
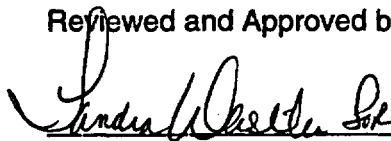


U. S. NUCLEAR REGULATORY COMMISSION  
OBSERVATION AUDIT REPORT OAR-99-06  
OF THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION  
AUDIT M&O-ARC-99-13  
OF THE  
CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM  
MANAGEMENT AND OPERATING CONTRACTOR

 09/27/99  
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## **1.0 INTRODUCTION**

A member of the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management Quality Assurance (QA) staff observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division (YMQAD) performance based audit of the Civilian Radioactive Waste Management System Management and Operating (M&O) Contractor. The audit, ARC-98-13, was conducted on August 16-19, 1999.

The NRC staff objective was to gain confidence that OQA and the M&O are properly implementing the requirements of their QA programs in accordance with OCRWM Quality Assurance Requirements and Description (QARD): DOE/RW-0333P and Title 10 of the Code of Federal Regulations (10CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B). This report addresses the effectiveness of the OQA audit and the adequacy of implementation of QA controls in the audited areas of the M&O QA program.

## **2.0 MANAGEMENT SUMMARY**

The NRC staff has determined that OQA Audit ARC-99-13 was useful and effective. The audit was organized and conducted in a professional manner. Audit team members were independent of the activities they audited. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan.

The audit team identified six deficiencies that were corrected during the audit. Additionally, there were two recommendations resulting from the audit. The NRC staff agrees with the audit team findings and recommendations.

## **3.0 AUDIT PARTICIPANTS**

### **3.1 NRC**

Ted Carter	QA Observer
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### **3.2 Audit Team**

The audit team consisted of the following staff from the Office of Quality Assurance/Quality Assurance Technical Support Services (OQA/QATSS), Las Vegas, Nevada.

Emily Jensen	Audit Team Leader (ATL)
Patrick Auer	Auditor
Linda Galyon	Auditor
David Mitchell	Auditor
Edward Opelski	Auditor

#### **4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION**

This OQA audit of the M&O was conducted in accordance with OCRWM QA Procedure (QAP) 18.2, "Internal Audit Program," QAP 16.1Q, "Performance/Deficiency Reporting" and AP 16.2Q, "Corrective Action and Stop Work." The NRC staff's observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

##### **4.1 Scope of the Audit**

The audit team conducted a compliance audit of the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) at Sandia National Laboratory (SNL). Implementation, adequacy, and determination of effectiveness of SNL's implementation of the QA Program was assessed by the audit team. In addition, review of the status of past OCRWM deficiency documents identified during previous QA audits and surveillances of SNL and CRWMS M&O were included in the scope of this audit to determine the effectiveness of completed corrective actions, as well as the status of any open deficiency documents.

The programmatic elements audited were contained in checklist developed from the latest-available revision of the following documents:

- QARD DOE/RW-0333P
- OCRWM procedures as directly implemented by SNL
- SNL Implementing Documents

The conduct of the audit was guided by the documents listed below:

- QAP 18.2, Internal Audit Program
- AP 16.1Q, Management of Conditions Adverse to Quality
- AP-16.2Q, Corrective Action and Stop Work

Applicable QA Program Elements reviewed during the compliance audit were:

- 1.0 Organization
- 2.0 QA Program
- 4.0 Procurement Document Control
- 5.0 Implementing Procedures
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 12.0 Control of Measuring and Testing Equipment
- 15.0 Nonconformances
- 16.0 Corrective Action
- 17.0 QA Records
- Supplement I Software
- Supplement II Sample Control
- Supplement III Scientific Investigation
- Supplement V Control of the Electronic Management of Data
- Appendix C Mined Geologic Disposal System

The following QA Program Elements were also considered during the development of the audit plan and found not to be applicable, since SNL currently has no activities to which these elements apply:

- 3.0 Design Control
- 8.0 Identification and Control of Items
- 9.0 Control of Special Processes
- 10.0 Inspection
- 11.0 Test Control
- 13.0 Handling, Storage, and Shipping
- 14.0 Inspection, Test, and Operating Status
- 18.0 Audits
- Supplement IV Field Surveying
- Appendix A High-Level Waste Form Production
- Appendix B Storage and Transportation

#### **4.2 Conduct and Timing of the Audit**

The audit was performed in a professional manner and the audit team was well prepared and demonstrated a sound knowledge of the M&O and DOE QA programs. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit. The NRC staff believes the timing of the audit was appropriate for the auditors to evaluate the ongoing activities and implementation of the QA program.

The DOE audit team and NRC observer caucused at the end of each day. Also, meetings of the audit team and SNL management (with the NRC observer present) were held each morning to discuss the current audit status and preliminary findings.

#### **4.3 Examination of QA Programmatic Elements**

Programmatic audit activities were conducted in accordance with the OCRWM QA Audit Plan for Audit M&O-ARC-99-013. The auditors reviewed documents identified in the audit plan and used checklists as a basis for inquiries. In addition, related documentation supporting report conclusions was reviewed to verify data source and status of qualification. Personnel directly responsible for document products or appropriate representatives with sufficient levels of knowledge were interviewed by the auditors. The checklists used were effective and additional inquiries were made beyond specific checklist items, when appropriate. The NRC observer was briefed on audit conduct procedures, including the inquiry process and method for raising concerns. The NRC observer was given ample opportunity to provide comments and ask questions.

The audit team reviewed training, education, and experience records for personnel conducting scientific studies to assure such personnel were in compliance with their individual position descriptions. Objective evidence was provided and reviewed by the auditors, and it was determined that all personnel were appropriately qualified and assigned design tasks commensurate with their qualifications. In addition, training, education, and experience records

for audit team members were also reviewed by the observation team to verify that audit team members had appropriate qualifications and met the requirements of QA Procedure 18.2, "Internal Audit Program".

The NRC observer found that the requirements of QA Procedure 18.2, "Internal Audit Program," were implemented in an effective and satisfactory manner. These planning and implementation activities were accomplished and observed by the NRC observer as follows:

(1) Preparation of distribution of a quality assurance audit plan, M&O-ARC-99-13; (2) Preparation of a performance based audit checklist; (3) Coordination and communications with all team members; (4) Conduct of an introductory pre-audit kickoff meeting with the audit team and observers; (5) Conduct of a kickoff meeting with M&O personnel including high level management; (6) Daily caucus meetings held for the audit team and observer; (7) Daily management status meetings held for M&O management; and (8) Conduct of a post audit meeting with M&O management, audit teams members and NRC observer.

#### **4.4 NRC Staff Findings**

The audit was conducted in a professional manner and the audit team adequately evaluated activities and objective evidence. The ATL was effective in her daily presentation to the SNL management and staff and provided guidance to the audit team. Both the auditors and SNL staff were knowledgeable in their respective disciplines. The checklist was an excellent tool for providing a sound basis from which to conduct the audit.

The NRC observer believed that the SNL audit was thorough and effective. The NRC observer determined that the audit was effective in determining SNL compliance with procedural controls in the areas examined and that the SNL QA program controls are being adequately implemented. The qualifications of the audit team members were satisfactory. The NRC observer agreed with the audit team's findings and the audit team's assessment that, overall, SNL is implementing its QA program satisfactorily.

#### **5.0 Summary of OQA Findings**

The audit team identified six deficiencies that were considered isolated in nature and only requiring remedial action. The six deficiencies were corrected during the audit. Additionally, there were two recommendations resulting from the audit. The NRC staff agrees with the audit team findings and recommendations. As a result of the audit, no Deficiency Reports were issued.

##### **Deficiencies Corrected During the Audit (CDA)**

1. AP-6.1Q, "Controlled Documents," Revision 3, Paragraph 5.1 (b) requires the document control function to log, track, and maintain a list of assigned document identifiers. SNL was utilizing the web pages for Quality Assurance Implementation Procedures (QAIP), Technical Procedures, and other tracked identifiers. This was corrected by the development of a log during the audit.
2. QAIP 12-1, Revision 8, states, in part, "that calibration certificates identify calibration procedure revision number." Primary Standards Lab (PSL) Calibration Certificate for Digital Caliper #13397 did not have a procedure revision number. This was identified and corrected

during the audit by contacting PSL and adding the revision number to the calibration certificate. The procedure had not been revised since the calibration.

3. QAIP 12-1, Revision 8, states, in part, "The PI or designee has performed an acceptance check of the calibration report and the M&TE before use and resolved any abnormalities. The acceptance check will be documented." The Measuring & Test Equipment (M&TE) Coordinator was performing the function by informal assignment. This was corrected during the audit by a Management letter of delegation assigning the coordinator as the designee.
4. QARD 17.2.2B, requires QA records to be identifiable to the items or activities to which they apply. QAIP 6-3 review forms for Drift Scale Technical Data Information Forms (TDIF) did not specify the record being corrected providing appropriate traceability.
5. QAIP 20-2, Revision 2, requires that scientific notebooks included a list of M&TE. Scientific Notebook #UNM-WA-0752 list showed a serial number 11397, Digital Caliper, when the number should have been 13397, as indicated on the Certificate of Calibration. This was corrected during the audit by the list being corrected to reflect the correct serial numbers.
6. AP-SIII.1Q, Revision 0, Paragraph 5.2 a requires that a document identifier be obtained from the Yucca Mountain Site Characterization Project (YMP) Scientific Notebook Register and is placed in a notebook. SNL had 45 days (8/15/99) to transition notebooks from QAIP 20-2. Notebook (formerly 1-WA-0353-T1) did not have YMP scientific notebook number in notebook SN-SCI-008-VI. The number had not been obtained prior to the transition date. This was corrected during the audit by the identifier being denoted in the scientific notebook.

#### Follow-up of Previously Issued Deficiency Documents

*Deficiency Report (DR) SNL-98-D-129.* This DR identified that AP-17.1Q had not been implemented by SNL personnel and that SNL had retained completed records in excess of the one-year temporary storage. The DR was satisfactorily verified and closed by the OQA on February 23, 1999. No other instances of this condition were identified during the audit.

DR SNL-98-D-130. Follow-up on this DR was not required due to the fact that although the DR identified that SNL failed to generate lists of cited references and submit them to the OCRWM Technical Information Center, the requirements for submittal of cited references were removed from AP-17.1Q, per ICN 2, effective October 30, 1998. This DR was satisfactorily verified and closed by the OQA on May 20, 1999.

DR SNL-98-D-131. This DR identified that scientific notebooks did not comply with the requirements of QAIP 20-2. This deficiency was satisfactorily verified and closed by the OQA on April 4, 1999.

DR SNL-98-D-138. This DR identified that the organizational structure as well as training, indoctrination, and qualification of SNL extended staff at UNM did not comply with mandatory requirements of American Society of Testing and Materials C1077. This DR was satisfactorily verified and closed by OQA on December, 27, 1998. No other instances of this condition were

identified, with the exception of a transportation of serial numbers. This was corrected during the audit as CDA #5.

DR SNL-99-D-33. This DR identified that the PSL was in non-compliance with QA requirements. It was verified that corrective actions are currently in process and on target for completion.

Recommendations

The following are recommendations that were presented to CRWMS M&O and SNL management for consideration:

1. It is recommended that AP-3.1Q, "Conduct of Performance Assessment" be canceled. Performance assessment activities are now covered in appropriate PVAR procedures (e.g., AP-2.13Q, AP-2.15Q, AP-3.10Q, AP-3.12Q).
2. It is recommended that SNL personnel who are involved with the initiation and disposition of Nonconformance Reports (NCRs) be retained in the basic concepts of YAP-15.1Q, "Control of Nonconformances", specifically Section 5.1.1, Initiating NCRs.