

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

AUDIT REPORT

OF THE

SANDIA NATIONAL LABORATORIES (SNL)
BURNUP CREDIT ACTIVITIES

AUDIT NUMBER HQ-ARC-95-11

ALBUQUERQUE, NEW MEXICO
MAY 15-18, 1995

Prepared by:

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Date:

6/7/95

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Approved By:

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Date:

7/31/95

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1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit HQ-ARC-95-11, the audit team determined that Sandia National Laboratories (SNL) is satisfactorily implementing an effective QA program in accordance with the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) QA Requirements and Description (QARD), DOE/RW-0333P, Revision 1 and SNL's implementing procedures for QA Program Elements 1, 2, 4, 5, 10, 16, and 17. QA Program Elements 12, 18, and Supplement III had lack of activity; Element 6 was Marginal; and QA Element 7, and Supplement I were unsatisfactory.

The audit team identified twelve (12) deficiencies during the audit that resulted in the issuance of six (6) Corrective Action Requests (CARs). There were six (6) deficiencies identified by the audit team and corrected prior to the postaudit meeting. These conditions are described in Section 5.5.2 of this report. Additionally, there were six (6) recommendations resulting from the audit, which are detailed in Section 6.0 of this report.

2.0 SCOPE

This audit evaluated the SNL QA Program adequacy and implementation as described in the Quality Assurance Requirements and Description (QARD, DOE/RW-0333P) and the related implementing procedures used to perform Burnup Credit Activities. This audit of Burnup Credit Activities is based on the SNL QA Program being evaluated as adequate and satisfactorily implemented during OCRWM Audit YMP-94-09 conducted August 29 - September 2, 1994. Burnup Credit activities were transferred under the present QA Program in October, 1994.

The QA program elements/requirements evaluated during the audit, in accordance with the approved audit plan, are as follows:

QA PROGRAM ELEMENTS/REQUIREMENTS

1	Organization
2	Quality Assurance Program
4	Procurement Document Control
5	Implementing Documents
6	Document Control
7	Control of Purchased Items and Services
10	Inspection
12	Calibration

16	Corrective Action
17	Quality Assurance Records
18	Audits (SNL Surveillance activities)
Supp. I	Software
Supp. III	Scientific Investigation

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 Technical Areas, Processes, Activities or End-products</u>
Walter Coutier, Audit Team Leader, QATSS	Element 1
Charles Betts, Auditor, QATSS	Elements 2, 5, 6 & 17
Vance Cannaday, Auditor, QATSS	Elements 2, 12, Supp. I & III
F. Hugh Lentz, Auditor, QATSS	Elements 1,2, 4, 7, 10, 16 & 18
Susan Zimmerman, Observer, State of Nevada	

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

A preaudit meeting was held at the SNL offices in Albuquerque, NM on May 15, 1995. A daily debriefing and status meeting was held with SNL management and staff to discuss issues and potential deficiencies. The audit was concluded with a postaudit meeting held at SNL's Albuquerque, NM offices on May 18, 1995. Personnel contacted during the audit are listed in Attachment 1. The list also identifies 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, the Sandia National Laboratories' QA Program is adequate and is being satisfactorily implemented for the scope of this audit. Individually, QA Program Elements 1, 2, 4, 5, 10, 16 and 17 are satisfactorily implemented. QA Program Element 7 and Supplement I were

determined to be unsatisfactory and no implementation of QA Program Elements 12, 18 and Supplement III could be identified due to lack of activity. Implementation of QA program Element 6 was determined to be marginal.

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 Technical Audit Activities

There were no technical audit activities within the scope of this audit.

5.5 Summary of Deficiencies

The audit team identified twelve (12) deficiencies during the audit for which six (6) CARs have been issued. Six (6) additional deficiencies were identified and corrected prior to the postaudit meeting.

Synopses of deficiencies documented as CARs and those corrected during the audit are detailed below. The CARs have been transmitted to you under a separate letter.

5.5.1 Corrective Action Requests (CARs)

CAR HQ-95-006

Work Agreement WA-BUC09-01 requires the SCALE software package be treated as acquired software and therefore subject to QAIP 19-1 controls. QARD, supplement I, Para. I.2.5 requires that acquired software be documented sufficiently to demonstrate the ability of the software to meet the needs of the affected organization. QARD, Supplement I, Para. I.2.1A requires that affected organizations document and approve a life cycle plan for each software item prior to

modification of software or qualification of acquired software. Contrary to the above requirements, the SCALE software package being used in support of the Burnup Credit Analytical Studies has not been documented to meet the requirements of acquired software per QAIP 19-1. The SNL Staff have made changes to the software source code without following the requirements for making changes to software per QAIP 19-1.

CAR HQ-95-007

QARD, Section 7.2.6, Acceptance of Items or Services, states: Methods for supplier furnished items or services shall include one or more of the following, as appropriate to the items or services procured: (List of 5 methods)

Contrary to the above requirements, QAIP 7-1, Procurement Acceptance Verifications, Rev. 01 is not being implemented.

Explanation: The policy on the SNL Invoice Action form, used to document the QARD requirement, was revised in early 1995; but procedure QAIP 7-1 has not been revised.

CAR-HQ-95-008

QARD, Section 6.2.5 states in part that, the distribution and use of documents, including changes and editorial corrections to documents, shall be controlled. List shall be established to identify the current status of each document that is required to be controlled.

Contrary to the identified requirement, the distribution list and use of QAIPs for Burnup Credit Activities, including changes and editorial corrections, are not being adequately controlled. In addition, the list identifying the current status of each YMP QAIP is not being properly maintained.

CAR-HQ-95-009

Appendix C to QAIP 5-1, Rev. 4 [Interim Change Notice (ICN) Form and Instructions] states in part to "Identify the ICN by number next to the affected paragraph."

Contrary to the identified requirement, the ICN Numbers were not being identified next to the affected paragraph of the affected procedures.

CAR-HQ-95-010

QAIP 17-1, Rev. 02, Section 4.1 states in part that, once authenticated, the record source shall place QA records in temporary storage (Dual storage or a certified one-hour fire rated container/facility) until submitted to the LRC.

Contrary to the above identified requirement, the process for authenticating and transmitting the Burnup Credit (BUC) Procurement Documents into SNL's LRC is not clearly defined /controlled by SNL's program documents, (i.e., YMP QAIP 17-1 and 17-3). It was identified that SNL's BUC procurement record packaging practices are not sufficiently reflected in those procedures that generate the record. Presently, BUC procurement records are being packaged and submitted to the LRC as record segments; however, the method by which this process is being controlled has not been established in SNL's program documents.

CAR-HQ-95-011

QAIP 6-1, Rev. 02, Section 4.2 states that the Document Control Staff upon receipt of a controlled document, or a revision, or an ICN to a controlled document, the document control staff shall stamp any forms in the controlled document with the "SAMPLE" stamp.

Contrary to the identified requirement, forms attached to controlled documents are not being stamped "SAMPLE".

5.5.2 Deficiencies Corrected During the Audit (CDA)

Deficiencies which are considered isolated in nature and only require remedial action may be corrected during the audit. The following deficiencies were corrected during the audit:

1. QAIP 1-5, Paragraph 4.2, Step 3 requires a documented description and rationale for revisions to Work Agreements. A documented rationale was not provided for Revision 1 of the Work Agreements developed for Burnup Credit (BUC). The auditor verified that Rationale for Revision forms were completed and distributed for the BUC Work Agreements.
2. QAIP 2-5, Paragraph 5.2, Step 4 requires the Training Manager to complete Section II of the Qualification of Trainer form. Section II for two of three Qualification of Trainer forms, required for instructors of the BUC Personnel Orientation course, were not completed. The auditor verified the completion and distribution of the forms during the audit.
3. QAIP 2-7, Paragraph 4-2, Step 10 requires that objective evidence regarding type and content of the lead auditor examination to be filed in the SNL YMP Records Management Systems. This objective evidence was not found in the file for one SNL lead auditor. The filing of the missing exam information was verified during the audit.
4. QAIP 4-1 requires that Procurement Planning Checklist (PPC) be completed, reviewed, approved, and submitted as a QA Record. The PPC form was not found in Revision 5 of the Martin Marietta Procurement QA Records Package. The auditor verified that the form was added to the file. Also, the auditor observed that the PPC related QA requirements had been incorporated into the appropriate revision of the contract.
5. QAIP 16-1, Paragraph 6.2, Step 5 requires if a due date for corrective action cannot be met, the Responsible Manager will provide justification with a written request for a new date to SNL YMP QA. A timely response or request for extension was not received for the CAR related to the BUC activity. The auditor verified that a justified request for extension was received during the audit.

6. QAIP 6-1, Revision 2, Section 4.3 states that the document recipient/users of SNL YMP controlled documents shall acknowledge receipt of document(s), and revisions and ICNs to documents, as instructed on the "Controlled Document Transmittal and Acknowledgement form".

The Transmittal/Acknowledgement form for one individual for QAGR BUC18, Revision 0 had not been submitted to the document control staff. The form was submitted and verified by the auditor.

6.0 RECOMMENDATIONS

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

1. Training Attendance Record sheet reviewed for the Orientation course provided to BUC personnel did not identify course, title, and date of training. The audit team recommends that all Training Attendance Record forms include course title and date for training conducted.
2. During the evaluation of BUC training activities, a future support person was identified (a calibration technician). The audit team recommends that all similar type BUC support personnel be identified and added to the Qualification Certification/Training program.
3. The upcoming Management Assessment should assure the "Team" composition satisfies the independence intended by QAIP 2-8 and that the QA Records Package provides sufficient objective evidence to confirm procedure compliance.
4. The procurement for AEA Technology, United Kingdom, is in the process of being developed. Because UKAEA works to an ISO 9000 QA Program, the issue of qualified data needs to be resolved. The audit team recommends that this issue continue to be worked and resolved prior to data being used for BUC activities.
5. For the Spent Fuel Safety Experiment (SFSX), the only constant between successive experiments is the elapsed time. In order to establish assurance of consistent time intervals, perform a calibration of the timing device being used to establish elapsed time for the SFSX experiment.

6. QAIP 17-1, Revision 2, Section 4.2.3 Bullets 1 and 2 identify several items that the record source shall include on the first page of the record when preparing record packages. However, it was noted during the audit that not all the items identified would be required for every record package. Therefore, it is recommended that QAIP 17-1, Section 4.2.3 Bullets 1 and 2 be revised to add the phrase "as applicable". The revised section should read as follows:

The record source shall:

- Prepare individual records, not included in a package, to include the following information on the first page of the record as applicable.
- Prepare record packages to include as applicable.

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	ORGAN.	TITLE	PRE	CONTACT	POST
Yolanda R. Aragon	SNL/6352	Financial Assistant		X	X
Doug Brosseau	SNL/6319	SMTS		X	X
Philip J. Cooper	SNL/6514	Criticality Analyst		X	
Freddie Davis	SNL/6302	Task Leader	X	X	X
Thomas F. Ehrhorn	Intera SNL/6319	S/W QA	X	X	
David Eley	SNL/6352	Training Manager	X	X	X
Ronald I. Ewing	SNL/6643	PI/BUC	X	X	
Ray E. Finley	SNL/6313	Acting Manager			X
John Ford	SNL 6521	Reactor (SPR) Supervisor		X	
Dave Hawkinson	MACTEC SNL/6319	QA Engineer	X	X	X
Gary Harms	SNL/6514	PI/SFSX	X	X	
Kevin Harrison	GEO/6352	Lead Records Tech.	X	X	X
Claudette P. Jaramillo	Technadyne SNL/6319	QA Coordinator	X	X	X
Michelle Malloy	SNL/6352	Controlled Document Training and Database Coordinator		X	
Boyce McAnelly	SNL/6521	Cal. Tech		X	
Ellen Edge	SNL/6352	Procurement		X	
Paul Pickard	SNL 6514	Manager		X	
Robert Richards	SNL/NWM- QA	QA Dept. Manager	X	X	X
Michelle Rogo	SNL/6352/GE O-Centers	Records		X	X
Kevin D. Seager	SNL/6643	SMTS	X		
Ken R. Sorenson	SNL/6643	Manager	X	X	
Thomas Vanderbeek	SNL/6502	AREA V QA Coordinator	X	X	
James V. Voigt	MACTEC SNL/6319	QA Engineer	X	X	X
Peggy Warner	6352/SNL	Records Manager		X	X
Nicole Willis	SNL/6352	Training & Database Coordinator (WST)		X	

SUMMARY OF AUDIT RESULTS
ATTACHMENT 2

Audit Report
HQ-ARC-95-11
Page 11 of 12

Audit HQ-ARC-95-11

ELEMENT	DOCUMENTS REVIEWED	DETAILS (✓ List)	CARs	CDAs	RECs	ADEQUACY	COMPLIANCE	OVERALL
1	QAIP 1-2	Pg. 1-2					SAT	SAT
	QAIP 1-3	Pg. 1					LOA	
	QAIP 1-4	Pg. 1-3					LOA	
	QAIP 1-5	Pg. 1-5		No 1			SAT	
2	QAIP 2-4	Pg. 1-3					LOA	SAT
	QAIP 2-5	Pg. 1-5		No 2	No 1 No 2		SAT	
	QAIP 2-6	Pg. 1-3			No 1		SAT	
	QAIP 2-7	Pg. 1-4		No 3			SAT	
	QAIP 2-8	Pg. 1-4			No 3		SAT	
	QAIP 2-9	Pg. 1-3					SAT	
	QAIP 2-10	Pg. 1-2					SAT	
4	QAIP 4-1	Pg. 1-5		No 4	No 4		SAT	SAT
5	QAIP 5-1	Pg. 1-7	HQ-95-009				SAT	SAT
6	QAIP 6-1	Pg. 1-4	HQ-95-008 HQ-95-011	No 6			MARGINAL	MARGINAL
	QAIP 6-2	Pg. 1-6					LOA	
	QAIP 6-3	Pg. 1-4					LOA	
7	QAIP 7-1	Pg. 1-3	HQ-95-007				UNSAT	UNSAT
	QAIP 7-3	Pg. 1-2					LOA	
10	QAIP 10-1	Pg. 1-3					SAT	SAT
12	QAIP 12-1	Pg. 1-4			No 5		LOA	LOA

**SUMMARY OF AUDIT RESULTS
ATTACHMENT 2**

Audit Report
HQ-ARC-95-11
Page 12 of 12

Audit HQ-ARC-95-11

ELEMENT	DOCUMENTS REVIEWED	DETAILS (✓ List)	CARs	CDAs	RECs	ADEQUACY	COMPLIANCE	OVERALL
16	QAIP 16-1	Pg. 1-4		No 5			SAT	SAT
17	QAIP 17-1	Pg. 1-4	HQ-95-010		No 6		SAT	SAT
	QAIP 17-2	Pg. 1-5					N/A	
18	QAIP 18-1	Pg. 1-5					LOA	LOA
SI	QAIP 19-1	Pg. 1-3	HQ-95-006				UNSAT	UNSAT
SIII	QAIP 20-1	Pg. 1-3					LOA	LOA
	QAIP 20-2	Pg. 1-3					LOA	
TOTAL		102	6	6	6			

CARs *Corrective Action Request*
CDAs *Corrected During Audit*
RECs *Recommendations*
ADEQUACY *Requirements in Procedures*
COMPLIANCE .. *Procedure Implementation*
OVERALL *Summary of Element*
N/A *Not Applicable*
LOA *Lack of Activity*
SAT *Satisfactory*
UNSAT *Unsatisfactory*
MARGINAL *Conditions of noncompliance, could lead to unsatisfactory condition*

* Procedure adequacy was evaluated under audit YMP-94-09, reference CAR YM-94-096.