

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

AUDIT REPORT

OF THE

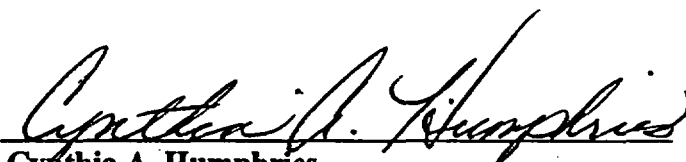
**CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM
MANAGEMENT AND OPERATING CONTRACTOR**

AT

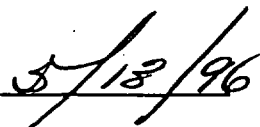
**LAWRENCE LIVERMORE NATIONAL LABORATORY
LIVERMORE, CALIFORNIA**

**AUDIT YM-ARC-96-11
APRIL 22 THROUGH 26, 1996**

Prepared by:



Date:



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Audit Team Leader

Yucca Mountain Quality Assurance Division

Approved by:



Date:



Donald G. Horton

Director

Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit YM-ARC-96-11, the audit team determined that the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) at Lawrence Livermore National Laboratory (LLNL) is satisfactorily implementing an adequate and effective QA program, with the exception of those areas where deficiencies existed, in accordance with the U.S. Department of Energy Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 4 (procedures are currently in transition to Revision 5) and LLNL's implementing procedures for QA Program Elements 1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 13.0, 17.0, 18.0 and Supplements I, II, and III. Implementation of QA Program Element 12 was determined to be unsatisfactory. There was no implementation of QA Program Elements 8.0, 15.0 and 16.0.

The audit team identified five deficiencies during the audit that resulted in the issuance of four Deficiency Reports (DR) and one Performance Report (PR) by the Yucca Mountain Quality Assurance Division (YMQAD). DR YMQAD-96-D054 identifies a requirements conflict between the QARD, Revision 4, Section 2.2.4, "Applying Quality Assurance Controls" and Yucca Mountain Project Quality Procedure 033-YMP-QP-2.8, Revision 4, "Quality Assurance Grading;" DR YMQAD-96-D055 identifies the absence of reviews of the Generic QA Requirement Specification in relation to QARD revisions as required by 033-YMP-QP 4.1, Change Notice (CN) 4.1-3-2, "Preparation of QA Requirements Specifications and Approval of Subcontractor QA Programs;" DR YMQAD-96-D056 identifies that Measuring and Test Equipment (M&TE) used in the collection of quality-affecting data was neither identified nor contained on the M&TE Master Status List as required by 033-YMP-QP 12.0, Revision 6, "Control of Measuring and Test Equipment;" and DR YMQAD-96-D057 identifies the use of an unapproved activity plan for quality-affecting work, contrary to the requirements of 033-YMP-QP 2.1, CN 2.1-6-3, "Preparation, Approval, and Revision of Procedures, Requirements, Plans, and the Quality Assurance Program Description." PR YMQAD-96-P026 identifies an inconsistency between 033-YMP-QP 2.8, Revision 4, "Quality Assurance Grading," and the associated QA Grading Report Review Record, form YMP075, Revision 8.

In addition, seven deficiencies identified by the audit team were corrected prior to the postaudit meeting as described in Section 5.5.4 of this report. Furthermore, there were five recommendations resulting from the audit, which are detailed in Section 6.0 of this report.

Please note that LLNL uses a unique identifier for their procedures after a CN has been issued. The CN number consists of the procedure number, dash revision number, dash CN number, e.g. 033-YMP-QP 4.1, CN 4.1-3-2.

2.0 SCOPE

The audit was conducted to evaluate adequacy of, compliance to, and effectiveness of LLNL's QA Program as described in the QARD and LLNL's implementing procedures.

The QA program elements/requirements evaluated during the audit are in accordance with the approved audit plan as follows with the exception of QA Program Element 8.0 which was added to fully evaluate 033-YMP-QP 8.0, CN 8.0-2-1, "Identification and Control of Items, Samples, and Data."

QA PROGRAM ELEMENTS

- 1.0 Organization
- 2.0 Quality Assurance Program
- 4.0 Procurement Document Control
- 5.0 Implementing Documents
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Items
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Storage, and Shipping
- 15.0 Nonconformances
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits (Surveillances only)
- Supplement I Software
- Supplement II Sample Control
- Supplement III Scientific Investigation

The following QA program elements/requirements were not reviewed during the audit because LLNL has no activity for which these elements apply:

- 3.0 Design Control
- 9.0 Control of Special Processes
- 10.0 Inspection
- 11.0 Test Control
- 14.0 Inspection, Test and Operating Status
- Supplement IV Field Surveying
- Supplement V Electronic Management of Data

3.0 AUDIT TEAM

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

<u>Name/Title</u>	<u>QA Program Element/Requirement</u>
Cynthia A. Humphries, Audit Team Leader, YMQAD	15.0, 16.0
Donald J. Harris, Auditor, YMQAD	1.0, 2.0, 18.0
Stephen D. Harris, Auditor, YMQAD	17.0, Supplement I
John E. Therien, Auditor, YMQAD	4.0, 5.0, 6.0, 7.0
Richard L. Weeks, Auditor, YMQAD	8.0, 12.0, 13.0, Supplements II and III

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The preaudit meeting was held at the LLNL offices in Livermore, California on April 22, 1996. Briefing and coordination meetings were held with the LLNL management and staff on a daily basis. Audit team meetings were also held daily to discuss issues and potential deficiencies. The audit was concluded with a postaudit meeting held at the same LLNL offices on April 26, 1996. A list of personnel contacted during the audit is found in Attachment 1 of this report. The list includes those who attended the preaudit and postaudit meetings.

Cooperation afforded to the audit team during the entire course of the audit was exceptional.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, in general, the LLNL QA Program is adequate and is being satisfactorily implemented for QA Program Elements 1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 13.0, 17.0, 18.0 and Supplements I, II, and III. Implementation of QA Program Element 12 was determined to be unsatisfactory. There was no implementation of QA Program Elements 8.0, 15.0 and 16.0.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders issued; however, immediate corrective action was taken in the form of a management hold for those activities affected by the issuance of DRs YMQAD-96-D056 and -D057.

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 objective evidence reviewed, are contained within the audit checklists. The checklists are kept and maintained as QA Records.

5.4 Technical Audit Activities

None.

5.5 Summary of Deficiencies

The audit team identified five deficiencies during the audit for which four DRs and one PR have been issued. Seven additional deficiencies were identified and corrected prior to the postaudit meeting.

A synopsis of the deficiencies documented as DRs, the PR, and those corrected during the audit are detailed below. The DRs and PR have been issued to the responsible individual by separate letter dated May 8, 1996, YMQAD:RBC-1699, in accordance with Administrative Procedure (AP)-16.1Q, Revision 0, "Performance/Deficiency Reporting."

5.5.1 Corrective Action Requests (CARs)

None.

5.5.2 Deficiency Reports (DRs)

YMQAD-96-D054

033-YMP-QP 2.8, Revision 4, "Quality Assurance Grading," provides a process or methodology that is contrary to the QARD, Revision 4, Section 2.2.4, "Applying Quality Assurance Controls." If within the Statement of Work section contained on the Participant Planning Sheets the notation is made that the "QARD applies to this effort," the process allows for the

activity to be graded out to either nonquality affecting or specifies the QA requirements that apply. In the majority of QA grading reports reviewed, the activities had been graded-out to nonquality affecting.

YMQAD-96-D055

033-YMP-QP 4.1, CN 4.1-3-2, "Preparation of QA Requirements Specifications and Approval of Subcontractor QA Programs," requires the QA Manager to review the QARD revisions vis-a-vis the Generic QA Requirements Specification document and revise the specification, as appropriate. The Generic QA Requirements Specification has not been revised since July 1, 1991, nor is there any evidence that this specification has been reviewed in relation to the various QARD revisions issued since July, 1991.

YMQAD-96-D056

M&TE used in the collection of quality-affecting data was not identified on the M&TE Master Status List as required by 033-YMP-QP 12.0, Revision 6, "Control of Measuring and Test Equipment." M&TE was not labeled with appropriate stickers as required.

YMQAD-96-D057

Contrary to the requirements of 033-YMP-QP 2.1, CN 2.1-6-3, "Preparation, Approval, and Revision of Procedures, Requirements, Plans, and the Quality Assurance Program Description," work was being conducted on "Quality-Affecting Studies for Metal Barrier Studies," Work Breakdown Structure No. 1.2.2.5.1, prior to the approval and issuance of an activity plan. Specifically, Activity Plan E-20-43 and 44, "Critical Pitting Potential Measurements and Critical Crevice Potential Measurements" had not been approved or issued for use. Additionally, an uncontrolled copy of Technical Implementing Procedure (TIP)-YM-6, Revision 6, "Measurement of the pH of Aqueous Solutions with the Glass Electrode," was being utilized for quality-affecting data collection.

5.5.3 Performance Report (PR)

YMQAD-96-P026

The QA Grading Report Review Record, form YMP075, Revision 8, was revised to remove the Task Leader (TL) designation from the form without revising procedure 033-YMP-QP 2.8, Revision 4, "Quality Assurance

Grading." The procedure still has the responsibility for initiating the QA Grading Review process assigned to the TL and this position no longer exists on the LLNL-YMP project.

5.5.4 Deficiencies Corrected During the Audit

Deficiencies that are considered isolated in nature and only requiring remedial action can be corrected during the audit. The following deficient conditions were identified and corrected during the course of the audit:

1. 033-YMP-QP 3.0, CN 3.0-4-3, "Scientific Investigation Control," Section 3.0.4.1 requires that Scientific Investigation Plans (SIP) include a discussion of a number of areas including Issues and Information Needs. SIP-CM-02, Revision 0, "Waste Package Basket Materials," did not address "Issues and Information Needs."

CN SIP-CM-02-0-2 was issued to correct this condition and became effective on April 26, 1996. Section 1.1 of the SIP was added to describe "Issues and Information Needs."

2. 033-YMP-QP 3.2, CN 3.2-3-2, "Software Quality Assurance," requires documentation of a specific life cycle plan. Two codes VTOUGH v. 7.8 and NUFT v. 01 need to have specific information included in the Individual Software Plans (ISP) to describe the process activities LLNL used (or will use for NUFT since it is on hold) for the life cycle plan. ISP-NF-01 for VTOUGH was changed to comply with the above requirements. The ISP for NUFT will be changed upon receipt of funding.
3. 033-YMP-QP 3.2, CN 3.2-3-2, "Software Quality Assurance," requires Scientific Engineering Software (SES) documentation to include a statement "...whether or not the software is to be treated as Blue SES." The above statement was not in the SES documentation for VTOUGH. This was corrected in the VTOUGH ISP, ISP-NF-01, Revision 2.
4. 033-YMP-QP 3.2, CN 3.2-3-2, "Software Quality Assurance," requires identification of the software platform and initials of party making distribution on the Software Distribution Log. This had not been done for VTOUGH distributions. The appropriate corrected information was added to the log.

5. 033-YMP-QP 17.0, CN 17.0-6-3, "Quality Assurance Records," requires corrections to records to have a single line drawn through that part needing correction. New information is to be inserted nearby with the initials and date of the authorized person. Some changes had line-throughs, no initials and date, some had line-throughs with initials but no date. The records were corrected prior to the end of the audit.
6. 033-YMP-QP 17.0, CN 17.0-6-3, "Quality Assurance Records," states that magnetic or optical disks will be kept in a tape vault with controlled humidity and temperature and will be exercised to extend effective shelf life. Two magnetic disks for Borehole USW-G2 Gravity Field Data and Preliminary Density were not being held in this environment. The intent of the section was to control magnetic tapes. The procedure was corrected to require the controlled environment for magnetic tapes rather than magnetic disks.
7. 033-YMP-QP 18.1, CN 18.1-5-2, "Surveillances," was revised during the audit to disallow the correction of findings regardless of significance without performing investigative action, action to prevent recurrence, or documentation of a deficiency document. The procedure now reflects the requirements of OCRWM AP 16.1Q, "Performance/Deficiency Reporting."

5.5.5 Follow-up of Previously Identified CARs

There were no previously identified deficiencies that were determined to be applicable to the scope of this audit.

6.0 RECOMMENDATIONS

The following recommendations resulted from the audit and are presented for LLNL management consideration:

1. LLNL should incorporate grading requirements contained in 033-YMP-QP-2.8, "Quality Assurance Grading," into 033-YMP-QP 2.1, "Preparation, Approval, and Revision of Procedures, Requirements, Plans, and the Quality Assurance Program Description" for inclusion into the activity plan and cancel QP 2.8. This will allow the grading requirements to be fully integrated into the activity plan which is the actual working document.

2. It is recommended that LLNL initiate surveillances as scheduled or revise the schedule to reflect current status of activities proposed for surveillance. Prior to the approval of the surveillance reports, assure that any deficiencies corrected during the course of the surveillance complies with OCRWM AP 16.1Q, "Performance /Deficiency Reporting." Performance conditions and any corrective action are documented in the report with sufficient description to allow traceability of the affected document or activities.
3. Qualification of software is not being completed for certain software, (e.g., PIGS and YMM), that has been graded as nonquality-affecting but is expected to be used to support Yucca Mountain studies. It is recommended that further evaluation of software be conducted to determine if additional qualification activities or documentation is necessary to support viability assessment or a licensing application.
4. 033-YMP-QP 3.2, Revision CN 3.2-3-2, "Software Quality Assurance," Section 3.2.2.10.B states that for the use of software, specific information shall be included in the documentation (date of use, software package name, distribution package version number, etc.). For report UCRL-ID-121791, "Thermal-Hydrological Analysis of Large-Scale Thermal Tests in the Exploratory Studies Facility at Yucca Mountain," dated October 30, 1995, this information was very difficult to obtain even for someone familiar with the report. It is recommended a process be developed and described in a LLNL procedure that will permit this information to be easily obtainable and available upon request.
5. 033-YMP-QP 17.0, CN 17.0-6-2, "Quality Assurance Records," states, "...the Local Records Center (LRC) shall submit all records received to the CRWMS M&O Records Management Organization within three months of receipt." The LRC has a traceable date of receipt for records packages, but not for individual records. It is recommended LLNL develop and describe in one of their procedures a process for documenting the date of receipt of individual records in the LRC.

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>
Alegre, B.	LLNL-YMP/Administration - Records	X	X	X
Bell, V.	LLNL-YMP/Resource Analyst	X	X	X
Brumburgh, C.	LLNL-YMP/QA Administrative Specialist	X	X	X
Bryan, B.	LLNL-YMP/Project Administrator	X	X	X
Buscheck, T.	LLNL-YMP/LPI Geohydrology		X	
Clarke, W.	CRWMS LLNL-YMP Manager	X	X	X
Dalder, E.	LLNL-YMP/PI Metallic Barriers		X	
Develer, S.	LLNL-YMP/PI Software Quality Engineer NFE		X	
Estill, J.	LLNL-YMP/Senior Technologist EBS		X	
Fleming, D.	LLNL-YMP/Technologist EBS		X	
Gordon, S.	LLNL-YMP/Laboratory Assistant EBS Materials		X	
Gdowski, G.	LLNL-YMP/PI Corrosion Testing		X	X
Halsey, W.	LLNL-YMP/TAL Performance Assessment & Systems		X	
Henshall, G.	LLNL-YMP/PI Corrosion Modeling		X	
McCreary, J.	LLNL-YMP/Administration - Publications		X	
McCright, D.	LLNL-YMP/TAL EBS Materials	X	X	X
Monks, R.	LLNL-YMP/QA Manager	X	X	X
Palmer, C.	LLNL-YMP/PI TDD	X		
Podobnik, J.	LLNL-YMP/Project Control Manager	X	X	X
Revelli, M.	LLNL-YMP/PI Systems	X		X
Roy, A.	Framatome Cogema Fuels/PI EBS		X	
Sharp, J.	LLNL-YMP/Training Coordinator		X	
Steward, S.	LLNL-YMP/LPI WFC Spent Fuel Dissolution	X	X	X
Stewart, M.	LLNL-YMP/ Document Control Coordinator		X	
Stout, R.	LLNL-YMP/TAL WFC	X	X	X
Strauch, M.	FESSP/ADAD	X		X
VanKonynenburg, R.	LLNL-YMP/PI Basket Materials	X		X
Weed, H.	LLNL-YMP/PI Scientist/Engineer Flow-Through UO ₂ Test	X		
Wilder, D.	LLNL-YMP/TAL NFE Characterization	X	X	X
Wilgus, C.	Laser-Computer Programs/Software Engineer		X	

LEGEND:

ADAD	Assistant Deputy Associate Director	PI	Principal Investigator
EBS	Engineered Barrier Systems	TAL	Task Area Leader
FESSP	Fission Energy and Systems Safety Program	TDD	Thermo Dynamic Data
LPI	Lead Principal Investigator	WFC	Waste Form Characterization
NFE	Near Field Environment		

ATTACHMENT 2

Summary of Audit Results

AUDIT YMP-ARC-96-11 DETAIL SUMMARY

QA ELEMENT	DOCUMENTS REVIEWED	DETAILS (Checklist)	CAR (5.5.1)	DR (5.5.2)	PR (5.5.3)	CDA (5.5.4)	REC (6.0)	ADEQUACY	COMPLIANCE	OVERALL
1	033-YMP-QP 1.0, R5	pg. 3	N	N	N	N	N	SAT	SAT	SAT
2	033-YMP-QP 2.0, CN 2.0-2-3	pg. 4	N	N	N	N	N	SAT	SAT	SAT
	033-YMP-QP 2.1, CN 2.1-6-3	pgs. 5-7	N	YMQAD -96- D057	N	N	N	SAT	SAT	
	033-YMP-QP 2.2, CN 2.2-1-2	pgs. 8-9	N	N	N	N	N	SAT	SAT	
	033-YMP-QP 2.3, R1	pgs. 10-12	N	N	N	N	N	SAT	SAT	
	033-YMP-QP 2.4, CN 2.4-1-1	pgs. 13-15	N	N	N	N	N	SAT	N/I	
	033-YMP-QP 2.5, CN 2.5-1-2	pgs. 16-18	N	N	N	N	N	SAT	N/I	
	033-YMP-QP 2.6, CN 2.6-2-1	pgs. 19-20	N	N	N	N	N	SAT	SAT	
	033-YMP-QP 2.8, R4	pgs. 21-22	N	YMQAD -96- D054	YMQAD -96- P026	N	1	SAT	SAT	
	033-YMP-QP 2.9, CN 2.9-5-3	pgs. 23-26	N	N	N	N	N	SAT	SAT	
	033-YMP-QP 2.10, CN 2.10-5-2	pgs. 27-29	N	N	N	N	N	SAT	SAT	

AUDIT YMP-ARC-96-11 DETAIL SUMMARY

QA ELEMENT	DOCUMENTS REVIEWED	DETAILS (Checklist)	CAR (5.5.1)	DR (5.5.2)	PR (5.5.3)	CDA (5.5.4)	REC (6.0)	ADEQUACY	COMPLIANCE	OVERALL
4	033-YMP-QP 4.0, R5	pgs. 30-31	N	N	N	N	N	SAT	SAT	SAT
	033-YMP-QP 4.1, CN 4.1-3-2	pgs. 32-33	N	YMQAD -96- D055	N	N	N	SAT	SAT	
5	033-YMP-QP 5.0, CN 5.0-4-1	pgs. 34-36	N	N	N	N	N	SAT	SAT	SAT
6	033-YMP-QP 6.0, R4	pgs. 37-40	N	N	N	N	N	SAT	SAT	SAT
7	033-YMP-QP 7.0, CN 7.0-1-1	pgs. 41-44	N	N	N	N	N	SAT	SAT	SAT
8	033-YMP-QP 8.0, CN 8.0-2-1	pgs. 45-47	N	N	N	N	N	SAT	N/I	N/I
12	033-YMP-QP 12.0, R6	pgs. 52-57	N	YMQAD -96- D056	N	N	N	SAT	UNSAT	UNSAT
13	033-YMP-QP 13.0, CN 13.0-1-3	pg. 58	N	N	N	N	N	SAT	SAT	SAT
15	YAP 15.0, R3	pgs. 59-64	N	N	N	N	N	SAT	N/I	N/I
16	AP 16.1, R0	pgs. 65-75	N	N	N	N	N	SAT	N/I	N/I
	AP 16.2, R0	pgs. 76-82	N	N	N	N	N	SAT	N/I	
17	033-YMP-QP 17.0, CN 17.0-6-3	pgs. 83-88	N	N	N	5&6	5	SAT	SAT	SAT

AUDIT YMP-ARC-96-11 DETAIL SUMMARY

QA ELEMENT	DOCUMENTS REVIEWED	DETAILS (Checklist)	CAR (5.5.1)	DR (5.5.2)	PR (5.5.3)	CDA (5.5.4)	REC (6.0)	ADEQUACY	COMPLIANCE	OVERALL
18	033-YMP-QP 18.1, CN 18.1-5-2	pgs. 89-91	N	N	N	7	2	SAT	SAT	SAT
	033-YMP-QP 18.2, CN 18.2-3-2	pgs. 92-95	N	N	N	N	N	SAT	SAT	
SI	033-YMP-QP 3.2, CN 3.2-3-2	pgs. 96-113C	N	N	N	2,3 &4	3&4	SAT	SAT	SAT
SII	033-YMP-QP 8.0, CN 8.0-2-1	pgs. 48-51	N	N	N	N	N	SAT	SAT	SAT
SIII	033-YMP-QP 3.0, CN 3.0-4-3	pgs. 114-119	N	N	N	1	N	SAT	SAT	SAT
	033-YMP-QP 3.3, CN 3.3-3-2	pgs. 120-121	N	N	N	N	N	SAT	SAT	
	033-YMP-QP 3.4, CN 3.4-3-4	pgs. 122-127	N	N	N	N	N	SAT	SAT	
	033-YMP-QP 3.5, CN 3.5-1-1	pg. 128	N	N	N	N	N	SAT	SAT	
	033-YMP-QP 3.6, R0	pg. 129	N	N	N	N	N	SAT	SAT	
TOTAL		132	0	4	1	7	5			

LEGEND:

AR Corrective Action Request
R Deficiency Report
R Performance Report
DA Corrected During the Audit
..... None
/A Not Applicable
/I No Implementation

ADEQUACY Requirements in Procedure meet QARD
COMPLIANCE Procedures Implemented
OVERALL Summary of Element
SAT Satisfactory
REC Recommendations
UNSAT Unsatisfactory