U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

13.7.1 FITNESS FOR DUTY − OPERATIONAL PROGRAM

REVIEW RESPONSIBILITIES

Primary- Organization responsible for the review of all Fitness for Duty programs

Secondary- Organization responsible for the review of Title 10 of the *Code of Federal Regulations* (10 CFR), Part 26, “Fitness for Duty Programs.” Subpart I, “Managing Fatigue”

This Standard Review Plan (SRP) applies to all licensees and entities as described in Section I of this SRP.

Table 1 of this SRP is a matrix aligning persons subject to an FFD program, the applicable 10 CFR Part 26 requirement, and the milestones when the requirement becomes effective. The table is helpful in describing the applicability of FFD program requirements as an applicant or licensee transitions from construction, under Subpart K, to operations, under Subparts A – I, N and O, including the initial loading of fuel. An operational licensee’s FFD program shall be implemented before the receipt of special nuclear material. Instead of following Subpart K, the applicant or licensee may also apply the full operational licensee FFD program, with the exception of Subpart I, to personnel who are constructing or directing the construction of safety-

or security-related structures, systems and components (SSCs) as explained in 10 CFR 26.4(f). Otherwise, the FFD program for construction is governed by Subpart K which is addressed in SRP Chapter 13.7.2**, "**Fitness for Duty – Construction."

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Note that where the term "applicant" is used, it refers to all licensees and entities as described in Section I of this SRP.

I. AREAS OF REVIEW

The specific areas of review in this SRP are applicable to the following licensees and entities:

1. All holders of operating licenses for nuclear power reactors issued under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," except those licensees that have certified that they have permanently ceased operations and that fuel has been permanently removed from the reactor vessel;

2. All holders of nuclear power plant construction permits (CPs) and early site permits (ESPs) with a limited work authorization (LWA) under the provisions of 10 CFR Part 50, and applicants for nuclear power plant CPs and ESPs that have an LWA;

3. All applicants for and holders of a combined license (COL) for a nuclear power plant issued under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants;"

4. All licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material under the provisions of 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material;"

5. Any entity that obtains a certificate of compliance or an approved compliance plan under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants," and engages in activities involving formula quantities of strategic special nuclear material; and,

6. All C/Vs who implement FFD programs or program elements to the extent that the licensees and other entities listed above rely on those C/V FFD programs or program elements to comply with 10 CFR Part 26.

The review will seek evidence that effective policies and procedures are adequately described to provide reasonable assurance that individuals are trustworthy and reliable as demonstrated by the avoidance of substance abuse and that individuals are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties. The reasonable measures for the early detection of individuals who are not fit to perform their duties and to keep workplaces free from the presence and effects of illegal drugs and alcohol will be based on a drug and alcohol testing and behavioral observation program (BOP).

This review also will seek evidence that effective policies and procedures are adequately described to manage fatigue. The applicant's FFD program must provide reasonable assurance that the effects of fatigue and degraded alertness on individuals' abilities to safely and

competently perform their duties are managed commensurate with maintaining public health and safety.

The specific areas of review are as follows:

1. Performance Objectives
2. Written Policy and Procedures
3. Training
4. Drug and Alcohol Testing
5. Behavioral Observation
6. Employee Assistance Programs (EAP)
7. Protection of Information
8. Review Process for Fitness-for-Duty Policy Violations
9. Audits and Corrective Action
10. Sanctions
11. Management Actions Regarding Possible Impairment
12. Managing Fatigue
13. Recordkeeping
14. Fitness-for-Duty Program Performance Data
15. Determining Fitness-for-Duty Policy Violations and Determining Fitness
16. Reporting Requirements
17. Granting and Maintaining Authorization
18. Licensee Testing Facilities (LTF)
19. Laboratories

Table 1 provides a matrix describing the applicability of FFD program requirements to certain individuals as an applicant or licensee transitions from construction to reactor operation.

Table 1 - FFD Program Applicability and Milestones

Item	Persons Subject to FFD Program	10 CFR Part 26 requirement	Milestone (e.g., timeline)	Applicable 10 CFR Part 26 Subparts
1	Construction (workers and first-line supervisors)	§ 26.4(f)	Prior to initiating 10 CFR Part 26 construction activities	Subpart K or Subparts A-H, N, and O
2	Construction (management and oversight personnel)	§ 26.4(e)(2) - (6)	Prior to initiating 10 CFR Part 26 construction activities	Subparts A-H, N, and O
3	Security Personnel	§ 26.4(e)(1)	Prior to fuel assemblies being received onsite	Subparts A-H, N, and O

Item	Persons Subject to FFD Program	10 CFR Part 26 requirement	Milestone (e.g., timeline)	Applicable 10 CFR Part 26 Subparts
		§ 26.4(a)(5)	Prior to the earlier of: A. Licensee's receipt of fuel assemblies onsite or B. Establishment of a protected area or C. The 10 CFR 52.103(g) finding	Subparts A-I, N, and O
4	FFD Program Personnel	§ 26.4(g)	Prior to initiating 10 CFR Part 26 construction activities	Subparts A, B, D-H, N, and O. (Subpart C is at the applicant's discretion)
5	Persons required to physically report to the technical support center or emergency operations facility	§ 26.4(c)	Prior to the conduct of the first full-participation emergency preparedness exercise under 10 CFR Part 50, Appendix E, Section F.2.a	Subparts A-I, N, and O, except for 10 CFR 26.205-209
6	FFD Operational Program Personnel	§ 26.4(a) and (b)	Prior to the earlier of: A. Licensee's receipt of fuel assemblies onsite or B. Establishment of a protected area or C. The 10 CFR 52.103(g) finding	10 CFR Part 26, Subparts A-I, N, and O, except for individuals listed in 10 CFR 26.4(b), who are not subject to 10 CFR 26.205-209

Notes:

1. For entities subject to Subpart K who desire to implement an operational licensee FFD program in lieu of 10 CFR Part 26, Subpart K, "FFD Programs for Construction," license conditions for the above milestones are not necessary

since the implementation requirements are described in 10 CFR Part 26. See staff requirements memorandum for SECY-05-0197, February 22, 2006 (ADAMS Accession No. ML060530316).

2. Operational Licensee Program Description and Implementation. For 10 CFR Part 50 and ESP applicants, description of the 10 CFR Part 26 FFD operational program is not required.

3. For COL reviews, the NRC staff will review the description of the operational program and proposed implementation milestone for the construction FFD program in accordance with 10 CFR 26.4, "FFD Program Applicability to Categories of Individuals," and Table 1, FFD Program Applicability and Milestones above.

Review Interface

Other SRP sections interface with this section as follows:

1. The review of the adequacy of the physical security plan performed under SRP Section 13.6.1, "Physical Security − Combined License and Operating Reactors" (ADAMS Accession No. ML102230082).

2. The review of administrative procedures performed under SRP Section 13.5.1.1, **"**Administrative Procedures – General" (ADAMS Accession No. ML112730402).

3. For COL reviews of operational programs, the review of the applicant's implementation plan is performed under SRP Section 13.4, "Operational Programs" (ADAMS Accession No. ML070470463).

The specific acceptance criteria and review procedures are contained in the referenced SRP section.

II. ACCEPTANCE CRITERIA

Requirements

The U.S. Nuclear Regulatory Commission (NRC) bases its acceptance criteria on the relevant requirements of 10 CFR Part 26, "Fitness for Duty Programs."

1. 10 CFR Part 26, Subpart A, "Administrative Provisions"

2. 10 CFR Part 26, Subpart B, "Program Elements"

3. 10 CFR Part 26, Subpart C, "Granting and Maintaining Authorization"

4. 10 CFR Part 26, Subpart D, "Management Actions and Sanctions To Be Imposed"

5. 10 CFR Part 26, Subpart E, "Collecting Specimens for Testing"

6. 10 CFR Part 26, Subpart F, “Licensee Testing Facilities”

7. 10 CFR Part 26, Subpart G, “Laboratories Certified by the Department of Health and Human Services”

8. 10 CFR Part 26, Subpart H, “Determining Fitness-for-Duty Policy Violations and Determining Fitness”

9. 10 CFR Part 26, Subpart I, “Managing Fatigue”

10. 10 CFR Part 26, Subpart N, “Recordkeeping and Reporting Requirements”

SRP Acceptance Criteria

Specific SRP acceptance criteria that meet the relevant requirements of the above regulations are listed below and should be used for the review described in this SRP section. The SRP is not a substitute for the NRC’s regulations and compliance with it is not required. However, the NRC requires, in 10 CFR 50.34(h)(3), 10 CFR 52.17(a)(1)(xii), and 10 CFR 52.79(a)(41), an applicant or an operating reactor licensee to identify differences between the design features, analytical techniques, and procedural measures proposed for its facility and the SRP acceptance criteria and to evaluate how the proposed alternatives to the SRP acceptance criteria provide acceptable methods of compliance with the NRC regulations.

Applicants should consider the guidance in Table 1 when preparing an application for a COL or ESP under 10 CFR Part 52 or an operating license, CP, or LWA under 10 CFR Part 50. These licensing documents for the FFD program and the conduct of licensee activities pursuant to 10 CFR Part 26 shall provide reasonable assurance that when the FFD program is implemented: (1) individuals are trustworthy and reliable as demonstrated by the avoidance of substance abuse; (2) individuals are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties; (3) measures are established and implemented for the early detection of individuals who are not fit to perform their duties; (4) the construction site is free from the presence and effects of illegal drugs and alcohol; (5) the workplaces are free from the presence and effects of illegal drugs and alcohol; and (6) the effects of fatigue and degraded alertness on individuals’ ability to safely and competently perform their duties are managed commensurate with maintaining public health and safety.

The SRP acceptance criteria are as follows:

1. 10 CFR Part 26, Subpart A - Administrative Provisions – The applicant should describe how it would implement administrative provisions described in this subpart for the establishment, implementation, and maintenance of its FFD program.

2. 10 CFR Part 26, Subpart B - Program Elements – The applicant should describe how it would establish, implement, and maintain an FFD program that includes the program elements contained in 10 CFR Part 26, Subpart B.

3. 10 CFR Part 26, Subpart C - Granting and Maintaining Authorization – An applicant should describe how it would ensure that the requirements in this subpart have been met

in order to grant an individual initial authorization, authorization update, authorization reinstatement, or authorization with potentially disqualifying FFD information, as applicable.

4. 10 CFR Part 26, Subpart D - Management Actions and Sanctions to be Imposed – The applicant should describe how it would, in part, implement the minimum sanctions described in this subpart or define its site-specific sanctions that exceed these minimum requirements when an individual has violated the drug and alcohol provisions of its FFD policy.

5. 10 CFR Part 26, Subpart E - Collecting Specimens for Testing – The applicant should describe how it would implement actions to meet the requirements for collecting specimens for drug and alcohol testing by or on behalf of the licensee or other entities in 10 CFR 26.3(a) through (d) for the categories of individuals specified in 10 CFR 26.4(a) through (d) and (g).

6. 10 CFR Part 26, Subpart F - Licensee Testing Facilities – The applicant should describe how each LTF would have the capability, at the same premises, to perform either validity screening tests or initial validity tests or both, and initial drug tests for each drug and drug metabolite for which testing is conducted.

7. 10 CFR Part 26, Subpart G - Laboratories Certified by the Department of Health and Human Services – Applicants who would be subject to this part should describe how they would use only laboratories certified under the most recent version of the U.S. Department of Health and Human Services' (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs for specimen validity and drug testing, except as permitted under 10 CFR 26.31(d)(3)(ii).

8. 10 CFR Part 26, Subpart H - Determining Fitness-for-Duty Policy Violations and Determining Fitness – The applicant should describe how it would implement the requirements of this subpart for determining whether a donor has violated the FFD policy and for making a determination of fitness.

9. 10 CFR Part 26, Subpart I - Managing Fatigue – The requirements in Subpart I, Sections 26.203 and 26.211 apply to the individuals identified in section 26.4(a) – (c). The requirements in Subpart I, Section 26.205 – 26.209 apply to the individuals identified in Section 26.4(a). A fatigue management policy should be incorporated into the written policy statement required in 10 CFR 26.27(b), and applicants should describe how they would develop, implement, and maintain procedures that are described in 10 CFR 26.203(b).

10. 10 CFR Part 26, Subpart N - Recordkeeping and Reporting Requirements – Each applicant should describe how it would maintain records and submit certain reports to the NRC as required by this subpart. Records that are required by the regulations in this part must be retained for the period specified by the appropriate regulation.

Technical Rationale

The following paragraphs contain the technical rationale for applying these acceptance criteria to the areas of review addressed by this SRP section:

1. 10 CFR Part 26 establishes the requirement that licensees and other applicable entities implement an FFD program to provide reasonable assurance that applicable personnel are fit for duty. This means that the subject personnel can safely and competently perform their duties because they are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, including fatigue.

2. Because most of the provisions of 10 CFR Part 26 are prescriptive, an applicant's description of its FFD program should reflect, and may reference, these provisions.

3. The technical basis for 10 CFR Part 26 is summarized in "Fitness for Duty Programs; Final Rule," pages 16970-17170 (73 FR 16966; March 31, 2008). This technical basis should assist and provide the technical rationale in the review of a licensee's discussion of its FFD program.

III. REVIEW PROCEDURES

The scope of the review of a COL application is dependent on whether the COL applicant references a DC, an ESP, an LWA, or other NRC approvals (e.g., manufacturing license).

The reviewer will select material from the procedures described below, as may be appropriate for a particular case. The reviewer verifies that the applicant's FFD program is adequately described.

For COL applicants, implementation of FFD programs will be inspected in accordance with NRC Inspection Manual Chapter (IMC)-2504, "Construction Inspection Program - Inspection of Construction and Operational Programs."

For operating reactor licensees, implementation of FFD programs will be inspected in accordance with NRC IMC-2201, "Security Inspection Program for Commercial Nuclear Power Reactors."

When conducting the review of the FFD program, the reviewer should determine whether the FFD program conforms to regulations, and address the guidance of Section I and the requirements of Section II.

Site-specific information will be reviewed and evaluated against the requirements of 10 CFR Part 26.

The FFD programs for those applicants at sites whose licensees already have an existing NRC-approved FFD program will be considered acceptable if the full operational program is applied to the applicable personnel as described in 10 CFR 26.4(f) (see Table 1 for more information). These applicants will need to provide a description of their intent to use the operating reactor plant licensee's FFD program at the construction site(s) and any site-specific program

considerations, such as deviations from the operating reactor plant FFD program. To be acceptable, this description should meet the requirements of 10 CFR 52.79(a)(44) and as discussed in Section I of this guidance.

Performance Objectives, 10 CFR 26.23

Each licensee and other applicable entity, per the requirements in 10 CFR 26.27(a), must establish, implement, and maintain written policies and procedures to meet the general performance objectives and applicable requirements of this part that:

a. Provide reasonable assurance that individuals are trustworthy and reliable as demonstrated by the avoidance of substance abuse;

b. Provide reasonable assurance that individuals are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;

c. Provide reasonable measures for the early detection of individuals who are not fit to perform the duties that require them to be subject to the FFD program;

d. Provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs and alcohol; and,

e. Provide reasonable assurance that the effects of fatigue and degraded alertness on individuals' abilities to safely and competently perform their duties are managed commensurate with maintaining public health and safety.

Written Policy and Procedures, 10 CFR 26.27 and 10 CFR 26.53

The reviewer should ensure that the applicant's description of its FFD program depicts a clear and concise written FFD policy statement that would be readily available, in its most current form, to all individuals who are subject to the program. The policy statement must explain what is expected of individuals subject to the program and the consequences for violating the policy. The policy statement must contain all the elements described in 10 CFR 26.27(b).

The applicant's description of its FFD program shall describe the written procedures that implement the FFD program during operations and as it transitions from construction to operations. The procedures must contain all the elements described in 10 CFR 26.27(c). The description should include, but not be limited to, procedures for implementing the drug testing program and the BOP, for determining fitness for duty, and for protecting the privacy of the individual. If applicable, the applicant should assess and describe how it would integrate its construction site staff with the operational unit FFD program staff to provide reasonable assurance of the continued effectiveness of the FFD program.

The reviewer should ensure that the applicant describes how the FFD program supports the granting of authorization to individuals. The description should describe the requirements for initial authorization, authorization update, authorization reinstatement, and authorization with potentially disqualifying FFD information.

Training, 10 CFR 26.29 and 10 CFR 26.203(c)

The applicant's description of its FFD program must describe the FFD training program. The description must include how the applicant's training program would be implemented as required by 10 CFR 52.79(a)(44).

This training program must encompass the knowledge and abilities set forth in 10 CFR 26.29(a), "Training" and 10 CFR 26.203(c), "Training and examinations."

The training program description must include a description of the comprehensive examination process required by 10 CFR 26.29(b).

The training program description must include initial training requirements and refresher training requirements pursuant to 10 CFR 26.29(c). Refresher training must be completed on a nominal 12-month frequency, or more frequently where the need is indicated.

Drug and Alcohol Testing, 10 CFR 26.31, 10 CFR 26.127, and 10 CFR 26.153

The applicant must describe the process and procedures required for drug and alcohol testing. The applicant should include the elements described below:

The applicant should identify whether it intends to utilize an LTF. The applicant should also identify its proposed primary and secondary HHS-certified laboratories and blind performance test specimen provider.

The applicant must describe, in general, its inspection audit program for its HHS-certified laboratories and other C/Vs implementing 10 CFR Part 26 requirements. The description should include who would be authorized to conduct the inspection audit and how the program would ensure the HHS-certified laboratory meets the requirements of 10 CFR 26.153(f), "Using Certified Laboratories for Testing Urine Specimens."

The applicant shall describe the roles, responsibilities and qualification of FFD personnel. At a minimum, the applicant shall discuss the roles, responsibilities and qualification of the Medical Review Officer, Substance Abuse Expert, Urine Collector, Alcohol Collector and any other personnel involved in the FFD determination and/or drug and alcohol testing, if different than required in 10 CFR Part 26. Reference to applicable sections of 10 CFR Part 26, Subparts F, G, and H are acceptable. The description should include the circumstances and procedures in which a determination of fitness must be made.

The applicant's description of its FFD program shall describe how and where drug and alcohol specimens would be collected. This should include a description of how the applicant would maintain the chain of custody of samples. The applicant's description of its FFD program should describe the procedures for the specimen collection process if they differ from that described in 10 CFR Part 26, Subpart E. If validity testing is conducted by an LTF, the applicant should describe its process and quality controls for imposing temporary sanctions.

The applicant's description of its FFD program should describe the situations in which individuals would be subject to testing, if different than that described in 10 CFR Part 26,

Subpart B. This should include pre-access, for cause (including observed behavior), post-accident (including occupational injury or illness resulting in an Occupational Safety Health Administration recordable event), follow-up, and random testing.

The applicant's description of its FFD program shall describe what drugs (including alcohol) would be included in the testing program. The applicant's FFD program must test for those drugs specified by and at the cutoff levels listed in 10 CFR 26.133 and 10 CFR 26.163, and alcohol. The applicant should describe whether Limit of Detection testing would be conducted and whether it would lower drug cutoff levels.

The applicant should either confirm that the site would utilize the latest revision of Nuclear Energy Institute (NEI) Standard Form 06-06-01 (Consent Form) or, if the applicant does not intend to utilize NEI Standard Form 06-06-01, describe or provide the site specific drug and alcohol testing Consent Form that contains equivalent, or better, reporting information as NEI Standard Form 06-06-01.

The applicant's description of its FFD program shall describe its proposed random testing program. The random testing program description should include the following:

- How the applicant's random selection process would provide reasonable assurance that individuals are unable to predict the time periods during which specimens will be collected.
- The frequency of testing (e.g., testing would be conducted at least once per week).
- The description of persons to be tested (e.g., personnel operating or performing onsite direction of the operation of risk-significant SSCs).
- How personnel would be selected, specifically how the applicant would verify true identity and how the applicant would determine that the person is onsite and subject to testing.
- Time allowances and requirements for reporting for testing.
- How individuals would be notified to report for drug testing and how these notifications would be conducted and documented.
- What actions would be taken if a selected individual fails to report at the collection location within the allowances and requirements established by the licensee or other entity.
- The process to ensure that all individuals subject to testing would have an equal probability of being selected and tested.
- The process to ensure that the number of random tests performed annually would be equal to at least 50 percent of the population subject to testing.

- How the applicant would assess a C/V's program for the conduct of drug and alcohol testing and the frequency/periodicity of such assessments.

- The applicant's proposed actions regarding a positive drug or alcohol test result. This description should include, but is not limited to, the Medical Review Officer's actions and responsibilities, reanalysis of results, reporting of positive results, and consequences of violating the FFD program.

The general performance objective of the random testing program description is that sufficient information is provided to enable the reviewer to ascertain that the testing would be statistically random and unannounced; that there would be no safe time or day in which a person knows that he/she will not be tested; that all individuals in the population subject to testing would have an equal probability of being selected and tested each time a random test is administered; and that the applicant's random testing methodology would meet or exceed the required random testing rate under all circumstances.

Behavioral Observation, 10 CFR 26.33

The reviewer should verify that the applicant would implement a BOP. The applicant shall describe how the BOP would be implemented and provide a description of any implementing procedures. An acceptable BOP should identify or describe the individuals who would be trained, the frequency of the training, the qualification process for these individuals, the individuals designated in the FFD policy to receive concerns about individuals subject to the program, and who would be subject to the program. Individuals who would be responsible for conducting behavioral observations should be able to detect behaviors that may indicate possible use, sale, or possession of illegal drugs; use or possession of alcohol onsite or while on duty; or impairment from fatigue or any cause that, if left unattended, may constitute a risk to public health and safety or the common defense and security.

The applicant's proposed BOP also could assess: characteristics representative of persons intent on causing immediate or latent damage to public health and safety or the common defense and security through overt or surreptitious actions; and whether a graded approach to behavioral characteristics can be implemented to focus on specific safety- or security-related activities.

Employee Assistance Programs, 10 CFR 26.35

The applicant shall describe the components of its proposed EAP. These components would include, but would not be limited to, confidential assessment, short-term counseling, referral services, and treatment monitoring. The description of the EAP should include which employees would be eligible for the EAP.

The applicant should describe how the EAP would be designed to achieve early intervention and provide for confidential assistance.

The EAP description should include how the applicant intends to protect the identity and privacy of individuals seeking EAP assistance.

Protection of Information, 10 CFR 26.37

Applicants who intend to collect personal information about an individual for the purpose of complying with 10 CFR Part 26 shall describe how the files (and other record management processes) that contain personal information would be established and maintained to protect personal information. Comparable provisions should be in place for C/Vs who would maintain this or similar information for the applicant, such as HHS-certified laboratories and specimen collection providers. FFD programs must maintain and use such records with the highest regard for individual privacy.

Review Process for Fitness-for-Duty Policy Violations, 10 CFR 26.39

The applicant shall describe the review process for FFD policy violations. Acceptability of an applicant's review process would be evident if the applicant proposed to use an impartial and objective review such as referring the matter to an individual who has no knowledge of the subject individual and his/her area of work, and who is external to the individual's chain-of-command. The procedure must ensure that the individual who conducts the review is not associated with the administration of the FFD program (see the description of FFD program personnel in 10 CFR 26.4(g)). The applicant should provide review process milestone dates (e.g., the affected individual has 10 days to request a review and 14 days to provide new, pertinent, and factual information).

Audits and Corrective Action, 10 CFR 26.41

The applicant shall describe a proposed audit, or joint audit, with a corrective action process, and audit frequency, to ensure the continuing effectiveness of the FFD program including elements provided by C/Vs. The applicant must ensure that the entire FFD program would be audited as needed, but no less frequently than nominally every 24 months. FFD services that are provided to a licensee or other entity by C/V personnel who are offsite or are not under the direct daily supervision or observation of the licensee's or other entity's personnel and HHS-certified laboratories must be audited on a nominal 12-month frequency.

The applicant shall describe its proposed audit program for contracted HHS-certified laboratories and the frequencies of these audits.

The applicant should describe how the results of audits would be documented and reported, including the resolution of audit findings and the corrective actions implemented.
If the applicant would jointly conduct or accept audits of C/Vs and HHS-certified laboratories, the applicant should include a description of how this would be accomplished. The applicant may propose to jointly conduct or accept audits of C/Vs and HHS-certified laboratories, as long as those audits would comply with 10 CFR 26.41(g).

The reviewer should confirm that the applicant commits to a full FFD program audit within 2 years of the commencement of construction of safety- and security-related SSCs.

Sanctions, 10 CFR 26.75

The applicant shall describe how sanctions would be administrated at their site if different than described in 10 CFR 26.75. The description should include the reason a sanction would be

administered and the particular details of the sanction (i.e., the first violation of the FFD policy involving a confirmed positive drug or alcohol test result must, at a minimum, result in the immediate unfavorable termination of the individual's authorization for at least 14 days from the date of the unfavorable termination). These sanctions must meet or exceed those described in 10 CFR 26.75(b) through (g) and (i). An applicant may impose more stringent sanctions, except as specified in 10 CFR 26.75(h).

Management Actions Regarding Possible Impairment, 10 CFR 26.77

The applicant's description of its FFD program shall describe proposed management's actions regarding possible impairment and/or if an individual shows indications that he or she may not be fit to safely and competently perform his or her duties, if the applicant's proposed management actions are different than described in 10 CFR 26.77. This description should include actions regarding observed behavior or physical condition that would create a reasonable suspicion of possible substance abuse, observed behavior or physical condition that would indicate fatigue, and indications of other possible impairment. The applicant should describe the immediate action or actions to prevent an individual who appears to be impaired or whose fitness is questionable from performing the duties that require him or her to be subject to 10 CFR Part 26.

Managing Fatigue, 10 CFR 26, Subpart I

The applicant's description of its FFD program shall describe how the FFD program would implement fatigue management (e.g., whether the licensee would implement the minimum days off requirements in 10 CFR 26.205(d)(3) or maximum average work hours requirements in 10 CFR 26.205(d)(7)). The description should include how and when fatigue assessments would be conducted, who could conduct a fatigue assessment, and how self-declarations would be defined and handled, as well as the requirements for training, record keeping, waivers, exceptions, reporting, and audits if different than that described in 10 CFR Part 26, Subpart I or applicable NRC regulatory guides (RGs). The applicant shall describe how it would provide assurance that the policy for fatigue management applies to individuals who are subject to the applicant's FFD program, as described in Table 1.

Recordkeeping, 10 CFR 26.711 and 10 CFR 26.713

The applicant's description of its FFD program shall describe how records would be stored and maintained. Records that are required by regulation must be retained for the period specified by the appropriate regulation. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the facility's license. The applicant shall describe how these records would be protected from unauthorized disclosure (e.g., cyber-attack).

The applicant shall describe how it would ensure that only correct and complete information about individuals would be retained and shared with other licensees and entities. This should include how errors in recordkeeping would be corrected.

Fitness-for-Duty Program Performance Data, 10 CFR 26.717

The applicant should inform the NRC whether it intends to use the FFD electronic reporting system.

Determining Fitness-for-Duty Policy Violations and Determining Fitness, 10 CFR Part 26, Subpart H

The applicant shall describe its proposed procedures for determining fitness and determining FFD policy violations. At a minimum, the applicant shall discuss the roles, responsibilities and qualification of the Medical Review Officer, Substance Abuse Expert, and any other personnel involved in an FFD determination if different than that described in 10 CFR Part 26. The description should include the circumstances in which an FFD determination must be made.

Reporting Requirements, 10 CFR 26.719

The applicant's description of its FFD program shall describe how the applicant would manage notifications to the NRC of significant violations of the FFD policy, significant FFD program failures, and errors in drug and alcohol testing. The description should include timelines and what would constitute a significant violation of the FFD policy and significant FFD program failures.

The applicant should describe how it would document, trend, and correct non-reportable indicators of FFD programmatic weaknesses under the corrective action program. The applicant may not propose to track or trend drug and alcohol test results in a manner that would permit the identification of any individuals (see 10 CFR 26.37).

Granting and Maintaining Authorization, 10 CFR Part 26, Subpart C

The applicant's description of its FFD program shall describe the authorization program, in accordance with 10 CFR Part 26, Subpart C. Specifically, the description must include how the applicant would meet the subpart's requirements for initial authorization, authorization update, authorization reinstatement, or authorization with potentially disqualifying FFD information. A full description is not necessary when the applicant confirms that the most current revision of RG 5.66, "Access Authorization Program for Nuclear Power Plants" has been used. RG 5.66 provides acceptable language for insertion into site security plans to describe the access authorization program. RG 5.66 endorses the use of NEI 03-01, "Nuclear Power Plant Access Authorization Program," Revision 3, issued May 2009, as an acceptable approach to meet the requirements in 10 CFR 73.56 and 10 CFR Part 26 that relate to granting and maintaining unescorted access and to certifying and maintaining unescorted access authorization.

Licensee Testing Facilities (LTF), 10 CFR Part 26, Subpart F

If the applicant relies on an LTF, the applicant shall describe its procedures for performing initial tests of urine specimens for validity, drugs, and drug metabolites at the LTF. At a minimum, the applicant shall discuss the roles, responsibilities and qualification of the LTF personnel, cutoff levels for validity screening and initial validity tests, cutoff levels for drugs and drug metabolites (if different than that described in 10 CFR Part 26), split specimens, quality assurance and quality control, and reporting initial validity and drug test results.

Laboratories, 10 CFR Part 26, Subpart G

The applicant shall describe its procedures for using HHS-certified laboratories for testing urine specimens for validity and the presence of drugs and drug metabolites. At a minimum, the

applicant shall discuss the roles, responsibilities and qualification of the laboratory facility and personnel; assuring specimen security, chain of custody, and preservation; cutoff levels for validity testing; cutoff levels for drugs and drug metabolites (if different than that described in 10 CFR Part 26); testing split specimens and retesting single specimens; quality assurance and quality control; blind performance testing; and reporting results.

IV. EVALUATION FINDINGS

The staff should describe why the applicant is submitting a description of its FFD program for NRC review, the components of 10 CFR Part 26 used to determine the adequacy of the applicant's program, and whether the program is acceptable for the purposes of the submittal. For example: "In accordance with 10 CFR Part 52, Subpart C, "Combined Licenses," ABC Corporation submitted the description of the operational FFD program for The Newest Power Plant, Units 7 and 8, to the NRC on [date], as part of its COL application. The staff has reviewed the applicant's description of its operational FFD program and has determined that the program is acceptable and meets the requirements of 10 CFR Part 26 and 10 CFR 52.79(a)(44)."

The staff will review the applicant's description of its proposed FFD program to verify that it meets the requirements of 10 CFR Part 26. The reviewer(s) should make determinations as to whether the program is acceptable based on the criteria described in this SRP. Unresolved matters should be discussed with the FFD Program Manager and affected offices (e.g., Office of New Reactors [NRO]), as appropriate, before conducting a call or writing a letter to the applicant requesting additional information.

The staff reviewer should note that different 10 CFR parts, most notably 10 CFR Parts 26 and 73, refer to the FFD program requirements associated with BOP and access authorization requirements. With several requirements in different parts, portions of a submitted program will not necessarily be formatted to follow the 10 CFR Part 26 regulations. The reviewer should cross-reference key components from the rule with specific sections of the applicant's program, documenting sections of compliance and noncompliance, as a basis for accepting, questioning, or denying the acceptability of the applicant's proposed FFD program. A formal request for additional information may be necessary to complete the acceptance review.

The staff's findings should be documented in a safety evaluation, protected as required under, 10 CFR 73.21, "Protection of Safeguards Information: Performance requirements," and entered into the NRC's ADAMS following concurrence by the appropriate Branch Chief in the Office of Nuclear Security and Incident Response and affected NRC program office representative.

For COL reviews, the findings will also summarize the staff's evaluation of how the COL applicant addressed those COL action/information items included in the referenced design control document that are relevant to this SRP section.

V. IMPLEMENTATION

The staff may use this SRP section in performing safety evaluations of license applications submitted pursuant to 10 CFR Parts 50 or 52. Except when the applicant proposes an acceptable alternative method for complying with specified portions of the Commission's

regulations, the staff will use the method described here to evaluate conformance with Commission regulations.

VI. REFERENCES

1. Correia, Richard P., U.S. Nuclear Regulatory Commission, Letter to Jack W. Roe, Nuclear Energy Institute, December 2, 2009, ADAMS Accession No. ML092880812.

2. Leeds, Eric J., U.S. Nuclear Regulatory Commission, Letter to Holders of Licenses for Operating Power Reactors, June 8, 2009, ADAMS Accession No. ML091060582.

3. Nuclear Energy Institute, NEI 03-01, "Nuclear Power Plant Access Authorization Program," Revision 3, Washington, DC, May 2009 (not publically available).

4. Reckley, William D., U.S. Nuclear Regulatory Commission, Letter to Russell J. Bell, Nuclear Energy Institute, August 16, 2007, ADAMS Accession No. ML072270296.

5. Shults, Theodore F., *Medical Review Officer Handbook*, 9th Edition, Quadrangle Research, LLC, Research Triangle Park, N.C., page 206, 2009.

6. *U.S. Code of Federal Regulations*, "Fitness for Duty Programs," Part 26, Title 10, "Energy."

7. *U.S. Code of Federal Regulations*, "Written Communications," § 50.4 and § 52.3, Title 10, "Energy."

8. *U.S. Code of Federal Regulations*, § 50.70(b)(3), Title 10 "Energy."

9. *U.S. Code of Federal Regulations*, "Application for Amendment of License, Construction Permit, or Early Site Permit," § 50.90, Title 10, "Energy."

10. *U.S. Code of Federal Regulations*, § 52.79(a)(44), Title 10, "Energy."

11. *U.S. Code of Federal Regulations*, "Requirements for Physical Protection of Licensed Activities in Nuclear Power Reactors against Radiological Sabotage," § 73.55, Title 10. "Energy."

12. *U.S. Code of Federal Regulations*, "Personnel access authorization requirements for nuclear power plants," § 73.56, Title 10, "Energy."

13. *U.S. Code of Federal Regulations*, "Licenses, Certifications, and Approvals for Nuclear Power Plants," Subpart C, "Combined Licenses," Part 52, Title 10, "Energy."

14. U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, "Mandatory Guidelines for Federal Workplace Drug Testing Programs," *Federal Register*, Vol. 73, No. 228, November 25, 2008, pp. 71855-71907.

15. U.S. Nuclear Regulatory Commission, "Power Reactor Security Requirements; Final Rule," *Federal Register*, Vol. 74, No. 58, March 27, 2009, pp. 13926-13993.

16. U.S. Nuclear Regulatory Commission, “Fitness for Duty Programs; Final Rule,” *Federal Register*, Vol. 73, No. 62, March 31, 2008, pp. 16966-17235.

17. U.S. Nuclear Regulatory Commission, “Access Authorization Program for Nuclear Power Plants,” Regulatory Guide 5.66, ADAMS Accession No. ML112060028.

18. U.S. Nuclear Regulatory Commission, “Guidance for the Application of the Radiological Sabotage Design-Basis Threat in the Design, Development and Implementation of a Physical Security Program That Meets 10 CFR 73.55 Requirements,” Regulatory Guide 5.69, (safeguards information. not publicly available).

19. U.S. Nuclear Regulatory Commission, “Training and Qualification of Security Personnel at Nuclear Power Reactor Facilities.” Regulatory Guide 5.75, ADAMS Accession No. ML091690037.

20. U.S. Nuclear Regulatory Commission, “Insider Mitigation Program,” Regulatory Guide 5.77, ADAMS Accession No. ML090721034.

21. U.S. Nuclear Regulatory Commission, “Combined License Applications for Nuclear Power Plants (LWR Edition),” Regulatory Guide 1.206, ADAMS Accession No. ML070720184.

22. U.S. Nuclear Regulatory Commission, Order EA-03-038, “Compensatory Measures Related to Fitness-For-Duty,” *Federal Register*, Vol. 68, No. 88, May 7, 2003, pp. 24510 – 24514.

23. U.S. Nuclear Regulatory Commission, Inspection Manual Chapter-2504, “Construction Inspection Program - Inspection of Construction and Operational Programs,” issued Oct. 15, 2009, ADAMS Accession No. ML092610093.

24. U.S. Nuclear Regulatory Commission, “Physical Protection Programs at Nuclear Power Reactors,” Regulatory Guide 5.76, (safeguards information, not publicly available).

Copies of the non-NRC documents included in these references may be obtained directly from the publishing organization.

Publicly available NRC published documents such as regulations, Regulatory Guides, NUREGs, and Generic Letters listed herein are available electronically on the NRC’s public Web site at: http://www.nrc.gov/reading-rm/doc-collections/. Copies are also available for inspection or copying for a fee from the NRC’s Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, D.C. 20555; telephone at 301-415-4737 or 1-800-397-4209; fax at 301-415-3548; and e-mail: PDR.Resource@nrc.gov.

PAPERWORK REDUCTION ACT STATEMENT

The information collection requirements contained and referenced in the Standard Review Plan are covered by the requirements of 10 CFR Parts 26, 50, 52 and 73, which were approved by the Office of Management and Budget, approval numbers 3150-0146, 3150-0011, 3150-0151, and 3150-0002.

PUBLIC PROTECTION NOTIFICATION

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

SRP Section 13.7.1
Description of Changes

Section 13.7.1 "FITNESS FOR DUTY - OPERATIONAL PROGRAM"

Section 13.7.1 is a new SRP section not previously included in NUREG-0800. It was developed to provide guidance for the review of Fitness for Duty programs submitted in applications under 10 CFR Part 50 or 10 CFR Part 52.