

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

AUDIT REPORT SNL-ARC-97-24
OF
SANDIA NATIONAL LABORATORY
ALBUQUERQUE, NEW MEXICO
AUGUST 18 - 22, 1997

Prepared by: Stephen D. Harris Date: 9-5-97
Stephen D. Harris
Audit Team Leader
Office of Quality Assurance

Approved by: R. W. Carl Date: 9/23/97
for Donald G. Horton
Director
Office of Quality Assurance

9710010310 970924
PDR WASTE
WM-11 PDR

ENCLOSURE

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit SNL-ARC-97-24, the audit team determined that the Sandia National Laboratories (SNL) is satisfactorily implementing the Office of Civilian Radioactive Waste Management (OCRWM) QA program, with the exception of those areas where deficiencies existed, in accordance with the U.S. Department of Energy (DOE) OCRWM Quality Assurance Requirements and Description (QARD) document, DOE/RW-0333P, Revision 7, and SNL's implementing procedures. Implementation of QA Program elements 1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 12.0, 16.0, 17.0, Supplements II, and III were considered satisfactory. Two procedures implementing Program Element 2.0, Supplement I and Supplement V were determined to be unsatisfactory. There was no implementation of QA Program Elements 3.0 and 15.0 and currently no activities apply to QA Program Elements 8.0, 9.0, 10.0, 11.0, 13.0, 14.0, 18.0 and Supplement IV.

The audit team identified three deficiencies during the audit that resulted in the issuance of three OCRWM Deficiency Reports (DR) described in section 5.5.2.

There were seven deficiencies identified by the audit team and corrected prior to the postaudit meeting. These conditions are described in Section 5.5.4 of this report. Additionally, there were seven recommendations resulting from the audit, which are detailed in Section 6.0 of this report.

2.0 SCOPE

The audit was conducted to evaluate the adequacy, compliance, and effectiveness of implementation of the OCRWM QA Program at SNL.

The following QA program elements/requirements were evaluated during the audit, in accordance with the approved audit plan:

QA PROGRAM ELEMENTS/REQUIREMENTS

1.0	Organization
2.0	Quality Assurance Program
3.0	Design Control
4.0	Procurement Document Control
5.0	Implementing Documents
6.0	Document Control
7.0	Control of Purchased Items and Services
12.0	Control of Measuring and Test Equipment
15.0	Nonconformances
16.0	Corrective Action
17.0	Quality Assurance Records

Supp. I	Software
Supp. II	Sample Control
Supp. III	Scientific Investigation
Supp. V	Control of the Electronic Management of Data
Appdx. C	Mined Geologic Disposal System (amplifications to above elements/requirements, as applicable)

The following QA program elements were not reviewed during the audit since SNL currently has no activities to which these elements apply:

8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
11.0	Test Control
13.0	Handling, Storage, and Shipping
14.0	Inspection, Test and Operating Status
18.0	Audits
Supp. IV	Field Surveying

3.0 AUDIT TEAM AND OBSERVERS

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

<u>Name/Title/Organization</u>	<u>QA Program Elements/Requirements.</u>
Stephen D. Harris, Audit Team Leader, OQA	Supplements I and V.
Patrick V. Auer, Auditor, OQA	3.0, 5.0, 6.0, 12.0, 2.0
James Blaylock, Auditor, OQA	4.0, 7.0, 15.0, 16.0
Robert P. Hasson, Auditor, OQA	Supplements II and III
Charles D. Osborne, Auditor, OQA	1.0, 2.0, 17.0
James M. Graff, Observer, OQA Rep. at SNL	

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The preaudit meeting was held on August 18, 1997, at the SNL offices located in Albuquerque, New Mexico. Daily debriefing and coordination meetings were held with SNL's management and staff, and daily audit team meetings were held to discuss audit status. The audit was concluded with a postaudit meeting held on August 22, 1997, at the SNL offices in Albuquerque, New Mexico. 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, overall, the QA program implemented at SNL is adequate and satisfactory for the scope of this audit with the following exceptions: there was no implementation of QA Program Elements 3.0 and 15.0; QA Program Elements Supplement I and V were considered unsatisfactory; QAIP 2-4, Revision 3, and QAIP 2-5, Revision 4, were considered unsatisfactory due to inadequate detail as to how to implement the requirements. The results for each program element evaluated are contained in Attachment 2, Summary Table of Audit Results.

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

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 Summary of Deficiencies

The audit team identified three deficiencies during the audit for which three DRs have been issued. Seven deficiencies were corrected prior to the postaudit meeting.

Synopses of deficiencies documented as DRs, and those corrected during the audit, are presented below. The DRs have been transmitted under a separate letter.

5.5.1 Corrective Action Requests (CAR)

None

5.5.2 Deficiency Reports (DR)

DR YM-97-D-083

SNL has not issued a procedure to implement QARD, Supplement V, requirements for an electronic data maintenance system for Performance

Assessment activities and their controlled document system. A draft procedure is being prepared but has not been issued.

DR YM-97-D-084

QAIP 19-1, Revision 3, "Software Quality Assurance Requirements," does not include Supplement I requirements I.2.6A.2.b., I.2.8B. and I.2.8C. Also, this procedure needs to have more step-by-step methods described such that implementers can perform the procedure the same way each time.

DR YM-97-D-085

WINFIT, software used for X-ray diffraction analysis, is not identified in the Configuraton Management system.

JAC3D, Rev. 6.1-04, User Requirements were deficient in required information, the Validation Plan and an independent technical review for this software were incomplete. A Change Request form for retirement for retirement of the code contained conflicting information.

TOUGH2, version 3.0, Validation Plan and Report does not indicate the version of the code in the text. A Change Request form prepared for an enhanced capability indicated no affected baselines yet included baseline changes.

5.5.3 Performance Reports (PR)

None.

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. QAIP 2-5, Revision 4, "Training," Section 4.1.4, Note 2, requires all personnel to be trained to QAIP 1-4, "Resolution of QA Disputes." QAIP 1-4 had been combined into QAIP 1-2, "Organization and Quality Assurance Program." As determined by review of the "Master Training Matrix," training was given to all personnel for QAIP 1-2, Revision 4, with the exception of six persons who were inadvertently overlooked (B. Arnold, I. Block, L. Carlson, L. Costin, G. Mace, and P. Nguyen). These persons were issued "Training Assignment Forms" for QAIP 1-2 and were added to the training list for future revisions. The Training Assignment Forms have been completed to resolve this deficiency.

2. QAIP 2-5, Revision 4, "Training," Section 4.3.1, requires the Department Manager to evaluate the need for additional training in accordance with QAIP 2-6, Revision 4, "Qualification and Certification of Personnel," Section 4.2. This section also requires the Department Manager to evaluate current proficiency of each individual. Both requirements use the same form "Periodic Evaluation of Personnel Proficiency" from Appendix B of QAIP 2-6. Many of the forms were not filled out by the Department Managers indicating both of these evaluations were performed. These incomplete forms were sent back to the appropriate Department Managers and were completed to indicate both reviews had been performed.
3. The QARD, Section 6.2.5.A., requires documents either in hardcopy or electronic media, used to perform work, to be distributed to, or made available to, and used at, the work location. SNL personnel performing work at the University of New Mexico did not have controlled copies of QAIP 20-1, Revision 5, "Technical Procedures," and Work Agreement (WA)-0329, Revision 1, which were being used to perform work. These documents were obtained and submitted to the appropriate personnel.
4. QAIP 17-1, Revision 3, "Protecting, Preparing, and Submitting CRWM QA Records," Section 4.2.5, requires machine readable media records to be submitted and labeled in accordance with a specific form identified in Appendix A. Contrary to this requirement a different computer generated form was being used to label the SNL report SANDS95-1546. An Expedited Change to this procedure was prepared and issued to permit the use of a form other than the one in Appendix A as long as the appropriate information is included.
5. QAIP 20-3, Revision 2, "Sample Control," Section 4.4, step 3, requires the Principal Investigator (PI)/Task Leader, Custodian, or designee to assure the sample Use/Test/Experiment portion of Appendix B is completed each time the sample is tested or an experiment is performed, if applicable. Contrary to this requirement, the Use/Test/Experiment form is not being completed when samples are tested or used for an experiment. An expedited change to the procedure QAIP 20-3 was issued to delete the need for this form since the data is captured through other documentation.

6. QAIP 6-3, Revision 5, "Conducting and Documenting Reviews of Documents," requires a document reviewer to document acceptance of comment resolution on the Document Reviewer and Comment (DRC) form. SNL reviewers had performed reviews for issued procedures QAIP 19-1, Revision 3, and QAIP 1-2, Revision 12, "Organization and Quality Assurance Program," but documentation had not been completed. The DRC forms for these reviews were completed during the audit in accordance with QAIP 6-3.
7. QAIP 20-2, Revision 1, "Scientific Notebooks," Section 4.1, step 1, requires the PI to document when a scientific notebook (SN) is to be used in a Work Agreement (WA). Contrary to this, WA-0329, Revision 1, "Laboratory Testing for the Exploratory Studies Facility," did not address the use of a SN being used for the X-ray Diffraction activities conducted at the University of New Mexico. A revision was performed to correct this in the WA during the audit. WA-0329, Revision 2, was issued August 21, 1997, identifying the use of a SN for these activities.

5.5.5 Follow-up of Previously Identified CARs and DRs

Follow-up of one DR (YM-96-D-004) was performed during the audit. The DR states that SNL procedures are inadequate in detail. The QA Representative discussed the status of this DR with SNL management and agreed to close the DR when two procedures are modified to add appropriate detail: QAIP 2-4, Revision 3, "Conducting and Documenting Analyses Calculations," and QAIP 2-5, Revision 4, "Training."

6.0 RECOMMENDATIONS

The following recommendations resulted from the audit and are presented for consideration by the SNL's management.

1. The information required to be documented by QAIP 20-2, "Scientific Notebooks," is being met by the content of scientific notebooks, however, it is not easily verified by review. It is recommended a QA review be performed on the SNs along with the technical review performed. This QA review would be done to verify that SNs have addressed the requirements of the procedure.
2. The independent technical reviewer for SNs is required to document their concurrence that the SN has sufficient detail to retrace the investigation and confirm the results, or repeat the investigation and achieve comparable results without recourse to the original author. Although the independent technical

reviewers have provided a documented statement that the SN is acceptable, the documentation doesn't delineate the criteria that was used to perform the review. It is recommended that the documentation include or reference the acceptance criteria used to perform these reviews.

3. It is recommended SNL management conduct training regarding the implementation of YAP-15.1Q, Revision 3, "Control of Nonconformances." It should be emphasized that it is required to implement YAP-15.1Q for out-of-calibration Measuring and Test Equipment (M&TE). The use of M&TE is increasing within SNL and personnel need to be familiar with the requirements of this procedure should the need arise to use it.
4. It is recommended when using the Request to Provide Training on Controlled Documents form contained in QAIP 2-5, "Training," justification be given when not requiring training. An example would be for QAIP 17-1, Revision 3, "Protecting, Preparing, and Submitting CRWM QA Records," which states that it is a total rewrite and incorporates new requirements. The form is marked "No Additional Training Required (Rollover)." Rollover is not defined in the procedure and, even though it was explained during the audit, it is unclear on the form why training was not required to this procedure.
5. It is recommended the procedures that contain forms provide instructions for completion in order to avoid confusion and assure that all forms are completed consistently and accurately.
6. It is recommended QAIP 2-5, "Training," and QAIP 2-6, "Qualification and Certification of Personnel," be revised, in the next revision cycle, to reflect the transition of QA/Quality Control to the DOE OQA. For example, QAIP 2-5, Section 4.2, Step 1, references the SNL CRWMS QA Manager and QAIP 2-6, Section 4.1, Step 5, note 3, references the QA Manager being responsible for certification of the Lab Lead.
7. It is recommended SNL cancel QAIP 3-12, Revision 1, "Peer Review," from their list of implementing documents. The procedure has not been implemented and Peer Reviews are requested by the DOE to be performed using an OCRWM procedure QAP 2.5, "Peer Review."

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

<u>Name</u>	<u>Organization/Title</u>	<u>Preaudit Meeting</u>	<u>Contacted During Audit</u>	<u>Postaudit Meeting</u>
Altman, S.	SNL/Senior Member Tech. Staff	X		
Arnold, B.	SNL/Senior Member Tech. Staff	X		
Barnard, R.	SNL/Senior Member Tech. Staff	X		X
Barr, G.	SNL/ Distinguished Mem.Tech.Staff	X		
Berg, E.	SNL/Contractor (COMPA)	X		
Bouldin, M.	SNL/Training Doc. Control	X		
Brodsky, N.	SNL/Principal Investigator	X	X	
Connolly, J.	UNM/X-ray Diffraction		X	
Costin, L.	SNL/Geomechanical Mgr.	X	X	
Cox, D.	SNL/Budget Coordinator	X	X	
Dockery, H.	SNL/Manager	X		
Francis, N.	SNL/Performance Assessment	X		
Garcia, N.	SNL/Records	X	X	
Gauthier, J.	SNL/Contractor (SPECTRA)	X		
Ho, C.	SNL/Senior Member Tech. Staff	X		
Harrison, K.	SAIC/Records Lead	X	X	X
Hart, K.	SNL/Tech. Reports Coordinator	X		
Heerdt, M.	SNL/Office Admin. Assistant	X		
Itamura, M.	SNL/Performance Assessment	X		
Jackson, B.	SNL/Supports Secretary	X	X	
James, E.	SNL/Tech. Data Records	X	X	X
Martell, M.	SNL/Member Tech. Staff	X		
Martinez, A.	SNL/Training and Doc. Control Lead	X	X	
Orrell, S. A.	SNL/Lab. Lead	X	X	X *
Pelletier, J.	SNL/Performance Assessment	X	X	X
Pickering, S.	SNL/QA Manager	X		
Price, R.	SNL/Senior Member Tech. Staff - EA	X	X	
Schelling, J.	SNL/Engineering Assurance	X	X	X
Schenker, A.	LATA/Tech. Support	X		
Sobolik, S.	SNL/ Principal Investigator		X	

<u>Name</u>	<u>Organization/Title</u>	<u>Preaudit Meeting</u>	<u>Contacted During Audit</u>	<u>Postaudit Meeting</u>
Tucker, M.	SNL/Records Operations Mgr.	X	X	
Warner, P.	SNL/Records Mgr.	X	X	X
Washburn, L.	SNL/Budget Coordinator	X	X	
Yrene, S.	SNL/Budget Coordinator	X		

* By telephone

LEGEND:

EA Engineering Assurance
LATA Los Alamos Technical Associates
QATSS Quality Assurance Technical Support Services

ATTACHMENT 2
Summary of Audit Results
For Procedural Compliance Evaluations

ELEMENT	IMPLEMENTING DOCUMENTS	DETAILS (Checklist)	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
1	QAIP 1-2, R. 12	pg. 2-3	N	N	SAT	SAT	SAT
2	QAIP 1-5, R. 12	pg. 4-7	N	N	SAT	SAT	SAT
	QAIP 2-4, R. 3	pg. 8-14	Exisiting DR YM-96-D-004	N	UNSAT	SAT	
	QAIP 2-5, R. 4	pg. 15-21	YM-96-D-004 CDA #1	#4,5,6	UNSAT	SAT	
	QAIP 2-6, R. 4	pg. 22-26	CDA #2	#6	SAT	SAT	
3	QAIP 3-12, R. 1	pg. 27-30	N	#7	NI	NI	NI
4	QAIP 4-1, R. 8	pg. 31-33	N/A	N/A	SAT	SAT	SAT
5	QAIP 5-1, R. 7	pg. 34-38	N	N	SAT	SAT	SAT
	QAIP 20-1, R. 5	pg. 89-91	CDA #3	N	SAT	SAT	
6	QAIP 6-1, R. 3	pg. 39-42	N	N	SAT	SAT	SAT
	QAIP 6-2, R. 5	pg. 43-50	N	N	SAT	SAT	
	QAIP 6-3, R. 5	pg. 51-53	CDA #6	N	SAT	SAT	
7	AP-7.4Q, R. 2	pg. 54-56	NA	NA	SAT	SAT	SAT
12	QAIP 12-1, R. 5	pg. 57	N	N	SAT	NI	SAT
15	YAP-15.1Q, R.3 11	pg. 58	NA	#3	SAT	NI	NI

ELEMENT	IMPLEMENTING DOCUMENTS	DETAILS (Checklist)	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
16	AP-16-1Q, R. 2	pg. 59-60	N	N	SAT	SAT	SAT
	AP-16.2Q, R. 2	pg. 61-62	N	N	SAT	NI	
	AP-16.4Q, R. 0	pg. 63-64	N	N	SAT	NI	
17	QAIP 17-1, R. 3	pg. 65-69	CDA #4	N	SAT	SAT	SAT
	QAIP 17-2, R. 3	pg. 70-73	N	N	SAT	SAT	
	QAIP 17-3, R. 3	pg. 74-77	N	N	SAT	SAT	
Supl. I	QAIP 19-1, R. 2	pg. 78-83	YM-97-D-085	N	UNSAT	UNSAT	UNSAT
	QAIP 19-1, R. 3	pg. 78-83	YM-97-D-084	N	UNSAT	NI	
Supl. II	QAIP 20-3, R. 2	pg. 84-88	CDA #5	N	SAT	SAT	SAT
Supl. III	QAIP 20-2, R. 1	pg. 92-94	CDA #7	#1, 2	SAT	SAT	SAT
	YAP-SIIL.1Q, R.1	pg. 95	N	N	SAT	SAT	
	YAP-SIIL.3Q, R. 1	pg. 96-99	N	N	SAT	SAT	
Supl. V	No procedures	pg. 100-101	YM-97-D-083	N	UNSAT	UNSAT	UNSAT

Legend:

CDA Corrected during audit
N/A Not applicable
N/I Not Implemented
N None

REC Recommendation
SAT Satisfactory
UNSAT Unsatisfactory