

QUALITY ASSURANCE AUDITS	Identifier: PRD-5089 Revision*: 16 Page: 1 of 8
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Companywide	Program Requirements Document	For Additional Info: http://EDMS	Effective Date: 09/18/13
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Manual: 13—Quality Assurance Program

Change Number: 339174

*The current revision can be verified on EDMS.

1. PURPOSE

This program requirements document (PRD) identifies requirements and responsibilities for quality assurance (QA) *audits* (see def.).

2. APPLICABILITY

This PRD applies to company organizations involved in the performance of QA audits.

3. RESPONSIBILITIES

3.1 Quality Assurance Organization

The QA organization is responsible for the following:

- A. Conducting audits using personnel qualified/certified in accordance with PRD-5073, “Audit Personnel Qualification and Certification”
- B. Implementing an effective audit program
- C. Developing and distributing audit schedules
- D. Ensuring implementation of *corrective actions* (see def.) is verified.

3.2 Audited Organizations

Audited organizations are responsible for the following:

- A. Providing audit personnel with reasonable and timely access to the facilities, documents, and personnel needed for planning and performing audits.
- B. Evaluating findings reported on audit reports for reportability to the Department of Energy (DOE).
- C. Providing responses to findings that describe the actions taken (or planned) to correct the problem. For significant conditions adverse to quality (SCAQ), the measures to prevent recurrence shall also be determined.
- D. Providing *auditors* and *lead auditor* (see defs.) access to appropriate levels of management, ensuring resolution of audit findings.

QUALITY ASSURANCE AUDITS	Identifier: PRD-5089 Revision*: 16 Page: 2 of 8
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- E. Implementing corrective actions within specified time frames identified in responses to findings.

3.3 Procurement Quality Assurance Organization

The Procurement QA organization is responsible for the following:

- A. Conducting supplier audits using personnel qualified/certified in accordance with PRD-5073
- B. Establishing and maintaining a sitewide schedule for all required *supplier* (see def.) audits
- C. Performing supplier audits to evaluate supplier conformity with approved contractual requirements
- D. Establishing and implementing supplier qualification and requalification processes.

4. REQUIREMENTS

4.1 Companywide Applications

The 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, Department of Energy (DOE) Order 414.1D, “Quality Assurance,” and the other standards listed in FWD-7, “Foreword.” These requirements apply to the entire company as defined by FWD-7.

4.1.1 Basic

- 4.1.1.1 Audits will be performed to *verify* (see def.) that performance criteria are met and to determine the effectiveness of the program.
- 4.1.1.2 The lead auditor organizes and directs audits, reports audit findings, and evaluates corrective actions.

4.1.2 Scheduling Audits

- 4.1.2.1 Audits will be scheduled in a manner to provide coverage, consistency, and coordination with on-going work.
- 4.1.2.2 Audits will be scheduled at a frequency commensurate with the status and importance of the work.

QUALITY ASSURANCE AUDITS

Identifier: PRD-5089

Revision*: 16

Page: 3 of 8

4.1.2.3 Audits will be scheduled to begin as early in the life of the work as practical, and will be scheduled to continue at intervals consistent with the schedule for accomplishing the work.

4.1.2.4 Regularly scheduled audits will be supplemented by additional audits of specific subjects when necessary to provide an adequate assessment of compliance or effectiveness.

4.1.3 Audit Plan

4.1.3.1 The auditing organization will develop and document an audit plan for each scheduled audit.

4.1.3.2 The audit plan will identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

4.1.3.3 Audits will include technical evaluations of the applicable procedures, instructions, activities, and *items* (see def.).

4.1.3.4 The scope of each audit will be based on evaluation of implementing documents, activities, and items to be audited; the results of previous audits; and the impact of significant changes in personnel, organization, or the QA program

4.1.4 Audit Team Independence

4.1.4.1 Audits will be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited.

4.1.4.2 Audit personnel will have sufficient authority and organizational freedom to make the audit process meaningful and effective.

4.1.4.3 Personnel having direct responsibility for performing the work being audited will not be involved in the selection of the audit team.

QUALITY ASSURANCE AUDITS

Identifier: PRD-5089

Revision*: 16

Page: 4 of 8

4.1.5 Selection of the Audit Team

- 4.1.5.1 An audit team will be identified before the beginning of each audit.
- 4.1.5.2 Lead auditors and auditors will be qualified in accordance with the requirements of PRD-5073.
- 4.1.5.3 *Technical specialists* (see def.) may be used by the auditing organization to assist in assessing the adequacy of technical processes.
- 4.1.5.4 Technical specialists, when used, will be indoctrinated, trained, and qualified in accordance with the requirements of PRD-5072, “Personnel Training and Qualification,” and PRD-5073.
- 4.1.5.5 The audit team shall have experience or *training* (see def.) commensurate with the scope, complexity, or special nature of the activities to be audited.

4.1.6 Performing Audits

- 4.1.6.1 Audits will be performed in accordance with written procedures or checklists.
- 4.1.6.2 Elements selected for audit will be evaluated against specified requirements.
- 4.1.6.3 *Objective evidence* (see def.) will be examined to the depth necessary to determine whether these elements are being implemented effectively.
- 4.1.6.4 Audit results will be documented and reported to and reviewed by *responsible managers* (see def.).
- 4.1.6.5 Conditions requiring prompt corrective action will be reported immediately to management of the audited organization.
- 4.1.6.6 Identified *conditions adverse to quality* (see def.) will be documented and corrected in accordance with PRD-5087, “Corrective Action.”

QUALITY ASSURANCE AUDITS

Identifier: PRD-5089

Revision*: 16

Page: 5 of 8

4.1.6.7 Nonconforming items identified during an audit will be controlled by the audited organization in accordance with PRD-5086, “Control of Nonconforming Items.”

4.1.7 Reporting

4.1.7.1 The audit report will be signed or otherwise endorsed by the lead auditor and issued to the audited organization and impacted organizations.

4.1.7.2 The audit report will:

- A. Describe the audit scope
- B. Identify auditors and persons contacted
- C. Summarize audit results, documents reviewed, persons interviewed, including a statement on the effectiveness of the elements audited
- D. Describe each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

4.1.8 Response

4.1.8.1 Management of the audited organization or activity will investigate adverse audit findings, determine and schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of the actions taken or planned.

4.1.8.2 The adequacy of corrective actions for conditions adverse to quality will be evaluated by the auditing organization in accordance with the requirements of PRD-5087.

4.1.9 Follow-Up Action

4.1.9.1 Follow-up action will be taken by the auditing organization to verify that corrective action is accomplished as scheduled in accordance with the requirements of PRD-5087.

QUALITY ASSURANCE AUDITS

Identifier: PRD-5089

Revision*: 16

Page: 6 of 8

4.2 Specific Requirement for DOE/RW-0333P, Quality Assurance Requirements and Description, Applications

This subsection contains additional requirements from the *Quality Assurance Requirements and Description* (Department of Energy/Office of Civilian Radioactive Waste [DOE/RW] -0333P) that are specific to the spent nuclear fuel and high-level waste activities as defined in FWD-7.

4.2.1 Scheduling Internal Audits

- 4.2.1.1 Internal audits of applicable QARD elements to verify Office of Civilian Radioactive Waste Management (OCRWM) QA program compliance and effectiveness shall be performed at intervals not to exceed 12 months or at least once during the life of the work, whichever is shorter.
- 4.2.1.2 Performance-based internal audits shall be performed on select work to determine OCRWM QA program effectiveness.

4.2.2 Scheduling Supplier Audits

- 4.2.2.1 Supplier audits for compliance and effectiveness shall be performed triennially or at least once during the life of the work, whichever is shorter. Regularly scheduled supplier audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate assessment of compliance and effectiveness (performance based).
 - 4.2.2.1.1 Annual audits shall be performed by the purchaser on suppliers or other external organizations when the supplier or external organization does not maintain a purchaser-accepted audit program.
 - 4.2.2.2 Pre-award surveys, if applicable, may serve as the first triennial audit, provided the following:
 - A. The supplier is implementing the same QA program for other contracts that is proposed for the *purchasers* (see def.) contract
 - B. The pre-award survey satisfies the same audit elements and criteria as those used in the performance of a triennial audit.

QUALITY ASSURANCE AUDITS	Identifier: PRD-5089 Revision*: 16 Page: 7 of 8
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4.2.3 Audit Team Qualification and Certification

- 4.2.3.1 Personnel performing audits, including auditors, technical specialist, and lead auditors shall be qualified and certified in accordance with PRD-5073, “Audit Personnel Qualification and Certification.”

5. RECORDS

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

Audit records will include audit plans, audit reports, written responses, and the record of completion of corrective action.

6. DEFINITIONS

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

audit

auditors

condition adverse to quality

corrective action

item

lead auditor

objective evidence

purchaser

quality assurance record

responsible manager

supplier

technical specialist

training

verify

7. REFERENCES

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

QUALITY ASSURANCE AUDITS

Identifier: PRD-5089

Revision*: 16

Page: 8 of 8

DOE Order 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 Qualifications”

PRD-5073, “Audit Personnel Qualification and Certification”

PRD-5086, “Control of Nonconforming Items”

PRD-5087, “Corrective Actions”

PRD-5088, “Quality Assurance Records”