U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 92-16
FOR THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION
AUDIT NO. YMP-92-22
OF SANDIA NATIONAL LABORATORIES-YUCCA MOUNTAIN PROJECT

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1.0 INTRODUCTION

During August 24-28, 1992, U.S. Nuclear Regulatory Commission (NRC) staff members participated as observers of the U.S. Department of Energy, Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, Yucca Mountain Quality Assurance Division (YMQAD) Quality Assurance (QA) Audit YMP-92-22 of the Sandia National Laboratories (SNL)-Yucca Mountain Project (YMP) QA program at the SNL-YMP offices in Albuquerque, New Mexico. The audit scope included six programmatic areas and four technical areas.

2.0 OBJECTIVES

The objective of this YMQAD audit was to evaluate the implementation and effectiveness of the SNL-YMP QA program in meeting the applicable requirements of the SNL-YMP Quality Assurance Program Description (QAPD). The NRC staff's objective was to gain confidence that YMQAD and SNL-YMP are properly implementing the requirements of their QA programs in accordance with the OCRWM Quality Assurance Requirements Document, DOE/RW-0214, Revision 4 and Title 10 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-YMP program on direct observations of the auditors; discussions with audit team, SNL-YMP, and contractor personnel; and reviews of the audit plan, the audit checklists, and pertinent SNL-YMP documents. The staff has determined that YMQAD Audit No. YMP-92-22 was useful and effective. The audit was well organized and conducted in a thorough and professional manner with minimal logistic delays. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary YMQAD audit team findings that the SNL-YMP QA program has adequate procedural controls in place, and program implementation is generally adequate. One of the programmatic elements audited (Design Control) was found to be indeterminate, due to a lack of quality-affecting work in this area since the last audit. Three preliminary Corrective Action Requests (CARs) were issued by the YMQAD audit team, none of which is significant in terms of the overall QA program.

OCRWM should closely monitor the SNL-YMP QA program to ensure that the deficiencies identified during this audit and earlier audits and surveillances are corrected in a timely manner and future implementation is carried out effectively. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits later to assess the SNL-YMP QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

Kenneth R. Hooks	Observer	
Bruce Mabrito	Observer	Center for Nuclear Waste Regulatory Analyses

4.2 DOE

Frank J. Kratzinger	Audit Team Leader	Science Applications International Corporation (SAIC)/YMQAD
Neil D. Cox	Auditor	SAIC/YMQAD
Gerard Heaney	Auditor	SAIC/YMQAD
Cynthia H. Prater	Auditor	SAIC/YMQAD
Kenneth T. McFall	Lead Technical Specialist	SAIC/YMQAD
Keith M. Kersch	Technical Specialist	SAIC
William R. Sublette	Technical Specialist	SAIC
Donald Horton	Observer	OCRWM Headquarters
Mario Diaz	Observer	YMQAD

4.3. State of Nevada

Susan Zimmerman	Observer

4.4 Clark County, Nevada

Engelbrecht von Tiesenhausen	Observer

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This audit was conducted in accordance with OCRWM QA Administrative Procedure (QAAP) 18.2, "Audit Program," Revision 5, effective January 3, 1992 and OCRWM QAAP 16.1, "Corrective Action," Revision 4, effective November 12, 1991. The NRC staff observation audit of this YMQAD audit of SNL-YMP was based on the NRC procedure, "Conduct of Audits," issued October 6, 1989.

5.1 Purpose/Scope of Audit

The purpose of the YMQAD audit was to evaluate the implementation and effectiveness of the SNL-YMP QA program relative to six programmatic elements and four technical areas.

(a) Programmatic Elements

The audit was based on the requirements in the SNL-YMP QAPD Revision 00, effective July 29, 1991, Sections 3.0, 5.0, 6.0, 17.0, 19.0 and 20.0 (10 CFR 50 Appendix B Criteria III, V, VI and XVII) and other applicable documents pertaining to QA controls.

(b) Technical Areas

The following technical areas were audited for compliance to procedural controls and adequacy of technical products.

WBS Number	Title
1.2.1.3.1.	Site and Engineering Data Base
1.2.1.4.7.	Supporting Calculations for Post Closure Performance Analyses
1.2.4.2.1.2.	Rock Mass Analyses
1.2.4.2.3.2	Exploratory Studies Facility Design - Far Field Thermal and Structural Analyses

Because no technical specialists were included on the NRC observation audit team, no evaluation of technical products was performed by the NRC staff, and discussion of technical areas is incorporated in the discussion of programmatic elements.

5.2 Timing of the Audit

The NRC staff believes the timing of the QA audit of SNL-YMP was acceptable. None of the programmatic elements included in the scope of this audit have been audited by YMQAD since August 1991.

5.3 Examination of Programmatic Elements

The audit checklists covered the QA program controls for the six programmatic elements listed below:

3.0 Design Control
5.0 Instructions, Procedures, Plans and Drawings
6.0 Document Control
17.0 Quality Assurance Records
19.0 Computer Software
20.0 Scientific Investigations

The NRC staff observed the YMQAD audit team's evaluation of programmatic elements 3.0, 6.0, 17.0, 19.0, and 20.0. Only these programmatic elements will be discussed in detail.

(a) Design Control/Scientific Investigations (Programmatic Elements 3.0/20.0)

The Design Control and Scientific Investigations programmatic elements were considered as a single element for audit purposes. They were audited in conjunction with technical areas by a programmatic auditor and technical specialist team. Both the programmatic and technical checklists were used during this portion of the audit.

The audit team reviewed Problem Definition Memos, SNL-YMP technical reports (SAND reports), test interference and test planning packages, and other SNL-YMP documents. Data reported in these documents were traced to the source documents such as the Reference Information Base (RIB) and the Site and Engineering Properties Data Base (SEPDB). Identification of the source and qualification of data reported in SNL-YMP documents was reviewed and verified. The audit team also investigated whether various activities were traceable to the authorizing documents.

In general, the audit team found that data in the documents could be traced to its source, although references were not always complete (e.g., the version of the RIB was not specified) or accurate (e.g., a SAND report referenced was an intermediate report, not the source report). In some cases, traceability of the data would have been very difficult without discussion with the author(s) of the documents. The NRC staff believes that additional guidance and training concerning specific identification of references should be provided to SNL-YMP personnel.

The audit team determined the technical report SAND91-0607 does not comply with the requirements of SNL-YMP Department Operating Procedure (DOP) 3-17 that the qualification or quality level of data be identified in reports, and a preliminary Corrective Action Request (CAR) was issued. A second preliminary CAR was issued against SNL-YMP for failure to retain a copy of marked-up pages of SAND92-0450 to provide objective evidence of incorporation of review comments.

At the time of this audit, SNL-YMP had the responsibility for generating the SEPDB. Only data specifically submitted by the participants is entered into the SEPDB; it is not manipulated in any fashion, even to change units. Entry is made only after extensive checks for consistency, whether the data has been previously entered, etc. During discussion about the SEPDB, it was identified that responsibility for this data base is being transferred from SNL-YMP to EG&G in Las Vegas, NV. SNL-YMP has delivered tapes of the SEPDB data to EG&G and has prepared a transition plan for the transfer.

The team was competent, thorough, used its checklists appropriately, and performed a useful and effective audit. The team determined that implementation of the SNL-YMP QA program for Design Control was indeterminate due to the lack of quality-affecting design activity since the last audit of this programmatic element. The audit found that SNL-YMP QA program implementation is adequate in the area of Scientific Investigations. The NRC staff agrees with these team findings.

(b) Document Control (Programmatic Element 6.0)

The audit of the Document Control programmatic element involved a detailed investigation by the auditors to fully cover the 25 checklist items. The auditors were conscientious and persistent in tracking down information and went beyond the checklist items when it appeared there might be a collateral deficiency in other parts of the SNL-YMP QA Program.

The auditors reviewed objective evidence and interviewed SNL-YMP document control personnel to obtain answers to checklist items. The SNL-YMP Master List of Control Documents was requested by the auditors and was used throughout the audit. There was a sampling inspection of controlled documents distributed to SNL-YMP staff and no discrepancies were noted in either the listing or control of the documents.

In addition to the document distribution issues addressed in this element, implementation of the SNL-YMP procedure "Reviewing, Approving, and Issuing Technical Information Documents" was checked for compliance. Three SAND reports (SAND91-0790, SAND91-0791, and SAND91-0792) were selected and the associated record packages were audited to determine if the record packages were complete and if the following information was present when required: Document Review and Comment forms, cross references to peer reviews, manuscript review sheets, and Technical Project Officer transmittal letter to the Yucca Mountain Project Office. The three SAND reports had complete records packages and no problems or nonconformances were noted. However, during the audit of another criterion, a preliminary CAR was identified concerning the lack of completed Document Review and Comment forms being retained for Interim Change Notices.

Based upon observation of this portion of the audit, the NRC staff determined that the auditors conducted a sufficiently detailed audit of document control by asking appropriate questions, requesting and reviewing sufficient objective evidence, and thoroughly utilizing the audit checklist. The NRC staff agrees with the audit team finding that SNL-YMP program implementation is adequate in this area.

(c) Quality Assurance Records (Programmatic Element 17.0)

During this portion of the audit, the two YMQAD auditors observed the facilities for records processing, reviewed records packages, and audited general and specific compliance to Quality Assurance Implementing Procedures (QAIPs) 17-1 and 17-2. Both of the auditors, working separately, asked to see the safe containing the record source materials, were shown the basement-located safe and verified that it met the storage, preservation and safekeeping requirements.

Both auditors used matrices to ensure thorough coverage of their assigned areas. Record packages were audited for table of contents, record package identifier, QA designation, unique identifiers, a record package title page, a listing of all records in the package with the data and number of pages of each record, the total number of pages, and the SNL-YMP file

code. An adequate sampling of the records packages indicated compliance with the QAIP.

One of the auditors checked the DOE "System 80" personnel records at the SNL-YMP Local Records Center (LRC), which were duplicates of those submitted to the Central Records Facility in Nevada. There was prompt access to the personnel records and no nonconformances were identified.

At a separate location, the Data Records Management System (DRMS) was visited by one of the auditors and an audit of data packages was accomplished. Although at the time of the audit no data packages from the SNL-YMP work had been closed, the packages were orderly, protected, and well maintained. The auditor reviewed six data packages randomly sampled from the DRMS index in order to answer the audit checklist questions. The implementing procedure was being complied with for all the packages reviewed.

Based upon the responses to questions asked by the auditors, it was apparent that personnel in the LRC and the DRMS office had adequate knowledge of their responsibilities. One preliminary CAR was initiated regarding the document review sheets for a QAIP not being retained as QA records; it was resolved during the audit by SNL-YMP management and no CAR was issued.

The NRC staff determined that the audit of this programmatic element was effective and agrees with the audit team finding that SNL-YMP program implementation is adequate in this area.

(d) Computer Software Controls (Programmatic Element 19.0)

Immediately after the Pre-Audit Conference, the auditor requested a complete listing of current software used on the SNL-YMP work. A total of 63 separate software items were listed on the software Master Log Document as of August 24, 1992. These included Scientific and Engineering Software (SES), calculational non-SES, auxiliary software, and peripheral software. The auditor used that Master Log Document (which could more accurately be titled the Software Life Cycle Chart) as the basis to start the audit of software controls.

The auditor interviewed the SNL-YMP Software QA Manager, Software Coordinator, and a QA staff member, all of whom answered the auditor's questions and provided the requested objective evidence. Of the 63 software items in the Master Log Document, the auditor reviewed 35 of them in detail, concentrating mainly on SES and calculational software items. The auditor worked closely with other audit team members to determine if certain software had been identified during the audit as having special significance to current projects at SNL-YMP.

Included in the software documentation audited were codes NORIA-SP, TOSPAC, STRES3D, GENMODEL, GRADEMODE, LEHGE, COYOTE II, FST2D, AMOD, and MM4BAT. The auditor determined that the magnetic media was being

maintained in a condition meeting the storage requirements of the QA program.

The auditor satisfactorily completed the software audit checklist. No deficiencies were identified. SNL-YMP personnel appear to be properly fulfilling their organizational responsibilities in controlling computer software.

The NRC staff determined that the audit of this programmatic element was effective and agrees with the audit team finding that SNL-YMP program implementation is adequate in this area.

5.4 Conduct of Audits

This audit was performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the SNL-YMP QA program. The audit checklists generally included the important controls addressed in SNL-YMP's QAPD. The auditors used the checklists effectively during the interviews with personnel and review of documents. Potential deficiencies identified during each day were thoroughly reviewed during the audit team/observer meetings each afternoon. The observers were kept well informed during the entire audit.

5.5 Qualification of Auditors

The qualifications of the QA auditors on this audit team had been previously reviewed by the NRC staff and found to be acceptable, meeting the requirements of Yucca Mountain Site Characterization Project Office Quality Management Procedure 02-02, "Qualification of Quality Assurance Program Audit Personnel."

5.6 Audit Team Preparation

The auditors were prepared in the areas they were assigned to audit and knowledgeable in the SNL-YMP QA procedures. Overall, Audit Plan YMP-92-22 was complete and included (1) the audit scope and schedule, (2) a list of audit team personnel, (3) a list of the audit activities, (4) the audit notification letter, (5) the previous audit report, and (6) the programmatic and technical checklists.

5.7 Audit Team Independence

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

5.8 Review of Previous Audit Findings

There were no previous unresolved audit findings to review.

5.9 Summary of NRC Staff Findings

(a) Observations

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

(b) Good Practices

1. The audit team was well prepared, thorough, and displayed a detailed knowledge of the appropriate SNL-YMP procedures.

2. The SNL-YMP staff demonstrated a good understanding of QA program responsibilities and a commitment to its requirements.

5.10 Summary - YMQAD Audit Team Findings

The audit team wrote three preliminary CARs against SNL-YMP's QA program:

1. Document Review and Comment forms were not filled out/retained for some Technical Procedure Interim Change Notices as required by DOP 3-13. (See Section 5.3(b).)

2. SNL-YMP report SAND91-0607 does not identify the QA level of the included data as required by DOP 3-17. (See Section 5.3(a).)

3. Marked-up pages of documents reviewed were not included in the QA records packages for verification of incorporation of accepted comments as required by DOP 3-13. (See Section 5.3(a).)

None of these preliminary CARs is significant in terms of the overall SNL-YMP QA program.