

U.S. NUCLEAR REGULATORY COMMISSION  
OBSERVATION AUDIT REPORT 93-14  
OF THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION  
AUDIT YMP-93-17  
OF SANDIA NATIONAL LABORATORIES

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## **1.0 INTRODUCTION**

During September 13-17, 1993, members of the quality assurance (QA) staff of the U.S. Nuclear Regulatory Commission Division of High-Level Waste Management observed a U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, Yucca Mountain Quality Assurance Division (YMQAD) audit of the Sandia National Laboratories (SNL). The audit, YMP-93-17, was conducted at the SNL offices in Albuquerque, New Mexico. The audit evaluated the adequacy and effectiveness of the SNL QA program in seven programmatic areas and seven technical areas. A State of Nevada representative was an observer at this audit.

This report addresses the effectiveness of the YMQAD audit and the adequacy and implementation of the QA controls in the audited areas of the SNL QA program.

## **2.0 OBJECTIVES**

The objectives of the audit by YMQAD were to determine whether the SNL QA program and its implementation meet the applicable requirements and commitments of the OCRWM Quality Assurance Requirements and Description document (QARD), the SNL Quality Assurance Program Description (QAPD), and associated implementing procedures.

The NRC staff's objective was to gain confidence that YMQAD and SNL are properly implementing the requirements of their QA programs in accordance with the OCRWM QARD, the SNL QAPD, and Title 10 of the Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

## **3.0 SUMMARY AND CONCLUSIONS**

The NRC staff based its evaluation of the YMQAD audit process and the SNL QA program on direct observations of the auditors; discussions with audit team, SNL and contractor personnel; and reviews of the audit plan, the audit checklists, and other pertinent documents. The NRC staff has determined that YMQAD Audit YMP-93-17 was useful and effective. The audit was organized and conducted in a thorough and professional manner. Audit team members were independent of the activities they audited. The audit team was well qualified in the QA and technical disciplines, and its assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary YMQAD audit team finding that implementation of the SNL QA program is adequate in four of the programmatic areas audited, marginally adequate in the area of Procurement Document Control, and indeterminate in two areas due to lack of implementation. Five preliminary Corrective Action Requests (CARs) were discussed by the YMQAD audit team at the post-audit meeting. Four other potential CARs were acceptably resolved by the SNL organization during the audit. None of the preliminary CARs identified by the YMQAD audit team is significant in terms of the overall SNL QA program.

YMQAD should continue to closely monitor implementation of the SNL QA program to ensure that the deficiencies identified during this audit are corrected in a timely manner and that future QA program implementation is effective. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits at a later date to assess implementation of the SNL QA program.

#### 4.0 AUDIT PARTICIPANTS

##### 4.1 NRC

Kenneth R. Hooks	Observer	
Banad Jagannath	Observer	
Bruce Mabrito	Observer	Center for Nuclear Waste Regulatory Analyses (CNWRA)
Mikko Ahola	Observer	CNWRA

##### 4.2 DOE

Charles C. Warren	Audit Team Leader (ATL)	YMQAD/Quality Assurance Technical Support Services (YMQAD/QATSS)
James Blaylock	Auditor	YMQAD
Mario R. Diaz	Auditor	YMQAD
Richard S. Ladd	Technical Specialist	Management and Operating Contractor
Kenneth T. McFall	Lead Technical Specialist	YMQAD/QATSS
John S. Martin	Auditor	YMQAD/QATSS
John R. Matras	Auditor	YMQAD/QATSS
Forrest D. Peters	Technical Specialist	Technical and Management Support Services
Richard L. Weeks	Auditor	YMQAD/QATSS

##### 4.3 STATE OF NEVADA

Susan Zimmerman	Observer	
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##### 4.4 OTHER

Richard Lark	Observer	DOE/Waste Isolation Pilot Project (WIPP)
Tilak Verma	Observer	WIPP/Advanced Science International

#### 5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This YMQAD audit of SNL was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program" (Revision 5 plus Interim Change Notice 1) and QAAP 16.1, "Corrective Action" (Revision 4).

The NRC observation audit of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

### 5.1 Scope of Audit

This audit was designed to be performance-based to the maximum extent possible. The auditors were directed to focus on work products rather than programmatic requirements.

#### 5.1.1 Programmatic Elements

The audit scope included the seven QA programmatic elements listed below:

- 3.0 Design Control
- 4.0 Procurement Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Materials, Parts, Components, and Samples
- 15.0 Control of Nonconforming Items
- 19.0 Computer Software
- 20.0 Scientific Investigation

#### 5.1.2 Technical Areas

The following technical activities were reviewed by the YMQAD audit team.

<u>Work Breakdown Structure/Activity</u>	<u>Title</u>	<u>Study Plan Number</u>
1.2.3.2.6.2.1/460	Surface Facilities Exploration Program	8.3.1.14.2
1.2.3.2.6.2.2/470	Surface Facilities Laboratory Tests and Material Property Measurements	8.3.1.14.2
1.2.3.2.6.2.3/490	Surface Facilities Field Tests	8.3.1.14.2
1.2.3.2.7.1.1/420	Laboratory Thermal Properties, Develop Procedures and Conduct Tests	8.3.1.15.1.1
1.2.3.2.7.1.2/430	Laboratory Thermal Expansion Testing, Develop Procedures and Conduct Tests	8.3.1.15.1.2
1.2.3.2.7.1.4/451	Scoping/Preparation Activities for Mechanical Properties of Rock Fractures	8.3.1.15.1.4
1.2.4.2.1.1.4/621	Begin Starter Tunnel Construction Monitoring	8.3.1.15.1.8

The NRC staff observed the YMQAD audit team evaluation of Programmatic Elements 3.0, 19.0 and 20.0; only these programmatic areas are discussed in this report. The technical areas were reviewed as part of the programmatic reviews.

### 5.2 Timing of the Audit

The NRC staff believes the general timing of this audit was appropriate for YMQAD to evaluate the pertinent QA activities of SNL and for the NRC staff to evaluate the YMQAD audit process and implementation of the SNL QA program. However, although this audit was scheduled in conformance with OCRWM's

practice of auditing each applicable QA programmatic element at least annually, the precise timing was questionable as discussed in 5.10.3.

### 5.3 Examination of QA Programmatic Elements

The NRC staff observed that each of the auditors reviewed related documentation and interviewed at least a representative sample of SNL personnel to determine their understanding and degree of implementation of the procedures. The auditors observed were well prepared and knowledgeable of the QA program requirements. They used their checklists effectively and pursued issues beyond the checklists when appropriate. They provided adequate opportunities for comments and questions from the NRC observers. The NRC staff observations regarding the audit and the implementation of each appropriate QA programmatic element are discussed below.

#### 5.3.1 Design Control (Programmatic Element 3.0)

SNL presently has no design responsibilities; however, some SNL procedures included in this programmatic element are used in scientific investigation activities. The audit of this element included activities controlled by SNL Yucca Mountain Project Quality Assurance Implementing Procedure 3-10 "Routine Calculations," Revision 00. The auditor and technical specialist both reviewed calculation notebooks and interviewed SNL personnel who had worked on the calculations.

Although some hand calculations did not list assumptions, input data, and other items as required by procedure, all the required information was documented on separate check calculations. The SNL personnel were familiar with procedural requirements, and their calculations appeared to meet the intent of the controlling procedure.

The audit team was effective in its audit of this programmatic element using the checklists effectively and asking appropriate questions of SNL personnel. The NRC staff agrees with the YMQAD audit team that SNL is adequately implementing QA controls for activities under this programmatic element.

An Observer Inquiry form was submitted by the NRC staff concerning requirements for feedback from field investigators to the authors of study plans when field changes are made to procedures, drawings, and other documents. YMQAD stated that such feedback is controlled by procedures, and the NRC observers requested that a future surveillance be made to verify that the procedures are being implemented effectively.

#### 5.3.2 Computer Software (Programmatic Element 19.0)

To begin this portion of the audit, the auditor requested the current software master log of SNL codes. There were a total of 172 codes listed, which included 23 scientific and engineering software (SES) codes, if all versions were counted. The auditor selected four SES items as the initial primary areas of interest: TOUGH2, JAC3D, VEC/DYNA3D, and MM4BAT. Because of a request by one of the technical specialists on the audit team, the graphing/plotting code MATLAB was added to the original list of four.

In the discussions of the SES codes and review of objective evidence, the SNL Software Quality Assurance Requirements Implementing Procedure was utilized to determine whether the selected SES met minimum documentation requirements. Included as documentation requirements were the following: Software Acquisition Cover Sheet and Submittal Form, Software Requirements Memorandum, Software Evaluation Report & Review, Request for All Available Documentation, Software Design Description & Review, Software Installation Report & Review, Software Checkout Report & Review, and the Software Memo to File. SNL software documentation was reviewed by the auditor in great detail, and no nonconformances were noted.

Interviews were held with three SNL software QA staff members. In addition, discussions were held with Principal Investigators (PIs) involved in the development and testing of the SES reviewed. Following the initial interviews, the auditor worked over a period of three days to complete the 22 high-order QA checklist items by verifying objective evidence obtained from the computer software QA coordinator. When necessary, follow-up interviews were conducted with the appropriate PI to clarify or obtain additional objective evidence. Such was the case with the SES JAC3D, a three-dimensional finite element computer program for the nonlinear quasi-static response of solids with the gradient method. A demonstration verification run on a single module was made using JAC3D and then two test problems were shown using the same SES for the auditor and observers.

The auditor also traced the progression of the identified SES through the individual processes that each is required to meet. Included in those processes were: computer software categorization; software evaluation and report; transition of acquired and developed software to the SNL software QA program; meeting the software requirements specification; verification of the software design specification; verification of good programming practices; verification of test and debug processes; and that the software qualification forms were correctly completed. In some of these processes, because there was no internally developed software, there was no activity and the audit item was not applicable. There were no nonconformances noted.

The interview method of auditing, combined with periodic checking of objective evidence, allowed for thorough responses to the questions and permitted many additional questions to be answered. In this criterion, no significant deficiencies were identified. The auditor's familiarity with software quality assurance and the ongoing YMP SES software code activities was particularly beneficial. The audit and implementation of this element of the SNL QA program appeared effective.

### 5.3.3 Scientific Investigation (Programmatic Element 20.0)

The audit of Scientific Investigations was conducted by two teams, each composed of a technical specialist and an auditor. Although only portions of the interviews pertinent to Scientific Investigations were observed, it appeared during those times that the audit teams were thorough and followed the audit checklists, asking additional questions as required.

Considerable attention was given to Work Agreements (WAs), which are utilized as the instruments to clearly provide instructions on how work is to be accomplished, and the controlling process through which work must flow. In six such WAs reviewed during a portion of the audit, the documents were consistently approved by the "Customer/Organization," "Supplier/Organization," "Technical Reviewer," and by the "Quality Assurance Reviewer." Each WA had the required topics addressed: Table of Contents, Scope of Work, Task Descriptions, Use of Scientific Notebooks, QA Grading Reports, QA Records and File Locations, Deliverables, Anticipated Schedule, Personnel and Assignments, Work Acceptance Criteria, and Definition of Completion. No discrepancies were noted by either of the two auditing teams observed during the Scientific Investigation portion of the audit.

The technical specialist on each team went into considerable technical detail during the interviewing process with the PIs to determine if appropriate decisions had been made during the planning and execution of the Study Plans and WAs. Programmatically, the audit itself and the implementation of Scientific Investigation controls appeared to be adequate.

#### 5.3.4 Conclusions

The programmatic portion of the audit was conducted in a professional manner, and the auditors adequately evaluated activities and objective evidence. The audit was effective in determining the adequacy and degree of implementation of the SNL QA program.

### 5.4 Examination of Technical Activities

#### 5.4.1 Begin Starter Tunnel Construction Monitoring

This work is part of Study Plan 8.3.1.15.1.8, "In-Situ Design Verification," wherein the Starter Tunnel was monitored. WAs, scientific note books, and technical procedures developed for this task were used in evaluating the task and questioning the investigators. This monitoring task involved: (1) evaluation of mining methods (monitor blasting activities, generate preliminary rock mass classification and record installed support, and assess blast damage); (2) monitoring of ground support system (install load cells to measure backfill pressures on liners and load on rock bolts); and (3) monitoring drift stability (install convergence points on the tunnel perimeter, install multipoint borehole extensometer, and install stress change gases). The work agreements and technical procedures for these tasks were reviewed and found to be adequate. The technical auditors also reviewed the scientific notebooks, and questioned the investigators on the details of the monitoring program. The technical auditors were satisfied with the QA aspects of the work completed to date.

#### 5.4.2 Scoping/Preparation Activities for Mechanical Properties of Rock Fractures

The technical questions during this discussion with the PI were based on the associated Study Plan 8.3.1.15.1.4. It was emphasized by the PI that although a WA had been drafted to conduct the mechanical fracture property testing, no

data had been gathered under the new QA procedures. As a result, much of the work conducted to date was regarded by the PI as being 'scoping' in nature. No scientific notebooks were being utilized and no technical operating procedure had been drafted at this time for this scoping work. It was made quite clear that this scoping work fell under the old SNL QA classification and was classified as QA Level 3, i.e. does not follow any QA procedures. Therefore, all the scoping work completed to date was not QA qualified and will not be used in this project. However, it is noted that quite a number of Sandia reports and other publications were being generated based on this scoping work.

The technical specialist raised a number of questions regarding the sample preparation, shipping, and storage prior to testing. The PI indicated that for this task, no special instructions were given to the Sample Management Facility to specially wrap the core to preserve its in situ moisture state, nor to assure that the core was not exposed to excessive heat/sunlight in the field or kept from freezing during shipping. The PI did not think that these effects, in addition to oven-drying the samples and re-saturating them, would have any significant impact on the mechanical properties of the fractures determined by the study. The technical specialist suggested the use of ASTM or other standard procedures as much as possible for the specimen preparation, shipping, and storage prior to testing, to ensure that the designer gets as accurate information on the in situ properties as possible.

The observers and technical specialists were given a tour of the rock mechanics laboratory facilities to be used by SNL for conducting the mechanical fracture properties testing. The testing equipment, including the rotary direct shear testing machine and laser rock profilometer, is in place. However, significant work needs to yet be done in getting the equipment under a quality control program including proper operating procedures, calibration schedules, in addition to those procedures for control, preparation, and custody of fracture specimens.

#### 5.4.3 Laboratory Thermal Properties - Develop Procedures and Conduct Tests, and Laboratory Thermal Expansion Testing - Develop Procedures and Conduct Tests

The technical questions during this discussion with the PI were based on the associated Study Plans 8.3.1.15.1.1 and 8.3.1.15.1.2. These two particular studies were focused on evaluating properties including the thermal conductivity, specific heat, and thermal expansion coefficients of various rock units at the Yucca Mountain repository site. The specific experimental work was primarily subcontracted out to Holometrix, Inc. Again, the technical specialist focused a good deal of time on questioning the specimen handling and preparation prior to testing and stressed the use of established protocol. The study plans and corresponding WAs describing the various thermal experiments to be conducted at different temperatures and constant saturations levels were reviewed and appeared adequate. Applicable technical operating and quality assurance procedures were clearly identified in the work agreements.

#### **5.4.5 Surface Facilities - Exploration Program; Laboratory Tests and Material Property Measurements; and Field Tests**

The work under these tasks consisted of preparing final logs from field logs of exploratory boreholes, conducting basic laboratory tests on soil samples, and conducting field tests such as in situ density and percolation tests. PIs were questioned by the technical specialists on the details of the work done under these tasks. The WAs, scientific notebooks, and technical procedures for core hole logging and tests were reviewed and found to be adequate. Applicable quality assurance procedures were clearly identified in the work agreements.

#### **5.4.6 Conclusions**

In general, the technical portion of the audit was effective. The technical checklists were followed and were sufficient to determine the technical qualifications of the principal investigators and technical quality of the product. The audit team conducted the audit in a professional manner and asked questions to ascertain complete understanding of the technical program and applicable QA requirements. During the audit, no CARs related to the technical aspect of work were identified. The SNL technical personnel appeared well qualified and, in general, were properly trained in and had an overall understanding of QA requirements.

The observers raised one issue regarding how the continuing design changes for the ESF and repository are reflected back into the specific study plans. It was not clear whether any interaction took place to coordinate the changing design's needs for information and the scope of work in the study plans. There should be a required procedure to transmit changes to the design of ESF and repository to the PIs of study plans so that the changed design's information needs are appropriately factored in the work done under various study plans.

#### **5.5 Conduct Of Audit**

The audit was performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the SNL QA program. In general the audit team personnel were persistent in their interviews, challenged responses when necessary, and performed an acceptable audit. Daily caucuses were held between auditors and observers, and daily audit status meetings were held between SNL management and the ATL (with an NRC observer present) to discuss the preliminary findings.

#### **5.6 Qualification Of Auditors**

The qualifications of the ATL and auditors were found to be acceptable in that each auditor and the ATL met the requirements of QAAP 18.1, "Qualification of Audit Personnel."

## **5.7 Audit Team Preparation**

The auditors were prepared in the areas they were assigned to audit and were knowledgeable of the applicable procedures. The Audit Plan for this audit included the audit scope, the audit schedule, a list of audit team personnel, a list of the activities to be audited, and audit checklist references.

## **5.8 Audit Team Independence**

The audit team members did not have prior responsibility for performing the activities they audited. The audit team members had sufficient independence to carry out their assigned functions without adverse pressure or influence.

## **5.9 Review of Previous Audit Findings**

During this audit, two previously issued CARs were reviewed to determine the effectiveness of corrective actions. The corrective action for both CARs was determined by the audit team to be effective.

## **5.10 Summary of NRC Staff Findings**

### **5.10.1 Observations**

The NRC staff did not identify any Observations relating to deficiencies in either the audit process or the SNL QA program.

### **5.10.2 Good Practices**

No new good practices were identified.

### **5.10.3 Weaknesses**

Some inconvenience and delay to the audit resulted from SNL staff vacations (use or lose by the end of the year) and a one-time relocation of SNL-YMP personnel taking place the following week. Every effort should be made by YMQAD to schedule audits at more propitious times.

## **5.11 Summary of YMQAD Audit Findings**

Within the scope of this audit, the audit team concluded that the SNL QA procedures are adequate and that SNL's QA program implementation is adequate for Programmatic Elements 3.0, 8.0, 19.0, and 20.0. Implementation of Programmatic Element 4.0 was marginally satisfactory, and Programmatic Elements 7.0 and 15.0 were indeterminate due to the lack of activity. The NRC staff agrees with these conclusions. At the post-audit meeting, the audit team provided observations of the SNL QA program and discussed the five preliminary CARs resulting from the audit (listed below). Four other potential CARs were acceptably resolved by the SNL organization prior to the post-audit meeting.

5.11.1 During a portion of the audit of Criterion 20 that was not observed by the NRC staff, the YMQAD auditor determined there was no documented evidence

that a technical review was conducted by SNL personnel for Study Plan 8.3.1.4.3.1. Technical reviews are required to be documented on review and comment forms.

5.11.2 There was no documented evidence that SNL subcontractor personnel employed by J. F. T. Agapito & Associates have been trained to seven procedures listed in SNL WA-0065.

5.11.3 QA records are being kept by SNL personnel without dual storage provided and are maintained in containers that do not have a one hour fire rating or bear an Underwriters Laboratory label certifying one hour fire protection.

5.11.4 Contracts have been awarded by SNL without all QA requirements being incorporated into pertinent procurement documents.

5.11.5 Several records for SNL procurement activities have not been submitted to the SNL Local Records Center as soon as practical after record completion.