



U.S. NUCLEAR REGULATORY COMMISSION

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

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REGULATORY GUIDE 1.144

AUDITING OF QUALITY ASSURANCE PROGRAMS FOR NUCLEAR POWER PLANTS

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 structures, systems, and components of nuclear power plants important to safety. Criterion XVIII, "Audits," of Appendix-B to 10 CFR Part 50 establishes requirements for conducting audits of the quality assurance program. This guide describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to auditing of quality assurance programs for nuclear power plants.

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

B. DISCUSSION

Working Group N45-2.12 of the American National Standards Committee N45, Reactor Plants and their Maintenance, has prepared a standard that provides requirements and guidance for establishing and implementing a system of internal and external audits of quality assurance programs for nuclear power plants, including the preparation, performance, reporting, and followup of audits by both the auditing and audited organizations.

The proposed standard (Draft 4, Revision 3, dated November 29, 1976) was approved and designated N45.2.12-1977¹ by the American National Standards Institute on November 17, 1977.

*Lines indicate substantive changes from January 1979 issue.

¹ANSI/ASME N45.2.12-1977, "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants," may be obtained from the American Society of Mechanical Engineers, 345 East 47th Street, New York, New York 10017.

WASH-1283, Revision 1, "Guidance on Quality Assurance Requirements During Design and Procurement Phase of Nuclear Power Plants," dated May 24, 1974 (Gray Book, Revision 1), and WASH-1309, "Guidance on Quality Assurance Requirements During the Construction Phase of Nuclear Power Plants," dated May 10, 1974 (Green Book, Revision 0), contain Draft 3, Revision 4, of proposed standard N45.2.12 (February 22, 1974), which is used by the NRC staff in the evaluation of applications for construction permits and operating licenses. ANSI/ASME N45.2.12-1977 reflects development of the standard from the proposed version included in the above WASH documents.

ANSI/ASME N45.2.12-1977, subject to the regulatory exceptions in Section C of this guide, will replace N45.2.12 (Draft 3, Revision 4) contained in WASH-1283 and WASH-1309 in the evaluation of proposed auditing procedures for the applicant's quality assurance program included in construction permit and operating license applications.

An unqualified indication of conformance to the recommendations of this regulatory guide in an application means that the NRC staff will use the requirements of ANSI/ASME N45.2.12-1977 as supplemented or modified by the regulatory position of this guide in its review of the application.

C. REGULATORY POSITION

The requirements that are included in ANSI/ASME N45.2.12-1977 for auditing quality assurance programs for nuclear power plants are acceptable to the NRC staff and provide an adequate basis for complying with the pertinent quality assurance requirements of Appendix B to 10 CFR Part 50, subject to the following:

1. Section 1.5, "Referenced Documents," of ANSI/ASME N45.2.12-1977 states that documents that are required to be included as a part of the standard are identified at the point of reference or described in Section 6 of the standard.

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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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The specific applicability of these listed documents has been addressed in the latest revision of the following regulatory guides:

ANSI Standard	Regulatory Guide
N45.2	1.28
N45.2.9	1.88
N45.2.10	1.74

2. The Foreword and Section 1.2, "Applicability," of ANSI/ASME N45.2.12-1977 state: "The ASME Boiler and Pressure Vessel Code (hereafter referred to as the 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 activities covered by Section III, Div. 1 and 2, and Section XI of the Code for those activities covered by the Code." While Section III, Divisions 1 and 2, and Section XI of the ASME Boiler and Pressure Vessel Code address general requirements for quality assurance program audits, these sections do not explicitly address all the activities described in ANSI/ASME N45.2.12-1977. ANSI/ASME N45.2.12-1977, subject to the exceptions of the regulatory position, should be used in conjunction with Section III, Divisions 1 and 2, and Section XI of the ASME Boiler and Pressure Vessel Code for auditing quality assurance programs where the ASME Code does not address the activities covered by ANSI/ASME N45.2.12-1977.

3. Section 3.5.2 of ANSI/ASME N45.2.12-1977 requires that audits of quality assurance activities be regularly scheduled to ensure that the quality assurance program is adequate and that activities are being performed in accordance with the quality assurance program. The frequency of the scheduling of audits is dependent on the status and importance of the activities to be audited, and the following is considered acceptable scheduling:

a. Internal Audits

(1) *Operational Phase Activities*—Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)," should be followed.

(2) *Design and Construction Phase Activities*—Applicable elements of an organization's quality assurance program should be audited at least annually or at least once within the life of the activity, whichever is shorter. In determining the scope of the audit, an evaluation of the area being audited may be useful. The evaluation may include some or all of the following: prior quality assurance program audits; results of audits from other sources; nature and frequency of identified deficiencies; and significant changes in personnel, organization, or quality assurance program.

b. External Audits

(1) External audits, after the award of a contract, are not necessary for procurement actions when the items or services are all of the following:

(a) Relatively simple and standard in design, manufacture, and test, and

(b) Adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery, and

(c) Such that receiving inspection does not require operations that could adversely affect the integrity, function, or cleanness of the item.

(2) For other procurement actions not listed in Item C.3.b.(1), audits should be conducted as follows:

Elements of a supplier's quality assurance program should be audited by the purchaser on a triennial basis with the audit implemented in accordance with Section 4, "Audit Implementation," of ANSI/ASME N45.2.12-1977. The triennial period should begin with performance of an audit when sufficient work is in progress to demonstrate that the organization is implementing a Quality Assurance Program having the required scope for purchases placed during the triennial period. When a subsequent contract or a contract modification that significantly enlarges the scope of activities performed by the same supplier is executed, an audit should be conducted of the increased requirements, thus starting a new triennial period. If, at the time of the pre-award survey, the supplier is already implementing the same quality assurance program for other customers that he proposes to use on the auditing party's contract, then the pre-award survey, if it was conducted in accordance with Section 4 of ANSI/ASME N45.2.12-1977, may serve as the first triennial audit. Therefore, when such pre-award surveys are employed as the first triennial audits, those surveys should satisfy the same audit elements and criteria used on other triennial audits.

A documented evaluation of the supplier should be performed annually. Where applicable, this evaluation should take into account (1) review of supplier-furnished documents such as certificates of conformance, non-conformance notices, and corrective actions, (2) results of previous source verifications, audits, and receiving inspections, (3) operating experience of identical or similar products furnished by the same supplier, and (4) results of audits from other sources, e.g., customer, ASME, or NRC audits.

4. The guidelines (indicated by the verb "should") of ANSI/ASME N45.2.12-1977 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. The guideline concerning supplementing regularly scheduled audits for Sections 3.5.3.3 through 3.5.3.5.

b. Section 4.3.2.7—The guideline concerning corrective action on program deficiencies identified during previous audits. In this regard, corrective action on program deficiencies identified during previous audits is construed to

mean "corrective action on program deficiencies in the area that is being audited."

5. Regulatory Position C.3 provides guidance on scheduling internal and external audits. Section 1.3, "Responsibility," of ANSI/ASME N45.2.12-1977 states: "The work of establishing practices and procedures and providing the resources in terms of personnel, equipment and services necessary to meet the requirements of this standard may be delegated to other organizations and such delegation shall also be documented." Where more than one purchaser buys from a single supplier, a purchaser may perform an audit of the supplier on behalf of more than one purchaser in order to reduce the number of external audits of the supplier. The results of this audit should be distributed to all purchasers for whom the audit was conducted.

6. The guideline in Section 3.5.3.6 of ANSI/ASME N45.2.12-1977 recommending an audit "when necessary to verify implementation of required corrective action" does not meet the provisions of Criterion XVIII of Appendix B to 10 CFR Part 50. Audits as well as other methods of surveillance can be used to verify implementation of required corrective action.

7. The requirements of ANSI/ASME N45.2.12-1977 contained in the second sentence of Section 5.2, "Audit Records," read "Records shall include the audit system plan, individual audit plans, audit reports, written replies, and the record of completion of corrective actions." Additionally, these records should include documents associated with the conduct of audits that support audit findings (for example, audit checklists or procedures).

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the method described herein will be used in the evaluation of the following applications that are docketed after November 28, 1980:

1. Preliminary Design Approval (PDA) applications and Preliminary Duplicate Design Approval (PDDA) applications.
2. Final Design Approval, Type 2, (FDA-2) applications and Final Duplicate Design Approval, Type 2, (FDDA-2) applications.
3. Manufacturing License (ML) applications.
4. Construction Permit (CP) applications except for those portions of CP applications that reference standard designs (i.e., PDA, FDA-1, FDA-2, PDDA, FDDA-1, FDDA-2, or ML) or that reference qualified base plant designs under the replication option.
5. Operating License (OL) applications.

If an applicant wishes to use this method in developing submittals for applications docketed on or before November 28, 1980, the pertinent portions of the application will be evaluated on the basis of this regulatory guide.

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