in § 26.5 may change for Part 53 licensed facilities, this provision may also need to change. Also, the use of terminology such as “safety-related” may change for Part 53 licensed facilities; this may cause a conforming change to this paragraph.
(g) All FFD program personnel who are involved in the day-to-day operations of the program, as defined by the procedures of the licensees and other entities in § 26.3(a) through (c), and, as applicable, (d) and whose duties require them to have the following types of access or perform the following activities shall be subject to an FFD program that meets all of the requirements of this part, except subparts I, ~~and~~ K, and M of this part, and, at the licensee’s or other entity’s discretion, subpart C of this part. All personnel described, who have the types of access and perform those duties and responsibilities described in this paragraph at facilities licensed under Part 53, shall be subject to the requirements in subpart M or an FFD program that meets all of the requirements of this part, except subparts I, K, and M of this part, and, at the licensee’s or other entity’s discretion, subpart C of this part. (1) All persons who . . .	Paragraph (g) - This is the applicability paragraph for FFD program personnel (e.g., the FFD manager, Medical Review Officer, and technicians) and persons who perform access authorization determinations (e.g., the licensee-designated Reviewing Official). A Part 53 licensee would use FFD program personnel to implement the FFD program and assigned individuals to implement the Part 26 FFD program. However, since the staff is proposing a risk-informed FFD program based on the requirements in subpart K, the prescriptive requirements in Subpart B would no longer be required for licensees or other entities who implement the requirements in subpart M.

(h) Individuals who have applied for authorization to have the types of access or perform the activities described in paragraphs (a) through (d) of this section shall be subject to §§ 26.31(c)(1), 26.35(b), 26.37, 26.39, and the applicable requirements of subparts C, and E through H, and, if applicable M, of this part.	Paragraph (h) - This is the applicability paragraph for individuals who have applied for authorization when authorization becomes applicable before reactor operation. The regulatory concept of authorization is necessary immediately before and during commercial power plant operation.
§ 26.5 Definitions	
Certified Operator means an individual certified under the provisions of §§ 53.770 through 53.779 to manipulate a control of a facility. Certified operators are not licensed by the Commission.	The NRC is proposing a new category of individuals called "Certified Operators." The FFD program would apply to these individuals. Although the definition is provided here, the NRC may elect to instead reference the definition of Certified Operator in Part 53.
Change as used in § 26.603(e) means an action that results in a modification of, addition to, or removal from, the licensee's or other entity's FFD program.	The NRC is proposing a definition for the word change as it is used on the § 26.603(e), "FFD program change control," process. The proposed definition is consistent with that being proposed for the amended security requirements in the NRC's draft proposed decommissioning rule.
Contractor/vendor (C/V) means any company, or any individual not employed by a licensee or other entity specified in § 26.3(a) through (c) and (f), who is providing work or services to a licensee or other entity covered in § 26.3(a) through (c) and (f), either by contract, purchase order, oral agreement, or other arrangement.	This proposed amendment makes the definition of *contractor/vendor* applicable to Part 53 licensees.
Other entity means any corporation, firm, partnership, limited liability company, association, C/V, or other organization who is subject to this part under § 26.3(a) through (c) and (f), but is not licensed by the NRC.	This proposed amendment makes the definition of *other entity* applicable to Part 53 licensees.
Questionable validity means the results of validity screening or initial validity tests at a licensee testing facility indicating that a urine specimen may be adulterated, substituted, dilute, or invalid. For a Part 53 licensee, *Questionable validity* means the results of validity screening or initial validity tests that a biological specimen obtained from an individual pursuant to subpart M may be adulterated, substituted, dilute, or invalid.	The risk-informed approach being proposed for FFD programs for Part 53 licensees would not preclude Part 53 licensee use of alternative testing methodologies or alternative biological specimens (such as oral fluid) for drug testing as long as FFD program effectiveness does not diminish – see the proposed FFD performance monitoring and review program in § 26.603(b)(3) and the FFD change control process in § 26.603(b)(4).

Reduction in FFD program effectiveness means a change or series of changes to an element of the FFD program that reduces or eliminates the licensee's ability to meet or maintain site-specific FFD program performance when compared to historical site-specific performance, the licensee's fleet-level program performance, or generic industry performance.	The NRC is proposing a definition for "reduction in FFD program effectiveness" because this phrase is used in proposed requirement § 26.603(e). The proposed definition is generally consistent with that being proposed for the amended security requirements in the NRC's proposed decommissioning rule, "Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning" (NRC-2015-0070; RIN 3150-AJ59). The Commission's markup of the proposed rule and its approval for publication can be viewed in a Staff Requirements Memorandum at Agencywide Documents and Management System (ADAMS) Accession No. ML21307A046. The NRC may propose a definition of "FFD program" because external stakeholders may have a different understanding of this phrase than the NRC. Typically, "FFD program" was that FFD program implemented by a licensee for a specific NRC-licensed facility. However, over time, companies have acquired additional NRC-licensed facilities, establishing a fleet of nuclear power plants. Some of these companies then have elected to implement one common FFD program for all its NRC-licensed facilities even if these facilities are not co-located. The NRC expects that facilities licensed under Part 53 may be owned and operated in a similar manner.
Reviewing official means an employee of a licensee or other entity specified in § 26.3(a) through (c), and (f) who is designated by the licensee or other entity to be responsible for reviewing and evaluating any potentially disqualifying FFD information about an individual, including, but not limited to, the results of a determination of fitness, as defined in § 26.189, in order to determine whether the individual may be granted or maintain authorization.	This proposed amendment makes the *Reviewing official* definition applicable to Part 53 licensees.
Safety-related structures, systems, and components (SSCs) mean, for licensees and other entities described in § 26.3(a) - (d) and for the purposes of this part, those SSCs that are relied on to remain	The current Part 26 definition for "safety-related" would not be applicable to licensees under Part 53. Therefore, Part 26 would use the Part 53 proposed definition for

functional during and following design basis events to ensure the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure comparable to the guidelines in § 50.34(a)(1). For licensees and other entities described in § 26.3(d) and (f), safety-related has the meaning provided in § 53.020.	licensees described in § 26.3(f). The NRC staff plans to issue regulatory guidance to describe this term in Part 53 and Part 26.
Security-related SSCs mean, for the purposes of this part, those structures, systems, and components that the licensee will rely on to implement the licensee's physical security and safeguards contingency plans that either are required under Part 73 of this chapter if the licensee is a construction permit applicant or holder or an early site permit holder, as described in § 26.3(c)(3) through (c)(5), respectively, or are included in the licensee's application if the licensee is a combined license applicant or holder, as described in § 26.3(c)(1) and (c)(2), respectively, or a licensee or other entity described in § 26.3(d) and (f).	The NRC staff is assessing whether the Part 26 definition of "security-related" needs to be further changed. The proposed amendment would, at minimum, make this definition applicable to Part 53 licensees.
Subpart M — Fitness for Duty Programs for Facilities Licensed Under Part 53.	
§ 26.601 Applicability. At the licensee's or other entity's discretion, a licensee or other entity in § 26.3(f) may establish, implement, and maintain an FFD program that meets the requirements of this subpart for the individuals specified in § 26.602. If a licensee or other entity in § 26.3(f) does not elect to implement an FFD program that meets the requirements of this subpart, then the individuals specified in § 26.602 shall be subject to an FFD program that meets all Part 26 requirements, except for those requirements in subparts K and M.	This proposed section makes subpart M applicable to Part 53 licensees, at their discretion.
§ 26.602 FFD program applicability to categories of individuals. The requirements of this subpart apply to those categories of individuals in § 26.4, as applicable, and any Certified Operator, as defined in § 26.5, as designated by the licensee or other entity.	This proposed section requires Part 53 licensees and other entities to apply subpart M to those individuals described in § 26.4, as applicable.
§ 26.603 General provisions. (a) *FFD Program Description*. As required by §§ 53.1245(e)(3), [53.1266], 53.1275(y), and 53.1289(a)(24) of subpart H of Part 53, the	Paragraph (a) – The proposed Part 53 framework would require an applicant to provide a description of its FFD program within its application for a license. This

applicant's description of the FFD program in its final safety analysis report must include—	description must be clear and contain certain information to inform the NRC of its plans. This description requirement is based on the requirements of §§ 26.401(b),52.79(a)(44), and proposed rule language in § 53.1275(y) and supplemented by sub-paragraphs (a)(1)-(5) to account for operating experience during the construction of light water reactors.
(1) A summary of the analysis performed under paragraph (c)(2) of this section, if performed, including the assumptions, methodology, conclusion, and references;	Paragraph (a)(1) – This paragraph requires a summary description of the analysis performed to assess the risk-informed determination criterion for FFD programs. This description could be the same evaluated for security programs.
(2) A statement whether the FFD program will be implemented pursuant to §§ 26.604 or 26.605, or will meet all Part 26 requirements, except for the requirements in subparts K and M;	Paragraph (a)(2) – This statement makes clear what FFD program the licensee would implement. This determination would be dependent on the risk-informed determination criterion. The licensee or other entity may choose to implement all Part 26 requirements, except those in subparts K and M.
(3) A discussion of the applicability of the FFD program to those individuals described in § 26.602 and how the program will be implemented offsite at an NRC-licensed facility authorized to fabricate, construct, and/or test a nuclear reactor module, if applicable;	Paragraph (a)(3) – This description informs the NRC of the applicability of the FFD program to individuals who perform safety or security significant activities, including the situation where the licensee's risk-informed evaluation process has shown that the duties and responsibilities performed by the individual would be significant to public health and safety. The NRC staff continues to evaluate the applicability of FFD programs to a facility licensed to fabricate, construct, and/or test a nuclear reactor module offsite from the NRC-licensed site for commercial power reactor operation.
(4) A description of the drug and alcohol testing and fitness determination process to be implemented by the licensee's or other entity's procedures, including the collection and testing facilities to be	Paragraph (a)(4) – This description enables the NRC's and public's understanding of FFD program

used, biological specimens to be collected, and sanctions to be imposed upon a confirmed FFD policy violation; and (5) A summary of the FFD performance monitoring and review program, including expected measures and metrics required by paragraph (d)(1) of this section. (b) *FFD Program Implementation and Availability*. For the licensees and other entities in § 26.4(f), the FFD program shall be established, implemented, and maintained before the start of construction, as defined in § 26.5, and during reactor operation and until the NRC's docketing of the license holder's certifications described in §§ 50.82(a)(1) or 52.110(a). For licensees that have been issued a manufacturing license, the FFD program shall be established, implemented, and maintained before the loading of nuclear fuel into the reactor vessel module and until expiration of the manufacturing license.	implementation, specifically how drug and alcohol testing would be conducted. Paragraph (a)(5) – This description is designed to inform the NRC and public of those FFD performance measures that the licensee would use upon implementation of its FFD program. Paragraph (b) – This requirement establishes when the FFD program must be implemented and the longevity of the FFD – this proposal is consistent the current FFD framework and includes the requirement that an FFD program would not be applicable during decommissioning of the Part 53 licensed facility. The current Part 26 framework requires the implementation of an FFD program for the construction of commercial nuclear power reactor facilities licensed under Parts 50 and/or 52. Then, as construction nears completion, the licensee or other entity is required to implement all Part 26 requirements, except those in Subpart K, because the radiological risk consequences begin to increase. However, the current FFD framework does not apply to a facility where its licensee has submitted its certifications under 10 CFR 50.82 or 52.110(a), which places the facility in decommissioning (either SAFSTOR or dismantlement). The NRC describes decommissioning at https://www.nrc.gov/waste/decommissioning.html. The NRC is still evaluating how to describe the milestone when the FFD program would need to be initiated to support the loading of fuel into the reactor vessel module at the manufacturing facility. For example, the NRC staff position is that the FFD program be implemented before individuals at the manufacturing facility begin assembling or directing the assembly of those SSCs that a risk-informed evaluation process has shown to be significant

	to public health and safety, such as those associated with an inspection, test, analysis and acceptance criteria (ITAAC) and will be used in the reactor vessel module. Are there other milestones that should be considered? The staff requests feedback on this topic.
(c) *Criterion and Analysis for an FFD Program*. (1) *Criterion*. The criterion to be used for the analysis in § 26.603(c)(2) shall be the criterion in 10 CFR 53.830(a)(2)(i).	Paragraph (c) – This is a new requirement detailing the use of the criterion to determine which FFD program described in Subpart M (i.e., § 26.604 or § 26.605) a Part 53 licensee may establish, implement, and maintain unless it elects to implement all requirements in Part 26, except those in Subpart M. The requirement in paragraph (c)(2) explains the analysis to be conducted in the licensee's or other entity's evaluation of the criterion. Specifically, the FFD criterion is equivalent to that used in § 53.830(a)(2)(i). And, the analysis requirement is based on the equivalent provision in Part 53.
(2) *Analysis*. In order for a licensee or other entity to implement an FFD program under § 26.604, the licensee or other entity must perform a site-specific analysis to demonstrate that the criterion in § 26.603(c)(1) is met. The licensee or other entity must maintain the analysis until permanent cessation of operations under § 53.XXX of this chapter.	Paragraph (c)(2). The applicant may conduct this analysis to assess whether it could implement the FFD program described in § 26.604. If the licensee finds that its facility and operation does not meet the criterion, (or, at their discretion, if the criterion is satisfied) the applicant must implement the FFD program described in § 26.605 or one that meets all Part 26 requirements, except those in subparts K and M.
(d) *FFD Performance Monitoring and Review*. A licensee or other entity must establish performance measures and associated thresholds as described in § 26.603(d)(1) and monitor the effectiveness of its FFD program against these performance measures and thresholds, in a manner sufficient to provide reasonable assurance that individuals subject to the program can safely and competently perform assigned duties and responsibilities and are trustworthy and reliable to maintain the types of access making them subject to this subpart.	Paragraph (d) – This is a new requirement based on the NRC's Reactor Oversight Process. A performance monitoring and review program is proposed to be consistent with a performance-based and risk-informed regulatory framework. This program is also required because the subpart M requirements are not prescriptive, and they enable program implementation and change based on consequences and human performance. Since FFD programs under subpart M may be site specific (e.g.,

	using oral fluid instead of using urine for drug testing), this helps provide reasonable assurance that the FFD program would remain effective as determined by an evaluation against site-specific and industry metrics and averages, as well as qualitative considerations. This requirement helps enable performance-based and risk-informed NRC inspections.
(1) The performance monitoring and review program shall be documented and maintained and include the following program elements: (i) *Performance Measures*. Performance measures must be identified and designed to monitor FFD program performance in a manner sufficient to provide reasonable assurance that the 10 CFR 26.23 performance objectives are met.	Paragraph (d)(1) – This paragraph requires the licensee or other entity to monitor its own performance through the establishment of their own performance measures and thresholds designed to initiate corrective actions. The NRC staff is developing a draft proposed regulatory guide to provide guidance on the types of performance measures that the licensee should consider and one set of measures that the NRC finds acceptable – where applicable, guidance would be based on and conform to that already implemented under the NRC's Reactor Oversight Process. The measures are both qualitative and qualitative (discussed below) and should be based on year-to-year site-specific performance and site performance compared to industry performance. Additionally, if the FFD program applies to more than one NRC-licensed site, a site-to-site comparison within the FFD program should be performed. Prescriptive thresholds are not proposed by the NRC. Licensees and other entities currently subject to Part 26 already must annually report FFD performance data to the NRC—no change would be proposed for current facilities. This information is docketed, publicly available, and displayed on the NRC's external website.
(A) If the licensee or other entity is subject to the requirements in § 26.604, then the monitoring program must include a performance measure for the effectiveness of the behavioral observation program.	Paragraph (d)(1)(i)(A) – The program must include the periodic assessment of the behavioral observation program for a licensee or other entity that does not implement drug and alcohol testing. This requirement is

	necessary to provide reasonable assurance that individuals are performing their duties and responsibilities safely and competently and not acting in a manner that may adversely affect, either directly or indirectly, the licensee's capability to prevent significant core damage and spent fuel sabotage.
(B) If the licensee or other entity is subject to the requirements in § 26.604 and has implemented a drug testing program at its discretion, or is subject to the requirements of § 26.605, then the monitoring program must include performance measures for the pre-access and random positive testing rates, and subversion attempts;	Paragraph (d)(1)(i)(B) – FFD performance data associated with pre-access and random testing and subversion attempts in the commercial nuclear industry subject to Part 26 is well established and publicly available. From this data, a licensee or other entity may make reasonably equivalent comparisons to other operating commercial nuclear facilities, based on, for example, megawatts-electric of the facility and number of individuals subject to the FFD program. Other considerations such as geographic location, use of laboratories and collection facilities, and conduct of large maintenance activities (such as refueling or engineering design changes) could also be used to inform the program. The NRC acknowledges that there may be cases where the existing FFD performance data generated by the current large light-water reactor fleet may not be directly applicable to a facility licensed under Part 53 For example, this could occur if the Part 53 facility maintains a very small licensee employee workforce. The NRC staff intends to address this issue in a draft regulatory guide and is working to complete a technical study on FFD performance monitoring.
(ii) *Monitoring Program*. Assessments must be conducted as data is received. Monitoring must enable year-to-year comparisons for the site and when data is available against FFD program and industry performance.	Paragraph (d)(1)(ii) – This paragraph states that the licensee or other entity must evaluate FFD data as it is received. This is important because the licensee or other entity is required under paragraph (d)(1)(i)(B) to monitor subversions. Operating experience indicates that some sites have very few subversion attempts, therefore, for these sites, the licensee- or other entity-established

	threshold could be quite low, such that a single or few occurrences could initiate corrective actions.
(iii) *Thresholds*. Licensee- or other entity-specific thresholds for its site-specific performance measures must be established and used to facilitate corrective actions to maintain FFD program performance. Initial thresholds must be based on FFD performance data from comparable facilities subject to part 26, FFD program information if the program has more than one site subject to part 26, and generic industry FFD performance data. Licensees and other entities must re-evaluate their performance measures and thresholds every two years and adjust their performance measures and thresholds to maintain FFD program effectiveness based on historical site-specific, licensee's fleet-level program performance, and comparable industry performance or any identified areas for improvement.	Paragraph (d)(1)(iii) – This paragraph regarding thresholds introduces the concept of "maintaining FFD program effectiveness." This terminology is proposed because it implements a performance-based regulatory strategy where the license or other entity must initially establish a level of performance that is representative of other facilities in its FFD program and the FFD performance of comparable facilities subject to Part 26. Since NRC oversight has demonstrated that FFD performance in the industry has met and continues to meet the FFD performance objectives in § 26.23, that level of historical FFD performance (e.g., number of FFD policy violations per site per year) when combined with the 10 CFR defense-in-depth regulatory framework, contributes to the protection of public health and safety, common defense and security, and protection of the environment. The proposed FFD change control process and NRC inspection of the FFD program and its annual and biennial reports will help provide assurance that measures and thresholds are not adjusted over time in a manner that lessens the effectiveness of the FFD program. The phrase reduction in FFD program effectiveness is a proposed definition in § 26.5.
(iv) *Quantitative and Qualitative Reviews*. The performance monitoring and review program shall include a documented review of the elements in § 26.603(d)(1)(i)-(iii) and the following elements.	Paragraph (d)(1)(iv) – This paragraph regarding quantitative and qualitative reviews lists those elements within the FFD program for which the NRC staff believes would be difficult for the licensee or other entities to establish quantitative performance measures, because there are very few data points in which to establish an effective monitoring program. However, since these listed elements involve multi-step processes, detailed

	procedures, and human performance, a qualitative review (i.e., audit) can be performed to evaluate performance.
(A) *Appeals Process*. The review must include a documented assessment of the licensee's or other entity's implementation of the protections described in §§ 26.606(b)(1), 26.611, and 26.613.	Paragraph (d)(1)(iv)(A) - This paragraph requires the licensee to monitor whether the FFD program is affording appropriate protections (protection of sensitive information, protection of privacy, due process, etc.) to individuals subject to the FFD program.
(B) *Laboratory Test Results and Medical Review Officer Performance*. The review must include a documented assessment whether the actions taken by the Medical Review Officer met the requirements in § 26.185 based on the laboratory test results reported under § 26.169.	Paragraph (d)(1)(iv)(B) – The NRC proposes that laboratory test results and Medical Review Officer (MRO) performance be included in the biennial program review for three reasons: (1) this is a worker protection consideration that the drug testing program is resulting in outcomes consistent laboratory test results; (2) this review provides a performance-based assessment of both the laboratory and MRO; and (3) this review facilitates actions to improve laboratory performance and/or MRO training under § 26.607(l)(2).
(C) *Change Control Process*. The review must include a documented assessment of the changes made under § 26.603(e) to provided assurance that the summation of program changes have not resulted in a reduction in FFD program effectiveness.	Paragraph (d)(1)(iv)(C) - The NRC staff proposes that the change control process be included in the biennial program review to help ensure that changes implemented over the life of the facility do not result in an unevaluated decrease in program effectiveness. The use of the word "summation" in this requirement is to require a holistic assessment of all changes because the proposed change control process in § 26.603(e) focuses only on a particular change being pursued for implementation and not a retrospective analysis of the potential aggregated effect of all changes on program effectiveness.
(2) *Corrective Actions*. Corrective actions shall be implemented to address when FFD performance meets a licensee-established performance threshold or to resolve a finding resulting from a	Paragraph (d)(2) - This provision helps ensure that corrective actions would be effective.

qualitative review or audit in a manner that restores performance and corrects root and/or contributing causes.	
(3) *Program Review Periodicity*. The documented review in § 26.603(d)(1)(iv) shall be conducted biennially to assess and modify licensee or other entity implementation of its FFD program. This documented review must demonstrate that the performance measures and thresholds are appropriate based on site- and FFD program-specific historical performance, and informed by industry performance.	Paragraph (d)(3) - The licensee must monitor, periodically assess, and document its FFD performance monitoring program – this report is not required to be submitted to the NRC. This report may summarize the results/findings obtained from the reviews conducted in § 26.603(d)(i)(iv). All Part 26 licensees must annually submit FFD performance data to this NRC (10 CFR 26.417(b)(2) and 26.717). Two principal outcomes result from this effort: (1) the licensee lessons learned would contribute to their own performance assessment to maintain program effectiveness and (2) the NRC is informed of FFD performance and can then aggregate industry data for use in licensee performance monitoring and review programs.
(i) Identified program weaknesses must be summarized in the annual reporting requirement described in § 26.617.	Paragraph (d)(3)(i) - This provision helps ensure that the NRC is informed of FFD program weaknesses to facilitate regulatory oversight, if necessary. The reference to § 26.617 enables the licensee to use the pre-existing and free, NRC-developed, electronic reporting system designed to minimize regulatory burden and enhance reporting consistency (https://www.nrc.gov/site-help/e-submittals.html). This enhances consistency across the industry and supports NRC aggregation of data. As proposed in § 26.617 and as currently required in § 26.719, all licensees and other entities subject to Part 26 would be required to submit FFD performance data to the NRC before March 1 for the previous calendar year. (https://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/submit-ffd-reports.html)
(ii) The program review must be completed and approved by the licensee or other entity before November 15 of every even year, and	Paragraph (d)(3)(ii) - This provision helps ensure that the review is periodically performed because of the flexibilities

corrective actions implemented before May 15 of the following year.	afforded in the Part 53 FFD framework and the annual reporting of FFD performance data to the NRC. The November 15th date provides assurance of completion and informs NRC oversight, and implementing corrective actions within the next 6 months supports a possible full year of implementation prior to the next biennial FFD performance review.
(e) *FFD Program Change Control.* The licensee or other entity shall establish, implement, and maintain a change control process that meets the following requirements—	Paragraph (e) - This section is based on § 50.54(p) and (q), the change control processes for security and emergency plans respectively. The staff proposes a change control process for Part 26 for two reasons. First, there must be change control for the assessment for the FFD criterion, which establishes the minimum FFD program that must be implemented, because if this assessment changes, then the licensee's FFD program may change. Second, the requirements in subpart M are objective and performance based. Since this regulatory approach focuses on desired results (e.g., individuals are fit for duty and trustworthy and reliable) and measurable outcomes (e.g., performance measures and thresholds that demonstrate the FFD program is maintaining effectiveness), respectively, rather than prescriptive processes, techniques, or procedures, the licensee or other entity is essentially free to implement its own methods to achieve the desired results or measurable outcomes. In this case, the change control process helps provide assurance that FFD program changes do not result in a reduction in FFD program effectiveness and that a documented history is maintain should FFD program effectiveness unknowingly decreases
(1) The licensee or other entity may make changes to its FFD program under this subpart without prior NRC approval only if:	Paragraph (e)(1) – As will be further described in draft guidance, the following are types of changes a licensee or other entity may make: (1) If HHS determines that the societal risk posed by a particular drug or drug metabolite

(i) the licensee or other entity performs and retains an analysis demonstrating that the changes do not reduce the effectiveness of the FFD program or (ii) the change was necessitated or justified by a change to Part 26 or laboratory processes or procedures, including the full panel of drugs, drug metabolites, and cutoffs, implemented to maintain their U.S. Department of Health and Human Services' (HHS) laboratory certification.	does not warrant its testing in its Mandatory Guidelines for Federal Workplace Drug Testing Programs (HHS Guidelines) because it is no longer used in society or does not cause an impairing condition of concern, then the change is justified. (2) If HHS changes its laboratory validity testing to account for a change in adulteration techniques, HHS may revise its validity testing requirements, this change is justified.
(2) A licensee or other entity desiring to make a change that decreases FFD program effectiveness must submit an application for amendment to its license, in addition to the filing requirements in §§ 53.YY and 53.ZZ. The request must include a detailed description of the change, the reason for the change, and the use of any mitigating strategy needed to provide reasonable assurance that if the change is approved, the FFD program, as revised, will continue to meet the performance objectives in § 26.23.	Paragraph (e)(2) - If a change reduces FFD program effectiveness, then NRC approval is required. As will be described in draft guidance, the following are examples where a change may represent a reduction in program effectiveness. (1) If the licensee elects to reduce the severity of its established sanction for an FFD policy violation; this change can reduce FFD program effectiveness because the deterrent value of the sanction would be reduced. (2) If the licensee elects to reduce the number of individuals onsite and subject to the FFD program; this change could reduce the effectiveness of the behavioral observation and, if applicable, random testing programs. (3) If the licensee elects to change its supplier of oral fluid test kits and the testing accuracy decreases, cutoffs increase, or panel of drugs to be tested decreased from that tested previously; these types of changes could represent a reduction in program effectiveness.
(3) The credited technical analysis used to justify meeting the risk-informed determination criterion of this section must be maintained, including updates to reflect changes made pursuant to § 26.603(e) to the staffing, FFD programs, or offsite support resources described in the analysis, to show that the facility and its operation continues to meet the risk-informed determination criteria, if applicable.	Paragraph (e)(3) - This requirement provides assurance that changes to the facility, its operation, personnel, safeguards, etc., are managed and evaluated to prevent unanticipated change to the justification used to assess the FFD criteria.

(4) The licensee shall retain a record of each change made under this section for a period of at least five years from the date the change was implemented and summarize this change in its annual FFD performance report required by § 26.617(b)(2).	Paragraph (e)(4) - Records shall be maintained in a manner similar to records maintained for § 50.54(p) and (q) changes. Five years is based on the current NRC practice to conduct triennial inspections of the FFD program.
§ 26.604 FFD program requirements for facilities that meet the FFD criterion (a) *FFD Program*. Licensees and other entities with an analysis as described in § 26.603(c)(2) that demonstrates the criterion in § 26.603(c)(1) is met, may elect to establish, implement, and maintain an FFD program under this section. That FFD program must contain the following elements: (1) applies to those individuals described in § 26.602, as applicable; (2) implements the program elements and requirements described in in § 26.603; and, (3) implements the following requirements and subparts in this part: (i) § 26.23, Performance objectives (ii) § 26.606, Written policies and procedures, (a) and, if applicable (b) (iii) § 26.608, FFD program training (iv) § 26.609, Behavioral observation (v) § 26.610, Sanctions (vi) § 26.611, Protection of information (vii) § 26.613, Review process (viii) § 26.615, Audits (ix) § 26.617, Recordkeeping and reporting (x) § 26.619, Suitability and fitness determinations (xi) Subpart A—Administrative Provisions (xii) Subpart O—Inspections, Violations, and Penalties	
§ 26.605 FFD program requirements for facilities that do not meet the FFD criterion (a) Licensees and other entities implementing § 26.604, at their discretion, and licensees and other entities that implement an FFD program under this subpart must establish, implement, and maintain	Section 26.605 is written for a Part 53 licensee that does not meet the FFD criterion in § 26.603(c) and a Part 53 licensee that meets the FFD criterion yet elects to implement this section. This section also applies to the holder of a Part 53 manufacturing license that allows the

an FFD program under this section during either construction activities as defined in § 26.5, or during activities performed under a manufacturing license that allows the assembly and fueling of a reactor vessel module, as applicable. That FFD program must contain the following elements: (1) applies for those individuals described in § 26.602, as applicable; (2) implements the program elements and requirements described in in § 26.603; (3) implements the following requirements and subparts in this part— (i) § 26.23, Performance objectives (ii) § 26.606, Written policy and procedures (iii) § 26.607, Drug and alcohol testing (iv) § 26.608, FFD program training (v) § 26.609, Behavioral observation (vi) § 26.610, Sanctions (vii) § 26.611, Protection of information (viii) § 26.613, Review process (ix) § 26.615, Audits (x) § 26.617, Recordkeeping and reporting (xi) § 26.619, Suitability and fitness evaluations; and (xii) Subpart A—Administrative Provisions (xiii) Subpart I—Fatigue Management (xiv) Subpart O—Inspections, Violations, and Penalties	fabrication and fueling of a reactor vessel module. However, the proposed FFD requirements will only be applicable to those individuals who assemble and direct the assembly of the reactor vessel module and its SSCs, and those individuals who conduct QA/QV activities for the assembly of the reactor vessel module at the manufacturing licensee's fabrication facility. An FFD program under § 26.605 is commensurate with the risk of a reactor facility licensed under Part 53 that uses plant technologies, engineered features, and controls that are applied in an integrated defense-in-depth manner to provide reasonable assurance that the facility construction and operation would not result in radiological consequences inimical to public health or safety. Such a facility presents a risk profile much lower than that of a traditional commercial light water reactor power plant. For example, advanced reactors would meet (1) the safety criteria of §§ 53.210 and 53.220, (2) the safety functions of § 53.230, (3) the requirements associated with defense in depth, as described under § 53.250, and (4) the analysis of licensing basis events in accordance with § 53.450. These facilities may also use SSCs that function through inherent characteristics or have engineered protections against human failures (e.g., system misalignments). Meeting these licensing and design requirements provides assurance that a reactor licensed under Part 53 presents a radiological risk that enables the establishment of an objective, risk-informed, and performance-based FFD regulatory framework that was developed from the existing FFD program requirements detailed in subpart K of Part 26. Paragraphs (a)(1) - (3) establish the FFD program requirements during construction and decommissioning. As mentioned above, the requirements listed on this

	paragraph are based on the current requirements in subpart K, FFD Program for Construction. Similar to the requirements in § 26.604, the Part 53 licensee implementing this section must be subject to the minimum requirements needed to make Part 26 applicable to a Part 53 licensee, establish the regulatory framework, protect workers, and support NRC licensing and oversight.
(b) Licensees and other entities implementing § 26.604, at their discretion, and licensees and other entities that implement an FFD program under this subpart, before the loading of fuel onsite into a reactor vessel; before receiving a reactor vessel module loaded with fuel; or before operating, testing, performing maintenance of, or directing the maintenance or surveillance of security-related equipment or equipment that a risk-informed evaluation process has shown to be significant to public health and safety, shall establish, implement, and maintain an FFD program that— (1) applies to those individuals described in § 26.602, as applicable. (2) implements the program elements and requirements described in § 26.603(a)-(e); and (3) Implements the following requirements and subparts— (i) § 26.23, Performance objectives (ii) § 26.606, Written policy and procedures (iii) § 26.607, Drug and alcohol testing (iv) § 26.608, FFD program training (v) § 26.609, Behavioral observation (vi) § 26.611, Protection of information (vii) § 26.613, Review process (viii) § 26.615, Audits (ix) Subpart A—Administrative Provisions	Paragraph (b) - An FFD program under § 26.605(b) is based on the risk presented by the facility as the licensee readies it for commercial nuclear power plant operation. These requirements must be implemented immediately before “operation” (i.e., a consequential change in reactor core reactivity) and other significant activities that affect the design, operation, or maintenance of the licensed facility. This operational milestone is similar to that of initial core loading currently used in, for example, §§ 50.54(a)(1), 50.55a(f)(4)(i), 50.71(h)(1), 50.120, Part 50 appendix E, 52.99(a) and (c), 52.103(a) and (e). At this operational milestone, the Part 53 licensee must implement an FFD program that (1) provides assurance that the facility would be operated and maintained in a manner in which it was designed and licensed and (2) implements regulatory requirements that seamlessly integrate the FFD program with the rest of the commercial nuclear industry regarding, in part, FFD policy violations, sanctions, authorization determinations, fatigue management, records, and reports. This assurance is obtained by requiring the implementation of subparts C, D, H, I, and N. Additional language is being included among the requirements in Paragraph (b) to apply FFD controls (including fatigue management) to individuals who may be

(x) Subpart C—Granting and Maintaining Authorization (xi) Subpart D—Management Actions and Sanctions to be Imposed (xii) Subpart H—Determining Fitness-for-Duty Policy Violations and Determining Fitness (xiii) Subpart I—Fatigue Management (xiv) Subpart N—Recordkeeping and Reporting Requirements (xiv) Subpart O—Inspections, Violations, and Penalties.	loading fuel into a pre-fabricated module at an offsite facility. Also, similar to Paragraph 26.4(a)(6), additional language is included in these requirements to address FFD needs in instances where individuals, likely at an offsite facility, would be installing components into a pre-fabricated nuclear reactor module, and where those component are located such that the licensee would be unable to perform inspection, test, analysis, and acceptance criteria (ITAAC) examination or otherwise to identify potential latent human error in installation. The NRC staff finds that certain passive SSCs (for example, a component – such as a fusible link – internal to the reactor module designed to melt at a particular temperature setpoint to trigger an actuation mechanism) could be included in a design in such a way that those components are relied upon for safe operation but cannot be inspected for proper installation, configuration, or operation after-the-fact. In such instances, the safety-significance of correctly-performed installation could warrant the application of FFD requirements on the individual(s) performing the installation of such a component.
§ 26.606 Written policy and procedures. (a) Licensees and other entities that implement an FFD program under this subpart shall ensure that— (1) A written FFD policy statement is provided to each individual who is subject to the program before the individual is subject to behavioral observation and/or drug and alcohol testing under this part.	Section 26.606 is based on § 26.403, “Written policy and procedures.” Paragraph (a)(1) - This requirement is based on § 26.403(a), except that the phrase “clear, concise” was removed because it is not defined. To enhance protections afforded to individuals a new requirement is also proposed that the policy must be provided to individuals before being subject to behavioral observation and any FFD program drug and alcohol test; this new requirement helps ensure that individuals know what is expected of them prior to being subject to the FFD program and possibly entering the NRC-licensed facility.

(2) The FFD policy statement describes the performance objectives in § 26.23.	Paragraph (a)(2) - This requirement is proposed to help ensure that the FFD programs of all licensees required to meet in Part 26 have the same performance objectives.
(3) The FFD policy statement must be written in sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy, including those elements described in paragraph (b) of this section, Part 26-required sanctions, and required medical/clinical treatment and follow-up testing for FFD policy violations.	Paragraph (a)(3) - This requirement is based on § 26.403(a), with additional clarity provided on what the policy statement must include. This protects the worker and enhances consistency.
(b) Licensees and other entities shall establish, implement, and maintain written procedures that address the following topics:	Paragraph (b) - This requirement is based on § 26.403(b). Minor changes were made to apply to a Part 53 FFD program.
(1) If implementing a drug and alcohol testing program under this subpart, (i) the methods and techniques to be used in collecting, testing, shipping, and temporarily storing biological specimens for drugs and alcohol testing, and (ii) procedures for protecting the privacy of an individual who provides a specimen, protecting the integrity of the specimen, and ensuring that the test results are valid and attributable to the correct individual.	Paragraph (b)(1) - This requirement is based § 26.403(b)(1) to clarify program processes (e.g., collecting, testing, shipping, and temporary storage of biological specimens) that licensees and other entities must detail in its procedures because alternative testing methods are enabled by subpart M.
(2) The immediate and followup actions that will be taken, and the procedures to be used, in those cases in which individuals who are subject to the FFD program:	Paragraph (b)(2) - This requirement is based on § 26.403(b)(2) and helps ensure the effectiveness of the FFD program and its consistent implementation. It also helps inform individuals subject to Part 26 of FFD program requirements.
(i) Have been involved in the use, sale, or possession of illegal or illicit substances;	Paragraph (b)(2)(i) is based on § 26.403(b)(2)(i) except that the phrase “illicit substances” was added to include individuals who use, sell, or possess legal substances in a manner inconsistent with federal or state law, or can cause impairment while at the NRC-licensed facility.

(ii) Are impaired by any substance or the consumption of alcohol as determined by behavioral observation or a test that measures blood alcohol concentration;	Paragraph (b)(2)(ii) is based on § 26.403(b)(2)(ii) except that it was revised to remove the phrases "to excess." and "accurately," because these phrases are not defined. Alcohol impairment can be determined by behavioral observation and by whether the individual's BAC meets or exceeds the alcohol limits in §§ 26.99, 26.101, and 26.103. The phrase "by any substance" was added based on operating experience. The phrase "before or while constructing or directing construction" was removed because § 26.606 applies during construction, operation, and decommissioning. The term "behavioral observation" was added because impairment can be visibly or audibly observed in an individual and individuals are trained in behavioral observation. The behavioral observation program requirement is provided in § 26.609, with training requirement provided in § 26.608.
(iii) If drug and alcohol testing is conducted, attempted to subvert the testing process by adulterating or diluting specimens (in vivo or in vitro), substituting specimens, or by any other means;	Paragraphs (b)(2)(iii) is based on § 26.403(b)(2)(iii), except the phrase "if drug and alcohol testing is conducted" was added to address the licensee who implements § 26.604.
(iv) If drug and alcohol testing is conducted, refused to provide a specimen for analysis or follow instructions provided by FFD program personnel;	Paragraph (b)(2)(iv) is based on § 26.403(b)(2)(iv), except the phrase "or follow the instructions provided by FFD program personnel" which is based on § 26.89(c) and the phrase "if drug and alcohol testing is conducted" were added to address the licensee who implements § 26.604.
(v) Had legal action taken relating to drug or alcohol use; or	Paragraphs (b)(2)(v) is based on § 26.403(b)(2)(v).
(vi) Demonstrated character or actions indicating that the individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities or sensitive information.	Paragraph (b)(2)(vi) is proposed to gather information for the insider threat program. This also helps to align the Part 26 behavioral observation program with the behavioral observation program implemented under proposed Part 53 requirement § 73.120.

(3) The process to be followed if an individual's behavior or condition raises a concern regarding: the possible use, sale, or possession of illegal drugs on or off site; the possible use or possession of alcohol on the NRC-licensed facility; impairment from any cause which in any way could adversely affect the individual's ability to safely and competently perform his or her duties; or the receipt of credible information indicating that the individual cannot be trusted or relied on to perform those duties and responsibilities making the individual subject to this part.	Paragraph (b)(3) - This requirement is based on § 26.403(b)(3) and is designed to help ensure that when individuals may be in violation of the FFD policy, they are removed from the duties and responsibilities making them subject to Part 26. The § 26.403(b)(3) phrase "while constructing or directing the construction of safety- or security-related SSCs" was replaced with "on the NRC-licensed facility" because this provision applies during construction and operation and this would apply to holders of an NRC manufacturing license. The requirement regarding credible information is proposed to help address the insider threat.
§ 26.607 Drug and alcohol testing. (a)(1) To provide means to deter and detect substance abuse, licensees and other entities implementing § 26.604, at their discretion, and licensees and other entities implementing § 26.605 shall perform drug and alcohol testing that complies with the following requirements— (2) Split specimen collections of oral fluid or urine must be used for the test conditions described in paragraph (b) of this section. A split specimen collection need not be used if the licensee or other entity elects to use a point of collection testing and assessment devise for a screening test conducted during random testing under § 26.605(b)(2) and (i). (b) Individuals identified in § 26.602 shall be subject to drug and alcohol testing under the following conditions: (1) *Pre- access*. Before performing or directing the conduct of roles and responsibilities making the individual subject to this subpart or being granted unescorted access to the protected area of the NRC-licensed facility;	Section 26.607(a) - These requirements are based on the requirements in § 26.405(a) and changes are proposed commensurate with the risk consequences presented by a Part 53 licensed facility. For § 26.607(a)(2), a split specimen need not be taken when using a point of collection testing and assessment device is use for a screening test conducted for random testing, because if the individual screens positive, invalid, dilute, adulterated, or substituted, the individual is subject to an immediate re-collection (i.e., another drug test) using a device approved for use for validity, if required, initial, and confirmatory drug testing at an HHS-certified laboratory. Paragraph (b) - These test conditions are based on § 26.405(c) with the except of the random testing provisions in § 26.607(b)(2) which are based on § 26.405(b). Paragraph (b)(1) - This requirement is based on § 26.405(c)(1); however it was revised to remove "construct or direct the construction of safety- or security-related SSCs" because for licensees or other entities under

	Part 53, the pre-assignment/access test condition applies to construction, operation, and decommissioning to help inform a licensee's or other entity of whether the individual can be trusted and relied upon to perform those duties and responsibilities making the individual subject to subpart M.
(2) *Random Testing*. Random testing for drugs and alcohol must—	Paragraph (b)(2) - This requirement is based on § 26.405(b). Random testing must be conducted by a licensee or other entity who does not meet the FFD criterion, and may be conducted at the licensee's discretion for those licensees and other entities that do meet the FFD criterion. This provision is different than that in § 26.405(b) because § 26.406, "Fitness monitoring" may not be performed in lieu of random testing for a Part 53 licensee.
(i) Be administered in a manner that provides reasonable assurance that individuals are unable to predict the time periods during which specimens will be collected;	Paragraph (b)(2)(i) - This requirement based on § 26.405(b)(1) helps ensure that individuals do not know when they would be subject to a random test.
(ii) Require individuals who are selected for random testing to report to the collection site as soon as reasonably practicable after notification, within the time period specified in the FFD program procedure;	Paragraph (b)(2)(ii) - This requirement based on § 26.405(b)(2) helps ensure that individuals would be subject to a timely test and that the test result would be a good indication of the drugs, drug metabolites, and alcohol concentration(s) in the individual with access to the NRC-licensed facility prior to the time of test.
(iii) Ensure that all individuals in the population that is subject to random testing on a given day have an equal probability of being selected and tested; and	Paragraph (b)(2)(iii) - This requirement based on § 26.405(b)(3) helps ensure that random testing is equally applied to all individuals.
(iv) Ensure that an individual completing a test is immediately eligible for another random test.	Paragraph (b)(2)(iv) - This requirement based on § 26.405(b)(4) helps ensure that there are no breaks in the random testing program providing an opportunity for the individual to illicitly use substances that may cause impairment.

(v) Ensure that the sampling process used to select individuals for random testing provides that the number of random tests performed annually is equal to at least 50 percent for licensee employees and 50 percent for contractor/vendors at the NRC-licensed site.	Paragraph (b)(2)(v) - This requirement is not in subpart K; the requirement is from § 26.31(d)(2)(vii) which establishes the random testing rate for the population of individuals subject to testing. Based on operating experience, a 50 percent random testing rate provides reasonable assurance of public health and safety and the common defense and security, by providing sufficient detection and deterrence. However, operating experience demonstrates that the contractor/vendor population is tested at rate lower than 50 percent, even though this population results in the majority of all FFD policy violations. Furthermore, the proposed framework enables the use of immunoassay point of collection testing and assessment (POCTA) devices for the conduct of random testing. In order to maintain program effectiveness (e.g., the detection and deterrent value of random testing does not substantially decrease with the use of a POCTA device) the random testing rates for both populations (licensee employees and contractor/vendors) must remain at or above 50 percent. The NRC staff has commenced a study to assess the effectiveness of a 50 percent random testing rate when there is a large transient worker population that may be onsite for only a short period of time. Information from this study would be used to inform proposed Paragraph (b)(2)(v).
(3) *For-cause*. In response to an individual's observed behavior or physical condition indicating possible substance abuse or after receiving credible information that an individual is engaging in substance abuse, as defined in § 26.5;	Paragraph (b)(3) - This for-cause testing requirement is equivalent to that used in current FFD programs implementing § 26.405(c)(2).
(4) *Post-accident*. (i) As soon as practical after an accident involving a human error that was committed by an individual specified in § 26.602, where the human error may have caused or contributed to the accident, the licensee or other entity shall test the individual(s)	Paragraph (b)(4) - This post-accident testing requirement is from § 26.405(c)(3). It is essentially equivalent to that used in current FFD programs. However, for Part 53 licensees, the staff proposes that the post-accident testing

who committed or directed the error(s). The licensee or other entity need not test individuals who were affected by the accident and whose actions likely did not cause or contribute to the accident. The licensee or other entity shall describe in its procedures what constitutes a human error and accident. (ii) A post-accident test shall be conducted within 4-hours of an accident unless immediate medical intervention precludes the conduct of the test, on the individual(s) who caused or contributed to the accident if the accident results in—	language be amended to clearly require testing under two conditions: sub-paragraph (i) human errors that result in accidents and sub-paragraph (ii) accidents that result in adverse health consequences. Editorial changes are also proposed (e.g., replace the word "event" with "accident"). The NRC proposes that the licensee or other entity define in its procedures the terms "human error" and "accident." Although this Part 26 requirement is based on an Occupational Safety and Health Administration (OSHA) provisions that enables post-incident drug testing (OSHA Memorandum, Kim Stille, Acting Director, Enforcement Programs, October 11, 2018, 29 CFR 1904.35(b)(1)(iv)), the reference to OSHA was removed based on operating experience learned from program implementation.
(A) An illness or personal injury to the individual(s) who caused or contributed to the event or another individual which 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 licensee- or other entity-designated 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; or	Paragraph (b)(4)(ii)(A) - This requirement is from § 26.405(c)(3)(i). The staff removed the word "significant" as used in "significant illness or personal injury" because the requirement describes what illnesses or injuries are covered.
(B) Damage to any safety- or security-related SSC.	Paragraph (b)(4)(ii)(B) - This requirement from § 26.405(c)(3)(ii) was changed based on operating experience to remove the word "significant" because this term is not defined; NRC may propose guidance on what constitutes "damage" or leave it to the licensee to define. Also, the term "construction" was removed because this provision applies during construction and operation. Note that § 26.5 defines safety-related SSCs and security-related SSCs, if these definitions change, then a conforming change may be provided to this requirement.

(iii) The conduct of a post-accident test for an accident involving human error, if conducted within 4 hours of the accident, satisfies the post-accident test requirement in paragraph (b)(4)(ii) of this section; and	Paragraph (b)(4)(iii) - This is a new requirement proposed to clearly state that the human error post-accident test (§ 26.607(b)(4)(i)) can meet the requirement for the conduct of a health consequence-based post-accident test (§ 26.607(b)(4)(ii)). Two tests on a particular individual for a single event should never be conducted.
(5) *Followup*. As part of a followup plan to verify an individual's continued abstinence from substance abuse.	Paragraph (b)(5) - This requirement is based on § 26.405(c)(4).
(c) At a minimum, the following requirements shall be met—	Paragraph (c) - This requirement is based on § 26.405(d) and ensures that drug testing is technology inclusive. Specifically, the provisions enable the use of alternative testing technologies.
(1) For the use of urine as the biological specimen to be tested, the following requirements shall be implemented— (i) § 26.115, Collecting a urine specimen under direct observation; § 26.119, Determining "shy" bladder; (ii) § 26.161, Cutoff levels for validity testing, and (iii) § 26.163, Cutoff levels for drugs and drug metabolites.	Paragraph (c)(1) - This requirement is based on § 26.405(d) but was modified to apply to directly reference the drugs, drug metabolites, and cutoffs that are applicable to NRC-licensees subject to Part 26. Instead of the general non-specific statement of drugs and drug metabolites in § 26.405(d). Section 26.607(c)(1) refers to § 26.161, Cutoff levels for validity testing, and § 26.163, Cutoff levels for drugs and drug metabolites, for validity testing and the specific drugs and drug metabolites for urine testing, respectively. Sections §§ 26.115 and 26.119 are required for program effectiveness and as a worker protection. On September 16, 2021, the NRC staff provided the Commission a draft Final Rule that recommends changes to Part 26 drug testing requirements. This draft Final Rule (RIN 3150-AI67; NRC-2009-0225; SECY-21-0082) can be viewed on the NRC's website at ADAMS Accession No. ML21111A017. If the Commission approves this Final Rule package, conforming changes may be necessary in the proposed FFD requirements for Part 53 licensees.

(2) For alcohol testing, the following requirements shall be implemented— (i) § 26.91, Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use; (ii) § 26.93, Preparing for alcohol testing; (iii) § 26.95, Conducting an initial test for alcohol using a breath specimen; (iv) § 26.97, Conducting an initial test for alcohol using a specimen of oral fluids; (v) § 26.99, Determining the need for a confirmatory test for alcohol; (vi) §26.101, Conducting a confirmatory test for alcohol; and, (vii) §26.103 Determining a confirmed positive test result for alcohol.	Paragraph (c)(2) - This ensures that the Part 53 licensee or other entity implements an alcohol testing program that is consistent with that implemented by other NRC licensees or other entities subject to Part 26. This is a program effectiveness and worker protection consideration.
(3) For all test conditions in paragraph (b) of this section and MRO-directed tests under § 26.185, drug testing must be performed at an HHS-certified laboratory for the specific biological specimen to be tested. Only HHS-certified laboratory test results using urine or oral fluid may be used for the issuance of a Part 26-required sanction. The licensee or other entity must establish and maintain a contract with a primary and back-up HHS-certified laboratory (with a different Certifying Scientist) for the specimen(s) to be tested.	Paragraph (c)(3) - This requirement is from § 26.405(f) but was modified to apply to facilities licensed under Part 53. For all current FFD programs, confirmatory drug testing must be performed at a laboratory certified by the U.S. Department of Health and Human Services; this too would be applied to Part 53 licensees. Wording is proposed to enable the testing of alternative biological specimens and to ensure that the licensee or other entity has a secondary (back-up) HHS-certified laboratory should additional testing be directed by the MRO or problems occur with the primary laboratory. The back-up laboratory may be of the same corporate entity but at a different location using a different Certifying Scientist. This is an operating experience lesson learned.
(d) Licensees and other entities may add drugs and drug metabolites to their panel of drugs and drug metabolites to be tested if the requirements in § 26.31(d)(1)(i) are met.	Paragraph (d) - This requirement is not from subpart K, but from subpart B, “Program Elements.” Similar to current FFD programs, this preliminary proposed requirement enables a Part 53 licensee or other entity to add or remove drugs or drug metabolites from its panel of drugs to be tested. This is important for two reasons.

	First, a licensee or other entity may desire to align with the HHS recommendation should HHS add a new drug to their recommended panel of drugs to be tested because it may improve FFD program effectiveness. Second, aligning with the HHS drug panel also benefits protections afforded to workers because HHS' National Laboratory Certification Program evaluation of the laboratory processes (and its blind performance testing program) would be those same processes used for a biological specimen submitted by the licensee or other entity drug. As currently proposed, should a licensee or other entity desire to add or remove a drug or drug metabolite from its panel of drugs, then it would implement the FFD change control process in §26.603(e); for these types of changes based on HHS recommendations, NRC review and approval would not be necessary.
(e) The specimen collection and drug and alcohol testing procedures of FFD programs under this subpart must protect the donor's privacy and the integrity of the specimen and implement quality controls to ensure that test results are valid and attributable to the correct individual.	Paragraph (e) - This requirement is from § 26.405(e), except the word "stringent" was removed from the phrase "stringent quality controls," because the word "stringent" is not defined.
(f) At the licensee's or other entity's discretion, specimen collections and alcohol testing may be conducted at a local hospital or other facility licensed and audited by the State (or State-designated entity) to conduct specimen collections and perform alcohol testing. The licensee or other entity shall audit these facilities, if used, on a biennial basis to provide reasonable assurance that the facility procedures are comparable to those described in subpart E of this part for urine and oral fluid. The licensee or other entity must establish measures to help prevent subversion of the drug and/or alcohol test onsite or offsite.	Paragraph (f) - Similar to paragraph (e) above, this requirement is from § 26.405(e), yet an audit requirement is proposed to ensure that the collection facility procedures are comparable to those in Part 26, subpart E, "Collecting Specimens for Testing," including the prevention of subversion attempts. This is a program effectiveness and worker protection consideration. The subpart K reference to the U.S. Department of Transportation drug and alcohol collection and testing requirements in 49 CFR Part 40 was removed based on operating experience.

(g) Any initial drug test performed by a licensee or other entity subject to this subpart must use an immunoassay, or a testing process implemented under the licensee's or other entity's change control process under § 26.603(e), that meets the requirements of the U.S. Food and Drug Administration (FDA) for commercial distribution. Specimens that yield positive, adulterated, substituted, or invalid initial validity or drug test results must be subject to confirmatory testing by the HHS-certified laboratory, certified for that biological specimen, except for invalid specimens that cannot be tested.	Paragraph (g) - This requirement is from § 26.405(f) and was modified for a facility licensed under Part 53 implementing an FFD program that may implement alternative biological specimen testing. For example, the phrase "or better testing process" enables a licensee to use its change control process in § 26.603(e) to evaluate and document a change to its collection and analysis procedures to enable the use of a better or perhaps more cost-effective collection and/or testing technology.
(h) If the licensee or other entity elects to use oral fluid for drug testing, the collection, packaging, temporary storage, and shipment of an oral fluid specimen to an HHS-certified laboratory must be performed in accordance with the instructions provided with the oral fluid collection kit or on the manufacturer's website. The kit must have received premarket approval from the FDA and must not expire before laboratory testing. All site processes shall be conducted by licensee- or other entity-designated FFD program personnel. The drugs, drug metabolites, and initial and confirmatory testing cutoffs shall be comparable to those established for urine testing in this part as determined by a documented forensic toxicologist review conducted pursuant to § 26.31(d)(1)(i)(D).	Paragraph (h) - A licensee or other entity implementing subpart K, FFD programs for construction, may implement a drug testing program using oral fluid. The paragraph (h) requirement enables a Part 53 licensee to use oral fluid as a biological specimen for testing. Also, oral fluid testing may currently be conducted under direction of an MRO as enabled in § 26.31(d)(5). HHS has issued guidelines on the use of oral fluid and urine as drug testing matrices and has determined that these test methods are comparable. These guidelines may be viewed at https://www.samhsa.gov/workplace/resources.
(i) *Point of collection testing and assessment*. (1) If the licensee or other entity elects to use a point of collection testing and assessment device, then it may only be used for random drug and/or alcohol testing using urine or oral fluid as the test specimen and only for screening. A forensic toxicologist must review and document their evaluation that the validity, accuracy, and precision of the device for alcohol and/or all the drugs and drug metabolites listed in §§ 26.161 and 26.163 is comparable to the performance achieved by initial testing conducted using a similar technology at an HHS-certified laboratory before its use. (2) If the performance of the point of collection testing and assessment device used for random testing is not comparable to that achieved from initial testing conducted by an HHS-certified laboratory	Paragraph (i)(1) – (3) - Under subpart K, a licensee or other entity is not precluded from using a point of collection testing and assessment (POCTA) device for initial drug and alcohol testing. Using the proposed framework, subpart M enables the use of POCTA for only oral fluid and urine specimens and only for random testing. This test methodology is acceptable because the individuals subject to testing have already been subject to pre-access/pre-assignment drug and alcohol testing and were evaluated by the licensee or other entity and found to be acceptable to perform those duties and responsibilities making them subject to Part 26. The confidence afforded by a licensee or other entity pre-

as determined by the forensic toxicologist, then the licensee or other entity must propose a mitigating strategy to maintain program effectiveness to the NRC and obtain NRC approval under § 26.603(e)(2) before its use.	access drug screening, hiring, and implementing NRC regulations to grant, restore, or maintain unescorted access to the NRC-licensed facility or sensitive information helps provide assurance that reasonable reductions in accuracy and precision of the POCTA device would not be averse to the overall effectiveness of the FFD program. Furthermore, the individual is required to take FFD training (§ 26.608) and is subject to behavioral observation (§ 26.609). The proposed requirements enable licensees and other entities to use POCTA devices if their evaluation demonstrates that its use does not reduce program effectiveness. The device would typically provide a visual indication (e.g., color or a highlighted line) to reveal whether a drug or drug metabolite exceeded its initial test cutoff as listed in § 26.163(a), or as found to be comparable by the § 26.603 change control process. Many devices also test for adulterants and subversion attempts and this would be required for the forensic toxicologist's assessment of comparable equivalency to the urine specimen drug testing program. It would be the licensee's or other entity's responsibility to demonstrate that its intended use of a POTCA device is comparable to testing conducted by an HHS-certified laboratory. A comparable analysis is considered acceptable because both test processes (point of collection testing device and initial testing at a laboratory) provide an indication (above a pre-established setpoint) whether the individual may possibly be impaired, may be using an illegal drug, may have a concentration of a drug or drug metabolite indicative of illicit use, or may indicate that the specimen is adulterated or subverted. From this initial test, if any initial test cutoff is exceeded, additional (i.e., confirmatory) testing is required at the HHS-certified

	laboratory under § 26.607(i)(3). A finding that the devise is comparable is also based on the fact that accuracy, precision, and repeatability are not requirements in Part 26 for any drug test.
(3) If the use of a point of collection testing and assessment device indicates a test result that exceeds the initial test cutoff and/or indicates that the specimen is invalid or the individual subverted the drug or alcohol test, the individual must be immediately removed from duties, responsibilities, and access making him/her subject to this subpart, and subject to an immediate drug/alcohol test using the alcohol testing process in paragraph (c)(2) of this section for a positive alcohol screen and either oral fluid or urine by a collection kit that is not a point of collection testing and assessment device for a positive drug, drug metabolite, adulterated, substituted, or invalid drug screen, that enables validity, if required, initial, and confirmatory testing by an HHS-certified laboratory.	Paragraph (i)(3) provides the immediate actions for the licensees and other entity to ensure that the individual is removed from all activities making him/her subject to the rule and is immediately subject to a drug test that provides quantified confirmatory test results from which an FFD policy violation may be issued. Paragraph (i)(3) also requires that if the individual screens position on a POTCA device, a second specimen must be obtained by the individual to facilitate validity (if required), initial, and confirmatory testing be conducted at an HHS certified laboratory.
(j) *Blood Testing*. The testing of blood specimens may only be conducted under the order of the licensee- or other entity-designated Medical Review Officer for a valid medical reason as confirmed by the Medical Review Officer pursuant to § 26.31(d)(5). This testing must be subject to testing by a laboratory that meets quality control requirements that are comparable to those required for certification by the HHS (e.g., a hospital certified by the State, Commonwealth, or territory).	Paragraph (j) - Using a blood specimen for drug testing is currently allowed in Part 26, but only for certain medical conditions as determined by the MRO, § 26.31(d)(5). However, the requirement is clarified to ensure that a licensee- or other entity-designated MRO is used and not one designated by a 3rd party. This MRO requirement is important because subpart M, like subpart K, enables the use of a hospital for the collection of biological specimen for drug and alcohol testing. A medical doctor or MRO, who is not familiar with Part 26 requirements, may not implement a review required by Part 26.
(k) *Custody and Control Form*. For the collection of urine and oral fluid specimens, the licensee and other entity must use a custody and control form approved by the U.S. Office of Management Budget. For the use of a point of collection testing and assessment device, the licensee or other entity shall implement a licensee or other entity approved and maintained procedure that ensures the reliability of the	Paragraph (k) - This requirement to use an Office of Management and Budget approved and valid federal custody and control form is based on current Part 26 requirements. Since subpart M enables the use of point of collection testing and assessment devices for random testing, the licensee or other entity must implement a

tracking, handling, and storage of a specimen from the point of specimen collection to final disposition of the specimen and the reliability of an identification system to uniquely assign the specimen to the donor.	process/procedure that ensures the specimen collected is uniquely assigned to the donor.
(l) *Medical Review Officer.* Licensees or other entities shall—	
(1) Require their designated Medical Review Officer (MRO) to review positive, adulterated, substituted, invalid, and dilute confirmatory drug and validity test results to determine whether the donor has violated the FFD policy for urine and oral fluid specimens. The review must be completed before reporting the results to the individual designated by the licensee or other entity to perform the suitability and fitness evaluations required under § 26.619, or, if required, that are described in subpart H of this part.	Paragraph (l)(1). This provision is based on § 26.405(g).
(2) Require their MRO to meet the requirements in § 26.183 and, prior to conducting any activities under this part, to attend and pass a medical- or clinical-based training session to improve his/her knowledge of MRO duties and responsibilities, drug and alcohol testing processes and procedures, and evaluation of drug testing results. This training session must be conducted by a nationally-recognized MRO training and certification organization that has been assessed by the NRC to include § 26.185 requirements. The MRO must also attend a medical- or clinical-based training session on a triennial basis to improve his/her knowledge of changes in drug and alcohol testing processes/procedures and evaluation of drug testing results.	Paragraph (l)(2) - This helps ensure that MRO reviews are consistent with those at other NRC-licensed facilities subject to Part 26 and that the MRO has and maintains knowledge of drug collection, testing and evaluation. This is necessary because of the flexibilities afforded to Part 53 licensees or other entities to collect, test, and assess alternative biological specimens for the presence of drugs or drug metabolites.
(3) Require their MRO to determine whether a biological specimen is positive, adulterated, substituted, invalid, or dilute by implementing the requirements in § 26.185. If § 26.185 is insufficient to make this determination, the guidance issued by State (in which the NRC-licensed facility resides) or Federal agencies or nationally recognized MRO training and certification organizations may be used to inform an MRO determination.	Paragraph (l)(3) - This helps ensure that MRO decisions are informed with appropriate regulatory requirements and medical- or clinically-based information. Section 26.185 is a requirement in Part 26, subpart H, that MROs must follow while assessing drug test results to ensure consistency, program effectiveness, and worker protection.
(4) Require their MRO to determine and approve the use of oral fluid or urine as an alternative biological specimen when the donor cannot provide a specimen for testing. This determination and the	

retest shall be completed as soon as reasonably practicable and documented. (m) *Limitations of testing*. Specimens collected under NRC regulations may only be designated or approved for testing as described in this part and may not be used to conduct any other analysis or test without the written permission of the donor. Analyses and tests that may not be conducted include, but are not limited to, DNA testing, serological typing, or any other medical or genetic test used for diagnostic or specimen identification purposes. No biological specimens may be collected and or tested in a manner different than described in this subpart.	Paragraph (m) - This requirement is based on § 26.31(d)(6) and is a worker protection consideration.
§ 26.608 FFD Program Training (a) *FFD Program Training.* (1) Individuals must be trained in the FFD policy and procedure and their FFD program responsibilities. These responsibilities include reporting for work, either on or offsite, in a physiological and psychological condition that enables the safe and competent performance of assigned duties and responsibilities and informing licensee- or other entity-designated individual when the individual determines that this cannot be accomplished. (2) FFD program training must include training on the behavioral observation program (BOP). The BOP training must include the detection of physiological or physiological behaviors or conditions that may indicate— (i) possible use, sale, or possession of illegal drugs or illicit drugs, or substance abuse on or off site; (ii) use or possession of alcohol on site or use while on duty off site; (iii) impairment from fatigue or any cause that, if left unattended, could result in inattentiveness or human errors; and	The preliminary proposed rule text for the FFD training program in subpart M does not use the prescriptive training requirements in § 26.29, "Training," and modeled on the framework presented in 10 CFR 50.120, "Training and qualification of nuclear power plant personnel." Paragraph (a)(1). The proposed text makes clear that the training shall include the individual's responsibility to not only report FFD concerns about others but to report for work fit for duty and to inform a licensee-or other-designated individual that he/she cannot or may not be able to safely and competently perform assigned duties and responsibilities. Paragraph (a)(2) - This proposed requirement is based, in part, on § 26.33, "Behavioral observation," and includes a training element and the security-related behavioral observation requirements in § 73.120. The inclusion of elements from § 26.33 and § 73.120 is necessary because § 26.608 applies during construction, operation, and decommissioning. The specific § 73.120 element is in § 26.608(a)(2)(iv) since drug and alcohol impairment could result in aberrant behavior or changes in behavior indicative of the individual not being trustworthy or reliable. The phrase "or illicit drug or substance abuse" is

(iv) an individual's inability to safely and competently perform assigned duties and responsibilities or act in a trustworthy and reliable manner while having access to protected areas, NRC-licensed material, or sensitive information. (3) Training must explain that an individual's FFD policy violation will— (i) subject the individual to an FFD program-required sanction designed to preclude recurrence of an FFD policy violation; (ii) contribute to the licensee's or other entity's assessment of whether the individual can be trusted and relied upon to safely and competently perform the assigned duties and responsibilities making him or her subject to this subpart; (iii) be used to inform the licensee's or other entity's access authorization and insider mitigation programs under Part 73, if applicable; and, (iv) be used to inform other NRC licensees and other entities subject to Part 26 when FFD program information is requested to support authorization determinations under Part 26, subpart C, or §§ 73.56 or 73.120. (b) *Training Periodicity*. Training must be conducted before pre-access/pre-assignment testing and refresher training must be conducted periodically. (c) *Training Review*. The FFD training program must be periodically evaluated and revised as appropriate to reflect industry experience as well as applicable changes to the regulations in this part and specimen collection and testing processes implemented by the licensee or other entity.	from operating experience that demonstrates individuals have reported to work under the influence of over-the-counter drugs or chemical substances that can cause impairment. Paragraph (a)(3) - This requirement helps ensure that individuals subject to the FFD program understand that FFD policy violations would result in an FFD program sanction and that program information learned or generated by FFD program implementation would be used to aid licensee or other entity authorization determinations and be shared, as requested, with other licensees or other entities subject to Parts 26 and 73. This requirement is therefore a worker protection consideration (because the worker would understand how FFD program information would be used) and a program effectiveness requirement because it helps ensure that Part 26 and 73 implementation by other licensees or other entities are informed with information on an individual's ability to follow licensee instructions and safely and competently perform assigned duties and responsibilities in a trustworthy and reliable manner. Paragraph (b) - This is a worker protection requirement. The periodicity is based on § 50.120, Training and qualification of nuclear power plant personnel." Paragraph (c) - The periodicity is based on § 50.120, "Training and qualification of nuclear power plant personnel."
§ 26.609 Behavioral observation. (a) Licensees and other entities shall ensure that the individuals who are subject to this subpart are subject to behavioral observation	Section 26.609 is based on the behavioral observation program (BOP) requirements in § 26.33 "Behavioral observation," but is provided for separately in subpart M because § 26.609 applies during construction, operation,

and that behavioral observation is performed by all individuals subject to this subpart. (b) Licensees and other entities shall require all individuals subject to the FFD program to report to the licensee- or other entity-designated official behaviors or activities by individuals subject to this part, that occur on or offsite, that may constitute an unreasonable risk to the safety or security of the NRC-licensed facility or materials or may cause harm to individuals. This reporting must include any information relating to character or reputation indicating that the observed individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities or sensitive information. (c) Behavioral observation shall be performed visually, in-person or remotely by video, to observe the behavior of individuals in the workforce subject to the requirements in this subpart, and to detect and promptly report to plant supervision aberrant behavior or changes in behavior that might adversely reflect on an individual's fitness or trustworthiness and reliability.	and decommissioning for all licensee's and other entities subject to subpart M. The principle behavioral observation requirement is to observe individuals, and report if human performance concerns are identified and this is an element in §§ 26.33 and 26.407. Additionally, paragraph (c) includes elements from the behavioral observation program required by the access authorization program described in § 73.120. Section 26.33 use of the phrase "FFD concerns" was replaced with "behaviors or activities, on or offsite, that may constitute an unreasonable risk to the safety and security of the licensee's facility, including character or reputation indicating that the observed individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities or sensitive information." The NRC staff intends to propose regulatory guidance for behavioral observation that would include examples of behaviors, activities, character, or reputation that should be reported to license- or other entity-designated persons. These examples may include, but are not limited to: sale, use, or possession of illegal drugs; threats to cause harm to facilities or people; threats to aid or abet a threat to the facility, people, NRC-licensed material, or sensitive information.
§ 26.610 Sanctions. Licensees and other entities that implement an FFD program under this subpart shall establish sanctions for FFD policy violations that, at a minimum, prohibit the individuals specified in § 26.602 from being assigned to perform or direct those duties and responsibilities making them applicable to this subpart. The severity of the sanction must escalate with the number of occurrences and severity of the FFD policy violation, with a permanent denial of access to the NRC-	Section 26.610 is based on § 26.409, "Sanctions." The wording was modified to align with the Part 53 FFD program. For example, the phrase "unless or until the licensee or other entity determines that the individual's condition or behavior does not pose a potential risk to public health and safety or the common defense and security," was removed because a sanction must be administered for an FFD policy violation to help deter future FFD policy violations (i.e., positive drug tests,

licensed facility for three FFD policy violations or any subversion attempt.	subversions, and impairment while working at the NRC-licensed facility) and a sanction facilitates counseling, training, rehabilitation, and/or treatment prior to the licensee reinstating the individual's access to the facility. The last sentence states that the sanction must account for the severity of the FFD policy violation (this is partly based on § 26.75(b) and (c)) and the number of FFD policy violations (this is partly based on § 26.75(e)(1) and (2) and (g).
§ 26.611 Protection of information. (a) Licensees and other entities that collect personal information about an individual for the purpose of complying with this subpart shall establish and maintain a system of files and procedures to protect the personal information. (b) Licensees and other entities shall obtain a signed consent that documents the individual's acceptance of being subject to the FFD program and authorizes the disclosure of the personal information collected and maintained under this subpart, except for disclosures to the individuals and entities specified in § 26.37(b)(1) through (b)(6), (b)(8), and persons deciding matters under review in § 26.613. This signed and dated consent shall be obtained before making the individual subject to the FFD program.	Paragraph 26.611(a) is based on § 26.411, "Protection of information." The phrase "FFD programs must maintain and use such records with the "highest regard for individual privacy," was removed because the term "highest regard for individual privacy" is not defined. Paragraph (b) - This requires that the consent-to-test shall be signed by the individual before making him or her subject to the FFD program. This proposal is to enhance an individual's knowledge of why he or she is being tested and what the drug and alcohol testing information would be used for by the licensee or other entity before the Part 26-required test. This is a worker protection enhancement.
§ 26.613 Review process. Licensees and other entities that implement an FFD program under this subpart shall establish and implement procedures for the review of a determination that an individual in § 26.602 has violated the FFD policy. The procedure must provide for an objective and impartial review of the facts related to the determination that the individual has violated the FFD policy.	Section 26.613 is based on the requirements in subpart K, § 26.413, "Review process." The wording was modified to align with the Part 53 FFD program. The phrase "review process" is consistent with that of an "appeals process."
§ 26.615 Audits (a) Licensees and other entities that implement an FFD program under this subpart shall ensure that audits are performed to ensure the continuing effectiveness of the FFD program, including FFD	Section 26.615 is based on § 26.415, "Audits."

program elements that are provided by C/Vs, and the FFD programs of C/Vs that are accepted by the licensee or other entity. (b) Each licensee and other entity shall ensure that FFD program elements that are not part of the FFD program performance and monitoring review described in § 26.603(d) are audited at a frequency that ensures their continuing effectiveness and that corrective actions are taken to resolve any problems identified. The subject matter, scope, and frequency of audits must be revised as necessary to improve or maintain program performance based on findings resulting from licensee or other entity implementation of its FFD performance monitoring and review program in § 26.603(d). (c) Licensees and entities may conduct joint audits or accept audits of C/Vs so long as the audit addresses the relevant C/Vs' services. (d) Licensees and other entities need not audit HHS-certified laboratories if their panel of drugs and drug metabolites to be tested is equivalent to that by which the laboratory is certified by HHS. Licensees and other entities shall audit any hospital or other facility licensed by the State (or State-designated entity) if used to conduct specimen collections and perform alcohol testing under this part on a biennial basis to provide reasonable assurance that the facility procedures are comparable to those described in subpart E, "Collecting Specimens for Testing," for urine and oral fluid, of this part.	Paragraph (b) - This would require licensee and other entities to revise their audit program based on the results of its FFD performance monitoring program. A non-prescriptive and performance-based audit program that would be implemented to supplement the FFD performance monitoring requirement is consistent with NRC generic efforts to establish performance-based and risk-informed regulatory requirements. For comparison purposes only, the NRC staff notes that Part 50 requires auditing four times: twice for security plans in §§ 50.34(c)(3) and 50.54(p)(4) and then in Criteria XVII and XVIII of Part 50, Appendix B, quality assurance program requirements. Paragraph (c) - This requirement is based on § 26.415(b). Paragraph (d) - This requirement is based on § 26.415(c); however, it was revised to remove its reference to 49 CFR Part 40, "Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs" (65 FR 41944; August 9, 2001) and to align with the Part 53 FFD program. Additionally, an audit requirement is proposed to ensure that collection facility procedures are comparable to that required in Part 26.
§ 26.617 Recordkeeping and reporting (a) Licensees and other entities that implement FFD programs under this subpart shall ensure that records pertaining to the administration of the program, which may be stored and archived electronically, are maintained so that they are available for NRC inspection purposes and for any legal proceedings resulting from the	Section 26.617 is based on the requirements in § 26.417, "Recordkeeping and reporting." However, if the Part 53 facility operates under an FFD program described in § 26.605, the licensee must implement subpart N—Recordkeeping and Reporting Requirements, which would align with the requirements placed on other licensees and

administration of the program. FFD performance data required by § 26.617 shall be retained until license termination. (b) Licensees and other entities shall make the following reports: (1) Reports to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers any intentional act that casts doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals who are subject to this subpart. These events must be reported under this subpart, rather than under the provisions of § 73.71; and (2) Annual program performance reports for the FFD program, including the FFD program performance data listed in § 26.717(b), as applicable. Licensees and other entities shall submit FFD program performance data (for January through December) to the NRC annually, before March 1 of the following year and shall use NRC Forms 890, Single Positive Test Form, and 891, Annual Reporting for Drug and Alcohol Tests.	other entities subject to Part 26, namely those facilities licensed under Parts 50, 52, and 70. This is necessary to support consistent FFD program performance assessments by licensees, NRC oversight, and NRC-required authorization requirements. Paragraph (b)(1) - This requirement parallels the reporting requirements in § 26.417, "Recordkeeping and reporting." The wording was modified to align with a Part 53 FFD program. Paragraph (b)(2). This paragraph is based on the annual program performance requirement in § 26.417, "Recordkeeping and reporting." However, the requirement was modified to apply to the Part 53 FFD program and to clarify the reporting period and milestone. A new requirement is proposed that licensees must use the NRC electronic reporting forms. This is necessary to account for the flexibilities in drug testing afforded to Part 53 licensees and to ensure consistent operating experience data in the advance reactor, Category I fuel cycle facility, and existing light water reactor communities. Operating experience has demonstrated that 100 percent of all current licensees subject to Part 26 use the NRC's forms and its electronic reporting system to annually report FFD performance data to the NRC. The use of this system informs licensee audits and correctives and represent a low burden to complete, store, and submit. Use of the forms should also enhance the subpart M FFD performance monitoring program, and NRC oversight because it aids consistency and clarity of reported data. The NRC staff finds that the use of Form 891, Annual

(c) Licensees and other entities subject to this subpart shall describe in sufficient detail an individual's FFD policy violation (while protecting privacy information under § 26.611) and FFD program weakness to NRC licensees and other entities subject to Part 26 when requested to support authorization determinations under with Part 26, Subpart C, or § 73.56, or to support licensee or other entity performance monitoring.	Reporting Form for Drugs and Alcohol, should also aid the licensee's biennial FFD program performance review required by § 26.603(b)(3) because much of the data on this form is applicable to a performance monitoring program. Paragraph (c) - This requirement helps ensure that FFD-related information is shared within the commercial nuclear industry. This helps ensure that individuals who become employed by another NRC-licensed facility subject to FFD (10 CFR Part 26, subpart C) and access (10 CFR 73.56) authorization requirements complete their licensee-administered NRC-required sanctions and implementation of drug and/or alcohol abuse treatment plans before the restoration of authorization.
§ 26.619 Suitability and fitness determinations Licensees and other entities that implement FFD programs under this subpart shall develop, implement, and maintain procedures for evaluating whether to assign individuals to perform or direct those duties and responsibilities making them subject to this subpart. These procedures must provide reasonable assurance that the individuals are fit to safely and competently perform their duties, and are trustworthy and reliable, as demonstrated by the avoidance of substance abuse.	Section 26.619 is based on § 26.419, "Suitability and fitness determinations."
NOTE: The proposed amendments in the following sections are conforming and enable Part 53 FFD programs.	
Subpart B — Program Elements	
§ 26.21 Fitness-for-duty program. (a) The licensees and other entities specified in § 26.3(a) through (c) shall establish, implement, and maintain FFD […] (b) The licensees and other entities specified in § 26.3(f) that do not implement the requirements in subpart M, shall implement the requirements in this subpart.	This section is amended to apply to licensees and other entities described § 26.3(f) should they chose to implement an FFD program that implements all Part 26 requirements, except those in subpart M. Also, the applicability statement is proposed to be split into two smaller paragraphs for clarity.
Subpart C — Granting and Maintaining Authorization	
§ 26.51 Applicability	This section is amended to apply to licensees and other entities described § 26.3(f). Also, the applicability

(a) The requirements in this subpart apply to the licensees and other entities identified in § 26.3(a), (b), and, as applicable, (c) for the categories of individuals in § 26.4(a) through (d), and, at the licensee's or other entity's discretion, in § 26.4(g) and, if necessary, § 26.4(j) . . . (b) The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) for the categories of individuals in § 26.602 that elect not to implement the requirements in subpart M and those licensees and other entities that elect to implement the requirements in § 26.605.	statement is proposed to be split into two smaller paragraphs for clarity.
§ 26.53 General provisions. …… (e) Licensees and other entities in § 26.3(a) through (c), and, if applicable, (f) may also rely on a C/V's FFD program […] (1) A C/V's FFD program may grant and maintain an individual's authorization, as defined in § 26.5, under the C/V's FFD program. However, only a licensee or other entity in § 26.3(a) through (c), and if applicable, (f) may grant or maintain […] (3) If an individual is maintaining authorization under a C/V's FFD program, a licensee or other entity in § 26.3(a) through (c), and if applicable, (f) may grant authorization […] (g) The licensees and other entities specified in § 26.3(a) and, as applicable, (c), ~~and~~ (d), and (f) shall identify any violation […] (h) The licensees and other entities specified in § 26.3(a) and, as applicable, (c), ~~and~~ (d), and (f) […] (i) The licensees and other entities specified in § 26.3(a) and, as applicable, (c), ~~and~~ (d), and (f) shall inform, in writing, any individual who is applying for […]	Section 26.53(e) and (e)(1) and (3), (g) – (i) are amended to apply to licensees and other entities described § 26.3(f).
§ 26.63 Suitable inquiry …… (d) When any licensee or other entity in § 26.3(a) through (d), and, if applicable, (f) is legitimately seeking the information […]	This section is amended to apply to licensees and other entities described § 26.3(f).

Subpart D—Management Actions and Sanctions To Be Imposed	
§ 26.73 Applicability. (a) The requirements in this subpart apply to the licensees and other entities identified in § 26.3(a), (b), and, as applicable, (c) for the categories of individuals specified in § 26.4(a) through (d) and (g) […] (b) The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) for the categories of individuals in § 26.602 that elect not to implement the requirements in subpart M and those licensees and other entities that elect to implement the requirements in § 26.605.	This section is amended to apply to licensees and other entities described § 26.3(f). Also, the applicability statement is proposed to be split into two smaller paragraphs for clarity.
Subpart E—Collecting Specimens for Testing	
§ 26.81 Purpose and applicability. (a) This subpart contains requirements for collecting specimens for drug testing and conducting alcohol tests by or on behalf of the licensees and other entities in § 26.3(a) through (d) for the categories of individuals specified in § 26.4(a) through (d) and (g) […] (b) The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) for the categories of individuals in § 26.602 that elect not to implement the requirements in subpart M and those licensees and other entities that elect to implement the requirements in § 26.605.	This section is amended to apply to licensees and other entities described § 26.3(f). Also, the applicability statement is proposed to be split into two smaller paragraphs for clarity.
Subpart I—Managing Fatigue	
§ 26.201 Applicability. (a) The requirements in this subpart, with the exception of § 26.202, apply to the licensees and other entities identified in § 26.3(a); if applicable, (c) and (d); and (f), for licensees and other entities not implementing the requirements in subpart M. For these licensees and other entities, the requirements in §§ 26.203 and 26.211 apply to the individuals identified in § 26.4 (a) through (c). In addition, the requirements in § 26.205 through § 26.209 apply to the individuals identified in § 26.4(a). (b) The requirements in this subpart, with the exception of § 26.203, apply to the licensees or other entities identified in § 26.3(f) implementing this subpart in accordance with § 26.605. For these licensees and other entities, the requirements in §§ 26.202 and	This section is amended to apply to licensees and other entities described § 26.3(f). Also, the applicability statement is proposed to be split into two smaller paragraphs for clarity.

26.211 apply to the individuals identified in § 26.4 (a) through (c) and, as applicable, any Certified Operator; and the requirements in § 26.205 through § 26.209 apply to the individuals identified in § 26.4(a).	
§ 26.202 General provisions for acilities licensed under Part 53 (a) *Policy*. Licensees shall establish a policy for the management of fatigue for all individuals who are subject to the licensee's FFD program and incorporate it into the written policy required in § 26.606(a). (b) *Procedures*. In addition to the procedures required in § 26.606(b), licensees shall develop, implement, and maintain procedures that— (1) Describe the process to be followed when any individual identified in § 26.4(a) through (c) makes a self-declaration that he or she is not fit to safely and competently perform his or her duties for any part of a working tour as a result of fatigue. The procedure must— (i) Describe the individual's and licensee's rights and responsibilities related to self-declaration; (ii) Describe requirements for establishing controls and conditions under which an individual may be permitted or required to perform work after that individual declares that he or she is not fit due to fatigue; and (iii) Describe the process to be followed if the individual disagrees with the results of a fatigue assessment that is required under § 26.211(a)(2); (2) Describe the process for implementing the controls required under § 26.205 for the individuals who are performing the duties listed in § 26.4(a); (3) Describe the process to be followed in conducting fatigue assessments under § 26.211; and (4) Describe the disciplinary actions that the licensee may impose on an individual following a fatigue assessment, and the conditions and considerations for taking those disciplinary actions. (c) *Training and examinations*. Licensees shall add the following KAs to the content of the training that is required in § 26.608:	This section is based on § 26.203, "General provisions," as applied to licensees or other entities described in § 26.3(f). The amendments to the requirements are proposed because the § 26.203 general provisions refer to various requirements (26.2X, 26.3X, or 26.4X, under subpart B of Part 26), which would not be applicable to facilities licensed under Part 53 that implement subpart M, given that the new requirements in subpart M replace the subpart B requirements applied to sites licensed under Part 50 and Part 52. The proposed requirements in Section 26.202 are essentially identical to the existing provisions listed in § 26.203, with the exception of the revised references to account for the newly developed sections in subpart M. This approach would also allow the NRC to reconsider/revise general provisions for facilities licensed under Part 53, as appropriate, based on feedback received during the period when we are receiving input/comment period from public stakeholders. Paragraph (c) - The staff proposed to not include a comprehensive training requirement for licensees and

(1) Knowledge of the contributors to worker fatigue, circadian variations in alertness and performance, indications and risk factors for common sleep disorders, shiftwork strategies for obtaining adequate rest, and the effective use of fatigue countermeasures; and (2) Ability to identify symptoms of worker fatigue and contributors to decreased alertness in the workplace. (d) *Recordkeeping*. Licensees shall retain the following records for at least 3 years or until the completion of all related legal proceedings, whichever is later: (1) Records of work hours for individuals who are subject to the work hour controls in § 26.205; (2) For licensees implementing the requirements of § 26.205(d)(3), records of shift schedules and shift cycles, or, for licensees implementing the requirements of § 26.205(d)(7), records of shift schedules and records showing the beginning and end times and dates of all averaging periods, of individuals who are subject to the work hour controls in § 26.205; (3) The documentation of waivers that is required in § 26.207(a)(4), including the bases for granting the waivers; (4) The documentation of work hour reviews that is required in § 26.205(e)(3) and (e)(4); and (5) The documentation of fatigue assessments that is required in § 26.211(g). (e) *Reporting*. Licensees shall include the following information in a standard format in the annual FFD program performance report required under § 26.617: (1) A summary for each nuclear power plant site of all instances during the previous calendar year when the licensee waived one or more of the work hour controls specified in § 26.205(d)(1) through (d)(5)(i) and (d)(7) for individuals described in § 26.4(a). The summary must include only those waivers under which work was performed. If it was necessary to waive more than one work hour control during any single extended work period, the summary of instances must include each of the work hour controls that were waived during the period. For each category of individuals specified in § 26.4(a), the licensee shall report:	other entities described in § 26.3(f).

(i) The number of instances when each applicable work hour control specified in § 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), (d)(3)(i) through (d)(3)(v), and (d)(7) was waived for individuals not working on outage activities; (ii) The number of instances when each applicable work hour control specified in § 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), (d)(3)(i) through (d)(3)(v), (d)(4) and (d)(5)(i), and (d)(7) was waived for individuals working on outage activities; and (iii) A summary that shows the distribution of waiver use among the individuals applicable within each category of individuals identified in § 26.4(a) (e.g., a table that shows the number of individuals who received only one waiver during the reporting period, the number of individuals who received a total of two waivers during the reporting period). (2) A summary of corrective actions, if any, resulting from the analyses of these data, including fatigue assessments. (f) *Audits*. Licensees shall audit the management of worker fatigue as required by § 26.615.	
§ 26.205 Work Hours …… (d) *Work hour controls*. Licensees shall control the work hours of individuals who are subject to this section. […] (7) Licensees may, as an alternative to complying with the minimum days off requirements in § 26.205(d)(3), comply with the requirements for maximum average work hours in this paragraph. […] (iii) Each licensee shall state, in its FFD policy and procedures required by § 26.27 ~~and~~ or § 26.606(a), in addition to § 26.203(a) and	Overall, the specific provisions for Work Hours requirements are not being changed. However, as addressed in the discussion of § 26.4(a) requirements above, whether or not a licensee under Part 26 would need to implement work hour controls would be dependent on determinations reached by that licensee's risk-informed evaluation process. (See discussion above for more details) Paragraphs (7) and (8) - The proposed revisions update the references, which currently refer to requirements under subpart B that would not be applicable to facilities licensed under Part 53, given that the new requirements in subpart M replace the subpart B requirements for facilities licensed under Part 53.

(b), the work hour counting system in § 26.205(d)(7)(ii) the licensee is using. […] (8) Each licensee shall state, in its FFD policy and procedures required by § 26.27 ~~and~~ or § 26.606(a), in addition to § 26.203(a) and (b), the requirements with which the licensee is complying: the minimum days off requirements in § 26.205(d)(3) or maximum average work hours requirements in § 26.205(d)(7). […]	
§ 26.207 Waivers and exceptions. (a) *Waivers*. Licensees may grant a waiver of one or more of the work hour controls in § 26.205(d)(1) through (d)(5)(i) and (d)(7), as follows: […] (1) To grant a waiver, the licensee shall meet both of the following requirements: […] (ii) A supervisor assesses the individual face to face and determines that there is 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 supervisor performing the assessment shall be trained as required by § 26.29 or § 26.608, ~~and~~ in addition to § 26.202(c) or 26.203(c), and shall be qualified [...]	The proposed revisions update the references, which currently refer to requirements under subpart B that would not be applicable to facilities licensed under Part 53, given that the new requirements in subpart M replace the subpart B requirements for facilities licensed under Part 53. Paragraph(a)(1)(ii) - The proposed revisions update the references, which currently refer to requirements under subpart B that would not be applicable to facilities licensed under Part 53, given that the new requirements in subpart M replace the subpart B requirements for facilities licensed under Part 53.
§ 26.211 Fatigue assessments. (a) Licensees shall ensure that fatigue assessments are conducted under the following conditions: (1) *For cause*. In addition to any other test or determination of fitness that may be required under §§ 26.31(c), ~~and~~ 26.77, and	The revisions proposed update the references, which currently point to requirements under subpart B that would not be applicable to facilities licensed under Part 53, given that the new requirements in subpart M replace the

26.607(c), a fatigue assessment must be conducted in response to an observed condition of impaired individual alertness creating a reasonable suspicion that an individual is not fit to safely and competently perform his or her duties […] (3) *Post-event*. A fatigue assessment must be conducted in response to events requiring post-event drug and alcohol testing as specified in § 26.31(c) or § 26.607(c). Licensees may not delay necessary medical treatment in order to conduct a fatigue assessment; and […] (b) Only supervisors and FFD program personnel who are trained under either §§ 26.29 and 26.203(c) or 26.608 and 26.202(c) may conduct a fatigue assessment. The fatigue assessment must be conducted face to face with the individual whose alertness may be impaired.	subpart B requirements for facilities licensed under Part 53.
Subpart N—Recordkeeping and Reporting Requirements	
§ 26.709 Applicability. (a) The requirements of this subpart apply to the FFD programs of licensees and other entities specified in § 26.3, except for FFD programs that are implemented under subpart K of this part. (b) The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) that elect not to implement the requirements in subpart M and those licensees and other entities that elect to implement the requirements detailed in § 26.605.	Section 26.709. This proposed change makes subpart N applicable to facilities licensed under Part 53.
§ 26.711 General provisions. ….. (c) The licensees and other entities specified in § 26.3(a) and, as applicable, (c), ~~and~~ (d), and (f) shall inform each individual […] (d) Licensees and other entities shall ensure that only correct and complete information about individuals [. . .] a licensee and other	Paragraphs (c) and (d) - These proposed changes make this section applicable to licensees or other entities described in § 26.3(f).

entity specified in § 26.3(a) and, as applicable, (c), ~~and~~ (d), and (f) who has discovered the incorrect information […]	