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U.S. Nuclear Regulatory Commission
ATTN: Mr. Larry Campbell
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Subject: Predecisional Input to U.S. Nuclear Regulatory Commission (NRC) Observation Audit Report of the Engineered Barrier System Process Model Report (IM 20.01402.331.113)

Dear Mr. Campbell:

The enclosed predecisional input to the NRC Observation Audit Report on the U.S. Department of Energy audit of the Engineered Barrier System Process Model Report work at the Yucca Mountain Program facilities in Las Vegas, Nevada, was performed on February 20–23, 2001. An electronic version of this report is included and can be used as input to the final NRC Observation Audit Report. This submittal fulfills Intermediate Milestone 20.01402.331.113. Prior to the NRC sending out the final Observation Audit Report, it is our understanding all team members will be afforded an opportunity to review the final report and shall sign the Observation Audit Report indicating their acceptance.

In addition to the attached limited input, we understand that you may be adding text from other sources to complete the report.

These NRC observations of DOE audits are to ensure that the DOE audits are accomplished in an effective and adequate manner, the DOE quality assurance program has been satisfactorily implemented in the areas being evaluated, and the technical discipline activities are adequately observed.

If you have questions regarding this report, please contact me at (210) 522-5149. Your cooperation in this matter is appreciated.

Sincerely,



Bruce Mabrito
Director of Quality Assurance

BM:re

Enclosures

cc:	J. Linehan	T. Carter	T. Essig	P. Maldonado
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U.S. NUCLEAR REGULATORY COMMISSION
INPUT FOR THE OBSERVATION AUDIT REPORT NO. OAR-01-04
OBSERVATION OF THE OFFICE OF
CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE
AUDIT NO. M&O-ARP-01-01
ENGINEERED BARRIER SYSTEM (EBS)
PROCESS MODEL REPORT

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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 (DOE), Office of Civilian Radioactive Waste Management (OCRWM), 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 (BSC) LLC offices in Las Vegas, Nevada. BSC became the DOE Management and Operating (M&O) contractor on February 12, 2001.

Selected Analysis Model Reports (AMR) 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 four 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 four 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/are 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 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 on corrective action escalation detailed later in this report.

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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 (QATSS) and recently 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.

[More input for NRC report]

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. A determination was made that details were insufficient, and that could result in a technical product that cannot be mapped to specific requirements in either planning document. Because of the vague requirements, uniqueness 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 unique technical product. The observers agreed with the recommendations made in this area.

4.4.2 AP-3.4Q, Change Control; 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 eighteen Impact Review Action Notices (IRAN) had been initiated between the two documents and had been properly completed by the responsible individuals. No discrepancies were noted or recommendations for improvement were made.

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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 two 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 (DR) 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 audit observer inquiry (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 engineered barrier system (EBS) emplacement drifts. Output from these models are intended for use 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 made a recommendation that the planning of this AMR be revised to more clearly document specific work tasks. The audit observer agrees with this recommendation.

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The audit team technical specialist made several other recommendations to improve this AMR. These included: (1) additional clarification on 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 of 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 4 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 the 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 FY2002. The observer was concerned that if the data and analyses required to fulfill NRC/DOE agreements are not presented in a FY2002 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.

5.1 NRC Audit Observer Inquiries

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

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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 FY2002. The following NRC/DOE agreements point specifically to the FY02 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 FY2002 revision of the ANL-EBS-MD-000033 AMR, where will this information be presented?