



U.S. NUCLEAR REGULATORY COMMISSION

Revision 1
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REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 1.28 QUALITY ASSURANCE PROGRAM REQUIREMENTS (DESIGN AND CONSTRUCTION)

A. INTRODUCTION

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Licensing of Production and Utilization Facilities," establishes overall quality assurance requirements for the design, construction, and operation of safety-related structures, systems, and components. This guide describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to overall quality assurance program requirements during design and construction of nuclear power plants.

B. DISCUSSION

Subcommittee N45-2.7 (formerly N45-3.7) of the American National Standards Committee for Reactor Plants and Their Maintenance, developed ANSI N45.2-1971 that included general requirements for establishing and executing a quality assurance program during the design and construction phases of nuclear power plants. This standard was endorsed by Regulatory Guide 1.28 (Safety Guide 28). To update the requirements of the standard and to make it applicable to other nuclear facilities subject to 10 CFR Part 50, Appendix B, the standard was revised by the N45-2.7 Working Group in cooperation with the N46-2 subcommittee.

The revised standard was approved by Subcommittee N45-2, Nuclear Quality Assurance Standards, of the American National Standards Committee N45 and the N45 committee and by Subcommittee N46-2, the N46 committee, and the N18 committee. It was subsequently approved and designated N45.2-1977, "Quality Assurance Program Requirements for Nuclear Facilities," by the American

National Standards Institute on April 7, 1977.*

Some uncertainty has arisen with regard to the NRC staff's position when a regulatory guide endorses, as an acceptable method, the "guidelines" as well as the "requirements" included in a standard. The NRC staff has endorsed the guidelines contained in N45.2-1977 with respect to importance to safety. This regulatory guide is intended to clarify the NRC staff's position on the "requirements" and "guidelines" included in ANSI N45.2-1977. Where conformance to the recommendation of this regulatory guide is indicated in an application without further qualification, this indicates that the applicant will comply with the "requirements" of ANSI N45.2-1977, as supplemented or modified by the regulatory position of this guide.

C. REGULATORY POSITION

The overall quality assurance program requirements for the design and construction phases that are included in ANSI N45.2-1977 provide an adequate basis for complying with the quality assurance program requirements of Appendix B to 10 CFR Part 50, as supplemented or modified by the following:

1. Section 2 of N45.2-1977 requires, in part, that "A documented Quality Assurance Program which complies with the applicable sections and elements of this standard shall be established at the earliest practical time consistent with the schedule for accomplishing the activities for the nuclear facility." The following information should be used to clarify the requirement of Section 2 of ANSI N45.2-1977.

* Copies may be obtained from the American Society of Mechanical Engineers, United Engineering Center, 345 East 47th Street, New York, N.Y. 10017.

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Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. However, comments on this guide, if received within about two months after its issuance, will be particularly useful in evaluating the need for an early revision.

Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

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For those safety-related activities that are initiated by the applicant prior to submitting its application for a construction permit, the requirements set forth in ANSI N45.2-1977 and amplified in the applicable N45.2 series standards should be in effect prior to accomplishing the activities. The following are examples of such activities that are or may be initiated prior to submitting the application:

- a. Activities performed in the establishment of the information required to be included in the Preliminary Safety Analysis Report.

- b. Activities pertaining to the preparation of design and procurement documents affecting safety-related structures, systems, and components.

2. The guidelines (indicated by the verb "should") of ANSI N45.2-1977 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard:

- a. Section 14, second paragraph—The guidelines on procedures for critical, sensitive, perishable, or high-value articles and on use and control of special handling tools.

- b. Section 19, second paragraph—The guideline on when to perform audits.

- c. Section 19, third paragraph—The guideline in the first sentence of the paragraph that indicates the three general areas of evaluation to include in an audit.

- d. Section 19, fifth paragraph—The guideline on developing an audit plan.

- e. Section 19, sixth paragraph—The guideline on scheduling of audits and the guideline that specifies the conditions that require conducting audits.

3. The Foreword and Section 1.2, "Applicability," of ANSI N45.2-1977 state: "The ASME Boiler and Pressure Vessel Code, as well as other American National Standards, have been considered in the development of this standard, and this standard is intended to be compatible with their requirements. However, this standard does not apply to the activities covered by Section III and Section XI of the Code." It is important to consider the relationship of the quality assurance requirements included in Section III of the Code with those included in ANSI N45.2. Code-covered activities are primarily intended to ensure the integrity of the pressure boundary of an item. Section III of the Code does not address activities necessary to ensure functional operability of some Code-covered items such as pumps or valves. Therefore, to ensure functional operability of these items, the quality assurance program for design and construction should be extended to these other activities, and the guidance in N45.2 should be used, as appropriate.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide. Except in those cases in which the applicant proposes an alternative method for complying with specified portions of the Commission's regulations, the method described herein will be used in the evaluation of submittals for construction permit applications docketed after November 30, 1978. If an applicant whose application for a construction permit is docketed on or before November 30, 1978, wishes to use this regulatory guide in developing submittals for applications, the pertinent portions of the application will be evaluated on the basis of this guide.