



DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-5036

(Proposed New Regulatory Guide)

FITNESS-FOR-DUTY PROGRAMS AT NEW REACTOR CONSTRUCTION SITES

A. INTRODUCTION

Purpose

This regulatory guide describes methods and procedures that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable when developing fitness-for-duty (FFD) programs at new reactor construction sites. Licensees, applicants, and contractors/vendors (C/Vs) who implement FFD programs should consider this guidance when preparing an application for a combined license (COL), a limited work authorization (LWA), construction permit (CP), or early site permit (ESP).

Applicable Rules and Regulations

- Part 26 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 26), “Fitness-for-Duty Programs,” (Ref. 1), describes the categories of licensees and permit holders who are required to implement a FFD program. Section 26.4(f) requires that any individual who is constructing or directing the construction of safety- or security-related SSCs (structures, systems and components) shall be subject to a FFD program that meets the requirements of Subpart K, “FFD Programs for Construction,” unless the licensee or other entity subjects these individuals to an FFD program that meets all of the requirements of Part 26, except for subparts I and K.

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. Methods

This regulatory guide is being issued in draft form to involve 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. Public comments are being solicited on this draft guide and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Comments may be submitted through the Federal-rulemaking Web site, <http://www.regulations.gov>, by searching for Docket ID: NRC-2014-0253. Alternatively, comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments must be submitted by the date indicated in the *Federal Register* notice.

Electronic copies of this draft regulatory guide, previous versions of this guide, and other recently issued guides are available through the NRC’s public Web site under the Regulatory Guides document collection of the NRC Library at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/>. The draft regulatory guide is also available through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML14205A141. The regulatory analysis may be found in ADAMS under Accession No. ML14218A861.

and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission

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 guide endorses the methods 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, dated April 2013, (Ref. 2) with the exception that is identified in the following Staff Regulatory Guidance section, as acceptable methods of meeting the Commission's regulations.

Background

In 2008 and 2009, respectively, the NRC revised its comprehensive FFD regulations in 10 CFR Part 26 to adopt and reflect selected provisions of the U.S. Department of Health and Human Services "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).

FFD programs as described in 10 CFR Part 26.4 are applicable to specific categories of individuals. 10 CFR Part 26.4(a) requires all persons who have unescorted access to nuclear reactor protected areas to be subject to a FFD program that meets all of 10 CFR Part 26, except for Subpart K (FFD program for construction). 10 CFR Part 26.4(f) requires that "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 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 of this part," (Fatigue management and FFD program for construction, respectively), as might be encountered at a site with an operating reactor adjacent to a reactor under construction. The introduction to NEI 06-06, Revision 6, states that it remains in effect until the construction site transitions to an operations related FFD program, requiring implementation of 10 CFR 26 subparts A-I, N and O. It also goes on to say that it does not include guidance for those individuals with duties specified in 10 CFR Part 26.4(f) who may also be subject to an FFD program that meets all the requirements of 10 CFR Part 26, except Subparts I and K.

Harmonization with International Standards

The International Atomic Energy Agency (IAEA) has established a series of safety guides and standards constituting a high level of safety for protecting people and the environment. IAEA safety guides present international good practices and increasingly reflects best practices to help users striving to achieve high levels of safety. The NRC staff reviewed guidance from the International Atomic Energy Agency (IAEA) and other organizations and found guidance applicable to FFD. However, staff did not

identify any other standards that provided detailed guidance specifically addressing requirements of 10 CFR Part 26.

Documents Discussed in Staff Regulatory Guidance

This regulatory guide endorses the use of a process developed by NEI. NEI 06-06 may contain references to other standards or 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.

C. STAFF REGULATORY GUIDANCE

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

In NEI 06-06, Revision 6, section 2.1, the sentence after a discussion of Item h states: “In addition, individuals who perform the duties specified in 10 CFR 26.4(e) may be included in the program covered by this guidance.” This sentence is inconsistent with the discussion in Section 1 regarding the regulatory treatment of these individuals. As stated in Section 1 of NEI 06-06, “It [NEI 06-06] 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.” The NRC staff has determined that NEI 06-06, Revision 6, is not an acceptable method of complying with the requirements specified in 10 CFR 26.4(e). Individuals listed in 10 CFR 26.4(e) must be subject to all the requirements of Part 26, except subparts I and K, and NEI 06-06, Revision 6, does not provide guidance for those requirements. For these reasons the sentence quoted above from section 2.1 of NEI 06-06, Revision 6 should be deleted.

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 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 which 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 or applicable parts 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 which 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

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.

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.

Additionally, an existing applicant may be required to comply with new rules, orders, or guidance if 10 CFR 50.109(a)(3) applies.

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. 5) and the NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection" (Ref. 6).

REFERENCES³

1. U.S. Code of Federal Regulations (CFR), Part 26, "Fitness-for-Duty Programs, Chapter 1, Title 10, "Energy."
2. Nuclear Energy Institute (NEI) 06-06, "Fitness-for-Duty Program Guidance for New Nuclear Power Plant Construction Sites," Revision 6, NEI, Washington, DC, April 2013.
3. 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. 71858-71938.
4. CFR, Part 73, "Physical Protection of Plants and Materials," Chapter 1, Title 10, "Energy."
5. U.S. Nuclear Regulatory Commission (NRC), NUREG-1409, "Backfitting Guidelines."
6. NRC, Management Directive 8.4, "Management of Facility Specific Backfitting and Information."

3 Publicly available NRC documents are available electronically online through the NRC Library on the NRC's public Web site at <http://www.nrc.gov/reading-rm/doc-collections/> and through the NRC's Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>. The documents can also be viewed online or printed for a fee in the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD. For problems with ADAMS, contact the PDR staff at 301-415-4737 or (800) 397-4209; fax (301) 415-3548; or e-mail pdr.resource@nrc.gov.