

HLW DIVISION PROCEDURE FOR CONDUCTING
OBSERVATION AUDITS OF DOE HIGH LEVEL WASTE
REPOSITORY PROGRAM QA AUDITS

1.0 PURPOSE

This procedure describes the High-Level Waste Management Division's methodology for conducting observation audits of quality assurance (QA) audits performed by the Department of Energy (DOE). These audits may be performed on DOE, its contractors and subcontractors, its participating organizations, and may include contractor audits of their subcontractors. For example, the staff may observe a USGS audit of one of their contractors.

The primary objective of the Nuclear Regulatory Commission's (NRC) observation audit program is to gain confidence that the DOE is implementing a program which meets the NRC's QA program requirements established in 10 CFR 60, Subpart G. This confidence is gained by assessing DOE's ability to identify and correct problems through their audit program. Observation audits will be the principal means for the staff to assess the implementation of the DOE program prior to the start of extensive site characterization activities. Observation audits also enable the staff to provide guidance to the DOE on QA program implementation and the overall DOE audit program. The staff will follow-up on staff concerns with respect to the audit and/or deficiencies identified by the audit team. This will assure the staff that corrective action is being performed and QA programs are being properly implemented.

2.0 OBJECTIVE

The objective of this procedure is to describe techniques for assessing the overall effectiveness of a quality assurance program audit conducted in the DOE program. Guidance on the following areas is provided:

- (a) Qualifications required for the observers.
- (b) Responsibilities
- (c) Criteria for selection of audits for observation
- (d) Areas to be observed
- (e) Protocol during the observation audit
- (f) Reporting requirements
- (g) Follow-up

3.0 QUALIFICATIONS OF THE OBSERVERS

Personnel selected for observation audits shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited (e.g., technical observers shall be selected based on their education and experience in the technical area being audited). The observers shall be selected based on the following qualifications: auditing and technical experience, education, auditor training, communication skills, and knowledge of QA, technical, and regulatory requirements. All observers shall meet the requirements of ANSI/ASME NQA-1-1983 for auditor qualifications.

The training program for observers should address the following:

- 3.1 (a) The basics of the audit process

- (b) Applicable requirements documents
- (c) DOE/NRC protocol for observers
- (d) Conduct of observers

Attendance and successful completion of an exam covering the topics above should be completed prior to any staff member participating as an observer.

4.0 RESPONSIBILITIES

The following identifies the responsibilities of individuals involved in the observation audit process:

4.1 Operations Branch Chief

- (a) Approval of observation audit schedule.
- (b) Reviewing and approving the final report.
- (c) Transmitting the final report to the DOE.

4.2 Functional Section Leaders (QA and technical sections)

- (a) Preparation of observation audit schedule in consultation with P/M and technical branch (QA Section Leader only)
- (b) Selection of observers.
- (c) Assuring that observers are indoctrinated and trained for the audit observation. This information shall be documented and retained.
- (d) Concurring on final report.
- (e) Revising observation audit procedure as needed.

4.3 Project Manager (HLOB)

- (a) Coordinating the arrangements for the observation, including meeting notices for the State, letters to DOE, coordinating with TRB and QA section to assure integration.
- (b) Acting as the principal spokesperson for the NRC during the audit. P/M will rely on functional staff to explain observations or other topics within their discipline.
- (c) Ensuring during the audit that all concerns, positions, methods, etc. are consistent with Commission and Office policies.
- (d) Writing the transmittal letter to DOE.
- (e) Co-authoring report.
- (f) Integrating evaluations of technical section and QA section observers, as necessary.
- (g) Leading observation audit team during the audit.

4.4 Observers

- (a) Evaluating the DOE audit program in accordance with this procedure, reviewing pertinent background information (such as the DOE audit plan, previously identified open items, the checklist, the QA plan, and any necessary technical procedures or documents).
- (b) Completing the checklist described in Attachment A.
- (c) Writing the report (for their area of responsibility).
- (d) Concurring on report.
- (e) Explaining NRC observations to DOE audit team, as necessary.

Technical staff members will be primarily responsible for evaluating the effectiveness of the DOE audit team in assessing the quality of the technical work. QA staff will primarily be responsible for evaluating the audit team's assessment of the controls applied to work. Because these areas overlap, and because individual team members may possess qualifications in areas outside of their specific responsibilities, QA and technical staff should coordinate and integrate their review of the DOE audit.

5.0 CRITERIA FOR SELECTION OF AUDITS FOR OBSERVATION

The selection of audits for observation should be based on the following:

- (a) The importance of the activity being audited (for example, critical path activities which provide site characterization data which are important to public radiological health and safety and/or waste isolation).
- (b) The time since the last audit (NRC, DOE, WMPO, etc).
- (c) The results of previous audits, observation audits, or other reviews by NRC or DOE, particularly those which identified major concerns.

The OCRWM Consolidated Audit Schedule should be used for determining which audits are planned by DOE.

6.0 AREAS TO BE OBSERVED

See Attachment A for instruction on the areas to be observed and the use of a checklist to document results.

7.0 PROTOCOL DURING AUDIT

During the observation audit, the staff shall conduct themselves in a professional and cooperative manner. Observers should coordinate with the DOE audit team leader to assure that the effectiveness of the audit team is not disrupted. Observers are encouraged to participate fully by furnishing their questions, observations, and recommendations to the DOE audit team leader. Efforts should be made by the observer to minimize direct questions of the audited organization. It may be necessary to exclude observers from certain portions of the audit (such as procurement actions that are in-process, or sensitive personnel records). Observers should obtain a copy of the audit checklist as soon as it is available and should prevent predisclosure of the list to the audited organization.

All staff concerns should be communicated to the audit team leader in a clear and timely manner. Observers shall indicate the acceptable areas of the audit program as well as express concerns, or recommendations to the DOE audit team leader prior to leaving the site. Every attempt should be made to express their concerns daily to the DOE audit team leader. Whenever possible, the observers should attend the entrance and exit meetings and audit team caucuses. The observers should also express their concerns about the adequacy and implementation of the audited organization's QA program to the audit team leader prior to the exit meeting. Observer concerns about the conduct of the audit should be addressed only to the audit team leader unless directed otherwise by the audit team leader. The audit team leader should be given the opportunity to respond to staff concerns. The observer should consider any new

information provided to determine if concerns are still valid. Efforts should be made to reach agreement with the audit team leader on the nature of the concern and where necessary, that appropriate corrective action will be taken. All observations should be based on facts and personal opinions should be avoided.

8.0 REPORTING REQUIREMENTS

A report shall be written upon completion of the audit and will be sent to the Director, Office of Systems Integration and Regulations, Office of Civilian Radioactive Waste Management, Department of Energy. The DOE Project Office (WMPO), the State of Nevada, and the organization that conducted the audit shall also receive a copy of the report. The report shall evaluate the overall effectiveness of the DOE audit in assessing the implementation of the QA program. Needed improvements in the audit, which would make future audits acceptable to the staff, should be identified. The areas addressed in the checklist (Attachment A) should be included in the report to the extent that each was observed. In addition, each report shall address the audit results. The report should address the positive as well as the negative aspects of the audit.

The format of the report should include the following headings:

8.1 Summary

- (a) Objective of audit and audit observation
- (b) Scope of audit
- (c) Main conclusions on overall effectiveness of audit and major areas needing improvement.

8.2 Introduction

- (a) Contents of report (observations, DOE findings, audit team members, etc.)
- (b) Date(s) of audit observation and the organization being observed
- (c) General background information about the audited organization (e.g., their scope of work and importance to safety or waste isolation.

8.3 Audit Purpose and Scope

- (a) Based on DOE's and NRC's perspective
- (b) QA criteria and technical work audited

8.4 Audit Team Members and Observers (name, title, and affiliation)

8.5 NRC Observations of the Audit Team

- (a) Addresses each area described in the checklist (Attachment A) to the extent that each was observed.
- (b) Conclusions should be based on facts. Subjective judgements should be minimized.
- (c) Supporting detail (i.e., examples) should be provided as necessary to clearly support the observations.

8.6 Preliminary Results/Findings of Audit Team

- (a) Attach a copy of the draft results or summarize the results.

8.7 Appendices may be attached which address specific observations such as:

- (a) Observations and open items with respect to the audited organization's QA program identified by the audit observer.

9.0 FOLLOW-UP

The staff may elect to observe follow-up audits or surveillances by DOE which are needed to verify that the audited organization is implementing the necessary corrective action. Likewise, follow-up audits by the staff may be necessary to ensure that those recommendations for improving the DOE audit program are being implemented. It is the responsibility of the observers to track all staff concerns. All concerns shall be documented and subsequently closed out upon satisfactory resolution of the concern. The actions taken to resolve the issue shall be documented.

10.0 REFERENCES

ASME/ANSI NQA-1-1983
10 CFR Part 50 Appendix B
OCRWM Consolidated Audit Schedule
DOE Memo on Observer Protocol (July 14, 1987)

ATTACHMENT A

AREAS TO BE OBSERVED AND CHECKLIST COMPLETION

This attachment provides guidance on the areas to be addressed before or during the observation audit. A checklist (attached) shall be used which documents the area investigated and the results. The checklist is intended to be a guide for the audit observers. Observers should rely on their professional judgement in deciding which areas to emphasize or de-emphasize in the checklist. The staff should place a greater focus on performance of the audit team rather than just programmatic compliance. This means did the audit team verify that the audited organization's QA program is producing quality products (i.e., reports, data, test procedures) and the documentation necessary to defend that work in licensing. In addition, concerns should be put into perspective. For example, does a missing signature have a negative effect on the effectiveness of the audit? If not, the staff should clearly indicate that a noncompliance exists but it did not result in reduced product quality. The product, in this case, is an effective audit.

HLWM DIVISION OBSERVATION
AUDIT CHECKLIST

1. Observation Audit No:
2. Observer:
3. Date(s) of Audit:
4. Audited Organization:
5. Audit Conducted By:

PROCEDURE: The areas listed should be addressed either before or during the audit. When information used to support staff conclusions is obtained by verification of documented evidence, appropriate documents should be referenced. However, in those instances where only verbal information can be obtained, this shall be noted and the person contacted documented, so that appropriate follow-up action can be taken to verify that supporting documentation exists.

The observation audit number shall be placed on each successive checklist sheet. In addition, upon completion of the respective checklist, the NRC observer shall sign and date each checklist sheet in the space provided. Lastly, for those areas not covered or not applicable (NA) the auditor shall document this and provide justification in the "RESULTS" section of the checklist.

The following checklist has been organized in relative order of importance. This will emphasize audit performance rather than procedural compliance.

Staff should not be limited to only those questions on the list, but should pursue any others which will assist in achieving the objective of the observation audit.

REQUIREMENT	INVESTIGATING GUIDELINE	EVIDENCE EXAMINED	RESULTS
	<u>I. Selection of Areas to be Audited</u>		
NNWSI/88/9 XVIII Section 1.1	(a) Were all 18 criteria and associated requirements of Appendix B examined? If not, was an acceptable rationale provided?		
	(b) What was the scope of important to safety or waste isolation activities being audited? Was the audit scope of important to safety or waste isolation work sufficient to assess the overall effectiveness of the QA program?		
NQA-1-1983 Supp. 18S-1 Section 4	(c) Was the checklist comprehensive in its coverage of Appendix B QA requirements? If not, was an acceptable rationale provided?		
	<u>II. Timing of Audit</u>		
NRC Review Plan Section 18.2	(a) Was the audit scheduled based on the status and safety importance of the activities being performed?		
	<u>III. Examination of Technical Products</u>		
NQA-1-1983 Supp. 2S-3 Section 2.1	(a) Were technical specialists part of the audit team?		
10 CFR 50 App.B XVIII	(b) Were the technical specialists knowledgeable in the areas being audited (i.e., geochemists for geochemistry)?		
NQA-1-1983 Supp. 18S-1 Section 4	(c) Were technical checklists utilized during the audit?		
NQA-1-1983 Supp. 2S-3 Section 2.1	(d) Did the quality assurance audit team members perform an integrated review (e.g. were problems identified by technical team members examined to determine if a quality assurance program deficiency caused them)? Also, were QA program deficiencies examined to determine their effect on technical products?		

Signature/Date _____

OBSERVATION AUDIT No. _____

REQUIREMENT	INVESTIGATING GUIDELINE	EVIDENCE EXAMINED	RESULTS
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(e) In the examination of technical products,

- were calculations checked
- did the technical procedures reflect standard industry practice
- for exotic techniques, was a peer review conducted
- was sufficient information recorded in the lab notebook to reconstruct the test or reproduce the data by an independent investigator
- were technical procedures consistent with test plans or technical plans
- were all technical comments, by technical reviewers, documented and resolved
- were the resolutions valid
- was the work classified correctly as important to safety or waste isolation (i.e., have quality levels been properly assigned)
- Note: WMPO classifies major activities for participating organizations. Specific activities, however, classified by the audited organization should be reviewed.
- were nonconformances appropriately dispositioned

(f) Were software QA controls audited for conformance to appropriate criteria? What were the criteria?

IV. Conduct of the Audit

NQA-1-1983
 Supp. 18S-1
 Section 4

QMP-16-03
 Section 5.2.1.2

- (a) Were the auditors persistent and thorough in their investigations?
- (b) Was the nature of the findings significant or trivial (e.g., lack of an inspection/surveillance program or lack of one signature from a large sample)?

Signature/Date _____

OBSERVATION AUDIT No. _____

REQUIREMENT	INVESTIGATING GUIDELINE	EVIDENCE EXAMINED	RESULTS
NNWSI/88-9 XVIII Section 1.4	(c) Did the auditors reach a conclusion based on facts?		
10 CFR 50 App. B XVI	(d) Did the auditors do research to determine if the finding is a system discrepancy or an isolated flaw?		
NRC Review Plan Section 18.8	(e) Did the auditor verify evidence for root cause analysis before closing out past findings?		
NQA-1-1983 Supp. 18S-1 Section 4	(f) Were conditions requiring prompt corrective action reported immediately to management of the audited organization?		
NQA-1-1983 Supp. 18S-1 Section 4	(g) Was objective evidence examined to the depth necessary to determine if the 18 criteria elements are being implemented effectively?		
	(i) Was an appropriate mix of technical and programmatic auditing performed based on the area being audited?		
QMP-18-01 Figure 2	(j) Review the audit checklist for the following: <ul style="list-style-type: none"> - can the audit be reconstructed from the evidence recorded on the checklist - did the checklist document the persons contacted of ref. the documents reviewed - was the sample size recorded - was the auditor and the audit number identified - were the requirements listed - were conclusions/results recorded 		

Signature/Date _____

OBSERVATION AUDIT No. _____

REQUIREMENT	INVESTIGATING GUIDELINE	EVIDENCE EXAMINED	RESULTS
	<u>V. Qualification of the Auditors</u>		
10 CFR 50 App. B II NQA-1-1983 Supp. 2S-3	(a) Nuclear licensing experience (b) Nuclear QA experience (c) Years of experience (d) Training in auditing techniques (e) Technical expertise in area being audited (f) Conformance with NQA-1 for auditors and lead auditors		
	<u>VI. Audit Team Preparation</u>		
NQA-1-1983 Supp. 18S-1 Section 3.1	(a) Did the audit plan include: - audit scope - requirements - audit personnel - activities to be audited - organizations to be notified - applicable documents - schedule - procedure of checklist to be used (b) Were checklist questions, which can be answered during a desk audit, completed prior to the conduct of the audit?		
NQA-1-1983 Supp. 2S-1 Section 2.1	(c) Was the audit team knowledgeable in the following: - the audited organization's policies and procedures - applicable industry standards - the applicable regulations - the applicable NUREGs on peer review and old data		
NQA-1-1983 Supp. 2S-3 Section 2.1	(d) Can "technical" checklist questions be answered by "non-technical" personnel who lack expertise in the given subject matter?		
QMP-18-01 Section 5.3	(e) Did the audit team attend the preaudit conference and is this documented? (f) Was the applicable auditing procedure properly used by the audit team?		

Signature/Date _____

OBSERVATION AUDIT No. _____

REQUIREMENT	INVESTIGATING GUIDELINE	EVIDENCE EXAMINED	RESULTS
	<u>VII. Conduct of Entrance/Exit Meeting</u>		
NQA-1-1983 App. 18A-1, Section 4.1	(a) Was the scope and objective of the audit clearly discussed?		
NNWSI/88-9 Section XVIII, 1.4	(b) Were the audit results clearly communicated to the audited organization?		
NNWSI/88-9 Section XVIII, 1.6	(c) Did the auditor obtain a commitment from the audited organization to evaluate noted discrepancies and to respond?		
DOE Memo on Observer Protocol (July 14, 1987)	(d) Were the audited organization and observers afforded the opportunity to present additional information or make comments?		
	<u>VIII. Audit Team Coordination</u>		
NQA-1-1983 Supp. 18S-1 Section 3.3	(a) Did the lead auditor coordinate the audit team and integrate individual findings, trends, etc.		
QMP-18-01 Section 5.8.1.	(b) Did the audit report reflect what was discussed by the audit team? This will be verified at a later date since staff observation audit reports should be completed before the audit team issues their audit report.		
	(c) Were daily or an appropriate frequency of audit team caucuses held?		
	<u>IX. Audit Team Independence</u>		
NQA-1-1983 Supp. 18S-1 Section 3.2	(a) Were audit personnel independent of any direct responsibility for performance of the activities which they will audit?		

Signature/Date _____

OBSERVATION AUDIT No. _____

REQUIREMENT	INVESTIGATING GUIDELINE	EVIDENCE EXAMINED	RESULTS
NQA-1-1983 Supp. 18S-1 Section 3.2	(b) For internal audits, were personnel having direct responsibility for performing the activities being audited involved in the selection of the audit team?		
NQA-1-1983 Supp. 18S-1 Section 3.2	(c) Did audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective?		

Signature/Date _____