

**YUCCA MOUNTAIN PROJECT OFFICE**

**QUALITY ASSURANCE AUDIT PLAN**

**AUDIT 90-08**

**NOVEMBER 13 THROUGH NOVEMBER 19, 1990**

**1.0 PURPOSE AND SCOPE**

The purpose of this audit is to evaluate the Science Applications International Corporation (SAIC) QA Program as it applies to the Yucca Mountain Project QA Program.

The scope of the audit will be to verify adequacy of the SAIC QA Program and the effectiveness of implementation. In addition, implementation of corrective actions(s) as provided in the response(s) to open Project Office Standard Deficiency Reports (SDRs), as applicable, will be evaluated and if found satisfactory, will be closed.

**2.0 ORGANIZATION TO BE AUDITED**

Science Applications International Corporation, Las Vegas, Nevada

**3.0 AUDIT SCHEDULE**

Pre-Audit Team/Observer Meeting	8:15 a.m., November 13, 1990, Las Vegas, Nevada
Pre-Audit Conference	9:00 a.m., November 13, 1990, Las Vegas, Nevada
Audit Activities	10:00 a.m. to 4:00 p.m., November 13, 1990, Las Vegas, Nevada
	8:00 a.m. to 4:00 p.m., November 14 to 16, 1990, Las Vegas, Nevada
	8:00 a.m. to 3:30 p.m., November 15, 1990, Nevada Test Site, Mercury, Nevada
Post-Audit Conference	3:00 p.m., November 19, 1990, Las Vegas, Nevada

#### 4.0 REQUIREMENTS TO BE AUDITED AND APPLICABLE REFERENCES

Technical and Management Support Services (T&MSS) Quality Assurance Program Description (QAPD), Revision 3.

T&MSS Standard Practices (SPs), Operation Procedures (OPs), and Work Instructions (WIs) as applicable to quality related activities associated with the Yucca Mountain Project.

The conduct of the audit will be accomplished in accordance with the Office of Civilian Radioactive Waste Management (OCRWM) and Department of Energy (DOE) Project Office documents listed below:

- o QAAP 18.2, "Audit Program," Revision 1
- o QAAP 16.1, "Corrective Action Requests," Revision 1
- o QA Task Organization
- o Audit Observer Inquiry
- o Policy for Participation of State, Tribal, and U.S. Nuclear Regulatory Commission (NRC) Representative Observers on DOE Audits, dated July 14, 1987
- o High Level Waste (HLW) Division Procedure for Conducting Observation DOE Audits of HLW Repository (HLWR) Program QA Audits

#### 5.0 ACTIVITIES TO BE AUDITED

The activities to be audited during the audit include:

##### Programmatic Elements

The following elements will be reviewed and evaluated:

<u>Criteria</u>	<u>Subject</u>
1	Organization
2	Quality Assurance Program
4	Procurement

<u>Criteria</u>	<u>Subject (Cont'd)</u>
5	Instructions, Procedures, Plans and Drawings
6	Document Control
7	Control of Purchased Items and Services
8	Identification and Control of Items, Samples, and Data
10	Inspection
12	Control of Measuring and Test Equipment
13	Handling, Storage, and Shipping
15	Control of Nonconforming
16	Corrective Action
17	Quality Assurance Records
18	Audits
19	Software Quality Assurance
20	Scientific Investigation Control

This audit will not address Criteria 3, 9, 11, and 14.

#### Technical Activities

Technical Specialists will review and evaluate the technical activities related to the following:

- o Meteorological Monitoring Plan, Revision 1, June 5, 1989
- o Radiological Monitoring Plan, Revision 0, May 25, 1988

#### 6.0 AUDIT TEAM MEMBERS

Richard L. Maudlin	- MACTEC, Las Vegas, Nevada, Audit Team Leader
A. Edward Cocoros	- MACTEC, Las Vegas, Nevada, Auditor
Kerby L. Tyger	- MACTEC, Las Vegas, Nevada, Auditor
Charles C. Warren	- MACTEC, Las Vegas, Nevada, Auditor
Robert B. Constable	- DOE, Las Vegas, Nevada, Auditor
Mario R. Diaz	- DOE, Las Vegas, Nevada, Auditor
Catherine E. Hampton	- DOE, Las Vegas, Nevada, Auditor
Albert C. Williams	- DOE, Las Vegas, Nevada, Auditor
Thomas Rogers	- CER Corporation, Arlington, Virginia Auditor-In-Training
Sam Smith	- Weston, Arlington, Virginia, Auditor-In- Training
Byron T. Kesner	- MACTEC, Albuquerque, New Mexico, Technical Specialist
Diane Harrison-Giesler	- DOE, Las Vegas, Nevada, Technical Specialist

7.0 AUDIT CHECKLISTS, ANNEXES, AND ATTACHMENTS

90-08-01 QA Programmatic Checklist

90-08-02 Technical Checklist

Annex A DOE Procedure on Protocol (July 1987)

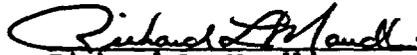
Annex B NRC Draft QA Procedure for Observing DOE/OGR HLWR

Program Audits

Attachment 1 - YMP Quality Assurance Task Organization

Attachment 2 - YMP Audit Observer Inquiry

Prepared by:

  
Richard L. Maudlin  
Audit Team Leader

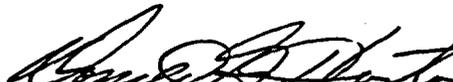
Date: 10-12-90

Approved by:

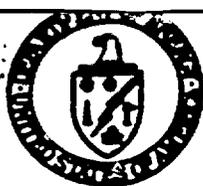
  
James Blaylock, Branch Chief  
Quality Assurance Division  
Yucca Mountain Project Office

Date: 10/12/90

Approved by:

  
Donald G. Horton, Director  
Office of Quality Assurance

Date: 10/12/90



Department of Energy  
Washington, DC 20585

JUL 14 1987

SAIC/T&MSS

JUL 20 1987

CCF RECEIVED

NMA.870720.0053

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



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

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 DOI 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 QACC meeting for State, Tribal and NRC representatives to discuss their comments and recommendations.

Requirements of WMPO QMP-18-0' 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)?

## 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 TRS 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 OCRM 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  
OCRAM 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 OF WPMO 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?