

April 30, 2001

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-01-04, "OBSERVATION AUDIT OF THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT, QUALITY ASSURANCE DIVISION, AUDIT NO. M&O-ARP-01-01"

Dear Mr. Milner:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report (No. OAR-01-04), 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 of activities regarding to the "Engineered Barrier System Process Model Report" (EBS PMR). The EBS PMR was prepared by, and the supporting activities performed by, the OCRWM Management and Operating Contractor (M&O). This audit was conducted on February 20 through 23, 2001, at the M&O facilities in Las Vegas, Nevada.

Selected Analysis Model Reports (AMRs) supporting the EBS PMR were previously audited on February 7-11, 2000 (OQA Audit No. M&O-ARP-00-06), and at that time several of the documents audited were still in the process of being developed. The purpose of this audit was to evaluate the implementation of the applicable provisions contained in the OCRWM Quality Requirements and Description, DOE/RW-0333P, Revision 10, by evaluating two selected AMRs supporting the EBS PMR. Also, the audit evaluated action taken as a result of the findings and recommendations from the February 2000 EBS audit.

The NRC observers (observers) determined that this audit was effective in identifying potential deficiencies and recommending improvements for the PMR and AMRs reviewed. During the conduct of the audit, both the OQA audit team (audit team) and the observers independently reviewed applicable analysis reports and supporting data, models, and software. The observers were disappointed to note that though previous observation audits indicated effective corrective measures had been taken with procedural compliance in the AMR development process, some of the AMRs selected for this evaluation still indicated discrepancies similar to what had been found during the 2000 audit. The observers submitted two audit observer inquiries (AOIs) requesting clarification and information on audited documents. The AOIs addressed the corrective action process and data usefulness.

Although the audit team identified some potential deficiencies, and two AOIs requesting clarification and information were generated, the observers believe that the AMRs and PMR reviewed during the audit were generally technically sound with the exception of AMR ANL-EBS-MD-000033, Revision 00, ICN 1, "Physical and Chemical Environmental Abstraction Model" (E0100) which had problems in the areas of traceability/transparency, calculations, and model validation. This is further discussed in sections 4.4 and 4.5 of this report. The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit.

Although a written response to this letter and the enclosed report is not required, we do request that you respond to the two AOIs. If you have any questions, please contact Ted Carter at (301) 415-6684.

Sincerely,

/RA/

C. William Reamer, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report
No. OAR-01-04, "Observation Audit
of the Office of Civilian Radioactive
Waste Management, Quality Assurance
Division, Audit No. M&O-ARP-01-01"

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 Division, Audit No. M&O-ARP-01-01"

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Letter to R. Milner from C.W. Reamer dated: April 30, 2001

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1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management and contractors from the Center for Nuclear Waste Regulatory Analyses (CNWRA) observed the U.S. Department of Energy's (DOE's), Office of Civilian Radioactive Waste Management, Office of Quality Assurance (OQA), audit of the process and activities that support the Engineered Barrier System (EBS) Process Model Report (PMR). This audit was conducted on February 20–23, 2001, at the Bechtel SAIC Company, LLC (BSC) offices in Las Vegas, Nevada. BSC became the DOE Management and Operating (M&O) contractor on February 12, 2001.

Selected Analysis Model Reports (AMRs) supporting the EBS PMR were previously audited on February 7–11, 2000, (OQA Audit No. M&O–ARP–00–06), and at that time several of the documents audited were still in the process of being developed. The purpose of this audit was to evaluate the implementation of the applicable provisions contained in the OCRWM Quality Requirements and Description (QARD), DOE/RW–0333P, Revision 10, by evaluating two selected AMRs supporting the EBS PMR. Also, the audit evaluated action taken as a result of the findings and recommendations from the February 2000 EBS audit. The two selected AMRs of this audit were subjected to a technical evaluation as well as an evaluation to ensure that the applicable programmatic requirements contained in the QARD and implementing procedures were met.

The objective of the NRC Observation Team (observers) was to assess whether the previous and current M&O contractors had properly implementing the provisions contained in the QARD and the requirements contained in Subpart G, "Quality Assurance," to Part 60 of Title 10 of the U.S. Code of Federal Regulations (10 CFR Part 60). Because of the anticipated DOE submittal of the Site Recommendation (SR) for a high-level waste repository, the following observation activities were emphasized: (1) confirming that data, software, and models supporting the SR are properly qualified; (2) evaluating the progress being made by DOE and contractors in meeting the data and software qualification goals for the SR; and (3) ensuring the technical adequacy of the four AMRs within the scope of the OQA audit.

This report addresses the observers' determination of how effective the OQA audit was, and whether the M&O implemented adequate QARD controls during the AMR development process.

2.0 MANAGEMENT SUMMARY

The observers agreed with the audit team's conclusions, findings and recommendations. The observers determined that the OQA Audit M&O–ARP–01–01 was planned and effectively implemented. However, the observers were disappointed to note that though previous observation audits indicated effective corrective measures had been taken with procedural compliance in the AMR development process, some of the AMRs selected for this evaluation still indicated discrepancies similar to what had been found during the 2000 audit. This concern led to the initiation of an Audit Observation Inquiry (AOI) on corrective action escalation detailed later in this report.

The audit team members were independent of the activities they audited and were knowledgeable of the quality assurance (QA) requirements and the technical disciplines within

the scope of the audit. Those members of the audit team that were formerly part of the Quality Assurance Technical Support Services and recently had joined BSC had documentation indicating they were not involved with any of the audited AMR development processes. The audit team members' qualifications were reviewed and were found to be acceptable.

3.0 AUDIT PARTICIPANTS

3.1 Observers

Ted Carter	Team Leader	NRC
Lauren Browning	Technical Specialist	CNWRA
Thomas Trbovich	Quality Assurance Specialist	CNWRA

3.2 OQA Audit Team

Don Harris	Audit Team Leader	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
Lester Wagner	Auditor	OQA/QATSS
Floyd Dove	Auditor	OQA/QATSS
Michael Goyda	Auditor	OQA/QATSS
Chet Wright	Auditor	OQA/QATSS
Kristi Hodges	Technical Specialist	OQA/QATSS
Harris Greenberg	Technical Specialist	Management & Technical Services
David Sassani	Technical Specialist	Management & Technical Services
Steve Sobkowski	Technical Specialist	Management & Technical Services

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This OQA audit of the M&O was conducted in accordance with OCRWM Quality Assurance Procedure (QAP) 18.2, "Internal Audit Program," and QAP 16.1Q, "Performance/Deficiency Reporting." The NRC staff's observation of this audit was based on NRC Manual Chapter 2410, "Conduct of Observation Audits," dated July 12, 2000.

4.1 Scope of the Audit

The EBS PMR activities and selected AMRs were previously audited on February 7-11, 2000, and at that time, several of the documents audited were in the process of being developed. The audit team conducted a limited-scope, performance-based audit of activities and processes related to the development of the AMRs supporting the EBS PMR. Audit activities included evaluation of the EBS PMR, two AMRs, selected software, and associated data. The audit also included review of the programmatic controls governing the AMRs and technical requirements contained in the AMRs. Further, the audit evaluated action taken as a result of the findings and recommendations from the February 2000 EBS PMR audit.

The preparation of the following two AMRs and the EBS PMR were evaluated by the audit team and the observers during the audit:

- ANL-EBS-MD-000032, Revision 00, ICN1, "Water Distribution and Removal Model" (E0090)

- ANL-EBS-MD-000033, Revision 00, ICN 1, “Physical and Chemical Environmental Abstraction Model” (E0100)

The evaluations ANL-EBS-MD-000026 and 000027 were limited to verification of the incorporation of recommendations from audit M&O-AP-00-06.

- ANL-EBS-MD-000026: The recommendations were incorporated in the AMR, Revision 0, ICN 1, satisfactorily.
- ANL-EBS-MD-000027: The recommendations were either incorporated in the AMR revision or will be addressed by the closure of the open items from the Repository Design, Thermo-Mechanical Effects Key Technical Issues Resolution Status Report, Revision 3.

4.2 Conduct and Timing of the Audit

The audit was performed effectively and the audit team demonstrated a sound knowledge of the applicable M&O and DOE programs and procedures. Audit team members conducted thorough interviews, they challenged responses, when appropriate, and they effectively employed their detailed audit checklists. The observers concluded that the timing of the audit was appropriate for the auditors to evaluate ongoing EBS PMR activities. The audit team and the observers caucused at the end of each day. Meetings between the audit team and M&O management (with the observers present) were also held to discuss the current audit status and preliminary findings.

4.3 Audit Team Qualification and Independence

The qualifications of the audit team leader and the audit team were reviewed for accuracy and completeness in accordance with the requirements of Procedure QAP 18.1, “Auditor Qualification.” The observers’ review included an examination of the training, education, and experience of the audit team members. The observers concluded that the audit team members, including the technical specialists, had the necessary expertise and were well-prepared to audit the subject matter in the AMRs.

4.4 Examination of the QA Elements

The OQA programmatic and technical audit activities were conducted simultaneously using sub-audit teams consisting of one technical specialist and one or more QA auditors. Often during the audit, certain programmatic aspects of the audited documents were independently reviewed by an audit team member. The observers determined that the limited-scope audit focused on the QA elements closely associated with the critical process steps of AMR development. BSC had initiated a review of all existing procedures and issued a Blue Sheet Change Notice indicating any changes required in the procedure with regard to activity responsibility and denoting BSC acceptance of the document. The observers evaluated the audit team’s review of the following QA elements.

4.4.1 AP-2.21Q, “Quality Determinations and Planning Activities for Scientific, Engineering, and Regulatory Compliance Activities”

The auditor reviewed the Technical Development Plan and Work Plan for the AMR, ANL-EBS-MD-000033, Rev. 01, “Physical and Chemical Model.” It was determined that there was not enough detailed information. This lack of information could result in a technical product that could not be mapped to specific requirements in either planning document. Because of the vague requirements, the results of the technical products could not be assured. It was recommended that AP-2.21Q be revised to establish planning guidance that will result in sufficient detail to produce a sound technical product. The observers agreed with the recommendations made in this area.

4.4.2 AP-3.4Q, “Change Control” and AP-3.17Q, “Impact Reviews”

These procedures had been accepted by BSC via the Blue Sheet Change Request process. The auditor determined that two change requests had been initiated: TCR-T2000-0253, on ANL-EBS-MD-000032, “Water Distribution and Removal Model” and TCR-T2000-0315, on ANL-EBS-MD-000033, “Physical and Chemical Model.” A total of 18 Impact Review Action Notices had been initiated between the two documents and had been properly completed by the responsible individuals. No discrepancies were noted nor were recommendations for improvement made.

4.4.3 AP-3-10Q, “Analysis and Models”

This procedure applies to activities pertaining to the development, documentation, checking, review, approval and revision of analyses or models, and the calibration, validation or use of models to support scientific, engineering, or performance assessment work activities. This procedure has had significant revisions and modifications made to it during the past 2 years. Four process-level models identified in the Physical and Chemical Model, ANL-EBS-MD-000033, were determined not to be in compliance with the six alternative validation approaches identified in AP-3.10Q, section 5.3(c). The models identified included:

- a. Gas Flux and Fugacity Model
- b. Invert Evaporation Model
- c. Microbial Effects Model
- d. EBS Colloids Model

A Discrepancy Report was to be initiated for inadequate model validation on these models. The observers agreed with the deficiency noted in this area.

4.5 Examination of Technical Activities

The technical specialists on the audit team performed detailed reviews of the technical adequacy of the AMRs audited. The observers assessed the audit team’s performance of these reviews and were given an opportunity to perform a review of the technical adequacy of the documents. Also, the observers were given an opportunity to ask questions during the audit.

The observers generally agreed with the audit team findings in this area. An AOI was submitted, however, for reasons discussed in the following paragraphs.

4.5.1 AMR No. ANL-EBS-MD-000033, “Engineered Barrier System: Physical and Chemical Environment Model,” Revision 01

The audit team technical specialist assigned to review this AMR was well-prepared to conduct the audit. The AMR originator and cognizant PMR-development relevant support staff were available to answer the audit team’s technical questions and provide information about software, data, and model documentation.

This AMR documents conceptual models for the evolution of physical and chemical environments in the EBS emplacement drifts. Models’ output was to be used in modeling the performance of the EBS, the waste package, and the waste form. However, the audit team technical specialist pointed out that model output did not fulfill its intended purposes. This was one of several inconsistencies, identified by the audit team technical specialist, between the technical work plan (TWP-MGR-MD-000013) for this AMR and the actual work product. In response to these shortcomings, the audit team technical specialist recommended that the planning of this AMR be revised to more clearly document specific work tasks. The audit observer agrees with this recommendation.

The audit team technical specialist made several other recommendations to improve this AMR. These included: (1) additional clarification of the model assumptions and justifications, (2) further explanation of model inputs; (3) more detailed referencing in FEP table 6.8-1; (4) more detailed referencing in KTI AC table 6.9-1; and (5) more quantitative treatment of model uncertainties. The observer concurs with all the recommendations made by the audit team technical specialist.

The audit team technical specialist identified three potential deficiencies with this AMR. The first potential deficiency is in the area of document traceability/transparency. The audit team technical specialist identified 40 specific problems in this area, including incorrect reference citations and tables containing incorrect or conflicting data. The second potential deficiency with this AMR that was identified by the audit team technical specialist is an incorrect calculation associated with table 6.3-1. The final potential deficiency noted by the audit team technical specialist is that four model validations are not in compliance with the requirement of AP-3.10Q, section 5.3c, as claimed in the document. The observer concurs with the audit team technical specialist and considers the last one as the most serious potential deficiency.

As indicated above, the audit team technical specialist determined that model output from this AMR did not fulfill its intended purposes. More specifically, the auditors established that output from this AMR does not provide input to total system performance assessment or other process-level models used to support DOE’s safety case for the proposed nuclear repository at Yucca Mountain, NV. There were a number of informal discussions amongst the DOE audit team and associated technical support staff about whether or not it would be useful to the Yucca Mountain Project to continue the work in this AMR. During one of these discussions, the observer noted that several agreements made at the NRC/DOE technical exchange (January 9–12, 2001, Pleasanton, CA) on Evolution of the Near Field Environment (ENFE) indicate that new data and analyses will be presented in the *EBS: Physical and Chemical Environment Model AMR* (ANL-EBS-MD-000033), expected to be available in fiscal year (FY) 2002. The observer was concerned that if the data and analyses required to fulfill NRC/DOE agreements are not presented in a FY 2002 revision of the ANL-EBS-MD-000033 AMR, then the NRC reviewers would not know where to look for the data and analyses. At the suggestion of the audit team leader, the observer wrote an AOI regarding this concern.

5.0 NRC STAFF FINDINGS

The observers determined that OQA Audit M&O-ARP-01-01 was effective in determining the level of compliance of M&O activities associated with the subject AMRs. The observers agreed with the audit team's conclusion that the OCRWM QA program had been satisfactorily implemented except, for the identified potential deficiencies. The following sections address the observers findings.

5.1 NRC AOIs

The following AOIs were generated during the audit:

a. OAR-01-04-1

Previous OQA audits of the M&O AMR/PMR development and review processes have provided both discrepancies and recommendations involving calculations, the check process, model validation, and software validation. During the observation of this audit, it appears from the auditor discussions and caucus meetings that similar discrepancies and recommendations are being made involving the same conditions as previously noted. A quick review of a DR corrective action request summary search of these discrepant conditions appears to indicate 16 documents involving similar conditions were identified, during 2000 and 2001, of which 12 documents have been closed, indicating acceptable response and verification. What is the process for identifying ineffective corrective action, improper implementation of corrective action, or lack of training and determining if more severe corrective action notices are warranted?

b. OAR-01-04-2

Several agreements made at the NRC/DOE Technical Exchange (January 9-12, 2001, Pleasanton, CA) on ENFE indicate that new data and analyses will be presented in the *EBS: Physical and Chemical Environment Model AMR* (ANL-EBS-MD-000033), expected to be available in FY 2002. The following NRC/DOE agreements point specifically to the FY 02 revision of this AMR: ENFE.2.04; ENFE.2.06; ENFE.2.08; ENFE.2.11; ENFE.2.13; and ENFE.2.18. ENFE.2.05 and ENFE.2.17 also point to this AMR, although it states the information can be provided in other documents as appropriate. During the M&O-ARP-01-01 audit of ANL-EBS-MD-000033, Rev. 01, in Las Vegas, NV (February 20-23, 2001), however, audit team members questioned the usefulness of producing additional revisions of this AMR. If data and analyses required to fulfill NRC/DOE agreements listed above are not presented in a FY 2002 revision of the ANL-EBS-MD-000033 AMR, where will this information be presented?

5.1.1 AOI Response

Subsequent to the audit, the NRC received a response to AOI OAR-01-04-1. In the response, OQA describes the current process for identifying and managing conditions adverse to quality. Further, the response indicated that two Suspect Trend Investigation Reports were issued to investigate conditions similar to those identified in the AOI in order to determine if more severe corrective action is required. This response addresses the concern of OAR-01-04-1 and is found to be acceptable based on reference letter from DOE to NRC, "U. S. Nuclear Regulatory Commission (NRC) Audit Observer Inquiry," dated April 19, 2001.

5.2 Open NRC AOIs

The following AOIs were generated during the observation of DOE's Audit No. M&O-ARP-01-02 of the Unsaturated Zone Flow and Transport Model Process Model Report (NRC Observation Report No. OAR-01-03, dated March 5, 2001):

- a) AOI No. M&O-APR-01-02-1, dated February 9, 2001, was written to identify an observer inquiry for ANL-NBS-HS-00032. The AOI states: "Arbitrary upper-bound vegetation cover percentages and bedrock root-zone thicknesses were assigned: 20% and 2.0 m for the modern climate; 40% and 2.5 m for the monsoon climate and 60% and 3.0 m for the glacial transition climate. A more detailed discussion of the assumed values is needed since the values may be excessive, thus leading to an over-prediction of ET and under-prediction of shallow infiltration. (Refer to U.S. NRC's Observation Audit Report No. OAR-00-04)."
- b) AOI No. M&O-APR-01-02-2, dated February 9, 2001, was written to identify an observer inquiry for ANL-NBS-HS-00032. The AOI states: "The instantaneous flow routing (IFR) method assumes that the duration of surface-water flow at Yucca Mountain is less than 24 hours and episodic in nature. This assumption is the basis for not using time-steps smaller than 24 hours when performing surface-water flow routing and calculating daily net infiltration. Please provide the NRC with adequate justification. (Refer to U.S. NRC's Observation Audit Report No. OAR-00-04)."
- c) AOI No. M&O-APR-01-02-3, dated February 9, 2001, was written to identify an observer inquiry for ANL-NBS-HS-00032. The AOI states: "An implicit assumption of the distribution-parameter water-balance model is that capillarity is not an important component of UZ flow processes for the objective of estimating annual average infiltration rates in the semi-arid climate of Yucca Mountain. The INFIL ver. 2.0 contains both the distribution-parameter water-balance module and the Richards module and could readily be used to confirm the basis for this assumption for a small scale region. The NRC recommends that the assumptions in the distribution-parameter water-balance model be validated by comparison against a numerical Richards equation-based code to assure that mean annual shallow infiltration estimates are not under-predicted. (Refer to U.S. NRC's Observation Audit Report No. OAR-00-04)."
- d) AOI No. M&O-APR-01-02-4, dated February 9, 2001, was written to identify an observer inquiry for ANL-NBS-HS-00032. The AOI states: "The work upon which this model is based (Flint et al., 1996, Conceptual and Numerical Model of Infiltration at Yucca Mountain) is unqualified. (See OCRWM QA Audit Report M&O APR-00-04)(p. 9). Was information used to support conclusions made in the Infiltration AMR? If yes, describe how the Flint et al. (1996) data was qualified and assumptions verified. NRC requests additional information and details. (Refer to U.S. NRC's Observation Audit Report No. OAR-00-04)."