

QA: QA

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

AUDIT REPORT LBNL-ARC-02-06

OF

LAWRENCE BERKELEY NATIONAL LABORATORY

AT

BERKELEY, CALIFORNIA

MARCH 18-22, 2002

Prepared by: _____ **Date:** _____

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Approved by: _____ **Date:** _____

**Ram Murthy
Acting Director
Office of Quality Assurance**

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit LBNL-ARC-02-06, the audit team determined that the Lawrence Berkeley National Laboratory (LBNL) located in Berkeley, CA, is satisfactorily and effectively implementing the applicable portions of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM) QA Program in accordance with DOE/RW-0333P, Revision 10, *Quality Assurance Requirements and Description (QARD)*, OCRWM program procedures, and LBNL implementing procedures.

In addition, the effectiveness of corrective actions related to one previously closed Deficiency Report (DR) was evaluated with satisfactory results. The details are described in paragraph 5.5.5.

2.0 SCOPE

Auditors representing the DOE's OCRWM Office of Quality Assurance (OQA) conducted a compliance audit to evaluate LBNL's implementation of the OCRWM QA Program as described in the QARD and applicable implementing procedures at the LBNL facilities. In addition, observers representing the U.S. Nuclear Regulatory Commission (NRC) observed the audit.

The audit team, through interviews of cognizant personnel, reviews of documentation, and evaluation of procedures, assessed implementation, adequacy, and effectiveness of LBNL's implementation of the QA program.

In addition, the audit team also reviewed one closed OCRWM deficiency document related to LBNL activities to determine the effectiveness of completed corrective actions.

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

1.0	Organization
2.0	Quality Assurance Program
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
Supplement I	Software
Supplement II	Sample Control
Supplement III	Scientific Investigation
Supplement V	Control of the Electronic Management of Data
Appendix C	Monitored Geologic Repository

The following QA Program Sections were not evaluated, as LBNL is currently not implementing them:

3.0	Design Control
4.0	Procurement Document Control
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

3.0 AUDIT TEAM AND OBSERVERS

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

<u>Name/Title/Organization</u>	<u>QA Program Sections</u>
Marilyn A. Kavchak, Navarro Quality Services (NQS) Las Vegas, NV, Audit Team Leader	1.0, 2.0, and 16.0
Patrick V. Auer, NQS, Las Vegas, NV, Auditor	7.0, SIII, SV, App. C
Donald Harris, NQS, Las Vegas, NV, Auditor	6.0, 15.0, SI
Christian Palay, NQS, Las Vegas, NV, Auditor	3.0, 5.0, 17.0 and SII
Robert Toro, NQS, Las Vegas, NV, Auditor	2.0, 3.0, 5.0, 6.0, 12.0

Observers

Wilkins Smith, NRC, Rockville, MD

Rod Weber, Southwest Research Institute, San Antonio, TX

4.0 AUDIT TEAM MEETINGS AND PERSONNEL CONTACTED

The pre-audit meeting was held at LBNL's offices in Berkeley, CA on March 18, 2002. Daily debriefings were held to apprise cognizant management and staff of the progress of the audit and any conditions adverse to quality. The audit was concluded with a post-audit meeting held on March 22, 2002, at LBNL's Berkeley, CA facility.

Personnel contacted during the audit, including those who attended the pre- and post-audit meetings, are listed in Attachment 1, "Personnel Contacted During the Audit."

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

Based on the objective evidence and the sample of information reviewed the audit team concluded overall LBNL's implementation of the QA program is adequate and effective. The results for each QA program section 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 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 section audited. The details of the audit, including the objective evidence reviewed, are documented in the audit checklist. The checklist is maintained as a QA record.

5.4 Technical Audit Activities

There were no technical activities evaluated during this audit.

5.5 Summary of Deficiencies

There were seven conditions adverse to quality identified during the audit resulting in one Deficiency Identification and Referral (DIR) and six corrected during the audit (CDA).

5.5.1 Corrective Action Reports

None.

5.5.2 Deficiency Reports

None.

5.5.3 Deficiency Identification and Referrals

One DIR was issued since a condition adverse to quality was identified that was part of the extent of condition for Corrective Action Report, BSC-01-C-001, related to model validation. DIR 02-7 was written to document that within the Analysis and Model Report, MDL-NBS-HS-000012, Revision 00, *Unsaturated Zone Flow Patterns and Analysis*, a

lack of objective evidence that the modeling of the “Focusing and Discrete Flow Paths in the TSW” had undergone one of the approved approaches for validation of a model. The discussion of model validation in Section 6.4.2.4, “Validation and Alternate Models,” of the cited report states that the model is valid for its intended use because it meets the validation criterion. However, the validation method discussed relies solely on obtaining the modeling approach from a published journal, which implies that the approach has been technically reviewed and accepted via its publication in the open literature. This method does not meet the requirements for model validation detailed in AP-3.10Q, Revision 2, ICN 5, *Analyses and Models*, Section 5.3, “Model Validation” since the actual model was never submitted for technical review through publication in the open literature.

5.5.4 Deficiencies Corrected During the Audit

Six deficiencies CDA are summarized below:

CDA 1 – No sidebars were shown to denote changes or revisions to the LBNL Technical Implementing Procedures AFT-14.0, Revision 0, Mod 1, *Seepage Collection for the Cross-Over Test Between Alcove 8 and Niche 3* and TT 13.0, Revision 0, Mod. 1, *Thermo-Hydrologic Laboratory Studies Sample Collection and Chemical Analysis* as required by the QARD Section 6.2.6.C, and the LBNL-QIP-5.2, Revision 4, Mod 1, *Preparing Quality and Technical Implementing Procedures*. Subject procedures were re-issued during the audit with the sidebars indicating where changes were made as required. This was isolated to a single issue of procedures with these two the only ones missing the bar.

CDA 2 – The LBNL QARD Requirements Matrix defining the implementation of the OCRWM QARD, Revision 10 requirements does not provide adequate justification where requirements are “not applicable.” Justification is required by the QARD, Section 2.2.1.c.1.b, as well as the LBNL-QIP-5.2, Section 3.4.3.B, Revision 4, Mod 1, *Preparing Quality and Technical implementing Procedures*. The LBNL QARD Requirements Matrix was revised during the audit to indicate that all ‘not applicable’ is clarified as not within the LBNL scope of work.

CDA 3 – The LBNL Quality Policy Statement, dated 7/18/95, was out of date since it referenced the commitment to implement LBNL procedures but failed to reference other OCRWM procedures now implemented at LBNL. The LBNL Quality Policy Statement, Revision 1, dated 3/20/02 was issued during the audit to correct this condition.

CDA 4 – ‘File Names’ were not entered in the log of electronic data as required by YMP-LBNL-QIP-SV.0, Revision 2, Mod 0, *Management of YMP-LBNL Electronic Data*. Since the file name is not used for traceability and has not impacted the intended use of the log, the requirement was deleted from the procedure, and a revision to the procedure reflecting the change was issued during the audit.

CDA 5 – LBNL personnel were not completing the “Procurement Initiation Form” as required by YMP-LBNL-QIP-4.3, Revision 1, Mod 1, *Procurement Request Initiation and Acceptance of ‘Q’ Products/Services*, for quality-affecting procurements from suppliers on the OCRWM Qualified Suppliers List (QSL). The subject procedure was revised during the audit to exclude the use of the form for procurements for suppliers on the QSL, where quality-affecting determination has already been made.

CDA 6 - Ultra Scientific Certificates of Analysis did not have a date with the approval signature as required by Blanket Purchase Order 25540-100-PO-17359, Release LBNL-FY2002-01 and AP-12.1Q, Revision 0, ICN 2, *Control of Measuring & Test Equipment*. Ultra Scientific faxed corrected certificates to LBNL to correct the oversight. Correct certificates were transmitted to the Records Processing Center on 3/21/02. Condition was limited to a single release from this supplier.

5.5.5 Follow-up of Previously Identified Conditions Adverse to Quality

One DR was evaluated for effectiveness of corrective action.

DR LBNL-01-D-033 cited scientific work being conducted and tracked electronically without using the scientific notebook to record daily activity. Based on the review conducted during this audit of Supplement III, “Scientific Investigation,” the corrective action (training and a memo issued to cognizant Principal Investigators) was deemed to be effective in controlling the scientific investigations as required. Additionally, the use of copies for performing reviews also was effective since sampled notebooks were accessible during the audit. Previously, notebooks were not available due to the reviews in progress.

6.0 RECOMMENDATIONS

No recommendations were documented for LBNL Management consideration.

7.0 LIST OF ATTACHMENTS

Attachment 1 “Personnel Contacted During the Audit”
Attachment 2 “Summary Table of Audit Results”
Attachment 3 “Acronyms/Abbreviations”

ATTACHMENT 1
Personnel Contacted During the Audit

Name	Organization	Pre-audit Meeting	Contacted During Audit	Post-audit Meeting
Aden-Gleason, Nancy	LBNL/Engineering Assurance Manager	X	X	X
Ahlers, Fredrick	LBNL/Technical Staff		X	
Andrews, Robert	BSC/Performance Assessment Manager	X		X
Beall, George K.	BSC/Commitments Management	X		X
Bodvarsson, Bo	LBNL/Project Manager			X
Burton, Terry	LBNL/Software Quality	X		X
Darnell, Sounia	BSC/Technologist	X		
Dotterer, Marlene	LBNL/Training Coordinator	X	X	X
Fissekidou, Vivi	LBNL/Engineering Assurance	X	X	X
Garland, Vanessa	LBNL/Data Coordination	X		x
Han, Lijie	LBNL/Scientist	X		X
Hardin, Earnie	BSC/Deputy Natural Systems Manager	X		
Harris, Steve	BSC/On-Site QA Representative	X	X	X
Houseworth, Jim	BSC/Unsaturated Zone Deputy Manager	X		
Hu, Qinhong	LBNL/Scientist		X	
Jackson, June	LBNL/Engineering Assurance	X		X
Kneafsey, Tim	LBNL/Principal Investigator		X	
Lau, Peter	LBNL/Project Control Lead	X		
Lewis, Chris	BSC/Science & Engineering		X	
McClung, Ivelina	LBNL/Engineering Assurance & M&TE Coordinator	X	X	X
McDaniel, Mary	BSC/Technical Processes			X
Menendez-Baretto, Melani	LBNL/Research Technician	X	X	X
Persoff, Peter	LBNL/Technical Work Plans	X	X	X
Powe, Richard	BSC/Quality Assurance	X		
Simmons, Ardyth	LBNL/Natural Systems Staff		X	
Swenning, Steve	BSC/Chief Science Officer Staff			X
TerBerg, Robert	LBNL/Technical Data Coordination	X	X	X
Tsang, Yvonne	LBNL/Deputy Project Manager	X	X	X
Valladao, June	LBNL/Engineering Assurance	X	X	X
Watson, William	BSC/Performance Assessment Deputy Manager	X		X
Williams, Nancy	BSC/Manager of Projects			X
Woods, Katherine	LBNL/Research Technician		X	
Yunker, Jean	BSC/Principal Technical Staff	X		X
Zinkovitz, Fred	BSC/Commitment Management Staff	X		

ATTACHMENT 2
SUMMARY TABLE OF AUDIT RESULTS

QARD Sections	Implementing Documents	Checklist Pages	Deficiencies/ DIRs	CDA	REC	Program Adequacy	Procedure Compliance	Overall
1.0	YMP-LBNL-QIP, Rev 3, Mod 1	1-3	N/A	CDA 3	N/A	SAT	SAT	SAT
2.0	AP-2.1Q, Rev.2, ICN 0 AP-2.2Q, Rev1, ICN 0 AP-2.14Q, Rev 2, ICN 0 AP-2.19Q, Rev 0, ICN 0 AP-2.20Q, Rev1, ICN 0 AP-2.21Q, Rev 1, BSCN 1	4-5 6 7-11 12-13 14 15	N/A N/A N/A N/A N/A N/A	N/A N/A N/A CDA 2 N/A N/A	N/A N/A N/A N/A N/A N/A	SAT SAT SAT SAT SAT SAT	SAT SAT SAT SAT SAT SAT	SAT
5.0	YMP-LBNL-QIP-5.2, Rev 4, Mod 0	18-22	N/A N/A	CDA 1 CDA 2	N/A N/A	SAT SAT	SAT SAT	SAT
6.0	AP-6.1Q, Rev 6, ICN 3	23-27	N/A	N/A	N/A	SAT	NI	SAT
7.0	AP-7.7Q, Rev 0, ICN 1 YMP-LBNL-QIP-4.3, Rev 1	28-31 16-17	N/A N/A	CDA 6 CDA 5	N/A N/A	SAT SAT	SAT SAT	SAT SAT
12.0	AP-12.1Q, Rev 0, ICN 2	32-40	N/A	N/A	N/A	SAT	SAT	SAT
15.0	AP-15.2Q, Rev 0, ICN 1	41-43	N/A	N/A	N/A	SAT	NI	SAT
16.0	AP-16.1Q, Rev 4, ICN 1	44-46	N/A	N/A	N/A	SAT	SAT	SAT
17.0	AP-17.1Q, Rev 2, ICN 2	47-53	N/A	N/A	N/A	SAT	SAT	SAT
Supp. I	AP-SI.1Q, Rev 3, ECN 3	54-62	N/A	N/A	N/A	SAT	SAT	SAT
Supp. II	YMP-LBNL-QIP-SII.0, Rev 1, MOD 2	68-73	N/A	N/A	N/A	SAT	SAT	SAT
Supp. III	AP-SIII.1Q, Rev 1, ICN 1 AP-3.10Q, Rev 2, ICN 5	74-93 63-67	N/A DIR 02-7	N/A N/A	N/A N/A	SAT SAT	SAT SAT	SAT SAT
Supp. V	AP-SV.1Q, Rev 0, ICN 2 YMP-LBNL-QIP-SV.0, Rev 2 MOD 0	94-101 101	N/A	CDA 4	N/A	SAT	SAT	SAT
App. C	AP-7.6Q, Rev 0, ECN 1	103-104	N/A	N/A	N/A	SAT	NI	SAT

Legend: CDA = Corrected During Audit
 NA = Not Applicable
 UNSAT = Unsatisfactory

DIR = Deficiency Identification and Referral
 NI = No Implementation
 SAT = Satisfactory

ATTACHMENT 3

ACRONYMS/ABBREVIATIONS

BSC	Bechtel SAIC Company, LLC
CDA	Corrected during the audit
DIR	Deficiency Identification and Referral
DOE	U.S Department of Energy
DR	Deficiency Report
LBNL	Lawrence Berkeley National Laboratory
M&TE	Measuring and Test Equipment
NRC	U.S. Nuclear Regulatory Commission
NQS	Navarro Quality Services
OCRWM	Office of Civilian Radioactive Waste Management
OQA	Office of Quality Assurance
QA	Quality Assurance
QARD	Quality Assurance Requirements and Description
QSL	Qualified Suppliers List