

U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE
AUDIT REPORT
FOR AUDIT OF
SANDIA NATIONAL LABORATORIES
AUDIT NO. YMP-92-09
FEBRUARY 11 THROUGH 13, 1992

PRIMARY ACTIVITIES EVALUATED:

- 1.0 Organization
- 2.0 Quality Assurance Program
- 7.0 Control of Purchased Items and Services
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Storage, and Shipping
- 15.0 Control of Nonconforming Items
- 16.0 Corrective Action
- 18.0 Audits

Prepared by: Neil D. Cox Date: 2/27/92
Neil D. Cox
Audit Team Leader
Yucca Mountain Quality Assurance Division

Prepared by: D.G. Horton Date: 3/6/92
Donald G. Horton
Director
Office of Quality Assurance

ENCLOSURE

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EXECUTIVE SUMMARY

As a result of Quality Assurance Audit YMP-92-09, it was determined that Sandia National Laboratories (SNL) is satisfactorily implementing an effective Quality Assurance Program in accordance with the SNL Quality Assurance Program Description and implementing procedures for Criteria 1.0, 2.0, 7.0, 12.0, 16.0, and 18.0. No implementation of Criteria 13.0 and 15.0 had occurred in order to determine compliance.

The Audit Team identified two deficiencies during the course of the audit. One deficiency was on planning for readiness reviews. This resulted in the issuance of Corrective Action Request (CAR) No. YM-92-021. The other deficiency was loss of a calibration certificate transmitted by New England Research, a subcontractor. This deficiency was corrected during the audit by obtaining a duplicate certificate; therefore, a CAR was not issued.

1.0 INTRODUCTION

This report contains the results of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Audit No. YMP-92-09 performed at Sandia National Laboratories (SNL) by a team of auditors from the Yucca Mountain Quality Assurance Division (YMQAD) of the Office of Quality Assurance (OQA). The audit was conducted February 11 through 13, 1992, at the SNL offices in Albuquerque, New Mexico.

2.0 AUDIT SCOPE

This audit evaluated portions of the SNL QA Program, in accordance with the published audit schedule. The purpose of the audit was to determine whether the requirements and commitments imposed by the OCRWM, as reflected in the SNL Quality Assurance Program Description (QAPD), Revision 0, and implementing procedures were being met. This was done by verifying implementation and effectiveness of the system in place, as well as verifying adequate compliance with requirements.

The applicable programmatic elements evaluated during the audit, in accordance with the published audit schedule, are identified below along with the auditor responsible for the evaluation:

<u>CRITERIA</u>	<u>AUDITORS</u>
1.0 Organization	J Blaylock
2.0 Quality Assurance Program	J. Blaylock
15.0 Control of Nonconforming Items	C. H. Prater
16.0 Corrective Action	N. D. Cox
18.0 Audits	K. T. McFall

In addition, no implementation of three criteria was found during Audit YM-92-03. Therefore, these three criteria were added to the scope of this audit.

<u>CRITERIA</u>	<u>AUDITORS</u>
7.0 Control of Purchased Items and Services	C. H. Prater
12.0 Control of Measuring and Test Equipment	C. H. Prater
13.0 Handling, Storage, and Shipping	C. H. Prater

3.0 AUDIT TEAM AND OBSERVERS

Audit Team

Neil D. Cox, Audit Team Leader, Programmatic Element 16.0
James Blaylock, Auditor, Programmatic Elements 1.0 and 2.0
Kenneth T. McFall, Auditor, Programmatic Element 18.0
Cynthia H. Prater, Auditor, Programmatic Elements 7.0, 12.0, 13.0, and 15.0

Observers

Kenneth R. Hooks, NRC, Washington, DC
Pauline P. Brooks, NRC, Washington, DC

4.0 PERSONNEL CONTACTED

SNL personnel contacted during the audit, see Enclosure 1.

5.0 AUDIT RESULTS

5.1 Program Effectiveness

Overall, SNL is satisfactorily implementing an effective QA Program in accordance with the SNL QAPD and implementing procedures. No program elements or procedures were found to be ineffective; however, there was no implementation of Criteria 13.0 and 15.0 in order to determine compliance. An effectiveness statement for each element audited is provided below:

1. Criteria 1 and 2

Based on the objective evidence examined during the audit, these criteria were found to be implemented satisfactorily.

2. Criterion 7

Based on (1) the satisfactory implementation of QAIP 07-03, Revision 00, for the renewal of the quality-affecting contract with the National Center for Atmospheric Research (NCAR) and (2) on the results of audit YMP-91-07 of SNL, conducted in August 1991, this element of the SNL QA Program is being satisfactorily implemented.

3. Criterion 12

With the exception of one misplaced certificate of calibration which had to be duplicated for SNL by New England Research during the audit, this criterion is being implemented satisfactorily, as applicable, by SNL and its subcontractors.

4. Criterion 13

There was no implementation of this element of the SNL QA Program in order to determine compliance due to the lack of quality-affecting activities involving identification, handling, shipping, and storage of items (DOP 13-01, Rev. D).

5. Criterion 15

There is a system in place for the tracking of nonconformances (NCRs) that has been satisfactorily implemented for one item that was not quality-affecting. However, there have been no quality related NCRs written to date in order to determine compliance.

6. Criterion 16

Based upon the objective evidence examined during the audit, this program element is being implemented effectively.

7. Criterion 18

For the purposes of this of this audit, audits and surveillances were considered parts of Criterion 18. (Note that SNL places surveillances under Criterion 10 in their program). Both audits and surveillances were found to be procedurally adequate and effectively implemented.

5.2 Corrective Action Requests (CARs)

One CAR, YM-92-021, was issued as a result of this audit (see Enclosure 4). There were no open CARs from previous audits that required verification of corrective actions.

5.3 Corrective Action Taken During the Audit

A deficiency was identified during the audit concerning SNL procedure QAIP 12-01, Revision 0, Paragraph 4.3.3 (g). This deficiency pertained to the inability to find a calibration certificate sent to SNL by New England Research. A CAR was closed by SNL prior to the audit exit by obtaining a duplicate copy of the certificate of calibration.

5.4 Audit Details

For details of items and activities examined during the audit, see Enclosures 2 and 3.

6.0 RECOMMENDATIONS

The temporary loss of certificates of calibration transmitted by subcontractors is a potential significant condition adverse to quality. It is strongly recommended that a systematic process be established to store and safeguard these certificates prior to their transmittal to the Local Records Center.

7.0 ENCLOSURES

- Enclosure 1: Personnel Contacted During The Audit
- Enclosure 2: Audit Details
- Enclosure 3: Objective Evidence Reviewed During The Audit
- Enclosure 4: Information Copy of CAR YM-92-021

ENCLOSURE 1

SANDIA NATIONAL LABORATORIES
 YMF-92-09 AUDIT ROSTER

<u>Name</u>	<u>Organization</u>	<u>Title</u>	<u>Pre- Audit</u>	<u>Contacted</u>		<u>Post Audit</u>
				<u>During Audit</u>		
Blaylock, James	DOE/YMQAD	Audit Manager	X			X
Blejwas, Thomas E.	Sandia (6310)	TPO	X	X		
Brooks, Pauline P.	NRC	Observer	X	X		X
Cheek-Martin, Francis	Sandia (6318)	Trainer	X			
Cox, Neil D.	SAIC/YMQAD	Audit Team Leader	X			X
Friend, John C.	MACTEC (6319)	Quality Engineer	X	X		X
Hawkinson, David R.	MACTEC (6319)	Quality Engineer	X	X		
Hooks, Kenneth R.	NRC	Observer	X			X
Hotchkiss, Alice	Sandia (6318)	Records Manager	X	X		X
James, Eliose	Sandia	Records Tech.		X		
Letz, Jerry A.	Sandia (6319)	QA Engineer	X	X		X
Lewis, Barbara	Sandia (6319)	Database Tech.	X	X		X
McFall, Kenneth T.	SAIC/YMQAD	Auditor	X			X
Nimick, Fran	Sandia (6315)	Supervisor	X			
Ostrander, Mary L.	Sandia (6318)	Records Coordinator	X	X		X
Prater, Cynthia H.	SAIC/YMQAD	Auditor	X			X
Price, Ronald H.	Sandia (6315)	PI/TL		X		
Richards, R. R.	Sandia	QA Supervisor	X	X		X
Sandoval, Robert P.	Sandia (6316)	Supervisor	X			
Sharpton, Sarah E.	Sandia (6318)	Supervisor	X			
Thomas, Jessica C.	Teledyne (6318)	Data Base Tech.	X			
Voigt, James V.	MACTEC (6319)	Quality Engineer	X	X		X

ENCLOSURE 2

AUDIT DETAILS

The following is a summary of programmatic activities evaluated during the audit. A list of objective evidence reviewed for these activities is identified in Enclosure 3.

1.0 and 2.0, Organization and Quality Assurance Program

The organizational chart shown in Quality Assurance Implementing Procedure (QAIP) 1-2, Revision 01, Interim change Notice (ICN) No. 1, depicts the current structure. The major change, per ICN 1, was formal deletion of Division 6311 from the organization. The work plans for FY91 and FY92 were reviewed to verify that the Division 6311 responsibilities had been deleted from the Sandia National Laboratories (SNL) scope of work. Minor support tasks have been reassigned to either Division 6313 or Division 6316. The Task Leader delegates the tasks to Task Leaders, based on Work Breakdown Structure (WBS) designation. Each Division supervisor has the requisite administrative, programmatic, and technical control for his/her division. Some of the technical work is performed within the secured area; several of the Quality Assurance (QA) personnel have security clearances and have unfettered access to all work areas. The QA personnel are independent and overview the program through audits, surveillances, and review of documents originated by other than the QA organization. The QA Division has the ability to control/stop work through Quality Assurance Procedure (QAP) 01-03, Quality-Related Work Stoppages. Two of the QAPs, QAP 01-03 and QAP 01-04, Resolution of Quality Assurance Disputes, have not been implemented since the full scope audit of FY91.

Within Criterion 2, two of the QAIPs had not been implemented since the full scale audit. QAIP 02-08, Management Assessment, was implemented during July 1991 and SNL is still within the annual requirement. QAIP 02-02, Study Plan Requirements, was issued during December 1991, and has not been implemented since that time. QAIP 02-10, Determination of Applicable QA Controls, was checked by selecting WBS elements and checking to see that an approved grading report was available. The following elements were checked: s1236216, s12611, s124212, s121441, and s1232711. Reports were available for each element; all had been approved by late 1990 or early 1991. There had been no revisions to any of the grading reports.

Training and qualifications of personnel was also verified. QAP 02-05, Training and Familiarization Procedure, and QAIP 02-06, Qualification and Certification of Personnel, overlap quite a bit. A sample of 15 personnel from SNL and their support contractors was selected to verify that the requisite training and qualification/requalification were current. All files were readily retrieved from the SNL Local Records Center (LRC) and found to contain the needed information. Likewise, QAP 02-07, Qualification of Quality Assurance Audit Personnel, was verified through a sample of 8 auditor/lead auditors. These files were also found to be complete and current with procedural requirements.

7.0 Control of Purchased Items and Services

Since the last audit, YMP-92-03, the quality-affecting contract with the National Center for Atmospheric Research (NCAR) had been renewed. There was satisfactory compliance with the requirements of QAIP 07-03, Evaluation of QA Program Documents.

12.0 Control of Measuring and Test Equipment

SNL states that there is no equipment in-house that requires the controls of Criterion 12. SNL does have subcontractors working to the SNL QA Program. One is New England Research (NER), and the work is quality affecting. Therefore, the records for calibrating the measuring and test equipment must be transmitted to SNL to ultimately become QA Records.

QAIP 12-01, Revision 00, provides the procedure for accomplishing this activity. It was found that NER had transmitted three calibration certificates since the last audit, YMP-92-03; however, just two of these could be found. A duplicate copy of the missing certificate was transmitted by NER during the audit, thus obviating the need to issue a Corrective Action Request (CAR).

13.0 Handling, Storage and Shipping

At the time of the audit, there were no quality-affecting items at SNL. Hence, there was no way of evaluating compliance.

15.0 Nonconformance Control and Reporting

At the time of the audit, there had not been any nonconformance of a quality-affecting item. Hence, compliance of Criterion 15 could not be determined. However, the implementing procedure, QAP 15-01, Nonconformance Control and Reporting, had been satisfactorily applied to a non-quality affecting item, a defective television camera.

16.0 Corrective Action

SNL utilizes three implementing procedures to govern the activities under this criterion. These are:

QAP 16-01, Rev. B, ICN 01, Corrective Action
QAIP 16-02, Rev. 00, Deviation Reporting
QAP 16-03, Rev. A, Quality Assurance Program Report

The results under these are discussed separately.

QAP 16-01, Rev. B. ICN 01

The requirements of this procedure are limited to deficiencies that are significant conditions adverse to quality. SNL states that there have been no such deficiencies. The log set up to track such deficiencies is empty. Therefore, there has been no implementation of this procedure, and its compliance cannot be determined.

QAIP 16-02, Rev. 00

This procedure is implemented for all those deficiencies that are not significant conditions adverse to quality. Such deficiencies are reported either as Deficiency Reports (DRs) or as Audit Finding/Observation Reports (AF/ORs), depending on whether SNL is directly responsible or a subcontractor is, respectively.

The DR log contained 10 entries, 92-01 through 92-10. Three were shown to be closed by corrective actions (92-01, -04, and -05). The DR initiators all provided the specified information, and this was transferred to the DR log as directed. All other required information (such as dispositioner, corrective action, and due date were provided). No deficiency in implementing the procedure was found.

The AF/OR log contained the specified information for three entries, 92-01, 92-02, and 92-03. Just as described above, all of the prescribed information appeared on the forms (such as name of the initiator, the deficient condition, the dispositioner, and the corrective action to be taken). No deficiency in implementing the procedure was found. This procedure was being implemented satisfactorily.

QAP 16-03, Rev. A

This procedure provides the requirements for (1) a semiannual report on the analysis of quality trends and identification of root causes, and (2) bimonthly QA Program reports. Two semiannual reports were found for the periods of September 1990 through April 1991, and April 1991 through October 1991. Three bimonthly reports were found for the composite period July through December of 1991. All reports were found to comply with the requirements for content. No deficiency was found. This procedure was being implemented satisfactorily.

18.0 Quality Assurance Audits With Surveillances Included

For the purposes of this audit Criterion 10, Inspections, and Criterion 18, Audits, were combined. SNL places Surveillances under Criterion 10 rather than 2 or 18, and that is the reason for its inclusion on the audit. There were no deficiencies identified with this criterion.

Compliance to two procedures were reviewed while examining Criterion 18. Audits; specifically:

SNL QAP 18-1, Revision C, ICNs 1 through 3, Quality Assurance Audits

SNL QAIP 10-1, Revision 0, Surveillances

SNL QAP 18-1, Rev. C, Quality Assurance Audits

The examination of QAP 18-1 was limited due to the fact that only one external and no internal audits were conducted since the last full-scope YMP SNL audit which was held in August, 1991. The external audit was conducted on NCAR in Boulder, Colorado.

The SNL audit schedules for internal and external audits was in place as required. The audit schedule was considerably reduced from the prior year due to the decrease in funding for activities. All elements that were applicable to the SNL-NWRT-QAPD for both internal and external activities were either audited or scheduled for audit during the annual time-frame of the schedule. The audit schedule contained all the required information.

The one audit plan available for examination contained all the required information and was properly approved.

All auditors and the lead auditor that participated in the NCAR audit were documented as being properly trained and/or certified as required.

The audit checklists for the NCAR audit were properly prepared according to the directed format and addressed the required parameters as laid out in the audit plan. The checklist also contained a question concerning follow-up on areas of concern resulting from previous audits of NCAR.

The audit was assigned an Audit Designator (unique identifier). The Audit Designator for the NCAR audit was "NCAR-A91-1."

The audit report for the NCAR audit was signed by both the Lead Auditor (Dave Hawkinson) and the QA Coordinator (Bob Richards), as required. The audit report contained the audit scope, personnel contacted, a summary of the audit results, and a description of each reported finding. The requirements that the audited organization investigate the findings, devise and schedule corrective actions, and provide a written response specifying and scheduling corrective action are included in the AF/ORs included as Appendix C of the audit report. Requirements for root cause determination and measures to prevent recurrence of the problem are also included in Appendix C of the audit report.

The SNL NWRT QA organization maintains a tracking system to monitor and keep audit findings and deficiency reports controlled. The system is not proceduralized, nor is it required to be, but it seems to be working well.

QAIP 10-1, Rev. 0, Surveillances

In contrast to QAP 18-1, there were a total of five surveillances that were conducted since the last full-scale YMP audit of SNL. The surveillances were as follows:

Surveillance conducted and report distributed	Surveillance conducted and report not yet distributed
JVV91-04	DRH91-01
JVV92-01	JVV92-03
JVV92-02	

Scheduled surveillances are documented and tracked using Appendix B of this procedure as required. The surveillance schedule was reviewed as updated on a semi-annual basis. The current schedule is dated October 1, 1991, with the prior schedule dated March 25, 1991. The next schedule will be prepared in March of 1992.

Two surveillances (JVV91-04 and JVV92-01) were technical in nature and both surveillances teams consisted of an individual(s) from the QA organization and an individual that was technically qualified to examine the work being conducted. The remainder of the surveillances were non-technical in nature and did not require a technically qualified individual to participate. The surveillance team leader and Team members were verified as being certified by examination of training files. All team leaders and team members are trained as auditors.

The surveillance requester is required to be identified. The "surveillance requester" is identified but not documented. It can be a technical supervisor, the Principle Investigator (PI) for surveillances (Jim Voigt), or the QA Manager. Usually the surveillance PI requests input from knowledgeable technical and QA personnel and receives back either a description of the QA work or lack of work going on. Also, any QA concerns are conveyed back to the surveillance PI. This helps set up the surveillance schedule. There are copies of the requests for input and the associated responses but they are not retained in a formal manner.

Surveillance planning is documented to include a brief description of the area surveilled, identification of the team, the surveilled organization, and the criteria for determining acceptability. The surveillance plans are approved by the SNL Division Supervisor, as required. All were signed by either R. Richards (QA Supervisor) or, as in the case of JVV92-02, L. Costin (supervisor for the technical division where the work was being conducted).

All 5 Surveillance Reports were examined for compliance with paragraph 3.5.1 of this procedure. All the reports contained the required information (a. through i.) or either marked "N/A." as appropriate. Examination of the "cc" lists indicated that the distribution of the 3 Surveillance Reports (that had been distributed) was accomplished, as required.

All documentation that required submittal to the LRC was verified to be located in the LRC.

ENCLOSURE 3

OBJECTIVE EVIDENCE REVIEWED DURING THE AUDIT

PLANS

SNL QAPD, Revision 00
QAP 01-01, Revision 0, ICNs 1 & 2, Quality Assurance Program Plan Control
QAIP 01-02, Revision 01, ICN 1, Organization
QAP 01-03, Revision A, Quality-Related Work Stoppages
QAP 01-04, Revision 0, ICNs 1 & 2, Resolution of Quality Assurance Disputes
QAIP 01-10, Revision 00, Determination of Applicable QA Controls
QAIP 02-02, Revision 00, Study Plan Requirements
QAP 02-05, Revision C, ICNs 1 & 2, Training and Familiarization Procedures
AP 02-07, Revision D, ICN 1, Qualification of Quality Assurance Audit Personnel
QAIP 02-08, Revision 00, Conduct and Reporting of Management Assessments
QAIP 07-03, Revision 00, Evaluation of Contractor QA Program Documents
QAIP 10-01, Revision 00, Surveillances
QAIP 12-01, Revision 00, Measuring and Test Equipment Calibration
DOP 13-01, Revision D, Identification, Handling, Shipping, and Storage of Items
QAP 15-01, Revision A, Nonconformance Control and Reporting
QAP 16-01, Revision B, ICN 1, Corrective Action
QAIP 16-02, Revision 00, Deviation Reporting
QAP 16-03, Revision A, Quality Assurance Program Report
QAP 18-01, Revision C, ICNs 1 & 3, Quality Assurance Audits
DOP 02-09, Revision A, ICNs 1 & 2, Preparedness Review

CONTRACT RENEWAL

National Center for Atmospheric Research, PO No. 35-0035

CALIBRATION CERTIFICATION RECORDS

Sartorius Model L610D, conducted 10/22/91
Voltmeter, HP, Model #3465 A, conducted 1/2/92
Omega Trendicator, 40081A0 1C, 5045089, conducted 10/15/91

AUDIT REPORT - EXTERNAL

Audit NCAR-A91-1

SURVEILLANCE REPORTS

JVV91-04 JVV92-01 JVV92-02 JVV92-03 DRH91-01

DEVIATION REPORTS

92-0192-06
92-0292-07
92-0392-08
92-0492-09
92-0592-10

AUDIT FINDING/OBSERVATION REPORTS

92-01
92-02
92-03

MISCELLANEOUS

Deficiency Report Log-in Notebook

Audit Finding/Observation Report Log-in Notebook

Corrective Action Request Log-in Notebook

QA Control Specification Records (Grading Reports) for WBS Elements: s1236216, s124212, s12611, s121441, and s1232711.

Training Records of 15 SNL and support contractor personnel.

Qualification Records of eight auditor/lead auditor personnel.

ENCLOSURE 4

**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.**

8 CAR NO.: _____
DATE: 2/14/92
SHEET: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document Quality Assurance Requirements Document (QARD), Rev. 4		2 Related Report No. YMP-92-09	
3 Responsible Organization Sandia National Laboratories (SNL)		4 Discussed With R. R. Richards/ Jerry Letz	
5 Requirement: OCRWM QARD (RW-0214), Rev. 4, Section 2.4 requires Readiness Reviews be planned, conducted, and documented.			
6 Adverse Condition: SNL DOP 2-9, Rev. A, paragraph 5.1 implements the planning requirement through the identification and maintenance of a list of preparedness reviews. Such a list does not now exist; furthermore, the requirement for this list of reviews is to be deleted by ICN #2 which becomes effective 2/14/92.			
9 Does a significant condition adverse to quality exist? Yes ___ No ___ If Yes, Circle One: A B C		10 Does a stop work condition exist? Yes ___ No ___; if Yes - Attach copy of SWO If Yes, Circle One: A B C D	
11 Response Due Date:			
12 Required Actions: <input type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination			
13 Recommended Actions:			
7 Initiator James Blaylock Date		14 Issuance Approved by: QADD Date	
15 Response Accepted QAR Date		16 Response Accepted QADD Date	
17 Amended Response Accepted QAR Date		18 Amended Response Accepted QADD Date	
19 Corrective Actions Verified QAR Date		20 Closure Approved by: QADD Date	