OBSERVATION OF DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE AUDIT YMP-94-09 OF THE SANDIA NATIONAL LABORATORIES

Prepared for

Nuclear Regulatory Commission
Contract NRC-02-93-005

Prepared by

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November 1994

This report was prepared to document work performed by the Center for Nuclear Waste Regulatory Analyses (CNWRA) for the Nuclear Regulatory Commission (NRC) under contract No. NRC-02-93-005. The activities reported here were performed on behalf of the NRC Office of Nuclear Material Safety and Safeguards (NMSS), Division of Waste Management (DWM). The report is an independent product of the CNWRA and does not necessarily reflect the views or regulatory position of the NRC.

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Mr. Ronald A. Milner, Acting Director
Office of Program Management and Integration
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, D.C. 20585

Dear Mr. Milner:

SUBJECT: OBSERVATION AUDIT OF THE SANDIA NATIONAL LABORATORIES

I am transmitting the Nuclear Regulatory Commission's Observation Audit Report 94-11 for the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, Yucca Mountain Site Characterization Quality Assurance Division (YMQAD) audit of the Quality Assurance (QA) program of the Sandia National Laboratories (SNL). The audit, YMP-94-09, was conducted from August 29 through September 2, 1994, at the SNL offices in Albuquerque, New Mexico. The audit evaluated the adequacy and effectiveness of the SNL QA program in all applicable QA programmatic areas and in nine technical areas. The State of Nevada did not have a representative at this audit.

The NRC staff evaluated the YMQAD audit to gain confidence that OCRWM and SNL are properly implementing the requirements of their QA programs. The NRC staff based its evaluation of the YMQAD audit process and the SNL QA program on direct observations of the audit team members; discussions with audit team and SNL personnel; and reviews of the audit plan, the audit checklists, and other pertinent documents.

The NRC staff has determined that YMQAD Audit YMP-94-09 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's finding that the overall implementation of the SNL QA program is adequate. Thirteen 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 CARs identified by the YMQAD audit team are significant in terms of the overall SNL QA program.

OCRWM 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 SNL implementation of its QA program.

A written response to this letter or the enclosed report is not required. If you have any questions, please call Jack Spraul of my staff at (301) 415-6715.

Sincerely,

Joseph J. Holonich, Chief
High-Level Waste & Uranium
Recovery Projects Branch
Division of Waste Management
Office of Nuclear Material
Safety and Safeguards

Enclosure: As stated
cc: R. Loux, State of Nevada
T. J. Hickey, Nevada Legislative Committee
J. Meder, Nevada Legislative Counsel Bureau
R. Nelson, YMPO
M. Murphy, Nye County, NV
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
D. Weigel, GAO
P. Niedzielski-Eichner, Nye County, NV
B. Mettam, Inyo County, CA
V. Poe, Mineral County, NV
F. Mariani, White Pine County, NV
R. Williams, Lander County, NV
L. Fiorenzi, Eureka County, NV
J. Hoffman, Esmeralda County, NV
C. Schank, Churchill County, NV
L. Bradshaw, Nye County, NV
W. Barnard, NWTRB
R. Holden, NCAI
E. Lowery, NIEC
S. Brocoum, YMPO

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NAME	JGSpraul/jk		RLJohnson		JJHolonich					
DATE	11/18/94	H	10/ /94		10/ /94					

U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT 94-11

OF THE U.S. DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

AUDIT YMP-94-09

OF

SANDIA NATIONAL LABORATORIES

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Center for Nuclear Waste
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ENCLOSURE

1.0 INTRODUCTION

During August 29 through September 2, 1994, members of the U.S. Nuclear Regulatory Commission (NRC), Division of Waste Management quality assurance (QA) and technical staff observed a U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, Yucca Mountain Site Characterization Quality Assurance Division (YMQAD) audit of the QA program of the Sandia National Laboratories (SNL). The audit, YMP-94-09, was conducted at the SNL offices and laboratories in Albuquerque, New Mexico. The audit evaluated the adequacy and effectiveness of the SNL QA program in all applicable QA programmatic areas and in nine technical areas.

Representatives of the U.S. Environmental Protection Agency (EPA) also observed this audit. The State of Nevada did not have a representative at this audit.

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

2.0 OBJECTIVES

The objectives of the audit by the YMQAD team 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 - DOE/RW-0333P), the SNL Quality Assurance Implementing Procedures (QAIPs), and other documents which comprise the SNL QA program.

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

3.0 MANAGEMENT SUMMARY AND CONCLUSIONS

The NRC staff has determined that YMQAD Audit YMP-94-09 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 the overall implementation of the SNL QA program was effective. Thirteen 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. Neither the preliminary nor potential CARs identified by the YMQAD audit team were significant in terms of the overall SNL QA program.

OCRWM 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 Observers

John Spraul	Observer	
Banad Jagannath	Observer	
John Buckley	Observer	
Robert Brient	Observer	Center for Nuclear Waste Regulatory Analyses (CNWRA)
Donald Dunavant	Observer	CNWRA
Simon Hsiung	Observer	CNWRA
Robert Baca	Observer	CNWRA

4.2 DOE Audit Team

Kenneth McFall	Audit Team Leader (ATL)	YMQAD/Quality Assurance Technical Support Services (QATSS)
Keith Kersch	Technical Specialist	Technical and Management Support Services Contractor (T&MSS)
William Sublette	Technical Specialist	T&MSS
James Blaylock	Auditor	YMQAD/QATSS
Robert Harpster	Auditor	YMQAD/QATSS
Kristi Hodges	Auditor	YMQAD/QATSS
John Matras	Auditor	YMQAD/QATSS
Richard Maudlin	Auditor	YMQAD/QATSS
Mary McDaniel	Auditor	YMQAD/QATSS
Steven Nolan	Auditor	YMQAD/QATSS
Charles Betts	Auditor	Headquarters Quality Assurance Division (HQAD)/QATSS
James George	Auditor	HQAD/QATSS

4.3 Other Observers

John Hauschild	Observer	EPA
Thomas Vandel	Observer (Part time)	EPA
Robert Keele	Observer	QATSS

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 6) and QAAP 16.1, "Corrective Action" (Revision 6). The NRC staff observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued on October 6, 1989.

5.1 Scope of the Audit and Observations

This audit was designed to evaluate the adequacy and implementation of the SNL QA Program as defined in its QAIPs and other implementing procedures to meet the OCRWM QARD.

5.1.1 QA Programmatic Elements

The audit scope included the applicable QA programmatic elements which are listed below:

1 Organization
2 Quality Assurance Program
4 Procurement Document Control
5 Implementing Documents
6 Document Control
7 Control of Purchased Items and Services
12 Control of Measuring and Test Equipment
16 Corrective Action
17 Quality Assurance Records
18 Audits
Supplement I, Software
Supplement II, Sample Control
Supplement III, Scientific Investigations

5.1.2 Technical Areas

The following technical areas were evaluated during the course of this audit of the SNL QA program:

WBS 1.2.3.2.6.2.1	Surface Facilities Exploration Program
WBS 1.2.3.2.6.2.2	Surface Facilities Laboratory Tests and Material Properties Measurements
WBS 1.2.3.2.6.2.3	Surface Facilities Field Tests and Characterization Measurements
WBS 1.2.3.2.7.1.3	Laboratory Determination of Mechanical Properties of Intact Rock
WBS 1.2.3.2.7.1.4	Laboratory Determination of Mechanical Properties of Fractures
WBS 1.2.4.2.1.1.4	In Situ Design Verification
WBS 1.2.5.4.1	Total System Performance Assessment
WBS 1.2.5.4.6	Development and Validation of Flow and Transport Models
WBS 1.2.5.4.7	Supporting Calculations for Postclosure Performance Assessment Analyses

5.1.3 Observations

The NRC staff observed all or part of the YMQAD audit team evaluation of QA Programmatic Elements 4, 5, 6, 7, 12, 16, 18, and Supplements I, II, and III; only these QA programmatic areas are discussed in Section 5.3 of this report.

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. The last YMQAD QA program audit of the SNL organization was held on September 13-17, 1993.

5.3 Examination of QA Programmatic Elements

The NRC staff observations regarding the audit and the implementation of each QA programmatic element observed are discussed below.

5.3.1 Procurement Document Control and Control of Purchased Items and Services (QA Programmatic Elements 4 and 7)

The observed portion of the audit of QA Programmatic Elements 4 and 7 involved reviewing procurement documents for a number of services suppliers. These suppliers provide technical assistance to SNL. They perform work under the controls of the SNL QA program rather than under their own QA programs. Therefore, some QA aspects of procurement (such as proposal evaluation, supplier qualification, and acceptance inspection) are not applicable. The auditor discussed with SNL technical staff the basis for acceptance of technical assistance work, much of which did not have specific deliverable items. CAR YM-94-097 was initiated by the auditor concerning procured calibration services.

The checklist and audit were effective, and SNL implementation was adequate.

5.3.2 Implementing Documents (QA Programmatic Element 5)

The portion of the audit of this element that was observed involved especially convened meetings between the SNL Technical Project Officer, the SNL QA Manager, the ATL, and the auditor to discuss the audit team's concern over the low level of detail provided in a number of SNL QAIPs. The audit team noted that QAIPs restated QARD requirements, but did little to elaborate on these requirements or to prescribe methods for implementation. The conclusion of the audit team was to issue CAR YM-94-096, citing its concerns and the fact that procedures lacked qualitative or quantitative acceptance criteria. A number of examples were provided as well. SNL management expressed its desire to follow guidance that the audit team or YMQAD could provide to them, as the appropriate level of detail is highly subjective.

The NRC staff concurs with the audit team's action as the appropriate mechanism for addressing this issue.

5.3.3 Document Control (QA Programmatic Element 6)

The audit of QAIP 06-02, "Reviewing, Approving, and Issuing Technical Information Documents," was observed. A representative sample of review documentation packages was evaluated. QAIP 06-02 allows: (1) for review comments to be written on individual Manuscript Review Sheets, (2) for a list of comments to be attached to a single Manuscript Review Sheet, or (3) for a marked-up copy of the document under review to be attached to a Manuscript Review Sheet. One of the review packages evaluated had editorial and technical comments marked in the margins of the document, and the author's resolution was to "accept (the comments) as appropriate." In other words, the resolution of each technical comment was not individually documented. The auditor then interviewed the technical reviewer, who indicated that resolution of each comment had been discussed with their originator (but this was not indicated in the review documentation). Apparently, SNL considers the acceptance signature of the reviewer as the primary indicator of comment resolution. This condition appeared to be due to the lack of specificity in QAIP 06-02, and it contributed to the initiation of CAR YMP-94-096.

The auditor (while auditing QA Programmatic Element 5) identified other examples of procedures that, while allowing for flexibility, do not provide sufficient detail and acceptance criteria for conducting quality-affecting activities, resulting in CAR YM-94-096 being initiated.

Overall, SNL document controls were adequate. However, as noted in CAR YM-94-096, SNL procedures need review to determine whether sufficient detail is provided and whether the detail implements the spirit as well as the specific requirements of the QARD. The audit of QA Programmatic Element 6 was effective.

5.3.4 Control of Measuring and Test Equipment (QA Programmatic Element 12)

The auditor reviewed technical activities to determine where and how measuring and test equipment (M&TE) had been utilized. For WBS 1.2.5.4.6, "Development and Validation of Flow and Transport Models," experimental methods were being developed and quality-affecting data was not yet being generated. Therefore, M&TE controls had not been applied. Rock joints were being tested under WBS 1.2.3.7.1.4, "Laboratory Determination of Mechanical Properties of Fractures," so the majority of the M&TE audit focused on this activity. The experiments were being conducted in the Rock Mass Laboratory of SNL, which provides matrixed support to the SNL Yucca Mountain Project organization. Force measuring equipment had been calibrated by a qualified supplier, and other equipment was calibrated by SNL facilities. The auditor identified supplier calibration certificates which omitted some of the required information, resulting in CAR YM-94-098. In addition to calibration certificates, the auditor viewed test reports for proper identification of equipment used and equipment logs for calibration histories.

The audit was extensive and effective. SNL implementation was adequate.

5.3.5 Corrective Action (QA Programmatic Element 16)

The audit of this area was conducted by reviewing a representative sample of 1993 and 1994 CARs issued by SNL and discussing the CARs with the cognizant QA and technical staff for clarifications as necessary. The auditors identified a number of minor issues with the CARs, many of which reflect the low level of detail provided by QAIP 16-01, "Corrective Action." For example, remedial action, as defined by QAIP 16-01, includes investigation of the impact of the deficiency on other products and the extent of the deficiency, but this is not reflected in the text of the procedure. The CARs do not indicate that these investigations were performed. The documentation of corrective action verification provided very little detail. Here, again, SNL apparently considers the verification signature as sufficient evidence of acceptance. These and other similar deficiencies were identified in CAR YM-94-087.

CAR YM-94-090 was issued by the auditors because two Quarterly Program reports, which document SNL's trending program, were not forwarded to YMQAD as required, and CAR YM-94-091 was initiated because three SNL CARs incorrectly identified violations of requirements as observations rather than as deficiencies.

Overall, the audit of this area was effective, and implementation was adequate. However, as noted above, SNL needs to tightens up the corrective action procedure and put more effort into documenting corrective actions.

5.3.6 Audits (QA Programmatic Element 18)

The auditors reviewed a significant sample of reports of the internal (SNL) and external (supplier) audits performed by SNL in 1993 and 1994 and auditor qualifications. Annual supplier evaluations (to determine the need for audit) were also reviewed. The audit checklist was covered thoroughly and objective evidence reviewed to determine compliance to the QARD and QAP 18-01, "Quality Assurance Audits." Auditors' qualifications were found to be acceptable, and audit performance appeared to be in accordance with requirements.

Several areas of concern were discussed with SNL audit personnel, which included: (1) SNL audit checklists not being maintained as QA records, (2) the lack of pre-award surveys, and (3) a Qualified Suppliers List not being maintained. These concerns were acceptably resolved during the audit.

The audit of QA Programmatic Element 18 was effective, and implementation was adequate.

5.3.7 Sample Control (QARD Supplement II)

The Rock Mass Laboratory and Sample Library were visited to determine if samples were being properly identified, tracked, controlled, and handled. In the Rock Mass Laboratory, the auditor was able to determine how samples were obtained from the Sample Management Facility at Yucca Mountain, how sample identification was assigned and maintained through sample preparation, and how tested samples were maintained. Sample identification was correlated between the sample package and custody logs. Likewise in the Sample Library, sample identification traceability to the sample inventory was verified. The sample inventory documentation also identified the data sets associated with tested samples.

The auditor was thorough and reviewed a significant number of samples. Implementation was adequate, and SNL was commended by the ATL in the post-audit conference for its control of samples.

5.3.8 Software and Scientific Investigations (QARD Supplements I & III)

Two audit sub-teams, each composed of an auditor and a technical specialist, audited the technical areas listed in Section 5.1.2. The NRC staff observed the sub-teams as they conducted this portion of the audit. The results of the audits of Software and Scientific Investigations are discussed below in Section 5.4.

5.4 Examination of Technical Areas

The audit of each of the technical areas identified in Section 5.1.2 were observed by the NRC staff. The technical areas were audited to assess:

- Understanding of requirements as they pertain to scientific investigations.
- Adequacy of technical procedures/instructions.
- Development of scientific investigation planning documents, study plans, work agreements, and work related products.
- Technical qualifications of scientific investigators.

This portion of the audit consisted of: (1) examining the Work Agreements (WAs), scientific notebooks, technical procedures/instructions, calculations, documents transmitted to DOE by SNL, and other pertinent documents and (2) discussions with the Task Leader and other personnel involved with the technical area being audited.

Following are specific audit sub-team observations in the audited technical areas. The audit sub-teams determined that activities at SNL were controlled by Work Agreements (WAs). Each WA specifies the QA controls to be placed on the work performed in accordance with the WA.

5.4.1 Surface Facilities Exploration Program (WBS 1.2.3.2.6.2.1)

The work in this technical area consisted of preparing final logs of borings based on field logs, inspection of cores in the sample storage facility, and video presentation of the cores taken as the cores were removed from the core barrel and stored in the core boxes at the site. The sub-team members interviewed the Task Leader and other involved personnel on the details of the work done under this task. The sub-team used the "vertical slice" approach. That is, they verified one item from the beginning to the end through all the relevant documents. The WAs, scientific notebooks, and technical instructions for core hole logging were reviewed using the vertical slice approach and found to be adequate, with the exception of the conditions identified in CARs 94-YM-089 and 099, which are detailed in Section 5.8 of this report.

5.4.2 Surface Facilities Laboratory Tests and Materials Properties Measurements (WBS 1.2.3.2.6.2.2) and Surface Facilities Field Tests and Characterization Measurements (WBS 1.2.3.2.6.2.3)

The work performed under these technical areas consisted of performing laboratory and field tests to determine geotechnical physical properties of the soil for the surface facilities. The sub-team interviewed the Task Leader and involved SNL contractor personnel on the details of the work done under this task. The WAs, scientific notebooks, and test data were reviewed, again using a vertical slice approach, and found to be acceptable. Applicable QA requirements and test procedures were clearly identified in the WAs.

5.4.3 Laboratory Determination of Mechanical Properties of Intact Rock (WBS 1.2.3.2.7.1.3) and Laboratory Determination of Mechanical Properties of Fractures (WBS 1.2.3.2.7.1.4)

The work under these technical areas consisted of performing laboratory tests to determine the physical and strength properties of intact rock samples taken from the north ramp geologic borings. The sub-team interviewed the Task Leader. The WAs, scientific notebooks, and laboratory test data were reviewed, using a vertical slice approach, and found to be acceptable. Applicable QA requirements were clearly identified in the WAs. However, the sub-team could not independently follow some of the calculations in the scientific notebook and the Task Leader had to explain the missing notes. This condition is identified in CAR 94-YM-099.

5.4.4 In Situ Design Verification (WBS 1.2.4.2.1.1.4)

The work under this technical area consisted of planning the monitoring program for the starter tunnel construction, installing appropriate field instrumentation and the data acquisition system, and managing the data. The sub-team interviewed the Task Leader and other involved personnel on the details of the work done under this task. The work agreements, scientific notebooks, and technical instructions for rock mass classification were reviewed using the vertical slice approach and found to be adequate. Several technical comments were offered by the audit team, and more evidence was found of scientific notebooks lacking sufficient detail (CAR 94-YM-099).

Applicable QA requirements were clearly identified in the work agreements.

5.4.8 Total-System Performance Assessment (WBS 1.2.5.4.1)

WBS 1.2.5.4.1 was one of seven technical areas evaluated during the course of the audit. The specific area of evaluation was Activity No. 228, "Complete Total System Performance Assessment." The sub-team began by examining the software verification and validation procedures and documentation for the computer codes used in the total system performance analyses (TSPA). The audit sub-team determined that SNL currently does not have the TSPA codes under configuration management because the TSPA calculations were "not quality-affecting," based on the conclusion that they will not be used for licensing. However, this was contradicted by the fact that the results of the

TSPA were used to make recommendations on site characterization and repository design. This was also contradicted by subsequent statements by the SNL Program Manager who indicated that all of SNL's work in this technical area is quality-affecting. That is, all the QA procedures were applicable.

The audit team then evaluated the following three software documentation packages for compliance with applicable QA controls: (1) NORIA-SP; (2) COYOTE II; and (3) XREF. These codes were developed under QAIP 3-2, prior to the implementation of the new QARD in 1992. QAIP 3-2 has been superseded by QAIP 19-1, but SNL has not completed development of any performance assessment software under QAIP 19-1. However, based on the information evaluated, the audit sub-team concluded that QAIP 19-1 is insufficient to provide that acquired or developed software would be suitable for use in licensing and that the requirements in the QAIP are merely a restatement of the QARD requirements. In addition, the sub-team concluded that unsatisfactory conditions were identified in verification and validation control of acquired and developed software, change control, and use of software. These findings are reported on CAR YM-94-096. The audit team recommended that QAIP 19-1 be revised to improve the verification testing for acquired software by requiring SNL to develop independent test cases rather than merely repeat vendor test cases.

5.4.9 Development and Validation of Flow and Transport Models (WBS 1.2.5.4.6)

This technical area contains the following four activities:

- Continue Fracture/Matrix Interaction Model Development/Validation.
- Continue Flow and Transport Property Scaling Development/Validation.
- Conduct Nonisothermal Flow Model Development/Validation.
- Develop Retardation Model and Validate for Performance Assessment.

Evaluation of this technical area included a review of the WA's for each of the above activities to determine which QA controls were applicable. There appeared to be considerable confusion on the part of the audit sub-team and the SNL technical staff over the meaning of "quality-affecting work" and its implication on the QA controls applied to the work activities. It was asserted that the data currently being collected in this technical area will not be used for licensing purposes. However, the WA's clearly specify applicable QA controls. As part of the technical evaluation of this technical area, the audit sub-team examined several SNL reports. During this examination, the audit sub-team concluded that several published papers did not contain reference to the quality assurance level assigned to the work described within as required by Department Operating Procedure (DOP) 3-17. CAR YM-94-095 was written to address this issue.

The sub-team also examined the scientific notebooks documenting the activities of this technical area. Adverse conditions which were identified included insufficient technical detail and insufficient documentation. With regard to insufficient technical detail, the audit sub-team noted that: (1) rock mass classification process was not traceable, (2) test control parameters were not defined, and (3) the description of work performed was inadequate. Examples of insufficient documentation include: (1) missing titles, and names, (2) use of pencil, (3) use of loose leaf notebooks, and (4) nonsequentially numbered pages. These conditions contributed to CAR 94-YM-099.

5.4.10 Supporting Calculations for Postclosure Performance Assessment Analyses (WBS 1.2.5.4.7)

The audit sub-team examined several QA grading reports and WAs controlling the work activities in this technical area. The audit team identified deficiencies with WAs in the lack of references to

technical procedures and scientific notebook usage (CAR YM-94-088).

Due to the nature of the performance assessment activities examined during the audit, the audit sub-teams were also able to gain insight into the effectiveness of implementation of QA Programmatic Elements 1 and 5 and Supplement I. As noted in the above discussion, the technical specialists observed by the NRC identified deficiencies in Programmatic Elements 1 and 5, and Supplement III. For detailed observations regarding Elements 1 and 5, refer to section 5.3.

The audit sub-teams concluded that the effectiveness of implementation of Supplement I, "Software," is indeterminate at this time due to the lack of software which has been developed since the implementation of QAIP 19-1 on May 31, 1994. The NRC staff agrees with this assessment. The NRC staff also agrees with the audit sub-teams' assessment that implementation of Supplement III, "Scientific Investigations," is marginally effective due to inadequacies in the scientific notebooks.

The NRC staff concludes that the audits of Programmatic Element Supplements I and III were adequate. However, the audit process could have benefitted by evaluating the software developed under QAIP 3-2 even though it is no longer in effect.

5.5 Conclusions

The audit was conducted in a professional manner and the auditors/audit sub-teams adequately evaluated activities and objective evidence.

The auditors/audit sub-teams were well prepared and demonstrated a sound knowledge of the SNL QA program. They interviewed appropriate SNL and support staff personnel. Checklists generally included requirements directly from the QARD as well as requirements from QAIPs. Auditors/audit sub-teams were thorough in their questioning, using their checklists effectively and pursuing issues beyond the checklists when appropriate by asking follow-up questions. The questions were sufficient to determine the compliance to the QAIPs and QARD. They solicited comments and questions from the NRC staff in an appropriate manner. In addition to identifying items needing CARs, the auditors/audit sub-teams suggested recommendations to improve the overall quality of the program.

In general, the technical portion used the vertical slice approach in reviewing the task related documents. This was both useful and sufficient to determine the technical quality of the products.

A caucus of the audit team and observers was held at the close of each work day, resulting in good interfacing and coordination. A meeting of the ATL and SNL management (with observers present) was held each morning to discuss the audit status and preliminary findings.

The SNL personnel appeared well qualified and properly trained, and they had an overall understanding of QA requirements. The SNL Yucca Mountain Project management displayed sincere interest in utilizing the results of the audit to improve the controls and implementation of the SNL QA program. The audit was effective in determining the adequacy and degree of implementation of the SNL QA program.

5.6 Qualification Of Auditors and Technical Specialists

The qualifications of the ATL and auditors were found to be acceptable in that each auditor and the ATL met the requirements of QAP 18.1, "Qualification of Audit Personnel." The sub-teams verified the technical qualifications of the personnel working in the technical areas and found them to be acceptable.

5.7 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.

5.8 Summary of NRC Staff Findings

The NRC staff agrees with the preliminary YMQAD audit team findings that the overall implementation of the SNL QA program is adequate and with the individual Program Element findings presented in Section 5.9. Two areas that were identified as deficient deserve close attention because of their significance to scientific investigations: (1) QAIPs do not meet QARD requirements in a number of areas and do not provide sufficient detail beyond QARD requirements (CAR YM-94-096), and (2) scientific notebooks lack detail to retrace experiments and lack required information (CAR YM-94-099).

The NRC staff did not observe any deficiencies in the audit process.

5.8.1 Good Practice

After auditors identified an apparent trend of insufficient detail in SNL procedures, the ATL promptly arranged for a meeting with SNL management to discuss this issue. In a follow-up meeting, the ATL explained the action (a CAR) that the team was taking and basis for this action. The NRC staff feels that this action should be accepted by SNL in a positive light and that this should lead to appropriate and effective corrective measures.

5.8.2 Weaknesses

The NRC staff did not note any weaknesses in the audit process.

5.9 Audit Team Findings

The audit team determined that, overall, implementation of the SNL QA program was adequate. The status of the specific program elements and CARs associated with those elements were as follows:

Program Element	Status	CARs YM-94-
1 Organization	Effective	
2 Quality Assurance Program	Marginally Effective	090, 092, 094, 099
4 Procurement Document Control	Effective	093
5 Instructions, Procedures,and Drawings	Marginally Effective	096
6 Document Control	Effective	
7 Control of Purchased Items and Services	Effective	097
12 Control of Measuring & Test Equipment	Effective	098
16 Corrective Action	Effective	087, 091
17 Quality Assurance Records	Effective	
18 Audits	Effective	
Supplement I, Software	No Implementation Lack of Activity under new procedure.	
Supplement II, Samples	Effective	
Supplement III, Scientific Investigations	Marginally Effective	088, 089, 095

At the post-audit meeting, the ATL discussed thirteen draft CARs developed during the audit. The CARs are summarized as follows:

CAR YM-94-087 Some closed-out CARs did not show: (1) the extent of the condition, (2) effectiveness of the corrective action, or 3) verification that the corrective action had been completed.

CAR YM-94-088 Work Agreements did not reference applicable technical procedures or address scientific notebook usage.

CAR YM-94-089 No evidence that calculations were conducted in accordance with QAIP 02-04.

CAR YM-94-090 No evidence that two Quarterly Program Reports were provided to YMQAD.

CAR YM-94-091 Three CARS identified deviations from requirements as Observations rather than as Deviations.

CAR YM-94-092 No evidence that personnel training needs were updated.

CAR YM-94-093 Procurement documents were not being forwarded to the Central Records Facility.

CAR YM-94-094 Several records were missing from duplicate training files.

CAR YM-94-095 Quality Assurance Levels were not referenced in published technical documents.

CAR YM-94-096 QAIPs do not meet QARD requirements in a number of areas and do not provide sufficient detail beyond QARD requirements.

CAR YM-94-097 Calibration certificates were accepted but did not conform to procurement document requirements.

CAR YM-94-098 Calibration documentation lacked required information.

CAR YM-94-099 Scientific notebooks lacked detail to retrace experiments, and lacked required information.

Four other potential CARs were acceptably resolved by the SNL organization prior to the post-audit meeting.

ACRONYMS

ATL	Audit Team Leader
CAR	Corrective Action Request
CFR	Code of Federal Regulations
CNWRA	Center for Nuclear Waste Regulatory Analyses
DOE	Department of Energy
DOP	Department Operating Procedure
DWM	Division of Waste Management
EPA	Environmental Protection Agency
EQA	External Quality Assurance
M&TE	Measuring and Test Equipment
NMSS	Nuclear Material Safety and Safeguards
NRC	Nuclear Regulatory Commisssion
OCWRM	Office of Civilian Radioactive Waste Management
QA	Quality Assurance
QAAP	Quality Assurance Administrative Procedure
QAIP	Quality Assurance Implementing Procedure
QARD	Quality Assurance Requirements and Description
QATSS	Quality Assurance Technical Support Services
SNL	Sandia National Laboratories
T&MSS	Technical and Management Support Services
TSPA	Total System Performance Analyses
WA	Work Agreements
YMQAD	Yucca Mountain Site Characterization Quality Assurance Division