

U.S. NUCLEAR REGULATORY COMMISSION



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, "Domestic 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.

* The Advisory Committee on Reactor Safeguards has been consulted concerning this guide and has concurred in the regulatory position.

B. DISCUSSION

Subcommittee N45-2.7 (formerly N45-3.7) of the American National Standards Committee N45, Reactor Plants and Their Maintenance, developed a standard designated 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 Appendix B to 10 CFR Part 50, the standard was revised by the N45-2.7 work group in cooperation with the N46-2 subcommittee.

The revised standard was approved by Subcommittee N45-2, Nuclear Quality Assurance

* Lines indicate substantive changes from previous issue.

Standards, of the American National Standards Committee N45 and the full N45 committee and by Subcommittee N46-2, the full 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, 1977.¹

The NRC staff has evaluated the guidelines contained in N45.2-1977 and has identified those that are important to safety. The indication of conformance to this regulatory guide in an application without qualification means that the requirements of ANSI N45.2-1977 as supplemented or modified by the regulatory position of this guide will be followed.

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, "Quality Assurance Program," 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.

¹Copies 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. This guide was revised as a result of substantive comments received from the public and additional staff review.

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. Examples of such activities that are or may be initiated prior to submitting the application are:

a. Activities performed in establishing the information to be included in the Preliminary Safety Analysis Report.

b. Activities pertaining to preparing design and procurement documents that affect 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, "Handling, Storage, and Shipping," second paragraph - The guidelines on procedures for critical, sensitive, or perishable articles and on use and control of special handling tools.

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

3. In Section 19, "Audits," the second and fifth paragraphs include general guidelines for audit scheduling. Audit scheduling, including the guidelines of these paragraphs, is addressed separately and in more detail in Regulatory Guide 1.144, "Auditing of Quality Assurance Programs for Nuclear Power Plants."

4. 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 com-

patible 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 the satisfactory performance of activities affecting the functional operability of these items, the quality assurance program for design and construction should be extended to these other activities, and the requirements in N45.2 should be used, as appropriate.

D. IMPLEMENTATION

Except in those cases in which the applicant proposes an acceptable alternative method for complying with the specified portions of the Commission's regulations, the method described herein will be used in the evaluation of applications docketed after October 1979 for:

(1) standard reference system preliminary or Type-2 final design approvals (PDA or FDA-2),

(2) licenses to manufacture, and

(3) construction permits (CP), except those portions that:

(a) reference an approved standard reference system preliminary or final design (PDA or FDA) or applications for such approval,

(b) reference an approved standard duplicate plant preliminary or final design (PDDA or FDDA),

(c) reference parts of a base plant design qualified and approved for replication,

(d) reference a plant design approved or being reviewed for approval for manufacture under a Manufacturing License or applications for such approval.

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