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OFFICE OF NUCLEAR REGULATORY RESEARCH

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Division 2

DRAFT REGULATORY GUIDE

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(Proposed Revision 1 of Regulatory Guide 2.5, dated May 1977)

QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR RESEARCH AND TEST REACTORS

A. INTRODUCTION

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 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.

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.

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.

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 (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 Rulemaking 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 November 13, 2009.

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's Electronic Reading Room 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. ML091460620.

B. DISCUSSION

The American National Standards Institute (ANSI) and the American Nuclear Society (ANS) issued the first version of ANSI/ANS-15.8-1976, the "Quality Assurance Program Requirements for Research Reactors," in August 1976. 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. 2) and reaffirmed it in September 2005, to incorporate the acknowledged enhancements to quality assurance programs.

Research and test reactor licensees can find additional guidance in the regulatory guides developed for power reactor licensees. For example, the guidance developed for power reactors regarding the procurement of safety-related items may be useful.

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 draft regulatory guide. The NRC does not intend or approve any imposition or backfit in connection with its issuance.

The NRC has issued this draft guide to encourage public participation in its development. The NRC will consider all public comments received in development of the final guidance document. In some cases, applicants or licensees may propose an alternative 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.

REGULATORY ANALYSIS

Statement of the Problem

The guidance endorsed in the current version of this guide is outdated. Therefore, a revision of this regulatory guidance is necessary to endorse the updated quality assurance guidance provided in the industry standard.

Objective

The objective of this regulatory action is to update the regulatory guidance.

Alternative Approaches

The NRC staff considered the following alternative approaches:

Do not revise Regulatory Guide 2.5.
Revise Regulatory Guide 2.5.

Alternative 1: Do Not Revise Regulatory Guide 2.5

Under this alternative, the NRC would not revise its guidance, and the current guidance would be retained. If the NRC does not take action, there would not be any changes in costs or benefit to the public, licensees, or the NRC. However, the "no-action" alternative would not address identified concerns with the current version of the regulatory guide. The NRC would continue to review each application on a case-by-case basis. This alternative provides a baseline condition from which any other alternatives will be assessed.

Alternative 2: Revise Regulatory Guide 2.5

Under this alternative, the NRC would revise Regulatory Guide 2.5, taking into consideration the availability of updated industry standards for quality assurance.

One benefit of this action is that it would assist license applicants in preparing the application package, as the current guidance is well known to both the applicants and the NRC staff.

The impact to the NRC would be the costs associated with preparing and issuing the regulatory guide revision. This guide requires minimal cost and effort to update. The impact to the public would be the voluntary costs associated with reviewing and providing comments to the NRC during the public comment period. The value to the NRC staff and its applicants would be the benefits associated with enhanced efficiency and effectiveness in using a common contemporary guidance document as the technical basis for license applications and other interactions between the NRC and its regulated entities.

Conclusion

Based on this regulatory analysis, the NRC staff recommends the revision of Regulatory Guide 2.5. The staff concludes that the proposed action will enhance its review of license applications by providing the current standard accepted for use by research and test reactor licensees. It could also lead to cost savings for the industry, especially with regard to the use of current standards in license applications and supporting documentation of program elements for research and test reactors.

REFERENCES[1]

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

2. ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors," American Nuclear Society, La Grange Park, IL, reaffirmed September 2005.[2]

[1] Publicly available NRC published documents such as Regulations, Regulatory Guides, NUREGs, and Generic Letters 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/. 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 the non-NRC documents included in these references may be obtained directly from the publishing organization.