

FEB 10 1988

RJ 2/3-M1 BALLARD

- 1 -

MEMORANDUM FOR: Ronald Ballard
Technical Review Branch

FROM: B. J. Youngblood, Chief
Operations Branch

SUBJECT: REQUEST FOR TECHNICAL SUPPORT FROM HLTR FOR OBSERVATION OF
DOE/NNWSI QA AUDITS

The purpose of the memo is to request technical support from HLTR for observing three DOE QA audits of DOE contractor programs. The general purpose of technical support is to evaluate the technical effectiveness of DOE audit team members in their evaluation of the quality of work in the audited organization. Therefore, technical staff supporting the observation need only have expertise in the technical area of the audit; an in-depth background in the DOE/NNWSI-Yucca Mountain project is not necessary. One technical staff member is needed for each of the observations listed below:

Materials Characterization Center, materials testing, February 23-26, 1988	- 1 materials engineer waste package
Fennix and Scisson, A-E for subsurface facility construction and testing, February 22-26, 1988	- 1 geotechnical/design engineer with shaft/mine design experience
Holmes and Narver, A-E for surface facility construction, March 28 - April 1, 1988	- 1 geotechnical/design engineer with surface facility design experience

We estimate that a maximum of about eight staff days are needed to completely support each observation.

I have enclosed a plan that gives more specific information regarding these audit observations. After these audit observations are completed, we will evaluate the use of technical staff in future observations of DOE QA audits.

8903310178 880210
PDR WASTE
WM-11 DCD

102-4
WM-11
HLOB
NH16

RJ 2/3 M1 BALLARD

- 2 -

Please give John Linehan the names of the technical staff you assign to this task before February 16, 1988.

B.J. Youngblood, Chief
Operations Branch

Enclosure:
As stated

cc: R. Browning
J. Kennedy
J. Linehan

OFFICIAL CONCURRENCE AND DISTRIBUTION RECORD

MEMORANDUM FOR: Ronald Ballard
 Technical Review Branch

FROM: B.J. Youngblood, Chief
 Operations Branch

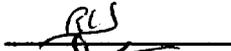
SUBJECT: REQUEST FOR TECHNICAL SUPPORT FROM HLTR FOR OBSERVATION OF
 DOE/NNWSI QA AUDITS

DATE: FEB 10 1988

DISTRIBUTION

Central Files	NMSS RF	RBrowning, HLWM
MBell, HLWM	JBunting, HLSE	BJYoungblood, HLOB
RBallard, HLTR	RJohnson, HLOB	SCoplan, HLOB
JLinehan, HLOB	HLOB r/f	

CONCURRENCES

ORGANIZATION/CONCUREE	INITIALS	DATE CONCURRED
HLOB/RJohnson		2/10/88
HLOB/JLinehan		2/16/88
HLOB/BJYoungblood: km		2/10/88

E



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

FEB 10 1988

MEMORANDUM FOR: Ronald Ballard
Technical Review Branch

FROM: B. J. Youngblood, Chief
Operations Branch

SUBJECT: REQUEST FOR TECHNICAL SUPPORT FROM HLTR FOR OBSERVATION OF
DOE/NNWSI QA AUDITS

The purpose of the memo is to request technical support from HLTR for observing three DOE QA audits of DOE contractor programs. The general purpose of technical support is to evaluate the technical effectiveness of DOE audit team members in their evaluation of the quality of work in the audited organization. Therefore, technical staff supporting the observation need only have expertise in the technical area of the audit; an in-depth background in the DOE/NNWSI-Yucca Mountain project is not necessary. One technical staff member is needed for each of the observations listed below:

Materials Characterization Center, - - 1 materials engineer waste package
materials testing, February 23-26,
1988

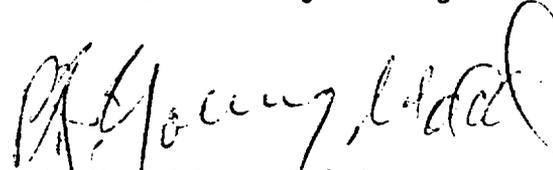
Fennix and Scisson, A-E for - 1 geotechnical/design engineer with
subsurface facility construction shaft/mine design experience
and testing, February 22-26, 1988

Holmes and Narver, A-E for surface - 1 geotechnical/design engineer with
facility construction, March 28 - surface facility design experience
April 1, 1988

We estimate that a maximum of about eight staff days are needed to completely support each observation.

I have enclosed a plan that gives more specific information regarding these audit observations. After these audit observations are completed, we will evaluate the use of technical staff in future observations of DOE QA audits.

Please give John Linehan the names of the technical staff you assign to this task before February 16, 1988.



B.J. Youngblood, Chief
Operations Branch

Enclosure:
As stated

cc: R. Browning
J. Kennedy
J. Linehan

PLAN FOR OBSERVATION OF
DOE/NNWSI QA AUDITS OF MATERIALS
CHARACTERIZATION CENTER, FENNIX AND SCISSION,
HOLMES AND NARVER

1.0 OBJECTIVES

1. Evaluate the effectiveness of the DOE QA audits, including both QA and technical considerations. The DOE audits which will be observed are:
 - (a) Material Characterization Center, Battelle Pacific Northwest Laboratories (waste package materials testing), Richland Washington, February 23-26, 1988.
 - (b) Fennix and Scission (A-E for subsurface facility construction and testing), Tulsa, Oklahoma and Las Vegas, Nevada, February 22-26, 1988
 - (c) Holmes and Narver (A-E for surface facilities construction), Las Vegas, Nevada, March 28 - April 1, 1988.
2. Provide DOE with concerns observed during the audits and make recommendations for improvements.
3. Obtain understanding of DOE's audit program and the DOE contractors QA and technical program being audited.

2. APPROACH AND ACTIVITIES

The three observations of DOE audits identified above will be conducted as a combined QA and technical observation using this plan and the enclosed NRC procedures as guidance.

Preparations for these audit observations by the QA observers should follow the enclosed draft procedures for observing DOE QA audits and would include (1) audit training (if not already taken); (2) obtaining audit background by reading available documents such as DOE's audit notification letters, audit plans and checklist, QA Plan for each organization being audited, and CDSCP information in 8.6 describing the organizations responsibilities; and (3) preparing specific QA related questions to guide the observation audit based on Section 5.0 of the enclosed procedure. Preparations for the audit observation by the technical observers would include (1) obtaining an overview briefing on the audit process in general and NRC observation procedures, (2) reading the enclosed NRC observation procedure and QA questions developed for each audit observation, (3) obtaining background on the technical areas to be covered by DOE audit by

reading the CDSCP information in 8.6 describing the organizations responsibilities and technical work and discussing the scope of the audit with the NRC QA observer, and (4) preparing specific questions to guide the technical part of the observation based on Section 5.0 of the enclosed procedure.

Followup to each audit observation will include (1) a briefing to management summarizing preliminary concerns and recommendations, and (2) preparing a report including concerns and recommendations (open items) which will be transmitted by letter to DOE.

3.0 ORGANIZATION AND RESPONSIBILITIES

Project Manager: Coordinates preparations and followup; prepares letter transmitting observation report/open items to DOE.

QA observer: Conducts QA part of observation activities following enclosed procedures for observers in section 3.0.

Technical observer: Provides technical support to QA observer following specific questions developed for the technical observation. In general the technical observer should focus on (1) use and effectiveness of DOE audit team members (both technical and/or QA) in evaluating the technical quality of the work in the audited organization, (2) attention in audit to parts of the program of major technical significance to repository performance. This audit observation is not an NRC technical review of the NNWSI program area.

Management: See section 3.0 in enclosed procedure. In addition respective section leaders should review the observation questions and portions of the observation report/open items prepared by their staff.

4.0 SCHEDULE

The schedule for each DOE audit as follows:

Materials Characterization Center: February 23 - 26, 1988

Fennix and Scission: February 22 - 26, 1988

Holmes and Narver: March 28 - April 1, 1988

Preparations should be conducted prior to the audit date and the followup letter to DOE should be completed within 2-4 weeks following the audit.

5.0 RESOURCE ESTIMATES AND PPSAS/TAC NOS.

General Resources estimates for each observation are as follows:

QA observer:

Preparation - 5 staff days

Observe audit and travel - 5 staff days

Followup - 3 staff days

Technical observer:

Preparation - 2 staff days

Observe audit and travel - 5 staff days

Followup - 1 staff day

PPSAS and TAC numbers are as follows:

PPSAS	TAC	TITLE
411521		Conduct Audits of Repository Program - Tuff
	L60026	Materials Characterization Center Audit Observation
	L60027	Fennix and Scisson Audit Observation
	L60028	Holmes and Narver Audit Observation

6.0 PRODUCTS

1. Observation questions
2. Letter report to DOE

A report will be prepared for each observation and transmitted by letter to DOE. The report should be prepared following Section 7.0 of the enclosed procedure. Concerns and recommendations prepared will be considered open items that will be tracked by the NRC open item tracking system.

TRANS .

- 1 -

TO: Those on Enclosed Distribution

FROM: B.J. Youngblood, Chief

SUBJECT: NRC's DRAFT QA PROCEDURE FOR OBSERVING DOE HIGH-LEVEL WASTE REPOSITORY
PROGRAM QA AUDITS

Enclosed for your information is a procedure prepared by the staff for observing DOE QA audits of the repository program. Observing DOE audits has been and will continue to be an integral part of NRC's overall review of DOE's geologic repository QA program. This procedure has been prepared to create a common baseline by which different NRC staff members can observe DOE's QA program. This procedure is intended to standardize the process for observations and eliminate or reduce subjective judgements by observers. Revisions are expected to be made as experience is gained with its use.

If you have any questions or need further clarification, please contact Alan Duncan of my staff at (301) 427-4685.

B.J. Youngblood, Chief
Operations Branch
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure:
As stated

QUALITY ASSURANCE PROCEDURE FOR
AUDITING DOE HIGH LEVEL WASTE
REPOSITORY PROGRAM QA AUDITS

1.0 PURPOSE

This guidance describes the HLW Operations Branch QA Section methodology for auditing quality assurance (QA) audits performed by the Department of Energy (DOE) of their contractors and subcontractors. The DOE audits may be performed on the DOE, DOE contractors and subcontractors, or any other participating organization. This may include contractors auditing other contractors.

The objective of the QA audit observation program is to assess the quality of DOE's QA audit program for the geologic repository program. Where necessary, recommendations for improving the DOE audit program will be made by the staff. Audit observations by the staff will enable them to give guidance to DOE on QA programs that are being developed and should help to provide confidence that DOE is meeting NRC's QA program requirements.

2.0 OBJECTIVE

The objective of this procedure is to provide guidance on the following areas:

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

3.0 RESPONSIBILITIES

NMSS Management - The appropriate NMSS management has the following responsibilities:

- (a) Preparation of an audit schedule. (Branch Chief)
- (b) Selection of one or more observer(s). (Section Leader)
- (c) Evaluating the training needs of the observers. (Section Leader)
- (d) Assuring that the observers are adequately prepared. (Section Leader)
- (e) Transmitting the final observation report to DOE. (Branch Chief)

Observers - The observers have the following responsibilities:

- (a) Notification of the DOE audit team leader.
- (b) Reviewing all pertinent background documents including audit plan, audit checklist, and QA Plan. (Within constraints of lead time provided by audit team leader)

PROCEDURE FOR QA AUDIT

- (c) Preparation of audit report.
- (d) Presentation of observations to auditors.

4.0 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, data collection activities important to safety or waste isolation).
- (b) The time since the last audit (NRC, DOE, WMPO, etc).
- (c) The results of previous audits or observations.
- (d) The identification of potential problems by the onsite representatives or other NRC staff.
- (e) Availability of qualified observers.
- (f) OGR Consolidated Audit Schedule.

5.0 AREAS TO BE OBSERVED

The following areas should be addressed before or during the audit to the extent practicable:

5.1 Qualification of the auditors

- (a) Nuclear licensing experience (if any)
- (b) Nuclear QA experience (if any)
- (c) Years of experience
- (d) Communication skills
- (e) Training in auditing techniques
- (f) Technical expertise

5.2 Audit team preparation

- (a) Content of audit plan and checklist
- (b) Knowledge of audited organization
- (c) Knowledge of audited organization procedures, policies, standards, etc. (b and c can only be evaluated by observing the auditors during the audit and interviewing the auditors)

5.3 Selection of areas to be audited

- (a) Technical versus programmatic based on subject matter
- (b) Known problem areas including followup from previous audits

5.4 Conduct of entrance/exit interviews

- (a) Was the scope of the audit clearly discussed?
- (b) Are the audit results clearly communicated to the auditee?
- (c) Did the auditor obtain commitments from the audited organizations to correct noted discrepancies.

PROCEDURE FOR QA AUDIT

5.5 Coverage of the audit

- (a) If applicable, have all 18 criteria been covered?
- (b) What is the purpose or objective of the audit?
- (c) Were the auditors knowledgeable about the regulations and standards they were auditing to?
- (d) What was the nature of the findings (i.e., significant, trivial, etc.)?
- (e) Did the auditor reach a conclusion on a solid foundation of facts?
- (f) Did the auditor research any findings or deficiencies to attempt to determine the root cause?
- (g) Is the audit plan/checklist adequate?

5.6 Examination of technical products - extent and depth of review.

5.7 Involvement of audit team members, use of technical team members.

- (a) Are the technical specialists knowledgeable in the areas being audited (i.e., geochemists for geochemistry)?

5.8 Audit team coordination

- (a) Does the technical specialist complement the audit team?
- (b) Does the lead auditor take charge and run the audit?
- (c) Does the audit report reflect what was discussed by the audit team?
- (d) Were daily or appropriate frequency of caucuses held?

6.0 QUALIFICATIONS OF THE OBSERVERS

Personnel selected for observations shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. The observers should be selected based on the following qualifications: auditing and technical experience, education, auditor training, communication skills, and knowledge of QA, technical, and regulatory requirements. The audit observers will be selected by the High-Level Waste Operations Branch QA Section Leader. When technical specialists are utilized, the selection will be coordinated with the Technical Review Branch. All QA section observers shall meet the requirements of ASME/ANSI NQA-1 for auditor qualifications. Technical observers may also be utilized and shall be selected based on their education and experience in the technical area being audited. If they do not meet the requirements above for QA observers they will not be expected to comment on the QA aspects of the audit.

7.0 REPORTING REQUIREMENTS

A report shall be written upon completion of the audit and will be sent to the Director of Siting, Licensing, and Quality Assurance Division, Office of Civilian Radioactive Waste Management, Department of Energy. The report shall address each area covered in Section 5.0 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.

PROCEDURE FOR QA AUDIT

The following is a sample format for the report:

- 7.1 Purpose of audit - state the objective of the audit and observations of the audit.
- 7.2 Summary
 - (a) Areas audited - brief listing of general areas that were audited, date of audit and agenda
 - (b) Observations - brief summary of general observations
- 7.3 Scope of audit
- 7.4 Observations/conclusions, effectiveness of audit with supporting facts.
- 7.5 Auditors - list of auditors, observers, titles, and affiliations

All concerns raised will be tracked and followed up.

8.0 PROTOCOL DURING AUDIT

Observers should coordinate with the 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 from the audited organization.

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 auditee's QA program at the auditor caucus prior to the exit meeting. Observer concerns about the conduct of the audit should be addressed only to the audit team. The audit team should be given the opportunity to respond to staff concerns. The staff should consider any new information provided to determine if concerns are still valid. Efforts should be made to reach agreement 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.

PROCEDURE FOR QA AUDIT

9.0 REFERENCES

ASME/ANSI NQA-1-1986

10 CFR Part 50 Appendix B

DOE Procedure on Observer Protocol (July 19, 1987)

OGR Consolidated Audit Schedule