WITHDRAWN

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U.S. NUCLEAR REGULATORY COMMISSION

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 1.146
(Task RS 810-5)

QUALIFICATION OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL 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 safety-related structures, systems, and components of nuclear power plants. Criterion XVIII, "Audits," of Appendix B 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 qualification of quality assurance program audit personnel 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 N45-2.23 of the American National Standards Committee N45, Reactor Plants and their Maintenance, has prepared a standard that provides requirements and guidance for the qualification of personnel who participate in audits of quality assurance programs for nuclear power plants. The standard was approved and designated N45.2.23-1978* by the American National Standards Institute on April 20, 1978.

C. REGULATORY POSITION

The requirements that are included in ANSI/ASME N45.2.23-1978 for qualification of quality assurance program audit personnel 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 of ANSI/ASME N45.2.23-1978 states that documents that are referenced in this standard are identified at the point of reference and described in Section 6 of the standard. 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. ANSI/ASME N45.2.23-1978 does not include the statement that is found in other N45.2 series standards excluding activities covered by ASME Boiler and Pressure Vessel Code Section III, Divisions 1 and 2, and Section XI from the requirements of the standard. The NRC staff considers that ANSI/ASME N45.2.23-1978 applies to these Code-covered activities where the ASME Code does not address the requirements covered by ANSI/ASME N45.2.23-1978.

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.

This regulatory guide will be used in the evaluation of applications for construction permits and operating licenses docketed after August 29, 1980. In addition, the NRC intends to apply this regulatory guide to operating plants and plants under construction. Implementation schedules will be determined on a case-by-case basis for these facilities by the Office of Nuclear Reactor Regulation. It is expected that this regulatory guide will be required to be implemented by these facilities by February 2, 1981.

*ANSI/ASME N45.2.23-1978, "Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants," may be obtained from the American Society of Mechanical Engineers, 345 East 47th Street, New York, NY 10017.

VALUE/IMPACT STATEMENT

1. THE ACTION

1.1 Description

The applicant (licensee) of a nuclear power plant is required by the Commission's regulations to establish and implement a quality assurance program. The applicant (licensee) is also required to carry out audits to verify compliance with the quality assurance program. This regulatory guide presents guidance for qualification of personnel who perform quality assurance audits.

1.2 Need

Until ANSI N45.2.23 was published, no definition of qualification guidelines for quality assurance audit personnel had been published by the NRC or the industry, resulting in nonuniform audit programs with varying standards of excellence. A draft standard, ANSI N45.2.23 (Draft 3, Revision 1), "Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants," was approved on April 20, 1978, and designated ANSI/ASME N45.2.23-1978. Guidance on qualification of quality assurance audit personnel is provided in this regulatory guide endorsing the approved national standard to ensure more uniformity in audit programs and associated standards of excellence.

1.3 Value/Impact of the Action

1.3.1 NRC

Value - Prior to the issuance of this guide endorsing a standard, no guidance has existed in the area of auditor and lead auditor qualifications. The NRC has been making case-by-case determinations in this area, which has resulted in nonuniform practices with regard to requirements placed on qualification of auditors and lead auditors in the industry. This guidance will eliminate the need for most case-by-case determinations, which should (a) reduce staff review time, and (b) provide for more uniformity in qualification of auditors and lead auditors.

Impact - No impact can be foreseen.

1.3.2 Other Government Agencies

Not applicable, unless the government agency is an applicant.

1.3.3 Industry

This action establishes an NRC position to an existing national standard and therefore reduces uncertainty as to what the staff considers acceptable in the area of qualification of quality assurance audit personnel. Most of the impact on industry has already occurred during development, review, and approval of the national standard. Additional impact associated with NRC endorsement of the standard should be as follows:

1. Some individuals may not qualify as lead auditors, thereby creating a need for more experience and training of auditors.

2. Conformance to the standard with the exceptions noted will require administrative effort on the part of the employer.

These impacts may have an initial monetary effect on the industry but should be compensated by increased quality assurance as a result of the audit.

1.3.4 Workers (relative to ALARA)

Not applicable.

1.3.5 Public

Value - Uniform standards for auditors and lead auditors should result in more uniform audits. More uniform audits should lead to increased reliability of nuclear power plants.

Impact - Any costs generated by upgrading training to qualify auditors and lead auditors will eventually be passed on to the public as rate increases.

Regulatory Position 1 provides information to the user of the guide on how to apply referenced standards and has no impact.

Regulatory Position 2 clarifies the coverage of ANSI/ASME N45.2.23-1978 concerning ASME Code-covered activities by stating that the code should be used in conjunction with ANSI/ASME N45.2.23-1978.

1.4 Decision on the Action

This guide is being issued to provide recommendations acceptable to the NRC staff on qualification of quality assurance audit personnel for nuclear power plants.

2. TECHNICAL APPROACH

There are several approaches that could be taken to the qualification of lead auditors and auditors. They are as follows:

1. Qualification by National Board of Examiners.
2. Qualification by Management (subjective decision).
3. Qualification by establishment of minimum standards.

The pros and cons of these approaches will be analyzed in the following paragraphs:

Approach 1

Pro - It would provide a definite and uniform standard of qualification.

Con - It would be expensive to maintain the Board and pay for the travel of the candidates.

Con - The physical numbers of auditors and lead auditors make this approach impractical.

Approach 2

Pro - It provides the easiest method of qualification for the employer.

Con - It makes it difficult for outside agencies such as the NRC to determine or review qualifications.

Con - It provides for nonuniform standards of qualification of auditors and lead auditors.

Approach 3

Pro - It provides minimum acceptable standards for qualification allowing easy determination of qualifications by outside agencies like the NRC.

Pro - It provides uniformity in qualification.

Con - It can reduce the flexibility of an organization to recognize exceptional talent.

ANSI/ASME N45.2.23-1978 uses a combination of Approaches 2 and 3. The NRC staff considers this combination an acceptable approach and has been involved in the development of this standard. Endorsement of this standard, subject to the supplemental provisions, is the proper method for the NRC to recognize the acceptability of the standard.

3. PROCEDURAL APPROACH

The following are alternative approaches for issuing this guidance.

1. Regulation.
2. Regulatory Guide.

These alternatives are discussed below:

Approach 1. The NRC's regulation (10 CFR Part 50, Appendix B, Criterion XVIII) has a requirement to conduct audits. ANSI N45.2.23-1978 provides sufficient guidance to meet the requirements of this section.

Approach 2. A regulatory guide endorsing the national standard provides the industry with the NRC staff position relative to a method that is acceptable for qualification of auditors and lead auditors. Since there are many alternatives for qualifying auditors and lead auditors, it is not desired to make any single method a requirement through the regulatory process; therefore, a regulatory guide endorsing a national standard is the proper procedural approach.

4. STATUTORY CONSIDERATIONS

4.1 NRC Authority

Authority for this guide is derived from the safety requirements of the Atomic Energy Act as implemented by the Commission's regulations; in particular, Criterion XVIII of Appendix B to 10 CFR Part 50 requires, in part, that a comprehensive system of planned audits be performed by appropriately trained personnel.

4.2 Need for NEPA Assessment

This action is not a major action as defined by paragraph 51.5(a)(10) of 10 CFR Part 51 and does not require an environmental impact statement.

5. RELATIONSHIP TO OTHER EXISTING OR PROPOSED REGULATIONS OR POLICIES

No conflicts or overlaps with requirements promulgated by other agencies are foreseen. Implementation of this action is discussed in Section D of this guide.

6. SUMMARY AND CONCLUSIONS

Regulatory Guide 1.146, "Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants," has been prepared. This guide, with certain exceptions, endorses ANSI/ASME N45.2.23-1978.

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