QA: QA

U. S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALTY ASSURANCE

AUDIT REPORT M&O-ARP-01-01

OF THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM
MANAGEMENT AND OPERATING CONTRACTOR

AT

LAS VEGAS, NEVADA

FEBRUARY 20-23, 2001

Prepared by: _____ **Date:** _____
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Approved by: _____ **Date:** _____
Robert W. Clark
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1.0 EXECUTIVE SUMMARY

This performance-based quality assurance (QA) audit was conducted on the processes and activities related to the Engineered Barrier System (EBS) Process Model Report (PMR) at the Bechtel SAIC Company, LLC (BSC) offices in Las Vegas, Nevada, February 20-23, 2001. The purpose of the audit was to evaluate the effectiveness of the Analyses and Model Report (AMR) process and quality of the four AMR products, completed prior to February 12, 2001, under the previous Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O).

The audit team determined that the CRWMS M&O had effectively implemented the critical process steps relative to the EBS AMRs evaluated, with the following exceptions: deficiencies were identified in the areas of AP-3.10Q, *Analyses and Models* (Traceability/Transparently/Calculations and Model Validation), and AP-3.14Q, *Transmittal of Input* (Processing Input transmittals Through Closure). Based on the review of the AMRs, interviews of personnel, and examination of the process and documentation, the audit team determined that the EBS activities reviewed during the time of the audit meet the Office of Civilian Radioactive Waste Management (OCRWM) QA program requirements, with the exception of AMR ANL-EBS-MD-000033, "Physical and Chemical Environmental Model" (E-0100).

The audit team identified conditions adverse to quality that are addressed in two Deficiency Reports (DR) and one Deficiency Identification and Referral (DIR) document that was added to the Extent of Condition of a previously-issued open deficiency document.

DR BSC-01-D-050 addresses Model Validation documentation that did not meet one of the alternative approaches allowed by AP-3.10Q, paragraph 5.3.c.

DR BSC-01-D-051 addresses AP-3.10Q, traceability, transparency, and calculation problems in AMR ANL-EBS-000033, Revision 1, "Physical and Chemical Environmental Model."

DIR 01-01 addresses AP-3.14Q, where the Input Transmittals were not acknowledged, remained open and their need date exceeded.

Additionally, the audit team identified 13 recommendations, which are documented in the Condition/Issue Identification and Reporting Resolution System (CIRS) Numbers 1446-1458. The CIRS will be used for the response and tracking of the recommendations.

2.0 SCOPE

The auditors representing U.S. Department of Energy (DOE) Office of Quality Assurance (OQA) conducted a performanced-based audit to evaluate the adequacy and effectiveness of the EBS Organization Controls for the process development of the EBS AMRs. The audit was intended to determine the degree to which the resultant AMRs meet the program requirements, management commitments and expectations, as well as to

determine if the EBS organization completed the work in accordance with pertinent sections of the OCRWM DOE/RW-0333P, *Quality Assurance Requirements and Description* (QARD) document. The process and activities for the following approved AMRs were evaluated during the audit, in accordance with the approved Audit Plan:

ANL-EBS-MD-000032, Revision 1, "Water Distribution and Removal Model" (E0090)
ANL-EBS-MD-000033, Revision 1, "Physical and Chemical Environmental Model" (E0100)
ANL-EBS-MD-000027, Revision 1, "Drift Degradation Analysis" (E0080), and
ANL-EBS-MD-000026, Revision 0, ICN 1, "In-Drift Thermal-Hydrological-Chemical" (E0065) (Limited to verification of the incorporation of recommendations from Audit M&O-ARP-00-06).

2.1 <u>Process/Activities/End Product</u>

Activities involving development of the AMRs were selected for evaluation. Performance of the following critical process steps were evaluated:

Planning
Model Development
Qualification of Data/Software
Calculations
Checking/Technical Reviews
Validation of Models
Impact Reviews
Document Change Control
Submittal of Data to Technical Data Management System
Submittal of Records

2.2 The performance-based evaluation of process effectiveness and product acceptability was based on:

1) Satisfactory completion of the critical process steps,
2) Documentation that substantiates quality of the product,
3) Implementation of the applicable QA program sections, and
4) Effectiveness of related corrective actions.

2.3 In addition, a sample of the applicable QA program requirements and controls as they applied to the Process/Activity/End Product was examined to evaluate the degree of compliance. The following QA program sections are directly related to EBS organization's process/activities in developing the AMRs. These sections were evaluated for compliance:

2.0	QA Program
3.0	Design Control
16.0	Corrective Action
17.0	Quality Assurance Records

Supplement I	Software
Supplement III	Scientific Investigation
Supplement V	Control of the Electronic Management of Data.

2.4 Technical Areas

The audit included a technical evaluation of process effectiveness and product acceptability. Details of the technical evaluation are included in subsection 5.4.

3.0 AUDIT TEAM MEMBERS AND OBSERVERS

Audit Team Members

Donald J. Harris, OQA/Quality Assurance Technical Support Services (QATSS), Las Vegas, Nevada, Audit Team Leader
Lester W. Wagner, OQA/QATSS, Las Vegas, Nevada, Auditor
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Kristi A. Hodges, OQA/QATSS, Las Vegas, Nevada, Auditor
Harris R. Greenberg, Management & Technical Support (MTS), Las Vegas, Nevada, Technical Specialist
David C. Sassani, MTS, Las Vegas, Nevada, Technical Specialist
Steve Sobkrowski, MTS, Las Vegas, Nevada, Technical Specialist

Observers

Ted Carter, Nuclear Regulatory Commission (NRC), Headquarters, Maryland
Lauren Browning, NRC, Center for Nuclear Waste Regulatory Analysis, San Antonio, Texas
Don Shettel, State of Nevada/Geosciences Management Institute
Thomas Trbovich, NRC, Center for Nuclear Waste Regulatory Analysis, San Antonio, Texas

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The pre-audit meeting was held on February 20, 2001, in Las Vegas, Nevada. Daily team observer debriefing meeting were held by audit team members to report the progress of the audit and discuss any evaluations, including potential conditions adverse to quality. Daily management meetings were held to advise BSC management and staff on pertinent audit information as it was developed. The audit was concluded with a post-audit meeting held on February 23, 2001, in Las Vegas, Nevada.

Personnel contacted during the audit, including those who attended the pre-audit and post-audit meetings are listed in Attachment 1, “Personnel Contacted During the Audit.”

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall, the EBS organization process controls were implemented effectively for activities identified in the scope of the audit, except as noted in subsection 5.5, "Summary of Conditions Adverse to Quality."

The process controls for performing the critical process steps were found to be effective. The results for each activity evaluated are contained in Attachment 2, "Summary Table of Audit Results."

5.2 Stop Work or Immediate Corrective Actions Taken

There were no stop work orders or immediate corrective actions necessary as a result of the audit.

5.3 Audit Activities

Attachment 2, "Summary Table of Audit Results" provides the results for each process/activity/end product and related critical process steps and the results of the procedure compliance evaluations. Details of audit activities, including objective evidence reviewed, are documented in the audit checklist. The checklist is administered as a QA record in accordance with the directions of QAP 18.2, Revision 8, *Internal Audit Program.*

5.4 Technical Audit Activities

ANL-EBS-MD-000032: The AMR is well organized and logically presented. Revision 01 of the AMR provides improvements in a number of areas over Revision 00 in addressing both the Feature, Events, and Processes and the NRC Issue Resolution Status Report issues; however additional work could be performed to further improve the document in both of these areas. The recommendations are documented in CIRS 1446-1449.

The AMR summarizes work developed in two other EBS AMRs (ANL-EBS-MD-000028, "Water Diversion Model," and ANL-EBS-MD-000029, "Water Drainage Model"). This AMR discusses approximately six sub-models (three for under water diversion, one for water drainage, one for Thermo Hydrologic (TH) data development with prescribed seepage, and one for condensation under the drip shield). However, it appears that none of these models are currently used in Total System Performance Assessment (TSPA). The TH sub-model feeds data to the EBS ANL-EBS-MD-000033 and the results are used to screen out potential changes in invert porosity. Two of the water diversion sub-models may be used in future updates to the TSPA.

The AMR references one qualified software code and three software routines that are controlled by Software Configuration Management (SCM). In addition, it includes four software routines that are validated within the technical product. Based on a review of the AMR and attachments, the software routines are well-documented and transparent, with adequate traceability to input and output files. The test cases are clearly documented within the AMR.

Model validation for the Water Diversion model in AMR, ANL-EBS-MD-000032, Revision 1, Section 6.1.8, contains three sub-models developed in Attachments I, II, and III. The model validation as documented in this section did not utilize any of the available model validation options of AP-3.10Q, Section 5.3c and is documented in DR BSC-01-D-050.

TDP-EBS-MD-000007, Revision 00, "Technical Development Plan" states that pilot-scale test results and predictions will be compared to validate the EBS models. No pilot-scale test results were used for model validation since final test reports were unavailable. The author stated when the test reports are available, it is his intention to use the data to validate a number of elements of the sub-models, to increase confidence in those models that are eventually used in TSPA.

ANL-EBS-MD-000033: The AMR does not provide traceability to source information, clear discussion of the actual approach utilized, adequate bases for assumptions, and accurate documentation of calculations. These aspects, as well as additional problems with the transparency of the analyses were documented in DR BSC-01-D-051. In addition, review of one of the calculations utilized as the basis for the assessment of alkaline leachate from cement grout for rock bolts was found to contain errors. This was also documented in DR BSC-01-D-051. At this point, it is not clear how much of an impact the errors have on the calculations drawn from the specific analyses. An additional deficiency, DR BSC-01-D050, was found in the model validation of four of the six models developed within the document.

The AMR includes documentation of one qualified software code that is controlled by SCM and 15 software routines documented in 10 attachments. Based on a review of the AMR and attachments, the software routines lack transparency and traceability to input and output files. The BSC provided its status report for DR LVMO-00-D-039, which documents inadequacies in software routine documentation; and demonstrated that this AMR had been previously flagged as lacking adequate documentation. Since this AMR is already identified in the extent of condition for DR LVMO-D-00-039, no additional deficiency documents were generated.

In terms of traceability and transparency of the technical work, a number of data sets are not referenced to source documents and some references are incorrectly cited. Besides being within the text, this traceability error is found in some tables. For example, in Table 6.3-1, the values are indicated to have come from another

source, but in fact are values calculated in this AMR from using other values that are listed in the referenced source. This is the calculation that was found to be in error. In addition to these problems, there are instances in which assumptions are (a) missing, (b) incorrectly stated, (c) have no references cited for the information/ data used as the basis of this assumption, or (d) do not have adequate bases/ justification provided. There were a number of errors in the documentation, such as incorrect internal references (i.e., to sections that do not exist), tables with incorrect definition of variables used within equations, and incorrect data given within assumptions. Several routines are utilized within this document; however, traceability to the input/output files that is needed to ensure routine reproducibility is lacking. In some cases, the actual values used in calculations performed in this document were not found anywhere except within the spreadsheets themselves (where no documentation of sources for the values can be found). These conditions are documented in DR BSC-01-D-051.

The large number of the problems summarized above indicates major problems with the traceability and transparency of the work that was performed. The lack of documented traceability and transparency severely impedes evaluation of the conclusions in this product and degrades the utility of this document. The work documented cannot be assessed appropriately without elimination of the specific problems identified, as well as any similar problems not observed in this audit. Additionally, a number of recommendations documented in CIRS 1450-1458 are provided to improve the product.

ANL-EBS-MD-000027: This AMR evaluation was limited to verification of the incorporation of recommendations from audit M&O-ARP-00-06, as committed to in TRW letter to Robert W. Clark from George E. Dials, dated June 22, 2000. 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-Mechnical Effects Key Technical Issues Resolution Status Report, Revision 3, February 2001 meeting.

ANL-EBS-MD-000026: This AMR evaluation was limited to verification of the incorporation of recommendation from audit M&O-ARP-00-06, as committed to in TRW letter to Robert W. Clark from George E. Dials, dated June 22, 2000. The recommendations were incorporated in the AMR, Revision 0, ICN 1, satisfactorily.

5.5 Summary of Conditions Adverse to Quality

The audit team identified conditions adverse to quality that were addressed in two DR reports and one DIR document, which was added to the extent of condition of a previously open deficiency document.

5.5.1 Corrective Action Requests (CAR)

No CARs were issued.

5.5.2 Deficiency Reports (DR)

BSC-01-D-050
AP-3.10Q, Revision 2, ICN 3, *Analysis and Models.*

Contrary to the applicable requirements, validation of four process level models in AMR ANL-EBS-MD-000033, and one process level model in AMR ANL-EBS-MD-000032 did not utilize any of the alternative approaches specified by AP-3.10Q, paragraph 5.3.c.

Note: Due to the potential nature of these issues, Suspect Trend Investigation Report (STIR), number BSC-01-004 has been issued and will evaluate the effectiveness of corrective action in the area of model validation.

BSC-01-D-051
AP-3.10Q, Revision 2, ICN 3, *Analysis and Models* and QARD DOE/RW-0333P, Revision 10.

Contrary to the applicable requirements, numerous documentation errors were identified in AMR ANL-EBS-MD-000033 that do not provide adequate traceability to source information. In addition, the calculations associated with Table 6.3-1 were found to be incorrect.

Note: Due to the potential nature of this issue, STIR number BSC-01-003 has been issued and will evaluate the effectiveness of corrective action in the area of traceability and transparency.

5.5.3 Deficiency Identification and Referrals (DIR)

DIR-01-01 referred to LVMO-01-D-044
AP-3.14Q, *Transmittal of Input*

A review of four Input Transmittals revealed three had not been closed and their need (return) date had been past. A review of the open Input Transmittal Log identified that numerous Input Transmittals were still open and their need date exceeded.

5.5.4 Follow-up of Previously Identified Deficiencies

During the audit, previous corrective actions were evaluated relative to the conditions identified in the DRs that could impact the EBS AMR/PMR process. These corrective actions were evaluated for effectiveness.

LVMO-00-D-039
AP-SI.1Q, Revision 2, ICN 4, *Software Management*

The AMR, ANL-EBS-MD-000033, includes documentation of one qualified software code that is controlled by SCM and 15 software routines documented in 10 attachments. Based on a review of the AMR and attachments, the software routines lack transparency and traceabillity to input and output files. The BSC provided its status report for DR LVMO-00-D-039, which documents inadequacies in software routine documentation, and demonstrated that this AMR had been previously flagged as lacking adequate documentation. Corrective action is ongoing.

LVMO-00-D-043
AP-3.1Q, Revision 2, ICN 3, *Analysis and Models*

Checkers comments were deferred to next revision of the AMR. All checkers' comments were resolved. The corrective action was determined to be effective.

LVMO-00-D-070
AP-2.14Q, Revision 1, *Review of Technical Products and Data*

Comment sheets initialed by other than the designated reviewers. Comment sheets were initialed by the designated technical reviewer on the AMR evaluated during this audit. The corrective action was determined to be effective.

LVMO-00-D-071
AP-3.15Q, Revision 2, *Managing Technical Products Inputs*

To Be Verified (TBV) not assigned to data used as input. The AMRs Document Input Reference Sheets (DIRS) report included the appropriate TBVs. The corrective action was determined to be effective.

LVMO-00-D-095
AP-3.15Q, Revision 2, *Managing Technical Product Inputs*

The Determination of Importance Evaluations were implemented for the AMR included in this audit. The corrective action was determined to be effective.

LVMO-00-D-097
AP-3.15Q, Revision 2, *Managing Technical Product Inputs*

The TBV/To Be Determined (TBD) tracking numbers were not assigned prior to the Product Checking Group lockout of the DIRS Report. The

TBV/TBD tracking number was included in the DIRS report prior to lockout by the Product Checking Group. The corrective action was determined to be effective.

LVMO-00-D-099
AP-SI.1Q, Revision 2, ICN 4, *Software Management*

Software codes turned over to SCM could not be installed on personal computers. The corrective action on this DR is ongoing in a extended process phase; however, no software codes used in the development of these products were identified as being impacted by DR LVMO-00-D-099.

LVMO-00-D-118
AP-3.10Q, Revision 2, ICN 3, *Analyses and Models*

Data traceability and document transparency is to identify the principal lines of investigation. The corrective action for this DR is currently in process, which requires a revision to AP-3.10Q. A related DR (BSC-01-D-051) was issued as a result of this audit.

LVMO-00-D-119
AP-3.10Q, Revision 2 ICN 3, *Analysis and Models*

Model validation is not being performed in accordance with AP-3.10Q. The corrective action for this DR is currently in process. The draft AP-3.10Q was reviewed and found to provide additional clarification for validating models. Once this draft is approved it should preclude future problems in this area. As a result of this audit a new DR, BSC-01-D-050 was issued on model validation.

LVMO-00-D-135
AP-SV.1Q, Revision 0, ICN 2, *Control of Electronic Management of Information*

Ineffective identification of process controls for the Control of the Management of Electronic Data. The identification of electronic data was determined to be effective during this audit.

LVMO-00-D-136
AP-SI.1Q, Revision 2, ICN 4, *Software Management*

Software identified on the baseline as being qualified to run a multiple operating systems were actually qualified only to run on a single platform, with a single operating system. The Software Baseline Report (SBR) reflected the platform and operating systems specified for the software in

these AMRs. No additional deficiencies related to software platform were identified during the audit. The corrective action completion for this DR is pending.

6.0 RECOMMENDATIONS

The audit resulted in the issuance of six recommendations, which are documented in the CIRS Numbers 1446-1458. CIRS will be used for the response and tracking of the recommendations.

7.0 LIST OF ATTACHMENTS

Attachment 1 – "Personnel Contacted During the Audit"
Attachment 2 – "Summary Table of Audit Results"