



NUREG-0800

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

13.7.2 FITNESS FOR DUTY - CONSTRUCTION

REVIEW RESPONSIBILITIES

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

Secondary- Organization responsible for the review of Title 10 of the *Code of Federal Regulations* (10 CFR), Part 26, Subpart I, "Managing Fatigue"

For descriptions of FFD programs submitted in applications under 10 CFR Part 50 or 52, the review involves the evaluation of the applicant's FFD program pursuant to 10 CFR Part 26 both with respect to the FFD program during construction, addressed by Subpart K and this Standard Review Plan (SRP), and during operation, addressed by Subparts A-I, N, O and SRP Section 13.7.1. The review will seek evidence that effective policies and procedures are adequately described to provide reasonable assurance that individuals are (1) trustworthy and reliable as demonstrated by the avoidance of substance abuse, and (2) 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).

Draft Revision 0 – April 2014

USNRC STANDARD REVIEW PLAN

This Standard Review Plan (SRP), NUREG-0800, has been prepared to establish criteria that the U.S. Nuclear Regulatory Commission (NRC) staff responsible for the review of applications to construct and operate nuclear power plants intends to use in evaluating whether an applicant/licensee meets the NRC regulations. The SRP is not a substitute for the NRC regulations, and compliance with it is not required. However, an applicant is required to identify differences between the design features, analytical techniques, and procedural measures proposed for its facility and the SRP acceptance criteria and evaluate how the proposed alternatives to the SRP acceptance criteria provide an acceptable method of complying with the NRC regulations.

The SRP sections are numbered in accordance with corresponding sections in Regulatory Guide (RG) 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)." Not all sections of RG 1.70 have a corresponding review plan section. The SRP sections applicable to a combined license application for a new light water reactor (LWR) are based on RG 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)."

These documents are made available to the public as part of the NRC policy to inform the nuclear industry and the general public of regulatory procedures and policies. Individual sections of NUREG-0800 will be revised periodically, as appropriate, to accommodate comments and to reflect new information and experience. Comments may be submitted electronically by email to NRO_SRP@nrc.gov.

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I. AREAS OF REVIEW

Applicable to the licensees and entities specified in 10 CFR 26.3(c) and contractors/vendors (C/V) specified in 10 CFR 26.3(d) who implement FFD programs or program elements, to the extent that the licensee or applicant specified in 10 CFR 26.3(c) rely on those C/V FFD programs or program elements to meet the requirements of 10 CFR Part 26. Specifically, before the receipt of special nuclear material (SNM) in the form of fuel assemblies, the following licensees and entities shall comply with the requirements of 10 CFR Part 26, except for 10 CFR Subpart I, "Managing Fatigue" and, no later than the receipt of SNM in the form of fuel assemblies, the following licensees and other entities are required to develop a construction FFD program and submit it for U.S. Nuclear Regulatory Commission (NRC) review:

- (1) Combined license (COL) applicants under 10 CFR Part 52 who have been issued a limited work authorization (LWA) under 10 CFR 50.10(e), if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related structures, systems, and components (SSCs) under the LWA;
- (2) Combined license holders under 10 CFR Part 52 before the Commission has made the finding under 10 CFR 52.103(g);
- (3) Construction permit (CP) applicants under 10 CFR Part 50 who have been issued a LWA under 10 CFR 50.10(e), if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA;
- (4) Construction permit holders under 10 CFR Part 50; and
- (5) Early site permit (ESP) holders who have been issued a LWA under 10 CFR 50.10(e), if the LWA authorizes the ESP holder to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA.

For the above licensees, applicants, and entities, the construction FFD program applies to any individual, as described in 10 CFR 26.4(f), who is constructing or directing the construction of safety- or security-related SSCs. These individuals are subject to a construction FFD program that meets the requirements of 10 CFR Part 26, Subpart K, unless the licensee or other entity subjects these individuals to a full FFD program that meets all of the requirements of 10 CFR Part 26, except for Subparts I and K. Further, nothing prohibits the licensees and other described above from subjecting these individuals to a full FFD program that meets all of the requirements of this 10 CFR Part 26 or FFD program elements that meet all of the applicable requirements of this part.

The specific areas of review are as follows:

1. General Provisions
2. Written Policy and Procedures
3. Drug and Alcohol Testing
4. Fitness Monitoring*
5. Behavioral Observation*
6. Sanctions for FFD Policy Violations
7. Protection of Information
8. Review Process
9. Audits
10. Recordkeeping and Reporting
11. Suitability and Fitness Evaluations

* Note: Fitness monitoring is not required if the applicant subjects the individuals specified in 10 CFR 26.4(f) to random testing for drugs and alcohol. See SRP 13.7.2, Section III, “Fitness Monitoring,” 10 CFR 26.406. Behavioral observation is not required if the applicant has implemented a fitness monitoring program. Therefore, the applicant must either implement (1) random testing for drugs and alcohol and a behavioral observation program or (2) a fitness monitoring program.

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 |
| | Security Personnel | 26.4(e)(1) | Prior to fuel assemblies being received onsite | Subparts A-H, N, and O |
| | | 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, 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 |

| Item | Persons Subject to FFD Program | 10 CFR Part 26 requirement | Milestone (e.g., timeline) | Applicable 10 CFR Part 26 Subparts |
|------|--------------------------------|----------------------------|--|---|
| 6 | FFD Operational Program | 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. The FFD program is typically described in Chapter 13.7 of the licensee's or other entity's Final Safety Analysis Report (FSAR).
2. For entities subject to Subpart K who desire to implement an operational 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 (Agencywide Documents Access and Management System (ADAMS) Accession No ML060530316).
3. Holders of a COL under 10 CFR Part 52 should implement the operational FFD program and milestones as discussed in NUREG-0800, SRP Section 13.7.1, Table 1.

Individuals specified in 10 CFR 26.4(f): Any individual who is constructing or directing the construction of safety- or security-related SSCs shall be subject to an FFD program that meets the requirements of 10 CFR Part 26, Subpart K, unless the licensee or other entity subjects these individuals to an FFD program that meets all of the requirements of 10 CFR Part 26, except for Subparts I and K. If the license applicant intends to implement an FFD program under subpart K, pursuant to 10 CFR 26.401(b) requirements, then the applicant must submit a description of the FFD program and its implementation as part of the license, permit, or limited work authorization application. However, if the applicant is a 10 CFR Part 50 applicant or ESP/LWA applicant and does not intend to have a subpart K FFD program, then the applicant is not required to describe its FFD program in its application. The applicant, however, should inform the NRC whether or not it intends to implement a subpart K program.

4. Operational Program Description and Implementation. For the 10 CFR Part 50 and ESP applicants, description of the 10 CFR Part 26, FFD operational program is not required. For a COL (pursuant to 10 CFR 52.79(a)(44) and 26.401(b)) and CP, LWA, and ESP applicants that will implement an FFD program under Subpart K (pursuant to 10 CFR 26.401(b)), the reviewer reviews a description of

the FFD program and its proposed implementation milestones in the application. The reviewer also reviews the applicant's FSAR, typically at Chapter 13, Section 13.7, to ensure that the FFD Program is described.

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 sections.

II. ACCEPTANCE CRITERIA

Requirements

The NRC bases its acceptance criteria on the relevant requirements of 10 CFR Part 26, Subpart K, "Fitness for Duty Programs for Construction."

1. 10 CFR 26.401, "General"
2. 10 CFR 26.403, "Written Policy and Procedures"
3. 10 CFR 26.405, "Drug and Alcohol Testing"
4. 10 CFR 26.406, "Fitness Monitoring"
5. 10 CFR 26.407, "Behavioral Observation"
6. 10 CFR 26.409, "Sanctions"
7. 10 CFR 26.411, "Protection of Information"
8. 10 CFR 26.413, "Review Process"
9. 10 CFR 26.415, "Audits"
10. 10 CFR 26.417, "Recordkeeping and Reporting"
11. 10 CFR 26.419, "Suitability and Fitness Evaluations"

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), an applicant or other affected entity to identify differences between the design features, analytical techniques, and procedures 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 should provide reasonable assurance that: (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; and (5) the workplaces are free from the presence and effects of illegal drugs and alcohol.

The SRP acceptance criteria are as follows:

1. 10 CFR 26.401, General – The applicant describes how it would implement the requirements and standards for the establishment, implementation, and maintenance of FFD programs.
2. 10 CFR 26.403, Written Policy and Procedure – This section provides the requirements that the applicant will establish and implement a clear, concise, and written FFD policy statement and that this policy is provided to individuals who are subject to the FFD program. Applicants shall describe how they would develop, implement, and maintain written procedures that address the elements of the FFD program described in 10 CFR 26.403.
3. 10 CFR 26.405, Drug and Alcohol Testing – This section provides the requirements for the implementation of the drug and alcohol testing program. The implementation of these requirements provides the means to deter and detect substance abuse. These requirements are not applicable if the applicant plans to implement a fitness monitoring program under 10 CFR 26.406.
4. 10 CFR 26.406, Fitness Monitoring – Each applicant can elect to implement a fitness monitoring program to deter substance abuse and detect indications of possible use, sale, or possession of illegal drugs; use or possession of alcohol while constructing safety- or security-related SSCs; or impairment from any cause that if left unattended may result in a risk to public health and safety or the common defense and security. The requirements in this section apply only if a licensee or other entity does not elect to subject the individuals specified in 10 CFR 26.4(f) to random testing for drugs and alcohol under 10 CFR 26.405(b).

5. 10 CFR 26.407, Behavioral Observation – While the individuals specified in 10 CFR 26.4(f) would be constructing or directing the construction of safety- or security-related SSCs, the applicant shall describe how it would ensure that these individuals would be subject to behavioral observation, except if the applicant implemented a fitness monitoring program under 10 CFR 26.406.
6. 10 CFR 26.409, Sanctions – Applicants shall describe sanctions for FFD policy violations that, at a minimum, would prohibit the individuals specified in 10 CFR 26.4(f) from being assigned to construct or direct the construction of safety- or security-related SSCs 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.
7. 10 CFR 26.411, Protection of Information – Applicants who intend to collect personal information about an individual for the purpose of complying with Subpart K shall describe how they would establish, implement, and maintain a system of files and procedures to protect the personal information.
8. 10 CFR 26.413, Review Process – Applicants shall describe how they would establish, implement, and maintain procedures for the review of a determination that an individual in 10 CFR 26.4(f) 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.
9. 10 CFR 26.415, Audits – Applicants shall describe how they would ensure that audits would be performed to assure the continuing effectiveness of the FFD program, including FFD program elements that would be provided by contractor/vendors (C/Vs), and the FFD programs of C/Vs that would be accepted by the applicant.
10. 10 CFR 26.417, Recordkeeping and Reporting – Applicants shall describe how they would ensure that records pertaining to the administration of the program would be maintained so that they would be available for NRC inspection purposes and for any legal proceedings resulting from the administration of the program. In addition, the applicant should describe how it would report to the NRC 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 10 CFR Part 26, Subpart K. The applicant also shall state that it would submit the annual performance report and event reports, as required to the NRC Operations Center (see 10 CFR 26.417).
11. 10 CFR 26.419, Suitability and Fitness Evaluations – Applicants shall describe how they would develop, implement, and maintain procedures for evaluating whether to assign individuals to construct or direct the construction of safety- and security-related SSCs. These procedures must provide reasonable assurance that the individuals would be fit to safely and competently perform their duties, and would be trustworthy and reliable, as demonstrated by the avoidance of substance abuse.
12. For COL reviews, the NRC staff will review the description of the construction program in accordance with 10 CFR Part 26, Subpart K and proposed implementation milestones for the FFD program as discussed in Table 1.

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 10 CFR 26.4(f) personnel are fit for duty, meaning that they can safely and competently perform their duties because they are not under the influence of any substance, legal or illegal.
2. The technical basis for 10 CFR Part 26, Subpart K, is provided in "Fitness for Duty Programs; Final Rule," pages 16993-16996 and 17154-17163 (73 FR 16966; March 31, 2008). This technical basis discussed in staff's statement of consideration in the 73 FR 16966 should assist and provide rationales for the review of licensee's discussion of the FFD program.

III. REVIEW PROCEDURES

The scope of the review of a COL application is dependent on whether the COL applicant references a Design Certification (DC), ESP, 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 to enable the Commission to reach a final conclusion on all matters that must be resolved by the Commission before issuance of a COL.

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."

When conducting the review of the FFD program, the reviewer will determine whether the FFD program conforms to the regulations, and to the information requirements of Section I and the acceptance criteria of Section II.

The NRC is currently developing a Regulatory Guide (RG) to support implementation of a FFD program at new reactor construction sites. Revision to this SRP chapter is expected upon a final issuance of the RG. In the interim, the NRC staff determined in a December 2, 2009 letter to Nuclear Energy Institute (NEI) (ADAMS Accession No. ML092881085) that NEI 06-06, Revision 5 is acceptable for use as a reference in the development of site-specific applications; therefore, the reviewer will refer to the guidance provided by Revision 5 of NEI 06-06 (Ref 7) when determining the acceptability of the applicant's FFD program.

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

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 deviations from the operating

program. To be acceptable, the description should meet the requirements of 10 CFR 52.79(a)(44) and as discussed in Sections I and II of this guidance.

The reviewer also will consider the appropriateness of any identified COL action items. When the reviewer identifies additional COL action items, they should be added to the DC FSAR to ensure these COL action items are addressed during subsequent COL application evaluations.

General, 10 CFR 26.401

The applicant must submit a description of the FFD program and its implementation as part of an application submitted under 10 CFR Part 52. The reviewer shall ensure the description includes information as to how the applicant intends to establish, implement, and maintain an FFD program meeting the requirements of 10 CFR Part 26. The applicant must specify whether the individuals identified in 10 CFR 26.4(f) would be subject to a program implemented to meet the requirements of 10 CFR Part 26, Subpart K or the requirements of 10 CFR Part 26, Subparts A through H, N, and O.

Written Policy and Procedures, 10 CFR 26.403

The applicant must describe how the FFD program would provide a clear, concise, and written FFD policy statement that would be provided to individuals who are subject to the program. The reviewer shall ensure the policy discusses the applicant's expectations of individuals subject to the program, the consequences for violating the policy, and the responsibilities of management and oversight personnel to report concerns. The policy statement must address the FFD performance objectives described in 10 CFR 26.23 in a manner sufficient to provide reasonable assurance that persons subject to Subpart K are adequately informed prior to constructing or directing the construction of safety- or security-related SSCs.

The applicant must describe the written procedures developed, implemented, and maintained to address the following topics:

- a. The methods and techniques to be used in testing for drugs and alcohol, including procedures for protecting the privacy of the individual providing a specimen, procedures for protecting the integrity of specimens taken, and procedures to ensure that test results are valid and attributable to the correct individual (e.g., chain of custody procedures).
- b. The immediate and follow-up actions that will be taken under the circumstances described in 10 CFR 26.403(b)(2)(i) through (v). These circumstances include, but are not limited to: use, sale or possession of illegal drugs; excessive alcohol consumption; refusal to provide a specimen; legal action related to illegal drug or alcohol use; or, attempts to subvert the testing process. Note that excessive alcohol consumption is any situation in which the person tests positive for alcohol (10 CFR 26.103) and includes alcohol consumption within the 5-hour abstinence period (10 CFR 26.27(b)(5)).
- c. The process to be followed should an individual's behavior or condition raise concerns regarding the possible use, sale, or possession of illegal drugs on or offsite; the possible use or possession of alcohol while constructing or directing the construction of safety- or security-related SSCs; or impairment from any cause that could adversely affect the individual's ability to safely and competently perform

assigned duties. Impairment for any cause includes, but is not limited to, fatigue and ingestion, injection, or inhalation of synthetic compounds or chemicals whether legally or illegally obtained.

Drug and Alcohol Testing, 10 CFR 26.405

This section does not apply to applicants who would elect to subject the individuals specified in 10 CFR 26.4(f) to a fitness monitoring program under 10 CFR 26.406.

The reviewer shall ensure the applicant describes the processes and procedures required for drug and alcohol testing. These processes and supporting procedures shall have as their overall goal the performance objectives provided in 10 CFR 26.23. The applicant shall include, as a minimum, the elements described below.

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 (MRO), Substance Abuse Expert, urine collector, alcohol collector and any other personnel involved in the FFD determination and/or drug and alcohol testing. The description should include the circumstances in which a suitability and fitness evaluation must be made. Reference to applicable sections of 10 CFR Part 26, Subparts F, G, and H are acceptable.

The applicant shall describe how and where drug and alcohol tests would be analyzed and conducted including validity and confirmatory tests. This should include a general description of how the applicant would maintain the chain of custody of samples. The applicant should identify whether they intend to use a licensee testing facility (LTF) and where the LTF is physically located. If validity testing is to be conducted by an LTF, the applicant should describe how validity tests would be conducted, and its process and quality controls for imposing temporary sanctions. Confirmatory testing for alcohol must be conducted using an evidential breath measurement device, and confirmatory test for drugs must be conducted by a U.S. Department of Health and Human Services' certified (HHS-certified) laboratory. The applicant also should identify its intended supplier of blind performance test specimens and its primary and secondary HHS-certified laboratories. Reference to applicable sections of 10 CFR Part 26, Subparts F and G are acceptable.

The applicant's FFD program shall describe the procedures for the specimen collection process, if they differ from that described in 10 CFR Part 26, Subpart E. The applicant shall state whether they intend to use the provisions contained in 49 CFR Part 40.

The applicant shall describe the situations in which individuals would be subject to testing. This must include pre-assignment, for cause (including observed behavior), post-accident (including significant damage to any safety- or security-related SSC, and occupational injury or illness resulting in an Occupational Safety and Health Administration recordable event), follow-up, and random testing.

The applicant shall describe what drugs (including alcohol) are included in the testing program. At a minimum, the applicant's FFD program shall test for those drugs specified by and at the cutoff levels listed in 10 CFR 26.133 and 26.163, and alcohol.

The applicant should either confirm that the site would utilize the latest revision of NEI Standard Form 08-06-01 (Consent Form) or, if the applicant does not intend to utilize NEI Standard

Form 08-06-01, describe or provide the site specific drug and alcohol testing Consent Form that contains equivalent, or better, reporting information as NEI Standard Form 08-06-01.

The applicant shall describe its proposed random testing program if the applicant elects to impose random testing for drugs and alcohol on the individuals identified in 10 CFR 26.4(f). 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 (e.g., construction workers and persons directing construction activities) to be tested.
- 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 failed 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 on a given day 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 shall include, but is not limited to, the MRO 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.

Fitness Monitoring, 10 CFR 26.406

This section only applies to applicants who do not elect to subject the individuals specified in 10 CFR 26.4(f) to random testing for drugs and alcohol under 10 CFR 26.405(b). Fitness

monitoring is an alternative to random drug and alcohol testing. Consistent with a testing program, it must serve to deter substance abuse and detect indications of possible use, sale, or possession of illegal drugs; use or possession of alcohol while constructing safety- or security-related SSCs; or impairment from any cause that if left unattended may result in a risk to public health and safety or the common defense and security.

Should an applicant desire to implement a fitness monitoring program, the reviewer shall ensure that the applicant describes in detail its proposed fitness monitoring program, at a minimum, procedures and policies associated with the implementation of its fitness monitoring program and its assessment of this program to ensure its continuing effectiveness.

The program description should also describe the number of monitors required, the ratio of monitors to individuals specified in 10 CFR 26.4(f), the placement of monitors at the site, and the frequency with which the individuals would be monitored. The basis used by the licensee to determine the values listed above is necessary in order for the reviewer to determine the acceptability and viability of the fitness monitoring program. If necessary, the reviewer should also consult additional management guidance beyond that provided in this SRP to enable an effective review of the proposed fitness monitoring program that is consistent with NRC expectation.

Behavioral Observation, 10 CFR 26.407

The applicant must propose to implement a BOP when administering a random testing program for individuals specified in 10 CFR 26.4(f). Therefore, this section does not apply to applicants who elect to subject the individuals specified in 10 CFR 26.4(f) to a fitness monitoring program under 10 CFR 26.406 instead of a random testing program.

The reviewer shall ensure the applicant describes how the BOP would be implemented and provide a description of any implementing guidance or procedures. An acceptable BOP identifies or describes 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 BOP also could assess: characteristics representative of persons intent on causing immediate or latent failure of SSCs through overt or surreptitious actions; whether a graded approach to behavioral characteristics can be implemented to focus on specific safety- or security-related activities; and the changing work force at the construction site. For example, does the applicant's BOP provide reasonable assurance that persons (who are assigned to construct or direct the construction of safety- or security-related SSCs) who are onsite on an infrequent basis and only for a short period of time would be subject to behavioral observation?

Sanctions, 10 CFR 26.409

The applicant shall describe how sanctions would be administered at their site. The reviewer shall ensure the applicant's description explains, at a minimum, a sanction and the reason the

sanction is administered (e.g., the first violation of the FFD policy involving a confirmed positive drug or alcohol test result results in the immediate unfavorable termination of the individual's authorization for at least 14 days from the date of the unfavorable termination). The applicant must establish sanctions for FFD policy violations that, at a minimum, prohibit individuals specified in 10 CFR 26.4(f) from being assigned to construct or direct the construction of safety- or security-related SSCs 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.

The minimum requirement under Subpart K is that individuals in violation of the FFD policy must be immediately removed from constructing or directing the construction of safety- or security-related SSCs until it can be determined that the individual is in conformance with the applicant's FFD program. Sanctions such as restricted site access and progressively more severe measures for multiple violations of the FFD program are at the discretion of the applicant and are not required. The provisions of 10 CFR 26.75(e) for operating reactors require progressively more stringent disciplinary actions and could be proposed by an applicant under Subpart K.

The applicant's basis for its described sanctions should justify the particular sanction(s) developed by the applicant to deter individuals from violating the FFD policy and ensure that workers are fit to direct or perform construction of safety- or security-related SSCs.

Protection of Information, 10 CFR 26.411

The reviewer shall ensure that applicants who intend to collect personal information about an individual for the purpose of complying with 10 CFR Part 26, Subpart K, describe how the files (electronic and paper) that contain personal information would be established and maintained to protect personal information, how the files would be protected, who would have access to the records, and the types of processes in place to maintain a secure chain-of-custody for documents. Comparable provisions must be in place for contractors who would generate or maintain 10 CFR Part 26 related information for the applicant. This information may include, but is not limited to, drug testing results, medical information (e.g., shy bladder determinations), and other information obtained, generated, or maintained from the implementation of 10 CFR Part 26 requirements for employees or C/Vs. FFD programs must maintain and use such records with the highest regard for individual privacy. Electronic files should be protected by access rights and cyber protection. Use of "Cloud" data storage systems for protected information is discouraged unless justified.

The applicant shall describe the provisions to obtain a signed consent that authorizes the disclosure of personal information before disclosing the personal information. The applicant would not need consent to disclose personal information to the subject individual or his/her representative, the MRO and MRO staff, NRC representatives, law enforcement officials under court order, applicant personnel with a need to know to perform their duties under the FFD program, presiding officer in a judicial or administrative proceeding initiated by the subject individual, or other persons pursuant to court order, and persons deciding matters under review.

Review Process, 10 CFR 26.413

The applicant must describe the review process when an individual specified in 10 CFR 26.4(f) is determined to have violated the FFD policy. The reviewer shall ensure that the applicant includes a description of procedures that establish and implement the review process. The

description should describe the steps of the review process, who participates in the review process, and how the process maintains an objective and impartial review of related facts. Review process milestone dates should be provided (e.g., the affected individual has 10 days to request a review and 14 days to provide new, pertinent, and factual information).

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. Another example of impartiality would be a review by an individual, external to the subject individual's chain-of-command, at a higher level than the level of the initial decision-maker in the process within the subject individual's chain-of-command.

Audits, 10 CFR 26.415

The applicant must describe an audit process and its frequency to assure the continuing effectiveness of the FFD program including FFD program elements provided by HHS-certified laboratories, C/Vs, and the FFD programs of C/Vs that would be accepted by the applicant. The reviewer shall ensure the applicant describes, in general, its inspection audit program for its HHS-certified laboratories and other C/Vs providing 10 CFR Part 26 services. The description should include the qualifications of persons authorized to conduct the inspection audit and how the program would insure the HHS-certified laboratory meets the requirements of 10 CFR 26.153(f). Note that applicants need not propose to audit HHS-certified laboratories or the specimen collection and alcohol testing services that meet the requirements of 49 CFR Part 40.

The applicant should describe how its audit process would ensure that corrective actions are taken to resolve any problems identified. If an applicant proposes to utilize joint audits, or accept audits of C/Vs conducted by others, the applicant should describe this process and how it would ensure the effectiveness of the C/Vs' services.

Subpart K provides general information with regard to how FFD audits should be conducted for construction site programs. Audits may be developed and implemented to review all or portions of FFD programs to ensure or improve effectiveness and identify and prevent human error. Routine or random audits should begin with an audit plan that defines the scope of the review to include the purpose of the audit, the components of the program being examined, the sample size and the basis for it, and a schedule for when audit activities will be complete, and when the final report should be issued. For example, a limited scope audit for a fitness for duty program might be the review of personal privacy protection policies and procedures with the actual implementation processes associated with obtaining, handling and storing personal privacy information. These subject-area audits should be conducted periodically.

Furthermore, program audits can be conducted early in construction to provide reasonable assurance that the FFD program meets regulatory requirements and is effective. Full program audits should be conducted prior to major construction milestones (e.g., prior to fuel loading or the 10 CFR 52.103(g) finding) or if adverse program performance is identified.

The number of corrective actions identified during an audit may be used to assess the frequency of audits, the audit sample size during subsequent audits, or to change the scope of future audits.

Recordkeeping and Reporting, 10 CFR 26.417

The applicant must describe how FFD records would be stored, maintained, and protected from unauthorized disclosure (e.g., cyber attack). The applicant shall ensure records, electronic or hardcopy, would be available for NRC inspection and for any legal proceedings resulting from the administration of the FFD program. The applicant should describe which records must be retained and the retention period. At a minimum, the following records regarding FFD program administration should be maintained: a list of the random pool (including all updates); a list of individuals selected for random testing for each day of testing, including those individuals selected but not tested, and the reason individuals were not tested; policies and procedures and record of revisions; audits; implementation of sanctions and reviews; planned reports and reportable events; and test results.

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

The applicant should inform the NRC whether it intends to use the FFD electronic reporting system to meet the requirements of 10 CFR 26.717.

The applicant should describe how it would manage notifications to the NRC of 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 the FFD program. The description should describe what constitutes a programmatic failure, degradation or vulnerability.

Suitability and Fitness Evaluations, 10 CFR 26.419

The applicant shall describe its process for evaluating whether to assign individuals to construct safety- and security-related SSCs. The reviewer shall ensure the applicant describes how it would 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.

Examples of acceptable practices typically found in suitability and fitness evaluations include past FFD-related policy violations or denials or suspension of authorization at other nuclear facilities, prior performance at the site where the individual is seeking employment, background checks of a criminal history, performance evaluations, and acceptable completion of substance abuse rehabilitation programs.

IV. EVALUATION FINDINGS

The staff should describe why the applicant is submitting a description of an 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 construction 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 construction FFD program and has determined that

the program is acceptable and meets the requirements of 10 CFR Part 26, Subpart K and 10 CFR 52.79(a)(44).”

The 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 will review the applicant’s description of its proposed FFD program to verify that it meets the requirements of 10 CFR Part 26, Subpart K. The reviewer(s) will make determinations as to whether the program is acceptable based on the criteria described in this SRP. Unresolved matters identified by the reviewer should be discussed with the FFD Program Manager and affected NRC Offices, as appropriate, before conducting a call or writing a letter to the applicant, through the applicable program office to request additional information.

The staff shall document its findings in a safety evaluation and entered into the NRC’s ADAMS following concurrence by the appropriate Branch Chief in the Office of Nuclear Security and Incident Response and the 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 by applicants 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. 10 CFR Part 26, “Fitness for Duty Programs.”¹
2. 10 CFR 50.4 and 52.3, “Written Communications.”
3. 10 CFR 50.90, “Application for Amendment of License, Construction Permit, or Early Site Permit.”

¹ 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, RGs, NUREGs, and Generic Letters listed herein are available electronically on the NRC 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 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.

4. 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," Subpart C, "Combined License."
5. 10 CFR 73.55, "Requirements for Physical Protection of Licensed Activities in Nuclear Power Reactors against Radiological Sabotage."
6. 10 CFR 73.56, "Personnel access authorization requirements for nuclear power plants."
7. NEI 06-06, "Fitness for Duty Program Guidance for New Nuclear Power Plant Construction Sites," Revision 5, August 2009, ADAMS Accession No. ML092430016.
8. NRC, "Power Reactor Security Requirements; Final Rule," *Federal Register*, Vol. 74, No. 58, March 27, 2009, pp. 13926 – 13993.
9. NRC, "Access Authorization Program for Nuclear Power Plants," Regulatory Guide 5.66, ADAMS Accession No. ML112060028.
10. NRC, "Insider Mitigation Program," Regulatory Guide 5.77, ADAMS Accession No. ML090721034.
11. NRC, "Combined License Applications for Nuclear Power Plants (LWR Edition)," Regulatory Guide 1.206, ADAMS Accession No. ML070720184.
12. NRC, "Physical Protection Programs at Nuclear Power Reactors," Regulatory Guide 5.76, (safeguard information, not publicly available).
13. 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.
14. Leeds, Eric J., NRC Letter to Holders of Licenses for Operating Power Reactors, June 8, 2009, ADAMS Accession No. ML091060582.

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.

Description of Changes

SRP Section 13.7.2 -“Fitness for Duty - Construction”

Section 13.7.2 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 52.