

QA: QA

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

**AUDIT REPORT LLNL-ARC-00-18**

**OF THE**

**CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM  
MANAGEMENT AND OPERATING CONTRACTOR**

**AT**

**LAWRENCE LIVERMORE NATIONAL LABORATORY**

**LIVERMORE, CALIFORNIA**

**SEPTEMBER 11-14, 2000**

Prepared by: \_\_\_\_\_

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## 1.0 EXECUTIVE SUMMARY

As a result of the Quality Assurance (QA) Audit LLNL-ARC-00-18, the audit team determined that the Civilian Radioactive Waste Management System Management and Operating Contractor at Lawrence Livermore National Laboratory (LLNL) is satisfactorily implementing the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 10, and LLNL implementing documents.

QA Program elements 1.0, 2.0, 5.0, 6.0, 12.0, 15.0, 16.0, 17.0, and Supplements I, II, III, and V were determined to be effectively implemented based on the activities evaluated during the audit. Currently, elements 3.0, 4.0, 7.0, 8.0, 9.0, 10.0, 11.0, 13.0, 14.0, 18.0, Supplement IV, and Appendices A, B, and C are not implemented by LLNL.

The audit team identified conditions adverse to quality that are addressed in Deficiency Reports (DR) LLNL-00-D-149, LLNL-00-D-152, and Deficiency Identification and Referral (DIR) 00-23. DR LLNL-00-D-149 identified that LLNL Technical Implementing Procedures (TIP) do not meet the requirements of Yucca Mountain Site Characterization Project Administrative Procedure (YAP)-12.3Q, Revision 0, ICN 1, "Control of Measuring and Test Equipment and Calibration Standards." DR LLNL-00-D-152 identified that record packages for Scientific Notebooks did not meet Administrative Procedure (AP)-17.1Q, Revision 1, ICN 2, "Record Source Responsibilities for Inclusionary Records," requirements. DIR 00-023 identified that responses to two DRs by LLNL did not include impact statements. This will be addressed as part of existing DROQA-00-D-144. Details of these conditions adverse to quality are addressed in Section 5.5 of this report.

The audit team reviewed five deficiency documents identified during previous OCRWM Office of Quality Assurance (OQA) audits to determine the status of effectiveness of completed corrective actions by LLNL. Corrective actions were found to be effective. Details of this review are addressed in Section 5.5.4 of this report.

## 2.0 SCOPE

Auditors representing the U.S. Department of Energy OQA conducted a compliance-based audit to evaluate LLNL's implementation of the OCRWM OQA Program as described in the QARD and implementing procedures at the LLNL facilities. The audit team, through interviews of cognizant personnel, reviews of documentation, and evaluation of procedures, assessed implementation, adequacy and effectiveness of LLNL's implementation of the QA Program.

The audit team reviewed the status of open and closed OCRWM deficiency documents that may have been generated during previous OQA audits and surveillances to determine the effectiveness of in-process and completed corrective actions by LLNL.

The audit team did not evaluate LLNL activities that support the Analysis and Modeling Reports and Process Model Reports which have already been evaluated during previous performance-based audits.

In accordance with the approved audit plan, the following QA Program elements were evaluated.

QA PROGRAM ELEMENTS

1.0	Organization
2.0	QA Program
5.0	Implementing Documents
6.0	Document Control
12.0	Control of Measuring and Test Equipment
15.0	Nonconformances
16.0	Corrective Action
17.0	QA Records
Supplement I	Software
Supplement II	Sample Control
Supplement III	Scientific Investigation
Supplement V	Control of the Electronic Management of Data

The following QA Program elements were not evaluated since LLNL is not currently implementing activities in these areas.

3.0	Design Control
4.0	Procurement Document Control
7.0	Control of Purchased Items and Services
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
Supplement IV	Field Surveying
Appendix A	High-level Waste Form Production
Appendix B	Storage and Transportation
Appendix C	Monitored Geologic Repository

### 3.0 AUDIT TEAM MEMBERS/OBSERVERS

The following is a listing of audit team members and their assigned areas of responsibility.

<u>Name/Title/Organization</u>	<u>QA Program Element</u>
Daniel A. Klimas, Audit Team Leader, OQA/Quality Assurance Technical Support Services (QATSS)	1.0, 15.0, 16.0
John R. Doyle, Auditor, OQA/QATSS	12.0, Supplements II and V
Charles T. Taylor, Auditor, OQA/QATSS	Supplements I and III
Linda A. Galyon, Auditor, OQA/QATSS	2.0, 5.0, 6.0, 17.0

### 4.0 AUDIT TEAM MEETINGS AND PERSONNEL CONTACTED

The pre-audit meeting was held at LLNL on September 11, 2000. Daily debriefings were held to apprise LLNL management and staff of the progress of the audit and to discuss any conditions adverse to quality. A post-audit meeting was held at LLNL on September 14, 2000. Personnel contacted during the audit, including those who attended the pre-audit and post-audit meetings, are listed in Attachment 1, "Personnel Contacted During the Audit."

### 5.0 SUMMARY OF AUDIT RESULTS

#### 5.1 Program Effectiveness

The audit team concluded that, overall, LLNL implementation of the QA Program is adequate and effective. The results for each QA 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 or the need for immediate corrective actions as a result of the audit.

#### 5.3 QA Program Implementation

Attachment 2, "Summary Table of Audit Results," provides results for each QA Program element audited. The details of the audit, including the objective evidence reviewed, are documented in the audit checklists. The checklist is maintained as a QA record.

#### **5.4 Technical Audit Activities**

There were no technical areas evaluated during the audit.

#### **5.5 Summary of Conditions Adverse to Quality**

Two deficiency documents identifying conditions adverse to quality were issued as a result of the audit. One DIR was issued identifying a deficient condition previously identified on an existing DR. Details of the deficiencies and the DIR are documented in Sections 5.5.2 and 5.5.3, respectively.

##### **5.5.1 Corrective Action Request (CAR)**

None.

##### **5.5.2 Deficiency Reports (DR)**

###### LLNL-00-D-149

LLNL TIP-CM-13, “User Calibration of Orion 520A pH Meter,” TIP-CM-04, “User Calibration of Mettler AT2000 Analytical Balance,” and TIP-CM-17, “User Calibration of Denver Analytical Balance,” do not meet the requirements of YAP-12.3Q, such as:

- procedure, including revision level, used to calibrate the instrument;
- identification of and traceability to the calibration standards used for the calibration; and
- results of the calibration and statement of acceptability.

###### LLNL-00-D-152

Record Packages for Scientific Notebooks SN-LLNL-SCI-254-VI, SN-LLNL-SCI-452-VI, and SN-LLNL-SCI-426-VI do not meet the requirements of AP-17.1Q. Examples of missing information includes: Title that identifies the contents of the record; Unique Identifier; and QA Designator.

##### **5.5.3 Deficiency Identification and Referral (DIR)**

###### DIR 00-023

The responses from LLNL for two DRs, LLNL-00-D-003 and LLNL-00-D-006, did not include a statement of impact in the response as required by AP-16.1Q, Revision 4, ICN 1, “Management of Conditions Adverse to Quality.” This condition adverse to quality has been issued as a DIR to previously issued DR OQA-00-D-144.

#### **5.5.4 Follow-up of Previously Issued Deficiency Documents**

The audit team reviewed five DRs that were issued as a result of the previous OCRWM OQA compliance audit of LLNL. This review was to determine the status of in-process and/or effectiveness of completed corrective actions by LLNL. Corrective actions were found to be effective.

Follow-up of DR LLNL-00-D-002 was performed during the audit. The DR identified that LLNL's review of in-process record packages for changes to procedures did not contain objective evidence that the OCRWM OQA On-Site Representative reviewed and concurred with the Requirements Traceability Network/QARD matrix markups.

This DR was satisfactorily resolved, verified, and closed by OQA on December 15, 1999. No new instances of this condition were identified during the audit.

Follow-up to DR LLNL-00-D-003 was performed during the audit. The DR identified that LLNL did not implement procedure AP-17.1Q by not including the QA designator on Development Plans. This DR was satisfactorily resolved, verified, and closed by OQA on December 9, 1999. No new instances of this condition were identified during the audit.

Follow-up to DR LLNL-00-D-004 was performed during the audit. The DR identified that procedures on the controlled document server were not the same as hard copies available and being used at work locations. Additionally, procedures did not contain consistent revision and change notice information on all pages of the document in both hard copy and electronic versions. The DR was satisfactorily resolved, verified, and closed by OQA on January 21, 2000. No new instances of these conditions were identified during this audit.

Follow-up to DR LLNL-00-D-005 was performed during the audit. The DR identified that for QA records previously submitted, corrections and re-transmittal of those records did not contain the accession number of the original record on the corrected record as required by procedure. This DR was satisfactorily resolved, verified, and closed by OQA on January 26, 2000. No instances of these conditions were identified during this audit.

Follow-up to DR LLNL-00-D-006 was performed during the audit. The DR identified that LLNL implementing documents have not been updated to reflect current OCRWM QA requirements. This DR was satisfactorily resolved, verified, and closed by OQA on December 3, 1999. No new instances of these conditions were identified during this audit.

**6.0 RECOMMENDATIONS**

None.

**7.0 LIST OF ATTACHMENTS**

Attachment I, Personnel Contacted During the Audit  
Attachment II, Summary Table of Audit Results

**ATTACHMENT I**

**Personnel Contacted During The Audit**

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Beiriger, Joan	LLNL, Technologist		X	
Campbell, Barbara	LLNL, Code Qualification Manager		X	
Crozier, Christi	LLNL, YMP Administrator		X	
Estill, J. C.	LLNL, Laboratory Supervisor	X	X	X
Fix, David	LLNL, Technical Associate		X	
Horn, J. M.	LLNL, Principal Investigator		X	
King, Kenneth	LLNL, Senior Chemical Technician	X	X	
Kohler, M. H.	LLNL, Laboratory Lead	X	X	X
Lin, Wunan	LLNL, Technical Area Leader		X	X
Monks, Royce	LLNL, Engineering Assurance Manager	X	X	X
Palmer, C. E.	LLNL, Deputy Laboratory Lead			X
Reshel, Tanya	LLNL, QA Administration		X	
Sandoval, Paul	LLNL, Scientific Associate		X	
Scaggs, Kirk	LLNL, Technologist		X	
Stanworth, Pamela	LLNL, Training Coordinator		X	
Warren, C. C.	OQA/QATSS, LLNL On-Site Representative	X	X	X

## ATTACHMENT II

### Summary Table of Audit Results

QA Element/ Activities	Document Review	Checklist Pages	Deficiencies	Recommendation	Program Adequacy	Procedure Compliance	Over all
1.0	LLNL-033-YMP-OP-1.0, R6	Pg. 1	N/A	N/A	SAT	SAT	SAT
2.0	AP-2.1Q, R1 AP 2.2Q, R0 AP-2.19Q, R0, ECN 1 AP-2.20Q, R0 AP-3.15Q, R1, ICN 2	Pg. 6 Pg. 7 Pgs.3,4,5 Pg. 2 Pg. 3	N/A	N/A	SAT SAT SAT SAT SAT	SAT SAT SAT SAT SAT	SAT SAT SAT
5.0	AP-5.1Q, R0, ICN 4 AP-5.2,R0, ICN 1 LLNL-033-YMP-QP-2.1, R9, CN 2.1.9.2 LLNL-033-YMP-QP-5.0, R4, CN 5.00-4	Pg. 8 Pg. 15 Pgs. 13,14  Pgs. 9-12	N/A	N/A	SAT SAT SAT SAT SAT SAT	SAT SAT SAT SAT SAT SAT	SAT
6.0	AP-6.1Q, R5	Pgs. 16,17	N/A	N/A	SAT	SAT	SAT
12.0	YAP-12.3Q, R0, ICN 1	Pgs. 18-24	LLNL-00-D-149	N/A	SAT	UNSAT SAT	SAT
15.0	YAP-15.1Q, R5	Pgs. 25,26	N/A	N/A	SAT	SAT	SAT
16.0	AP-16.1Q, R4, ICN 1 AP-16.4Q, R1	Pgs. 27-31 Pg. 32	DIR-00-23	N/A	SAT SAT	UNSAT SAT	SAT
17.0	AP-17.1Q, R1, ICN 2	Pgs. 33,34	LLNL-00-D-152	N/A	SAT	UNSAT	SAT
SUPP I	AP-SI.1Q, R2, ICN 4	Pgs. 35-48	N/A	N/A	SAT	SAT	SAT
SUPP II	LLNL-033-YMP-QP-8.0, R2, CN 8.0.2.2 YAP-SII.1Q, R3, ICN 1 YAP-SII.2Q, R4 YAP-SII.4Q, R2, ICN 1	Pgs. 53,54  Pg. 49 Pgs. 50,51 Pgs. 51,52	N/A	N/A	SAT SAT SAT SAT SAT	SAT SAT SAT SAT SAT	SAT
SUPP III	AP-SIII.1Q, R1,	Pgs. 55-60	N/A	N/A	SAT	SAT	SAT
SUPP V	AP-SV.1Q, R0, ICN 2	Pgs. 61-63	N/A	N/A	SAT	SAT	SAT
TOTAL	PAGES = 63		2 DRs 1 DIR	0 REC	SATISFACTORY		

**Legend:**

DR                    Deficiency Report  
N/A                  Not Applicable  
REC                  Recommendations  
SAT                  Satisfactory  
UNSAT                Unsatisfactory

