



Office of Environmental Management

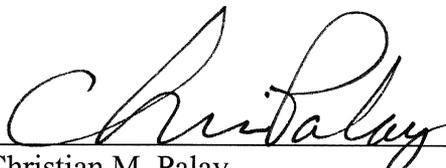
Administrative Procedure

Audits

AP-18.1Q, Revision 1

Effective Date: 12/14/2012

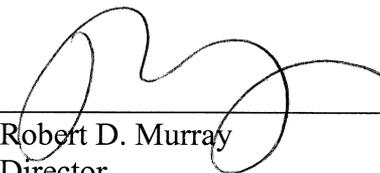
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11/20/2012
Date

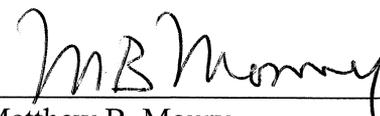
Approval:



Robert D. Murray
Director
Office of Standards and Quality Assurance

11-20-12
Date

Concurrence:



Matthew B. Moury
Deputy Assistant Secretary
Safety, Security and Quality Programs

11/20/12
Date

1.0 PURPOSE

The purpose of this procedure is to establish responsibilities and processes for the scheduling, planning, performing, and reporting of audits of the Quality Assurance (QA) programs associated with High-Level Radioactive Waste (HLW) and Used Nuclear Fuel (UNF).

2.0 SCOPE

The scope of this procedure is to assess the effective implementation of the QA requirements through audits.

3.0 APPLICABILITY

This procedure applies to EM personnel and contractors who are involved with the functions of QARD audits 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 Requirement

4.1.1. *Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 20*

4.1.2. *EM-QA-002, Quality Assurance Program Plan (QAPP)*

4.2 References

4.2.1. *AP-2.1Q, Qualification of Personnel*

4.2.2. *AP-16.1Q, Corrective Action*

4.2.3. *AP-17.1Q, Quality Assurance Records*

5.0 DEFINITIONS

N/A

6.0 RESPONSIBILITIES

6.1 Deputy Assistant Secretary (DAS), Safety, Security, and Quality Programs

6.1.1 Reviews and approves the HLW and UNF Annual Audit and Surveillance Schedule.

- 6.2 Director, Office of Standards and Quality Assurance
 - 6.2.1 Responsible for the preparation, change, and approval of this procedure.
 - 6.2.2 Responsible for providing the necessary resources for the completion of the oversight activities on the HLW and UNF Annual Audit and Surveillance Schedule.
 - 6.2.3 Reviews, approves, and issues the Audit Plan and transmittal letter.
 - 6.2.4 Reviews, approves, and issues the Audit report and the transmittal letter.
- 6.3 QA Lead, HLW and UNF Oversight Program
 - 6.3.1 Responsible for the selection of the Audit Team Leader (ATL), Audit Team Members (ATM), and Technical Specialists (TS).
 - 6.3.2 Responsible for the development and distribution of the HLW and UNF Annual Audit and Surveillance Schedule.
- 6.4 Environmental Management Consolidated Business Center (EMCBC) Coordinator, Office of Technical Support and Asset Management.
 - 6.4.1 Responsible for maintaining QA Records associated with this procedure.
- 6.5 ATL
 - 6.5.1 Responsible for developing the audit plan.
 - 6.5.2 Responsible for ensuring that the Audit Team Member(s) are qualified
 - 6.5.3 Responsible for leading the performance of the audit and for briefing the management of the audited organization.
 - 6.5.4 Responsible documenting the results of the audit.
- 6.6 Audit Team Member
 - 6.6.1 Responsible for getting qualified and preparing for the audit
 - 6.6.2 Responsible for auditing their assigned areas.
 - 6.6.3 Responsible for providing input to the ATL documenting the results of the audit

7.0 GENERAL INFORMATION

N/A

8.0 PROCEDURE

8.1 Audit Scheduling

- 8.1.1 The QA Lead develops the HLW and UNF Annual Audit and Surveillance Schedule in accordance with Attachment A.
- 8.1.2 The QA Lead shall revise the annual schedule as necessary to ensure coverage is maintained and audit requirements are met.
- 8.1.3 The QA Lead coordinates with the Director to ensure adequate resources are available for the conduct of the audits and surveillances on the HLW and UNF Annual Audit and Surveillance.
- 8.1.4 The QA Lead assigns an ATL for each audit AND ensure that the assigned ATL has no direct responsibility for the area being audited and is certified in accordance with AP-2.1Q, *Qualification of Personnel*.
- 8.1.5 The DAS reviews and approves the annual schedule and as necessary, revisions to the annual schedule.
- 8.1.6 The QA Lead distributes the annual schedule to the EMCBC Coordinator for posting on the EMCBC website.

8.2 Audit Planning

- 8.2.1 The ATL determines the audit scope in accordance with Attachment A, Audit Requirements.
- 8.2.2 The ATL selects an appropriate number of potential Audit Team Members who collectively have experience or training commensurate with the scope, complexity, or special nature of the work to be audited.
- 8.2.3 If the audit is performance based, the ATL shall 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 Personnel*.

- 8.2.4 The ATL ensures 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.
- 8.2.5 The ATL ensures that each assigned Audit Team Member, including Technical Specialist(s), is qualified in accordance with AP-2.1Q, *Qualification of Personnel*.
- 8.2.6 The ATL develops an audit plan that identifies, as a minimum:
- Audit scope
 - Requirements for performing the audit
 - Audit personnel
 - Work to be audited
 - Organization to be notified
 - Applicable documents
 - Audit schedule
 - Checklists to be used.
- 8.2.7 The ATL conducts audit-scoping activities with the audited organization and identify Critical Process Steps for Performance-Based Audits.
- 8.2.8 The ATL signs and dates the audit plan and audit notification letter and forward both to the Director.
- 8.2.9 After review and approval, the Director signs and dates the audit plan, and then issues the audit plan and notification letter to the appropriate organization. This should occur at least 30 days before the audit forwards the audit notification letter.
- 8.2.10 The ATL assigns and documents the audit functions on the Audit Team Member Record for each Audit Team Member per AP-2.1Q, *Qualification of Personnel*.
- 8.2.11 The ATL assigns and documents the Required Reading on the Audit Team Member Record for each Audit Team Member per AP-2.1Q, *Qualification of Personnel*.
- 8.2.12 The ATL ensures the audit team is prepared for the audit and directs the performance of the audit team throughout the audit process.
- 8.2.13 The Audit Team Member completes the required reading and signs the Audit Team Member Record per AP-2.1Q, *Qualification of Personnel*.

- 8.2.14 The Audit Team Member prepares a QA Audit Checklist, Form 18.1-1, for the areas assigned. As applicable, the checklist is based on:
- A review of requirements of the QARD or the audited organization's QA Program, as appropriate, and implementing documents;
 - Previous audit and surveillance results;
 - Programmatic and technical documents; and
 - Other related activity reports.
- 8.2.15 The ATL shall consolidate the Audit Team Member checklists into one master checklist, review the master checklist and approve the master checklist for use.
- 8.2.16 The ATL reviews the checklist for clarity, pertinent to the scope of the audit, and sufficient to evaluate the work.

8.3 Audit Performance

- 8.3.1 The ATL conducts a pre-audit meeting with the audit team, appropriate management and staff of the organization to be audited to review the audit scope and the status of work to be audited.
- 8.3.2 The ATL documents pre-audit meeting attendance on an attendance sheet. Form 18.1-2, provides a sample attendance sheet.
- 8.3.3 The Audit Team Member shall select technical processes or work activities for observation, personnel for interviews, and documents for review as needed to complete each checklist item.
- 8.3.4 The Audit Team Member examines objective evidence to the depth necessary to determine if elements are being effectively implemented.
- 8.3.5 The Audit Team Member shall complete the audit checklist and record the following:
- Identification of objective evidence reviewed
 - Number of samples reviewed
 - Examination results
 - A list of personnel contacted
 - Conditions adverse to quality, recommendations, and best practices
- 8.3.6 The Audit Team Member shall notify the ATL immediately of any potential Significant Conditions Adverse to Quality as defined in AP-16.1Q, *Corrective Action*.

- 8.3.7 For conditions adverse to quality, the Audit Team Member shall draft Corrective Action Reports (Part I) of Conditions Adverse to Quality in accordance with AP-16.1Q, *Corrective Action*.
- 8.3.8 The Audit Team Member shall provide the following to the ATL:
- Draft Corrective Action Reports (Part I) of Conditions Adverse to Quality; and
 - Completed checklists, including any identified best work practices;
 - List of Personnel Contacted during the audit
 - 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.
- 8.3.9 The ATL shall notify immediately, the audited organization, and the Director, of Significant Conditions Adverse to Quality that require prompt corrective action.
- 8.3.10 The ATL conducts a daily caucus with the audit team to discuss audit progress and any potential Conditions Adverse to Quality.
- 8.3.11 The ATL conducts daily meetings with the audited organization's management to report audit progress and status, and to coordinate required interfaces involved in the audit.
- 8.3.12 The ATL conducts a post-audit meeting to present audit results to appropriate audited organization management.
- 8.3.13 The ATL documents meeting attendance on an attendance sheet. Form 18.1-2, Attendance Sheet, provides a sample attendance sheet.

8.4 Post Audit Activities

- 8.4.1 The ATL prepares the audit report in accordance with Attachment B, Audit Report Requirements, and request input from Audit Team Members as needed.
- 8.4.2 The ATL shall process Conditions Adverse to Quality in accordance with AP-16.1Q, *Corrective Action*.
- 8.4.3 The ATL shall prepare the audit report transmittal letter, sign the audit report, and forward them to the Director for review and approval.

8.4.4 The Director reviews and signs the audit report and transmittal letter and then issues them to the audited organization and any additional distribution as appropriate.

8.4.5 The ATL shall assemble and process records in accordance with Section 9.0 of this procedure.

9.0 RECORDS MAINTENANCE

Records listed shall be collected and submitted to the EMCBC Coordinator in accordance with AP-17.1Q, *Quality Assurance Records*, as individual records or included in a records package, as specified.

9.1 QA Records

9.1.1 Lifetime Records

None

9.1.2 Nonpermanent Records

9.1.2.1 Audit Plan

9.1.2.2 Approved HLW and UNF Annual Audit and Surveillance Schedule and associated revisions

9.1.2.3 Audit Report

9.1.2.4 Completed QA Checklists

9.1.2.5 Personnel Contacted List

9.2 Non-QA Records

9.2.1 Audit Notification Letter

9.2.2 Audit Report Transmittal Letter

9.2.3 Attendance Sheets

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

AUDIT SCHEDULING

1. Schedule Considerations

The following shall be considered in developing the annual Audit and Surveillance Schedule for HLW and UNF Programs:

- a. Audits shall be scheduled in a manner to provide coverage, consistency, and coordination with ongoing work.
- b. Each EM site performing work under an approved QARD-compliant program shall be audited regularly with a frequency commensurate with the complexity of their work scope and not less than once every three years. The determination of audit frequency shall be included as part of the annual schedule.
- 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 or surveillances 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 schedule must provide the following information, as a minimum:

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

AUDIT PLANNING

1. Audit Scope

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

2. Management Interface with the Audited Organization:

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

3. Prepare and issue the notification letter with the audit plan.

4. Obtain a distribution list of key organizations/personnel for notification.

5. Develop the audit plan (based on the results of the scoping activities described in “Audit Scope Definition”, obtained during scoping activities).

Attachment B

Audit Report Requirements

AUDIT REPORT

1. Prepare a cover page that includes the following information:
 - a. The Office of Environment Management title
 - b. The audit report identifier
 - c. The focus of the audit report (e.g., Immobilized High-Level Waste Quality Assurance Program, Waste Treatment and Immobilization Plant Project)
 - d. The name and space for the signature and date from the ATL that prepares the report
 - e. The name and space for the signature and date from the Director that approves the report

2. Prepare a summary of the audit results using input from the team members and include the following information:
 - a. The Audit Identifier (e.g., 11-DOE-AU-003)
 - b. The Audited Organization (e.g., Waste Treatment and Immobilization Plant (WTP) Project)
 - c. Dates of the Audit
 - d. The Purpose and the 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).
 - e. The QARD Sections or Critical Process Steps audited
 - f. The Audit Team
 - g. Summary of the effectiveness of the QA program elements that were audited. Clearly state whether the implementation of the QA program elements were effective or not effective.
 - h. Results (e.g., the number of CAQs, recommendations, or Best Work Practices)
 - i. Description of the CARs, Recommendations, or Best Work Practices identified by the audit team.

3. Attach a list of the personnel involved during the audit and identify whether each individual was at the Pre-Audit Meeting, Contacted During the Audit, at the Post-Audit Meeting, or any combination thereof.

4. If used during the audit, attach the audit checklist completed by the audit team members. The audit checklist should contain the following information
 - a. Identify individuals by titles that were interviewed during the course of the audit.
 - b. Identify documents reviewed during the course of the audit.
 - c. 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.

Form 18.1-1 – Environmental Management Quality Assurance Checklist

1. Organization Evaluated:	2. <input type="checkbox"/> Audit <input type="checkbox"/> Surveillance	3. Prepared by: _____ Signature: _____ Date: _____
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4. Activity Evaluated:

5. Controlled Document:	6. Dates of Evaluation:
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7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results

Form 18.1-1 – Environmental Management Quality Assurance Checklist

Form 18.1-1 – Environmental Management Quality Assurance Checklist			
7. Item No.	8. Characteristics to be Evaluated	9. Remarks	10. Results

Form 18.1-1 – General Instructions

Document the following information on Form 18.1-1 QUALITY ASSURANCE CHECKLIST:

1. **Audit Number:** Indicate the audit number that corresponds to the use of this attendance sheet.
2. **Checkboxes:** Check the appropriate box to indicate if the checklist is being used for an audit or surveillance
3. **Prepared by, Signature, and Date:** Print the team leader for the audit or surveillance, the team leader signs and dates the checklist after the checklist has been completed.
4. **Activity Evaluated:** Indicate the activity being evaluated during this audit or surveillance.
5. **Controlled Document:** Indicate the requirements document that is the basis for the requirements that provides the characteristics to be evaluated.
6. **Dates of Evaluation:** Indicate the dates that the evaluation occurs in the field, job site, office location, etc.
7. **Item Number:** Sequence the checklist items in a format appropriate to the controlled document. For example, the QARD has 18 sections, 5 supplements, and 3 appendices. A numbering scheme that could be used would be 1-2 for QARD Section 1, checklist question #2. More examples:
 - a. SIII-5 QARD Supplement III, checklist question #5
 - b. App. A-3 QARD Appendix A, checklist question #3
8. **Characteristics to be Evaluated:** This is the block for the checklist question to be answered during the audit or surveillance process.
9. **Remarks:** This is the block where the team member for the audit or surveillance writes down the result of their evaluation using the audit or surveillance process.
10. **Results:** Indicate where the evaluation of the characteristic to be evaluated is Satisfactory (**SAT**), Unsatisfactory (**UNSAT**), or Not Applicable (**N/A**). As a general rule, the following guidance should be used:
 - a. **UNSAT:** There is a Corrective Action Report initiated as a result of the evaluation
 - b. **N/A:** There is no evidence of implementation to evaluate for that characteristic.
 - c. **SAT:** The evaluation demonstrates the characteristic has been satisfied.

Form 18.1-2 – ATTENDANCE SHEET

1. Audit/Surveillance Number:	2. Activity Evaluated:
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3. Summary of Material Covered:
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4. Team Leader:	5. Signature:	6. Date:
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Attendee	Signature	Organization	Position Title	Phone Number

Form 18.1-2 – ATTENDANCE SHEET Instructions

Document the following information on Form 18.1-2 – ATTENDANCE SHEET:

1. **Audit Number:** Indicate the audit number that corresponds to the use of this attendance sheet.
2. **Activity Evaluated:** Indicate the activity being evaluated during this audit or surveillance.
3. **Summary of Material Covered:** Indicate whether this attendance sheet is being used for a pre-audit or surveillance meeting, post audit or surveillance meeting, a management debriefing, etc.
4. **Team Leader:** Print the name of the audit or surveillance team leader.
5. **Signature:** The audit or surveillance team leader signs his or her name.
6. **Date:** Indicate the date that the meeting or debriefing occurred.

The rest of the blocks below are for each attendee to print his or her name, their signature, their organization, their position title and their phone number.

Form 5.1-1 – Record of Revision

DOCUMENT: AP-18.1Q, *Audits*

Revision Number	Description of Changes	Revision on Pages	Effective Date
0	Original	All	04/27/2011
1	General Revision	All	12/14/2012