

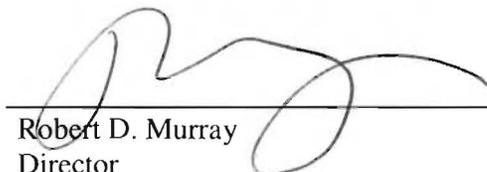


Office of Environmental Management (EM)

Subject: Audits

Administrative Procedure

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1.0 PURPOSE

- 1.1 This procedure establishes the responsibilities and process for scheduling, planning, performing, and documenting Quality Assurance (QA) audits of the High-Level Radioactive Waste (HLW) and Used Nuclear Fuel (UNF) programs. These HLW and UNF programs are based on the Quality Assurance Requirements and Description (QARD, DOE/RW-0333P).

2.0 SCOPE

- 2.1 The objectives of this program are to ensure effective, efficient programs and operations through application of comprehensive and integrated QA audits. The planning and application of this procedure is applied using the graded approach. Items, services, or programs that contribute the greatest risk to quality, safety, and mission are assessed with the greatest rigor and frequency.

3.0 APPLICABILITY

- 3.1 This procedure applies to EM personnel and contractors who are directly or indirectly involved with the QARD oversight/audit functions of programs related to HLW and UNF activities as conducted by the Office of Standards and Quality Assurance at EM Headquarters.

4.0 REQUIREMENTS and REFERENCES

- 4.1 Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 20
- 4.2 EM-QA-002, Quality Assurance Program Plan (QAPP)
- 4.3 AP-1.1Q, High Level Waste (HLW) and Used Nuclear Fuel (UNF) Independent Oversight Program Description
- 4.4 AP-2.2Q, Surveillances
- 4.5 AP-16.1Q, Corrective Action
- 4.6 AP-17.1Q, Quality Assurance Records

5.0 DEFINITIONS

Terms in this procedure are used as defined in the QARD Glossary. The following definitions are specific to this procedure:

- 5.1 Audit – A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance. Compliance elements include the flow down of requirements into approved implementing documents and implementation of the implementing documents. Performance-based elements address an evaluation of the end-products, services, and processes to determine whether the process produces the desired results (effectiveness).
- 5.2 Critical Process Steps – Those steps in a process that ensure the effectiveness of a process to meet its goals and objectives.
- 5.3 EM Oversight Audit – A verification activity performed as a Compliance-Based Audit or a Performance-Based Audit of EM high-level radioactive waste or spent nuclear fuel facilities or activities.
- 5.4 Performance-Based – An evaluation of the end products, services, and process to determine if the process produces the desired end-results (effectiveness).

6.0 GENERAL RESPONSIBILITIES

- 6.1 Director, Office of Standards and Quality Assurance
 - 6.1.1 Ensures that a QA program that meets regulatory management requirements is established, maintained, and implemented.
 - 6.1.2 Responsible for providing the necessary resources for the audit team to implement the audit.
 - 6.1.3 Verifies that activities subject to the QARD have been correctly performed by surveillances, and/or audits.
- 6.2 QA Lead, Office of Standards and Quality Assurance
 - 6.2.1 Responsible for the selection of Audit Team Leader (ATL), Audit Team Members (ATM), and Technical Specialist (TS).
 - 6.2.2 Responsible for the development and distribution of the HLW and UNF Audit/Surveillance Schedule.

6.3 Environmental Management Consolidated Business Center (EMCBC), Office of Logistics Management

6.3.1 Responsible for maintaining QA Records associated with this procedure.

6.4 Each individual is responsible for the quality of his/her work. All individuals are responsible for identifying potential and existing conditions adverse to quality, and reporting them through the appropriate program outlined in AP-16.1Q, Corrective Action.

7.0 GENERAL INFORMATION

N/A

8.0 PROCEDURE

Methods used to conduct audits or surveillances may include examination, evaluation, investigation, review, analysis, interview, and direct observation. Audits are the most formal type of assessment, requiring advance notification and entrance and exit briefings. Documentation of audits is most rigorous and usually includes an audit plan, completed checklist, and a formal audit report that may include observations and/or findings. Audit findings require corrective action (CA) follow-up and tracking.

8.1 Audit Scheduling

8.1.1 Director, Office of Standards and Quality Assurance

8.1.1.1 Direct the development of an Annual QA Oversight Audit Schedule and Resource Plan in accordance with Attachment A.

8.1.1.2 Direct the development of revisions to the audit schedule as necessary to ensure coverage is maintained and audit requirements are met.

8.1.1.3 Coordinate with the Lead for HLW and UNF to assign an Audit Team Lead (ATL) for each audit AND ensure that the assigned ATL has no direct responsibility for the area being audited and is a Lead Auditor certified in accordance with AP-2.1Q, Qualification of Audit Personnel.

8.1.1.4 Coordinate with the Technology Innovation and Development Program to assign at least one Audit Team Member for each UNF audit AND ensure that the assigned Audit Team Member has no direct responsibility for the area being audited and is an Audit

Team Member qualified in accordance with AP-2.1Q,
Qualification of Audit Personnel.

8.1.1.5 Coordinate with the Technical and Regulatory Support Program to assign at least one Audit Team Member for each HLW audit AND ensure that the assigned Audit Team Member has no direct responsibility for the area being audited and is an Audit Team Member qualified in accordance with AP-2.1Q, Qualification of Audit Personnel.

8.1.2 Deputy Assistant Secretary (DAS) , Safety and Security Program

8.1.2.1 Review and approve annual schedule and as necessary, the revisions to the annual schedule.

8.1.3 QA Lead, Office of Standards and Quality Assurance

8.1.3.1 Distribute the annual schedule to the EMCBC for posting on the web.

8.1.3.2 Distribute the annual schedule to the project managers that manage HLW or UNF activities.

8.2 Audit Planning

8.2.1 Audit Team Lead (ATL)

8.2.1.1 Determine the audit scope in accordance with Attachment A, Audit Requirements.

8.2.1.2 Select an appropriate number of potential Audit Team Members who collectively have experience or training commensurate with the scope, complexity, or special nature of work to be audited.

8.2.1.3 If the audit is performance based ensure that the following is accomplished:

- Select one or more Technical Specialists to assist in assessing the adequacy of technical processes.
- Ensure indoctrination of selected Technical Specialist(s) is accomplished in accordance with AP-2.1Q, Qualification of Audit Personnel.

8.2.1.4 Ensure qualification records for each assigned Audit Team Member, including Technical Specialist(s), provide required

evidence that each individual is qualified in accordance with AP-2.1Q, Qualification of Audit Personnel.

- 8.2.1.5 Ensure each Audit Team Member, including Technical Specialist(s), has no direct responsibility for the work that each will audit and has sufficient authority and organizational freedom to make the auditing process meaningful and effective.
- 8.2.1.6 Develop an audit plan that identifies, as a minimum:
 - Audit scope
 - Requirements for performing audit
 - Audit personnel
 - Work to be audited
 - Organization to be notified
 - Applicable documents
 - Audit schedule
 - Implementing documents or checklists to be used.
- 8.2.1.7 Conduct audit-scoping activities with the audited organization and identify Critical Process Steps for Performance-Based Audits.
- 8.2.1.8 Sign and date audit plan, signifying the audit team is qualified and the plan provides required information.
- 8.2.1.9 Prepare an audit notification letter AND forward it with the audit plan to the Director for the Office of Standards and Quality Assurance.
- 8.2.2 Director, Office of Standards and Quality Assurance
 - 8.2.2.1 After review and approval, forward the audit notification letter and the audit plan to the DAS for the Safety and Security Program.
- 8.2.3 DAS, Safety and Security Program
 - 8.2.3.1 Review and approve the audit notification letter and the audit plan.
 - 8.2.3.2 Issue audit plan and notification letter to appropriate organization. This should occur at least 30 days before the audit.
- 8.2.4 Audit Team Lead (ATL)
 - 8.2.4.1 Ensure audit team is prepared for audit.
 - 8.2.4.2 Direct performance of audit team throughout audit process.

8.2.5 Audit Team Member

8.2.5.1 Prepare a QA Checklist, Form 18.1-1, to guide the audit team member's work, ensuring coverage of all assigned elements and/or Critical Process Steps of the audit plan. As applicable, the checklist is based on:

- A review of requirements of the QARD or Auditee's QA Program, as appropriate, and implementing documents;
- Previous audit and surveillance results;
- Programmatic and technical documents; and
- Other related activity reports.

8.2.5.2 Review checklist for clarity, pertinence to the scope of the audit, and sufficient to adequately evaluate the work.

8.2.5.3 Sign and date checklist.

8.3 Audit Performance

8.3.1 Audit Team Lead (ATL)

8.3.1.1 Conduct a pre-audit meeting with audit team, appropriate management and staff of the organization to be audited, and observers to review audit scope and status of work to be audited.

8.3.1.2 Document pre-audit meeting attendance on an attendance sheet. Form 18.1-2, provides a sample attendance sheet.

8.3.1.3 Select technical processes or work activities for observation, personnel for interviews, and documents for review as needed to complete each checklist item.

8.3.1.4 Examine objective evidence to the depth necessary to determine if elements are being effectively implemented.

8.3.2 Audit Team Member

8.3.2.1 Complete audit checklist and record:

- Identification of objective evidence reviewed
- Number of samples reviewed

- Examination results
 - A list of personnel contacted
 - Conditions and best practices
- 8.3.2.2 Notify the ATL immediately of any potential Conditions Adverse to Quality.
- 8.3.2.3 Draft reports of Conditions Adverse to Quality in accordance with AP-16.1Q, Corrective Action.
- 8.3.2.4 Provide to the ATL:
- Completed checklists, including any identified best work practices;
 - Draft reports of Conditions Adverse to Quality; and
 - Provide a statement describing the adequacy and effectiveness of implementation of the QA Program (including technical aspects, as appropriate) for the work audited, if such statement is requested by the ATL.
- 8.3.3 Audit Team Lead (ATL)
- 8.3.3.1 Notify immediately, the audited organization, and the Director for the Office of Standards and Quality Assurance, of Significant Conditions Adverse to Quality that require prompt corrective action.
- 8.3.3.2 Conduct daily meetings with audit team to discuss audit progress and any potential Conditions Adverse to Quality.
- 8.3.3.3 Conduct daily meetings with audited organization's management to report audit progress and status, and to coordinate required interfaces involved in the audit.
- 8.3.3.4 Conduct a post-audit meeting to present audit results to appropriate audited organization management.
- 8.3.3.5 Document meeting attendance on an attendance sheet. Form 18.1-2, Attendance Sheet, provides a sample attendance sheet.
- 8.3.3.6 Process Conditions Adverse to Quality in accordance with AP-16.1Q.

8.4 Post Audit Activities

8.4.1 Audit Team Leader

8.4.1.1 Prepare audit report in accordance with Attachment B, Audit Report Requirements, and request input from other Audit Team Members as needed.

8.4.1.2 Prepare audit report transmittal letter.

8.4.1.3 Sign and forward audit report with transmittal letter to the Director for the Office of Standards and Quality Assurance for review and approval.

8.4.2 Director, Office of Standards and Quality Assurance

8.4.2.1 Review and sign audit report.

8.4.2.2 Forward audit report with transmittal letter to the DAS of the Safety and Security Program for approval and issuance.

8.4.3 DAS, Safety and Security Program

8.4.3.1 Review and sign the audit report and the transmittal letter.

8.4.3.2 Issue report to audited organization and the standard distribution.

8.4.3.3 Direct EM directed organizations to take corrective actions, as necessary, to address conditions identified during the audit.

8.4.4 Audit Team Lead

8.4.4.1 Assemble and process records in accordance with Section 9.0.

9.0 RECORDS MAINTENANCE

Records listed shall be collected and submitted to the EMCBC in accordance with AP-17.1Q, Quality Assurance Records, as individual records or included in a records package, as specified. Records listed in 9.2 shall be maintained and dispositioned through the EMCBC Records Management Center procedures.

9.1 QA Records

9.1.1 Lifetime Records

- 9.1.1.1 Audit Report
- 9.1.1.2 Completed QA Checklists
- 9.1.1.3 Personnel Contacted List

9.1.2 Nonpermanent Records

- 9.1.2.1 Audit Plan
- 9.1.2.2 Approved annual QA Audit Schedule and Resource Plan and associated revisions
- 9.1.2.3 Attendance Sheets

9.2 Non QA Records

9.2.1 Long Term Records

- 9.2.1.1 Audit Notification Letter
- 9.2.1.2 Audit Report Transmittal Letter

10.0 FORMS USED

Form 18.1-1, Quality Assurance Audit Checklist

Form 18.1-2, Attendance Sheet

Form 5.1-1, Record of Revision

11.0 ATTACHMENTS

Attachment A – Audit Requirements

Attachment B – Audit Report Requirements

ATTACHMENT A – Audit Requirements

SCHEDULING OF AUDITS

1. Schedule Considerations

The following shall be considered in developing the Annual QA Oversight Audit Schedule and Resource Plan:

- a. Audits shall be scheduled in a manner to provide coverage, consistency, and coordination with ongoing work.
- b. Each EM site shall be audited annually, unless a decrease in the frequency of oversight activities is determined jointly between EM and OCRWM based on the scope and complexity of the work. In no case will audit frequency be less than once every three years for a site performing work under an approved QARD-compliant program.
- c. Audits shall be scheduled to begin as early in the life of the work as practicable and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work.
- d. Regularly scheduled audits shall be supplemented by additional audits of specific subjects, when necessary, to provide an adequate assessment of compliance or effectiveness, or when requested by the management of the area to be evaluated.
- e. Audits to determine QA Program effectiveness and product adequacy (Performance-Based Audits) shall be performed on selected work.

For each scheduled audit, the annual audit schedule must provide the following information, as a minimum:

- a. Organization(s) to be audited
- b. Audit Team Lead (ATL)
- c. Audit location
- d. Planned dates of the audit
- e. Resources needed to support the audit team and administrative functions
- f. Documentation of deviations in audit frequency with justification.

AUDIT SCOPE AND PLAN

1. Audit Scope Definition

- a. Identify applicable QARD programmatic elements to be evaluated and determine amount of activity for each element.
- b. Identify new or ongoing work activities and critical processes subject to QARD requirements.
- c. Determine QA Program documents or procedures (and changes thereto) that may be subject to audit or applicable to a process or activity to be evaluated (e.g., QARD Requirements Matrix, last EM annual assessment report, conditions issued to the audited organization since completion of the last EM annual assessment report, any important historical documents).
- d. Determine changes planned or in process to QA Program.
- e. Identify key organizations/personnel that may be subjected to audit.
- f. Identify badging and security requirements applicable to audit team and observer(s).
- g. Determine any training requirements needed by audit team to get on site.
- h. Determine whether property passes are required for laptops, Personal Digital Assistants, and so forth (items that require a property pass are site specific; check with site security) used on site during audit.
- i. Determine logistical arrangements (e.g., meeting room, audit teamwork area, computer/administrative support, lodging).

2. Interface with management of audited organization (at least eight weeks prior to scheduled audit date):

- a. Discuss planned scope of audit.
- b. Confirm type of audit to be conducted (compliance- or performance-based).
- c. Confirm tentative schedule for performance of audit.
- d. Obtain commitments on availability of knowledgeable audited organization personnel to participate in audit.
- e. Identify anticipated date of audit plan issuance.

Scope definition activities should be completed no later than six weeks before scheduled audit date.

3. Prepare and issue notification letter with audit plan:
 - a. Obtain distribution list of key organizations/personnel for notification.
 - b. Complete activity at least 30 days before audit.
4. Develop audit plan (based on the results of the scoping activities described in “Audit Scope Definition”, obtained during scoping activities).

ATTACHMENT B – Audit Report Requirements

- a. Prepare a formal Audit report using input from the team members and include the following information:
 - i. Signature Page
 - ii. Executive Summary that addresses:
 1. Identification of Organizations Evaluated
 2. Dates the Audit was performed
 3. Base Requirements
 4. A summarized description of Conditions Adverse to Quality and Significant Conditions Adverse to Quality
 - iii. Table of contents
 - iv. Statement of the effectiveness of the QA elements that were audited. Clearly state whether the implementation of the QA program elements were effective or not effective.
 - v. Purpose and Scope of the audit. This should reflect criteria listed in the audit plan with a statement as to whether all criteria in the audit plan were evaluated and an explanation as to why criterion was not (if applicable).
 - vi. Quality Assurance Program discussion, including a description of each criterion or activity audited. Include a description of any Conditions Adverse to Quality or Significant Conditions Adverse to Quality.
 - vii. Identify individuals by titles that were interviewed during the course of the audit.
 - viii. Identify documents reviewed
 - ix. Identify the audit team members

Attach a copy of any Corrective Action Requests (Form 16.1-1)

Form 18.1-1 – Quality Assurance Audit Checklist

**Quality Assurance Audit
Checklist**

Form Number: 18.1-1
Page of
Activity Number:

Quality Assurance Audit Checklist				Form Number: 18.1-1 Page of Activity Number:
1. Organization Evaluated	2. <input type="checkbox"/> Audit <input type="checkbox"/> Surveillance	3. Prepared by: _____ Signature: _____ Date: _____		
5. Dates of Evaluation				
6. Controlled Document			7. Activity Evaluated	
8. Item No.	9. Characteristics to be Evaluated	10. Remarks	11. Results	

Quality Assurance Audit Checklist

Page of
Activity Number:

8. Item No.	9. Characteristics to be Evaluated	10. Remarks	11. Results

Form 18.1-2 – Attendance Sheet

ATTENDANCE SHEET				Form Number: 18.1-2
Page of				
Audit Number:	Audit Title:	<input type="checkbox"/> Pre-Audit Meeting <input type="checkbox"/> Post Audit Meeting		
Summary of Material Covered:				
Audit Team Lead: (Printed Name)		Signature:		Date:
Attendee (Print Name)	Signature	Organization/Employer	Position/Title	Phone Number

RECORD OF REVISION

DOCUMENT: AP-18.1Q, Audits

If there are changes to the controlled document, the revision number increases by one. Indicate changes by one of the following:

- I Placing a vertical black line in the margin adjacent to sentence or paragraph that was revised.
- I Placing the words GENERAL REVISION at the beginning of the text.

Rev. No.	Description of Changes	Revision on Pages	Date
0	Original	All	04/27/2011