

INSPECTION TECHNICAL PROCEDURE

I-125

**AUDITOR/LEAD AUDITOR QUALIFICATION AND CERTIFICATION
ASSESSMENT**

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INSPECTION TECHNICAL PROCEDURE I-125, REV. 1 AUDITOR/LEAD AUDITOR QUALIFICATION AND CERTIFICATION ASSESSMENT

1.0 PURPOSE

This inspection procedure provides guidance to assess the qualifications and certifications of the Contractor's auditors and lead auditors. This guidance is based on the requirements set forth in the Contractor's Quality Assurance Manual (QAM). Specifically, this procedure addresses assessment of the adequacy and effectiveness of the following:

- Auditor qualifications
- Lead auditor qualifications, including communications skills, training, audit participation, and examination
- Maintenance of lead auditor proficiency
- Requalification of lead auditors
- Certification of lead auditor qualification
- Technical specialist training.

2.0 OBJECTIVES

The objective of this procedure is to verify that the Contractor has implemented an effective program for qualifying auditors and lead auditors, and to verify that the Contractor implements auditor and lead auditor qualification requirements in accordance with the regulatory requirements in the following documents:

- 10 CFR 830, Subpart A, "Quality Assurance Requirements," *Code of Federal Regulations*, as amended
- DOE/RL-96-0006, Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the RPP Waste Treatment Plant Contractor, Rev. 1, U.S. Department of Energy, Office of River Protection
- DOE/RW-0333P, *Quality Assurance Requirements and Description*
- Contractor's commitments as set forth in the Quality Assurance Manual (QAM).

3.0 INSPECTION REQUIREMENTS

3.1 GENERAL

- 3.1.1 The inspectors should verify the Contractor's auditors and lead auditors were trained and qualified, and lead auditors were certified in accordance with the requirements of QAM

Policy Q-02.3, *Auditor/Lead Auditor Qualification and Certification*. (QAM Policy Q-02.3, Section 3.1.1)

- 3.1.2 The inspectors should verify personnel selected for quality assurance auditing assignments had experience or training commensurate with the scope, complexity, or special nature of the activities audited. (QAM Policy Q-02.3, Section 3.1.2)

3.2 AUDITOR QUALIFICATIONS

- 3.2.1 The inspectors should verify auditors had, or were provided, appropriate training or orientation to develop their competence for performing audits. (QAM Policy Q-02.3, Section 3.2.1)

- 3.2.2 The inspectors should verify competence of personnel for performing the various auditing functions was developed by one or more of the following methods:

- Orientation to provide a working knowledge and understanding of the QA program requirements, and the auditing organization's procedures for performing audits and reporting results.
- General and specialized training in audit performance, where the general training included auditing fundamentals such as objectives, characteristics, organization, performance, and reporting results of quality auditing; and the specialized training included methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.
- On-the-job training, guidance, and counseling under the direct supervision of a lead auditor, including planning, performing, reporting, and follow-up action involved in conducting audits. (QAM Policy Q-02.3, Section 3.2.2)

3.3 LEAD AUDITOR QUALIFICATIONS AND CERTIFICATIONS

The inspectors should verify lead auditors were capable of organizing and directing audits, reporting audit findings, and evaluating planned and implemented corrective actions. (QAM Policy Q-02.3, Section 3.3)

3.4 LEAD AUDITOR COMMUNICATION SKILLS

The inspectors should verify the Contractor's lead auditors were capable of effective written and oral communications, and that these communication skills were attested to in writing by the lead auditor's manager. (QAM Policy Q-02.3, Section 3.3.1)

3.5 LEAD AUDITOR TRAINING

The inspectors should verify the Contractor's lead auditors had received training to the extent necessary to assure auditing competence including:

- Knowledge and understanding of requirement documents and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable.
- General structure of QA programs as a whole, and applicable elements as defined in requirement documents.
- Auditing techniques of examining, questioning, evaluating, and reporting, methods of identifying and following up on corrective action items, and closing out audit findings.
- Planning audits of activities affecting quality.
- On-the-job training to include applicable elements of the audit program. (QAM Policy Q-02.3, Section 3.3.2)

3.6 LEAD AUDITOR AUDIT PARTICIPATION

The inspectors should verify the Contractor's lead auditors had participated in a minimum of five quality assurance audits within a period of time not to exceed three years prior to the date of qualification and certification. The inspectors should verify one of the five audits was a nuclear quality assurance audit that was conducted within the year prior to qualification and certification. (QAM Policy Q-02.3, Section 3.3.3)

3.7 LEAD AUDITOR EXAMINATION

- 3.7.1 The inspectors should verify the Contractor's lead auditors passed an examination (e.g., oral, written, practical, or any combination thereof) that evaluated comprehension of and ability to apply the body of knowledge identified above. (QAM Policy Q-02.3, Section 3.3.4)
- 3.7.2 The inspectors should verify the Contractor developed and maintained objective evidence regarding the type, content, and results of the examination. (QAM Policy Q-02.3, Section 3.3.4)
- 3.7.3 The inspectors should verify the Contractor maintained the integrity of the examination through confidentiality of files and, where applicable, proctoring of examinations. (QAM Policy Q-02.3, Section 3.3.7.4)

3.8 LEAD AUDITOR MAINTENANCE OF PROFICIENCY

3.8.1 The inspectors should verify the Contractor's lead auditors maintained their proficiency through one or more of the following:

- Regular and active participation in the audit process
- Review and study of codes, standards, procedures, instructions, and other documents related to the QA program and program auditing, or
- Participating in QA training program(s). (QAM Policy Q-02.3, Section 3.3.5)

3.8.2 The inspectors should verify the management of the auditing organization evaluated the proficiency of lead auditors annually, and the management evaluations were documented. (QAM Policy Q-02.3, Section 3.3.5)

3.9 LEAD AUDITOR RE-QUALIFICATION

The inspectors should verify lead auditors who failed to maintain their proficiency for a period of two years or more were required to re-qualify, including re-training, re-examination, and participation as an auditor in at least one nuclear quality assurance audit. (QAM Policy Q-02.3, Section 3.3.6)

3.10 CERTIFICATION OF LEAD AUDITOR QUALIFICATION

3.10.1 The inspectors should verify each lead auditor was certified by the auditing organization as being qualified to lead audits. (QAM Policy Q-02.3, Section 3.3.7.1)

3.10.2 The inspectors should verify the qualification of lead auditor personnel was certified in writing and included the following information:

- Employer's name
- Identification of person being certified
- Activities certified to perform
- Basis of qualification to include education, experience, indoctrination, and training; test results (where applicable); and capability demonstration results
- Results of periodic evaluation
- Results of physical examinations, when required

- Signature of employer's designated representative responsible for such certification
- Date of certification or re-certification and certification expiration. (QAM Policy Q-02.3, Section 3.3.7.2)

3.10.3 The inspectors should verify the responsible organization identified any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination. (QAM Policy Q-02.3, Section 3.3.7.3)

3.11 LEAD AUDITOR QUALIFICATION CREDITS

The inspectors should verify the Contractor's lead auditors had verifiable evidence that a minimum of ten credits accumulated under the following scoring system:

A. Education (four credits maximum)

- An Associate's Degree from an accredited institution scores one credit; if the degree is in engineering, physical sciences, mathematics, or QA, it scores two credits.
- A Bachelor's Degree from an accredited institution scores two credits; if the degree is in engineering, physical sciences, mathematics, or QA, it scores three credits.
- In addition, score one credit for a Master's Degree in engineering, physical sciences, business management, or QA from an accredited institution.

B. Experience (nine credits maximum)

Technical experience in such areas as scientific investigation, site characterization, production, transportation, engineering, manufacturing, construction, operation, maintenance, or experience applicable to the auditing organization's area of responsibility scores one credit for each full year, with a maximum of five credits for this aspect of experience:

- If two years of this experience have been in the nuclear-related field, score one additional credit; or
- If two years of this experience have been in QA, score two additional credits; or
- If two years of this experience have been in auditing, score three additional credits; or
- If two years of this experience have been in nuclear-related QA, score three additional credits; or
- If two years of this experience have been in nuclear-related QA auditing, score four additional credits.

C. Professional Competence (two credits maximum)

For certification of competency in engineering science or QA specialties issued and approved by a state agency or national professional or technical society, score two credits.

D. Rights of Management (two credits maximum)

When determined appropriate, the auditing organization may grant up to two credits for other performance factors applicable to auditing that are not explicitly called out in this section (such as leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and completed QA training courses). (QAM Policy Q-02.3, Section 3.3.8)

3.12 TECHNICAL SPECIALIST TRAINING

3.12.1 The inspectors should verify technical specialists were indoctrinated to achieve initial proficiency prior to performing or participating in audits, including familiarization with the QAM and its implementing procedures related to auditing and auditing qualifications. (QAM Policy Q-02.3, Section 3.4.1)

3.12.2 The inspectors should verify technical specialists had the level and experience or training commensurate with the scope, complexity, or special nature of the work being audited. (QAM Policy Q-02.3, Section 3.4.2)

4.0 INSPECTION GUIDANCE

Note that this is one of several procedures that address aspects of the Contractor's quality assurance (QA) program. For each area listed below, the inspector should review the Contractor's QAM policies and procedures for various self-assessment and corrective action activities, review objective evidence that the QAM policies and procedures have been implemented, and interview personnel responsible for various self-assessment and corrective action activities. In addition to reviewing 10 CFR 830, Subpart A, and applicable parts of the QAM, the inspector also should review G-830.120, *Implementation Guide for Use with 10 CFR 830.120, Quality Assurance*.

Suggested sample sizes are included in some of the inspection elements below. However, the inspector should use judgment in selecting a different sample size based on the status of the construction activities or on the initial observations in any area. The samples should be large enough to provide confidence: (1) the Contractor has approved procedures, (2) the procedures are being implemented, and (3) the personnel are properly qualified for the work they are performing. The intent is to establish a high level of assurance the end product meets requirements.

4.1 GENERAL

4.1.1 The inspectors should select a sample of three auditors and three lead auditors and review the training records to confirm these individuals had received indoctrination and training in the following areas before performing the audit to which they were assigned:

- Indoctrination in their job responsibilities and authority
- General criteria, including applicable codes and standards
- Company procedures
- QA program requirements.

4.1.2 The inspectors should review the training records and resumes for the sample of auditors and lead auditors selected in Section 4.1.1 above to confirm the personnel selected for each audit had experience or training in the scope, complexity, or special nature of the activities audited.

4.2 AUDITOR QUALIFICATIONS

4.2.1 The inspectors should confirm the auditors selected in Section 4.1.1 above had conducted audits previously, or were provided appropriate training or orientation to develop their competence for performing audits.

4.2.2 The inspectors should confirm the competence of the auditors selected in Section 4.1.1 above was developed by one or more of the methods provided in Section 3.2.2 of this procedure.

4.3 LEAD AUDITOR QUALIFICATIONS AND CERTIFICATION

The inspectors should interview the Contractor's management to determine whether or not planning for an audit is underway. If the Contractor's auditors are planning an audit while the inspection is conducted, the inspectors should attend the planning meetings in order to confirm the lead auditor was capable of organizing and directing the audit.

The inspectors should review at least two audit reports written by each lead auditor selected in Section 4.1.1 above to confirm the lead auditors were capable of reporting findings. The inspectors should review the planned and implemented corrective actions for the findings written above to confirm the lead auditor evaluated the effectiveness of the corrective actions and verified the implementation of the corrective actions.

4.4 LEAD AUDITOR COMMUNICATION SKILLS

The inspectors should review the lead auditor qualification and certification records for the lead auditors selected in Section 4.1.1 above to confirm each lead auditor's manager had attested in writing to each lead auditor's communication skills (written and oral). The inspectors should

review at least two audit reports written by each lead auditor to confirm the audit results were effectively written.

4.5 LEAD AUDITOR TRAINING

The inspectors should review the lead auditor qualification and certification records for the lead auditors selected in Section 4.1.1 above to confirm each had received training to the extent necessary to assure auditing competence, including each of the items listed in Section 3.5 of this procedure.

4.6 LEAD AUDITOR AUDIT PARTICIPATION

The inspectors should review the lead auditor qualification and certification records for the lead auditors selected in Section 4.1.1 above to confirm each had participated in a minimum of five quality assurance audits within a period of time not to exceed three years prior to the date of qualification and certification. The inspectors should confirm one of the audits was a nuclear quality assurance audit, and was performed within the year prior to qualification and certification.

4.7 LEAD AUDITOR EXAMINATION

4.7.1 The inspectors should review lead auditor's examination documentation to confirm the Contractor adequately evaluated the lead auditor's comprehension of and ability to apply the following:

- Knowledge and understanding of requirement documents and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable.
- General structure of QA programs as a whole, and applicable elements as defined in requirement documents.
- Auditing techniques of examining, questioning, evaluating, and reporting, methods of identifying and following up on corrective action items, and closing out audit findings.
- Planning audits of activities affecting quality.
- On-the-job training to include applicable elements of the audit program.

The inspectors should review lead auditor qualification and certification records for the lead auditors selected in Section 4.1.1 above to confirm each lead auditor had passed the Contractor's lead auditor examination or one similar.

4.7.2 The inspectors should review objective evidence of the type, content, and results of the each lead auditor's examination to confirm this information was maintained.

- 4.7.3 The inspectors should interview the Contractor's personnel who maintain the integrity of the lead auditor examination to confirm the examinations were maintained in confidential files and, where applicable, the examinations were proctored. The inspectors should review objective evidence of the maintenance of the integrity of the examinations.

4.8 LEAD AUDITOR MAINTENANCE OF PROFICIENCY

- 4.8.1 The inspectors should review lead auditor maintenance of proficiency records for the lead auditors selected in Section 4.1.1 above to confirm the lead auditors maintained proficiency through one or more of the methods described in Section 3.8.1 of this procedure.
- 4.8.2 The inspectors should review lead auditor maintenance of proficiency records for the lead auditors selected in Section 4.1.1 above to confirm management evaluated the proficiency of lead auditors annually, and documented the results of the evaluations.

4.9 LEAD AUDITOR RE-QUALIFICATION

The inspectors should interview the Contractor's personnel to determine whether or not any lead auditors had failed to maintain their proficiency for a period of two years or more. If so, the inspectors should review documented evidence to confirm the lead auditor had re-qualified by re-training, re-examination, and participation as an auditor in at least one nuclear quality assurance audit prior to leading an audit.

4.10 CERTIFICATION OF LEAD AUDITOR QUALIFICATIONS

- 4.10.1 The inspectors should review lead auditor qualification and certification records for the lead auditors selected in Section 4.1.1 above to confirm the records were current.
- 4.10.2 The inspectors should review lead auditor qualification and certification records for the lead auditors selected in Section 4.1.1 above to confirm the information listed in Section 3.10.2 of this procedure was included.
- 4.10.3 The inspectors should review lead auditor qualification and certification records for the lead auditors selected in Section 4.1.1 above to confirm whether any special physical characteristics were needed in performance of each activity, including the need for initial and subsequent physical examination. If no special physical characteristics were needed for the lead auditors selected in Section 4.1.1, the inspectors should interview the Contractor's management to determine whether or not any special physical characteristics were identified for lead auditors during any audits. The inspectors should review the documented objective evidence, if any, of the identification of special physical characteristics.

4.11 LEAD AUDITOR QUALIFICATION CREDITS

The inspectors should review lead auditor qualification and certification records for the lead inspectors selected in Section 4.1.1 above to confirm the assignment of lead auditor qualification credits. The inspectors should confirm each lead auditor had documented evidence lead auditor qualification credits were assigned in accordance with the requirements of Section 3.11 of this procedure.

4.12 TECHNICAL SPECIALIST TRAINING

4.12.1 The inspectors should interview the Contractor's management to determine when technical specialists were used on audits. The inspectors should select three technical specialists and review documented evidence these personnel were indoctrinated to achieve initial proficiency prior to performing or participating in audits. This initial proficiency should include familiarization with the QAM and its implementing procedures related to auditing and auditing qualifications.

4.12.2 The inspectors should review documented evidence of the technical specialists selected in Section 4.12.1 above to confirm the technical specialists had the level of training and experience commensurate with the scope, complexity, or special nature of the work being audited.

5.0 REFERENCES

10 CFR 830, "Nuclear Safety Management," *Code of Federal Regulations*, as amended.

10 CFR 830, Subpart A, "Quality Assurance Requirements," *Code of Federal Regulations*, as amended.

DOE/RW-0333P, *Quality Assurance Requirements and Description*.

DOE/RL-96-0006, Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the RPP Waste Treatment Plant Contractor, Rev. 1, U.S. Department of Energy, Office of River Protection.

Implementation Guide for Use with 10 CFR 830.120, Quality Assurance, G-830.120-Rev. 0, U.S. Department of Energy, 1994.

Quality Assurance Manual, 24590-WTP-QAM-QA-01-001, Revision 4, Bechtel National, Inc., 2003.

Attachments: None