

AN AMERICAN NATIONAL STANDARD

Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants

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AN AMERICAN NATIONAL STANDARD

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FOREWORD

(This Foreword is not a part of American National Standard for Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants.)

This standard delineates requirements for establishing and implementing a system of internal and external audits that would apply to quality assurance programs for nuclear power plants. The standard was developed by the American National Standards Institute's Committee N45 on Reactor Plants and their Maintenance. This committee has been chartered to promote the development of standards for the location, design, construction, and maintenance of nuclear reactors and plants embodying nuclear reactors, including equipment, methods, and components.

In April 1970, the N45 Committee of the American National Standard Institute established a subcommittee N45-3 to guide the preparation of nuclear quality assurance standards. This subcommittee is responsible for establishing guidelines and policy to govern the scope and content of the various standards; monitoring the status of standards in process; recommending preparation of additional standards; and approval of standards prior to their submittal to the N45 Committee for balloting.

In February 1972, the N45-3 Subcommittee of the American National Standards Institute established a work group N45-3.12 on Audits. The purpose of this work group was to prepare a standard for general industry use that would define an auditing practice applicable to quality assurance program activities used to assure attainment of quality construction. The work group was composed of representatives of key segments of the nuclear industry, including utilities, reactor suppliers, equipment manufacturers, architect-engineers, constructors, and insurance industry. The standard contained herein was developed from this activity. The initial draft of this standard was prepared in January 1973.

Working with the N45-3 Subcommittee and concurrently with the development of this standard, other working groups of N45 are developing a series of standards that set forth more detailed requirements for certain activities to assure quality of nuclear power plants. These requirements will be coordinated with the requirements of this standard as they are developed.

In October 1972, the N45-3 Subcommittee was numbered N45-2, and the work groups were renumbered accordingly.

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.

Suggestions for improvement gained in the use of this standard will be welcomed. They should be sent to the Secretariat, ASME Committee on Nuclear Quality Assurance, The American Society of Mechanical Engineers, United Engineering Center, 345 East 47th Street, New York, New York 10017.

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W. Traffas, Gilbert Associates, Inc., Reading, Pennsylvania
J. E. Wahler, Combustion Engineering, Windsor, Connecticut

Working Group on Audits (N45-2.12)

F. W. Knight, *Chairman*, Westinghouse Electric Corporation
H. R. Banks, Carolina Power and Light Company
J. N. Babcock, United Engineers and Constructors, Inc.
T. L. Bonnough, Project Management Corporation
A. W. Crevasse, Tennessee Valley Authority
A. E. Henderson, Jr., Louisiana Power & Light Company
G. R. Hosack, General Electric Company
A. K. Hasija, Nuclear Energy Liability-Property Insurance Association/Mutual Atomic Energy Liability Underwriters
F. J. Long, U.S. Nuclear Regulatory Commission
J. H. Marshall, Niagara Mohawk Power Corporation

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AMERICAN NATIONAL STANDARD

**REQUIREMENTS FOR AUDITING OF QUALITY ASSURANCE PROGRAMS
FOR NUCLEAR POWER PLANTS****1. INTRODUCTION****1.1 Scope**

This standard 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.

This standard amplifies the audit requirements of ANSI N45.2 and shall be used in conjunction with that standard.

1.2 Applicability

The requirements of this standard apply to both internal and external audits performed by or for the plant owner, contractors, and other organizations participating in activities affecting the quality of structures, systems, and components of nuclear power plants in accordance with requirements of ANSI N45.2. This standard is not applicable to surveillance or inspections for the sole purpose of process control or product acceptance.

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.

1.3 Responsibility

The organization or organizations responsible for implementation of the applicable requirements of this standard shall be identified and the scope of their responsibilities and authorities shall be documented. 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. It is the responsibility of each organization performing any activity covered by this standard to comply with the requirements of this standard applicable to its work.

The organizational structure, functional responsibilities, levels of authority, and lines of internal and external communication for management direction of audits of the quality assurance program shall be documented. Where multiple organizational arrangements exist, the interface responsibilities of each organization shall be clearly defined and documented. In no way shall the performance of audits by an organization diminish the responsibility of the audited organization or contractor for audit of his designated portion of the quality assurance program or the quality of his product or services.

1.4 Definitions

The following definitions are provided to assure a uniform understanding of select terms as they are used in this standard:

Audit—A documented activity performed in accordance with written procedures or checklists to verify, by examination and evaluation of objective evidence, that applicable elements of the quality assurance program have been developed, documented and effectively implemented in accordance with specified requirements. An audit should not be confused with surveillance or inspection for the sole purpose of process control or product acceptance.

Internal Audits—Audits of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

External Audits—Audits of those portions of an organization's quality assurance program not retained under its direct control and not within its organizational structure.

Auditor—Any individual who performs any portion of an audit, including lead auditors, technical specialists and others such as management representatives and auditors in training.

Lead Auditor—An individual qualified to organize and direct an audit, report audit findings and evaluate corrective action.

Program Deficiencies—Failure to develop, document or implement effectively any applicable element of the quality assurance program required by ANSI N45.2.

Other terms and their definitions are contained in ANSI N45.2.10.

1.5 Referenced Documents

Documents that are required to be included as a part of this standard are identified at the point of reference or described in Section 6 of this standard. The issue or edition of the referenced document that is required will be specified either at the point of reference or in Section 6 of this standard unless otherwise specified in the contract document.

2. PERSONNEL

2.1 General

The responsible auditing organization shall select and assign auditors who are independent of any direct responsibility for performance of the activities which they will audit.

In the case of internal audits, the persons having direct responsibility for performance of the activities

being audited shall not be involved in the selection of the audit team.

2.2 Personnel Qualification

The responsible auditing organization shall establish the audit personnel qualifications and the requirements for the use of technical specialists to assist in the auditing of the quality assurance programs. Personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity or special nature of the activities to be audited.

2.3 Training

Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits. Competence of personnel for performance of the various auditing functions shall be developed by one or more of the following methods:

2.3.1 Orientation to provide a working knowledge and understanding of ANSI N45.2, this standard, and the auditing organization's procedures for implementing audits and reporting results.

2.3.2 Training programs to provide general and specialized training in audit performance. General training shall include fundamentals, objectives, characteristics, organization, performance and results of quality assurance program auditing. Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

2.3.3 On-the-job training, guidance, and counseling performed under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and followup action involved in conducting audits.

2.4 Maintenance of Proficiency

Lead Auditors shall maintain their proficiency through one or more of the following methods:

2.4.1 Regular, active participation in the audit process.

2.4.2 Review and study of codes, standards, procedures, instructions, and other documents related to quality assurance programs and program auditing.

2.4.3 Participation in training programs as described in Section 2.3.

3. AUDIT SYSTEM

3.1 General

This section establishes requirements for a comprehensive audit system which shall be planned, documented, and implemented to verify compliance with the elements of a quality assurance program. The audit system shall be described in approved, written policies, plans, procedures, instructions, or such other documents as appropriate.

3.2 Objectives

The objectives of the audit system are:

3.2.1 To determine that a quality assurance program has been developed and documented in accordance with specified requirements;

3.2.2 To verify by examination and evaluation of objective evidence that the documented quality assurance program has been implemented;

3.2.3 To assess the effectiveness of the quality assurance program;

3.2.4 To identify nonconformances and quality assurance program deficiencies; and

3.2.5 To verify correction of identified quality assurance program deficiencies.

3.3 Essential Elements of the Audit System

An effective audit system shall be established and maintained and shall include the following essential elements:

3.3.1 A management policy statement or procedure which establishes organizational independence and authority of the auditors and commits the organization to an audit system meeting the requirements of this standard.

3.3.2 Manpower, funding, and facilities to implement the audit system.

3.3.3 Identification of those responsible for the audit system, including a delineation of their authorities, responsibilities, and organizational independence.

3.3.4 Provisions for reasonable and timely access of audit personnel to facilities, documents, and personnel necessary in the planning and performance of the audits.

3.3.5 Provisions for reporting on the effectiveness of the quality assurance program to the responsible management of both the audited and auditing organizations.

3.3.6 Provision for access by audit teams to levels of management of the auditing and audited organizations that have the responsibility and authority to assure corrective action.

3.3.7 Provision for verification of effective corrective action on a timely basis.

3.4 Audit Planning

The audit system, including both internal and external audits, shall be planned, documented, and conducted to assure coverage of the applicable quality assurance program, and overall coordination and scheduling of audit activities. The audit system shall be periodically reviewed, and revised as necessary, to assure that coverage and schedule reflect current activities.

3.5 Scheduling

3.5.1 Auditing shall be initiated as early in the life of the activity as practicable, consistent with the schedule for accomplishing the activity, to assure timely implementation of quality assurance requirements. In any case, auditing shall be initiated early enough to assure effective quality assurance during the design, procurement and contracting activities.

3.5.2 Audits shall be regularly scheduled on the basis of the status and importance of the activities to assure the adequacy of, and conformance with, the program.

3.5.3 Regularly scheduled audits should be supplemented by audits for one or more of the following conditions:

3.5.3.1 When it is necessary to assess the capability of a contractor's quality assurance program prior to awarding a contract or purchase order.

3.5.3.2 When, after award of a contract, sufficient time has elapsed for implementing the quality assurance program and it is appropriate to determine that the organization is adequately performing the functions as defined in the quality assurance program description, codes, standards, and other contract documents.

3.5.3.3 When significant changes are made in functional areas of the quality assurance program such as significant reorganization or procedure revisions.

3.5.3.4 When it is suspected that the quality of the item is in jeopardy due to deficiencies in the quality assurance program.

3.5.3.5 When a systematic, independent assessment of program effectiveness is considered necessary.

3.5.3.6 When necessary to verify implementation of required corrective action.

4. AUDIT IMPLEMENTATION

4.1 General

Individual audits shall be implemented as scheduled and planned in Section 3. The mechanics involved in implementation of an audit are preparation, performance, reporting, and followup.

4.2 Preparation

Preparation includes the development of a written audit plan, the selection and orientation of the auditor(s), and notification of the organization to be audited.

4.2.1 **Written Plan.** An individual audit plan describing the audit to be performed shall be developed and documented by the auditing organization. This plan shall identify the audit scope, the requirements, the activities to be audited, organizations to be notified, the applicable documents, the schedule, and written procedures or checklists.

4.2.2 **Team Selection.** One or more auditors comprise an audit team. A Lead Auditor shall be appointed team leader. His responsibilities include orientation of the team, coordinating the audit process, establishing the pace of the audit, assuring communications within the team and with the organization being audited, participation in the audit performance, and coordinating the preparation and issuance of reports. In selecting personnel for auditing assignments, consideration shall be given to special abilities, specialized technical training, prior pertinent experience, personal characteristics, and education.

4.2.3 **Team Orientation.** The team leader shall assure that the audit team is prepared prior to initiation of the audit. Pertinent policies, procedures, standards, instructions, codes, regulatory requirements and prior audit reports, shall be made available for information and review by the auditors. Each auditor shall be provided with the audit plan. The procedures or checklists shall be prepared to assure orderly accomplishment of the audit. During the familiarization phase of the audit, particular attention shall be directed toward an

understanding of internal and external organization and contractual interfaces and responsibilities of the organization to be audited.

4.2.4 **Audit Notification.** Involved organizations shall be notified of a scheduled audit a reasonable time before the audit is to be performed. This notification should be in writing and include such information as the scope and schedule of the audit and the name of the audit team leader. With prior agreement of the parties involved, unannounced audits may be performed.

4.3 Performance

4.3.1 **Pre-Audit Conference.** A brief pre-audit conference shall be conducted with cognizant organization management. The purpose of the conference shall be to confirm the audit scope, present the audit plan, introduce auditors, meet counterparts, discuss audit sequence and plans for the post-audit conference, and establish channels of communication.

4.3.2 Audit Process

4.3.2.1 Checklists or procedures shall be used to ensure depth and continuity of audits. The audit checklist is intended for use as a guide and should not restrict the audit investigation when findings raise further questions that are not specifically included in the checklist.

4.3.2.2 Objective evidence shall be examined for compliance with quality assurance program requirements.

4.3.2.3 Selected elements of the quality assurance program shall be audited to the depth necessary to determine whether or not they are being implemented effectively.

4.3.2.4 When a nonconformance or quality assurance program deficiency is identified as a result of an audit, further investigation shall be conducted by the audited organization in an effort to identify the cause and effect and to determine the extent of the corrective action required.

4.3.2.5 Nonconformances or quality assurance program deficiencies should be acknowledged by a member of the audited organization.

4.3.2.6 Conditions requiring immediate corrective action shall be reported immediately to management of the audited organization.

4.3.2.7 Specific attention should be given to

corrective action on program deficiencies identified during previous audits.

4.3.3 Post-Audit Conference. At the conclusion of the audit process, a post-audit conference shall be held with management of the audited organization to present audit findings and clarify misunderstandings.

4.4 Reporting

An audit report, which shall be signed by the audit team leader, shall provide:

4.4.1 Description of the audit scope.

4.4.2 Identification of the auditors.

4.4.3 Persons contacted during pre-audit, audit, and post-audit activities.

4.4.4 A summary of audit results, including an evaluation statement regarding the effectiveness of the quality assurance program elements which were audited.

4.4.5 Description of each quality assurance program deficiency in sufficient detail to assure that corrective action can be effectively carried out by the audited organization.

4.4.6 Recommendations for correcting program deficiencies or improving the quality assurance program as appropriate.

Distribution of the report shall include responsible management of both the audited and auditing organizations. The audit report shall be issued within thirty days after the post-audit conference.

4.5 Followup

4.5.1 By Audited Organization. Management of the audited organization or activity shall review and investigate any adverse audit findings to determine and schedule appropriate corrective action including action to prevent recurrence and shall respond as requested by the audit report, giving results of the review and investigation. The response shall clearly state the corrective action taken or planned to prevent recurrence. In the event that corrective action cannot be completed within thirty days, the audited organization's response shall include a scheduled date for the corrective action. The audited organization shall provide a followup report stating the corrective action taken and the date corrective action was completed. They shall also take appropriate action to assure that corrective action is accomplished as scheduled.

4.5.2 By Auditing Organization. When necessary, followup actions shall be performed by the audit team leader or management of the auditing organization to:

4.5.2.1 Obtain the written response when required by the audit report.

4.5.2.2 Evaluate the adequacy of the response.

4.5.2.3 Assure that corrective action is identified and scheduled for each adverse finding.

4.5.2.4 Confirm that corrective action is accomplished as scheduled.

Followup action can be accomplished through written communication, re-audit, or other appropriate means.

5. RECORDS

5.1 General

Records shall be retained by the auditing organizations responsible for activities associated with implementation of this standard. These records shall be collected, stored, and maintained in accordance with ANSI N45.2.9.

5.2 Audit Records

Records shall be generated and retained for all audits. Records shall include the audit system plan, individual audit plans, audit reports, written replies, and the record of completion of corrective actions.

5.3 Personnel Records

Records shall include documentary evidence of the qualifications and training of auditors and shall be retained for the same period of time as required for the audit report with which the auditors are associated.

6. REVISION OF AMERICAN NATIONAL STANDARDS REFERRED TO IN THIS DOCUMENT

When any of the following standards referred to in this document is superseded by a revision approved by the American National Standards Institute, the revision is not mandatory until it has been incorporated as a part of this standard.

Revisions to the referenced standards, and revisions to this standard issued after the date of a specific con-

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tract involving this standard may be used by mutual consent of the purchaser and the supplier.

N45.2 Quality Assurance Program Requirements for Nuclear Power Plants

N45.2.9 Requirements for Collection, Storage and maintenance of Quality Assurance Records for Nuclear Power Plants

N45.2.10 Quality Assurance Terms and Definitions