

January 24, 2003

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-03-01, "OBSERVATION AUDIT OF BECHTEL SAIC ACTIVITIES FOR THE UNSATURATED ZONE FLOW AND TRANSPORT AT THE LAWRENCE BERKELEY NATIONAL LABORATORIES IN BERKELEY, CALIFORNIA, AND AT THE BSC FACILITY IN LAS VEGAS, NEVADA, AUDIT NO. BQAP-BSC-03-02"

Dear Mr. Milner:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC) Observation Audit Report No. OAR-03-01. The audit was conducted by Bechtel SAIC Company (BSC) on November 11–20, 2002, at the Lawrence Berkeley National Laboratory (LBNL) and BSC.

The BSC audit team (hereafter, audit team) performed a limited scope performance-based audit to evaluate BSC's and LBNL's implementation of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description Document, DOE/RW-0333P, Revision 12, and associated implementing procedures pertaining to BSC's development of the Unsaturated Zone Flow and Transport Analysis/Model Reports.

The NRC observers (hereafter, observers) determined that BSC's audit of LBNL and BSC was effective in identifying potential deficiencies and recommending improvements for the reviewed BSC activities. During the audit, both the audit team and the observers independently reviewed applicable quality assurance procedure, and activities within the audit's scope.

The audit team identified five potential deficiencies and two areas for process improvement. The observers initiated two Audit Observer Inquiries and one NRC Observation. The Audit Observer Inquiries pertain to (1) the apparent use of unverified and unqualified data as inputs for modeling and analysis purposes, and (2) the approval by a checker and a Quality Engineering Representative of the Thermal Testing Measurement Report (U0220) apparently without reviewing all of the associated data. The subject of the Audit Observer Inquiries are described in paragraphs 5.2.1 and 5.2.2, respectively, in the enclosed report. The NRC observation pertains to an apparent violation of OCRWM Safety Conscious Work Environment as described in paragraph 5.3 in the enclosed report.

The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit meeting on November 20, 2002.

A written response to this letter and the enclosed report is not required. The NRC staff will continue to interface with OCRWM and follow the action that BSC is taking to address the issues identified during this audit. If you have any questions, please contact Ted Carter of my staff at (301) 415-6684.

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-03-01,
"Observation Audit of Bechtel SAIC (BSC)
Activities for the Unsaturated Zone Flow and
Transport at the Lawrence Berkeley
National Laboratory in Berkeley, California, and
at the BSC Facility in Las Vegas, Nevada,
Audit No. BQAP-BSC-03-02"

A written response to this letter and the enclosed report is not required. The NRC staff will continue to interface with OCRWM and follow the progress that BSC is making to address the issues identified during this audit. If you have any questions, please contact Ted Carter of my staff at (301) 415-6684.

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BSC, Audit No. BQAP-BSC-03-02"

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Letter to R. Milner from J. Schlueter dated January 24, 2003

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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
J. Leeds, Las Vegas Indian Center
K. Tilges, Shundahai Network
J. Triechel, Nuclear Waste Task Force
T. Kingham, GAO

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C. Bradley, Kaibab Band of Southern Paiutes
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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 Bechtel SAIC (BSC) audit of BSC's and Lawrence Berkeley National Laboratory's (LBNL) implementation of the Office of Civilian Radioactive Waste Management (OCRWM) quality assurance (QA) program regarding development of Unsaturated Zone (UZ) Flow and Transport Analysis/Model Reports (AMRs). The audit was conducted on November 11–20, 2002, at LBNL in Berkeley, California, and continued at the BSC facility in Las Vegas, Nevada.

The objectives of the audit were to assess the adequacy and effectiveness of LBNL's and BSC's implementation of the QA Requirements and Description (QARD), DOE/RW-033P, Revision 12, and implementing procedures, and to verify compliance with the applicable requirements in the QARD, to work performed in the development of UZ Flow and Transport AMRs for license application. The NRC observer's (hereafter, observer's) objective was to assess the effectiveness of the BSC audit team (hereafter, audit team) and audit process, as well as the LBNL and BSC implementation of the QA provisions in the QARD. This report documents the observers determination of the effectiveness of the BSC audit and LBNL/BSC implementation of the QA provisions of the QARD.

2.0 MANAGEMENT SUMMARY

The observers determined that BSC audit regarding the development of the UZ Flow and Transport AMRs (Audit BQAP-BSC-03-02) was effective in determining the level of compliance of BSC's and LBNL's QA program with the QARD and associated implementing procedures. The observers agreed with the audit team's conclusions, findings, and process improvement issues. The observers determined that the audit team members were qualified, independent of the areas being audited, and knowledgeable of the pertinent QA requirements. Based on these observations, the BSC QA program has been effectively implemented regarding the development of UZ Flow and Transport AMRs with the exception of the items noted in the three potential deficiency reports (DRs) and the two Document Input Reference Systems (DIRS). The potential DRs and DIRS were in the areas of QARD implementation, data inputs obtained from uncontrolled sources, errors documented on Technical Data Information Forms, personnel qualification, and scientific notebook entries.

3.0 AUDIT PARTICIPANTS

3.1 Observers

Ted Carter	Team Leader	NRC
Tom Matula	Senior QA Engineer	NRC
Mark R. Ehnstrom	QA Specialist	CNWRA
Randy Fedors	Technical Specialist	CNWRA

3.2 Audit Team

The audit team consisted of members from BSC, Integrated Science Solutions Inc., and Los Alamos National Laboratory (LANL). The audit team was also evaluated by members from the Office of QA (OQA), OCRWM, and from Navarro Quality Services. The following individuals comprised the audit team and OQA/OCRWM observers:

Kenneth O. Gilkerson	Audit Team Leader	BSC QA
Paul H. Lowe	Auditor	BSC QA
James B. Harper	Auditor	BSC QA
Gary M. Grant	Auditor	BSC QA
Charles C. Warren	Lead Auditor	BSC QA
Jefferson R. McCleary	Technical Specialist	BSC/ISSI
Hari Viswanathan	Technical Specialist	BSC/LANL
Jim Blaylock	Observer	OCRWM Office of QA
Harvey Dove	Observer	OQA/Navarro Quality Services

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The audit of LBNL and BSC regarding the development of UZ Flow and Transport AMRs was conducted in accordance with Administrative Procedure (AP)-18.3Q, "Internal Audit Program," and AP-16.1Q, "Management of Conditions Adverse to Quality." The NRC staff's observation of this audit and development of this report was based on NRC Manual Chapter 2410, "Conduct of Observation Audits," dated July 12, 2000.

4.1 Scope of the Audit

The audit team conducted a limited scope performance-based audit of activities and processes supporting UZ Flow and Transport scientific analyses activities. The QARD, DOE/RW-0333P, Revision 12, Scientific Process Guidelines Manual, TDR-WIS-MD-000001 R-01, and applicable implementing procedures were used to generate the performance-based audit checklist. This audit was to have focused on four AMRs at different stages of development. The four AMRs reviewed during the audit were:

- Development of Numerical Grids for UZ Flow & Transport Modeling, AMR U0000
- Analysis of Hydrologic Properties Data, AMR U0090
- Drift Scale Coupled Process MDL, AMR U0110
- Thermal Testing Measurement Report, AMR U0220

4.2 Conduct and Timing of the Audit

The audit was performed in a professional manner and the audit team demonstrated a sound knowledge of the applicable LBNL and BSC 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 LBNL or BSC process or pursue discrepancies. The audit team performed a thorough and effective audit. The audit did not include in-process work on two of the reports, AMR U0090 and AMR U0110. The observers conclude that these reports were too early in development to provide a meaningful evaluation on compliance with quality program requirements. Delaying this audit until the two in-process AMR reports were further along in development would have provided additional information to be evaluated during the audit. The audit team concentrated on two AMRs, the Thermal Testing Measurements Report and the Development of Numerical Grids for UZ Flow and Transport Modeling.

The audit team and observers caucused at the end of each day to discuss the audit status and any new and developing issues. The audit team encouraged the observers to participate in the discussions with any comments, concerns, or questions. The audit team met with LBNL or

BSC management, as appropriate, each morning, with observers present, to discuss the current audit status and potential discrepancies. The observers determined that the timing of the audit was appropriate for the team to evaluate the LBNL or BSC quality program, even though two of the AMRs could have been further along in development for a more thorough evaluation.

4.3 Audit Team Qualification and Independence

This audit team consisted of one audit team leader who is a qualified Lead Auditor, a lead auditor-in-training, three auditors, and two technical specialists who provided the technical expertise required for this type of performance based audit. The observers reviewed the qualifications for the Audit Team Leader and two of the auditors for compliance with procedure AP-18.1Q, "Audit Personnel Qualification." The observers determined that the qualifications of these audit members met the requirements of AP-18.1Q. 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 meaningful and effective.

4.4 Examination of Quality Elements

4.4.1 Design Control

The audit team reviewed the design controls used for development of the AMRs. Specifically, the review of the Thermal Testing Measurements Report, AMR 0220, found that some Data Tracking Numbers (DTNs) referenced in Section 4 of the report as "qualified" were comprised of QL-2 data (i.e., data that have not been verified to be qualified), and data that have a limitation for use as only for supporting "non-principal factors". These unverified and limited-use data can be incorrectly issued in output DTNs. The current process allows unverified and limited-use data to be processed as a Technical Product Output (TPO) without meeting the requirements for qualification of unqualified data (reference paragraph 4.6.1.3, Potential Audit Finding No. 3). Changes may be required in procedures AP-SIII.9Q, "Scientific Analyses", and AP-3.15Q, "Managing Technical Product Inputs," to be in compliance with requirements contained in the QARD addressing the control of data.

During additional review of the Thermal Testing Measurement Report the audit team found that not all inputs used in the report had been verified back to their origin. The assigned qualified checker and the Quality Engineering Representative failed to assure that inputs were appropriately verified in accordance with procedure AP-SIII.9Q (reference paragraph 4.6.1.4, Potential Audit Finding No.4).

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

4.4.2 Control of Measuring and Test Equipment and Calibration Standards

The audit team tracked one piece of calibrated measuring and test equipment was traced back through requirements contained in procedure AP-12.1Q, "Control of Measuring and Test Equipment and Calibration Standards." This flow measurement equipment had exceeded its calibration cycle. LBNL personnel initiated an Impact Evaluation on a Measuring and Test Equipment Out-of-Calibration Report. Personnel also documented this information, in accordance with procedure AP-12.1Q, in the appropriate scientific notebook. The audit team identified that LBNL does not currently have a positive recall system for calibrated measuring and test equipment (reference paragraph 4.7.1.2, Potential Process Improvement No. 2).

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

4.4.3 Software Management

The qualifications of individuals who develop and manage software must be documented and verified. During the review of verification for employment and education documentation for the individual responsible for the software management area, confirmation from a previous employer could not be found. This was due to the fact that the previous employer had gone out of business. This lack of review from a previous employer had not been documented and may be handled as a DIR to the earlier initiated DR No. BSC-(0)-02-176 (reference paragraph 4.6.1.1, Potential Audit Finding No.1).

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

4.4.4 Supplement III Scientific Investigation

The audit team reviewed documentation contained in scientific notebooks for compliance to procedure AP-SIII.1Q, "Scientific Notebooks." The audit team found that, although in general compliance with procedural requirements, there was some confusion when certain data was added to a scientific notebook. Initial entries on a scientific notebook page were documented days, and in some cases weeks, before other data and dates were entered on that same page creating confusion and making it difficult to track entries. This observation may be carried as a DIR to an existing DR No. BSC(B)-03-D-025 (reference paragraph 4.6.1.2, Potential Audit Finding No. 2).

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

4.5 Examination of Technical Activities

4.5.1 Development of Numerical Grids for UZ Flow and Transport Modeling, AMR U0000

The purpose of AMR U0000 is to document the generation of the numerical grid used for the three-dimensional site-scale unsaturated flow model. Inversions using this grid are used to develop values of hydrologic properties.

The audit team technical specialists focused on three topics contained in the AMR U0000: (1) water table data; (2) adequacy of grid refinement; and (3) distinction between grid development and assignment of properties. These three topics are discussed below.

Regarding water table data, the technical specialists reviewed the consistency of the water table data used in AMR U0000 with that used elsewhere in the project. With sparse data points to constrain the slope of the water table beneath the repository, different groups within the Yucca Mountain Project may have different estimates of the water table position. A study could be used to demonstrate the lack of sensitivity to interpolation methods used to develop water table locations across the grid.

Regarding the adequacy of grid refinement, the audit team technical specialists reviewed the basis for the cell sizes used in the grid. The primary author of AMR U0000 stated that adequacy of grid refinement was a task for the modelers and stated that an iterative process was informally in place with LBNL modelers. An iterative process, however, was not in place with other modelers who are dependent on properties and conditions developed using the grid.

Regarding the distribution between grid development and assignment of properties, the audit team technical specialists noted that the block size (based on fracture density) and zones of

vitric versus zeolitic nonwelded tuff below the repository were fixed by the grid development. Both of these parameters are highly uncertain.

All three of these issues tie into the potential Process Improvement No. 1 on adequacy of the grid (reference paragraph 4.7.1.1), specifically, whether flow and transport modelers can assume the grid is adequate for their intended usage.

The audit team reviewed Technical Data Information Records for the Development of Numerical Grids for UZ Flow and Transport Modeling and identified numerous errors and incorrect information (reference paragraph 4.6.1.5, Potential Audit Finding No. 5).

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

4.5.2 Analysis of Hydrologic Properties Data, AMR0090

Insufficient information was provided in AMR U0090 to perform an accurate assessment of quality program compliance.

4.5.3 Drift-Scale Coupled Processes (DST and THC Seepage) Models, AMRU0110

Insufficient information was provided in AMR U0110 to perform an accurate assessment of quality program compliance.

4.5.4 Thermal Testing Measurement Report, AMR U0220

The purpose of AMR U0220 is to assemble descriptions and references and graphically illustrate data collected during the Large Block Test (Fran Ridge), Single Heater Test (Alcove 5), and Drift-Scale Heater Test (Alcove 5).

The audit team technical specialists found that non-qualified data was not clearly noted as such in AMR U0220. This was data from pre-June 1999 that still needed to go through a verification checklist, AP-3.15Q, "Managing Technical Product Inputs - Attachment 5," before it could be used as input for principal factors. This is a potential problem since all output from this scientific analysis report was noted as fully qualified data. A further concern of the audit team specialists was that methods evolved during the Drift-Scale Heater Test, yet only early-program documents were cited as support of input data. For example, the technical specialist found that the gas chemistry and Rapid Estimation of Thermal Conductivity and Thermal Diffusivity measurements have been added during the test program, after the dates of cited documents supporting the input data. The Technical Lead for the thermal testing program said that the next revision of this AMR would focus more on the Drift-Scale Heater Test and would better document the methods and techniques. Potential Audit Finding No. 3 (reference paragraph 4.6.1.3) may be made in response to the data quality status issue.

The audit team reviewed Technical Data Information Records for the Thermal Testing Measurement Report and identified numerous errors and incorrect information. (reference paragraph 4.6.1.5, Potential Audit Finding No. 5).

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

4.6 Potential Audit Findings

4.6.1 Potential Deficiency Reports

The audit team identified five potential conditions adverse to quality during the audit as follows.

4.6.1.1 Potential Audit Finding No.1

During the audit, the audit team verified employment and education records for software development personnel at LBNL. The audit team could not confirm previous employment for an applicant for a software position and no justification had been given. This finding may be entered into the DIRS and will be attached to an existing DR Number BSC-(0)-02-D-176.

4.6.1.2 Potential Audit Finding No.2

During the review of scientific notebooks, the audit team determined that entries had been placed into the book after a specific page had already been initialed and dated. The new entries were entered days, and sometime even weeks, after that page had been first initialed and dated. Although the additions were added in accordance with current procedural requirements, these added entries can be a cause for confusion. This may be added to the DIR data base and may be attached to an existing DR Number BSC(B)-03-D-025.

4.6.1.3 Potential Audit Finding No.3

The audit team determined that LBNL used unqualified and unverified data as input data for the Thermal Testing Measurements Report. Procedure AP-3.15Q, "Managing Technical Product Inputs," is inadequate in defining the requirements contained in the QARD relative to data identification/qualification, control, and usage. The audit team found that a new classification of data, qualified but unconfirmed, exists and that this classification of data is not described in the QARD. A DR may be issued to address this audit finding. Changes may be required in procedures AP-SIII.9Q, "Scientific Analyses", and AP-3.15Q, "Managing Technical Product Inputs," to be in compliance with requirements contained in the QARD addressing the control of data. Changes may be required in procedures AP-SIII.9Q, "Scientific Analyses," and AP 3.15Q, "Managing Technical Product Inputs," to be in compliance with requirements contained in the QARD addressing the control of data.

4.6.1.4 Potential Audit Finding No.4

The audit team determined that data for the Thermal Testing Measurements Report did not come from controlled sources. BSC violated Procedure AP-SIII.9Q, "Scientific Analyses," when a qualified checker and the Quality Engineering Representative did not assure that inputs were appropriately sourced in accordance with procedural requirements. A DR may be issued to address this audit finding.

4.6.1.5 Potential Audit Finding No.5

During a review of Technical Data Information Records for the Thermal Testing Measurements Report and the Development of Numerical Grids for UZ Flow & Transport Modeling, the audit team identified numerous errors and incorrect information. A DR may be issued to identify the reason for these errors appearing on these records.

4.7 Potential Audit Process Improvements

4.7.1 Potential Process Improvements

The audit team identified two areas where process improvements could be made to enhance or assure product quality as listed below. These are strictly for management consideration as a means for possible program improvement.

4.7.1.1 Potential Process Improvement No.1

The audit team found that, although the reports and supporting documentation was adequate, some consideration for downstream users may be required. For example, in the Development of Numerical Grids for UZ Flow & Transport Modeling Report, a condition exists where flow and transport scientists may incorrectly assume that the numerical grids are adequate for their specific scope of work. Additional information in the scope of reports to more accurately identify parameters used in the development of the model could prevent this from occurring.

4.7.1.2 Potential Process Improvement No.2

Currently LBNL has no positive recall system for calibrated measuring and test equipment. Although there is no requirement to maintain a positive recall system, implementing such a system would provide assurance that calibrated measuring and test equipment is recalled before calibration expires.

5.0 NRC STAFF FINDINGS

The NRC observers determined that the audit team for Audit BQAP-BSC-03-02 was effective in determining the level of compliance of LBNL and BSC activities associated in the development of AMRs with the requirements contained in the QARD and associated procedures except for issues identified as the potential deficiencies.

5.1 NRC Audit Exit Summary

During the audit exit meeting, the observers expressed their appreciation for the cooperation and responsiveness given them during their observation activities. In addition, the observers stated that they agreed with the audit team's findings and recommendations, as presented at the audit exit meeting.

5.2 NRC Audit Observer Inquiries

NRC generated the following inquiries as a result of observing audit BQAP-BSC-03-02.

5.2.1 Inquiry No. 1

DOE/BSC used qualified, verification level 2 (QL-2), and unqualified data as inputs for modeling and analysis purposes, for low risk significant applications supporting site recommendation. Given that unqualified DTNs are being used in the development of TPOs, how will DOE/BSC assure that only qualified and verified data and software are used for high risk significant applications supporting license application?

5.2.2 Inquiry No. 2

The audit team identified an instance where, apparently because of time and schedule pressure, a BSC qualified checker and a BSC Quality Engineering Representative approved the Thermal Testing Measurement Report (U0220) without reviewing all of the associated data. How will DOE and BSC management create an environment to assure that personnel performing checking and quality assurance assignments will be afforded adequate time to perform their assigned tasks as time and schedule become even more important leading up to license application? What metric will be developed and used to assure that quality activities are not influenced by cost and schedule?

5.3 NRC Observation

DOE and BSC currently have a program in place that establishes an environment where employees are encouraged to raise concerns without fear of harassment, intimidation, retaliation, or discrimination. This program, the OCRWM Safety Conscious Work Environment, is fully endorsed by the NRC as an effective tool in establishing this type of environment. However, during the audit, the NRC staff observed a potentially intimidating environment. Specifically, the audit team identified instances where QL-2 data and unqualified data were used in the development of TPOs (reference paragraph 4.6.1.3 above). During a meeting with BSC management and technical staff, the Audit Team Leader presented his findings regarding this issue in great detail and in an apparently defensive manner. After the Audit Team Leader presented his findings, BSC management and technical staff asked numerous and repetitive questions, and did so in a tone that appeared to be intimidating. This action is contrary to the OCRWM Safety Conscious Work Environment policy established by DOE because it can potentially present a chilling effect on other staff members who may want to raise safety concerns but don't because of fear of possible harassment, intimidation, retaliation, or discrimination. Personnel when presenting potential issues, should be allowed a forum in which intimidation is not a potential factor.

5.4 Audit Observation Inquiry Follow-Up

During this audit, the observers followed up on the status of the Audit Observation Inquiry Log No. 1 from audit LLNL-ARC-02-07, dated April 15–19, 2002. This inquiry requirement reference is welded metal plates and services supplied by Framatome. The NRC has received the response and is actively evaluating this response, and the inquiry remains open.