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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

Title:

AUDIT PROGRAM

Procedure No.:

QAAP 18.2

Revision:

5

Date:

01/03/92

Page

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Concurrence

R.W. Chap

Date:

12/17/91

Approval

R.W. Chap

Date:

12/17/91

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1.0 PURPOSE

This procedure establishes the responsibilities and methods for planning, conducting, and documenting quality assurance (QA) audits.

2.0 SCOPE

This procedure applies to internal and external QA audits conducted by or for the Office of Civilian Radioactive Waste Management (OCRWM).

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 *Quality Assurance Requirements Document (QARD), DOE/RW-0214*

3.1.2 *Quality Assurance Program Description Document (QAPD), DOE/RW-0215*

3.2 DEFINITIONS

3.2.1 Audit Team Leader (ATL) - A Lead Auditor who is designated to direct the activities of an audit team.

3.2.2 External Audit - An OCRWM audit of another affected organization or supplier to determine the status, adequacy, compliance to and effectiveness of the audited organization's QA program.

3.2.3 Internal Audit - An audit conducted by or for the OCRWM QA organization to determine the status, adequacy, compliance to, or effectiveness of the OCRWM QA program.

3.2.4 Lead Auditor - An individual who is certified to organize, perform, and direct a QA audit; report observed conditions adverse to quality; and evaluate related corrective actions.



3.2.5 The definitions of other quality assurance related terms are found in the Glossary contained in Reference 3.1.1.

4.0 RESPONSIBILITIES

4.1 ASSOCIATE AND OFFICE DIRECTORS, OCRWM

The Associate and Office Directors, OCRWM are responsible for providing staff to participate as technical specialists in selected audits.

4.2 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA is responsible for the development, implementation, and maintenance of the QA audit program including:

- 4.2.1 Preparing and maintaining this procedure;
- 4.2.2 Scheduling of audits;
- 4.2.3 Approving audit plans and issuing notification letters;
- 4.2.4 Appointing Audit Team Leaders;
- 4.2.5 Ensuring that Audit Team Leaders are properly certified; and
- 4.2.6 Approving and issuing audit reports.

4.3 AUDIT TEAM LEADER (ATL)

The ATL is responsible for:

- 4.3.1 Planning and preparing for the audit activities;
- 4.3.2 Identifying the audit team;
- 4.3.3 Developing the audit plan and audit notification letter;
- 4.3.4 Signing the audit plan;
- 4.3.5 Ensuring that the audit team is properly oriented, trained, and qualified;
- 4.3.6 Ensuring that audit team members are independent of direct responsibility for the activities that they audit;
- 4.3.7 Coordinating audit planning sessions, itineraries, and logistics;
- 4.3.8 Directing the performance of the audit;



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- 4.3.9 Notifying auditees of problems requiring immediate attention;
- 4.3.10 Coordinating the preparation and issuance of the audit report;
- 4.3.11 Coordinating the preparation and issuance of Corrective Action Requests (CARs) for conditions adverse to quality identified during an audit;
- 4.3.12 Signing the audit report; and
- 4.3.13 Ensuring that audit record packages are prepared and submitted to the appropriate records center.

4.4 AUDIT TEAM MEMBERS

Audit team members are responsible for:

- 4.4.1 Preparing audit checklists or marked-up procedures as assigned;
- 4.4.2 Attending meetings scheduled by the audit team leader;
- 4.4.3 Conducting portions of the audit as assigned;
- 4.4.4 Completing assigned portions of the audit checklist or marked-up procedures;
- 4.4.5 Preparing drafts of CARs; and
- 4.4.6 Writing portions of the audit report.

5.0 GENERAL

- 5.1 A system of planned and scheduled audits are conducted to verify compliance with all aspects of the OCRWM QA program and to determine the effectiveness of the QA program.
- 5.2 Audits shall be scheduled to provide coverage and coordination with ongoing QA program requirements and at a frequency commensurate with the status and importance of the activity. Audits shall be initiated as early in the life of the activity as practical to ensure effective controls are implemented and shall be conducted at intervals consistent with the schedule for completing the specific activity. Audits of the QA program are conducted, as a minimum, once each year or at the least once during the life of an activity affecting quality, whichever is shorter.

The audit schedule shall identify the following, as a minimum:

- a) Organizations to be audited;



- b) Location and date; and
- c) QA program elements to be audited.

6.0 PROCEDURES

6.1 SCHEDULING

- 6.1.1 The Director, OQA shall develop an audit schedule in accordance with Subsection 5.2 that identifies internal and external audits planned for the fiscal year.
- 6.1.2 The Director, OQA shall review the audit schedule at least quarterly and revise as necessary to assure adequate coverage. The transmittal of updated schedules shall identify major changes in the previously scheduled audits with appropriate justification.
- 6.1.3 Following Director, OQA approval, the audit schedule and updates shall be transmitted to the Associate and Office Directors, Participant Technical Project Officers and Quality Assurance Managers.
- 6.1.4 Regularly scheduled audits may be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.

6.2 AUDIT TEAM SELECTION

- 6.2.1 The Director, OQA shall appoint an ATL for each audit and shall verify that the ATL is certified as a Lead Auditor in accordance with QAAP 18.1, *Qualification of Audit Personnel*.
- 6.2.2 The ATL shall identify the scope of the audit for inclusion in the audit plan. The scope of an audit may include evaluation of product quality and technical adequacy of work being done or completed, as appropriate, as well as programmatic compliance and implementation effectiveness. Technical requirements may be selected for audit evaluation from the governing technical requirements documents and be included in audit checklists or marked-up procedures prepared by the technical specialists.
- 6.2.3 A visit to the site of the planned audit and meetings with the organization to be audited may be considered to further define the scope and conduct of the audit.



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6.2.4 The ATL shall request that Associate and Office Directors assign individuals having technical expertise to participate as technical specialists. The ATL shall select additional audit team members as needed. Prior to the audit, the qualification records of each audit team member shall be reviewed by the ATL or a DOE QA staff member to verify that the individual is qualified to conduct audits in accordance with QAAP 18.1.

6.2.5 The ATL shall ensure that audit team members are independent of direct responsibility for the activities that they audit.

6.3 PREPARATION

6.3.1 The ATL shall develop an audit plan using the format shown in Attachment I, "Audit Plan Format and Content."

6.3.2 The ATL shall sign and date the audit plan signifying that the audit team is qualified and the plan reflects the required information.

6.3.3 The ATL shall prepare an audit notification letter and forward it with the audit plan to the Director, OQA.

6.3.4 The Director, OQA shall approve and issue the audit plan and notification letter to the appropriate organization.

6.3.5 The ATL shall ensure that the audit team is prepared for the audit. Preparation shall include the following:

- a) Studying procedures that apply to the activities being audited;
- b) Evaluating previous surveillance and audit results;
- c) Evaluating relevant corrective action history;
- d) Reviewing current status of the work; and
- e) Reviewing trend data.

6.3.6 The audit team shall develop a checklist using Attachment II, "Quality Assurance Checklist" or marked-up procedures to guide their audit activities and to ensure coverage of all elements of the audit plan. Checklist questions shall be based on a review of requirements, procedures, previous audit and surveillance reports, technical documents, and other related activity reports, as applicable.



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6.3.7 The ATL shall conduct a preaudit meeting with the audit team and appropriate management and staff members of the audited organization to review the audit scope, determine the status of activities to be audited, and meet counterparts. Attendance shall be documented using Attachment III, "Attendance Record."

6.4 PERFORMANCE

6.4.1 During the audit, the audit team shall:

- a) Perform reviews of documents and records to assess their adequacy and acceptability;
- b) Conduct activities in the audit checklist or marked-up procedures under the direction of the ATL;
- c) Examine objective evidence to the depth necessary to determine if the elements are being implemented effectively;
- d) Maintain a list of personnel contacted;
- e) Complete the checklist or marked-up procedures;
- f) Notify the ATL of any identified condition adverse to quality that may warrant the issuance of a CAR; and
- g) Notify the audited organization of any items identified as nonconforming.

6.4.2 The ATL shall conduct daily team meetings during the conduct of the audit to discuss conditions adverse to quality that were found during the audit. The audited organization shall be notified immediately of conditions requiring prompt corrective action.

6.4.3 The ATL shall conduct daily meetings with management of the audited organization to report the progress and status of the audit and to ensure that appropriate individuals continue to be involved in the audit.

6.4.4 The audit team shall draft CARs to document activity related conditions adverse to quality and ensure that any nonconforming items are documented as such on the audited organization's nonconformance reports. Adequacy and effectiveness statements (including technical aspects, as appropriate) shall be prepared by audit team members for the activities that they audited.

6.4.5 Prior to the postaudit meeting, or as deemed appropriate by the ATL, team members shall submit draft CARs, completed checklists, marked-up procedures, and adequacy and effectiveness statements to the ATL.



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6.5 POSTAUDIT

6.5.1 The ATL shall conduct a postaudit meeting with the audit team and appropriate management and staff members of the audited organization to present the results of the audit. Attendance shall be documented using Attachment III.

6.5.2 The ATL shall process CARs in accordance with QAAP 16.1, *Corrective Action*.

6.6 AUDIT REPORT

6.6.1 The ATL shall coordinate the preparation of the audit report using the format shown in Attachment IV, "Audit Report Format and Content."

6.6.2 The ATL shall ensure that all relevant information from the checklist or marked-up procedures used by the audit team has been addressed in the audit report or associated CARs.

6.6.3 The ATL shall prepare the audit report transmittal letter.

6.6.4 The ATL shall sign the audit report and forward it with the transmittal letter to the Director, OQA.

6.6.5 The audit report and transmittal letter shall be approved by the Director, OQA and distributed to the audited organization. Copies of the audit report shall also be distributed to other affected organizations. The audit is considered closed upon issuance of the audit report.

6.6.6 The ATL shall assemble the completed audit record package and submit the package to the appropriate records center in accordance with Section 7.0.

7.0 RECORDS

The audit plan, notification letter, audit report, and audit schedules generated as a result of this procedure are considered QA Records and shall be collected and maintained in accordance with requirements specified in QAAP 17.1, *QA Records Management* or QMP-17-01, *Records Management: Record Source Implementation*.

Note: CAR record packages shall be maintained as QA records separately from the audit record package.



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8.0 ATTACHMENTS

- 8.1 Attachment I - Audit Plan Format and Content
- 8.2 Attachment II - Quality Assurance Checklist
- 8.3 Attachment III - Attendance Record
- 8.4 Attachment IV - Audit Report Format and Content
- 8.5 Attachment V - QAAP 18.2 Flowchart



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**ATTACHMENT I (Example)
AUDIT PLAN FORMAT AND CONTENT**

Audit Number: _____

Organization: _____

Location of Audit: _____

Dates of Audit: _____

Audit Team Members: _____

AUDIT SCOPE

Activities/Contracts/Tasks to be Audited: _____

Requirements/Criteria to be Audited: _____

Governing Documents: _____

Marked-up Procedures/Checklists: _____

PRELIMINARY AUDIT SCHEDULE

Preaudit Meeting: _____

Conduct of Audit: _____

Daily Team Debriefing Time and Location: _____

Postaudit Meeting Date, Time and Location: _____

Prepared by: _____ Date: _____

ATL

Approved by: _____ Date: _____

Director, OQA



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ATTACHMENT II (Example)
QUALITY ASSURANCE CHECKLIST

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.				PAGE _____ OF _____ AUDIT/SURVEILLANCE NO. _____	
QUALITY ASSURANCE CHECKLIST					
ORGANIZATION EVALUATED		<input type="checkbox"/> EXTERNAL	<input type="checkbox"/> AUDIT	PREPARED BY _____ DATE _____	
DATES OF EVALUATION		<input type="checkbox"/> INTERNAL	<input type="checkbox"/> SURVEILLANCE		
CONTROLLING DOCUMENT (Title, Number, Revision)				ACTIVITY EVALUATED	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS	
* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)					

REV 09/91

U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

REV. 6/90



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**ATTACHMENT II (continued)
QUALITY ASSURANCE CHECKLIST**

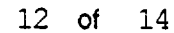
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AUDIT/SURVEILLANCE
NO. _____

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS





ATTACHMENT IV (Example)
AUDIT REPORT FORMAT AND CONTENT

COVER SHEET

Identify audit number, primary activities evaluated, organization evaluated, and location and dates of the audit. The cover sheet should also bear the dated preparer and approval signatures of the ATL and the Director, OQA.

MAIN BODY

SECTION 1.0 EXECUTIVE SUMMARY

Describe the results of the audit in brief, concise statements addressing any corrective action required.

SECTION 2.0 SCOPE

Repeat the scope as stated in the audit plan. Identify any additions or deletions to the audit scope that occurred during the course of the audit.

SECTION 3.0 AUDIT TEAM

List the name and assigned area of responsibility of each audit team member.

SECTION 4.0 PERSONNEL CONTACTED

Identify personnel attending the preaudit and postaudit meetings and contacted during the audit. Refer to attached Attendance Records, as applicable.

SECTION 5.0 AUDIT RESULTS

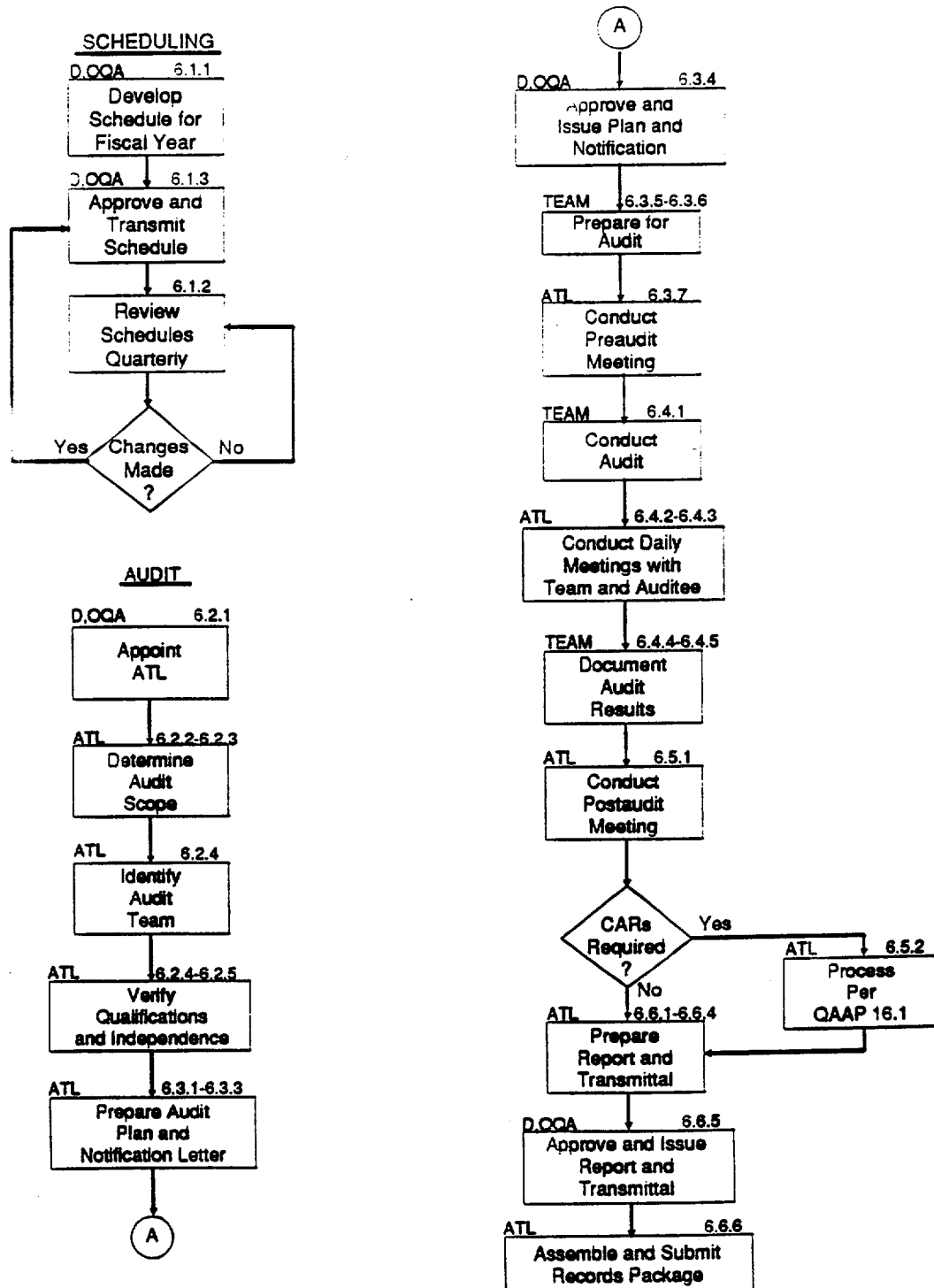
Briefly discuss and reference any Corrective Action Requests, and summarize any immediate corrective actions taken. Provide the detailed description of the items and activities examined during the audit, including all relevant information from the checklist or marked-up procedures. Include a statement as to the adequacy and effectiveness of the quality assurance program elements audited.

SECTION 6.0 RECOMMENDATIONS

Identify any recommendations the audit team considers appropriate to the audit.



ATTACHMENT V
QAAP 18.2 FLOWCHART



OFFICE OF CIVILIAN
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U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

REVISION RECORD

TITLE:

Audit Program

PROCEDURE NO.

QAAP 18.2

REV. NO. (current)

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DESCRIPTION OF PROPOSED REVISION AND RATIONALE:

Revise QAAP 18.2, Revision 4 per Approval copy, Revision 5. The contents of the Audit Schedule and Audit Plan have been revised for correctness.

PREPARER OF PROPOSED REVISION

Thomas E. Rodgers
Thomas E. RodgersDATE 12/13/91

TYPE OF REVISION (Check One):

MAJOR ☐MINOR ☒

SIGNATURE TO AUTHORIZE REVISION

R.W. Cleaf

Responsible Associate or Office Director

DATE 12/17/91

TYPE OF REVISION (Check One):

MAJOR ☐MINOR ☒

CONCURRENCE SIGNATURE

R.W. Cleaf

for Director, OQA

DATE 12/17/91

RECOMMENDED TRAINING:

READ ☒CLASSROOM ☐OTHER ☐

Self-study recommended for all OCRWM personnel who will be performing internal or external QA audits.

R.W. Cleaf

RESPONSIBLE ASSOCIATE OR OFFICE DIRECTOR OR QA TRAINING OFFICER

DATE 12/17/91