



Department of Energy

Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518

WBS #1.2.9.3
"QA"

SEP 06 1989

Robert F. Pritchett
Technical Project Officer for Yucca Mountain Project
Reynolds Electrical &
Engineering Co., Inc.
P.O. Box 98521
Las Vegas, NV 89193-8521

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA)
AUDIT 89-5 OF REYNOLDS ELECTRICAL & ENGINEERING CO., INC. (REECo) SUPPORT
OF THE YUCCA MOUNTAIN PROJECT (NN1-1989- 3416)

Please be advised that a team from the Project Office will conduct a QA audit of the REECo Quality Assurance Program Plan and quality-related activities starting on September 25, 1989. Please arrange facilities for a pre-audit conference for appropriate personnel at your Las Vegas, Nevada facility beginning at 10 a.m. on Monday, September 25, 1989. The post-audit conference is tentatively scheduled for 10 a.m. on Friday, September 29, 1989.

The audit will focus on the following areas:

QA Program Elements

- 1.0 Organization
- 2.0 QA Program
- 4.0 Procurement Document Control
- 5.0 Instructions, Procedures, and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Items
- 9.0 Control of Processes
- 10.0 Inspection
- 11.0 Test Control
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Shipping, and Storage
- 14.0 Inspection, Test, and Operating Status
- 15.0 Control of Non-Conforming Items
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits

8909110365 890906
PDR WASTE PDC
WM-11

FULL TEXT ASCII SCAN

Wm-11
102.7
N/A03

SEP 06 1989

Robert F. Pritchett

-2-

The audit team will consist of:

William H. Camp, Audit Team Leader/Lead Auditor, Science Applications
International Corporation (SAIC), Las Vegas, NV
Stephen P. Hans, Auditor, SAIC, Las Vegas, NV
Frederick J. Ruth, Auditor, SAIC, Las Vegas, NV
Frank J. Kratzinger, Auditor, SAIC, Las Vegas, NV
Amelia I. Arceo, Auditor, SAIC, Las Vegas, NV
Neil D. Cox, Auditor, SAIC, Las Vegas, NV
Mario R. Diaz, Auditor, U.S. Department of Energy/Yucca Mountain Project,
Las Vegas, NV
Catherine E. Hampton, Auditor-in-Training, U.S. Department of Energy/
Yucca Mountain Project, Las Vegas, NV

Observers from the State of Nevada, U.S. Nuclear Regulatory Commission,
U.S. Department of Energy/Headquarters, or other interested parties may
accompany the audit team.

If you have any questions, please contact James Blaylock of my staff at
(702) 794-7913, or Dale Hedges of SAIC at (702) 794-7239.

James Blaylock for
Edwin L. Wilmot, Acting Director
Quality Assurance Division
Yucca Mountain Project Office

YMP:JB-5725

Enclosure:
Audit Plan 89-5

SEP 06 1989

Robert F. Pritchett

-3-

cc w/encl:

Ralph Stein, HQ (RW-30) FORS
Dwight Shelor, HQ (RW-3) FORS
J. W. Gilray, NRC, Las Vegas, NV
J. E. Kennedy, NRC, Washington, DC 
S. W. Zimmerman, NWPO, Carson City, NV
M. A. Fox, REECo, Las Vegas, NV
R. J. Bahorich, SAIC, Las Vegas, NV
G. P. Fehr, SAIC, Las Vegas, NV, 517/T-12
W. H. Camp, SAIC, Las Vegas, NV, 517/T-06
A. I. Arceo, SAIC, Las Vegas, NV, 517/T-06
N. D. Cox, SAIC, Las Vegas, NV, 517/T-06
S. P. Hans, SAIC, Las Vegas, NV, 517/T-06
F. J. Ruth, SAIC, Las Vegas, NV, 517/T-06
F. J. Kratzinger, SAIC, Las Vegas, NV, 517/T-06
L. G. Scherr, SAIC, Las Vegas, NV, 517/T-06
J. J. Brogan, SAIC, Las Vegas, NV, 517/T-12
T. W. Noland, W, Las Vegas, NV, 517/T-06

YUCCA MOUNTAIN PROJECT QUALITY ASSURANCE AUDIT PLAN

AUDIT 89-5

SEPTEMBER 25 - 29, 1989

1.0 PURPOSE AND SCOPE

The purpose of this audit is to evaluate the Reynolds Electrical & Engineering Co., Inc. (REECo) Quality Assurance Program Plan (QAPP), and to verify any implementation of the Quality Assurance program requirements as they relate to the Yucca Mountain Project.

The scope of the audit will be to verify that the REECo Quality Assurance (QA) program meets the requirements of NNWSI/QAP-88-9, Revision 2, and project administrative procedures, and to verify the adequacy of implementation of the QA program. In addition, the Yucca Mountain Project Office is attempting to consolidate the number of calibration vendors who currently serve the project participants. REECo has been requested to provide such services for mechanical types of calibrations within their capabilities. These calibration services are to be performed in accordance with the Quality Assurance requirements contained within the project Quality Assurance Plan (QAP), NNWSI/88-9. The Project Office will attempt to verify that the REECo calibration program does meet the QA requirements of the QAP. Discrepancies identified during the previous audits/surveillances that have not been closed will be added to the scope of the audit to determine whether REECo has taken effective corrective actions.

2.0 ORGANIZATION TO BE AUDITED

Reynolds Electrical & Engineering Co., Inc.

3.0 AUDIT SCHEDULE

Pre-Audit Team/Observer Meeting	8:00 a.m., September 25, 1989, Las Vegas, NV
Pre-Audit Conference	10:00 a.m., September 25, 1989, Las Vegas, NV
Audit Activities	12:30 p.m. - 4:00 p.m., September 25, 1989, Las Vegas/ Mercury, NV
Audit Activities	8:00 a.m. - 4:00 p.m., September 26 - September 27, 1989, Las Vegas/Mercury, NV

3.0 AUDIT SCHEDULE (CONTINUED)

Audit Activities	8:00 a.m. - 11:00 a.m., September 28, 1989, Las Vegas/ Mercury, NV
Post-Audit Conference	10:00 a.m., September 29, 1989, Las Vegas, NV

4.0 REQUIREMENTS TO BE AUDITED AND APPLICABLE REFERENCES

NNWSI/QAP-88-9, Revision 2	
NNWSI Administrative Procedures 7	REECO QAPP, 568-DOC-115, Revision 7
REECO Quality Procedures	

The conduct of the audit will be guided by the documents listed below:

- o QAP-18-01, "Audit System for the Waste Management Project Office,"
Revision 3
- o QMP-16-03, "Standard Deficiency Reporting System," Revision 1
- o Quality Assurance Audit Task Organization
- o Audit Observer Inquiry
- o Policy for Participation of State, Tribal, and NRC Representatives as
Observers on Department of Energy (DOE) Audits, dtd. July 14, 1987
- o HLW Division Procedure for Conducting Observation Audits of DOE/HLWR
Program Quality Assurance Audits
- o Headquarters Observation of Project Office Quality Assurance Audits

5.0 ACTIVITIES TO BE AUDITED

The activities to be audited during the audit include the following:

Programmatic Elements:

All program elements identified in the REECO QAPP will be audited. The assessment of Section III will be confined to:

- o Change Control
- o Technical Assessment Review

Technical Areas:

No technical work has been identified. Interviews will be performed with technical personnel when warranted.

6.0 AUDIT TEAM MEMBERS

William H. Camp, Audit Team Leader/Lead Auditor, Science Applications
International Corporation (SAIC), Las Vegas, NV
Stephen P. Hans, Auditor, SAIC, Las Vegas, NV
Frederick J. Ruth, Auditor, SAIC, Las Vegas, NV
Frank J. Kratzinger, Auditor, SAIC, Las Vegas, NV
Neil D. Cox, Auditor, SAIC, Las Vegas, NV
Amelia I. Arceo, Auditor, SAIC, Las Vegas, NV
Mario R. Diaz, Auditor, U.S. Department of Energy/Yucca Mountain Project,
Las Vegas, NV
Catherine E. Hampton, Auditor-in-Training, U.S. Department of Energy/Yucca
Mountain Project, Las Vegas, NV

7.0 AUDIT CHECKLISTS, ANNEXES, AND ATTACHMENTS

Annex A - DOE Procedure on Protocol (July 1987)
Annex B - NRC Draft QA Procedure for Observing DOE/OGR/HLWR
Program Audits
Annex C - DOE/HQ/OGR Observation of YMP QA Audits (Draft)
Attachment 1 - YMP Quality Assurance Audit Task Organization
Attachment 2 - YMP Audit Observer Inquiry
Attachment 3 - Objectives for the Technical Phase of the Quality
Assurance Audit (as amended)

Prepared By: W. H. Camp
W. H. Camp, Lead Auditor

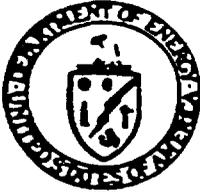
Date: 8-21-89

Prepared By: Dale Hedges
Dale Hedges, Verification
Department Manager

Date: 8-30-89

Prepared By: _____
Edwin L. Wilmot, Acting Director,
Quality Assurance Division,
Yucca Mountain Project Office

Date: _____



Department of Energy
Washington, DC 20585

JUL 14 1987

NNI.880913.0018

State and Tribal Representatives (List Attached)

At the last Quality Assurance Coordinating Group meeting DOE, State, Tribal and NRC representatives discussed the policy that should be used with regard to the participation of State, Tribal and NRC representatives on DOE audits. It appears that a general consensus was reached among the meeting participants on a procedure for participating in the DOE QA auditing process. Details are in the attached draft policy statement.

We are pleased to invite your review of the enclosed draft policy statement and would appreciate knowing of any remaining concerns you may have.

Sincerely,

Stephen H. Kale
Associate Director for
Geologic Repositories, Office of
Civilian Radioactive Waste Management

Enclosure

SAIC/T&MSS

MAY 27 1988

CCF RECEIVED



Celebrating the U.S. Constitution Bicentennial — 1787-1987

ENCLOSURE 2

POLICY FOR PARTICIPATION OF STATE, TRIBAL AND NRC REPRESENTATIVES
AS OBSERVERS ON DOE AUDITS

1. The QA Manager of OGR will furnish to the State, Tribal and NRC representatives a schedule of audits planned by DOE-HQ (OGR) and by the DOE project offices. Because of frequent changes to the schedule, the schedule will be updated at approximately monthly intervals and copies furnished to the State, Tribal and NRC representatives.
2. OGR and the project offices will make every effort to send an audit notification at least 30 days prior to each QA audit. The audit notification will, whenever possible, include an audit plan and a description of the scope of the audit. Copies of OGR audit notifications will be furnished to NRC and to all State and Tribal representatives; copies of project audit notifications will be furnished to NRC and to the affected State and Tribal representatives.
3. State, Tribal and NRC representatives may request to participate in any audit. Requests need not be in writing. Telephone contacts to request participation are:

OGR - Carl Newton - (202) 586-5059
BWIP - Pierre Saget - (509) 942-7250
WMPO - Jim Blaylock - (702) 295-1125
SRPO - Jerry Reese - (806) 374-2320

State, Tribal and NRC representatives who wish to participate will make every effort to contact the DOE representative at least two weeks prior to the audit so that arrangements for their participation can be made.

4. When a request to participate is received by DOE from a State, Tribal or NRC representative, it is DOE's policy to make every reasonable effort to honor the request. When small audit teams are used by DOE, and requests for many observers are received, it may be necessary for DOE to limit participation (but in no event to less than one observer per organizational entity, i.e., one from the affected State, one from each affected Tribe, and one from NRC), so that the auditing process will not be hampered by an excessive number of observers. In instances where the limit of one observer per affected party will still result in an excessive observer to auditor ratio, DOE will contact the affected parties and seek voluntary reductions. It is expected the parties will make every reasonable attempt to accommodate DOE's requests.

5. Observers on DOE audits will be under the authority of the audit team leader (or sub-team leader if the team is divided during the audit). Observers are encouraged to participate fully by furnishing their questions, observations and recommendations to the audit team leader (or sub-team leader). Direct interactions between observers and auditee personnel will generally be discouraged and it may be necessary to exempt observers from certain portions of an audit (such as procurement actions that are in-process, classified material, or sensitive personnel records). The DOE policy is that every effort is to be made to limit such exemptions and to include observers as full participants in all aspects of the audit possible.
6. The State, Tribal and NRC representatives who will be participating in a QA audit are to be furnished a copy of the audit checklist as soon as it is available. A target date of ten days prior to the audit will be attempted. The State, Tribal and NRC representatives who receive audit checklists are, of course, to keep their contents confidential and to not, under any circumstances, divulge its contents to representatives of the organization to be audited.
7. DOE encourages observers to receive formal QA auditor training and QA lead auditor training. Every effort to accommodate State, Tribal and NRC representatives in DOE sponsored training courses is to be made. There are, however, no DOE requirements for observers to have had such training.
8. DOE invites observers to express concerns and recommendations on the auditee's QA program to the audit team leader for his consideration in preparing the audit report. DOE also invites observations on the conduct of the audit and solicits recommendations on how we might improve our audit process. Observers will be afforded an opportunity to speak at exit meetings following each audit. Regular opportunities are to be provided to observers during the course of the audit and at the quarterly QACG meeting for State, Tribal and NRC representatives to discuss their comments and recommendations.

**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.

OBSERVATION AUDIT No. _____

REQUIREMENT	INVESTIGATING GUIDELINE	EVIDENCE EXAMINED	RESULTS
MWWSI/88/9 XVIII Section 1.1	<u>I. Selection of Areas to be Audited</u>		
	(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. 185-1 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. 25-3 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. 185-1 Section 4	(c) Were technical checklists utilized during the audit?		
NQA-1-1983 Supp. 25-3 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
	<p>(e) In the examination of technical products,</p> <ul style="list-style-type: none"> - 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) <p>Note: WFO classifies major activities for participating organizations. Specific activities, however, classified by the audited organization should be reviewed.</p> <ul style="list-style-type: none"> - were nonconformances appropriately dispositioned 		
	<p>(f) Were software QA controls audited for conformance to appropriate criteria? What were the criteria?</p>		
	<p>IV. <u>Conduct of the Audit</u></p>		
	<p>(a) Were the auditors persistent and thorough in their investigations?</p>		
	<p>(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)?</p>		

NQA-1-1983
 Supp. 185-1
 Section 4

QMP-16-03
 Section 5.2.1.2

Signature/Date _____

OBSERVATION AUDIT No. _____

REQUIREMENT	INVESTIGATING GUIDELINE	EVIDENCE EXAMINED	RESULTS
NWWSI/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 10.8	(e) Did the auditor verify evidence for root cause analysis before closing out past findings?		
NQA-1-1983 Supp. 165-1 Section 4	(f) Were conditions requiring prompt corrective action reported immediately to management of the audited organization?		
NQA-1-1983 Supp. 165-1 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 areas 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 or 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
10 CFR 50 App. B II NQA-1-1983 Supp. 25-3	<p>V. <u>Qualification of the Auditors</u></p> <p>(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</p>		
NQA-1-1983 Supp. 105-1 Section 3.1	<p>VI. <u>Audit Team Preparation</u></p> <p>(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</p> <p>(b) Were checklist questions, which can be answered during a desk audit, completed prior to the conduct of the audit?</p>		
NQA-1-1983 Supp. 25-1 Section 2.1	<p>(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</p>		
NQA-1-1983 Supp. 25-3 Section 2.1	<p>(d) Can "technical" checklist questions be answered by "non-technical" personnel who lack expertise in the given subject matter?</p>		
QMP-10-01 Section 5.3	<p>(e) Did the audit team attend the presudit conference and is this documented?</p> <p>(f) Was the applicable auditing procedure properly used by the audit team?</p>		

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?		
NHW51/88-9 Section XVIII, 1.4	(b) Were the audit results clearly communicated to the audited organization?		
NHW51/88-9 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. 185-1 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. 185-1 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. 185-1
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. 185-1
Section 3.2**

(c) Did audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective?

Signature/Date _____

OBSERVATION OF WMPO QUALITY ASSURANCE AUDITS

Audit No. _____
Audited Organization and Location _____
Date of Audit _____
Observer _____

General Observation Areas

1. Was the content of the Audit Plan and Checklist adequate?

2. Did the audit team have adequate knowledge of the audited organization (i.e., scope of work, procedures, policies, etc.)?

3. a) If appropriate, were technical areas as well as QA programmatic areas audited? b) Was the extent and depth of review of the technical areas adequate? c) Were the technical specialists knowledgeable in the areas being audited?

4. Were known problem areas identified from previous audits investigated?

5. Was the scope of the audit clearly presented to the audited organization?

6. Were the audit results clearly communicated to the audited organization?

7. Did the auditor obtain commitments from the audited organization to correct noted discrepancies?

8. If applicable, were all 18 criteria of 10CFR50, Appendix B covered?

9. Was the purpose or objective of the audit clearly presented?
10. Were the auditors knowledgeable about the documents they were auditing to?
11. What was the nature of the findings (i.e., significant, trivial, etc.)?
12. Were conclusions reached on a solid foundation of facts with objective evidence to back them up?
13. Did the Lead Auditor take charge and run the audit?
14. Were daily or appropriately frequent caucuses held?

Requirements of WMPO QMP-18: Revision 1

1. Sect. 3.4
...
Is the audit team leader certified to develop and perform an audit, report audit findings, and to follow-up and evaluate corrective actions?
2. Sect. 4.1.6
Are conditions adverse to quality evaluated and reported on Standard Deficiency Reports (SDRs) per QMP-16-03?
3. Sect. 5.2.2
Are the requirements of this section met?
4. Sect. 5.3.1
Was a pre-audit conference held per this section?
5. Sect. 5.4.1
Were pre-prepared audit checklists used in the conduct of the audit?
6. Sect. 5.4.1
Is objective evidence examined and documented for compliance with the checklist requirements?
7. Sect. 5.4.1.1
Is each "not applicable" or "not audited" entry on the checklist explained?
8. Sect. 5.4.1.2
Is reference to specific deficiencies noted on the checklist by documenting the sequential number of the SDR rough draft (or number of the observation)?

ATTACHMENT 1

YMPO QUALITY ASSURANCE AUDIT TASK ORGANIZATION

YMPO

PROJECT MANAGER

YMPO

PROJECT QUALITY MANAGER

AUDIT MANAGER

AUDIT TEAM LEADER/LEAD AUDITOR (1)

AUDITORS (2)

- (1)
 - o Responsible for the overall planning, conduct, and reporting of audits.
 - o Reports to manager of audits on administrative and operational matters.
 - o Is in charge of the audit team from activation to deactivation.
 - o Directs the activities of assigned auditors in accordance with the audit plan and associated checklists.
- (2)
 - o Develops programmatic checklists to NNWSI program requirements.
 - o Performs the programmatic phase of the audit to approved checklists.
 - o Initiates observations, recommendations, and standard deficiency reports (SDRs) as required.
 - o Authenticates SDRs co-authored by technical specialists.

**YUCCA MOUNTAIN PROJECT
AUDIT OBSERVER INQUIRY**

N-QA-084
4/89

Audit No. _____

Log No. _____

Name _____ Organization _____

YMP Requirement Reference _____

Question/Concern _____

Response _____

Observer's Acknowledgement

Cleared for Submittal to YMP Participant

Lead Auditor / Lead Technical Specialist

Incorporated in YMP Audit Checklist...Ref

Audit Team Leader

ATTACHMENT 3

OBJECTIVES FOR THE TECHNICAL PHASE OF THE QUALITY ASSURANCE AUDIT

In order to provide a unified approach to the conduct of the technical phase of a Quality Assurance audit, the following questions are provided. The intention is to have these questions serve as the basis for the questions developed in the technical checklist (XX-2).

- o Were there sufficient technical procedures for the activity under review?
- o Were the procedures in place technically adequate for the intended application?
- o Did the prime or critical methodologies employed consider existing/accepted approaches and technologies?
- o Where controversial methodologies were employed was an adequate peer review performed?
- o Was the background/credentials of those individuals engaged in the task activity appropriate to the desired/intended outcome of the activity?
- o Was the level of effort/rigor employed commensurate with the stated objectives of the task/activity?
- o Where concerns exist as to the efficacy of an activity is a further technical review indicated?
- o Where the interim analysis or interpretation of data supports reported results is the analysis/interpretation appropriate for the proposed activity/task?
- o Were the design calculations, design methods, and design analyses employed for an activity appropriate to the maturity of the design?