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REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 2.5

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QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR RESEARCH AND TEST REACTORS

A. INTRODUCTION

This guide describes a method acceptable to the staff of the U.S. Nuclear Regulatory Commission (NRC) of complying with the Commission's regulations with regard to the overall quality assurance program requirements for research and test reactors.

Title 10, Section 50.34(a)(7), of the *Code of Federal Regulations* (10 CFR 50.34(a)(7)) (Ref. 1), requires each applicant for a construction permit to build a production or utilization facility to include, in its preliminary safety analysis report, a description of the quality assurance program to be applied to the design and construction of the structures, systems, and components of the facility. Furthermore, 10 CFR 50.34(b)(6)(ii) requires that each applicant for a license to operate a facility include, in the final safety analysis report, a description of the managerial and administrative controls to be used to ensure safe operation.

This regulatory guide contains information collection requirements covered by 10 CFR Part 50 that the Office of Management and Budget (OMB) approved under OMB control number 3150-0011. 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.

The NRC issues regulatory guides to describe and make available to the public methods that the NRC staff considers acceptable for use in implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in reviewing applications for permits and licenses. 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.

This guide was issued after consideration of comments received from the public.

Regulatory guides are issued in 10 broad divisions—1, Power Reactors; 2, Research and Test Reactors; 3, Fuels and Materials Facilities; 4, Environmental and Siting; 5, Materials and Plant Protection; 6, Products; 7, Transportation; 8, Occupational Health; 9, Antitrust and Financial Review; and 10, General.

Electronic copies 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's Electronic Reading Room 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, under Accession No. ML093520099. The regulatory analysis may be found in ADAMS under Accession No. ML101650030.

B. DISCUSSION

The American National Standards Institute (ANSI) and the American Nuclear Society (ANS) issued the first version of ANSI/ANS-15.8-1976, "Quality Assurance Program Requirements for Research Reactors," in August 1976 (Ref. 2). The NRC subsequently endorsed this guidance in Revision 0 to Regulatory Guide 2.5, "Quality Assurance Program Requirements for Research Reactors," issued October 1977 and reaffirmed in 1986. Because of the significant changes subsequently made to management programs and to the expected level of detail and documentation of program elements for nonpower (research and test) reactors, ANSI and ANS issued ANSI/ANS-15.8-1995 in 1995 (Ref. 3) and reaffirmed it in September 2005 to incorporate the acknowledged enhancements to quality assurance programs.

Research and test reactor licensees can find other useful guidance in the regulatory information developed for power reactor licensees. For example, the guidance developed for power reactors regarding the procurement of safety-related items may be useful, such as, Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," (Ref.4).

The NRC staff note, that the International Atomic Energy Agency (IAEA) has established a series of safety standards reflecting an international consensus constituting a high level of safety for protecting people and the environment. Relative to this regulatory guide, IAEA Safety Requirements publication NS-R-4, "Safety at Research Reactors" (Ref. 5), provides quality assurance requirements in sections 4.5-4.13, as part of an overall system of management and verification controls. While the NRC has an interest in facilitating the harmonization of standards used domestically and internationally, the NRC does not specifically endorse NS-R-4, and is only acknowledging that it may be useful as a reference for general information. The NRC could consider the use of the international standard in a licensing action following adequate justification and technical review.

C. REGULATORY POSITION

The general requirements for establishing and executing a quality assurance program for the design, construction, testing, modification, and maintenance of research and test reactors in ANSI/ANS-15.8-1995 provide an acceptable method for complying with the program requirements of 10 CFR 50.34, "Contents of Applications; Technical Information."

The references identified in ANSI/ANS-15.8-1995 may provide applicable information and may be endorsed elsewhere or incorporated with the licensing basis of the facility. However, recognition of the acceptability of ANSI/ANS-15.8-1995 does not necessarily extend to other referenced standards.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC's plans for using this regulatory guide. The NRC does not intend or approve any imposition or backfit in connection with its issuance.

The issuance of this guide does not change the existing licensing basis of a facility, and no changes are required as a result of the publishing of this guidance.

In some cases, applicants or licensees may propose or use a previously established acceptable alternative method for complying with specified portions of the NRC's regulations. Otherwise, the methods described in this guide will be used in evaluating compliance with the applicable regulations for license applications, license amendment applications, and amendment requests.

REFERENCES

1. 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," U.S. Nuclear Regulatory Commission, Washington, DC.[1]

2. ANSI/ANS-15.8-1976, "Quality Assurance Program Requirements for Research Reactors," American Nuclear Society, La Grange Park, IL.[2]

3. ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors," American Nuclear Society, La Grange Park, IL, reaffirmed September 2005.

4. Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," U.S. Nuclear Regulatory Commission, Washington, DC.[3]

5. Safety Requirements, NS-R-4, "Safety at Research Reactors," September, 2005, International Atomic Energy Agency, Vienna, Austria.

[1] All NRC regulations listed herein are available electronically through the Electronic Reading Room on the NRC's public Web site, at http://www.nrc.gov/reading-rm/doc-collections/cfr/. Copies are also available for inspection or copying for a fee from the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail pdr.resource@nrc.gov.

[2] Copies of American National Standards (ANS) may be purchased from the American National Standards Institute (ANSI), 1819 L Street, NW., 6th floor, Washington, DC 20036 [phone: (202) 293-8020)]. Purchase information is available through the ASCE Web site at http://webstore.ansi.org/ansidocstore/.

[3] All generic letters (GLs) listed herein were published by the U.S. Nuclear Regulatory Commission and are available electronically through the Electronic Reading Room on the NRC's public Web site, at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/gen-letters/. Copies are also available for inspection or copying for a fee from the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555-0001; telephone (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail pdr.resource@nrc.gov.