



DRAFT REGULATORY GUIDE

Contact: James Vaughn
(301) 287-3686

DRAFT REGULATORY GUIDE DG-5036

(Proposed New Regulatory Guide)

FITNESS FOR DUTY PROGRAMS AT NEW REACTOR CONSTRUCTION SITES

A. INTRODUCTION

Purpose

This is a new regulatory guide written to support implementation of fitness-for-duty (FFD) programs at new reactor construction sites. This guide describes methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for use in satisfying the requirements of Title 10 of the *Code of Federal Regulations*, Part 26, “Fitness for Duty Programs” (10 CFR Part 26) (Ref. 1), Subpart K, “FFD Program for Construction.” In particular, this guide endorses the methodologies described in the industry guidance document Nuclear Energy Institute (NEI) 06-06, “Fitness for Duty Program Guidance for New Nuclear Power Plant Construction Sites,” revision 6, April 2013 (Ref. 2) with clarifications and exceptions as detailed in the Staff Regulatory Position of this guide and provides supplemental guidance to help ensure the effective and consistent implementation of the Subpart K requirements.

Applicable Rules and Regulations

Program licensees, applicants, and contractors/vendors (C/V) specified in 10 CFR 26.3(d) who implement FFD programs should consider this guidance when preparing an application for a combined license (COL) under 10 CFR Part 52 or a limited work authorization (LWA), construction permit (CP), or early site permit (ESP) with an LWA under 10 CFR Part 50 and when implementing an FFD program at a power reactor construction site. The overall performance goals of an FFD program during construction are to provide reasonable assurance that individuals subject to the program are (1) fit to safely and competently perform assigned duties, and are trustworthy and reliable, as demonstrated by the avoidance

This regulatory guide is being issued in draft form to involve specific members of the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official NRC final staff position. Comments are being solicited on this draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; submitted through the NRC’s interactive rulemaking Web page at <http://www.nrc.gov>; or faxed to (301) 492-3446. Copies of comments received may be examined at the NRC’s Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments will be most helpful if received by [insert date - 60 days from issuance].

Electronic copies of this draft regulatory guide are available through the NRC’s interactive rulemaking Web page (see above); the NRC’s public Web site under Draft Regulatory Guides in the Regulatory Guides document collection of the NRC Library at <http://www.nrc.gov/reading-rm/doc-collections/>; and the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML13XXX. The regulatory analysis may be found in ADAMS under Accession No. ML13YYYYYYY.

of substance abuse; (2) deterred from abusing legal or illegal substances; and (3) subject to behavioral observation (or fitness monitoring).

Purpose of Regulatory Guides

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance. However, regulatory guides are not substitutes for regulations and compliance with them is not required.

Paperwork Reduction Act

This regulatory guide contains information collection requirements covered by 10 CFR Part 26 that the Office of Management and Budget (OMB) approved under OMB control number 3150-0146. The NRC may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless the requesting document displays a current valid OMB control number.

B. DISCUSSION

Reason for Issue

This regulatory guide is 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 § 26.3(c) relies 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 Part 26, except for Subpart I, "Managing Fatigue,":

- (1) Combined license applicants under 10 CFR Part 52 who have been issued an LWA under § 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 § 52.103(g);
- (3) Construction permit applicants under 10 CFR Part 50 who have been issued an LWA under § 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 holders who have been issued an LWA under § 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, this regulatory guide applies to any individual, as described in § 26.4(f), who is constructing or directing the construction of safety- or security-related SSCs. These individuals 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. Further, nothing prohibits the licensees and other entities described above from subjecting these individuals to an FFD program that meets all of the requirements of 10 CFR Part 26 or FFD program elements that meet all of the applicable requirements of Part 26.

Background

In 2008 and 2009, respectively, the NRC comprehensively revised its FFD regulations in Part 26 (Ref. 1) to adopt and reflect selected provisions of the U.S. Department of Health and Human Services' (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (Ref. 3), and amended the Commission's access authorization requirements contained in 10 CFR Part 73, "Physical Protection of Plants and Materials" (Ref. 4). On July 20, 2006, NEI first presented NEI 06-06, revision 0, to the NRC for review and endorsement to support the nuclear power industry's efforts to obtain licenses for new nuclear power plants pursuant to 10 CFR Part 52. The stated purpose of NEI 06-06 was to establish program-level consistency throughout the nuclear power industry in the implementation of 10 CFR Part 26. Subsequently, the NRC staff conducted numerous public meetings on NEI 06-06 to obtain and discuss public comments and to ensure that the guidance comported with the new requirements of 10 CFR Part 26, Subpart K. The staff and public worked to incorporate into NEI 06-06 lessons learned from new nuclear power plant licensing and Subpart K implementation. These changes and others were evaluated by the NRC staff in the development of this draft regulatory guide.

On March 7, 2013, the staff conducted a public meeting to discuss specific comments on NEI 06-06, Revision 6. Specifically, the NRC did not agree with the expanded scope of NEI 06-06 to include individuals who perform the duties specified in § 26.4(e), such as security personnel, persons who perform quality assurance/quality verification activities of safety- or security-related construction, persons who supervise or manage construction activities, and persons who witness inspections, tests, and analyses in the program described in this document. The summary of this public meeting is available under ADAMS Accession No. ML13078A333 (Ref. 8).

By letter dated June 4, 2013, the NRC concluded that NEI 06-06, revision 6, dated April 2013 (ML13091A101) (Ref. 9) is acceptable, with an exception noted, for the staff to begin the process to formally endorse this guidance via a Regulatory Guide.

Harmonization with International Standards

The NRC staff has not identified any international standards related to this guide.

Documents Discussed in Staff Regulatory Guidance

This regulatory guide endorses the use of one or more methods developed by NEI and other third party guidance documents. These methods and third party guidance documents may contain references to other standards or third party guidance documents ("secondary references"). If a secondary reference has itself been incorporated by reference into NRC regulations as a requirement, then licensees and applicants must comply with that standard as set forth in the regulation. If the secondary reference has been endorsed in a regulatory guide as an acceptable approach for meeting an NRC requirement, then the standard constitutes a method acceptable to the NRC staff for meeting that regulatory requirement as described in the specific regulatory guide. If the secondary reference has neither been incorporated by reference into NRC regulations nor endorsed in a regulatory guide, then the secondary reference is neither a legally-binding requirement nor a "generic" NRC approval as an acceptable approach for meeting an NRC requirement. However, licensees and applicants may consider and use the information in the

secondary reference, if appropriately justified and consistent with current regulatory practice, consistent with applicable NRC requirements such as 10 CFR 50.59.

C. STAFF REGULATORY GUIDANCE

The NRC staff considers conformance with NEI 06-06, Revision 6, April 2013, to be a method that is acceptable for use in satisfying the regulations with respect to the implementation of FFD program at new reactor construction sites, subject to the following conditions:

- (1) In NEI 06-06, Revision 6, Section 2.1, the sentence after a discussion of Item h, “In addition, individuals who perform the duties specified in 10 CFR 26.4(e) may be included in the program covered by this guidance,” should be deleted because it is inconsistent with the discussion in Section 1 regarding the regulatory treatment of these individuals. Section 1 reads that NEI 06-06, Revision 6, “does not include guidance for those individuals with duties specified in 10 CFR 26.4(e) who must be subject to an FFD program that meets all the requirements of 10 CFR Part 26, except Subparts I and K.”
- (2) For the clarification and typographical error correction purposes, the followings should be made to the NEI 06-06 document:
 - a. Table 3-1, item 3, second column, 10 CFR 26.4(e)(I) should be corrected to indicate 10 CFR 26.4(e)(1).
 - b. Section 6.2.1, Pre-Assignment. The word “covered” in the first sentence of this paragraph should be deleted in order to minimize confusion as to what constitutes a covered activity for individuals within the construction site workforce.

Use of Examples

Although examples are appropriate as general templates for illustrating and reinforcing the guidance in NEI 06-06 and associated regulatory guidance, the NRC endorsement of NEI 06-06 should not be considered a determination that each NEI 06-06 example applies to any or all licensees, applicants, or other entities as presented and written in NEI 06-06 or this regulatory guide. A licensee should ensure that any example provided applies to its particular circumstance before implementation.

D. IMPLEMENTATION

The purpose of this section is to provide information on how applicants and licensees¹ may use this guide and information regarding the NRC’s plans for using this regulatory guide. In addition, it describes how the NRC staff complies with 10 CFR 50.109, “Backfitting” and any applicable finality provisions in 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.”

Use by Applicants and Licensees

Applicants and licensees may voluntarily² use the guidance in this document to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this regulatory guide may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Current licensees may continue to use guidance that the NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged.

Licensees may use the information in this regulatory guide for actions that do not require NRC review and approval, such as changes to a facility design under 10 CFR 50.59, “Changes, Tests, and Experiments.” Licensees may use the information in this regulatory guide to resolve regulatory or inspection issues.

Use by NRC Staff

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this regulatory guide. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this regulatory guide, unless the licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request licensees to voluntarily adopt this regulatory guide to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action that would require the use of this regulatory guide. Examples of such unplanned NRC regulatory actions include issuance of an order requiring the use of the regulatory guide, requests for information under 10 CFR 50.54(f) as to whether a licensee intends to commit to use of this regulatory guide, generic communication, or promulgation of a rule requiring the use of this regulatory guide without further backfit consideration.

During regulatory discussions on plant specific operational issues, the staff may discuss with licensees various actions consistent with staff positions in this regulatory guide, as one acceptable means of meeting the underlying NRC regulatory requirement. Such discussions would not ordinarily be considered backfitting even if prior versions of this regulatory guide are part of the licensing basis of the facility. However, unless this regulatory guide is part of the licensing basis for a facility, the staff may not represent to the licensee that the licensee’s failure to comply with the positions in this regulatory guide constitutes a violation.

If an existing licensee voluntarily seeks a license amendment or change and (1) the NRC staff’s consideration of the request involves a regulatory issue directly relevant to this new or revised regulatory guide and (2) the specific subject matter of this regulatory guide is an essential consideration in the staff’s determination of the acceptability of the licensee’s request, then the staff may request that the licensee either follow the guidance in this regulatory guide or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements. This is not considered backfitting as defined in 10 CFR 50.109(a)(1) or a violation of any of the issue finality provisions in 10 CFR Part 52.

If a licensee believes that the NRC is either using this regulatory guide or requesting or requiring the licensee to implement the methods or processes in this regulatory guide in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfit appeal with the NRC in accordance with the guidance in NUREG-1409, “Backfitting Guidelines,” (Ref. 6) and the NRC Management Directive 8.4, “Management of Facility-Specific Backfitting and Information Collection” (Ref. 7).

¹ In this section, “licensees” refers to licensees of nuclear power plants under 10 CFR Parts 50 and 52; and the term “applicants,” refers to applicants for licenses and permits for (or relating to) nuclear power plants under 10 CFR Parts 50 and 52.

² In this section, “voluntary” and “voluntarily” means that the licensee is seeking the action of its own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action.

REFERENCES¹

1. Title 10 of the *Code of Federal Regulation*, Part 26, “Fitness for Duty Programs,” Subpart K, “FFD Program for Construction,” 73 FR 16966, March 31, 1998.
2. Nuclear Energy Institute (NEI) 06-06, “Fitness for Duty Program Guidance for New Nuclear Power Plant Construction Sites,” revision 6, April 2013 (ADAMS Accession No. ML13093A331).
3. “Mandatory Guidelines for Federal Workplace Drug Testing Programs,” U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, (73 FR 75122; December 10, 2008).
4. “Power Reactor Security Requirements; Final Rule,” Title 10 of the *Code of Federal Regulations*, Parts 50, 52, 72, et al., 74 FR 13926, March 27, 2009.
5. Code of Federal Regulations (CFR), *Title 10, Energy*, Part 50, “Domestic Licensing of Production and Utilization Facilities.”
6. NRC, “Backfitting Guidelines,” NUREG-1409, July 1990 (ADAMS Accession No. ML032230247).
7. NRC, “Management of Facility-specific Backfitting and Information Collection,” NRC, Management 8.4, October 28, 2004.
8. Summary of Public Meeting on March 7, 2013 to Resolve Staff Comment On Nuclear Energy Institute Guidance Document NEI 06-06, “Fitness for Duty Program Guidance For New Nuclear Power Plant Construction Sites,” Revision 6 (ML13078A333).
9. June 4, 2013, NRC Response Letter to Endorse NEI for Regulatory Guide Development of NEI 06-06, Revision 6, Dated April 2013 (ML13091A101).

¹ Publicly available NRC published documents are available electronically through the NRC Library on the NRC’s public Web site at: <http://www.nrc.gov/reading-rm/doc-collections/>. The documents can also be viewed on-line or printed for a fee in the NRC’s Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone 301-415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail pdr.resource@nrc.gov.