April 22, 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-02-05, "OBSERVATION AUDIT OF THE OFFICE OF CIVILITAN RADIOACTIVE WASTE MANAGEMENT, OFFICE OF QUALITY ASSURANCE, AUDIT NO. LBNL-ARC-O2-06"

Dear Mr. Milner:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report (No. OAR-02-05) of the U.S. Department of Energy's (DOE's) Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance's (OQA's), audit LBNL-ARC-02-06. This audit of the Lawrence Berkeley National Laboratory (LBNL) was conducted on March 18-22, 2002, at the LBNL facilities in Berkeley, California.

The audit team performed a limited-scope compliance-based quality assurance (QA) audit to evaluate LBNL's implementation of the OCRWM QA program, as defined in the DOE/RW–0333P, Revision 10, Quality Assurance Requirements and Description (QARD) document and applicable implementing procedures. During the audit, the audit team assessed the adequacy and effectiveness of the QARD and procedures and verified compliance with requirements in the areas reviewed.

The NRC observers (hereafter observers) determined that this audit was effective in identifying potential deficiencies and recommending improvements for LBNL activities reviewed. During the conduct of the audit, both the OQA audit team (hereafter audit team) and the observers reviewed applicable documents, procedures, and activities within the audit's scope; discussed the QARD requirements and methods of implementation with the responsible individuals; and examined available in-process records and documentation, to verify evidence of compliance with the applicable requirements.

The audit team identified one deficiency in the area of model validation, as well as a number of minor deficiencies that were corrected during the audit. The observers did not submit any audit observer inquiries requesting clarification and information on audited documents or activities. This audit report also documents closeout of Audit Observer Inquiry EM-ARC-02-01, based on the OQA response.

The staff determined that the OQA audit was well-planned, thorough, and adequately evaluated LBNL's implementation of, and compliance with, the QARD requirements. The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit. The staff also concluded that LBNL's implementation of the QARD requirements is generally acceptable. The staff will continue to interface with OCRWM and follow the progress that is being made to address the issues identified during this audit.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Wilkins R. Smith 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-02-05, "Observation Audit
of the Office of Civilian Radioactive
Waste Management, Office of Quality Assurance's
Audit No. LBNL-ARC-02-06"

cc: See attached list

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cc: See attached list

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Letter to R. Milner from J. Schlueter dated April 22, 2002

cc:

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J. Birchim, Yomba Shoshone Tribe

L. Jackson, Timbisha Shoshone Tribe

C. Meyers, Moapa Paiute Indian Tribe

V. Miller, Fort Independence Indian Tribe

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

R. Quintero, Inter-Tribal Council of Nevada (Chairman, Walker River Paiute Tribe)

M. Bengochia, Bishop Paiute Indian Tribe

J. Egan, Egan & Associates, PLLC

R. Bahe, Benton Paiute Indian Tribe

C. Bradley, Kaibab Band of Southern Paiutes

R. Joseph, Lone Pine Paiute-Shoshone Tribe

L. Tom, Paiute Indian Tribes of Utah

E. Smith, Chemehuevi Indian Tribe

J. Charles, Ely Shoshone Tribe

D. Crawford, Inter-Tribal Council of Nevada

H. Blackeye, Jr., Duckwater Shoshone Tribe

D. Eddy, Jr. Colorado River Indian Tribes

J. Leeds, Las Vegas Indian Center

W. Briggs, Ross, Dixon & Bell

U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-02-05

"OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT,

OFFICE OF QUALITY ASSURANCE,

AUDIT NO. LBNL-ARC-O2-06"

04/ 19/02

Wilkins R. Smith
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

04/ /02

Rodney M. Weber
Center for Nuclear Waste
Regulatory Analyses

Reviewed and Approved by:

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N. King Stablein, Chief
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1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management and from the Center for Nuclear Waste Regulatory Analyses (CNWRA) observed all aspects of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division, Audit No. LBNL–ARC–02–06 of the Lawrence Berkeley National Laboratory (LBNL) program implementation. This audit was conducted at the LBNL facilities from March 18–22, 2002.

The objective of this audit was to evaluate LBNL implementation of the OCRWM Quality Assurance (QA) Program, as defined in the DOE/RW–0333P, Revision 10, Quality Assurance Requirements and Description (QARD) document and applicable implementing procedures. During the audit, audit team members evaluated the implementation, compliance, adequacy, and effectiveness of the QA Program and procedures in place for activities supporting the Yucca Mountain Site Characterization Project Office.

The NRC observers' objective was to assess effectiveness of the audit team and audit process. LBNL implementation of the provisions in the QARD, the requirements in the LBNL Quality Implementation Procedures (QIPs), and the Technical Implementing Procedures (TIPs) was also assessed.

This report documents the NRC staff determination of the effectiveness of the OQA audit and the programmatic LBNL implementation in the audited areas.

2.0 MANAGEMENT SUMMARY

The observers determined that OQA audit LBNL-ARC-02-06 was effective in determining the adequacy of compliance of LBNL activities with the QARD requirements. The observers generally agreed with the conclusions, findings, and recommendations of the audit team. The observers determined that the audit was properly planned and professionally conducted.

Within the areas evaluated, the audit team identified one potential deficiency in the use of an unapproved method of model validation for the Analysis and Model Report MDL–NBS–HS–000012, "Unsaturated Zone Flow Patterns and Analysis." This item was evaluated and discussed with OQA management during the audit. The audit team and OQA management initiated documentation to add this deficiency regarding model validation to the existing Corrective Action Report No. BSC–01–C–001. The audit team identified six additional potential deficiencies that were determined to be minor in significance and were corrected during the audit (CDA).

3.0 AUDIT PARTICIPANTS

3.1 NRC Observers

Wilkins R. Smith	Team Leader	NRC
Rodney Weber	QA Observer	CNWRA

3.2 OQA Audit Team

Marilyn Kavchack, Navarro Quality Services (NQS), Las Vegas, Audit Team Leader
Patrick Auer, NQS, Las Vegas, Auditor
Robert Toro, NQS, Las Vegas, Auditor
Donald Harris, NQS, Las Vegas, Auditor
Christian Palay, NQS, Las Vegas, Auditor

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This OQA audit of LBNL was conducted in accordance with OCRWM QA Procedure (QAP) 18.2—"Internal Audit Program," and QAP 16.1—"Performance/Deficiency Reporting." The NRC staff observation of this audit was based on NRC Procedure, "Conduct of Observation Audits," issued July 12, 2000.

4.1 Scope of the Audit

The audit team conducted a limited-scope compliance-based audit of activities and processes related to the LBNL implementation of the OCRWM QA Program, as defined in the DOE/RW–0333P, Revision 10, QARD document and applicable implementing procedures. LBNL provides research in support of groundwater flow models it provides to the Yucca Mountain Project.

In support of the assessment of the LBNL Program implementation by the audit team, documents related to modeling research and report development were reviewed. During the time period subsequent to the previous assessment, three analysis model reports (AMRs) were produced. These were:

- MDL–NBS–HS–000012, Revision 00, "Unsaturated Zone Flow Patterns and Analysis"
- ANL–NBS–MD–000001, Revision 1, "Features, Events, and Processes in Unsaturated Zone Flow and Transport"
- ANL–NBS–HS–000005, Revision 01A, *"In Situ* Field Testing of Processes"

Other supporting documents were reviewed, including quality records providing objective evidence of process compliance, scientific notebooks in support of laboratory research, and various LBNL operating procedures and work instructions.

4.2 Audit Conduct and Timing

The audit was performed effectively and the audit team demonstrated a sound knowledge of the applicable LBNL and OCRWM procedures. Audit team members conducted themselves in a highly professional manner while interviewing, verifying details of responses, and following the details of their checklists. The observers concluded that the timing of the audit was appropriate to evaluate the ongoing activities at LBNL. Caucuses were held at the end of each day, starting on the second day, and management status meetings were held with the appropriate LBNL management personnel each morning, to discuss the current audit status and preliminary findings.

4.3 Audit Team Qualifications and Independence

The observers reviewed the qualification records for all audit personnel during the course of the audit. These records were in order and met the requirements of QAP–18.1Q, "Auditor Qualification." It was noted that the lead auditor's certification was documented on the contractor letterhead. The contractor is no longer in existence and all auditors work for another contractor quality service. Discussions with the auditors determined that although the auditor's current organization had not issued the certification, OQA was responsible for reviewing all certification records and had reviewed the lead auditor's certification during the (January 2002) annual qualification review, as required by procedure. The observers determined that the audit team was qualified and satisfactorily certified.

4.4 Examination of QA Elements

The observation team determined that the audit activities were appropriately conducted in accordance with the OCRWM QA Audit Plan for Audit No. LBNL–ARC–02–06**.** The auditors reviewed selected documents identified in the audit plan and used a detailed checklist as the basis for their inquiries. The auditors conducted themselves in a professional manner and interviewed the appropriate personnel, who were knowledgeable in the areas being assessed. The audit team gave the observers adequate opportunities to provide comments and seek clarification on issues being discussed. The audit team was observed effectively interacting with each other during daily activities and during end-of-day caucus sessions.

The observers were present at the audit entrance meeting; observed team coordination and communication between members; were present during interviews and document/record reviews; and observed the development of preliminary audit findings and their verification of correction during the audit. The programmatic elements assessed are discussed below.

4.4.1 Organization and QA Program

The auditors reviewed the LBNL QARD Requirements Matrix. Planning and determination of QARD requirements must address the QIP-5.2 requirement that any item noted as not aplicable (N/A) be appropriatetly justified. There were some requirements, in the LBNL Matrix, identified as N/A, without documentation of the required justification. LBNL personnel agreed to process a change during the audit. This item was corrected during the audit.

LBNL has recently defined, scheduled, and implemented self-assessments. Only three assessments have occurred since the previous audit assessment. The auditors noted that there appeared to be minimal implementation. The auditors recommended that LBNL evaluate its needs and revise its schedule to assure focus on self-assessment, so as to fully implement the process.

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

4.4.2 Implementing Documents

The auditors verified that the QIPs and TIPs modified or changed since the last programmatic review had been processed as required by the applicable procedure. Two of the four revised QIPs were reviewed:

- YMP–LBNL–QIP–5.2, Rev. 4, Modification 1
- YMP–LCNL–QIP–6.1, Rev. 7, Modification 1

In addition, the following TIPs were reviewed:

- YMP–LBNL–TIP–GP–5.0
- YMP–LBNL–TIP/AFT–1, Revision 1, Modification 0
- YMP–LBNL–TIP/TT–1.0, Revision 1, Modification 0

The auditor verified that the determination of documentation classification, lifetime or nonpermanent, was clearly identified so that document storage facility personnel would be able to properly store the documents.

Auditor review of records of distribution raised a question about distribution lists. Each QIP appeared to have a different list of recipients. LBNL determined that the distribution of the QIPs was intended to be consistent, and the distribution lists for all QIPs were revised to identify the same recipients.

The auditor found the processing and classification of documents to be acceptable, and the observer concurred in that assessment.

4.4.3 Document Control

The auditor reviewed three documents to verify that the processes associated with document change have been followed. Documentation planning, change, and reviews were found to be in accordance with the applicable procedures. The auditor verified that the document preparer had complied with the requirements of QARD Supplement 1, “Software,” requirements. In addition, compliance with the requirements of QARD Supplement V, as prescribed by YMP–LBNL–QIP–SV–0, “Management of Electronics Data,” was evident within the following documents:

- AMR, MDL–NBS–HS–000012, Revision 00, “Unsaturated Zone Flow Patterns and Analysis”
- AMR, ANL–NBS–MD–000001, Revision 1, “Features, Events, and Processes in Unsaturated Zone Flow and Transport”
- AMR, ANL–NBS–HS–000005, Revision 01A, “*In Situ* Field Testing of Processes”

No process model reports were processed during the last year.

The auditor noted that planning was not consistent. One AMR, 00005, was revised when on initial review, it appeared it would have been more appropriately changed through the Interim Change Notice (ICN) process. In discussions with LBNL personnel, it was determined that the changes were significant enough to warrant a revision. The auditor noted that the procedure guidance or planning for documenting the nature of changes may not be sufficient.

During this review, a deficiency was documented for AMR, MDL–NBS–HS–000012, "Unsaturated Zone Flow Patterns and Analysis." This document did not contain objective evidence of use of an acceptable method of model validation. The model vallidation method relied upon selection of a 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.

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

4.4.4 Control of Measurement and Test Equipment

The auditors reviewed the listing of measuring and test equipment dated March 15, 2002. The Measuring and Test Equipment (MT&E) coordinator maintains these data. The coordinator performs the function of system monitor, gathering status of calibration for listed equipment. Not all functions performed by the coordinator documented in the procedures. These functions support the recall of equipment when upcoming calibration expiration dates are noted. At this time, the coordinator and equipment custodians share responsibilities to ensure that calibration due dates are anticipated and that equipment is sent out for calibration.

The system had all the elements required by an effective calibration system. Initially, the auditor questioned whether the functions and responsibilities of the coordinator and custodian were addressed in sufficient detail to characterize the system as implemented. Further discussions were held in collaboration with other auditors and a determination made that all requirements of the procedure were acceptably implemented and no clarification or additional details would be beneficial.

The audit team visited laboratories involved with the qualitative physical analysis of rock specimens and bore-hole condensate sample analysis. Documentation of calibration for balances and spectrometers were checked in each of these laboratories. In the Rock Physics Laboratory, traceability of a standard used for calibration was checked back to the original certification. All equipment and records were found to be satisfactory.

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

4.4.5 Control of Nonconformances and Corrective Action

The auditor reviewed three deficiency reports issued this year. All process requirements were determined to have been followed, and closeout was less than 100 days. The reports reviewed were:

- BSE–02–B–052
- LBNL–01–D–033
- LBNL–01–D–143

4.4.6 Supplement S-I, Software

The auditors and observers reviewed two software packages, FLAC 3D V2.0 and Tough React V2.4. Documents reviewed included:

- Software Defect Notification SDN 001121121524 for the software program RoutineRick1 V1.0
- Resolution memorandum, Bo Bodvarsson, September 24, 2001
- Software Defect Notification (see above)
- Software Baseline Request, September 20, 2001
- Software Management Report, September 24, 2001
- Software Routine Report, March 28, 2001
- SDN (Software Tracking No. 10356-1.2.00) for CutNiche V1.2
- Resolution Memorandum, Bo Bodvarsson, June 18, 2001
- Testing Checklist, April 6, 2001

Report processing and closeout of deficiencies were satisfactorily documented.

The auditor noted that the software management procedure AP-SI.1Q—"Software Management," has been revised a total of 12 times since February 15, 1999. The number of changes occurring over this period of time makes it harder to follow the documentation trail, because of form changes and changing document numbers (see the previous examples where designation of two software defect notifications differed). Also, the forms used in the documentation of the above processes varied in appearance and layout, making it difficult to compare for consistent process. However, no deficiencies were noted because of this condition.

The auditors and observers noted that the QARD does not require retention of software review comments and records. The audit team stated that this issue would be a follow-up item for resolution by OQA.

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

4.4.7 Supplement S-II, Sample Control

The auditors visited the Rock Lab in Building 51, to review the sample-receiving process for shipment ID 01000468. Core samples in this area had been recently received and no processing other than opening of the shipping container (box) had occurred. The auditor pursued the chain of custody (traceability) of the paperwork, including logs and notebook entries, and confirmed shipping information with the Las Vegas office to verify the custody records are continuous. No observations or concerns were noted.

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

4.4.8 Summary: Deficiencies and Recommendations Identified by the Audit Team

One 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. Analysis and Model Report, MDL-NBS-HS-000012, Revision 00, *Unsaturated Zone Flow Patterns and Analysis*, did not contain 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 Corrected During Audit (CDA) items noted were:

- Out-of-date quality policy statement
- Change annotation in TIPs
- QARD requirements matrix justification for N/A items
- Entering of “file names” in an electronic data log
- Lack of dated calibration certificates
- Completion of procurement initiation forms

In addition, the audit team discussed and resolved the following:

- The roles and responsibilities of the measuring and test equipment coordinator and the M&TE custodian
- The need to continue implementation of the self-assessment program

5.0 NRC STAFF FINDINGS

The observers determined that Audit No. LBNL–ARC–02–06 was effective in determining the level of compliance of LBNL activities associated with the Yucca Mountain Project QA Program requirements. The observers agreed with the audit team’s conclusion that the QARD requirements, applicable to LBNL, had been satisfactorily implemented.

5.1 NRC Audit Exit Summary

During the post-audit meeting, the observers stated that they agreed with the audit team findings and recommendations as presented. The observers discussed the deficiencies found during the course of the audit and at the post-audit meeting. The observers concluded that the audit was well planned and effectively executed. The audit team was independent of the activities they audited and was knowledgeable regarding the QA programmatic requirements within the scope of the audit. The observers generally agreed with the audit team’s conclusions, findings, and recommendations presented at the audit exit. The observers expressed appreciation for the excellent cooperation and responsiveness provided by LBNL and the audit team, and noted the excellent understanding of the QA Program requirements, and communication during the audit among all participants. The observers stated that the audit team conducted itself in accordance with OQA program requirements.

5.2 NRC Audit Observer Inquiries

There were no Audit Observer Inquiries (AOIs) written during this audit.

5.3 Closure of Previous NRC AOIs

AOI EM-ARC-02-01was written during the audit of EM-5 December 11-14, 2001, and is documented in NRC Observation Audit Report No. OAR-02-03. The AOI noted that OQA audit personnel stated that they reviewed the QARD Requirement Matrix, including exceptions or not applicable requirements, during the annual audit of the Affected Organization; that the audit checklists did not appear adequate for this review; and that the QARD Section 2.2.10 review provisions are adequate. The AOI also expressed concern that the apparent practice may

result in an unacceptable exception, or a requirement being incorrectly identified as not applicable for almost a year. It recommended that OQA evaluate the need for the QARD to be revised to require formal approval of exceptions or alternatives to QARD requirements, before they are implemented by the Affected Organizations. Staff has reviewed the OQA response provided in DOE Letter, R. Murthy to C. W. Reamer, dated February 4, 2002. Based on that letter's commitment to revise the QARD to require OQA approval of non-applicability determinations and exceptions or alternatives to QARD requirements before they are implemented by the Affected Organizations, AOI EM-ARC-02-01 has been closed. NRC staff will follow the progress of this change, and will review the revised QARD provisions for approval and review critera of non-applicability determinations, exceptions or alternatives to QARD requirements.