May 15, 2002

Mr. Ronald A. Milner, Chief Operating Officer
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION'S OBSERVATION AUDIT REPORT NO. OAR-02-06, "OBSERVATION AUDIT OF THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT, OFFICE OF QUALITY ASSURANCE, AUDIT NO. LLNL-ARC-O2-07"

Dear Mr. Milner:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report No. OAR-02-06. It is on the U.S. Department of Energy's (DOE's), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) audit of Lawrence Livermore National Laboratory (LLNL) on April 15-19, 2002.

The OQA audit team (audit team) performed a full-scope compliance-based quality assurance (QA) audit to evaluate LLNL's implementation of the applicable provisions of the OCRWM Quality Assurance Requirements and Description (QARD) document, DOE/RW-0333P, Revision 10, and associated implementing procedures relevant to LLNL activities supporting the Yucca Mountain Site Characterization Project Office. During the audit, the audit team examined the effectiveness of the actions taken to correct deficiencies identified during the previous audits and surveillances performed by OQA.

The NRC observers (observers) determined that DOE's audit of LLNL was effective in identifying potential deficiencies and recommending improvements for LLNL activities reviewed. During the conduct of the audit, both the audit team and the observers independently reviewed applicable QA procedures, and activities within the audit's scope.

Although the audit team identified potential deficiencies, and quality observations, the observers believe that LLNL has shown considerable improvement in the implementation of its QA program. The observers initiated an audit observation inquiry (AOI) regarding the Bechtel SAIC Company's implementation of the QARD, in the procurement of materials. The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit meeting.

A written response to this letter and the enclosed report is not required; however, we do request that you respond to AOI No. LLNL-ARC-02-07 provided to the audit team during the audit and discussed in the attached report. The staff will continue to interface with OCRWM and follow the progress that LLNL is making to address the issues identified during this audit. If you have any questions, please contact Wilkins Smith of my staff at (301) 415-5788.

Sincerely,
/RA/

Janet Schlueter, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report
No. OAR-02-06, "Observation Audit of the
Office of Civilian Radioactive Waste Management,
Office of Quality Assurance, Audit No. LLNL-ARC-02-07"

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No. OAR-02-06, "Observation Audit
of the Office of Civilian Radioactive Waste Management,
Office of Quality Assurance, Audit No. LLNL-ARC-02-07"

cc: See attached list.

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Letter to R. Milner from J. Schlueter dated May 15, 2002

cc:

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C. Meyers, Moapa Paiute Indian Tribe

V. Miller, Fort Independence Indian Tribe

A. Bacock, Big Pine Paiute Tribe of the Owens Valley

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D. Eddy, Jr. Colorado River Indian Tribes

J. Leeds, Las Vegas Indian Center

U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-02-06

"OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT,

OFFICE OF QUALITY ASSURANCE,

AUDIT NO. LLNL-ARC-O2-07"

/RA/ 05/09/02
Kamalakar R. Naidu
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

/RA/ 05/ /02
T. C. Trbovich
Center for Nuclear Waste Regulatory Analyses

Reviewed and Approved by:

/RA/ 05/12/02
N. King Stablein, Chief
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management and the Center for Nuclear Waste Regulatory Analyses (CNWRA) observed the U.S. Department of Energy's (DOE's) Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) audit of Lawrence Livermore National Laboratory (LLNL), Livermore, California.

In support of the Civilian Radioactive Waste Management System (CRWMS) contract, LLNL provides management support and technical services for the Yucca Mountain Project to the Bechtel SAIC Company (BSC). On March 1, 2001, BSC prepared a statement of work (SOW), in coordination with work assignments by each BSC project manager supporting the CRWMS BSC contract. This SOW documents what LLNL is authorized to do. All quality-affecting work is to be accomplished in accordance with DOE/RW-0333P, Revision 10, the Quality Assurance Requirements and Description Document (QARD), including Addendum 1, "Integrated Safety Management Quality Assurance Plan." LLNL is required to prepare a Technical Work Plan that describes how the quality assurance (QA) planning requirements from the QARD, including Addendum 1, are met. After BSC approves the Technical Work Plan, LLNL may begin any quality-affecting work.

The following are some of the activities in progress at LLNL:

- Material service investigations for waste packages, including microbiologically influenced corrosion.
- Thermalhydrological studies to provide information that is fed into Total System Performance Assessments (TSPA).
- Chloride 36 studies to test for the presence of chlorine 36 in rock sample pore water.
- Geochemistry studies related to the water chemistry in rock samples collected from the Yucca Mountain Site Characterization Project (YMSCP).
- Thermalhydrological modeling in support of the Engineered Barrier Systems and TSPA.
- Thermalhydrological Mechanical modeling in support of the unsaturated zone flow and transport model.

The objectives of the OQA audit were to assess the adequacy and effectiveness of the QARD and implementing procedures, and to verify LLNL's compliance with the requirements in the areas reviewed. The NRC observers' (observers') objective was to assess the effectiveness of the OQA audit team (audit team) and audit process, as well as the LLNL implementation of the provisions in the QARD. This report documents the observers' determination of the effectiveness of the OQA audit, and the LLNL implementation of QARD provisions.

2.0 MANAGEMENT SUMMARY

The observers determined that OQA Audit LLNL-ARC-02-07 was effective in determining the level of compliance, of LLNL QA activities, with the QARD and associated implementing procedures. The audit team identified two potential conditions adverse to quality that were documented as Potential Deficiencies (DRs), one Deficiency Identification Referral (DIR), and three potential Quality Observations (QOs). The observers identified one Audit Observer Inquiry (AOI) requesting OQA to verify that Bechtel SAIC Company (BSC) fully implemented the QARD requirements in the procurement of materials (welded metal plates) and non-destructive examination services. The observers agreed with the audit team's conclusions, findings, and recommendations. The observers found that the audit team members were qualified, independent of the activities that they reviewed, and knowledgeable of the QA requirements. Based on these observations, the observers concluded that LLNL had satisfactory implemented the OCRWM QA program, except for the items noted in the DRs, DIR, QOs, and AOI.

The potential deficiencies were for late submittal to records processing of completed project activity records and for lack of a required approval before publication of a technical paper. The DIR addressed overdue technical and compliance reviews of a scientific notebook (SN). The QOs documented recommendations to improve or assure implementation, documentation or compliance of LLNL activities. The AOI concerned procurement and processing of welded-plate material and compliance with QARD requirements.

3.0 AUDIT PARTICIPANTS

3.1 Observers

Kamalakar R. Naidu	Team Leader	NRC
Thomas C. Trbovich	QA Specialist	CNWRA
Engelbrecht von Tiesenhausen	Engineering Specialist	Clark County, Nevada

3.2 Audit Team

John R. Doyle	Audit Team Leader	OQA/Navarro Quality Services (NQS)
James E. Flaherty	Auditor	OQA/NQS
Christian M. Palay	Auditor	OQA/NQS
Lester W. Wagner	Auditor	OQA/NQS

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The audit team conducted this audit of LLNL in accordance with OCRWM QA Procedures AP 18.2Q, "Internal Audit Program," and AP 16.1Q, "Management of Conditions Adverse to Quality." The NRC staff's observation was based on NRC Manual Chapter 2410, "Conduct of Observation Audits," dated July 12, 2000.

4.1 Audit Scope

This audit was a full-scope and compliance-based audit and evaluated LLNL's implementation of the OCRWM QA program defined in the QARD and applicable implementing procedures. The audit team evaluated the implementation, compliance, adequacy, and effectiveness of the QA program and procedures in place for activities supporting the YMSCP. In addition, the audit evaluated the effectiveness of the actions completed to correct the deficiencies identified during the previous OQA audits and surveillances.

4.2 Audit Conduct and Timing

The audit was performed in a professional manner and the audit team demonstrated a sound knowledge of the applicable LLNL and DOE programs and procedures. The audit team personnel were unified in approach, persistent in their interviews, challenged responses when appropriate, and followed their checklist questions, deviating when necessary to more fully understand the LLNL process or pursue discrepancies. The audit team performed a thorough and effective audit.

The audit team and observers caucused at the end of each day to discuss the audit status and any new and developing issues. The observers were encouraged to participate in the discussions with any comments, concerns, or questions. The audit team met with LLNL management each morning, with some of the observers present, to discuss the current audit status and potential discrepancies. In addition, members of the BSC-Las Vegas organization participated in the discussions via teleconference. The observers determined that the timing of the audit was appropriate for the team to evaluate the LLNL quality program. The observers also noted that the LLNL personnel had a good understanding of the quality program requirements and the implementation was much improved over previous observation audits.

4.3 Audit Team Qualification and Independence

The observers determined that the qualifications of the audit team lead (ATL) and the OQA audit team members met the requirements of QAP-18.1, "Auditor Qualification." The ATL provided the qualification records for the two audit team members who were unfamiliar to the observers. The observers concluded that the audit team members had the necessary expertise to perform the audit and had sufficient authority and organizational freedom to make the audit process meaningfuland effective.

4.4 Examination of QA Elements

The audit team conducted detailed checks of the technical adequacy of LLNL activities related to the YMSCP. The audit team used a combination of technical-issue probing and procedural-compliance checks and verifications to thoroughly consider the technical adequacy of the corrosion testing, sample plans, measurement and test equipment (MT&E) calibration, and other activities.

4.4.1 Receiving Inspection

LLNL does not purchase quality-related materials and services directly. BSC implements the QARD requirements, develops procurement documents, and purchases quality-related materials and services for LLNL use. The vendor ships the material to LLNL. The audit team reviewed the receipt inspection activities related to the receipt of C-22 welded-metal plates, and a titanium plate shipped from Framatome ANP (Framatome). On December 18, 2001, LLNL received 18 C-22 welded-metal plates from Framatome. LLNL personnel were unable to perform receipt inspection until March 8, 2002, because they did not receive either a copy of the BSC purchase order to Framatome, or a SOW. Thus, they were unable to identify technical requirements to perform receipt inspections in accordance with Procedure AP-7.7Q, "Acceptance of Items and Services," Revision 0, ICN 1.

As a result of their observations in this area, the observers issued AOI No. LLNL-ARC-02-07, as discussed in Section 5.1 of this report.

4.4.2 Identification and Control of Items and Materials

Members of the audit team examined items and materials in the LLNL receipt inspection area for proper identification and control. All items received, and examined by the audit team, had been arranged in an acceptable manner. Each item received had been identified with "Hold" or "Acceptance" tags, as applicable.

During this review, the audit team also verified the validity of calibration stickers on several LLNL measuring items used for the Yucca Mountain Project studies.

The audit team found this area acceptable. The observers agreed with the audit team findings in this area.

4.4.3 Self-Assessments

The audit team reviewed LLNL's Self-Assessment (SAs) to determine if they had been performed at the frequency required by Section 5.1.b of AP-2.20Q, "Self Assessments," Rev. 1, ICN O. This procedure requires that the Responsible Manager (RM) develop an SA schedule annually, and ensure that assessments are conducted at a frequency commensurate with the status and importance of the work activities being performed within the organization. Contrary to these requirements, the audit team determined that two SAs were not performed, and one scheduled SA that was performed had not been scheduled. In addition, the audit team determined that the assessment report had not been submitted to the Records Processing Center (RPC) within the 60-day time limit imposed in Paragraph 5.2C, Procedure AP 17.1Q, Rev. 2, ICN2. The audit team identified this as QO1. AP-16.1Q, Rev. 5, eliminated the "Corrected During Audit (CDA)" category of minor conditions adverse to quality and replaced it with the "Quality Observation (QO)."

The observers agreed with the audit team findings in this area.

4.4.4 "Q" Procurement of Analytical Services from a Non-Qualified Supplier List (QSL) Laboratory

The audit team reviewed two prepared Sample Plans, QCSP-AS-8/18/01 and QCSP-MIC-001. It was noted that, in accordance with procedure LLNL-TIP-AC-10, "Q Procurement of Analytical Services from a Non-QSL Laboratory," Revision 0, the required approvals had been obtained. The procurement plans adequately described the process steps to be taken to control samples being sent out for analysis. However, it was noted that changes made to the effective date on the plans by the Principal Investigator (PI) were not in accordance with the requirements of AP-17.1Q, "Record Source Responsibility for Inclusionary Records." The audit team identified this condition on QO 3.

The audit team reviewed samples sent for analysis to Activation Laboratories under Work Order No. 23244. The LLNL Procurement Specialist had properly released the sample packages after review of the analytical results by the PI. However, the audit team's review of the analytical data raised a question regarding which three of the samples were the required NIST traceable standards. The audit team reviewed the SN of the PI and resolved this question.

The observers agreed with the audit team findings in this area.

4.4.5 Control of Measuring Equipment and Calibration Standards

The audit team collected a total of seven serial numbers of balances, weight sets, and flow meters currently in use in the various LLNL Corrosion Laboratories. It was also noted that several thermocouples and flowmeters currently in use beyond the required calibration due dates were properly tagged, indicating calibration was to be performed on test completion. After assuring the proper calibration stickers were on the items, the audit team reviewed the calibration certifications, item receiving/release records, and the M&TE Listing with the LLNL M&TE Coordinator. The audit team noted no calibration controls discrepancies, and determined the requirements of Procedure AP-12.1Q, Revision 0, ICN2, to be adequately implemented.

The audit team also reviewed two internal calibration procedures, TIP-CM-04, "User Calibration of the Mettler AT200 Analytical Balance," Revision 1, and TIP-CM-10, "User Calibration of Analytical Balances," Revision 1. The audit team determined that the information required by the procedures was recorded in a calibration SN (SN 452, Volume 2) maintained by the PI.

During the review of the calibration acceptance records packages, the audit team determined that five records packages had not been sent to the RPC within the 60 day time limit required by AP-17.1Q. Since a similar problem had been noted with internal surveillance record packages, the audit team identified a potential deficiency report (DR) with this item.

The observers agreed with the audit team findings in this area.

4.4.6 Review of Scientific Notebooks (SNs)

Scientists at LLNL document their activities on studies, tests and experiments in SNs. Established procedures require the RM or PI to periodically conduct compliance reviews or

technical reviews. Specifically, Section 5.5.2a of Procedures AP-SIII.1Q, "Scientific Notebooks," Revision 1, ICN1, and Revision 0, ICNO, requires the RM or PI to initiate a compliance or technical Review when the period since notebook origination, or the previous review, is approaching 1 year. A review of the notebook segment, and all related supplemental records is required. Further, the documentation for this review must indicate the page(s) or time period reviewed. The audit team identified the following examples where this requirement had not been met.

> On April 04, 2001, LLNL began work on SN-LLNL-SCI-459-V1, "Study of Effects of Laser Peening Process on Alloy 22 Base Metal." On April 14, 2001, the compliance review was completed and this SN was approved for closure. On April 13, 2001, LLNL opened SN-460-LLNL-SCI-460-V1, "Corrosion Potential Measurements of Proposed Container Materials." During the audit, the audit team found that the technical and compliance reviews for these two SNs were overdue. The team identified this condition as a DIR, because it is a condition adverse to quality (CAQ), and was identical to examples identified in a current Deficiency/Corrective Action Report No. BSC-01-D-087, dated July 18, 2001, which had not been closed.

The observers agreed with the audit team findings in this area.

4.4.7 Control of Technical Interfaces

The audit team selected four papers that had been presented at a recent National Association of Corrosion Engineers conference by LLNL scientists, to determine if the reviews and approvals required by the procedure had been accomplished. The audit team determined that the "Technical Data, Milestones and Records Form," for the publication of Technical Paper UCRL-JC-146506, "Micro Biologically Facilitated Effects on the Surface Composition of Alloy 22, a Candidate Nuclear Waste Packaging Material," did not contain documentation of the LLNL Engineering Assurance Manager's (EAMs) approval. The failure to obtain EAM approval for the technical paper is a violation of paragraph 3.3.5.8 of Procedure AP-12.1Q, Revision 0, ICN2. The audit team identified a potential DR for this item.

The observers agreed with the audit team findings in this area.

4.4.8 Software Management

The audit team selected three software packages that had been qualified under the latest revision of AP-S.1Q, Revision 3, ICN 3. It was noted that a number of revisions had been made to AP-S1.1Q during the past year, making the review of previous software qualification packages difficult (due to trying to make a determination of which revisions and changes of the procedure were in effect during the software qualification).

All packages selected were found to be in compliance with procedural requirements. In particular, package RADPRO 4.0, titled, "Computer 2D&3D Heat Flow for NUFT," contained the following properly executed forms: Software Baseline Request, Software Categorization Request, Software Management Report, and the Software User Request.

The audit team noted, at the audit exit meeting, that the software controls and records maintained by the LLNL Software Qualification Lead were in compliance with the procedural requirements and extremely well done.

The observers agreed with the findings in this area.

4.4.9 Summary: DRs, DIR, and QOs Identified by the Audit Team

Two potential DRs were initiated:

> Potential DR 1: Failure to comply with Procedure AP 17.1Q (See Section 4.4.5 of this report).
>
> Potential DR 2: Failure to comply with Procedure AP-12.1Q (See Section 4.4.7 of this report).

One DIR was initiated:

> The team identified a DIR because it is a CAQ, and is identical to examples identified in a current DR, BSC-01-D-087, dated July 18, 2001, which continues to remain open and has not been closed (See Section 4.4.6 of this report).

Three potential QOs were identified:

> QO 1: Self-Assessments (SAs) should be scheduled and performed according to schedule. The audit team observed that two scheduled SA were not performed, and one scheduled SA that was performed had not been scheduled (See Section 4.4.3 of this report).
>
> QO 2: The audit team observed that the results of a post-test analysis were documented in a SN with no direction being provided by a TIP (See Section 4.4.6 of this report).
>
> QO 3: LLNL should follow its established procedures when making corrections to documents. The audit team observed that LLNL did not follow its procedures when making alterations to quality control plans (See Section 4.4.4 of this report).

5.0 NRC STAFF FINDINGS

The observers determined that Audit No. LLNL-ARC-02-07 was effective in determining the level of compliance of LLNL activities in implementing the quality assurance program.

The auditors reviewed selected project documents identified in the Audit Plan and employed a detailed checklist as the basis for their reviews. The audit team also examined related project technical documentation to verify the accuracy of source material and the status of data qualification activities. The auditors conducted interviews with personnel with appropriate levels of knowledge who were directly responsible for developing travelers, in which they document

the sequence of the various steps for the research studies, and for associated quality requirements. During the conduct of these interviews, the auditors effectively used the audit checklist to focus the inquiries on areas of technical concern. The audit team also gave the NRC observers adequate opportunities to provide comments, and to seek clarification on technical issues.

The observers agreed with the audit team's conclusion that LLNL has shown considerable improvement in implementing the provisions of QARD, except for the identified deficiencies.

The observers expressed concern over BSC's implementation of OCRWM's QA program as described in the QARD related to the procurement of materials and services.

5.1 NRC AOI

The observers documented one AOI (LLNL-ARC-02-07) during this audit. In it, the observers requested OQA to determine if BSC implemented the provisions of the OCRWM QA program, as described in the QARD, for the procurement of purchased materials and non-destructive examination services related to welded-metal plates supplied to LLNL. LLNL did not receive the relevant purchase orders for the Titanium and C-22 welded plates that Framatome supplied, and the absence of purchase orders impeded its receipt inspections. OQA is requested to investigate and determine if this condition is generic or isolated. Should the OQA investigation determine that similar problems are prevalent in the purchases for other materials and services, appropriate corrective action should be identified and implemented.