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Companywide	Program Requirements Document	For Additional Info: http://EDMS	Effective Date: 12/06/12
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Manual: 13—Quality Assurance Program

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*The current revision can be verified on EDMS.

1. PURPOSE

This program requirements document (PRD) identifies requirements and responsibilities for quality assurance (QA) program *auditor* (see def.) *qualification* (see def.), technical specialist qualification, and *lead auditor* (see def.) *certification* (see def.).

2. APPLICABILITY

This PRD applies to company organizations performing QA *audit* (see def.) activities.

3. RESPONSIBILITIES

3.1 Managers

Managers are responsible for submitting documentation of a prospective auditor's work history/experience to the certifying authority.

3.2 Quality Assurance Organization

The QA organization is responsible for:

- A. Appointing a certifying authority
- B. Providing for auditor/lead auditor training
- C. Providing for a written examination of prospective lead auditors
- D. Ensuring records of auditor/lead auditor qualification are established and maintained.

3.3 Certifying Authority

The certifying authority is responsible for:

- A. Evaluating *objective evidence* (see def.) to determine acceptability for auditor/lead auditor qualification against criteria in this PRD
- B. Certifying lead auditors.

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3.4 Lead Auditors

Lead auditors are responsible for evaluating and counseling prospective auditors and technical specialists and for documenting their qualifications.

4. REQUIREMENTS

4.1 Companywide Applications

Requirements identified in this subsection meet the requirements in “Quality Assurance Requirements for Nuclear Facility Application,” American Society of Mechanical Engineers (ASME/NQA-1-2008 with Addenda through NQA-1a, 2009) and Department of Energy (DOE) O 414.1D, “Quality Assurance.” The requirements apply to the entire company as defined by FWD-7, “Foreword.”

4.1.1 Basic

4.1.1.1 Auditors and lead auditors will be trained, qualified, and certified in accordance with the requirements of this PRD and PRD-5072, “Personnel Training and Qualification.”

4.1.1.2 The certifying authority may certify a prospective lead auditor based on documented objective evidence from an external organization provided that objective evidence demonstrates equivalency to the qualification requirements of this PRD.

4.1.2 Auditor Qualifications

4.1.2.1 Auditors will have, or be given, appropriate training or orientation to develop their competence for performing audits.

4.1.2.2 Competence of personnel performing various auditing functions will be developed by one or more of the following methods:

- A. Orientation to provide a working knowledge and understanding of NQA-1 and Department of Energy/Office of Civilian Radioactive Waste (DOE/RW) -0333P, and the auditing organization’s procedures for implementing audits and reporting results.
- B. General and specialized training in audit performance, where the general training will include fundamentals, objectives, characteristics,

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organization, performance, and results of quality auditing; and the specialized training will include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

- C. On-the-job training, guidance, and counseling under the direct supervision of a lead auditor. Such training will include planning, performing, reporting, and follow-up action involved in conducting audits.

4.1.3 Lead Auditor Qualifications and Certification

A lead auditor will be capable of organizing and directing audits, reporting audit findings, and evaluating planned and taken corrective actions. An individual will meet the following requirements prior to being designated as a lead auditor.

Communication Skills

- 4.1.3.1 The prospective lead auditor will be capable of effective written and oral communication. These skills will be attested to in writing by the lead auditor's employer.

Training

- 4.1.3.2 Prospective lead auditors will receive training to the extent necessary to assure auditing competence including:
- A. Knowledge and understanding of requirement *documents* (see def.) and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable
 - B. General structure of QA programs as a whole and applicable elements as defined in requirement documents
 - C. Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; closing out audit findings
 - D. Planning audits of *activities affecting quality* (see def.)

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- E. On-the-job training to include applicable elements of the audit program.

Audit Participation

4.1.3.3 Prospective lead auditors will participate in a minimum of five quality assurance audits within a period of time not to exceed 3 years prior to the date of qualification and certification, one audit of which will be a *nuclear quality assurance audit* (see def.) within the year prior to qualification and certification. Participation in independent assessments including team assessment activities such as operations readiness reviews, regulatory inspections/surveys, or QA Surveillances may be used to satisfy up to four of the five required quality assurance audits (not applicable to DOE/RW 0333P revision 10 Lead Auditors, who must have five quality assurance audits), provided that the activities can demonstrate the following:

- A. Independence from the functional areas being assessed
- B. Planning that establishes the scope of the activities and associated evaluation criteria
- C. Performance by technically qualified and experienced personnel
- D. Results that are documented and reported to management
- E. Appropriate corrective action initiated and tracked to resolution.

4.1.3.4 Such participation shall be subject to review and acceptance by the organization responsible for quality assurance audits and/or the certifying authority prior to their use for qualification.

Examination

4.1.3.5 Prospective lead auditors will pass an examination which will evaluate comprehension of and ability to apply the body of knowledge identified above. The examination may be oral, written, practical, or any combination thereof.

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- 4.1.3.6 The development and administration of the examination for a lead auditor is the responsibility of the auditing organization. The auditing organization will develop and maintain objective evidence regarding the type and content of the examination.

Maintenance of Proficiency

- 4.1.3.7 Lead auditors will maintain 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 participation in training program(s).

NOTE: *Based on annual assessment, management may extend the qualification, require retraining, or require requalification.*

Requalification

- 4.1.3.8 Lead auditors who fail to maintain their proficiency for a period of two years or more will be required to re-qualify. Requalification will include retraining in accordance with the requirements of Paragraph 4.1.3.2 of this PRD, reexamination in accordance with the requirements of Paragraph 4.1.3.4 of this PRD, and participation as an auditor in at least one nuclear quality assurance audit.

Certification of Qualification

- 4.1.3.9 The qualification of lead auditor personnel will be certified in writing and will document the following information.
- A. Employer's name
 - B. Identification of person being certified
 - C. Activities certified to perform
 - D. Basis of qualification to include:
 - 1. Education, experience, indoctrination, and training
 - 2. Test results, where applicable

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3. Capability demonstration results.

- E. Results of periodic evaluation
 - F. Results of physical examinations, when required
 - G. Signature of employer's designated representative responsible for such certification
 - H. Date of certification or recertification and certification expiration.
- 4.1.3.10 The certifying authority will identify any special physical characteristics needed in the performance, including the need for initial and subsequent physical examination.
- 4.1.3.11 The certifying authority will maintain the integrity of the examination through confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) will be retained by the auditing organization in accordance with Subsection 4.1.5 of this PRD.

Qualification Credits Scoring System

- 4.1.3.12 The prospective lead auditor will have verifiable evidence that a minimum of 10 credits have been accumulated under the following scoring system.
- A. Education (four credits maximum)
 - 1. 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; or
 - 2. 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
 - 3. In addition, score one credit for a master's degree in engineering, physical sciences, business management, or QA from an accredited institution.

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- 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.
1. If two years of this experience have been in the nuclear-related field, score one additional credit; or
 2. If two years of this experience have been in QA, score two additional credits; or
 3. If two years of this experience have been in auditing, score three additional credits; or
 4. If two years of this experience have been in nuclear-related QA, score three additional credits; or
 5. 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).

4.1.4 Technical Specialist Qualification

Technical specialists (see def.) selected for auditing assignments will be indoctrinated and trained. The responsible audition organization shall

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establish the qualifications and requirements for use of technical specialists to accomplish the audition of quality assurance programs. Technical specialists will have the level of experience or training commensurate with the scope, complexity, or special nature of the work being audited.

4.2 Specific Requirements for DOE/RW-0333P, Quality Assurance Requirements and Descriptions

NOTE: *NRC Licensed Independent Spent Fuel Storage Installations (ISFSIs) maintain compliance with Revision 10 of DOE/RW-0333P.*

4.2.1 This subsection contains additional requirements from the *Quality Assurance Requirements and Descriptions (QARD)* (see def.) (DOE/RW-0333P) that are specific to the spent nuclear fuel and high-level waste activities as defined in FWD-7, “Foreword.”

4.2.1.1 Personnel performing as auditors and technical specialists shall be trained and qualified, and lead auditors shall be trained, qualified, and certified in accordance with the following requirements:

NOTE: *ASME NQA-1-2008 with Addenda through NQA-1a-2009 Edition will be used to meet the following requirements.*

A. *ASME NQA-1-1983 with ANSI/ASME NQA-1A-1983 addenda, as follows:*

B. *Supplementary Requirement 2S-3, Supplementary Requirements for the Quality Assurance Program Audit Personnel.*

C. *Appendix 2A-3, Nonmandatory Guidance on the Education and Experience of Lead Auditors.*

4.2.1.2 Supplement 2S-3 requires that personnel selected for auditing assignments shall have experience or training commensurate with the scope, complexity, or nature of the activities to be audited. In lieu of this requirement the lead auditor shall, before starting the audit, ensure that the assigned personnel collectively have experience or training commensurate with the scope, complexity, or nature of the work to be audited.

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5. RECORDS

All records designated in implementing documents as *quality assurance records* (see def.) will be controlled in accordance with PRD-5088, “Quality Assurance Records.”

6. DEFINITIONS

Refer to LST-199, “Quality Assurance Program Requirements Document Definitions,” for definitions of the following terms:

activities affecting quality

audit

auditor

certification

documents

lead auditor

nuclear quality assurance audit

objective evidence

qualification (personnel)

quality assurance audit

quality assurance records

Quality Assurance Requirements and Descriptions

technical specialists

7. REFERENCES

ASME NQA-1-2008 with Addenda through NQA-1a-2009, “Quality Assurance Requirements for Nuclear Facility Applications,” American Society of Mechanical Engineers.

DOE O 414.1D, “Quality Assurance”

DOE/RW-0333P, *Quality Assurance Requirements and Description*, Rev. 20, Office of Civilian Radioactive Waste Management.

FWD-7, “Foreword”

LST-199, “Quality Assurance Program Requirements Document Definitions”

PRD-5072, “Personnel Training and Qualification”

PRD-5088, “Quality Assurance Records”