U.S. NUCLEAR REGULATORY COMMISSION

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Revision 3

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 1.33

(Draft was issued as DG-1300, dated January 2013)

QUALITY ASSURANCE PROGRAM REQUIREMENTS (OPERATION)

A. INTRODUCTION

Purpose

This regulatory guide (RG) describes methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for managerial and administrative Quality Assurance (QA) controls to be used for nuclear power plants during operations.

Applicable Rules and Regulations

This guide describes methods that the NRC staff considers acceptable for complying with the provisions of regulations in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," of the *Code of Federal Regulations* (Ref. 1), §50.34(b)(6)(ii), Contents of applications; technical information and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," (10 CFR Part 52) (Ref. 2) §52.79(a)(27), Contents of applications; technical information in final safety analysis report. Both sections require compliance with 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," which, in part, requires the establishment of QA controls for the implementation of managerial and administrative controls to assure safe operation.

Related Guidance

Guidance for the establishment and execution of QA programs for nuclear power plants during their design and construction is in RG 1.28, "Quality Assurance Program Requirements (Design and Construction)," (Ref. 3).

Written suggestions regarding this guide or development of new guides may be submitted 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/contactus.html.

Electronic copies of this 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/. The 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 ADAMS Accession No. ML13109A458. The regulatory analysis may be found in ADAMS under Accession No. ML13109A459 and the staff responses to the public comments on DG-1300 may be found under ADAMS Accession No. ML13109A467.

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 to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required. Methods 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 50 and 10 CFR Part 52 that the Office of Management and Budget (OMB) approved under OMB control numbers 3150-0011 and 3150-0151, respectively. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number.

B. DISCUSSION

Reason for Revision

This revision (Revision 3) of RG 1.33 endorses ANSI/ANS 3.2-2012, "Managerial, Administrative, and Quality Assurance Controls for Operational Phase of Nuclear Power Plants," (Ref. 4). Revision 2 of RG 1.33 endorsed a previous version of the standard, which was ANS 3.2/ANSI N18.7-1976, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants," (Ref. 5). The updated standard incorporates operational experience since the original standard was developed, and is better focused on QA of plant operations because information on QA of design and construction was moved to another standard.

Background

Revision 2 of RG 1.33 (Ref. 6) endorsed ANS 3.2/ANSI 18.7-1976, but required numerous clarifications or modifications of the standard in the RG's Regulatory Position section. Since then, licensees have obtained NRC approval to use various alternate positions to Revision 2 of RG 1.33.

In addition, the American Society of Mechanical Engineers (ASME) issued NQA-1, "Quality Assurance Program Requirements for Nuclear Power Plants," (Ref. 7), which was focused on design and construction issues. The NRC has endorsed NQA-1 in 10 CFR 50.55a, "Codes and Standards". The NRC revised a related RG (RG 1.28) to endorse NQA-1-2008 and the NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications."

ANSI/ANS 3.2-2012 revised ANS 3.2/ANSI 18.7-1976 to remove information related to design and construction to be consistent with NQA-1, and to incorporate the alternate positions approved by the NRC since ANS 3.2/ANSI 18.7-1976 was issued. Revision 3 of RG 1.33 clarifies the distinction of the quality assurance program during design and construction from those managerial and administrative controls implemented during the operational phase of nuclear power plants.

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 reflect best practices to help users striving to achieve high levels of safety. Pertinent to this regulatory guide, the IAEA Safety Standards, and their Safety Requirement GS-R-3, "The Management System for Facilities and Activities," (Ref. 8), issued in 2006, address administrative and quality assurance controls for the operational phase of nuclear power plants. This regulatory guide incorporates similar administrative and quality assurance controls for the operational phase and is consistent with the basic safety principles provided in the IAEA Safety Standard.

Documents Discussed in Staff Regulatory Guidance

This regulatory guide endorses the use of one or more voluntary consensus codes or standards developed by external organizations. These codes or standards may contain references to other codes or standards. These references should be considered individually. If a referenced standard has been incorporated separately into NRC regulations, licensees and applicants must comply with that standard as set forth in the regulation. If the referenced standard has been endorsed in a regulatory guide, the standard constitutes a method acceptable to the NRC staff for meeting a regulatory requirement as described in the specific regulatory guide. If a referenced standard has been neither incorporated into NRC regulations nor endorsed in a regulatory guide, licensees and applicants may consider and use the information in the referenced standard, if appropriately justified and consistent with current regulatory practice.

C. STAFF REGULATORY GUIDANCE

The requirements included in ANSI/ANS 3.2-2012, "Managerial, Administrative and Quality Assurance Controls for the Operational Phase of Nuclear Power Plants", for implementation during the operation phase of nuclear power plants, are acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50, subject to the following condition on the use of ANSI/ANS 3.2-2012:

- ANSI/ANS 3.2-2012 requires the preparation of many procedures to carry out an effective QA program. Appendix A of ANSI/ANS 3.2-2012, "Typical Procedures for Pressurized Water Reactors and Boiling Water Reactors," should be used as guidance to assure the minimal procedural coverage for plant operating activities, including related maintenance activities. Appendix A lists typical safety-related activities that should be covered by written procedures, but does not provide a complete listing of necessary procedures. Many other activities carried out during the operation phase of a nuclear power plant require written procedures, which may or may not be applicable, because of the configuration of the nuclear power plant. The procedures listed in Appendix A may be added to, combined, separated or deleted to conform to the applicant's procedure plan.

D. IMPLEMENTATION

The purpose of this section is to provide information on how applicants and licensees[1] 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 voluntarily[2] 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 Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)," Revision 2 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.

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[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, and applicants for standard design approvals and standard design certifications under 10 CFR Part 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.

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.

Additionally, an existing applicant may be required to adhere to 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. 9) and NRC Management Directive 8.4, "Management of Facility-specific Backfitting and Information Collection" (Ref. 10).

REFERENCES[3]

1. *U.S. Code of Federal Regulations*, 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

2. *U.S. Code of Federal Regulations*, 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

3. Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction), "U.S. Nuclear Regulatory Commission, Washington, DC.

4. American National Standards Institute (ANSI)/ American Nuclear Society (ANS) 3.2-2012, "Managerial, Administrative, and Quality Assurance Controls for Operational Phase of Nuclear Power Plants."

5. American Nuclear Society[4] (ANS) 3.2/ American National Standards Institute[5] (ANSI) 18.7-1976, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants."

6. Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)," Revision 2, U.S. Nuclear Regulatory Commission, Washington, DC.

7. American National Standards Institute (ANSI)/American Society of Mechanical Engineers (ASME) NQA-1, "Quality Assurance Program Requirements for Nuclear Power Plants."[6]

8. International Atomic Energy Agency Safety Requirement GS-R-3, "The Management Systems for Facilities and Activities," issued 2006.[7]

9. NUREG 1409, "Backfitting Guidelines," U.S. Nuclear Regulatory Commission, Washington, DC.

10. Management Directive 8.4, "Management of Facility-specific Backfitting and information Collection," U.S. Nuclear Regulatory Commission, Washington, DC.

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[3] 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

[4] Copies of American Nuclear Society (ANS) standards may be purchased from the ANS Web site (http://www.new.ans.org/store/); or by writing to: American Nuclear Society, 555 North Kensington Avenue, La Grange Park, Illinois 60526, U.S.A., Telephone 800-323-3044.

[5] Copies of American National Standards Institute (ANSI) standards may be purchased from ANSI, 1819 L Street, NW., Washington, DC 20036, on their Web site at http://webstore.ansi.org/; telephone (202) 293-8020; fax (202) 293-9287; or e-mail storemanager@ansi.org.

[6] Copies of American Society of Mechanical Engineers (ASME) standards may be purchased from ASME, Two Park Avenue, New York, New York 10016-5990; telephone (800) 843-2763. Purchase information is available through the ASME Web-based store at http://www.asme.org/Codes/Publications/.

[7] Copies of International Atomic Energy Agency(IAEA) standards may be purchased from IAEA, Wagramerstrasse 5, P.O. Box 100, A-1400 Vienna, Austria; Telephone: +43 1 2600 22529 (or 22530). Purchase information is available through the ASME Web-based store at http://www-pub.iaea.org/MTCD/publications/publications.asp.