

U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE

AUDIT REPORT

OF THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM
MANAGEMENT AND OPERATING CONTRACTOR

AT

SANDIA NATIONAL LABORATORIES

ALBUQUERQUE, NEW MEXICO

AUDIT NUMBER YM-ARP-96-05
JANUARY 22 THROUGH 26, 1996

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Approved by: Donald G. Horton For Date: 2/28/96
Donald G. Horton
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1.0 EXECUTIVE SUMMARY

As a result of Performance Based Quality Assurance (QA) Audit YM-ARP-96-05, the audit team determined that the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) at Sandia National Laboratories (SNL) is satisfactorily implementing an effective QA program and process controls with regards to work performed under Work Breakdown Structure (WBS) 1.2.3.2.7.3.2, "In-Situ Thermomechanical Properties," except for the specific activity that was considered marginal and is documented in a Deficiency Report (DR). The SNL program examined during this audit is in accordance with the U. S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description document (QARD) DOE/RW-0333P, Revision 5. In addition, adequacy of and compliance to selected SNL Quality Assurance Implementing Procedures (QAIP) were found to be satisfactory.

Audit YM-ARP-96-05 was a performance based audit of activities associated with the development of the draft study plan for "In-Situ Thermomechanical Properties 8.3.1.15.1.6," and the Sandia Letter Report, (SLTR)95-0013, "ESF Thermal Test Design: Analysis Status." The study plan was the final SNL draft as delivered to the DOE, dated October 30, 1995, and the SLTR was a published document, dated September 29, 1995. These two documents were the deliverables that SNL produced and were evaluated to determine whether they were acceptable in meeting the needs of the Yucca Mountain Site Characterization Project (YMP) and were prepared under the QA controls required by the QARD.

The audit team identified two deficient conditions during the course of the audit resulting in the issuance of one Performance Report (PR) and one DR plus two deficient conditions being corrected prior to the postaudit meeting (see Section 5.5 of this report). Lack of retention of Technical and Management Review documentation for Work Agreements (WA) 185 and 205 is addressed in DR Yucca Mountain Quality Assurance Division (YMQAD)-96-D034 and PR YMQAD-96-P021 concerns out of sequence approval dates on WA 205, Revision 1. Additionally, there were two recommendations resulting from the audit which are presented in Section 6.0 of this report.

2.0 SCOPE

The performance based audit was conducted to evaluate the effectiveness of SNL's controls for developing the draft study plan for, "In-Situ Thermomechanical Properties

8.3.1.15.1.6,” and the SLTR, “ESF Thermal Test Design: Analysis Status.” The audit was intended to determine the degree to which the resultant products meet the program requirements and management commitments and expectations; as well as to determine that SNL completed the work in accordance with the pertinent sections of the QARD.

The process/activities/end-products evaluated during the audit, in accordance with the approved audit plan, are as follows:

PROCESS/ACTIVITY/END-PRODUCT

Based on scoping discussions with the SNL Technical Project Officer, two deliverables from WBS 1.2.3.2.7.3.2, “In-Situ Thermomechanical Properties,” were selected for evaluation. The specific deliverables evaluated were the draft study plan, “In-Situ Thermomechanical Properties 8.3.1.15.1.6,” and the SLTR, “ESF Thermal Test Design: Analysis Status.”

The performance based evaluation of process effectiveness and product acceptability was based on:

1. Satisfactory implementation of the critical process steps;
2. Use of trained and qualified personnel working effectively;
3. Documentation that substantiates the quality of the products, and
4. Acceptable results and adequate end-products

The SNL critical steps involved the development of the audited deliverables were as follows:

- Identify product based on Site Characterization Plan needs
- Identify process used to start work
- Personnel conducting work are qualified and trained
- Appropriate and effective reviews are conducted
- QA concerns are addressed
- WAs are controlled
- Records are adequately controlled
- Identify planning documents
- Software is controlled
- Interfaces are controlled
- QA oversight of work

In addition, a sample of the applicable QA program requirements and controls as they applied to the deliverable was examined to evaluate the degree of compliance.

Program Elements 3.0, 4.0, 7.0, 12.0, and Supplements I, II, and III were determined, as a result of scoping meetings, to have had no implementation in regards to the products reviewed. The following QA program elements were evaluated for applicability and compliance:

- 1.0 Organization
- 2.0 Quality Assurance Program
- 5.0 Implementing Procedures
- 6.0 Document Control
- 16.0 Corrective Action
- 17.0 Quality Assurance Records

TECHNICAL AREAS

The audit was conducted to evaluate the effectiveness of SNL controls applied the generation and issuance of the draft study plan, "In-Situ Thermomechanical Properties 8.3.1.15.1.6," and SLTR, "ESF Thermal Test Design: Analysis Status."

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of the audit team members and observers and their assigned areas of responsibility:

<u>Name/Title/Organization</u>	<u>QA Program Elements/Requirements Processes, Activities or End-products</u>
Kenneth McFall, Audit Team Leader, (YMQAD)	Programmatic and Critical Process Steps
John Doyle, Auditor, YMQAD	Programmatic and Critical Process Steps
Ronald Smith, Technical Specialist, CRWMS M&O	Critical Process Steps regarding WBS 1.2.3.2.7.3.2
Mysore Nataraja, Observer, U. S. Nuclear Regulatory Commission (NRC)	
Jack Spraul, Observer, NRC	

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

A preaudit meeting was held at the SNL offices in Albuquerque, New Mexico, on January 22, 1996. A daily debriefing and coordination meeting was held with SNL management and staff and observers, and daily audit team meetings were held to discuss issues and potential deficiencies. A daily audit team meeting was also held each evening to coordinate the pace of the audit, to discuss issues, process recommendations, and present potential deficiencies. The audit was concluded with a postaudit meeting held at SNL's offices in Albuquerque, New Mexico on January 26, 1996. Personnel contacted during the audit are listed in Attachment 1. The list includes those who attended the preaudit and postaudit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, in general, with the exception of the areas identified as deficiencies, the SNL's process controls are effectively being implemented for the areas identified in the scope of this audit. The process controls for the development of products associated with WBS 1.2.3.2.7.3.2, specifically, the draft study plan, "In-Situ Thermomechanical Properties 8.3.1.15.1.6," and the SLTR, "ESF Thermal Test Design: Analysis Status," were found to be effective and the products are adequate for the needs of the Project.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders, immediate corrective actions or related additional items resulting from this audit.

5.3 QA Program Audit Activities

The QA program elements evaluated were directly related to SNL activities in generating the draft study plan for, "In-Situ Thermomechanical Properties," and the SLTR, "ESF Thermal Test Design: Analysis Status." The QA program areas found to be directly related to the technical products and activities evaluated were Organization, QA Program, (Qualification and Training of Personnel), Implementing Procedures, Document Control, Corrective Action, and Quality Assurance Records. These areas were determined to be effective overall, except for the lack of retention of review forms which is documented in YMQAD-96-D034 and out of sequence reviews and approvals which is documented in YMQAD-96-P021 (see Section 5.5.2 and 5.5.3 of this report).

A summary table of audit results is provided in Attachment 2. The details of the audit evaluation, along with the objective evidence reviewed, are contained within the audit checklists. The checklists are kept and maintained as QA Records.

5.4 Technical Audit Activities

Technical Assessments were made of two SNL work products, namely:

- "ESF Thermal Test Design: Analysis Status," SLTR 95-0013, issued September 29, 1995
- Draft study plan, "In-Situ Thermomechanical Properties 8.3.1.15.1.6," Revision 0, dated October 30, 1995.

The reviews of these work products included reading of the work products, interviews with SNL technical professionals involved with developing the products, reviews of relevant SNL files and a review of other documents and files that had some relationship or relevance to the two specified work products. The technical professionals interviewed included: Laurence S. Costin, Roy E. Finley, John Pott, and Eric E. Ryder. The work product files reviewed were:

- SNL WA-185: This is the documentation file to cover the work reported in SLTR 95-0013.
- SNL Study Plan File 8.3.1.15.1.6: This is a documentation file that covers the development of the study plan.

Additional relevant technical information reviewed as a part of this assessment included:

- "In-Situ Thermal Testing Program Strategy," DOE/Yucca Mountain Site Characterization Office-003, dated June 1995.
- "Thermal Test Design, Chapters 2, 3, 5, and 7," as issued to CRWMS M&O on December 14, 1995.
- Pre-release Draft of "Operational Plan and Schedule for the First Exploration Studies Facility Thermal Test of Yucca Mountain," SLTR 96-001

- SNL WA-182: This is the working file for work that preceded the two thermal testing work products being reviewed for this audit.
- SNL WA-0116: This working file dealt with design verification instrumentation work in the Exploratory Studies Facility (ESF).

The evaluation of the information and documents indicated a pattern of well documented, quality technical work. It should be noted that the test design for the ESF thermal test design was changing rapidly, as reflected in the documents, and these changes were causing some difficulty for the technical staff. In part, this difficulty may have grown out of the study plan being overly prescriptive in providing "how to do" test design elements rather than restricting the study plan to a focus of data needs and data objects. In fact, the study plan and its predecessor documents, represent a very good job of making systematic analyses of data needs and data objects and, most importantly, of contacting and receiving input on data needs from the groups or customers, that will eventually use the output of the thermal test.

The working file for SLTR 95-0013, WA-185 is well documented and the technical work appears to be of high quality. However, the only observation of concern directly relevant to the audited work involves the working file for WA-185. At the time of our inspection it consisted of a five volume set of loose-leaf notebooks full of calculations, analyses, and summary memorandums. It is recommended that such information be submitted to records control on a more frequent basis. This recommendation is presented as Recommendation No. 1 in Section 6.1 of this report.

Conclusions: Based on the information reviewed and the interviews with the technical staff, it is the technical specialist's opinion that the work is being carried out in a manner that is, to date, both traceable and defensible. The work products were appropriately developed and address the needs of the YMP.

One thing became very obvious as these reports were reviewed, namely that the SNL thermal testing is but one part of a highly complex, multidisciplinary study of the heat effects on the host rock environment at Yucca Mountain. SNL's responsibilities lie in the areas of thermal (T) and mechanical (M) behaviors of the rock. There is no way to separate out the hydrologic (H) and chemical (C) behaviors that occur due to the same heating of the rock. Therefore, SNL's success is highly interdependent on their understanding of the influence of these other major factors, i.e., H and C. To that end, it is recommended that the ESF Thermal Testing Team hold planned, periodic interface meetings between the

Principal Investigators (PI) for all of the major factors, T-M-H-C. This will allow for the transfer of findings in each technology area and facilitate mid-course modifications to the testing program if necessary to optimize its effectiveness. Of special concern in this area is the comparison and discussion of model verification and calibration efforts between the PIs from different laboratories. This is a particularly critical interface issue because eventually these models must be compatible.

A second recommendation is that the thermal test plan include a schedule of customer; i.e., design group, performance assessment group, canister designers, etc., briefings and reviews. This will serve to keep the customers informed of any preliminary findings that could lead to impacts on the customer's output and at the same time make sure that new or developing customer concepts are conveyed to the testing community so that they can provide advice and council based on recent test findings.

Our final technical recommendation is to reiterate what we all know to be sound practice and this is to document, by simple minutes of the meetings, all major points of discussion at each of the interface meetings, i.e., PI, customer, etc. While this action is appropriate to document traceability, it is far more important in assuring a common understanding of what has transpired between the parties of the meeting. The written documentation allows for verification of the mutual understanding of the conclusions reached. The above three recommendations are combined and presented as Recommendation No. 2 in Section 6.2 of this report.

5.5 Summary of Deficiencies

The audit team identified two deficiencies during the audit for which one DR and one PR have been issued. Two additional deficiencies were identified and corrected prior to the postaudit meeting.

A synopsis of the issued DR and PR are detailed below. The DR and PR generated during the audit have been transmitted to you under separate letter, number YMQAD:RBC-1112, dated February 7, 1996.

5.5.1 Corrective Action Requests (CAR)

None

5.5.2 Deficiency Report (DR)

YMQAD-96-D034

The QARD, Revision 5, Subsection 2.2.10, "Document Review," Paragraph F, states: "Mandatory comments resulting from reviews shall be documented and resolved before approving the document." SNL QAIP 1-5, Revision 09, "Establishing Work Agreements," Paragraph 4.1.3, requires the technical and QA reviewers to perform WA reviews according to the criteria provided in QAIP 6-3, resolve comments, and sign and date the WA to document resolution of comments. SNL QAIP 6-3, Revision 03, "Conducting and Documenting Review of Documents," Appendix A, directs the reviewer to use the Document Review and Comment (DRC) Form for reviews and Paragraph 6.0, "Records," requires that the DRCs be retained as QA records. Contrary to the above requirements, there was no evidence that the DRC forms for the reviews of WAs 185 and 205 were completed for mandatory comments.

5.5.3 Performance Report (PR)

YMQAD-96-P021

SNL QAIP 1-5, Revision 09, Paragraphs 4.1.5, 4.1.6, and 4.2.1 require, in "playscript" format, that the technical and QA reviewers of documents sign and date the WA to document the review and resolution of comments followed by the supplier/customer signing and dating the WA indicating approval that all comments have been resolved and establishing an effective date. Contrary to the above requirements the supplier/customer signed and dated WA 205, Revision 01 before the QA reviewer signed and dated the WA.

5.5.4 Deficiencies Corrected During the Audit

Deficiencies which are considered isolated in nature and only requiring remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit.

1. SNL QAIP 6-3, Revision 03, Appendix A, Instruction "A," requires the Review Requester to complete the top portion of the DRC Form (which includes entering the date the request for review goes out and the date which its return is due). Contrary to

this requirement, the aforementioned dates were missing from the DRC Forms for the review of the draft study plan, "In-Situ Thermomechanical Properties." The dates were provided on the DRC Forms prior to the conclusion of the audit.

2. SNL QAIP 1-5, Revision 09, Paragraph 4.3.2 (second #2), requires the customer to provide a "Rationale for Revision" Form when a WA is changed. Contrary to this requirement, WA 205, Revision 01, did not contain a "Rationale for Revision" Form. This condition was corrected prior to the conclusion of the audit.

5.5.5 Follow-up to Previously Identified Deficiency Documents

There were no previously issued deficiency documents related to the deliverables examined that were determined to be applicable to the scope of this audit.

6.0 RECOMMENDATIONS

The following recommendations resulted from the audit and are presented for consideration by SNL management:

- 6.1 It is recommended that SNL start submitting WA records to the records system rather than waiting for all potential record segments to be assembled into one package and then be submitted. This would add additional protection from damage or loss.
- 6.2 It is recommended that SNL hold planned, periodic interface meetings between the PIs for all the major participants in this WBS and that SNL document the interfaces that take place between SNL and other Affected Organizations when information concerning, "In-Situ Thermal Properties," is exchanged. This would allow for verification of mutual understanding of the conclusions reached.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Summary Table of Audit Results

ATTACHMENT 1

Personnel Contacted During the Audit

Name	Organization/Title	Preaudit Meeting	Contacted During Audit	Postaudit Meeting
Arnold, W.	SNL/Technical Staff		X	
Blickley, J.	SNL/Training/Document Control Coordinator		X	
Brady, M.	SNL/Laboratory Lead	X		
Costin, L.	SNL/Manager Geotechnical Investigations	X	X	X
Hawkinson, D.	SNL/MACTEC, QAD		X	X
Jaramillo, C.	SNL/MACTEC QA Coordinator		X	
Pott, J.	SNL/SMTS	X	X	X
Richards, R.	SNL/QA Manager	X	X	X
Ryder, E.	SNL/SMTS	X		X

LEGEND:

QAD Quality Assurance Division
SMTS Senior Member Technical Staff

ATTACHMENT 2
Summary Table of Audit Results

AUDIT YM-ARP-96-05 DETAIL SUMMARY

TECHNICAL DETAILS

QA ELEMENT/ ACTIVITIES	PROCESS STEPS	CHECKLIST DETAILS YM-ARP-96-05	CAR (5.5.1)	DR (5.5.2)	PR (5.5.3)	CDA (5.5.4)	REC (6.0)	ADE- QUACY	COMP- LIANCE	OVER- ALL
In-Situ Thermo- mechanical Properties draft study plan and ESF Thermal Test Design: Analysis Status	Results meaningful	pp. 1, 10, 12, 13, 15 of 16	N	N	N	N	N	SAT	SAT	SAT
	Effect of lack of anticipated prior data	p. 2 of 16	N	N	N	N	N	SAT	SAT	
	Interfaces effective	p. 3 of 16	N	N	N	N	#2	SAT	SAT	
	Traceability Documentation	p. 4 of 16	N	N	N	N	N	SAT	SAT	
	Plans for peer review	p. 4 of 16	N	N	N	N	N	SAT	SAT	
	Adequate Instrumentation	pp. 5, 7, 8, 9, 10, 16 of 16	N	N	N	N	N	SAT	SAT	
	Adequate Reviews	p. 6 of 16	N	YM QAD- 96- D034	YM QAD- 96- P021	# 1 and 2	N	SAT	MARG	
	Adequate Procedures	p. 11 of 16	N	N	N	N	N	SAT	SAT	
	Proper Test Configuration	pp. 11-16 of 16	N	N	N	N	N	SAT	SAT	
	Appropriate methodology	pp. 14 & 16 of 16	N	N	N	N	N	SAT	SAT	

ATTACHMENT 2
Summary Table of Audit Results

QA ELEMENT/ ACTIVITIES	PROCESS STEPS	CHECKLIST DETAILS	CAR (5.5.1)	DR (5.5.2)	PR (5.5.3)	CDA (5.5.4)	REC (6.0)	ADE- QUACY	COMP- LIANCE	OVER- ALL
	Adaptability to change	p. 15 of 16	N	N	N	N	N	SAT	SAT	
PROGRAMMATIC DETAILS										
SNL Activities	Identify Product Based on SCP Needs	pp 1 of 8	N	N	N	N	N	SAT	SAT	SAT
In Situ Thermo- mechanical Properties draft Study Plan and ESF Thermal Test Design Analysis Status	Identify process used to start work	pp 1 of 8	N	N	N	N	N	SAT	SAT	
	Personnel conducting work are qualified and trained	pp 2 of 8	N	N	N	N	N	SAT	SAT	
	Appropriate and effective reviews are conducted	pp 2 and 6 of 8	N	YM QAD- 96- D034	YM QAD- 96- P021	# 1 and 2	N	SAT	MARG	
	Quality assurance concerns are addressed	pp.4 of 8	N	N	N	N	N	SAT	SAT	
	Work Agreements are controlled	pp 3 of 8	N	N	N	N	N	SAT	SAT	
	Records are adequately controlled	pp 3 and 8 of 8	N	N	N	N	#1	SAT	SAT	
	Identify planning documents	pp 4 of 8	N	N	N	N	N	SAT	SAT	

ATTACHMENT 2
Summary Table of Audit Results

QA ELEMENT/ ACTIVITIES	PROCESS STEPS	CHECKLIST DETAILS	CAR (5.5.1)	DR (5.5.2)	PR (5.5.3)	CDA (5.5.4)	REC (6.0)	ADE- QUACY	COMP- LIANCE	OVER- ALL
In Situ Thermo- mechanical Properties Study Plan and ESF Thermal Test Design Analysis Status (contd.)	Software is controlled	pp 5 of 8	N	N	N	N	N	SAT	N/I	SAT
	Interfaces are controlled	pp 5 of 8	N	N	N	N	#2	SAT	SAT	
	QA oversight of work	pp 7 of 8	N	N	N	N	N	SAT	SAT	

ATTACHMENT 2
Summary Table of Audit Results

PROGRAM ELEMENTS AND PROCEDURES

QA ELEMENT/ ACTIVITIES	DOCUMENTS REVIEWED	CHECKLIST DETAILS	CAR (5.5.1)	DR (5.5.2)	PR (5.5.3)	CDA (5.5.4)	REC (6.0) *	ADE- QUACY	COMP- LIANCE	OVER ALL
1	QAIP 1-4, Rev. 00, "Resolution of Quality Assurance Disputes"	pp. 4, 6 of 8	N	N	N	N	N	SAT	SAT	SAT
	QAIP 1-5, Rev. 09, "Establishing Work Agreements"	pp. 1, 3 of 8	N	N	N	N	N	SAT	SAT	
2	YAP-2.2Q, Rev. 0, "Preparation, Review, Approval, and Revision of Site Characterization Study Plans"	p. 2b of 8	N	N	N	N	N	SAT	SAT	SAT
	QAIP 2-4, Rev. 02, "Conducting and Documenting Analyses/ Calculations"	p. 5 of 8	N	N	N	N	N	SAT	SAT	
	QAIP 2-5, Rev 04, "Training"	pp. 2, 2a, 2b of 8	N	N	N	N	N	SAT	SAT	
	QAIP 2-6, Rev 03, "Qualification and Certification of Personnel"	pp. 2, 6 of 8	N	N	N	N	N	SAT	SAT	
5	QAIP 6-2, Rev 03, "Preparing, Reviewing, Approving, and Issuing Technical Information Documents"	p. 6 of 8	N	N	N	N	N	SAT	SAT	SAT

ATTACHMENT 2
Summary Table of Audit Results

QA ELEMENT/ ACTIVITIES	DOCUMENTS REVIEWED	CHECKLIST DETAILS	CAR (5.5.1)	DR (5.5.2)	PR (5.5.3)	CDA (5.5.4)	REC (6.0) *	ADE- QUACY	COMP- LIANCE	OVER- ALL
5 (contd.)	QAIP 6-3, Rev. 03, "Conducting and Documenting Reviews of Documents"	pp. 2, 2a of 8	N	YM QAD- 96- D034	YM QAD- 96- P021	# 1 and 2	N	SAT	MARG	SAT
6	QAIP 6-1, Rev. 02, "Document Control System"	p. 3 of 8	N	N	N	N	N	SAT	SAT	SAT
16	QAIP 16-1, Rev. 06, "Corrective Action"	p. 2b of 8	N	N	N	N	N	SAT	N/I	SAT
	AP-16.1Q, Rev 0, "Performance/Deficiency Reporting"	p. 2b of 8	N	N	N	N	N	SAT	SAT	
	AP-16.2Q, Rev. 0, "Corrective Action and Stop Work"	pp. 2b, 7 of 8	N	N	N	N	N	SAT	N/I	
17	QAIP 17-1, Rev. 02, "Protecting, Preparing, and Submitting YMP QA Records"	pp. 3, 8 of 8	N	N	N	N	#1	SAT	SAT	SAT

*NOTE: There was one additional recommendation concerning documentation of interfaces which was determined to be not applicable to this attachment.

Legend:

CDA Corrected During Audit

MARG .. Marginal

N None

N/I No Implementation

REC Recommendation

SAT Satisfactory