ENCLOSURE 5

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 4, 2000

Mr. Dwight Shelor, Acting Director
Program Management and Administration
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

SUBJECT: U. S. NUCLEAR REGULATORY COMMISSION AUDIT OBSERVATION AUDIT REPORT NO. OAR-00-02, "OBSERVATION AUDIT OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE DIVISION AUDIT M&O-ARP-00-001"

Dear Mr. Shelor:

I am transmitting the U.S. Nuclear Regulatory Commission (NRC) Observation Audit Report No. OAR-00-02 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 (YMQAD) limited scope, performance based audit of the OCRWM Quality Assurance (QA) program of the Civilian Radioactive Waste Management System Management and Operating (M&O) Contractor. The audit, M&O-ARP-00-001, was conducted on November 8-12, 1999, at the M&O offices in Las Vegas, NV.

This audit evaluated the activities that constitute scientific, engineering and performance assessment analyses and models pertaining to the Waste Package Process Model Report (PMR) and the technical activities associated with processes and controls related to the PMR. The following Analysis Model Reports (AMRs) were evaluated: Analysis of Mechanisms for Early Waste Package Failure (ANL-EBS-MD-000023, Rev 00); General Corrosion and Localized Corrosion of the Waste Package Outer Barrier (ANL-EBS-MD-000003, Rev 00C, Draft); Aging and Phase Stability of the Waste Package Outer Barrier (ANL-EBS-MD-000002, Rev 00C Draft); Environment on the Surface of the Drip Shield and Waste Package Outer Barrier (ANL-EBS-MD-000001, Rev 00B Draft). The audit also included a review of appropriate procedures directly related to the AMRs and PMRs and evaluated the effectiveness of the analysis and model processes and the quality of the resultant end products identified. This was done by verifying implementation adequacy of the critical process steps relative to analysis and models for the Waste Package PMR.

The audit team concluded that the M&O documentation of activities that constitute scientific, engineering and performance assessment analysis and models pertaining to the Waste Package were satisfactory. One deficiency was identified during the audit. Thirty-four recommendations were offered as improvements to the program.

The NRC staff agrees with the audit team's conclusion, findings, and recommendations. The NRC staff determined that this audit was effective and that the M&O implementation of the QA program for the subject AMRs was adequate. However, the selected AMRs were still in the revision process and the associated software, data, and model packages had not been qualified, verified or validated; therefore, no qualification packages were reviewed by the audit team or NRC staff.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Ken Hooks of my staff at (301) 415-7777.

Sincerely,

[Original signed by: N.King Stablein for:]

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

Enclosure: US Nuclear Regulatory Commission Observation Audit Report
OAR-00-02

cc: See attached list

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Letter to D. Shelor from C.W. Reamer dated: February 4, 2000

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U. S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT OAR-00-02

OF THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION

AUDIT M&O-ARP-00-001

OF THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM

MANAGEMENT AND OPERATING CONTRACTOR

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Enclosure

1.0 INTRODUCTION

Staff and consultants of the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division (YMQAD), limited scope, performance based audit of the Waste Package Process Model Report (PMR) at the Management & Operating Contractor (M&O) facilities. The audit, M&O-ARP-00-001, was conducted on November 8-12, 1999, for work being performed at the facilities in Las Vegas, Nevada and involved the review of selected Analysis Model Reports (AMRs) prepared by the Lawrence Livermore National Laboratory (LLNL).

The objective of this audit by YMQAD was to evaluate the implementation of the OCRWM program requirements and the technical activities associated with development of the Waste Package AMRs.

The NRC staff objective was to gain confidence that the M&O and OQA are properly implementing the provisions contained in the OCRWM Quality Assurance Requirements and Description (QARD) and the requirements contained in Subpart G, Quality Assurance, to Part 60, of Title 10 of the Code of Federal Regulations (10CFR Part 60). Because of the anticipated DOE submittal of the Site Recommendation (SR) in November 2000, the following observation activities were emphasized: (1) confirming that data, software, and models supporting SR are properly qualified; and (2) reviewing the progress being made by DOE and its contractors in meeting the qualification goals for SR.

This report addresses the NRC staff determination of the effectiveness of the OQA audit and the adequacy of implementation of QARD controls by the M&O in the areas of AMR development.

2.0 MANAGEMENT SUMMARY

The NRC staff has determined that OQA Audit M&O-ARP-00-001 was useful and effective. The audit was organized and conducted in a professional manner. Audit team members were independent of the activities they audited. The audit team was qualified in their respective disciplines, and its assignments and checklist items were adequately described in the audit plan.

The audit team concluded that the OCRWM QA program had been satisfactorily implemented in the areas evaluated. However, the selected AMRs were still in the revision process and the associated software, data, and model packages had not been qualified, verified or validated, therefore no packages were reviewed by the audit team or NRC staff. One deficiency was identified during the audit. Thirty-four recommendations were offered by the audit team during the closing meeting as improvements or enhancements to the AMR development process and to the QA program procedures. The NRC staff agrees with the audit team's conclusion and recommendations. The NRC staff determined that this audit was effective, that the QA program implementation was adequate and the recommendations should prevent future discrepancies in the AMR/PMR development process.

3.0 AUDIT PARTICIPANTS

3.1 NRC

Thomas Trbovich	Observer (Team Leader- CNWRA)
Charles Greene	Observer (Technical Specialist)
Ken Hooks	Observer (QA Specialist - NRC Task Force Member)
Darrell Dunn	Observer (Technical Specialist - CNWRA)

3.2 DOE Audit Team

Emily Jensen	Audit Team Leader (ATL)	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
Kristi Hodges	Auditor	OQA/QATSS
Victor Barish	Auditor	OQA/QATSS
Richard Powe	Auditor	OQA/QATSS
Robert Hartstern	Auditor	OQA/QATSS
Frank Wong	Technical Specialist	Management and Technical Services (MTS)
Robert Fish	Technical Specialist	MTS

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 the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989 (Draft).

4.1 Scope of the Audit

The audit team conducted a limited scope, performance based audit of activities and processes supporting the development of the Waste Package AMRs. The audit included review of the QA program procedures directly associated with preparation of the AMRs which included:

- AP-2.13Q "Technical Product Development Planning"
- AP-SI.1Q "Software Management"
- AP-3.15Q "Managing Technical Product Inputs"
- AP-SIII.2Q "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data"
- AP-3.10Q "Analysis and Models"
- AP-2.14Q "Review of Technical Products"
- AP-SIII.3Q "Submittal and Incorporation of Data to the Technical Data Management System (TDMS)"
- AP-3.11Q "Technical Reports"
- AP-2.15Q "Work Package Planning Summaries"
- AP-SIII.1Q "Scientific Notebooks"

The following AMRs supporting the Waste Package PMR were evaluated by the audit team:

- Analysis of Mechanisms for Early Waste Package Failure (ANL-EBS-MD-000023, Rev 00)
- General Corrosion and Localized Corrosion of the Waste Package Outer Barrier (ANL-EBS-MD-000003, Rev 00C Draft)
- Aging and Phase Stability of the Waste Package Outer Barrier (ANL-EBS-MD-000002, Rev 00C Draft)
- Environment on the Surface of the Drip Shield and Waste Package Outer Barrier (ANL-EBS-MD-000001, Rev 00B Draft)

The critical process steps examined in relationship to accomplishing the performance based aspect of this assessment included the following:

- Planning
- Resources
- Inputs to Analysis and Models
- Development and Documentation of Analysis and Models
- Validation of Models
- Use of Software or Models
- Documentation Check and Review
- Approvals
- Analysis or Model Revisions or Change
- Verification and Qualification of Data
- Submittal of Data and Models to the Technical Data Management System (TDMS)

4.2 Conduct and Timing of the Audit

The audit was performed in a professional manner and the audit team was prepared and demonstrated a sound knowledge of the M&O organization and DOE QA programs. The LLNL Principal Investigators (PIs) for the selected AMRs were brought to the M&O offices to be interviewed by the audit team members. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit. For each AMR, LLNL staff was present at the Nevada office for one day and contacted at LLNL by telephone for the remainder of the audit to resolve open items or questions. The NRC staff believes the timing of the audit was appropriate for the auditors to evaluate the ongoing activities and implementation of the QA program even though it was very early in the Waste Package AMR development process. QA audits at this stage of the AMR process development are crucial. Relatively minor corrections made at this point will result in a better quality product; however, delaying corrections to problems found by such an audit until the models are complete may result in non-qualifiable models and wasted effort.

The DOE audit team and NRC observers caucused at the end of each day. Also, meetings of the audit team and M&O management (with the NRC observers present) were held each morning to discuss the current audit status and preliminary findings or recommendations.

4.3 Audit Team Qualification and Independence

The qualifications of the Audit Team Leader and audit team members were found to be acceptable in that they each met the requirements of OCRWM QAP 18.1, "Auditor Qualification," as checked by the NRC Observation Audit Lead. The audit team OCRWM members did not have prior responsibility for performing the activities they audited. In addition, training, education and experience records for audit team members were reviewed and found acceptable.

The audit team members were prepared in the areas they were assigned to audit and were knowledgeable of applicable procedures. The checklist was adequately formulated and covered the subject matter well.

4.4 Examination of Programmatic Quality Requirements

Programmatic audit activities were conducted in accordance with the OCRWM QA Audit Plan for Audit M&O-ARP-00-001. The auditors reviewed documents identified in the audit plan and used checklists as a basis for inquiries. In addition, related documentation supporting report conclusions was reviewed to verify data source and status of qualification. Personnel directly responsible for document products or appropriate representatives with sufficient levels of knowledge were interviewed by the auditors. The checklists used were effective and additional inquiries were made beyond specific checklist items, when appropriate. The NRC observers were briefed on audit conduct procedures, including the inquiry process and method for raising concerns. The NRC observers were given ample opportunity to review documents, ask questions and provide comments.

The NRC observers found that the requirements of QA Procedure 18.2 were implemented in an effective and satisfactory manner. These planning and implementation activities were accomplished and observed by the NRC observers as follows:

(1) distribution of a quality assurance audit plan, M&O-ARP-00-001;
(2) development of a performance based audit checklist;
(3) coordination and communications with all team members;
(4) conduct of an introductory pre-audit kickoff meeting with the audit team and observers;
(5) conduct of a kickoff meeting with M&O personnel including high level waste management;
(6) daily caucus meetings held for the audit team and observers;
(7) daily management status meetings held for M&O management; and
(8) conduct of a post audit meeting with M&O management, audit team members and NRC observers.

In addition, implementation of corrective measures were evaluated on the significant deficiencies documented in existing Corrective Action Requests (CARs) that could impact the AMR development process. The following is a status of the CARs as a result of the evaluation:

CAR LVMO-99-C-001

The assessment of procedures AP-3.10Q, Revision 1, ICN 1, "Analysis and Models," was found to be satisfactory in addressing the traceability and technical adequacy of data. There was one recommendation regarding the checking process; however, there is no adverse impact on the

AMRs/PMR based on this recommendation to this point. Additional verification of implementation is required in order to adequately assess the effectiveness of the AP-3.10Q development and checking process of the AMRs/PMR. This CAR remains open.

CAR LVMO-98-C-002

AP-3.15Q, Data or Technical Information Confirmation Checklists continue to be completed. Two checklists, addressing a total of 10 data tracking numbers used as inputs to AMR ANL-EBS-MD-000023, were reviewed during the audit. Problems are still occurring during the completion of the checklists with respect to the transparency of conclusions and accuracy. However, positive steps are being taken to address these issues. This CAR remains open.

CAR LVMO-98-C-006

Additional corrective actions are necessary to address deficiencies identified during the audit. Although recent changes to AP-SI.1Q, Revision 2, ICN 1, "Software Management," authorized use of unqualified software while in the process of being qualified, specific requirements found in AP-SI.1Q (Section 5.12) were not implemented for software associated with the audited AMRs. In addition, instances of inadequate documentation to support verification for software macros and routines were identified during the audit. The results of this audit are included in the unsatisfactory verification documented as part of the OQA Phase 3 verification of the CAR Management Plan. This CAR remains open.

CAR LVMO-98-C-010

The remaining CAR-010, corrective action, i.e., generation of "family trees," a general schematic of AMRs that are inputs to the TSPA, were found to be adequate; however, there was not sufficient implementation of AP-3.10Q, Revision 1, ICN 1, "Analyses and Models," in regard to model validation. Therefore, additional verification of implementation is required in order to adequately assess the effectiveness of the model process. This CAR remains open.

4.5 Examination of Technical Activities

The work supporting these AMRs was conducted at LLNL. The four AMRs audited are indicated in Section 4.1.

4.5.1 NRC Observation Team Technical Specialists General Comments

Technical specialists on the YMQAD audit team were competent and independent. Appropriate programmatic and technical questions were asked by the DOE auditors and technical specialists. The technical specialists had sufficient knowledge of technical issues associated with the Analysis of Mechanisms for Early Waste Package Failure and Environment on the Surface of the Drip Shield and Waste Package Outer Barrier AMRs. However, some lack of understanding of a few significant technical issues associated with the General Corrosion and Localized Corrosion of Waste Package Outer Barrier and the Aging and Phase Stability of Waste Package Outer Barrier AMRs was noted.

The audit identified that confusion existed on which procedures to follow to ensure QA compliance. Demonstrated difficulty was noted in executing the new QA procedures

implemented program-wide in June of 1999. This may be due to lack of training or incentive to follow new procedures.

Theoretically, a very effective database and system is in place for documenting all inputs, codes and models; however, confusion of PIs and Administrators about entering the correct documents in the proper databases was evident during the audit.

These AMRs had gone through quite extensive review and checking, yet were still plagued by editing errors such as referring to the wrong section due to the addition/deletion of sections. None of the AMRs exhibited a model in a form near enough to completion for final presentation. The DOE technical specialists inquired about the model for each of the AMRs. With the exception of the Analysis of Mechanisms for Early Waste Package Failure, which is largely based on the probability of human error, all of the AMR authors indicated that the model development was incomplete. In several cases, the AMR authors indicated that additional data had been collected for the development of the models. This additional data was not included in the version of the AMR under review since this would slow the review process.

It is apparent in many cases that the output or result from one AMR is needed for input to another AMR, yet work on the AMRs is progressing in parallel, not waiting for the necessary input, but rather making assumptions that can later be modified. For example, the output of the Environment on the Surface of the Drip Shield and Waste Package Outer Barrier AMR should feed into the General Corrosion and Localized Corrosion of Waste Package Outer Barrier AMR in order to calculate corrosion rates and assess the possibility for localized corrosion. Because the experimental work on the Environment on the Surface of the Drip Shield and Waste Package Outer Barrier AMR was initiated within the last year, long term corrosion tests were performed in a range of environments that were assumed to be possible at the waste package and drip shield surfaces.

Several technical comments brought up by the observers during the audit were similar to those previously brought to the attention of the PIs during interactions with the DOE. Those comments did not appear to have been addressed in these AMRs. The most important examples of such comments are: (1) The deposition of SiO_2 and corrosion products on specimens from the Long Term Corrosion Test Facility (LTCTF); (2) The effect of welding and thermal treatments on the corrosion resistance of Alloy 22; and (3) The inconsistent use of critical potentials for the initiation of localized corrosion.

In the first example, DOE acknowledged during the July 7, 1999, Appendix 7 meeting at LLNL that there was deposition of corrosion products and SiO_2 on the test specimens of Alloy 22 from the LTCTF. The validity of the weight loss measurements was questioned by NRC at that time. The response from DOE was that the cumulative distribution curve (Figure 23 in the General Corrosion and Localized Corrosion of Waste Package Outer Barrier AMR) probably should be shifted to the right so that there are no specimens with a weight gain. The NRC believes this is not a defensible approach if there is no information regarding the rate of SiO_2 deposition. Another recommendation by NRC to DOE regarding the LTCTF tests prior to and at the time of the Appendix 7 meeting was the measurement of the corrosion potential of the specimens. Although this would have taken little additional effort to accomplish, measurement of the corrosion potentials was never performed in the LTCTF by DOE.

The second example refers to NRC recommendations to DOE regarding the effect of container fabrication and welding on the corrosion resistance of Alloy 22, also discussed in the July 7, 1999, Appendix 7 meeting. These NRC comments were also expressed to the DOE at the DOE Waste Package Degradation Modeling and Abstraction Workshop (April 20-21, 1999, Las Vegas, NV). The machining of specimens from the container mockups was discussed and CNWRA staff indicated that the CNWRA would like to have a section of the container mockup with a section of the weld to support NRC staff evaluation of DOE conclusions. CNWRA staff also discussed the effect of welding with LLNL staff at the 1998 Materials Research Society (MRS) meeting (Boston, MA) and indicated that NRC was interested in the corrosion resistance of the welded alloy. LLNL staff have done some interesting microstructural characterization studies on both welded and thermally aged specimens; however, the effect of welding on the corrosion resistance has not been addressed by DOE.

The third example of DOE not addressing NRC staff comments involves DOE's inconsistent use of critical potentials for the initiation of localized corrosion. There are inconsistencies in the interpretation of critical potentials from one chapter to the next in the 1998 Engineered Materials Characterization report (edited by McCright). The NRC and the CNWRA have consistently used the repassivation potential, and from circa 1994, the crevice corrosion repassivation potential. The NRC and CNWRA have published numerous reports, conference papers and journal papers indicating this is a valid approach and that one can easily get crevice corrosion at potentials below the pit initiation potential in a period of days or weeks. DOE's reluctance to use a consistent criteria for initiation of localized corrosion is a weakness in their evaluation of waste package degradation.

Conducting the audit in Las Vegas of activities at LLNL provided some logistical difficulties, but overall the audit was effective. Once database management comes up to speed, logistical problems should be eliminated.

4.5.2 Specific Technical Comments

Technical questions, comments, and concerns from the NRC observers are summarized in this section.

Analysis of Mechanisms for Early Waste Package Failure - ANL-EBS-MD-000023 Rev 00.

A question was asked if there was any alternative text or opposing authority to Swain and Guttmann (A.D. Swain and H.E. Guttman, NUREG/CR-1278, Handbook of Reliability Analysis with Emphasis on Nuclear Plant Applications, August 1983), since all of the probability numbers come from this handbook. For example, Swain and Guttmann is used as the sole reference for the probability of a worker performing a task incorrectly and then missing his mistake on self-check as well as the probability of an independent inspector missing a mistake or defect in the construction of an engineered repository system. The PI indicated that Swain and Guttman was the only source of the probability data used in this AMR and the text is the industry/discipline standard as well as a NUREG.

In answering a question from the NRC technical specialist, the PI indicated base metal flaws such as voids, stringers, inclusions and rolling laps were considered in this AMR. These flaws were considered to occur at a frequency of 10 times less than the frequency of flaws in the welds.

These base metal flaws were considered to occur due to temporary welds and subsequent grinding out on plate during processing.

The data from E. Siegman's report (Draft of AMR "Initial Condition of Cladding", ANL-EBS-MD-000048, Rev. 00, part of upcoming OQA audit of Waste Form AMRs) was considered and the present AMR was developed using this data. One additional question regarding the failure rates published in Timmins (P.F. Timmins,"Solutions to Equipment Failures ",1999, Materials Park, Ohio, ASM International) was not asked since it seemed like the author had considered a sufficient cross section and number of reports from industrial manufacturing processes. The annealing time for the fabricated Alloy 22 container was stated as 24 hours. The PI indicated that this did not mean that the container would be at temperature for 24 hours. The text in this section of the AMR will be reviewed and corrected and/or clarified.

General Corrosion and Localized Corrosion of Waste Package Outer Barrier - ANL-EBS-MD-000003 Rev 00C (Draft).

LLNL indicated that localized dry oxidation of the waste package outer barrier was not considered but indicated that this phenomena would be considered in future versions of the AMR since the Ni-Cr-Mo alloys tend to suffer grain boundary attack rather than general corrosion under dry oxidation conditions.

In response to a question from the NRC audit observation team, LLNL indicated test specimens are identified and tracked by a Metals Samples, Incorporated lot number. In addition, each sample is stamped with a unique number than can be traced to a Metals Samples lot number which has also had composition chemistry verified by an independent qualified laboratory. The Metals Samples procedure for assigning individual heats from the manufacturer unique lot numbers was audited. This traceability is maintained on a master spread sheet in Excel at LLNL that was not available in the database (Record Information System - RIS web). Hard copies are maintained as supplements to scientific notebooks which should also be in the database on the RIS web. The traceability of randomly selected samples from the AMR was not transparent and the documentation was not in the RIS web.

The basis for selecting the critical potential (E_{crit}) for the initiation of localized corrosion was questioned by the NRC audit observation team. LLNL indicated that since some cyclic polarization tests did not result in a repassivation potential, the breakdown potential is used for all samples and environments. There exists disagreement between NRC/CNWRA and LLNL on selection of the critical potential.

Critical potentials listed in this AMR are pitting corrosion repassivation potentials reported by Gruss et al. (K.A. Gruss, G.A. Cragnolino, D.S. Dunn, and N. Sridhar, "Repassivation Potential for Localized Corrosion of Alloys 625 and C22 in Simulated Repository Environments", Proceedings of Corrosion 98, March 22-27, 1998, San Diego, California, 149/1 to 149/15, Houston, Texas: NACE International) using a lead-in-pencil specimen geometry. Since Alloy 22 is resistant to pitting corrosion, the use of pitting corrosion repassivation potentials to predict the onset of localized corrosion does not appear to be conservative. Crevice corrosion has been identified in the AMR as the most probable localized corrosion mode for the container. It was also noted that the repassivation potential measurements with welded specimens were not reported, although it is recognized that welding may increase the localized corrosion susceptibility

of Alloy 22. Future versions of the AMR will consider both crevice corrosion and the effects of welds.

The effect of sulfate reducing bacteria on Stress Corrosion Cracking (SCC) of Alloy 22 will be considered in future AMRs. Nickel alloys are known to be susceptible to SCC in sulfide environments. In addition to SCC, questions were raised regarding the Alloy 22 corrosion rate in solutions inoculated with bacteria. While the weight loss of the specimen indicated the corrosion rate increased by a factor of 2, analyses of the corrosion products in solutions suggests preferential dissolution of Cr and Mo. Since these alloying additions are largely responsible for the localized corrosion resistance of Alloy 22, the long term effects of preferential dissolution may be much more severe than a 2x increase in the corrosion rate. The PI of this AMR suggested that the microbial induced corrosion data in the AMR was preliminary and that additional investigations are underway to further investigate the effect of microbes on the corrosion rate of Alloy 22.

Questions were raised on how the results of the Atomic Force Microscopy (AFM) examination of the Alloy 22 samples exposed for one year will be used to predict the performance of the waste package outer barrier. At the present time, the AFM work is relatively new and the knowledge that can be obtained by the examination of long term test specimens is not known. DOE stated that one possibility may be to determine if a silica layer will deposit on the waste package surface and form a protective covering.

There is a concern about validity of LTCTF weight loss measurements due to deposition of SiO_2 that could not be removed prior to final weight measurement. The deposition of silica on the specimens would alter the weight loss of the specimens. Corrosion rate calculations that do not properly consider the effect of silica deposition would under predict the actual corrosion rate. LLNL indicated that additional AFM studies are being conducted using lithography masks to measure metal volume loss and presumably, though not specifically mentioned, volume of SiO_2 deposited on LTCTF coupons.

Aging and Phase Stability of Waste Package Outer Barrier - ANL-EBS-MD-000002 Rev 00C (Draft).

Overall a concern was expressed about qualifying samples and procedures or specimens received from Haynes International. The long term thermal aging tests of several heats of Alloy 22 were performed by the research and development section of Haynes International. Efforts to qualify the data obtained from these material heats are ongoing. There is an overall concern about qualifying software used for calculations, e.g., THERMOCALC, used to determine phase stability for Ni-Cr-Mo alloy at low temperatures and long times.

A concern was raised about range of chemical composition of Alloy 22 allowed by ASTM specification and effect of extremes in chemistry still within specification on phase stability. The AMR author responded that these effects can be captured by data in the literature and by studying other alloys such as Alloy 59 and Alloy 686. There is general disagreement on this issue between NRC/CNWRA staff and authors of this AMR. The statement in this AMR that compositional variations of Alloy 22 within the limits of ASTM B575 are not expected to have a significant effect on the phase stability of the alloy based on a number of alloy heats examined, was not justified. The compositions of the heats had not been verified and examination of the entire range of tungsten, cobalt, and iron compositions to determine the effects of these alloying

elements/contaminants on the phase stability of the alloy were not performed. It was also noted that the composition specification of the Alloy 22 welds, performed by an independent, qualified, chemical analysis vendor, indicated a maximum molybdenum concentration of 4.5 weight percent. The specification for Alloy 22 weldments may be detrimental to the thermal stability of the alloy, however, this was not examined.

Environment on the Surface of the Drip Shield and Waste Package Outer Barrier - ANL-EBS-MD-000001 Rev 00B (Draft).

The author was asked by the NRC technical specialist if temporal variations in chemical composition of the water percolating through heated tuff, were considered. This may be significant if mineral sites in the tuff become saturated with ions from the simulated well J-13 water. The response was that this had not been considered but acknowledgment was made that future versions of the AMR would need to address this issue.

The parallel development of the AMR was a cause for concern since the General Corrosion and Localized Corrosion of Waste Package Outer Barrier AMR is based on the results of tests using Basic Simulated Water (BSW) for input, yet BSW is not considered in this AMR. As a result, there appears to be a disconnect between this AMR and the General Corrosion and Localized Corrosion of Waste Package Outer Barrier AMR. It was indicated by LLNL that discrepancies arising from some of the assumptions necessary for the parallel development of these AMRs will need to be resolved.

4.6 NRC Staff Findings

The NRC staff has determined that OQA Audit M&O-ARP-00-001 was useful and effective. The audit was organized and conducted in a professional manner. Audit team members were independent of the activities they audited. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan.

The audit team concluded that the OCRWM QA program had been satisfactorily implemented. The audit team performed a good review considering the early stage of development that was evident with the selected AMRs. However, one deficiency and thirty-four recommendations were identified by the audit team to improve the AMRs and associated quality program procedures. The NRC staff agrees with the audit team conclusion and recommendations. The NRC staff determined that this audit was effective and that the QA program implementation was adequate.

4.6.1 Audit Observer Inquiries

No NRC observer inquiries were initiated during the audit. A potential inquiry dealing with corrosion metal sample certification traceability was resolved with receipt of the hardcopy of certifications by the NRC staff.

4.6.2 NRC Summary Comments

The following comments were made at the closing meeting by the NRC Audit Observation lead:

1. The audit team has conducted an effective, performance based in-process review of the Waste Package AMR development process.

2. The issuance of the new procedures from the Process Validation and Reengineering (PVAR) process appears to have created confusion, misinterpretation and lack of coordination, thus creating implementation difficulties especially in database management and To Be Determined/To Be Verified (TBD/TBV) clearing process.

3. Additional self assessments of the AMR/PMR process prior to outside reviews would be beneficial. The results of the one self assessment performed had not resulted in any corrective measures prior to this audit.

4. The AMR/PMR development process, the data/model TBD/TBV clearing process and software qualification process appear to be conducted as separate entities when all these processes are interrelated and should come together before SR and License Application.

5. The comments discussed in 4.5.1 of this report have been made to PIs previously by the NRC staff on reports included as a basis of the AMRs at Technical Exchange meetings. However, the comments apparently have not been addressed.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 4, 2000

Mr. Dwight Shelor, Acting Director
Program Management and Administration
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- 00-03, "OBSERVATION AUDIT OF OFFICE OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT, QUALITY ASSURANCE DIVISION, AUDIT NO. M&O-ARP-00-002"

Dear Mr. Shelor:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report No. OAR-00-03 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 (YMQAD), audit of the Biosphere Process Model Report (PMR) activities performed by the OCRWM Management and Operating Contractor (M&O). The audit, M&O-ARP-00-002, was conducted on November 15-19, 1999, at the M&O facilities in Las Vegas, Nevada.

This audit was limited in scope and evaluated the effectiveness of the implementation of the OCRWM QA Program described in the Quality Assurance Requirements and Description (QARD) and its implementing procedures for selected analysis model reports (AMRs) supporting the Biosphere PMR.

The NRC staff determined that this audit was effective in identifying deficiencies and recommending improvements in the AMR process. During the conduct of the audit, both the audit team and the NRC observers reviewed data, analysis reports, and software within the scope of the audit to confirm that it was properly qualified. The NRC observers determined that: a) the software supporting the AMRs had been properly qualified; and b) certain data categorized as "accepted data" were determined to be controlled in accordance with established procedures and properly categorized as "accepted data."

The NRC staff generally agrees with the audit team conclusions, findings, and recommendations. However, as noted in Section 4.7 of this report, the NRC staff expressed a concern about the adequacy of the process controlling the preparation and use of procedures for the AMR process. Further, as discussed in various sections of this report, the NRC staff is concerned about the lack of data qualification activities for the AMRs reviewed during this audit and the two previous audits. Accordingly, this condition appears to be a condition requiring DOE's management attention.

As discussed in Section 4.7.1 of the attached report, the NRC observers generated two audit observer inquiries (AOIs) questioning the process used for the validation of analysis and models, and concerning documenting the resolution of a reviewer's comments. Also, we would

like to point out that we have not received a response to an AOI, dated September 22, 1999, which addressed the qualification status and use of the waste stream profiles.

A written response to this letter and the enclosed report is not required. However, we do expect OQA to provide replies to the open AOIs. If you have any questions, please contact Larry L. Campbell of my staff at (301) 415-5000.

Sincerely,

Ken Stablein for

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

Enclosure: NRC Observation Audit Report No. OAR-00-03, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. M&O-ARP-00-002"

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U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-00-03

OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE DIVISION

AUDIT NO. M&O-ARP-00-002

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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), Yucca Mountain Quality Assurance Division (YMQAD) audit of the Biosphere Process Model Report (PMR) activities performed by the OCRWM Management & Operating Contractor (M&O). The audit, M&O-ARP-00-002, was conducted on November 15–19, 1999, at the M&O facilities in Las Vegas, Nevada.

The objective of this audit was to evaluate the implementation of the applicable provisions contained in the OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 8, by reviewing selected analysis model reports (AMRs) supporting the Biosphere PMR. During the audit, selected AMRs were subjected to a technical review as well as review to ensure that the applicable programmatic requirements contained in the QARD and implementing procedures were met.

The NRC staff objective was to gain confidence that the M&O and OQA 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 Code of Federal Regulations (10 CFR Part 60). Because of the anticipated DOE submittal of the site recommendation (SR) in November 2000, the following observation activities were emphasized: 1) confirming that data, software, and models supporting SR are properly qualified; and 2) reviewing the progress being made by DOE and its contractors in meeting the qualification goals for SR.

This report addresses the NRC staff determination of the effectiveness of the OQA audit and the adequacy of implementation of QARD controls by the M&O in the audited areas of AMR development.

2.0 MANAGEMENT SUMMARY

The NRC staff has determined that OQA Audit M&O-ARP-00-002 was useful, effective, and conducted in a professional manner. Audit team members were independent of the activities they audited and appeared to be knowledgeable in the QA and technical disciplines within the scope of the audit. The audit team members' qualifications were reviewed and the members were found to be qualified in their respective disciplines.

The audit team concluded that the OCRWM QA program had been satisfactorily implemented in the areas evaluated. Seven deficiency documents were generated during the audit. Two deficiencies were documented on deficiency reports (DRs) and four were documented on deficiency identification and referral (DIR) documents that add the conditions identified in this audit to those previously identified in currently open corrective action requests (CARs) or DRs. One deficiency was corrected during the conduct of the audit. Eight recommendations were offered for improvements and enhancements to the AMRs and to the procedures controlling various elements of the AMR process.

The NRC staff determined that this audit was effective in identifying deficiencies and recommending improvements in the AMR process. During the conduct of the audit, both the audit team and the NRC observers reviewed data, analysis reports, and software within the scope of the audit to confirm that it was properly qualified. The audit team and the NRC observers determined that the software supporting the AMRs had been properly qualified. The audit team and the NRC observer's also determined that certain data, categorized as "accepted data," were controlled in accordance with procedures and properly categorized as "accepted data."

The NRC staff generally agrees with the audit team conclusion's, findings, and recommendations. However, as noted in Section 4.7 of this report, the NRC staff expressed a concern about the adequacy of the process controlling the preparation and use of procedures controlling the AMR process. Further, as discussed in various sections of this report, the NRC staff is concerned about the lack of data qualification activities for the AMRs reviewed during the audit and the two previous audits. This appears to be a condition requiring DOE's management attention.

3.0 AUDIT PARTICIPANTS

3.1 Nuclear Regulatory Commission Observers

Robert Brient	Team Leader	CNWRA
Kien Chang	Technical Specialist	NRC
Larry Campbell	Senior QA Engineer	NRC (Part time audit observer)
Patrick LaPlante	Technical Specialist	CNWRA

3.2 OQA Audit Team

Donald Harris	Audit Team Leader	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
Kenneth McFall	Auditor	OQA/QATSS
Larry Abenathy	Auditor	OQA/QATSS
Harvey Dove	Technical Specialist	OQA/QATSS
Brenda Bowlby	Technical Specialist	Management and Technical Services(MTS)
Chag-Hsiung Tung	Technical Specialist	M&O

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 the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

4.1 Scope of the Audit

The audit team conducted a limited scope, performance based audit of activities and processes related to the development of the AMRs supporting the Biosphere PMR. AMRs, software, and data were evaluated during the audit process. The audit included review of the programmatic controls governing the AMRs and technical requirements contained in the AMRs. The following procedures and AMRs supporting the Biosphere PMR were reviewed by the audit team and the NRC observers during the audit:

Procedures

a) AP-2.13Q, "Technical Product Development Planning," Revision 0, with Interim Change Notice (ICN) No. 1

b) AP-SI.1Q, "Software Management," Revision 2, with ICN No. 0

c) AP-3.15Q, "Managing Technical Product Inputs," Revision 0, with ICN No. 1

d) AP-SIII.2Q, "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data," Revision 0, with ICN No. 0

e) AP-3.10Q, "Analysis and Models," Revision 1, with ICN No. 0

f) AP-2.14Q, "Review of Technical Products," Revision 0, with ICN No. 0

g) AP-SIII.3Q, "Submittal and Incorporation of Data to the TDMS," Revision 0

h) YAP-SV.1Q, "Control of the Electronic Management of Data," Revision 0, with ICN No. 1

i) QAP-SIII-1, "Scientific Investigations", Revision 3

Analysis Model Reports

a) ANL-MGR-MD-000008, "Transfer Coefficient Analysis," Revision 00

b) ANL-MGR-MD-000002, "Dose Conversion Factor Analysis: Evaluation of GENII-S Dose Assessment Methods," Revision 00

c) ANL-MGR-MD-000003, "Disruptive Event Biosphere Dose Conversion Factor (BDCF) Analysis " (Draft)

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 M&O and DOE programs and procedures. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit. The NRC staff believes the timing of the audit was appropriate for the auditors to evaluate ongoing Biosphere PMR activities. However, the audit team was unable to confirm that data supporting the AMRs had been properly qualified because no qualification

activities had been initiated by M&O for this data. The NRC staff considers the lack of data qualification activities during this audit and the two previous PMR audits to be a condition requiring OQA management attention. The NRC staff suggests that OQA management evaluate the need to conduct audits specifically to evaluate the qualification of data.

The DOE audit team and NRC observers caucused at the end of each day. Also, meetings of the audit team and M&O management (with the NRC observers present) were held each morning 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 OQA audit team members were found to be acceptable in that they met the requirements of QAP 18.1, "Auditor Qualification," as verified by the NRC observation audit lead. The audit team members did not have prior responsibility for performing the activities they audited. In addition, training, education and experience records for audit team members were reviewed and found acceptable.

4.4 Examination of Quality Assurance Elements

The OQA programmatic and technical audit activities were conducted simultaneously using sub-audit teams consisting of a technical specialist and a QA auditor. The limited scope audit focused on the QA elements closely associated with the development of the AMRs. The NRC observation team evaluated the audit team's review of the following QA elements.

4.4.1 AP-2.13Q "Technical Product Development Planning"

The auditors reviewed technical development plans (TDPs) and work product planning sheets (WPPS) applicable to the subject AMRs. A deficiency in the implementation of planning was identified regarding electronic management of data not being addressed in the TDP and a TDP with content not meeting specified requirements.

4.4.2 AP-SI.1Q "Software Management"

GENII-S Version 1.485 is the computer software that will be used for many of the Biosphere AMRs, including those AMRs subject to this audit. The auditors reviewed its qualification documentation which was determined to meet the requirements of the software management procedure. This software had also been re-verified after general software qualification concerns were identified in the previously issued CAR-006. The NRC observers agreed with the audit team that the GENII-S software had been properly qualified.

4.4.3 AP-3.15Q "Managing Technical Product Inputs"

Each of the AMRs examined included document input reference sheets that list the inputs to and references cited in the AMR. The document input reference sheets also identify the status of the input, (e.g., qualified, to be verified (TBV)). At the time of the audit, the TBV status had not been removed for any of the Biosphere AMR input documents.

Documents cited as references or as corroborating data were given the status of not applicable along with a brief explanation. However, AP-3.15Q does not have provisions for this. The AMR developers consulted with the author of AP-3.15Q and came up with the N/A designation. During the audit, M&O staff initiated a change request to AP-3.15Q to attempt to clarify the use of references that are not directly used as inputs.

The auditors noted that one reference was inadvertently omitted from the document input reference sheets for the draft AMR for disruptive event BDCF analysis. This deficiency was corrected during the audit.

The status of the input documents for the three AMRs is summarized as follows:

a) Transfer Coefficient Analysis: Most of the documents were classified as unqualified corroborating data (N/A). One input is classified as TBV because it is unconfirmed after a CAR cast uncertainty about the qualification status of data. A TBV tracking number (3059) has been assigned to this document as required by AP-3.15Q.

b) Dose Conversion Factor Analysis: Evaluation of GENII-S Dose Assessment Methods: Several documents listed in the document input reference sheets are classified as N/A, used for reference only. One document is classified as 'Accepted,' its source being a Federal Guidance Report issued by the U.S. Environmental Protection Agency (EPA). A document tracked by TBV tracking number 3059 was used in this AMR.

c) Disruptive Event Biosphere Dose Conversion Factor Analysis: All of the inputs used in this AMR are from other Biosphere AMRs, most of which have not been issued. These inputs are classified as TBV. Several references are identified and given the N/A classification.

4.4.4 AP-SIII.2Q "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data"

Requests to qualify two reports concerning food consumption surveys had been initiated. At the time of the audit, no data qualification had been completed. The audit team confirmed that two sets of data from EPA Federal Guidance Reports used in the biosphere AMRs have completed the process for "accepted data" in accordance with AP-SIII.2Q. "Accepted data," as defined by the QARD, are data considered as established fact (e.g., engineering handbooks, density table, gravitational laws, or other physical constants) or data generally accepted by the scientific and engineering community and found to be technically defensible by those using it. The NRC observers agreed with the audit team that the subject data had been properly categorized.

4.4.5 AP-3.10Q "Analysis and Models"

The three AMRs evaluated during this audit are considered analyses. AP-3.10Q provides control for both analysis and models. The development and technical checking processes described in AP-3.10Q have been completed for the Transfer Coefficient Analysis and Dose Conversion Factor Analysis: Evaluation of GENII-S Dose Assessment Methods AMRs. The Disruptive Event Biosphere Dose Conversion Factor Analysis AMR was in review and comment resolution during the audit.

None of the three AMRs had been subjected to model validation at the time of the audit. An interview with Biosphere PMR management indicated that they were not certain when or if model validation was necessary. The audit team identified the lack of model validation as a deficiency and recommended that AP-3.10Q be revised to clarify the criteria for determining if an activity is an analysis, a model (therefore requiring validation), or both. The NRC observers initiated an audit observer inquiry (AOI) to the audit team to assure that the NRC staff is aware of the resolution of this issue (see Section 4.7.1 of this report). The NRC staff believes that to properly support licensing decisions, calculations must be performed using validated model(s) as well as qualified data and software.

The two completed AMRs had been subjected to the technical checking process. While described as checking, the review and reviewer criteria suggests that this activity represents the substantive review by a subject matter expert. The audit team noted that AP-3.10Q requires only that the checker document comments on a "check copy" of the document. AP-3.10Q does not require that the resolution of comments be documented except for the checker's signature. While responses were provided for some comments in the "check copy," many were not responded to.. In several cases, the auditors could not trace the checker's comment through to a revision in the document being reviewed. This condition was identified as a deficiency and the audit team made a strong recommendation that available comment resolution forms be used. The auditors also found one occasion where the checker failed to address one of the specified review criteria and the document was issued despite failing to meet the objective of its development plan.

The audit team determined that the AMR author had not included sufficient detail in the justification of technical judgements in the Dose Conversion Factor Analysis: Evaluation of GENII-S Dose Assessment Methods AMR. This was included in the deficiency concerning AP-3.10Q.

4.4.6 AP-2.14Q "Review of Technical Products"

The AMRs reviewed were subjected to the technical review process. The AP-2.14Q technical reviews are performed by organizations that are external to the organization that prepared the AMR and serve primarily as interface reviews.

AP-2.14Q allows several options for documenting comments and their resolution. For the AMRs in this audit, all used a markup of the document rather than requiring comment resolution. The audit team strongly recommended the use of the OCRWM comment sheet. The NRC staff concurs with this recommendation.

4.5 PRIORITIZATION OF QUALIFICATION ACTIVITIES

During the observation of the Biosphere PMR audit, the NRC observers met with DOE and M&O in order to obtain information on the process being used to prioritize the qualification of data, software, and models supporting its site recommendation (SR).

4.5.1 Background

The latest information provided by DOE at the time of the audit on its qualification of the data, software, and models supporting the SR was that: a) the qualification and validation of inputs

for the SR will be prioritized and evaluated in order of their importance; b) approximately 50 percent of the inputs for the SR will be qualified by the end of May 2000; c) approximately 80 percent of the inputs for the SR will be qualified mid-January 2001; and d) at the time the SR is issued in proposed form for NRC review in November 2000, the most critical inputs for the SR would be qualified with approximately 20 (+) percent of the inputs not qualified. Also, DOE informed the NRC that the inputs for the SR would be the basis for the license application (LA) and that all inputs for the LA would be qualified prior to its transmittal to the NRC.

NOTE: [Subsequent to the audit, on December 16, 1999, NRC and DOE management met and discussed a number of issues including prioritization of data used as inputs for SR. At this meeting DOE informed the NRC that it intended too only to qualify data that was initially qualified and later determined to be "suspect" data if such data was categorized as high-risk significant. Further, DOE emphasized that low-risk significant data that was initially qualified and later determined to be "suspect" data would not be subject to any additional qualification.]

4.5.2 Qualification Methodology

The NRC observers were provided the following information by DOE and M&O:

Data, software, and models supporting SR and LA will be prioritized based on their importance to waste isolation and to safety using the broad criteria contained in the "Repository Safety Strategy (RSS)," Revision 3 (currently issued by M&O and presently under review by DOE). The RSS contains the plan for preparing the post-closure safety case to support SR and the LA. The RSS evaluated the natural and engineered barrier systems relative to their roles in preventing or mitigating the release and migration of radionuclides to the public.

The RSS identifies seven principal factors, disruptive events, and 20 other factors that contribute to the performance of the proposed high-level waste repository at Yucca Mountain (YM). The seven principal factors represent those repository performance features which provide the preponderance of waste isolation performance. The seven principal factors are: 1) seepage into drifts; 2) performance of the drip shield; 3) solubility limits of dissolved radionuclides; 4) retardation of radionuclide migration in the unsaturated zone; 5) retardation of radionuclide migration in the unsaturated zone; 6) retardation of radionuclide migration in the saturated zone; and 7) dilution of radionuclide concentrations during migration. Disruptive events include earthquakes and volcanism.

The prioritization process groups the data, software, and models into categories by their use. If data, software, or models directly support the analysis used for a principal factor or a disruptive event having waste isolation significance (e.g., related to the 7 principal factors in the RSS), it is placed in the first priority category (high priority) and the qualification of these items will be identified for first priority qualification or verification, ahead of those related to the 20 other factors.

Data Tracking Numbers (DTN) will be assigned to data once the data has been confirmed as inputs to analyses, calculations, software, and models required to support SR and LA. Because the entry of data into the DTN system continues to occur well into the analytical development

process, the actual inventory of DTNs subject to qualification and verification is dynamic and will not be finalized until near the end of the AMR and PMR completion process.

4.5.3 Completeness of Site Recommendation Qualification Activities

DOE and M&O informed the NRC observers that they expect to have 80 percent of the data, 80 percent of the software, and 80 percent of the models supporting SR fully qualified by mid-January 2001.

NOTE: **[As previously noted, DOE informed the NRC during a December 16, 1999, public meeting that only data, categorized as high-risk significant that had not been initially qualified or was "suspect" data, requiring re-qualification, would be subject to the qualification process. Further, DOE stated that this decision was based on the sample of "suspect" data re-qualified to date. At the December 16, 1999, meeting the staff stated that it would evaluate bases for DOE's decision not to re-qualify the "suspect," low-risk significant data.]**

[DOE now plans to have 80 percent of the high-risk significant data qualified by mid-January 2001.]

4.5.4 Conclusions on Prioritization of Qualification Activities

Based on the discussions with DOE and M&O, the NRC observers concluded that the prioritization process used for qualifying data, software, and models supporting SR appears to be reasonable. However, to fully understand this prioritization process, the NRC staff needs to review its implementation. The NRC staff will review the implementation of the prioritization process and document the results in future NRC staff observations of DOE audits for PMRs and through the NRC Onsite Representative's activities.

The NRC staff will also continue to review the progress being made by DOE and M&O in meeting its qualification percent completion goals. This review will also be accomplished as part of the NRC staff observations of DOE audits of the PMRs and through the NRC Onsite Representative's activities.

4.6 Examination of Technical Activities

NRC staff observed the audit team technical specialists conducting detailed checks of the technical adequacy of the subject AMRs. At the start of the audit, NRC observers reviewed the technical specialists' qualifications (resumes) and found that the technical specialists had sufficient technical education, training and experience related to the AMRs reviewed. The technical specialists used a combination of technical issue probing and procedural compliance checks and verifications to thoroughly consider both the technical adequacy of the AMRs and the effectiveness of implementation of the QA program.

4.6.1 Analysis Model Report Transfer Coefficient Analysis (ANL-MGR-MD-000008, Rev 00)

The AMR for transfer coefficient analysis documents the M&O staff analyses to select transfer coefficients. Transfer coefficients (i.e., factors that determine concentrations of radionuclides in plants and animal products from radionuclide concentrations in soil and feed) are data inputs for the GENII-S Version 1.485 code used to calculate BDCFs for total system performance assessment (TSPA) calculations. Because transfer factors for plants vary with plant type and soil chemistry, wide variation exists in published values. The purpose of the AMR is to establish criteria for selection of transfer coefficients and apply the criteria to a number of data sources to select a set of transfer coefficients applicable to YM that can be qualified in accordance with procedures.

The audit of the transfer coefficient AMR included a combination of procedural and technical inquiries to verify that procedures were followed and that the technical quality of the product was satisfactory. The audit team inquired about the technical basis for the report including: a) planning and implementation of the technical approach; b) assumptions used; c) data acquisition and traceability; d) qualification of source data; e) treatment at data uncertainties; f) data selection criteria; g) rationales for data exclusion; and h) rationales for defining data as accepted. Selected key issues concerning source data analyzed to select transfer coefficients were investigated with extensive questioning and technical discussion. Discussions emphasized that data sources were summaries of available literature and these summaries constituted unqualified data. However, the selected transfer coefficients would eventually be qualified according to procedure even though the original sources would remain unqualified. After extensive discussions, the audit team and observers agreed that the selected transfer coefficients could be qualified according to procedures using the source data to corroborate the transfer coefficient selection.

In checking the collection of site-specific data associated with this AMR, auditors investigated the use of the food consumption survey results. Although the audit team determined that the data from the food consumption survey has not been qualified, no problems were identified with the use of the information.

Resolution of technical comments from checkers and reviewers was assessed by auditors thoroughly reviewing a number of examples in the records package. The qualifications of the document originator and checkers were checked (resumes reviewed) by the auditors and verified by observers and all were found to have sufficient technical experience to conduct the assigned work. The records package for the AMR was extensively reviewed to confirm that checkers had provided comments, that the comments were technically adequate, and that the comments were resolved by the originator. The auditors and NRC observers noted a variety of comments that were both editorial and detailed on technical issues. At least one of the checkers was found to have provided very detailed technical comments. While the final report could be checked to determined that comments had been resolved (in a number of cases the originator provided written responses to comments in the text of the report), the auditors and NRC observers noted that formal comment/response forms were not required by the procedure. This condition made comment resolution traceability difficult for the auditors. Nonetheless, the auditors and observers verified that procedures for review had been followed correctly. The inclusion of comment/response forms for report checking was noted by NRC observers as an inquiry at the conclusion of the audit (see Section 4.7.1 of this report).

4.6.2 Analysis Model Report Dose Conversion Factor Analysis: Evaluation of GENII-S Dose Assessment Methods (ANL-MGR-MD-000002, Rev 00)

The purpose of the dose conversion factor analysis AMR is to document analyses confirming the selection of internal and external dose conversion factors for use in the GENII-S Version 1.485 code as data inputs. GENII-S Version 1.485 is used to calculate Biosphere Dose Conversion Factors (BDCFs) for the TSPA. This AMR was necessary because the GENII-S code contains the dose conversion factors in binary data files that cannot be modified by the user. Because the GENII-S code was initially developed for analyses at the Hanford site in Washington State, the dose conversion factors in GENII-S Version 1.485 are based on material properties consistent with the waste materials existing at Hanford in the late 1980's. Since that time, other accepted sources of external and internal dose conversion factors have been published, for example, by the EPA in Federal Guidance Reports 11 and 12 (Environmental Protection Agency, 1988, 1993). Therefore, the AMR was prepared to address whether default dose conversion factors in GENII-S are consistent with currently accepted sources.

The audit of the dose factor analysis AMR included a combination of procedural and technical inquiries to verify that procedures were followed and the technical quality of the product was satisfactory. The audit team inquired about the technical basis for the report including: a) planning and implementation of the technical approach; b) assumptions used; c) data inputs, acquisition, and traceability; d) data selection criteria; e) rationales for data exclusion; f) software validation; and g) justification for conclusions. Upon initial inspection of the AMR report, one of the auditors commented that the bases for key assumptions needed to be stated clearly in the report. The auditor noted that many assumptions appeared to be considered common knowledge by the originator and not thoroughly explained. The NRC observers concurred that more explicit bases for assumptions would improve the report. However, it was recognized that the omissions were due to the originators familiarity with the material and were not intentional. Auditors also asked questions about the bases for selecting a limited set of radionuclides for the analysis and the decision was traced back to viability assessment conclusions. Inquiries about the sources for data clarified that most were taken from the available literature and some were unqualified but did not need TBV because of their use as corroborative evidence.

Resolution of technical comments from checkers and reviewers was assessed by auditors by thoroughly reviewing a number of examples in the records package. The qualifications of the document originator and checkers were checked (resumes reviewed) by auditors and verified by observers and all were found to have sufficient technical experience to conduct the assigned work. The records package for the AMR was extensively reviewed to confirm that the checker's comments were technically adequate and appropriately resolved by the originator. The auditors and NRC observers reviewed a variety of comments that were both technical and editorial. At least one of the checkers was found to have provided very detailed technical comments. Thus, the checker and technical reviews appeared to be adequate to ensure the technical quality of the report even though the procedures for the checker hampered traceability of comment resolutions (see discussion in section 4.6.1).

References:

Environmental Protection Agency. *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion: Federal Guidance Report No. 11.* EPA 520/1-88-20. Washington DC: Environmental Protection Agency, September, 1988.

Environmental Protection Agency. *External Exposure to Radionuclides in Air, Water, and Soil: Federal Guidance Report No. 12.* EPA 402-R-93-081. Washington DC: Environmental Protection Agency, September, 1993.

4.6.3 Analysis Model Report Disruptive Event Biosphere Dose Conversion Factor Analysis (ANL-MGR-MD-000003, Draft)

The purpose of the AMR for disruptive event BDCF analysis is to document DOE environmental pathway/dose calculations for radionuclides deposited in the biosphere following a volcanic eruption at the proposed YM repository site. The model assumes that radionuclides are released to the air and transported to the critical group location. The BDCFs are used in TSPA calculations to convert radionuclide concentrations deposited in soil to annual dose to the critical group.

The audit of the transfer coefficient AMR included a combination of procedural and technical inquiries to verify that procedures were followed and the technical quality of the product was satisfactory. The audit team inquired about the technical basis for the report; planning and implementation of the technical approach; assumptions; data acquisition and traceability; qualification of source data; data selection criteria; rationales for data exclusion; and software qualification. The planning documentation (Work Package Planning Summary) described in AP-2.15Q was in draft form. Auditors asked a number of detailed questions regarding assumptions for the work which led to a similar concern as with the dose conversion factor analysis (e.g., need more explicit rationales for modeling assumptions per AP-3.10Q). The auditors asked technical questions about assumptions. The NRC observers found these questions to be insightful and indicated that the auditors had conducted a detailed review of the material in formulating the QA checklist and were familiar with pertinent technical issues. NRC observations of the discussions about technical assumptions indicated the report originator had a comprehensive understanding of the important parameters and limitations of available data. Many of the difficult-to-determine parameter inputs were found to be the under the jurisdiction of other AMR reports. The auditors and NRC observers emphasized the importance of future audits for tracing data sources and key assumptions that support more than one AMR. Auditors tracked data successfully to its source by use of DTN and the technical document management system. Auditors requested input transmittal records for those parameters that did not have accession numbers. Data obtained from other AMR reports were tracked by auditors to those referenced reports. All software packages used for the technical analyses were checked by auditors for their qualification status.

In response to auditor and observer questioning about the qualification and validation status of the GENII-S Version 1.485 software, the AMR originator indicated that the software had been validated according to the procedure for software qualification (AP-SI.1Q); however, there was no attempt at model validation. The software qualification documentation (that includes software validation) was extensively reviewed by the auditors and observers. The auditors and

NRC observers found that the qualification documentation conformed to AP-SI-1Q. In response to further questioning about why the model in GENII-S was not validated, the originator noted that the procedures in AP-3.10Q do not require model validation if the report is considered to be an analysis rather than a model. The auditors and NRC observers noted this as a limitation of the procedures because the procedures intended models to be validated, however, originators could bypass the requirements for model validation by selecting the option to call the report an analysis rather than a model. NRC observers presented the lack of clarity of the procedures regarding model validation to the audit team as an inquiry (see Section 4.7.1 of this report).

Resolution of technical comments from checkers and reviewers was assessed by auditors thoroughly reviewing a number of examples in the records package. The qualifications of the document originator and checkers were checked (resumes reviewed) by auditors and verified by observers and all were found to have sufficient technical experience to conduct the assigned work. The records package for the AMR was extensively reviewed to confirm that checker's comments were resolved by the originator. The checker's comments were technically sound and adequate: The auditors and NRC observers noted a variety of depth in comments (from editorial to detailed technical issues). At least one of the checkers was found to have provided very detailed technical comments. Thus, the checker and technical reviews appeared to be adequate to ensure the technical quality of the report even though the procedures for the checker hampered traceability of comment resolutions (see discussion in section 4.6.1).

4.7 NUCLEAR REGULATORY COMMISSION STAFF FINDINGS

The NRC staff has determined that OQA Audit M&O-ARP-00-002 was effective in determining the level of compliance of M&O activities associated with the subject AMRs. The NRC staff agrees with the audit team conclusion that the OCRWM QA program had been satisfactorily implemented.

However, the NRC staff expressed the following concerns during the conduct of the audit:

a) There was no objective evidence that data qualification activities had been initiated for data supporting the selected AMRs for this audit and the previous two AMR audits.

b) The NRC staff questioned the adequacy of the process controlling the preparation and use of procedures for the AMR process. During this audit, OQA identified one deficiency and made five recommendations about the adequacy and clarity of the these procedures. During the previous two audits of selected AMRs, ten recommendations and one deficiency identified similar conditions. The NRC staff expressed a concern that the M&O management and its senior staff responsible for the supervision and use of these procedures should have recognized the need for the more apparent procedure clarifications prior to OQA making these recommendations.

4.7.1 Audit Observer Inquiries

Two NRC audit observer inquiries (AOIs) were presented to the audit team:

1. AOI No. M&O-ARP-00-02-1

   AP-3.10Q, "Analysis and Modeling" and the QARD are not specific regarding which calculations/analyses are subject to model validation and the timing of model validation. M&O Environmental, Safety, and Regional Programs Office involved with the biosphere AMRs do not appear to have an understanding or strategy of model validation as it applies to the biosphere AMRs/PMR.

2. AOI No. M&O-ARP-00-02-2

   Documented resolution of individual comments is not required for checks of analysis and models (AP-3.10Q) and is optional for reviews of technical products (AP-2.14Q). A lack of documented resolution is inconsistent with the QARD section 2.2.10 (f) which requires that mandatory comments shall be documented and resolved before approving the document. Note that the audit of the Integrated Site Model (ARP-99-009) also identified several recommendations concerning the review processes of AP-3.10Q and AP-2.14Q.

The two NRC Staff inquiries follow recommendations made by the audit team. The NRC staff is interested in DOE's and the M&O's resolution of these issues because of their potential significance in licensing. These inquiries remain open at the time of this report.

4.7.2 Closure of Previous NRC Audit Observer Inquiries

AOI No. M&O-ARP-99-009-1 was closed during the conduct of this observation. This AOI questioned aspects of the data qualification process (see the discussion is Section 4.5 of this report).

4.7.3 Open NRC Audit Observer Inquires (AOIs)

The following NRC AOIs remain open:

a) AOI No. OCRWM-ARC-99-015-1, dated September 22, 1999: OQA agreed to provide information to the NRC on the qualification status and use of the "Waste Stream Profiles" addressed in the "Design Basis Waste Stream for Interim Storage and Repository" and the "Waste Quantity, Mix and Throughput Study" documents.

b) AOI No. M&O-ARP-00-02-1, dated November 18, 1999: (See Section 4.7.1 of this report for a description of this AOI)

c) AOI No. M&O-ARP-00-02-2, dated November 18, 1999: (See Section 4.7.1 of this report for a description of this AOI)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON. D.C. 20555-0001

March 7, 2000

Mr. Dwight Shelor, Acting Director
Program Management and Administration
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- 00-05, "OBSERVATION AUDIT OF OFFICE OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT, QUALITY ASSURANCE DIVISION, AUDIT NO. M&O-ARP-00-005"

Dear Mr. Shelor:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report No. OAR-00-05 of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management, Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division, audit of the Waste Form Process Model Report (PMR) activities performed by the OCRWM Management and Operating Contractor (M&O). The audit, M&O-ARP-00-005, was conducted on January 31 through February 4, 2000, at the M&O facilities in Las Vegas, Nevada.

This audit was limited in scope and evaluated the effectiveness of the implementation of the OCRWM Quality Assurance QA Program described in the Quality Assurance Requirements and Description (QARD) and its implementing procedures for selected analysis model reports (AMRs) supporting the Waste Form PMR. During the conduct of the audit, both the audit team and the NRC observers reviewed the analysis reports, within the scope of the audit, and their supporting data and software. Because the AMRs reviewed were in draft and in the process of being completed, the DOE audit served more as a review than as an assessment. There were no deficiencies written. The NRC staff generally agrees with the audit team conclusions, findings, and recommendations. Further, the NRC staff agrees that this audit was effective in recommending improvements in the AMR process.

During the observation, the DOE provided information on the progress in reaching its goal of having 50 percent of the data supporting the Site Recommendation Considerations Report completed by May 2000. On January 31, 2000, the DOE had fully qualified 231 data-sets or data tracking numbers (DTNs) out of a projected 1600 DTNs. The DOE explained that the total number of DTNs was still evolving because several AMR preparers had not entered the data supporting the AMRs into the DTN tracking system. During the audit, the NRC staff expressed a concern about the lack of data qualification activities for the AMRs reviewed during the audit and the four previous audits. This appears to be a condition requiring DOE's management attention.

During the audit, the NRC observers questioned DOE's basis for not re-qualifying low-risk significant data. The DOE informed the NRC observers that the sample plan, serving as the basis for not performing re-qualification of low-risk significant data, would be documented in a procedure by the end of February 2000, and would provide for feedback and corrective action should problems be identified in re-qualifying similar high-risk significant data.

The NRC observers concluded that: (a) the AMR developers, within the scope of this audit, produced technically adequate AMRs; however, both the NRC observers and OQA audit team members provided several comments on the technical content of the AMRs; (b) the Document Input Reference System, which is used to track DTNs, has improved; and (c) the implementation of changes to procedures controlling the AMR process and the communicating of lessons learned from the audits to the preparers of the AMRs could be improved by providing additional training or formal instruction.

The NRC observers generated no audit observer inquiries (AOIs) during the audit. However, we would like to point out that we have not received a response to an AOI, dated September 22, 1999, which addressed the qualification status and use of the waste stream profiles, and to AOIs, dated November 18, 1999, which addressed procedural concerns on the AMR process.

A written response to this letter and the enclosed report is not required. However, we do expect OQA to provide replies to the open AOIs. If you have any questions, please contact Larry L. Campbell of my staff at (301) 415-5000.

Sincerely,

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

Enclosure: NRC Observation Audit Report No. OAR-00-05, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. M&O-ARP-00-005"

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Letter to D. Shelor from C.W. Reamer dated: March 7, 2000

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R. McCullum, NEI
S. Kraft, NEI
J. Kessler, EPRI
R. Wallace, USGS
R. Craig, USGS
W. Booth, Engineering Svcs, LTD
S. Trubatch, Winston & Strawn

U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-00-05

OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE DIVISION

AUDIT NO. M&O-ARP-00-005

Larry L Campbell 03/07/00

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N. King Stablein
Section Leader
Projects and Engineering Section
High-Level Waste and Performance
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Division of Waste Management

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 observed 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 of the Waste Package Process Model Report (PMR) activities performed by the OCRWM Management & Operating Contractor (M&O). The audit, M&O-ARP-00-005, was conducted on January 31 through February 4, 2000, at the M&O facilities in Las Vegas, Nevada.

The objective of this audit was to evaluate the implementation of the applicable provisions contained in the OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 8, by reviewing selected analysis model reports (AMRs) supporting the Waste Form PMR. During the audit, selected AMRs were subjected to a technical review as well as a review to ensure that the applicable programmatic requirements contained in the QARD and implementing procedures were met.

The NRC staff objective was to gain confidence that the M&O and OQA 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) in November 2000, the following observation activities were emphasized: 1) confirming that data, software, and models supporting the SR are properly qualified; and 2) reviewing the progress being made by the DOE and its contractors in meeting the qualification goals for the SR.

This report addresses the NRC staff determination of the effectiveness of the OQA audit and the adequacy of implementation of QARD controls by the M&O in the audited areas of AMR development.

2.0 MANAGEMENT SUMMARY

This audit was limited in scope and evaluated the effectiveness of the implementation of the OCRWM Quality Assurance (QA) Program described in the Quality Assurance Requirements and Description (QARD) and its implementing procedures for selected AMRs supporting the Waste Form PMR. During the conduct of the audit, both the audit team and the NRC observers reviewed the AMRs, within the scope of the audit, and their supporting data and software. Because the AMRs reviewed were in draft and in the process of being completed, the DOE audit served more as a review than as an assessment with. There were no deficiencies being written. The audit team concluded that the OCRWM QA program had been satisfactorily implemented in the areas evaluated. During the audit, several recommendations were made to improve the AMR preparation process.

The NRC staff generally agrees that OQA Audit M&O-ARP-00-005 was effective in recommending improvements in the AMR process and with the audit team conclusions, findings, and recommendations. The audit was conducted in a professional manner, using audit team members who were independent of the activities they audited. The DOE audit team members appeared to be knowledgeable in the QA and technical disciplines within the scope of

the audit, and their qualifications were found to be acceptable for their respective disciplines. Although the audit scope included data qualification, the audit team was unable to assess the data qualification process and activities because no data qualification activities had been performed for the data supporting the AMRs reviewed. The NRC staff considers the lack of data qualification activities during this audit and the four previous PMR audits to be a condition requiring OQA management attention.

During the observation, the DOE provided information on the progress in reaching its goal of having 50 percent of the data supporting the Site Recommendation Considerations Report (SRCR) completed by May 2000. On January 31, 2000, the DOE had fully qualified 231 data sets or data tracking numbers (DTNs) out of a projected 1600 DTNs. The DOE explained that the total number of DTNs was still evolving because several AMR preparers had not entered data supporting the AMRs into the DTN tracking system.

The NRC observers concluded that: (a) the AMR developers, within the scope of this audit, produced technically adequate AMRs; however, both the NRC observers and OQA audit team members provided several comments on the technical content of the AMRs; (b) the Document Input Reference System, which is used to track DTNs, has improved; and (c) the implementation of changes to procedures controlling the AMR process and the communicating of lessons learned from the audits to the preparers of the AMRs could be improved by providing additional training or formal instruction.

NOTE: **[Subsequent to the inspection, OQA decided to postpone the remaining 3 PMR audits that were scheduled to be performed during the months of March and April 2000. This decision was made, in part, because several AMR completion dates had slipped and lessons learned from the previous 6 PMR audits needed to be communicated to the preparers of the AMRs.]**

3.0 AUDIT PARTICIPANTS

3.1 Nuclear Regulatory Commission Observers

Larry Campbell	Team Leader	NRC
Tae Ahn	Technical Specialist	NRC
Tom Trbovich	Senior QA Engineer	CNWRA
David Pickett	Technical Specialist	CNWRA

3.2 OQA Audit Team

Kristi Hodges	Audit Team Leader	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
Patrick Auer	Auditor	OQA/QATSS
Victor Barish	Auditor	OQA/QATSS
James Baylock	Auditor	OQA/QATSS
Frank Wong	Technical Specialist	Management and Technical Services(MTS)
Robert Fish	Technical Specialist	MTS

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 the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

4.1 Scope of the Audit

The audit team conducted a limited-scope, performance-based audit of activities and processes related to the development of the AMRs supporting the Waste Form PMR. AMRs, software, and abstractions were evaluated during the audit process. The audit included review of the programmatic controls governing the AMRs and technical requirements contained in the AMRs. Several procedures, including the ones listed below, were used by the audit team and the NRC observers during the audit:

a) AP-2.13Q, "Technical Product Development Planning," Revision 0, with Interim Change Notice (ICN) No. 1.

b) AP-SI.1Q, "Software Management," Revision 2, with ICN No. 2.

c) AP-3.15Q, "Managing Technical Product Inputs," Revision 0, with ICN No. 1.

d) AP-SIII.2Q, "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data," Revision 0, with ICN No. 2.

e) AP-3.10Q, "Analysis and Models," Revision 1, with ICN No. 1.

f) AP-2.14Q, "Review of Technical Products," Revision 0, with ICN No. 0.

g) AP-SIII.3Q, "Submittal and Incorporation of Data to the TDMS," Revision 0, with ICN No. 2.

h) YAP-SV.1Q, "Control of the Electronic Management of Data," Revision 0, with ICN No. 1.

i) QAP-SIII-1, "Scientific Investigations," Revision 3.

The Waste Form PMR addresses the behavior of various waste forms, such as commercial spent nuclear fuel and high-level waste glass, and includes topics such as cladding protection, waste form degradation, and radionuclide release. The OQA selected the following four Waste Form AMRs for review during the audit:

a) AMR No. F0115 (ANL-WIS-MD-000012), "Waste-Form Colloid-Associated Concentration Limits," (Draft) Revision 00A.

b) AMR No. F0105 (ANL-EBS-MD-000021), "Colloid Stability and Attachment/Detachment Properties," (Draft) Revision 00A.

c) AMR No. F0110 (ANL-EBS-MD-000020), "Colloid-Associated Radionuclide Concentration Limits," (Draft) Revision 00A.

d) AMR No. F0045 (ANL-EBS-MD-000048), "Initial Cladding Condition," (Draft) Revision 00A.

All AMRs reviewed were drafts and at Revision 00A and were in the process of being revised in response to their initial checking. After the incorporation of the checker's comments, the AMRs will be subjected to an additional technical review.

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 M&O and DOE programs and procedures. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit. The NRC staff believes the timing of the audit was appropriate for the auditors to evaluate in-process Waste Form PMR activities. However, the audit team was unable to confirm that data supporting the AMRs had been properly qualified because no qualification activities had been initiated by M&O for these data. The NRC staff suggests that OQA management evaluate the need to conduct audits and surveillances specifically to evaluate the qualification of data.

The DOE audit team and NRC observers caucused at the end of each day. Also, meetings of the audit team and M&O management were held each morning 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 OQA audit team members were found to be acceptable in that they met the requirements of QAP 18.1, "Auditor Qualification," as verified by the NRC observation audit lead. The audit team members did not have prior responsibility for performing the activities they reviewed during the audit. One technical specialist had previously worked in M&O, but did not have responsibility for any AMR reviewed during the audit. In addition, training, education and experience records for audit team members were reviewed and found acceptable. Further, the NRC observers reviewed the technical specialists' qualifications (resumes) and found that the technical specialists had sufficient technical education, training, and experience related to the AMRs reviewed.

4.4 Examination of Q A Elements

The OQA programmatic and technical audit activities were conducted simultaneously, using sub-audit teams consisting of a technical specialist and a QA auditor. The limited-scope audit focused on the QA elements closely associated with the development of the AMRs. The NRC observation team evaluated the audit team's review of applicable QA elements. The NRC observers' findings related to the QA and programmatic areas of each AMR are provided for each AMR in Section 4.6 of this report.

4.5 Data Qualification

During the observation of the Waste Form PMR audit, the NRC observers met with the DOE and M&O to obtain information on the process being used to qualify data, software, and models supporting the site recommendation (SR) and the license application (LA). The status for the qualification of software and models is not addressed in this report. DOE has indicated that all software and models will be qualified at the time it submits the LA for the high-level waste repository at Yucca Mountain.

Background

In 1998 and 1999, the DOE identified several significant conditions adverse to quality and as a result, the quality of data and computer codes (software) supporting the SR and LA, qualified before June 1999, under DOE's QA Program, was identified as indeterminate and "suspect." The DOE determined that these data and software needed to be re-qualified and identified the status of these data, in a database, as "To Be Verified" (TBV).

In the fall of 1999, the DOE decided to categorize and prioritize the qualification data and software supporting the SR and the LA, based on their importance to waste isolation and importance to safety, using the broad criteria contained in the "Repository Safety Strategy (RSS)," Revision 3. The RSS contains the plan for preparing the post-closure safety case to support the SR and the LA. The RSS evaluated the natural and engineered barrier systems relative to their roles in preventing or mitigating the release and migration of radionuclides to the public.

The RSS identifies seven principal factors, disruptive events, and 20 other factors that contribute to the performance of the proposed high-level waste repository at Yucca Mountain. The seven principal factors represent those repository performance features that provide the preponderance of waste isolation performance. The seven principal factors are: 1) seepage into drifts; 2) performance of the drip shield; 3) solubility limits of dissolved radionuclides; 4) retardation of radionuclide migration in the unsaturated zone; 5) retardation of radionuclide migration in the unsaturated zone; 6) retardation of radionuclide migration in the saturated zone; and 7) dilution of radionuclide concentrations during migration. Disruptive events include earthquakes and volcanism.

The DOE informed the NRC that it would be applying a graded approach to the qualification of data supporting the SR and the LA. The DOE plans to categorize data related to a disruptive event or one of the seven principal factors as high-risk significant, and data related to the other 20 factors as low-risk significant. High-risk significant data, identified as "suspect" data, will be subjected to re-qualification. Low-risk significant data, identified as "suspect" data, will not be subjected to re-qualification, unless during the re-qualification of similar high-risk significant data, problems are identified.

DTNs will be assigned to data once the data have been confirmed as inputs to analyses, calculations, software, and models required to support the SR and the LA. Because the entry of data into the DTN system continues to occur well into the analytical development process, the actual inventory of DTNs subject to qualification and verification is dynamic and will not be finalized until near the end of the AMR and PMR completion process.

Basis for Not Re-Qualifying "Suspect" Low-Risk Significant Data

The review provisions contained in AP-3.15Q, Revision I, ICN-0, were revised and now provide specific guidance for reviewing data that were identified as "suspect" data and for determining if these data are low- or high-risk significant. This procedural change was an attempt to incorporate a graded approach to data re-qualification activities. AP-3.15Q requires that previously qualified high-risk significant data related to the principal factors and disruptive events identified in the RSS Report be re-verified to remove their TBV status. AP-3.15Q presently requires no re-qualification for "suspect" low-risk significant data (previously qualified data not related to the RSS principal factors and disruptive events) and permits this low-risk significant data to be categorized as Qualified-Verified Level 2 data, with no re-qualification required.

During the audit, the NRC observers expressed a concern that it appears AP-3.15Q has eliminated the need to apply any QA controls for re-verifying the quality of these data. Therefore, if data are determined to be Quality-Verified Level 2, the TBV can be lifted without performing any re-verification activities.

The NRC observers discussed the risk-informed graded QA process with the DOE. It was noted that this process consists of several elements, such as risk categorization, grading the QA controls, corrective action, feedback, etc. Further, it was discussed that AP 3.15Q appears to have only addressed risk categorization (e.g., whether or not data are high- or low-risk significant) and not other elements of the graded QA process.

The NRC observers expressed a concern that the basis for eliminating and not grading the QA controls for low-risk significant re-qualification activities is not documented. Thus, it appears that AP-3.15Q has not applied reduced QA controls for the re-verification of these data, but is applying no QA controls. It was further discussed that categorizing data as low-risk significant should not be the basis for eliminating QA controls, but should be the basis for permitting reduced QA controls to be applied for re-verifying data categorized as low-risk. Reduced QA controls need to be identified and the basis for not performing any re-verification of Quality-Verified Level 2 data needs to be documented. Additionally, it was discussed that reduced QA controls could be the use of a sample plan or other graded verification activities. Depending on the results of these reduced QA controls, there may then be justification to eliminate the need to re-verify data that is categorized as low-risk significant/Quality-Verified Level 2.

The DOE and M&O agreed that the basis for not re-qualifying low-risk significant data was that: (a) it was low risk-significant; and b) except for very minor documentation problems, there had been no problems with the re-qualification of high-risk significant data qualified to date. Also, the DOE agreed there should be a feedback mechanism in place to identify the need for re-qualification of certain low-risk significant data should the re-qualification of similar high-risk significant data identify problems with these data.

The DOE and M&O agreed that the sample plan serving as the basis for its re-qualification of low-risk significant data needs to be formally documented in a procedure and needs to address feedback and corrective action (e.g., identify the process used to evaluate the need to re-qualify low-risk significant data). DOE informed the NRC observers that this sample plan would be incorporated into a procedure by the end of February 2000.

Status of Data Qualification Activities

During the observation, the DOE provided information on its progress of reaching its goal of having 50 percent of the data supporting the SRCR completed by May 2000. On January 31, 2000, the DOE had fully qualified 231 data sets or DTNs out of a projected 1600 DTNs. During the audit, the NRC observers expressed a concern about the lack of data qualification activities for the AMRs reviewed during the audit and the four previous audits. This appears to be a condition requiring DOE's management attention.

4.6 Observation and Examination of Audit Programmatic and Technical Activities

The NRC staff observed the audit team (auditors and technical specialists) conducting detailed checks of the programmatic and technical adequacy of each AMR within the scope of the audit. The auditors and technical specialists used a combination of technical issue probing and procedural compliance checks and verifications to thoroughly consider both the technical adequacy of the AMRs and the effectiveness of implementation of the QA Program. The NRC staff's observations for each of the AMRs audited are discussed in the following sections.

4.6.1 AMR No. F0045 (ANL-EBS-MD-000048), "Initial Cladding Condition"

This report analyzes the cladding condition of the commercial spent nuclear fuel (SNF) as it is received at the Yucca Mountain (YM) repository. Because most commercial SNFs are encased in Zircaloy cladding, the analysis is developed to describe the degradation of Zircaloy from various sources. Primarily, Zircaloy-4 was analyzed since it represents all Zircaloy on a conservative basis in the cladding degradation. The analysis includes impacts from commercial nuclear power plant reactor operations such as incipient failures, degradation after reactor operation during wet or dry storage, and impacts from transportation. The potential degradation modes considered include creep, wall thinning from oxidation and crack development, delayed hydride cracking, and mechanical failure. The analysis defines the ranges and uncertainties of involved parameters. This analysis will serve as the initial boundary condition for the analysis of cladding degradation during the disposal period.

4.6.1.1 General Observations (Technical and Programmatic)

The checklist that the auditor prepared was extensive, thorough, and appropriate, indicating that both the auditor and technical specialist understood the AMR well. The AMR preparer answered most of the questions properly, and agreed to add several clarifications and editorial changes to the AMR text. After each section of the AMR had been reviewed by a DOE auditor and technical specialist, the NRC observer was provided an opportunity to asked additional questions and to comment on the AMR. The preparer agreed to modify the AMR and incorporate both the audit team and NRC observer's comments. The following paragraphs address the more significant recommendations made by the DOE audit team and the NRC observer.

4.6.1.2 Technical Observations

The DOE audit team provided the following recommendations:

a) Although the analysis was conducted using data from various literature sources, this data needs to be identified and submitted and justified as "accepted data." The technical specialist questioned whether some of these data should be submitted for review as "accepted" or as data to be qualified (e.g., the data on burn-up distribution needs to be submitted and qualified).

b) During the audit, the DOE technical specialist briefly reviewed five AMRs related to the initial cladding condition AMR, to determine the degree to which other cladding degradation AMRs and calculations were integrated and consistent in their use, with outputs from the initial cladding condition AMR. As a result of this review, the DOE technical specialist recommended that a thorough, in-depth, assessment be performed by all preparers of cladding degradation AMRs to ensure that their AMRs adequately and appropriately acknowledged and referenced the proper usage of assumptions, inputs, analyses, and results from the initial cladding condition AMR. The integration of the initial cladding condition AMR with related AMRs, such as the AMR on mechanical degradation, is recommended. The initial conditions developed in the initial cladding condition AMR need to be used in other AMRs. For example, the cladding thickness adjusted by the oxide formation needs to be used in the AMR on mechanical degradation where, currently, the oxide thickness is not taken into account in the input of the cladding thickness.

The NRC observer provided the following recommendations:

a) The localized corrosion, stress corrosion cracking (SCC), and hydride embrittlement (HE) caused by hydride reorientation need to be addressed, as identified in the NRC Issue Resolution Report (IRSR) on Container Life and Source Term (CLST). SCC and HE were identified in the audit checklist as review areas and, when questioned by the audit team, the originator responded that these would be covered in the related AMRs such as the "Features, Events, and Processes" AMR. The NRC observers recommended extending the coverage to localized corrosion in the related AMRs, and discussed that for these failure modes, this AMR needs to reference all the related AMRs. Further, it was discussed that where SCC and HE are discussed, they should consider and address the NRC IRSRs, especially the CLST IRSR, and the previous NRC/DOE interactions such as the Appendix 7 meeting on CLST in 1999. Further, it was discussed that unlike localized corrosion or SCC, the failure caused by HE may need to be fully analyzed in this AMR because it is likely to occur during storage and the transportation.

b) The effects of the weldment on the cladding performance need to be considered. For example, the fabrication-related failure during the reactor operation in Table 8 of the AMR needs to be extended to failures occurring during storage and transportation.

c) The creep failure criteria are not well-defined. The current criteria, an average strain at failure of 3.3 percent with a range of 0.4 percent to 11.7 percent, are not based on the

microstructural definition. For example, the NRC Review Plan for Dry Cast Storage adopts the diffusion controlled cavity growth (DCCG) criterion derived from cracking at grain boundaries. Although it is debatable whether the DCCG criterion needs to be adopted here, the failure criteria chosen here need to be sufficiently rationalized.

d) The Zircaloy-4 Pressurized Water Reactor cladding may not represent the Zircaloy-2 Boiling Water Reactor cladding on the conservative performance basis. This is of concern if the failure mode is extended from corrosion to hydride embrittlement.

The preparer agreed to address the following less significant topics: (a) providing a stronger technical basis and clear articulation of the framework associated with several assumptions and criteria used in the analysis; (b) test methods such as the use of irradiated or unirradiated samples at various temperatures need to be better-justified; (c) the primary sources of references will be quoted; (d) the chosen creep model needs to be better validated; (e) the terminology for the oxide thickness and the metal loss thickness should be clarified; (f) the experience and test results in storage will be updated; (g) the burn up effects on oxidation needs to be better stated; and (h) references on the DIRS form needs to be better-defined.

4.6.1.3 Programmatic Observations

There was no software requiring qualification for the initial cladding condition AMR; however, just before the audit, the AMR was updated as a result of a self-assessment. This update included a revision to identify the AMR's usage of the Excel spreadsheet application as a routine. The AMR was updated to include the appropriate information and test case to justify the software application as a routine.

There were no data qualification activities completed for the initial cladding condition AMR. Several data inputs existed. The preparer had not initiated any action to enter these data into the data tracking system.

4.6.2 Colloid AMRs - General Observations

This section contains the NRC staff observations of the DOE audit of the three colloid AMRs. Comments on specific colloid AMRs are addressed in Sections 4.6.3 through 4.6.5 of this report. The colloid abstraction AMR No. F0115 (ANL-WIS-MD-000012) provides direct input to the DOE total-system performance assessment (TSPA) in the form of a model abstraction describing colloid-associated radionuclide release from the waste form to the exterior of the waste package. The two additional colloid AMRs audited were AMR No. F0110 (ANL-EBS-MD-000020) and AMR No. F0105 (ANL-EBS-MD-000021). These AMRs provide direct data input to the abstraction AMR. During the audit, 2 days were devoted to the abstraction AMR, and 1 day for each of the two data AMRs.

4.6.2.1 General Technical Observations

The DOE audit team interviewed the AMR preparers and other AMR support personnel and performed a thorough review of the AMR and its supporting documentation. Although the assigned DOE technical specialist was not an expert in the field of colloid formation and transport, the technical specialist was well-qualified for conducting the audit and had a good

understanding and knowledge of technical context and aspects of the AMRs. His questions were appropriately focused on the transparency and traceability of the process leading to the colloid release abstraction. The technical specialist focused on both adherence to procedures and technical quality. The NRC technical specialist was afforded full participation, receiving ample time for follow-up questions and being allowed to raise new issues when appropriate within the scope of the audit. When warranted, the DOE technical specialist used issues raised by the NRC technical specialist in formulating his own recommendations. The NRC technical specialist's questions were adequately answered and no NRC audit observation inquires were needed. Although the DOE technical specialist controlled the agenda and was prepared to uncover inadequacies and recommend remedies, the sessions were nevertheless informal and collegial.

All three colloid AMRs were complete only through author-final status (Revision 00A) and were still in the checking stage. Therefore, it was not possible to assess fully the adequacy of the AMR process for producing reports of high quality and technical defensibility. Many of the issues raised by the technical specialists had previously been noted in the checking process, but it was apparent that the audit served as an in-process quality improvement exercise. In this sense, the audit did not completely fulfill its objectives.

The checker for two of the AMRs was present for the audit, providing much technical depth to the discussions. His presence was also useful in obtaining information on the ongoing checking process. In addition, it was indicated during the audit that the checker would likely head an effort to integrate colloid-related activities across PMRs and AMRs, assuring consistency in data and model treatments. Based on the checker's performance in the audit, it appears that this integration effort may serve as a model for other technical areas.

The AMRs reflected work of high technical quality. As noted by the DOE technical specialist, the abstraction AMR (see Section 4.6.3 of this report) was well-structured in showing the process leading from data input to abstraction output. However, there were general areas where improvement in the AMR preparation could be made. The three AMRs, collectively, could have been better integrated by making their inputs and outputs more explicit. A possible remedy, for example, would be to include in the conclusions section of the data AMRs lists of parameters, the parameter ranges, and plots that constitute the direct input to the abstraction AMR. In addition, the AMR preparation could be more explicitly directed toward effects on repository performance. As part of confidence building and model validation, the reports did contain data and references supporting their choices of data and models. However, these supporting technical bases did not always directly address whether the choices made could lead to potentially underestimating adverse effects on performance under repository conditions. Such a focus at the AMR level would better serve the DOE in making its safety case.

4.6.2.2 General Programmatic Observations

Technical and programmatic audit activities were conducted in accordance with the OQA Audit Plan for Audit M&O-ARP-00-005. The auditors and technical specialists reviewed documents identified in the audit plan and used checklists as a basis for inquiries. In addition, related documentation supporting report development and conclusions was reviewed to verify data source and status of qualification. Personnel directly responsible for document products or appropriate representatives with sufficient levels of knowledge were interviewed, including

personnel from the Los Alamos National Laboratory (LANL), Argonne National Laboratory (ANL), and Lawrence Livermore National Laboratory. The checklists used were effective and additional inquiries were made beyond specific checklist items, when appropriate.

4.6.3 AMR No. F0115 (ANL-WIS-MD-000012), "Waste-Form Colloid-Associated Concentration Limits: Abstraction and Summary"

The abstraction AMR was the main focus of the colloid sessions of the audit, because it represents the handoff of the model abstraction for colloid release from the waste form to TSPA. The AMR uses literature and Yucca Mountain Project data to support its construction of an algorithm for calculating colloid-associated radionuclide concentrations in solutions leaving the waste package (no credit is taken for colloid retardation within the waste package). Direct inputs for conceptual models and parameters were obtained from the two supporting AMRs that were reviewed during this audit. Also, a small number of literature sources that will be subjected to the DOE data acceptance procedure were used as inputs. The abstraction uses output from in-package geochemical models and uses pH, ionic strength, and dissolved radionuclide concentration to calculate colloid concentrations, irreversibly colloid-bound radionuclide concentrations, and reversible colloid binding of radionuclides. The results are combined to provide a total colloid-associated source term for a given radionuclide.

4.6.3.1 Technical

The preliminary status of this AMR was partly compensated for by the presence, at the audit, of its checker. The checker suggested revisions, to be incorporated into Revision 00B of the AMR, that were substantial, and addressed many of the technical concerns expressed by both the audit team and NRC technical specialists. The substantive revisions were, for the most part, in the areas of strengthening technical bases and clarifying the abstraction through the use of flow charts and logic statements. The checking process led to improvement in report quality.

A useful feature of this AMR was a pair of tables describing how the report addresses NRC IRSRs and the DOE's performance assessment (PA) peer review panel recommendations. This table should serve as a model for other AMRs, because it clearly facilitates using the information in the report to further issue resolution.

This AMR needed improvement in providing justification for assumptions and choices of data and models. Model validation exercises were scattered throughout the document and, at the suggestion of the DOE technical specialist, will be consolidated in the report. However, the technical bases were typically not explicit enough with respect to repository performance. The checker helped to correct many of these shortcomings, but direct relevance to the proposed repository in AMR preparation should be better emphasized early in the process. For example, the abstraction adopted a maximum concentration of plutonium irreversibly attached to colloids of 6×10^{-8} mol/L, based on results of 15 ANL experiments on static HLW glass degradation (reported in ANL-EBS-MD-000020 Rev 00A). The literature on this topic is admittedly sparse, but the AMR did not make a strong case that this value is likely to bound plutonium concentrations under particular repository conditions that may not be reflected in experiments using EJ-13 or deionized water at 90°C.

The abstraction was stated to apply only to plutonium and americium. However, no technical basis was provided for the choice of these radioelements and the exclusion of others. The author planned to add other elements, but such questions of scope should be addressed early in the process.

A preliminary list provided by the DOE technical specialist contained seven recommendations for improving the abstraction AMR. No formal deficiencies were issued. Most recommendations focused on strengthening or clarifying technical bases and addressing issues such as model validation and uncertainty. A notable recommendation was that model validation in the AMR be augmented with results of test runs of the abstraction within the Total System Performance Assessment (TSPA) code. A programmer has begun coding this abstraction into TSPA, and provided the audit team with a demonstration of the GoldSim software being used for TSPA. The audit team, observers, and the individuals being audited all agreed that code testing should, when possible, be a component of model validation for inclusion in the abstraction AMR - and not only within the TSPA effort.

4.6.3.2 Programmatic

The DIRS forms had been completed for this AMR. Twenty-five data packages had been identified as "TBV." After discussion on the use of "reference," "corroborative," and "accepted" data, the author stated the "B" revision of the AMR DIRS would only identify about four data sets as "TBV." This indicated that recommendations from previous OQA audits and the M&O Lessons Learned program have not been effective in communicating these issues with the AMR authors. The governing procedure, AP-3.15Q, clarified some of the above issues. However, discussions with the procedure author indicated the training plan is currently under development and has not been presented to any personnel.

A discussion occurred on whether data abstraction could be classified as a model. The governing procedure AP-3.10Q was not clear. The procedure author stated that the procedure revision was currently undergoing the management review process. During the discussion, notes were taken for clarification in the next procedure revision.

No software programs requiring qualification were noted with this AMR.

The planning documents and information contained in the Technical Data Tracking System (TDMS) were found to be acceptable.

4.6.4 AMR No. F0105 (ANL-EBS-MD-000021), "Colloid Stability and Attachment/Detachment Properties"

This AMR describes literature data and Yucca Mountain Project laboratory studies on colloid stability and colloid sorption of radionuclides. This AMR provides direct input to the abstraction AMR (ANL-WIS-MD-000012) in the form of a range of sorption coefficients, or K_ds, to be used in modeling reversible attachment of plutonium to colloids. The K_ds were based on batch colloid sorption experiments at LANL, which were obtained under the current DOE QA program and therefore are expected to be qualified. This report was at an even more preliminary stage than the abstraction AMR, having received only a preliminary read-through by the checker. As a result, the report is expected to be substantially revised.

4.6.4.1 Technical

The DOE audit team identified the need for several improvements for this AMR, including addressing the issues of clarity of outputs and confidence building in the context of repository performance previously discussed. For example, the direct output to the abstraction AMR was difficult to discern because it was not emphasized and restated at the end of the report. In addition, no technical basis was provided for the use of the mass-based coefficient K_d rather than the surface-area based coefficient K_A.

Two additional general areas in which the AMR could be improved are in the inappropriate focus on future work and the level of experimental detail. Because of emphasis, in the conclusions section on the paucity of relevant colloid sorption data, the draft report read more like a proposal than a data input report. In addition, the report omitted important experimental details such as pH variation during the experiments. This information was needed to support the applicability of the results. It appeared that the checker was addressing both of these issues in his comments.

A preliminary list provided by the DOE technical specialist contained five recommendations for improving the LANL AMR. No formal deficiencies were issued. These recommendations were appropriately focused on clarity, improving the technical bases supporting the results of analysis, and the applicability of these results to the proposed repository.

4.6.4.2 Programmatic

Planning documents for this AMR were found to be in accordance with applicable procedures.

The LANL scientific notebook containing the results of analyses and testing was reviewed during the audit and its author interviewed. This review indicated that the loose-leaf binder was in compliance with Procedure No. AP-S111.1Q. The notebook entries and required reviews were properly documented with no discrepancies noted. A recommendation was made to transmit this document to the DOE Records Center and have it entered into the TDMS before the issuance of Rev 00 of the AMR. The DIRS document indicated three sets of data requiring qualification and were identified by TBVs 0473, 0869, and 3348. No software packages required qualification for this AMR.

4.6.5 AMR No. F00110 (ANL-EBS-MD-000020), "Colloid-Associated Radionuclide Concentration Limits"

This AMR contains literature and previous ANL data from static and drip corrosion tests on HLW glass and SNF supporting a model of irreversible plutonium colloid attachment used in the colloid source term abstraction AMR. The direct inputs to the adopted abstraction were all based on ANL work and are: (a) a relationship between colloidal plutonium concentration and ionic strength, based on static HLW glass corrosion tests; (b) a relationship between ionic strength and colloid stability; and (c) a direct relationship between colloidal plutonium concentration and colloid concentration. The adopted abstraction uses data only from the HLW glass tests. The SNF results were included in the development of a model in an AMR that was used in the abstraction AMR as an alternative model. The use in the abstraction only of HLW

glass results appears to be conservative in that the ANL AMR concluded that colloid release was lower in SNF tests.

4.6.5.1 Technical

As was the case for the other AMRs, this report was of high technical quality and no significant differences over technical approaches were discussed. However, as previously discussed, adequately addressing the issues of clarity of outputs and confidence building was an area needing improvement. For example, the AMR needed to contain stronger justification that: a) the test samples were sufficiently representative of the range of waste forms expected in the proposed repository; b) deviation of repository physical and chemical conditions from those in the laboratory have been properly considered; and c) neglecting the effects of water chemical parameters other than pH and ionic strength in characterizing colloid behavior is appropriate.

A preliminary list provided by the DOE technical specialist contained four recommendations for improving the AMR. No formal deficiencies were issued. These recommendations were appropriately focused on clarity, uncertainty, and improving technical bases supporting the results and their applicability to the proposed repository.

4.6.5.2 Programmatic

The DIRS document contained 30 entries for data identified as "Qualified Verification Level 2," in accordance with procedure AP3.15Q. No software programs requiring qualification were noted for this AMR.

The work performed at ANL was governed by a subcontract from the M&O. The laboratory is listed on the Approved Vendors List and requires the DOE's annual evaluation and triennial audit of its quality system.

Various ANL scientific notebook pages identified on the DIRS form were pulled from the TDMS. No discrepancies were noted; however, a recommendation was made to have the complete scientific notebooks submitted to the Records Center.

4.7 NUCLEAR REGULATORY COMMISSION STAFF FINDINGS

The NRC staff generally agrees that OQA Audit M&O-ARP-00-005 was effective in recommending improvements in the AMR process and with the audit team conclusions, findings, and recommendations. The audit was conducted in a professional manner, using audit team members who were independent of the activities they audited. The DOE audit team members appeared to be knowledgeable in the QA and technical disciplines within the scope of the audit. Their qualifications were found to be acceptable for their respective disciplines. Although the audit scope included data qualification, the audit team was unable to assess the data qualification process and activities, because no data-qualification activities had been performed for the data supporting the AMRs reviewed.

During the observation, the DOE provided information on the progress in reaching its goal of having 50 percent of the data supporting the SRCR completed by May 2000. On January 31, 2000, the DOE had fully qualified 231 data sets or DTNs out of a projected 1600 DTNs. The

DOE explained that the total number of DTNs was still evolving because several AMRs preparers had not entered the data supporting the AMRs into the DTN tracking system. During the audit, the NRC staff expressed a concern about the lack of data qualification activities for the AMRs reviewed during the audit and the four previous audits. The NRC staff considers the lack of data qualification activities during this audit and the four previous PMR audits to be a condition requiring OQA management attention. The NRC staff suggests that OQA management evaluate the need to conduct audits specifically to evaluate the qualification of data.

Because the AMRs reviewed were in draft and in the process of being completed, the DOE audit served more as a review than as an assessment. No deficiencies were written. Technical discussions held during the audit were informal and detailed and at times resembled a technical exchange. The DOE technical specialist appropriately focused the discussions on transparency and traceability in the processes of data acquisition, data interpretation, model development, and validation. The colloid abstraction AMR appears to be a good example for illustrating an acceptable model development and model validation. It is recommended that M&O consider using this example as part of the training given to AMR preparers.

The preparers of AMRs need to provide more considerations to the regulatory process and issues of repository performance. In addition to the AMR being a sound technical document, it should also provide more explicit technical bases so that choices of data and models will not lead to underestimates of potentially adverse effects on repository performance.

During the audit the NRC observers questioned DOE's basis for not performing re-qualification of low-risk significant data. The DOE informed the NRC observers that the sample plan, serving as the basis for not performing re-qualification of low-risk significant data, would be documented in a procedure by the end of February 2000, and would provide for feedback and corrective action, should problems be identified in re-qualifying similar high-risk significant data.

The NRC observers concluded that: (a) the AMR developers, within the scope of this audit, produced technically adequate AMRs; however, both the NRC observers and OQA audit team members provided several comments on the technical content of the AMRs; (b) the DIRS, which is used to track DTNs, has improved; and (c) the implementation of changes to procedures controlling the AMR process and the communicating of lessons learned from the audits to the preparers of the AMRs could be improved by providing additional training or formal instruction.

M&O focus has been placed on AMR packages undergoing OQA review, which covers only a small percentage of the total number of AMRs and PMRs being developed. This calls into question the adequacy and condition of the remaining AMR/PMR packages not undergoing the same scrutiny.

4.7.1 Audit Observer Inquiries (AOI)

No NRC AOIs were generated during this audit.

4.7.2 Closure of Previous NRC AOIs

No AOIs were closed during the conduct of this observation.

4.7.3 Open NRC AOIs

The following NRC AOIs remain open:

a) AOI No. OCRWM-ARC-99-015-1, dated September 22, 1999: OQA agreed to provide information to the NRC on the qualification status and use of the "Waste Stream Profiles" addressed in the "Design Basis Waste Stream for Interim Storage and Repository" and the "Waste Quantity, Mix and Throughput Study" documents.

b) AOI No. M&O-ARP-00-02-1, dated November 18, 1999: AP-3.10Q, "Analysis and Modeling" and the QARD are not specific regarding which calculations/analyses are subject to model validation and the timing of model validation. M&O Environmental, Safety, and Regional Programs Office involved with the biosphere AMRs do not appear to have an understanding or strategy of model validation as it applies to the biosphere AMRs/PMR.

c) AOI No. M&O-ARP-00-02-2, dated November 18, 1999: Documented resolution of individual comments is not required for checks of analysis and models (AP-3.10Q) and is optional for reviews of technical products (AP-2.14Q). A lack of documented resolution is inconsistent with the QARD Section 2.2.10 (f), which requires that mandatory comments shall be documented and resolved before approving the document. Note that the audit of the Integrated Site Model (ARP-99-009) also identified several recommendations concerning the review processes of AP-3.10Q and AP-2.14Q.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 20, 2000

Mr. Dwight Shelor, Acting Director
Program Management and Administration
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- 00-04, "OBSERVATION AUDIT OF OFFICE OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT, QUALITY ASSURANCE DIVISION, AUDIT NO. M&O-ARP-00-004"

Dear Mr. Shelor:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report No. OAR-00-04 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 of the Unsaturated Zone (UZ) Flow and Transport Process Model Report (PMR) activities performed by the OCRWM Management and Operating Contractor (M&O). The audit, M&O-ARP-00-004, was conducted on January 24-28, 2000, at the Lawrence Berkeley National Laboratory (LBNL) in Berkeley, California.

This audit was limited in scope and evaluated the effectiveness of the implementation of the OCRWM QA Program described in the Quality Assurance Requirements and Description and its implementing procedures for selected analysis model reports (AMRs) supporting the UZ Flow and Transport PMR.

The NRC staff determined that this audit was effective in identifying deficiencies and recommending improvements in the AMR process. During the conduct of the audit, both the audit team and the NRC observers reviewed analysis reports and software within the scope of the audit to confirm that it was properly qualified. It was difficult to assess the adequacy of the AMRs, because much of the supporting data were in other incomplete, and/or unavailable AMRs.

NRC staff expressed a concern about the adequacy of the process controlling the preparation and use of procedures for the AMR process. As discussed in various sections of this report, the NRC staff is also concerned about software traceability and the lack of data qualification activities for the AMRs reviewed during this audit and the three previous audits. This condition continues to require DOE's management attention.

A written response to this letter and the enclosed report is not required. However, we do expect OQA to provide replies to the open AOIs. If you have any questions, please contact Ted Carter of my staff at (301) 415-6684.

Sincerely,

for

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

Enclosure: NRC Observation Audit Report No. OAR-00-04, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. M&O-ARP-00-004"

cc See attached list

Letter to D. Shelor from C.W. Reamer dated: March 20, 2000

cc: R. Loux, State of Nevada
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A. Brownstein, DOE/Wash, DC
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U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-00-04

OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE DIVISION

AUDIT NO. M&O-ARP-00-004

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High-Level Waste and Performance Assessment Branch
Division of Waste Management

03/08/00
Jeff Ciocco
High-Level Waste and Performance Assessment Branch
Division of Waste Management

03/9/00
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High-Level Waste and Performance Assessment Branch
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03/3/00
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03/16/00
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1.0 INTRODUCTION

Staff of the U.S. Nuclear Regulatory Commission (NRC), Division of Waste Management and 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), Yucca Mountain Quality Assurance Division performance-based audit of 4 Analysis Model Reports (AMRs) out of 24 AMRs supporting the Unsaturated Zone (UZ) Flow and Transport Process Model Report (PMR) activities performed for the Management & Operating Contractor (M&O). The audit, M&O-ARP-00-04, was conducted January 24-28, 2000 at Lawrence Berkeley National Laboratory (LBNL) in Berkeley, California.

The objective of this audit was to evaluate the implementation of the applicable provisions contained in the OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 8, by reviewing selected analysis model reports (AMRs) supporting the UZ Flow and Transport PMR. During the audit, selected AMRs were subjected to a technical review as well as review to ensure that the applicable programmatic requirements contained in the QARD and implementing procedures were met.

The NRC staff objective was to gain confidence that the M&O and OQA 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 Code of Federal Regulations (10 CFR Part 60). Because of the anticipated DOE submittal of the site recommendation (SR) in November 2000, the following observation activities were emphasized: 1) confirming that data, software, and models supporting SR are properly qualified; and 2) reviewing the progress being made by DOE and its contractors in meeting the qualification goals for SR.

This report addresses the NRC staff determination of the effectiveness of the OQA audit and the adequacy of implementation of QARD controls by the M&O in the audited areas of AMR development.

2.0 MANAGEMENT SUMMARY

The NRC staff has determined that OQA Audit M&O-ARP-00-04 was useful and effective. The audit was organized and conducted in a professional manner. Audit team members were independent of the activities they audited and their assignments and checklist items were adequately described in the audit plan. The audit team members' qualifications were reviewed and the members were found to be qualified in their respective disciplines.

The audit team concluded that the OCRWM QA program had been satisfactorily implemented in some of the areas audited. However, the selected AMRs were still in the revision process and the associated software, data, and model packages had not been qualified, verified, or validated. As a result, one "potential" deficiency was identified covering a range of problems with the U0010 AMR and a general software deficiency was identified for all the AMRs and the M&O. Seven recommendations were specified with four directed at particular AMRs and three directed at the general AMR development process and to the QA program procedures. The NRC agrees with the audit team's conclusion and recommendations. The NRC staff determined

that this audit was effective and that the QA program implementation overall was adequate. The recommendations should prevent future discrepancies in the AMR/PMR development process though the lessons learned from previous audits may not be clearly emphasized in the development of all AMRs.

Further, the NRC staff determined that this audit was effective in identifying deficiencies and recommending improvements in the AMR process. During the conduct of the audit, both the audit team and the NRC observers reviewed data, analysis reports, and software within the scope of the audit to confirm that it was properly qualified. The audit team and the NRC observers determined that the software supporting three of the four AMRs had been generally properly qualified.

The NRC staff generally agrees with the audit team conclusion's, findings, and recommendations. However, as noted in Section 4.7 of this report, the NRC staff expressed a concern about the adequacy of the implementation of the process to close the 4 super-Corrective Action Reports. Further, as discussed in various sections of this report, the NRC staff is concerned about the lack of data qualification activities for the AMRs reviewed during the audit and the three previous audits. This appears to be a condition requiring DOE's management attention.

3.0 AUDIT PARTICIPANTS

3.1 NRC Observers

Ted Carter	Observer (Team Leader - NRC)
Robert Latta	Observer (Senior QA Engineer - NRC)
Jeff Ciocco	Observer (Technical Specialist - NRC)
Randy Fedors	Observer (Technical Specialist - CNWRA)

3.2 DOE Audit Team

Robert Hartstern	Audit Team Lead	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
Michael Eshleman	Auditor	OQA/QATSS
Richard Powe	Auditor	OQA/QATSS
Lester Wagner	Auditor	OQA/QATSS
Ronald Linden	Technical Specialist	OQA/QATSS-MTS, Golder Associates
Keith Kersch	Technical Specialist	OQA/QATSS-Science Applications International Corporation (SAIC)

Bob Hasson of OQA/QATSS also attended the audit as an observer and to present an update status on the 4 super-CARs.

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This OQA audit of the M&O was conducted in accordance with the OCRWM Quality Assurance Procedure (QAP) 18.2, "Internal Audit Program," and the QAP 16.1Q, "Performance/Deficiency Reporting." The NRC staff's observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989 (Draft).

4.1 Scope of the Audit

The audit team conducted a limited scope, performance based audit of activities and processes related to the development of the AMRs supporting the UZ Flow and Transport PMR. AMR content, software, and data were evaluated during the audit process. The audit included review of the programmatic controls governing the AMRs and technical requirements contained in the AMRs. The following procedures and AMRs supporting the UZ Flow and Transport PMR were reviewed by the audit team and the NRC observers during the audit:

Procedures

a) AP-2.13Q, "Technical Product Development Planning," Revision 0, with Interim Change Notice (ICN) No. 1
b) AP-SI.1Q, "Software Management," Revision 2, with ICN No. 0
c) AP-3.15Q, "Managing Technical Product Inputs," Revision 0, with ICN No. 1
d) AP-SIII.2Q, "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data," Revision 0, with ICN No. 0
e) AP-3.10Q, "Analysis and Models," Revision 1, with ICN No. 0
f) AP-2.14Q, "Review of Technical Products," Revision 0, with ICN No. 0
g) AP-SIII.3Q, "Submittal and Incorporation of Data to the TDMS," Revision 0
h) YAP-SV.1Q, "Control of the Electronic Management of Data," Revision 0, with ICN No. 1
i) QAP-SIII-1, "Scientific Investigations", Revision 3

Analysis Model Reports

a) ANL-NBS-HS-0000015, "Development of Numerical Grids for UZ Flow and Transport Modeling," Revision 00 (U0000)
b) ANL-NBS-HS-000032, "Simulation of Net Infiltration for Modern and Potential Future Climates," Revision 00A (U0010)
c) ANL-NBS-HS-000005, "In Situ Field Testing of Processes," Revision 00E (U0015)
d) MDL-NBS-HS-000004, "Seepage Calibration Model and Seepage Testing Data," Revision 00D (U0080)

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 M&O and DOE programs and procedures. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit. The NRC staff believes the timing of the audit was appropriate for the auditors to evaluate ongoing UZ Flow and Transport PMR activities. However, the audit team was unable to confirm that data supporting the AMRs had been properly qualified since other related AMRs are developed in parallel, or in many cases, not as far along in the development process.

The NRC staff considers the lack of data qualification activities during this audit and the three previous PMR audits to be a condition requiring OQA management attention. The NRC staff suggests that OQA management evaluate the need to conduct audits specifically to evaluate the qualification of data.

The DOE audit team and NRC observers caucused at the end of each day. Also, meetings of the audit team and M&O management (with the NRC observers present) were held each morning 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 OQA audit team members were found to be acceptable in that they met the requirements of QAP 18.1, "Auditor Qualification," as verified by the NRC observation audit lead. The audit team members did not have prior responsibility for performing the activities they audited. In addition, training, education and experience records for audit team members were reviewed and found acceptable.

4.4 Examination of Quality Assurance and Administrative Requirements

The observation team determined that audit activities were appropriately conducted in accordance with the OCRWM QA Audit Plan for Audit M&O-ARP-00-04. The auditors reviewed selected project documents identified in the audit plan and employed a detailed checklist as the basis for their reviews. The audit team also examined related project technical documentation to verify the accuracy of source material and the status of data qualification activities. Cognizant personnel directly responsible for the development of the AMRs or representatives with appropriate levels of knowledge were interviewed by the auditors. During the conduct of these interviews the auditors effectively used the audit checklist to focus their inquiries on areas of technical concern. The audit team also afforded adequate opportunities for the NRC observers to provide comments and to seek clarification on technical issues.

The NRC observers determined that the programmatic elements of Quality Assurance Procedure (QAP) 18.2, "Internal Audit Program", were appropriately implemented by the audit team. Specifically, the well developed planning and implementation aspects of this audit were demonstrated during the conduct of the audit entrance meeting, coordination and communications between team members, the development of preliminary audit findings and the clear articulation of these findings during the daily audit caucus meetings. The NRC observers also concluded that the audit team's preliminary findings were accurately conveyed to M&O management personnel on a daily basis and that the audit results were effectively conveyed to M&O management personnel during the post audit meeting.

Within this area, the NRC observation team did not document any audit observation inquiries and it was concluded that the audit team conducted a thorough evaluation of the four AMRs which support the UZ Flow and Transport PMR.

4.5 Examination of Technical Activities

The NRC staff observed the DOE audit team technical specialists conducting detailed checks of the technical adequacy of the subject AMRs. A performance-based audit is used to address the adequacy of results given in the AMRs for the stated purpose of the work described in the document. The technical specialists used a combination of technical issue probing and procedural compliance checks and verifications to thoroughly consider both the technical adequacy of the AMRs and the effectiveness of implementation of the QA program. NRC staff found the qualifications of the DOE technical specialists satisfactory for the audit.

4.5.1 NRC Observation Team Technical Specialists General Comments

An important concern of NRC over the determination of adequacy for any AMR is that much of the supporting data cannot be assessed during the audit since other related AMRs are developed in parallel, or in many cases, not as far along in the development process. Many of NRC's questions were addressed by LBNL and U.S. Geological Survey (USGS) staff by simply stating that the basis and limitations of the input data were in another AMR. For example, fracture characterization data was used to support grid discretization in AMR U0000. The source of the fracture data could only be referenced as "another AMR," though the source could be tracked through the data tracking number (DTN) to AMR U0090, which itself had not progressed far enough for review in this audit. This is a limitation imposed on the audit team, whereby AMRs are evaluated prior to their completion of the development process.

Another general concern is the transparency of the equations and technical bases of assumptions and conclusions presented in the AMRs. Many of the comments noted in the following section allude to transparency. LBNL attempted to develop the AMRs as all inclusive, meaning that reference to milestone reports was to be reduced to usage for secondary or corroborating arguments. The USGS took a different stance and developed the AMR U0010 as a supplement to Flint et al. (1996). Better transparency is one of the DOE audit team's general recommendations for all AMRs. Since the specific items are not spelled out in the DOE audit summary, they are included in the following section.

Also, there was some confusion between validation and verification during the audit. The DOE definitions were not known or were not clear to the DOE auditors. The NRC defines software validation as confirmation that the software performs as designed; as such, software validation is equivalent to verification, which may otherwise be determined by hand-calculations to confirm that the code functions as expected (Eisenberg, et al, 1999). Model validation involves the process of assuring that equations and associated code adequately represent the physical system being modeled. Validation and model validation are taken as synonymous. The level of accuracy required for model validation depends on the objectives of the modeling. Benchmarking is often associated with software validation whereby a comparison is made with an existing documented code that represents the same conceptualization as the code being tested. The discussion at the audit was precipitated by section 7.2, Model Verification, in the Infiltration AMR (U0010). Based on Eisenburg, et al. (1999) the section should be labeled as "Model Validation" although DOE may choose to use different definitions.

4.5.2 Specific NRC Technical Comments

This section contains specific comments on each AMR. The title and AMR number are listed at the beginning of the discussion for each AMR. Other LBNL and USGS staff present at the audit are mentioned as warranted for specific discussion points.

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

The purpose of this AMR is to provide a basis for the 2D and 3D grids that will be used in the Calibrated Properties Model Data AMR (U0035), UZ Flow Model and Submodels AMR (U0050), and the Mountain-Scale Coupled Processes (TH) Model AMR (U0105). The Grid Generation AMR uses data from the GFM3.1, ISM3.0, fracture data sets, hydrogeologic units, water table map, and repository layout configuration. To streamline the text, this AMR is referred to as the Grid Generation AMR throughout the discussion below.

Throughout Grid Generation AMR, the horizontal locations are stated as being the Nevada State Plane projection. It is not clear to the NRC observers which coordinate projection is used, NAD27 or NAD83. The difference between NAD27 and NAD83 projections is about 196 m north-south and 80 m east-west in the vicinity of Yucca Mountain (YM); this is comparable to the shift from wash bottom to ridgetop on the east flank of YM. Since the grid development uses data from multiple sources, NRC recommends that LBNL staff confirm that there was no mixing of projections for the various input data used and that the projection be clearly stated in the AMR so that end users of output can ascertain which projection was used for spatial data.

> [Work after the audit by CNWRA staff appears to indicate that there was a problem with the conversion of alcove positions along the ESF to State Plane NAD27 (m) coordinates as listed in table 9. It is not clear if the error is caused by a projection conversion, or if there is another type of error in the calculations performed in the spreadsheet cited in the footnote of the table. This spreadsheet was reviewed by a DOE technical auditor as a check on traceability, but it is not known if the actual calculations were reviewed. The error leads to the alcoves being located as much as 100 m east of the ESF, assuming that the EDA II design coordinates from DOE are correct. Preliminary design GIS data dated October 1999 was obtained from DOE.]

The question of whether the grid was sufficiently refined for the intended usage was not included in the AMR but was discussed with LBNL staff. The DOE auditors determined that the basis for sufficiency of grid refinement to support transport calculations should be in another AMR, but that the basis to support spatial heterogeneity of shallow infiltration should be in the Grid Generation AMR. There are two grids described in the Grid Generation AMR, a calibration grid with highly refined horizontal and vertical discretization in the repository footprint and a performance assessment (PA) grid used to predict flow fields for PA usage. For grid refinement to support transport calculations, the NRC staff must review the transport AMRs, the UZ Flow AMR, and UZ Flow and Transport PMR to determine if the grid is sufficiently refined since this audit team concluded that the Grid Generation AMR did not directly feed the transport AMRs. For grid refinement to account for spatial variability of shallow infiltration, however, the bases for grid size sufficiency should be presented in the Grid Generation AMR for better transparency. Although the PTN may smooth out the spatial heterogeneity of shallow infiltration, the NRC staff believes that the coarse grid size (relative to the grid size for shallow infiltration) artificially smooths the shallow infiltration. Using distribution of percolation at the repository horizon for comparison, an analysis of results from two different grid sizes was described by LBNL staff. The NRC recommends that the grid refinement analysis be included in a scientific notebook and the text of the Grid Generation AMR should be modified to reflect the basis for the choice of the grid size.

The Grid Generation AMR states the assumption of a uniform, flat water table elevation of 730 m msl as opposed to the use of a sloping water table as suggested by data from the northwest corner of the repository block for a water table at 775 m msl (borehole H-5). This difference of 45 m would reduce the UZ travel path by 15% in the northwest portion of repository. This may not warrant a change in the grid if the initial conditions of the flow model account for the difference in the water table position. It is surmised that the flow calibration would have a difficult time matching water potential data in the northwest portion of the repository if the water table was assumed to be 45 m lower. The NRC agrees that there is little data to support the shape of the sloping water table; however, the decision to ignore a data point when there is only sparse data may not be acceptable. If the DOE contends that the effect of using a uniform, flat water table is negligible, then NRC recommends that the basis must be presented in the Grid Generation AMR or the UZ Flow AMR.

In the calibration grid, the finite volumes (blocks) in the repository footprint are vertically refined with five blocks laterally connected to one block outside the footprint. The NRC observers requested confirmation that the lateral connection of five stacked grid blocks all connected laterally to a single block outside the footprint did not lead to significant circular flow (horizontal counter-current flow) being created by the connection network. The LBNL staff discussed efforts that led to their conclusion that the circular flow effect was not significant, however, this was not presented in a scientific notebook or the text of the Grid Generation AMR. The NRC agrees that the artificial lateral dispersal of flow created by the network of connections is likely minimal, but recommends that the bases be included in a scientific notebook and noted in the AMR. If this grid was used for calculation of velocities for transport, artificial dispersion would be created. The DOE technical specialist pointed out that the PA grid does not have the refined block sizes in the repository footprint, hence, this is not considered an issue.

Assumption No. 6 pertaining to the fault geometry representation seems reasonable to the NRC observers, however, the basis is relegated to some unspecified AMR. Similarly, the fracture properties presented in table 5 (pages 20-21) are important for creating connection parameters for the grid, yet no basis is given for the fracture characteristics; no limitations are stated; and no indication of sensitivity of grid parameters to these highly uncertain data is mentioned. LBNL staff pointed out that the DTN for fracture properties would lead auditors towards documents that might answer the questions of basis and limitations for the fracture characteristics. Again, it is understood that the M&O removed references to other AMRs from the text, and, that this audit is reviewing AMRs that are works in progress and not yet complete.

The equations for connection spacing were stated in the AMR as coming from Warren and Root (1963). This reference, however, only provides a conceptual basis that may be used to estimate the coefficients in equations 4-6 on page 55. The coefficients for these equations were described by LBNL staff as being derived from modeling based on an assumption of single-phase, quasi-steady state flow for three different types of fractures. The NRC recommends that the calculations be added to a scientific notebook and the basis clarified in the text of the AMR. Equations 4-6 use coefficients of D/6, D/8, and D/10 instead of the widely used D/2 for connection lengths. The basis for DOE estimates of these coefficients appears to be valid. In going to this level of detail, a discussion of the anisotropy of the fracture frequency should also be included. The DOE auditors chose to explicitly draw out the transparency of the basis for the equations and state it as a separate recommendation of the audit.

Clarification was requested by the NRC observers on the estimation of the volume-area factor (A_{fm}) for matrix-fracture interaction. The basis for the A_{fm} values was stated as being in the AMR U0090, which could not be referenced since it was not yet completed. Also, without the AMR U0090, it was not clear in the Grid Generation AMR text how the A_{fm} parameter was used in the model; particularly, if there was a change in approach from that used for the Viability Assessment. The LBNL staff reaffirmed that the matrix-fracture interaction area is further modified by a calibration-derived coefficient that is dependent on saturation. This illustrates the problem with auditing AMRs when supporting AMRs are not yet completed and serves to emphasize that the purpose of the current audits is to analyze the progress of AMR development.

The equation relating 1-dimensional and 3-dimensional porosity in the footnote of table 5 on page 21 required further explanation. The proportionality of permeability with the cube of porosity is remindful of the parallel plate flow approximation but the terms used in the equation are not defined. LBNL staff responded by saying that it was not important for the development; the audit team concurred. The NRC recommends that the terms in the equation be clarified and that basis described in the AMR.

The choice of boundary conditions and the choice of the grid domain, often significantly affects flow model results. For the UZ site-scale model, the boundary conditions most likely to affect results pertain to flow below the repository where the lateral component of flow is prominent. Above the repository, 1D flow predominates in the current conceptualization of flow at YM. A discussion by LBNL staff was provided in written form describing the potential effect, or lack thereof, of boundary conditions on flow below the repository. The NRC staff recommends that their discussion be added to the Grid Generation AMR.

AMR U0010, Simulation of Net Infiltration for Modern and Potential Future Climates

This AMR produces spatially heterogeneous infiltration maps of average, high, and low infiltration rates for modern, monsoonal, and glacial transition climates for YM that will be used in Analysis of Infiltration Uncertainty AMR (U0095), Calibrated Properties Model AMR (U0035), UZ Flow Model and Submodels AMR (U0050), and Mountain-Scale Coupled Processes (TH) Models AMR (U0105). The Infiltration AMR uses data from surface geologic maps, rainfall data from stations at Nevada Test Site and YM, and output from the Climate AMR (U0005). To streamline the text, this AMR is referred to as the Infiltration AMR throughout the discussion below.

The decision to make the Infiltration AMR a supplement to the Flint et al. (1996) report meant that the Flint et al. (1996) report should also have been reviewed as part of this audit. Whereas the LBNL AMRs attempted to be self-contained, the Infiltration AMR stated as its first assumption that the model presented in Flint et al. (1996) was adequate to describe infiltration at YM. The data and results in the Flint et al. (1996) report are presently considered nonqualified, the model is not considered validated, and the report has not been released by the USGS. The NRC recommends that the Flint et al. (1996) report be directly incorporated into the Infiltration AMR.

Uncertainty analysis was stated as necessary in the Infiltration AMR but was relegated to the Analysis of Infiltration Uncertainty AMR. The objective of the Infiltration AMR was to present a methodology for estimating infiltration at YM. In doing so, the output of the model is presented as a single realization for YM; thus, the AMR is more than a methodology. The model validation of the infiltration model was said to be part of the Analysis of Infiltration Uncertainty AMR (U0095). Since the model is considered difficult to validate, the sensitivity of results to reasonable ranges of all parameters becomes an important tool for addressing the predictive reliability of the infiltration model. The NRC staff concurs with the DOE auditor recommendation that the sensitivity analysis be directly incorporated into the infiltration AMR.

The importance of a sensitivity analysis for evaluation of the model's predictive capability is illustrated by the uncertain calibration process. The infiltration model was calibrated for point estimates at locations where neutron probe (water content) and temperature data were collected. The neutron probe data may not reflect the entire flow through a fracture network since it is a point measurement of the matrix water content. This is not as severe a limitation, however, for the temperature data. The model was also calibrated at the watershed scale against sparse (2 events) streamflow data with root zone storage and percent area where runoff occurs as the primary calibration parameters. A final adjustment was made in the calibration process to ensure that the paleo-record of infiltration was not exceeded. The paleo-record is reflected in the recharge estimates based on geochemical data as will be described in another AMR (not yet completed). Each component of the calibration process has an associated uncertainty. Furthermore, given the uncertainty in the hydrologic properties of the soil and bedrock and the precipitation records, the predictive utility of the model should be considered suspect, thus the importance of a sensitivity analysis.

The highly uncertain hydrologic properties of the bedrock are derived from a composite matrix and fracture property data set presented in table 2 of Flint et al. (1996). USGS staff clarified during the audit that this data set has not changed, only the bedrock material defined for each pixel has changed since the 1996 report. The Day et al. (1998) map of the YM block is used where possible and other geologic maps are used to fill-in for surrounding areas. It was also clarified that the composite, or bulk, permeability values used in the model are the ones listed for the 250 μm filled fracture column, not the last column that lists a composite estimate in table 2 of Flint et al. (1996). The values from the "250 μm filled fracture" column best matched neutron probe data according to the USGS team at the audit. Even though the fracture data used to develop table 2 of Flint et al. (1996) has little supporting bases, the bulk permeability estimates were essentially calibrated parameters using the point estimates of temperature as constraints. The NRC recommends that a more complete description of the bases for the bulk permeability values for each bedrock layer be included in the AMR.

Soil depth is likely the most important porous media property for determination of shallow infiltration and it is another highly uncertain parameter. Soil depth is difficult to assess in the field, especially for shallow thicknesses where there is a strong sensitivity to shallow infiltration estimates. During the audit, the USGS team provided a more thorough description of the soil thickness model. Though the map is not presented in the Infiltration AMR, the YM area is divided into map areas of three soil-depth categories. Equations for slope dependent soil thickness for each category are presented in the AMR. Where surficial soil is thick, bedrock properties are not used because the soil at the bedrock/soil interface would be near saturation.

Uncertainty in soil depth would be expected to be significant using this soil thickness model, though the output generally seems reasonable. The NRC recommends that a more complete description of the soil map generation be included in the AMR.

Several concerns of NRC pertaining to the precipitation records were discussed during the audit. The first one is that spatial and temporal smoothing of the records would serve to under-predict infiltration. The use of 2 hour (summer) and 12 (winter) durations and the use of spatially uniform precipitation events, though adjusted for elevation, may not adequately reflect the actual localized, temporally varying storm events that occur, particularly during the summer. The second concern is that the length of the meteorologic data records from stations around YM are short, hence, large magnitude, long return period events are likely not represented in the short records. The 100-yr synthetic precipitation record constructed for the AMR explicitly limits the magnitude of storms to those seen in the short records. The smoothing of spatial and temporal precipitation events and the exclusion of large storms, otherwise expected in long precipitation records, would both lead to under-predictions of shallow infiltration because the BUCKET model compares precipitation rate (or flux input at the top of each layer) with saturated hydraulic conductivity to determine if infiltration proceeds down the UZ column. And lastly, the NRC is concerned that the infiltration model is constrained by future climate predictions that extend only to 10,000 yrs. Although proposed 10 CFR Part 63 specifies the compliance period as 10,000 yrs, there is a proposed specification that the analysis continue beyond 10,000 yrs to insure that peak dose does not occur during a short time period following the end of the compliance period. The NRC recommends that a discussion or an analysis be included in the AMR to address the sufficiency of the meteorological records to capture focused precipitation events and long-return period events and their effect on shallow infiltration estimates for a period up to and beyond 10,000 yrs.

The BUCKET model assumes plug flow through the multiple layers of the UZ vertical columns. An implicit assumption 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 YM. The INFIL version 2.0 contains both the BUCKET and the RICHARDS modules and could readily be used to confirm the basis for this assumption. Although Flint et al. (1996) extensively describe the RICHARDS module, it was never used to validate the reasonableness of the plug flow assumption used in the BUCKET module. Confidence in the BUCKET model would be enhanced by a comparison with the RICHARDS module or any other Richards equation-based numerical code. Infiltration rates are fastest when capillarity drive predominates at early times in storm events. However, the coarse layering used in the BUCKET model would tend to move water more quickly through the system as compared to results from a fine discretization, thus compensating for the neglect of capillary drive. The NRC recommends that the assumption of plug flow used in the BUCKET model be validated by comparison against a numerical Richards equation-based code to assure that mean annual shallow infiltration estimates are not under-predicted.

A number of items discussed during the audit fell under the category of transparency of equations, data, and scientific bases. The NRC had a number of specific concerns and is listing them here to support the DOE general recommendation of transparency:

1. The basis for the choice of a standard root zone depth of 2 meters were missing from the

AMR. USGS staff noted that the support for the estimate was contained in a report by Hudson and Flint (1996), which is not in the Infiltration AMR reference list.

2. Correction of the text defining field capacity to remove the word "significantly" since field capacity is the saturation at which capillary forces exceed gravitational forces (page 13).

3. A discussion is needed on the Markov chain analysis for wet-dry day prediction. The only source of information on the procedure was the comment lines in the Fortran code itself, although USGS staff believed that there might be an expanded discussion in another document. The handling of extremely low or zero-probability event sequences needs to be clarified.

4. During the audit, the justification for the time step for overland flow calculations was discussed as being inferred from work by Savard (1995). This should be discussed in the AMR.

5. The value of the slope in equation 3 for future climates (monsoonal and glacial transition) is never presented. Also, the modern coefficients for equation 3 are referenced to French (1983), however, Hevesi reported that coefficients estimated from the YM stations (14 stations, USGS and SAIC) were similar in magnitude to those reported in French (1983). The meteorological datasets used for this confirmation should be clarified in the AMR.

6. Equations 4 and 5 are presented with no basis or source reference.

7. A justification for the assumed changes in vegetation type and density and the evapotranspiration for future climates is needed. Also, rooting parameters that approximate 20% cover under modern climate are increased so that cover is 40% for the upper-bound of the monsoonal climate, and 60% for the upper-bound for the glacial transition. The percentages may be excessive, thus leading to an over-prediction of evapotranspiration and under-prediction of shallow infiltration. As discussed during the audit, justification might be obtained by analysis of analog sites. It is also noted that this item could be addressed as part of the uncertainty analysis slated for another AMR (if the DOE audit recommendation is not followed).

AMR U0015, In Situ Field Testing of Processes

This AMR summarizes the ambient field testing of processes using air and water injection tests performed in the ESF. This AMR directly feeds the Seepage Calibration Model and Seepage Testing Data AMR (U0080). To streamline the text, this AMR is referred to as the In Situ Field Testing AMR throughout the discussion below.

The oft-mentioned problems of representativeness of the tests to long-term, low flux rate, ambient conditions expected in any closed drift in the repository footprint were discussed by LBNL as part of this performance-based audit. Limited applicability for predicting seepage into drifts because of the high flux rate, short time-scale and length-scale injection tests from a limited number of locations and lithologies have all been discussed previously in peer reviews,

other audits, and this audit as discussed in the section on the Seepage Calibration Model and Seepage Data Testing AMR. The applicability constraint will not be repeated here. The stated objective by LBNL staff for the In Situ Field Testing AMR during the audit was that it simply presented field and laboratory data that addressed flow processes adjacent to and into a drift. The limitations of the data were mentioned in the AMR.

The effect of ventilation on the liquid injection tests was drawn out as a separate recommendation by the DOE auditors. Some of the test schedules for Niche 3650 included short time periods between injections. Though this injection schedule established that initial conditions significantly affect seepage results, it was not clear how the results of the test might relate to ambient conditions. Also, the ventilation effect has strong implications for physical, process-based modeling and the comparison of parameters between tests at one location and between test areas. Without establishing consistency for the ventilation effect, the parameter estimates for fracture porosity (which is assumed to account for initial condition and imbibition effects in the Seepage Model AMR) will vary solely due to the extent of the ventilation effect. LBNL staff discussed the efforts they have made to establish conditions similar to ambient including the grouting of rock fractures around bulkheads and artificial elevation of relative humidity. Monitoring relative humidity would allow for the ventilation effect to be integrated into the analysis. Experience noted by LBNL and USGS staff suggest that it is difficult to maintain high humidity in a closed niche when the Exploratory Studies Facility is ventilated. Also, the measurement error of probes used to measure relative humidity in the niches was stated in the discussion by LBNL staff as being ±2%. Even at high humidity, this magnitude of error may have a significant effect on seepage results for low flux rates prior to and during tests (Or and Ghezzehei, 1999). The magnitude of the effect caused by measurement error for high flux rate injections is not as significant, though knowledge of the relative humidity variations will remain important. The NRC recommends that DOE either explore alternative testing methods that control the ventilation effect or incorporate a ventilation model in their analysis of data and improve accuracy of relative humidity measurements.

There were a number of transparency, justification, and clarification questions directed to the authors during the audit that when addressed, should improve the AMR and improve any end users' understanding of the limitations of the output from this AMR. These are discussed below. The NRC recommends that these items be addressed in the AMR.

Table 19 on page 146 of the In Situ Field Testing of Processes AMR includes a psychrometer measurement of 0.4 meter for water potential. LBNL staff verified the data point, noted that the measurement error was ±5%, and concluded that this value reflected a small negative water potential since psychrometers cannot measure positive values of pressure head. The discussion switched to the meaning of the wide range of values of water potential in this table and the possible reflectance on flow pathways in fracture networks.

Confusion over the conversion of injection volume (or mass) over time values to linear rates of flow over time (e.g., Figure 20 of the In Situ Field Testing of Processes AMR) was clarified by LBNL staff. The area over which flow occurs is taken as the wetted half perimeter of the borehole times the test length along the borehole. Conversion of the volumetric (or mass) injection rates to linear measures of percolation and seepage ignores the dimensionality difference, and hence may be misleading. Flow from a point source injection leads to 3-

dimensional spreading over the niche ceiling. Ambient percolation over the entire projected areas of the niche is predominantly 1-dimensional except when capillary diversion takes place.

Four reasons were presented at the audit to explain the increase in permeability found by air injection tests in the small zone surrounding Niche 3650. Clearly, stress-induced fracturing should be considered as assumed in the In Situ Field Testing AMR. Other explanations include a skin effect due to dust filling fractures not being accounted for in the solution method, a change in the boundary conditions from pre- to post-excavation, and a change in the water content from pre- to post-excavation because of drying caused by ventilation. LBNL discussed their rationale at the audit for not addressing reasons other than stress-induced fracturing. The skin effect can not be separated from the permeability estimate using the analytical approach described in the In Situ Field Testing AMR. LBNL indicated that the fines were blown out as part of the air injection testing thus eliminating any skin effect. The change in the boundary conditions between pre- and post-excavation was not believed to affect the analysis because the volume of influence estimated by LBNL for the injection tests translated to a radius of 1 or 2 feet, which is slightly less than the distance between the borehole and niche ceiling (0.65 meter or 2.1 feet). Water content changes were believed to be minimal and relegated to the smallest fractures where any changes to permeability estimates were thought to be insignificant if they did de-water. Since the permeability is estimated directly from the air injection tests, and the van Genuchten α values are scaled to the permeability, and both are strongly important for estimating seepage threshold, the NRC staff recommends that a supporting basis for the assumed conceptual model describing pre- and post-excavation testing be included in the AMR.

AMR U0080, Seepage Calibration Model and Seepage Testing Data

This AMR develops a methodology for numerically modeling seepage rates and estimating seepage threshold values consistent with liquid injection tests performed in Niche 3650. This AMR produces parameter sets and calibrated models used in the Abstraction of Drift Seepage AMR (U0120), Drift-Scale Coupled Processes (DST, THC, Seepage) Models AMR (U0110), and Seepage Models for PA Including Drift Collapse AMR (U0075). To streamline the text, this AMR is referred to as the Seepage Model AMR throughout the discussion below.

The technical content of the seepage model AMR was considered to adequate by the DOE auditors based on the stated objectives. The Seepage Model AMR clearly states the limitations of the model; the seepage model is only valid for prediction of liquid injections 0.65 m above Niche 3650 at the high (relative to average annual ambient percolation rates for YM) injection rates used in the tests. In addition, the liquid injection tests are point sources of water above a large niche ceiling, rather than the ambient condition of percolation over the entire footprint of the niche. As such, the NRC staff views the seepage model as simply a transfer function model calibrated not only to this particular zone of fractured rock, but also to the conditions of the tests and the grid size used in the numerical inversions. The DOE auditors did include a general recommendation related to end users use of data from the audited AMRs, however, the author of the Seepage Model AMR clearly and adequately stated all limitations. The onus was put on the other seepage AMRs (U0075 and U00120) to apply this model to all of YM; this audit team was not charged with the task of auditing the other seepage AMRs. In spite of the declared limitations, the NRC is seriously concerned with the end use of the results from the Seepage Model AMR as discussed in the following paragraphs.

The three important hydrologic parameters estimated for the seepage model are fracture permeability, van Genuchten α, and porosity. The initial conditions are set using a uniform flux of 3 mm/yr. Permeability is estimated from the single-hole air injection tests reported in the In Situ Field Testing AMR. For the homogeneous case, the van Genuchten α is calibrated to the seepage threshold using data from the liquid injection tests. For the heterogeneous case, the Leverett scaling rule is specified in the Seepage Model AMR as the basis for the relationship between the permeability and the van Genuchten α. The fracture porosity is calibrated in all instances. As such, the calibrated porosity used in the analysis can be viewed as accounting not only for fracture porosity but also for matrix imbibition and water loss from measurement error or evaporation during the test. In the homogeneous case, the van Genuchten α can be viewed as accounting for fracture aperture distribution, particularly at the large aperture range as it varies across the niche ceiling; but the α value also accounts for film flow and rivulet flow in the fracture and roughness or irregularities of the niche ceiling. The NRC staff views this lumping of fracture hydraulic properties, test conditions, and grid size into hydrologic parameters acceptable if the seepage model is viewed strictly as a transfer function and the end users of the results used it as such.

Presuming that many in situ field tests are completed to support parameter ranges at YM for the seepage model, there is also a grid dependency of the parameter values. The model inversions assume a set grid discretization, any changes to the grid size will negate any comparison of parameter values between tests or any PA predictions. For example, seepage threshold is strongly correlated with the value of the van Genuchten α used in grid blocks adjacent to the drift opening (Winterle et al., 1999). When modeling seepage into drifts using grid independent parameters, the inverse of the van Genuchten α value (when converted to water pressure head) should remain smaller than the grid discretization near the drift opening. This is particularly important for large α values so that the strong non-linearity near saturation is captured by multiple grid blocks rather than being lost entirely in one large grid block adjacent to a drift opening. If large α values are used and the grid is not sufficiently refined, the model will lead to an over-prediction of the seepage threshold (the value of percolation below which there is no seepage into the drift) and an under-prediction of seepage rate at low flux rates. The calibration process within the Seepage Model AMR does not exhibit this problem because the model is clearly used as a transfer function for the specified injection tests, hence it does not matter that the $1/\alpha$ value is 2 cm (converted from table 10) and the first connection is 5 cm and the block dimension is 10 cm. The NRC recommends that a grid refinement (and connection length) analysis be done for large values of the van Genuchten α, similar to that done by Hughson and Codell (2000) before any Monte Carlo analysis of seepage threshold is performed using the seepage model.

Although grid refinement may be necessary to correctly capture seepage threshold because of the large van Genuchten α values, the fracture continuum approach still suffers from lack of supporting basis from the perspective of representative element volume. Based of borehole data and ESF data, the fracture spacing is larger than the grid block sizes. The NRC staff concurs with LBNL staff that alternative methods need to be explored; such efforts were said by LBNL staff to be underway, particularly in the area of discrete fracture models.

Since the seepage model has the trappings of a physical, process-based model, but is essentially a transfer function model, the parameters cannot be extrapolated to other areas, other injection rates, or even to a uniform flow or pulses percolating towards the drifts. The

Monte Carlo analyses reported in Seepage Model AMR imply that the goal is to establish a methodology for applying the seepage model to YM. The LBNL staff deferred questions on the basis for determination of ranges of parameters to another AMR, and then assumed ranges for the Monte Carlo analyses. The staff NRC considers the recommendations for more injection tests, at lower rates and longer durations, and in many locations that were included in the AMR to be an extremely important component of this approach. Until those tests are done, the NRC believes that there will be little basis for the hydrologic parameters of the seepage model because it is a transfer function model based on the conditions of the injection test and the grid size used for the inversions.

There were a number of comments raised by the DOE auditors and the NRC observers directed on clarity and transparency of the Seepage Model AMR, they were: (i) the discrete features model was describe as including elongated features with "low permeability obstacles" (p.22). The term "obstacles" was clarified to mean variation in discrete feature width, rather than an obstruction; (ii) the reference to "matrix" implied a dual-continuum model for the discrete feature model whereas the reader is otherwise led to infer that a single-continuum is used. The LBNL staff stated that "matrix" referred to the zones between discrete features (page 22 and 30). The discrete feature model and the fracture continuum model are just two different representations of a heterogenous domain; (iii) on page 25, Figure 3, the arrow pointing to "Flux entering the top of the model" refers to the flux going through the top layer of the model. It was clarified during the audit that the flux entering the top of the model does not refer to the top boundary condition. There is a uniform flux applied as a top boundary condition. The NRC staff is concerned that the use of a uniform boundary condition a few meters above the drift for PA could have the effect of smoothing the inherent natural variability of seeps and preferential flow paths, thus lowering seepage rates and raising seepage threshold values.

4.6 NRC Staff Findings

The NRC staff agreed with technical findings of the audit team. The following findings are added by the NRC staff. They are associated with the umbrella DOE audit recommendation regarding transparency. These findings were resolved in the audit and it is expected that they will be addressed in the next revision of the AMRs. Some of these items may also be addressed in other AMRs as those AMRs are completed:

NRC Staff General Findings

1. It was difficult to assess the adequacy of AMRs since much of the supporting data were in other incomplete, and/or unavailable AMRs.

2. The transparency of the equations and technical bases of assumptions and conclusions were lacking. LBNL developed AMRs as all inclusive, while the USGS developed an AMR as a supplement to a milestone report.

3. The distinction between validation and verification was not clear to the DOE audit team and the NRC observers, and was considered synonymous to the USGS.

NRC Staff Specific Findings

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

4. The AMR did not clearly identify the horizontal projections used. Input data projections should be stated and end-users need to know what projections were used for the spatial data output.

5. The grid refinement analysis was not included in a scientific notebook and the AMR did not reflect the bases for the choice of grid size.

6. The basis for using a flat water table was not presented. The AMR ignored a 45 m higher water elevation data in the northwest corner of the model.

7. Neither the scientific notebook or AMR text discussed the effects of grid connection network near the refined grids in the repository footprint.

8. No basis, limitation, or indication of sensitivity was presented for the fracture characteristics on page 20-21. This is considered highly uncertain data.

9. The basis for the equations on page 55, and the calculations used for connection spacing were not in the scientific notebook or in the text.

10. The basis for the volume-area factor (A_{fm}) was not stated in the text. This parameter has been modified since the Viability Assessment by a calibration-derived coefficient that is now dependent on saturation.

11. A discussion on the potential effect of lateral boundary conditions was not presented in the text.

AMR U0010, Simulation of Net Infiltration for Modern and Potential Future Climates

12. The Flint et al. (1996) report is unqualified, invalidated, and has not been released by the USGS. Yet, the AMR is a supplement to this report.

13. The model is difficult to validate; as such, uncertainty analysis is needed to assess the calibration process and evaluate the model's predictive ability. The uncertainty analysis was relegated to another, yet uncompleted, AMR.

14. The basis for the choice of a standard root zone depth of 2 m was not included in the text or references.

15. The exclusion of large storms from long meteorological records, temporally variable, and localized events may under predict shallow infiltration.

16. Confidence in the BUCKET model would have been enhanced if a direct comparison was made with the RICHARDS model in INFIL version 2.0.

17. The description of the development and methodology for using the third-order Markov chain analysis to predict wet-dry days was not included in the text.

18. The infiltration model is constrained to a 10,000 year analysis. Yet, proposed 10 CFR Part 63 requires an analysis beyond 10,000 years to insure peak dose does not occur shortly after the compliance period.

19. A complete description of the bases for the bulk permeability values for each bedrock layer was not included in the AMR.

20. The justification for the time step for overland flow calculations was not included in the text.

21. Equations 4 and 5, pages 22 and 23, are presented with no references or bases.

22. No justification was provided for the assumed changes in vegetation type, density, and the evapotranspiration for future climates.

AMR U0015, In Situ Field Testing of Processes

23. The high-flux rate, short time and spatial scale in-situ tests offer limited applicability for predicting seepage into drifts under ambient conditions.

24. Ventilation effects on liquid injection were not consistently established for the liquid release tests.

25. The AMR lacked a supporting bases for the assumed conceptual model describing pre- and post-excavation testing. The bases supporting stress-induced fracturing as the only significant explanation for the increase in permeability is needed.

AMR U0080, Seepage Calibration Model and Seepage Testing Data

26. The goal to establish a methodology to apply to YM seepage modeling was not accomplished. The seepage calibration model is simply a transfer function and is only valid for application to injection tests 0.65 m above Niche 3650 at rates much higher than the average annual ambient percolation rates. Until the recommended low rate, long duration injection tests are completed, there will be little basis for the transfer function parameters of the seepage model.

27. The difficulty in applying the transfer function seepage model to YM as a physical, process-based model lies in the lumping of test conditions and grid discretization characteristics into parameters that are otherwise hydrologic-based. Use of this seepage model in AMR U0075, where presumably ranges are defined for the parameters for this transfer function model, would be highly suspect, particularly the estimates of seepage threshold.

28. The use of a uniform boundary condition a few meters above the drift for performance assessment could smooth the natural variability of seeps and raise the seepage threshold values.

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4.6.1 Audit Observer Inquiries

No NRC audit observer inquiries were generated during this audit.

4.6.2 Closure of Previous NRC Audit Observer Inquiries

No audit observation inquires were closed during the conduct of this observation.

4.6.3 Open NRC Audit Observer Inquires (AOIs)

The following NRC audit observation inquiries remain open:

a. Audit Observation Inquire (AOI) No. OCRWM-ARC-99-015-1, dated September 22, 1999: OQA agreed to provide information to the NRC on the qualification status and use of the "Waste Stream Profiles" addressed in the "Design Basis Waste Stream for Interim Storage and Repository" and the "Waste Quantity, Mix and Throughput Study" documents.

b. AOI No. M&O-ARP-00-02-1, dated November 18, 1999: AP-3.10Q, "Analysis and Modeling" and the QARD are not specific regarding which calculations/analyses are subject to model validation and the timing of model validation. M&O Environmental, Safety, and Regional Programs Office involved with the biosphere AMRs do not appear to have an understanding or strategy of model validation as it applies to the biosphere AMRs/PMR.

c. AOI No. M&O-ARP-00-02-2, dated November 18, 1999: Documented resolution of individual comments is not required for checks of analysis and models (AP-3.10Q) and is optional for reviews of technical products (AP-2.14Q). A lack of documented resolution is inconsistent with the QARD section 2.2.10 (f) which requires that mandatory comments shall be documented and resolved before approving the document. Note that the audit of the Integrated Site Model (ARP-99-009) also identified several recommendations concerning the review processes of AP-3.10Q and AP-2.14Q.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 28, 2000

Mr. Dwight Shelor, Acting Director
Program Management and Administration
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- 00-06, "OBSERVATION AUDIT OF OFFICE OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT, QUALITY ASSURANCE DIVISION, AUDIT NO. M&O-ARP-00-006"

Dear Mr. Shelor:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report No.OAR-00-06 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 of the Engineered Barrier System (EBS) Process Model Report (PMR) activities performed by the OCRWM Management and Operating Contractor (M&O). The audit, M&O-ARP-00-006, was conducted on February 7–11, 2000, at the M&O facilities in Las Vegas, Nevada.

The scope of the audit was limited to evaluating the effectiveness of the implementation of the OCRWM QA Program described in the Quality Assurance Requirements and Description and its implementing procedures for selected analysis model reports (AMRs) supporting the EBS PMR.

The NRC staff determined that this audit was effective in identifying deficiencies and recommending improvements in the AMR process. During the conduct of the audit, both the audit team and the NRC observers reviewed data, analysis and model reports, and software within the scope of the audit to determine whether they were properly qualified. The audit team determined that the AMRs were adequate considering their stage of development, but could be substantially improved through incorporation of the recommendations provided by the audit team. The NRC staff agrees with the audit team conclusions, findings, and recommendations.

A written response to this letter and the enclosed report is not required. However, we do expect OQA to provide replies to the open Audit Observer Inquiries. If you have any questions, please contact Bob Latta of my staff at (301) 415-5228.

Sincerely,

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

Enclosure: NRC Observation Audit Report No. OAR-00-06, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. M&O-ARP-00-006"

cc See attached list

Letter to D. Shelor from C.W. Reamer dated: March 28, 2000

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U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-00-06

OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE DIVISION

AUDIT NO. M&O-ARP-00-006

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Division of Waste Management

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 the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division performance-based audit of the Engineered Barrier System (EBS) Process Model Report (PMR) activities performed by the OCRWM Management & Operating Contractor (M&O). The audit, M&O-ARP-00-006, was conducted on February 7–11, 2000, at the M&O facilities in Las Vegas, Nevada.

The objective of this audit was to evaluate the implementation of the applicable provisions contained in the OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 8, by reviewing selected Analysis Model Reports (AMRs) supporting the EBS PMR. During the audit, selected AMRs were subjected to a technical and programmatic review to ensure that the applicable requirements contained in the QARD were met.

The NRC staff objective was to gain confidence that the M&O and OQA 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 Code of Federal Regulations (10 CFR Part 60). Because of the anticipated DOE submittal of the site recommendation (SR) in November 2000, the following observation activities were emphasized: (1) confirming that data, software, and models supporting SR are properly qualified; and (2) reviewing the progress being made by DOE and its contractors in meeting the qualification goals for SR.

This report addresses the NRC staff determination of the effectiveness of the OQA audit and the adequacy of implementation of QARD controls by the M&O in the audited areas of AMR development.

2.0 MANAGEMENT SUMMARY

The NRC staff has determined that OQA Audit M&O-ARP-00-006 was useful, effective, and conducted in a professional manner. Audit team members were independent of the activities they audited and appeared to be knowledgeable in the QA and technical disciplines within the scope of the audit. The audit team members' qualifications were reviewed and the members were found to be qualified in their respective disciplines.

The audit team concluded the OCRWM QA program had been satisfactorily implemented in the areas evaluated. However, six apparent deficiencies were identified during the audit, and approximately eighteen recommendations were offered for improvements and enhancements to the AMRs.

The NRC staff determined that this audit was effective in identifying deficiencies and recommending improvements in the AMRs. During the conduct of the audit, both the audit team and the NRC observers reviewed data, analysis reports, and software within the scope of the audit to determine whether they were properly qualified. The audit team and the NRC observers determined that certain software supporting the AMRs, had not been properly qualified. The team also noted that most of the data were categorized as "to be verified." The NRC staff agrees with the audit team conclusions, findings, and recommendations. The AMRs were adequate for their current early stage of

development, but could be substantially improved in clarity and justification of assumptions and technical positions taken with incorporation of the audit team recommendations.

NOTE: [Subsequent to the audit, OQA decided to postpone the remaining 3 PMR audits that were scheduled to be performed during the months of March and April 2000. This decision was made, in part, because several AMR completion dates had slipped and lessons learned from the previous 6 PMR audits needed to be communicated to the preparers of the AMRs.]

3.0 AUDIT PARTICIPANTS

3.1 Nuclear Regulatory Commission Observers

Robert Brient	Observer (Team Leader-CNWRA)
Richard Codell	Observer (Technical Specialist-NRC)
Robert Latta	Observer (Senior QA Engineer-NRC)
Tamara Bloomer	Observer (Technical Specialist-NRC)
Hans Arlt	Observer (Technical Specialist-NRC)
Goodluck Ofoegbu	Observer (Technical Specialist-CNWRA)

3.2 Office of Quality Assurance Audit Team

Donald Harris	Audit Team Leader	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
Richard Weeks	Auditor	OQA/QATSS
Stephen Harris	Auditor	OQA/QATSS
Emily Jensen	Auditor	OQA/QATSS
George Harper	Auditor	OQA/QATSS
Harris Greenberg	Technical Specialist	DOE/Management and Technical Services (MTS)
David Sassani	Technical Specialist	DOE/MTS
Steve Sobkowski	Technical Specialist	DOE/MTS
Arthur Stein	Technical Specialist	DOE/MTS

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 the NRC draft procedure, "Conduct of Observation Audits," issued October 6, 1989 (Draft).

4.1 Scope of the Audit

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. AMRs, software, and data were evaluated during the audit process. The audit included review of the programmatic controls governing the AMRs

and technical issues discussed in the AMRs. Specifically, the following procedures and AMRs supporting the EBS PMR were reviewed by the audit team and the NRC observers during the audit:

Procedures

a) AP-2.1Q, "Indoctrination and Training Personnel," Revision 0, with Interim Change Notice (ICN) No. 0
b) AP-2.13Q, "Technical Product Development Planning," Revision 0, with ICN No. 1
c) AP-SI.1Q, "Software Management," Revision 2, with ICN No. 0
d) AP-3.15Q, "Managing Technical Product Inputs," Revision 0, with ICN No. 1
e) AP-SIII.2Q, "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data," Revision 0, with ICN No. 0
f) AP-3.10Q, "Analysis and Models," Revision 1, with ICN No. 0
g) AP-2.14Q, "Review of Technical Products," Revision 0, with ICN No. 0
h) AP-SIII.3Q, "Submittal and Incorporation of Data to the TDMS," Revision 0
i) YAP-SV.1Q, "Control of the Electronic Management of Data," Revision 0, with ICN No. 1
j) QAP-SIII-1, "Scientific Investigations," Revision 3

Analysis Model Reports

a) ANL-EBS-MD-000020, "In-Drift Corrosion Products," Revision 00
b) ANL-EBS-MD-000026, "In-Drift Thermal-Hydrological-Chemical Model," Revision 00
c) ANL-EBS-MD-000075, "Ventilation Model," Revision 00
d) ANL-EBS-MD-000080, "Drift Degradation Analysis," Revision 00

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 M&O and DOE programs and procedures. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit. Due to time constraints during the preparation phase, the programmatic and technical portions of the audit were not conducted simultaneously as has been common practice. While this did not adversely impact the audit overall, better integration of the programmatic and technical elements may have helped the technical specialists, who appeared to be relatively inexperienced in expressing their findings.

The DOE audit team and NRC observers caucused at the end of each day. Also, meetings of the audit team and M&O management (with the NRC observers present) were held each morning to discuss the current audit status and preliminary findings.

The NRC staff believes the timing of the audit was appropriate for the auditors to evaluate ongoing EBS AMR/PMR activities, however; recurring findings of this and other AMR/PMR audits suggest that improvements to the AMR/PMR development process may be appropriate before additional audits are conducted.

4.3 Audit Team Qualification and Independence

The qualifications of the DOE audit team leader and the OQA audit team members were found to be acceptable in that they met the requirements of QAP 18.1, "Auditor Qualification," as verified by the NRC observation audit lead. The audit team members did not have prior responsibility for performing the activities they audited. In addition, training, education and experience records for audit team members were reviewed and found acceptable. The NRC observers noted that this was the first experience for the audit team technical specialists and to some degree, they had difficulty in expressing their AMR technical comments and recommendations as findings on the AMR development/review processes and/or on the technical quality of the AMRs. By the completion of the audit, most of the technical specialists had resolved these difficulties.

4.4 Examination of Quality Assurance Elements

The OQA programmatic and technical audit activities were conducted separately. The limited scope audit focused on the QA elements closely associated with the development of the AMRs. The NRC observation team evaluated the audit team's review of the following QA elements.

4.4.1 AP-2.13Q "Technical Product Development Planning"

The DOE auditors reviewed technical development plans (TDPs) and work product planning sheets (WPPS) applicable to the subject AMRs. A deficiency was identified in the planning documents for the In-Drift Thermal-Hydrological-Chemical Model that had not been revised to reflect the current situation and to reflect the true scope of the AMR.

4.4.2 AP-SI.1Q "Software Management"

Some of the software used in support of the AMRs was not qualified or controlled in accordance with procedure AP-S1.1Q. The Ventilation Model and Drift Degradation calculations performed using spreadsheet (EXCEL and Mathcad) software were not documented and controlled as required. The DRKBA version 3.3 software, also used in the Drift Degradation Analysis, was not qualified, and the required Software Activity Plan was not prepared. Two processors for the NUFT code used in the In-Drift Thermal-Hydrological-Chemical Model, RADPRO and XTOOL, had not been qualified, and the output of the analysis had not been classified as to-be-verified (TBV) as required. In addition, one module of the (otherwise qualified) NUFT software used in this model was not qualified.

4.4.3 AP-3.15Q "Managing Technical Product Inputs"

Each of the AMRs examined included document input reference sheets that list the inputs to and references cited in the AMR. The document input reference sheets also identified the status of the input (e.g., qualified, TBV).

The status of the input documents for the AMRs is summarized as follows:

- Most of the data used are identified as TBV, with the reason as "unconfirmed." These are data that had been collected under the OCRWM QA program, but were placed in the TBV status due to a corrective action request that resulted in the data qualification being of indeterminate quality. The M&O has plans for confirming these data and removing the TBV; however, that has not been accomplished for the data affecting these AMRs.

- A few data in the AMRs are classified as TBV and unqualified. These data were not collected under the QA program, and require formal qualification.

- Some data are classified as N/A, used for reference only.

4.4.4 AP-SIII.2Q "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data"

As determined during the audit/observation the qualification process had not been initiated for the unqualified data used in these AMRs.

4.4.5 AP-3.10Q "Analysis and Models"

The four AMRs evaluated during this audit are classified as follows:

- In-Drift Corrosion Products - Conceptual Model

- In-Drift Thermal-Hydrological-Chemical Model - Model Documentation

- Ventilation Model - Conceptual Model

- Drift Degradation Analysis - Analysis

All four of these reports had been issued as Revision 00 and the development and technical checking processes described in AP-3.10Q had been completed.

The AMRs had been subjected to the technical checking process. Two potential deficiencies were identified associated with this process:

- Some technical checker comments on the In-Drift Thermal-Hydrological-Chemical Model AMR were not resolved and were deferred to a later revision. The procedure has no provision for deferring mandatory comments.

- The qualification documentation for the checker and a technical reviewer of the In-Drift Corrosion Products AMR did not reflect technical competencies in the AMR subject matter.

4.4.6 AP-2.14Q "Review of Technical Products"

The AMRs reviewed were subjected to the technical review process. In particular, the AP-2.14Q technical reviews are performed by organizations outside of the author's, so they may serve primarily as interface reviews.

As indicated in paragraph 4.4.5, a potential deficiency was identified in the qualification documentation for a technical reviewer of the In-Drift Corrosion Products AMR that did not reflect technical competencies in the AMR subject matter.

4.4.7 YAP-SV.1Q "Control of the Electronic Management of Data"

The audit team identified a potential deficiency in the implementation of this procedure in the Process Control Evaluations for the AMR activities. The evaluations failed to identify procedures that needed to be revised and/or the identified procedures had not been revised.

4.4.8 AP-2.1Q "Indoctrination and Training of Personnel"

The audit team evaluated personnel qualification records for key individuals performing the AMR development and review activities. Within this area, a potential deficiency was identified regarding employees that had transferred from other departments/labs that had been "grand- fathered" for previous training, but had not had their training re-baselined by their new managers.

4.5 Examination of Technical Activities

The DOE audit team prepared detailed checklists for each of the AMRs. Technical activities examined by the audit team, and in some cases those questions forwarded to the audit team, are summarized below for each of the AMRs. The DOE audit team and NRC observers identified a number of weaknesses in the AMRs that could adversely affect their value in supporting licensing decisions. However, the M&O intends for the "final" AMRs/PMRs to be fully justified and substantiated, with the goal of minimizing NRC requests for additional information. The comments provided in the following sections include the weaknesses. The AMRs, while adequate for their early stage of development, would not meet the standards needed to support licensing.

4.5.1 Analysis Model Report In-Drift Corrosion Products (ANL-EBS-MD-000020 Rev 00)

The In-Drift Corrosion Products AMR described the conceptual model exploring the possible effects of EBS corrosion products on the near-field environment and the geochemical environment. It may also provide input into the unsaturated and saturated zone modeling efforts. As a conceptual model, the AMR in Revision 00 was adequate, but future versions will need a greater level of detail and justification for positions taken.

The audit of the In-Drift Corrosion Products AMR included procedural and technical inquiries to verify that procedures were followed and that the quality of the product was satisfactory. The auditor inquired about the technical basis for the report including: a) assumptions used, b) justifications for inclusions and exclusions of elements within the conceptual model framework, c) conclusions, d) TDP, and e) technical checker comments. The DOE auditor followed a prepared checklist and identified several issues similar to those identified in the container life and source term (CLST) team review of the document. While these issues would be important to the final revision of the AMR, the audit team determined that the AMR was sufficient as a conceptual model.

The DOE audit team also evaluated the M&O technical checking and technical review processes. In reviewing the technical checker comments, it appeared that the vast majority of comments were editorial rather than technical in nature, which led to concerns regarding the checker's credentials. Furthermore, the documentation of the checker's qualification did not appear to support his selection to perform this task.

4.5.2 Analysis Model Report In-Drift Thermal-Hydrological-Chemical Model (ANL-EBS-MD-000026, Rev 00)

The THC model considered only thermal and hydrological components. One of the stated goals of the modeling was to estimate dripping within the drift. Because of time limitations, the investigators chose to use a qualified model (NUFT), which employed an Equivalent Continuum Model (ECM) approach to flow in the fracture/matrix system. A Dual Permeability Model (DKM) version of NUFT exists, but was not a qualified code. The analyses should be updated for the PMR stage, although they do not expect to make a new revision to the current AMR.

Convective heat transfer through the air space surrounding the waste package was added by specifying an artificial hydraulic conductivity adjusted to fit a textbook solution for convective heat transfer in coaxial heated cylinders. Actual dripping of water could not be modeled explicitly because the model resolution was too coarse, and the ECM practically precludes fracture flow. Ultimately, the main emphasis was not dripping from the drift onto the waste packages as implied, but rather conditions that could lead to condensation of water and subsequent dripping under the drip shield. Despite the limitations, the model could determine with reasonable reliability that the drip shield would always remain hotter than the floor under the waste package (the invert). Under these conditions, condensation under the drip shield is not likely.

Several shortcomings of the study were identified, including failure to follow the stated goals in the planning documents, inconsistent representation of the system (e.g., the WP sits directly on the invert instead of a pedestal), and not covering a wide enough range of possible conditions of heat loading, backfill and drip-shield placement.

4.5.3 Analysis Model Report Ventilation Model (ANL-EBS-MD-000075, Rev 00)

The purpose of the ventilation model was to predict the fraction of heat that would be removed from the repository during the preclosure stage. The analyses used a combination of two-dimensional models for heat transfer in drift-normal planes, and spread-sheet calculation for along-drift heat transfer. The numerical stability of the explicit stepping algorithm applied in the analyses to advance the solution along the drifts was not investigated, which raises the possibility that the calculated air and drift-wall temperatures, and, consequently the predicted amount of heat removal by ventilation, may not be correct. This possibility was strengthened by the results of calculations performed by CNWRA staff to check the consistency of the air and drift-wall temperatures given in the report. The two sets of temperatures are inconsistent: the drift-wall temperatures were not reproduced by analyses that used the air temperatures as input.

Because heat removal by ventilation is an important component of the thermal-load management strategy that is currently being proposed by DOE, the analyses of the ventilation design should be based on a rigorous and tested model. The model used in the report does not meet such a standard.

The authors of the AMR chose to investigate the ventilation process using qualified computer codes. The AMR authors believed there was insufficient time to qualify other software. The outcome of this choice was that the calculations were very time-consuming and cumbersome. The model was too slow to allow the exploration of alternative cases and to conduct sensitivity analyses. During the audit, other, more suitable, qualified codes such as RELAP were identified by the technical specialist.

The AMR indicated that the model used was validated for its intended use. However, the formal model validation process described in AP 3.10Q had not been accomplished.

4.5.4 Analysis Model Report Drift Degradation Analysis (ANL-EBS-MD-000080, Rev 00)

The AMR defined its objectives as: a) to provide a statistical description of block sizes formed by fractures around the emplacement drifts; b) to estimate changes in drift profiles resulting from progressive deterioration of the emplacement drifts both with and without backfill; and c) to provide an estimate of the time required for significant drift deterioration to occur.

The purpose of this AMR, as documented in the development plan (Development for Drift Degradation Analysis, TDP-EBS-MD-000014 Revision 1, dated September 29,1999) is to analyze the deterioration of the rock mass surrounding the potential repository emplacement drifts and provide data (information) to the EBS post-closure performance assessment as well as information for use in the design of the subsurface openings. The expected output of the analysis would document the anticipated drift deterioration for the EDA-II design and would provide information for ground-support design and input to the analyses of waste-package performance. The AMR would also provide input for two other EBS AMRs: The Physical and Chemical Environment Model, and the Water Distribution and Removal Model. The development plan did not identify the specific output information that is required from the AMR in order to satisfy the stated purpose.

The code used for the drift degradation analyses does not have the capability to account for the effects of thermal and seismic loading on rock fall and drift degradation. The investigators attempted to include the effects of thermal and seismic loading by reducing the shear strength of fracture surfaces. However, the inability of the code to account for external loading other than gravity is a fundamental shortcoming that cannot be remedied by reducing the fracture strength.

As a result, the conclusions in the report regarding the collapsed shape of drifts and the fraction of drift length that may experience collapse are not adequately supported by the analyses and may need to be re-examined considering the results from mechanical-analysis codes that explicitly account for the effects of thermal and seismic loading.

4.6 NRC STAFF FINDINGS

The NRC staff has determined that OQA Audit M&O-ARP-00-006 was effective in determining the level of compliance of M&O activities associated with the subject AMRs. The NRC staff agrees with the audit team conclusion that the OCRWM QA program had been satisfactorily implemented and that the AMRs are adequate considering their early stage of development and their planned continued development and refinement. However, areas where deficiencies were issued may be an indicator of ineffective implementation.

While the audit technical specialists generated numerous comments regarding the AMRs and offered many recommendations to the authors, they appeared to struggle with expressing their technical comments as findings on the effectiveness of the AMR development/review process and in terms of assessing the level of quality of the AMRs. The NRC staff recommends that additional efforts be made to assure that the technical specialists have adequate knowledge to express their findings. It is recommended that the OQA consider integrating the programmatic and technical portions of the audits when technical specialists, inexperienced in documenting findings, are part of the audit team. Under this circumstance, the experienced auditors could coach the less experience technical specialists in expressing technical shortcomings as programmatic root causes.

The NRC staff recommends that additional effort be made in preparing the technical specialists to be better able to express their findings. Whenever possible, the DOE audit teams should integrate the programmatic and technical portions of the audit: 1) to have experienced auditors coach the less experienced technical specialists; and 2) attempt to express technical shortcomings as programmatic root causes.

4.6.1 Audit Observer Inquiries

No audit observer inquiries were issued.

4.6.2 Closure of Previous NRC Audit Observer Inquiries

No NRC audit observer inquiries were closed during the conduct of this observation.

4.6.3 Open NRC Audit Observer Inquiries (AOIs)

The following NRC Audit Observer Inquiries remain open:

a. Audit Observation Inquiry (AOI) No. OCRWM-ARC-99-015-1, dated September 22, 1999: OQA agreed to provide information to the NRC on the qualification status and use of the "Waste Stream Profiles" addressed in the "Design Basis Waste Stream for Interim Storage and Repository" and the "Waste Quantity, Mix and Throughput Study" documents.

b. AOI No. M&O-ARP-00-02-1, dated November 18, 1999: AP-3.10Q, "Analysis and Modeling" and the QARD are not specific regarding which calculations/analyses are subject to model validation and the timing of model validation. M&O Environmental, Safety, and Regional Programs Office involved with the biosphere AMRs do not appear to have an understanding or strategy of model validation as it applies to the biosphere AMRs/PMR.

c. AOI No. M&O-ARP-00-02-2, dated November 18, 1999: Documented resolution of individual comments is not required for checks of analysis and models (AP-3.10Q) and is optional for reviews of technical products (AP-2.14Q). A lack of documented resolution is inconsistent with the QARD section 2.2.10(f) which requires that mandatory comments shall be documented and resolved before approving the document. Note that the audit of the Integrated Site Model (ARP-99-009) also identified several recommendations concerning the review processes of AP-3.10Q and AP-2.14Q.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 25, 2000

Mr. James H. Carlson, Acting Director
Program Management and Administration
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- 00-07, "OBSERVATION AUDIT OF OFFICE OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT, QUALITY ASSURANCE DIVISION, AUDIT NO. M&O-ARP-00-010"

Dear Mr. Carlson:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report No. OAR-00-07 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 (YMQAD), audit of activities pertaining to the Saturated Zone Flow and Transport Process Model Report (SZ PMR) performed by the OCRWM Management and Operating Contractor (M&O). The audit, M&O-ARP-00-010, was conducted on June 21-30, 2000, at the M&O facilities in Las Vegas, Nevada.

The purpose of this performance based audit was to evaluate the effectiveness of the implementation of the OCRWM QA Program described in the Quality Assurance Requirements and Description (QARD) and its implementing procedures for the SZ PMR and selected Analysis Model Reports (AMRs) supporting the SZ PMR.

The NRC staff determined that this audit was effective in identifying potential weaknesses and recommending improvements in the PMR/AMR process. During the conduct of the audit, both the audit team and the NRC observers independently reviewed applicable data, analysis reports, and software to confirm that it was properly qualified. As a result of these activities the NRC observers determined that the M&O had made substantial progress with respect to the qualification and verification of data and software which support the PMRs/AMRs. However, because of the importance of these activities which will sustain site recommendation and the potential license application, the staff recommends that DOE and the M&O maintain their emphasis on the timely qualification and verification of data and software which support the technical adequacy of PMRs/AMRs.

The NRC staff generally agreed with the audit team conclusions, findings, and recommendations as presented at the Post-audit Conference. Within the areas evaluated, no deficiencies were identified and the NRC observers concluded that the technical quality and completeness of the scientific products contained in the SZ PMR and the associated AMRs indicated an improving trend over the previous six PMR audits performed during the last quarter of 1999 and the first quarter of 2000.

As discussed in Section 4.6 of the attached report, the NRC observers identified three concerns pertaining to the clarification of "issue statements" in Appendix A of the SZ PMR, consideration of alternative conceptual models for the Saturated Zone Flow and Transport Model, and updating of the status of the regional Saturated Zone Flow Model. These concerns which complemented the audit team's findings will be addressed in DOE's report of the OCRWM QA Audit M&O-ARP-00-10.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Robert M. Latta of my staff at (702) 794-5048.

Sincerely,

N. King Stablein, Chief (Acting)
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report No. OAR-00-07, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. M&O-ARP-00-010"

cc:
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U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-00-07

OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE DIVISION

AUDIT NO. M&O-ARP-00-010

08/ /00

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U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-00-07

OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE DIVISION

AUDIT NO. M&O-ARP-00-010

08/25/00

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1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management and a contractor 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 (YMQAD) audit of activities pertaining to the Saturated Zone Flow and Transport Process Model Report (SZ PMR) performed by the OCRWM Management & Operating Contractor (M&O). The audit, M&O-ARP-00-010, was conducted on June 21–30, 2000, at the M&O facilities in Las Vegas, Nevada.

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The NRC staff objective was to gain confidence that the M&O and OQA 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 Code of Federal Regulations (10 CFR Part 60). Because of the anticipated DOE submittal of the site recommendation (SR) in November 2000, the following observation activities were emphasized: 1) confirming that data, software, and models supporting SR are properly qualified; and 2) evaluating the progress being made by DOE and its contractors in meeting the qualification goals for SR.

This report addresses the NRC staff determination of the effectiveness of the OQA audit and the adequacy of implementation of QARD controls by the M&O in the audited areas of SZ PMR/AMR development.

2.0 MANAGEMENT SUMMARY

The NRC staff generally agrees with the audit team conclusion's, findings, and recommendations. The NRC staff determined that OQA Audit M&O-ARP-00-010 was well planned and effectively implemented. Audit team members were independent of the activities they audited and were knowledgeable in the QA and technical disciplines within the scope of the audit. The audit team members' qualifications were reviewed and the members were found to be qualified in their respective disciplines.

The audit team concluded that the OCRWM QA program had been satisfactorily implemented in the areas evaluated. No deficiencies were identified during the audit. However, twelve recommendations were identified as improvements to the SZ PMR/AMRs or as enhancements to the procedures controlling various elements of the modeling reports process.

During the conduct of the audit, both the audit team and the NRC observers reviewed data, analysis reports, and software within the scope of the audit to confirm that it was properly

qualified. The audit team and the NRC observers determined that elements of the software supporting the AMRs had been properly qualified. The audit team and the NRC observer's also determined that certain data, categorized as "accepted data," were appropriately controlled and categorized in accordance with the governing procedures.

3.0 AUDIT PARTICIPANTS

3.1 Nuclear Regulatory Commission Observers

Robert Latta	Team Leader	NRC
John Bradbury	Technical Specialist	NRC
Latif Hamdan	Technical Specialist	NRC
Rod Weber	QA Specialist	CNWRA

3.2 OQA Audit Team

Lester Wagner	Audit Team Leader	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
Robert Hartstern	Auditor	OQA/QATSS
Michael Goyda	Auditor	OQA/QATSS
Kenneth McFall	Auditor	OQA/QATSS
Chet Wright	Auditor	OQA/QATSS
Charles Warren	Auditor	OQA/QATSS
Keith Kersch	Technical Specialist	SAIC
Thomas Doe	Technical Specialist	Management and Technical Services(MTS)
Richard Salness	Technical Specialist	MTS

3.3 Nevada State Observer

Susan Zimmerman	Administrator of Technical Programs	Nuclear Waste Project Office, Agency for Nuclear Projects, State of Nevada

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' observation of this audit was performed in accordance with NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

4.1 Scope of the Audit

The audit team conducted a limited scope, performance based audit of activities and processes related to the development of the AMRs supporting the SZ PMR. Audit activities included evaluation of selected AMRs, software, and associated data. The audit also included review of the programmatic controls governing the AMRs and technical requirements contained in the

AMRs. The following procedures, and SZ PMR and supporting AMRs were evaluated by the audit team and the NRC observers during the audit:

Procedures

a) AP-2.1Q, "Indoctrination and Training of Personnel," Revision 0, with Interim Change Notice (ICN) No. 0

b) AP-2.2Q "Establishment and Verification of Required Educational and Experience of Personnel," Revision 0, with ICN No. 0

c) AP-2.13Q, "Technical Product Development Planning," Revision 0, with ICN No.3

d) AP-2.14Q, "Review of Technical Products," Revision 0, with ICN No. 1

e) AP-2.15Q, "Work Package Planning Summaries," Revision 0, ICN No.1

f) AP-3.4Q, "Level 3 Change Control," Revision 1, ICN No.3

g) AP-3.10Q, "Analysis and Models," Revision 2, with ICN No. 2

h) AP-3.11Q, "Technical Reports" Revision 1, with ICN No. 1

i) AP-3.14Q, "Transmittal of Input" Revision 0, with ICN No. 0

j) AP-3.15Q, "Managing Technical Product Inputs," Revision 1, with ICN No. 1

k) AP-3.17Q, "Impact Reviews," Revision 0, with ICN No. 0

l) AP-SI.1Q, "Software Management," Revision 2, with ICN No. 4

m) AP-SIII-1Q, "Scientific Notebooks," Revision 0, with ICN No. 1

n) AP-SIII.2Q, "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data," Revision 0, with ICN No. 2

o) AP-SIII.3Q, "Submittal and Incorporation of Data to the TDMS," Revision 0, with ICN No. 3

p) AP-SV.1Q, "Control of the Electronic Management of Data," Revision 0, with ICN No. 1

q) QAP-18.1, "Auditor Qualification," Revision 6, with ICN No. 0

Process Model Report

a) TDR-NSB-HS-000001, "Saturated Zone Flow and Transport," Revision 00

Analysis Model Reports

a) ANL-NBS-HS-000033, "Hydrogeologic Framework Model for the Saturated-Zone Site-Scale Flow and Transport Model," Revision 00E

b) Analysis Model Report, Calibration of the Site-Scale Saturated Zone Flow Model (MDL-NSB-HS-000011, Rev 00F)

c) ANL-NBS-HS-00003, "Input and Results of the Base Case Saturated Zone Flow and Transport Model for TSPA," Revision 00

4.2 Conduct and Timing of the Audit

The audit was performed effectively and the OQA 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 NRC staff believes the timing of the audit was appropriate for the auditors to evaluate ongoing SZ PMR activities. However, the audit team was limited in their ability to confirm that data supporting the AMRs had been properly qualified because only a small number of the associated data sets had been qualified in accordance with the requirements of Procedure AP-3.15Q.

The DOE audit team and NRC observers caucused at the end of each day. Meetings between the audit team and M&O management (with the NRC observers present) were also held each morning 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 OQA audit team were reviewed for accuracy and completeness in accordance with the requirements of Procedure QAP 18.1, "Auditor Qualification". The NRC staff review included an examination of the training, education, experience, and annual evaluation records of the audit team members. As a result of these reviews, one item was identified and discussed with the Auditor Certification Coordinator. Specifically, paragraph 5.1.3 b, of Procedure QAP 18.1, states that the Certification Coordinator shall prepare a memorandum to file attesting to the completion of required training for the prospective auditor. However, the records for three of the more experienced auditors did not contain the specified memorandum. The significance of this issue was determined to be minor, in that the requisite training for these individuals had been accomplished and the only discrepancy was that the individual's files had not been updated to reflect this condition. Subsequent to the identification of this issue, the Certification Coordinator agreed to review the qualification records and take the necessary administrative action to address this oversight.

4.4 Examination of Quality Assurance Elements

As defined in the audit schedule, the OQA programmatic and technical audit activities were conducted simultaneously using sub-audit teams consisting of a technical specialist and a QA auditor. The limited scope audit focused on the QA elements closely associated with the development of the AMRs. The NRC observation team evaluated the audit team's review of the following QA elements.

4.4.1 AP-2.13Q "Technical Product Development Planning"

The auditors reviewed technical development plans and work product planning sheets applicable to the subject AMRs. In addition, the auditors reviewed the methodology for the product development, including the tracking of unresolved issues [inputs requiring qualification, to be verified (TBV), etc.]. No significant issues were identified within this area of review.

4.4.2 AP-SI.1Q "Software Management"

Software controls associated with the SZ PMR/AMRs were discussed during each of the technical interviews. The auditors reviewed qualification documentation and determined that the requirements of the software management procedure had been met. The Calibration of the Site-Scale Saturated Zone Flow Model draft AMR was found to be based on an older version of the Regional Saturated Zone flow model. The audit team recommended that a discussion of the impact on the AMR and justification for use of the model be included in the AMR. The software SZ-CONVOLUTE was found to be called out twice in the Input and Results of the Base Case Saturated Zone Flow and Transport Model for TSPA AMR. However, no information for this program was included in the reference listing. Accordingly, it was recommended that a reference be included in the next revision and that it indicate where the software can be found.

4.4.3 AP-3.15Q "Managing Technical Product Inputs"

Each of the AMRs examined included document input reference sheets that list the inputs to and references cited in the AMR. The document input reference sheets also identify the status of the input, [e.g. qualified, to be verified (TBV)]. The NRC observers examined the TBV status and determined that it included the appropriate statements in accordance with the Analysis/Model Documentation Outline. For the Calibration of the Site-Scale Saturated Zone Flow Model AMR, Rev. 00E, it was noted by the audit team that there are weaknesses in the statements related to TBV input effects on the model. Accordingly, it was recommended that future revisions provide clarification within this area.

4.4.4 AP-3.10Q "Analysis and Models"

Procedure AP-3.10Q was used by the audit team to evaluate the activities covered during the audit. By definition, 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.

Although the audit team generally concluded that the requirements of Procedure AP-3.10Q have been appropriately implemented, one item related to improved documentation was identified. Specifically, the audit team determined that the SZ PMR and the corresponding UZ PMR had been developed in parallel. This parallel development resulted in the use of input flux in the SZ PMR that is based on a 1997 UZ database which was subsequently updated in 1999. Although the revised data were properly used in the development of the UZ PMR they were not incorporated into the SZ PMR. The M&O staff indicated that an analysis was conducted to assess the impact of the new data, and that this analysis indicated that the impact on the SZ

PMR was insignificant. However, the audit team noted that there was no documentation of the impact analysis in the SZ PMR.

The NRC technical observers also noted that alternative conceptual models for SZ flow paths and potentiometric heads including the water table were neither identified nor analyzed as required by Procedure AP-3.10Q (i.e., in Attachment 1, Section 6: Analysis/Model Documentation Outline).

As established during the Post-audit Conference, these issues were analogous to the findings of the audit team, and they will be addressed in DOE's report of the OCRWM QA Audit M&O-ARP-00-10.

4.4.5 AP-2.14Q "Review of Technical Products"

The SZ PMR and two of the AMRs evaluated during this audit were subjected to the technical review process defined in Procedure AP-2.14Q. These AP-2.14Q reviews were performed by the M&O's Data/Software Qualification Department which is external to the organizations that prepared the SZ PMR and AMRs. However, ANL-NBS-HS-00003, "Input and Results of the Base Case Saturated Zone Flow and Transport Model for TSPA" Revision 00, had not undergone the AP-2.14Q review process.

The NRC observers also examined the process controls for the resolution of to-be-verified (TBV) data used as direct input to AMRs and PMRs, implicit to the review of technical products. As described in Procedure AP-3.15Q, the term "TBV", is used to identify information which is preliminary in nature, that needs to be re-evaluated and/or requires confirmation. The procedural controls of AP-3.15Q, which are applicable to the M&O, the National Laboratories and U.S. Geological Survey (USGS) establish the organizational responsibilities and processes required for the acquisition, tracking, and status of the technical product inputs necessary for the development of Yucca Mountain Site characterization project documents. This procedure also describes the necessary actions to resolve TBVs and to-be-determined (TBDs) and the administrative controls to track incomplete reference checks on inputs used in approved technical products.

The NRC observers held discussions with cognizant individuals in the Data/Software Qualification Department and reviewed selected data tracking number (DTN) sets in order to gain insights into the verification methodology to resolve TBVs.

As a result of these discussions and review activities the NRC observers ascertained that approximately 66% of the data supporting the site recommendation and the potential license application had been qualified and that approximately 85% of the data in the Document Input Reference System (DIRS) had been verified. Based on these values the NRC observers determined that the M&O had made substantial progress with respect to the qualification/verification of data and software which support the AMRs/PMRs. However, because of the importance of these activities which will sustain site recommendation and the potential license application, the staff recommends that DOE and the M&O maintain their emphasis on the timely qualification and verification of data and software which support the technical adequacy of the PMRs/AMRs.

4.6 Examination of Technical Activities

Technical specialists on the audit team performed detailed checks of the technical adequacy of the subject SZ PMR/AMRs. Technical observers from NRC observed the audit of the these activities.

The technical specialist qualifications (resumes) were reviewed. As a result of these reviews it was determined that appropriate educational backgrounds, training, and experience for these individuals had been documented.

The technical specialists on the audit team evaluated activities and processes supporting the development of the SZ PMR. The technical specialists used a combination of technical questioning and programmatic compliance checks to verify AMR technical adequacy and QA program effectiveness. The technical activities were evaluated using three evaluation criteria pertaining to transparency; traceability; and defensibility.

The audit checklist included items pertaining to the SZ PMR and three supporting AMRs, which were pre-selected by the auditors from a total of 13 AMRs supporting the SZ PMR. In addition to auditing the pre-selected AMRs, the technical specialists and NRC technical observers also examined information and analyses provided in one other draft AMR. This was a draft AMR pertaining to Water-Level Data Analysis for the Saturated Zone Site-Scale Flow and Transport Model (MDL-NSB-HS-000034, Rev C), which provided information that supported the Hydrogeologic Framework Model (HFM) and Calibration of the Site-Scale Model AMR.

Based on these reviews the NRC observers concurred with the DOE audit team that the technical content of the PMR/AMRs satisfied the audit evaluation criteria. However, the NRC technical staff did identify three concerns related to the SZ PMR which are described in sections 4.6.1 through 4.6.4, of this report. These concerns which complemented the audit team's findings will be addressed in DOE's report of the OCRWM QA Audit M&O-ARP-00-10.

4.6.1 Process Model Report, Saturated Zone Flow and Transport (TRD-NBS-HS-000001,Rev.00)

A total of 14 items pertinent to the SZ PMR were included in the audit checklist, and evaluated by the auditors. The following technical subjects were addressed: input data for the SZ site-scale model, unit breakthrough curves, unsaturated zone (UZ) mass flux, input to the convolution integral program, overview of the results of the TSPA calculation, uses of UZ expert elicitation on groundwater fluxes, code verification (FEHM, particle tracker), timing on inputs, and QA issues.

The technical specialists, on the audit team, reviewed the pertinent information concerning the above listed items. Based on the results of these reviews the technical specialists were generally satisfied that the SZ PMR met the audit evaluation criteria. The audit team further determined that the SZ PMR and the corresponding UZ PMR were developed in parallel, which resulted in using input flux in the SZ PMR that was based on a 1997 database that had subsequently been updated in 1999. The audit team ascertained that the new data were appropriately used in the development of UZ PMR, but they were not utilized in the SZ PMR. The M&O staff stated that an analysis was conducted to assess the impact of the new data,

and that the impact analysis indicated that the effect on the SZ PMR was insignificant. However, the audit team noted that there was no objective evidence of this analysis in the SZ PMR.

The NRC technical observers also noted that numerous comments on the site-scale and regional SZ flow models provided by outside reviewers had not been appropriately addressed in the SZ PMR. Abstractions of reviewer comments on the SZ flow models were provided in the SZ PMR (i.e., comments by the Nuclear Waste Technical Review Board, DOE's Peer Review Panel, and DOE's SZ Expert Elicitation Panel are provided in Appendix A; and NRC staff comments are provided in Appendix B of the PMR). However, many of the responses to the comment abstractions were unclear or non-responsive, and it appeared that many of the reviewers concerns were neither resolved nor mitigated.

The DOE audit team acknowledged the NRC technical observer's concerns which were complementary to the audit team findings and agreed to address these items in their report of the OCRWM QA Audit M&O-ARP-00-10.

4.6.2 Analysis Model Report, Hydrogeologic Framework Model for the Saturated-Zone Site-Scale Flow and Transport Model, (ANL-NBS-HS-000033, Rev 00E)

A total of 23 audit checklist items, pertinent to this AMR were evaluated by the auditors. The following technical subjects were addressed: data storage and control, scientific notebooks, correlation of borehole data and geologic sections, documentation of calculations and methods, description and documentation of hybrid gridding techniques, plans for qualification of input data, process of inputting borehole logs and geologic maps into the Hydrogeologic Framework Model (HFM), use of the Geologic Framework Model in the HFM, information on geologic cross sections incorporated in the HFM, timeliness of input data update and incorporation of updated HFM model in other models, measures for data sufficiency, method of integration of structural data into the HFM, use of input data to create Stratamodel files, stacking number sequences and consistency between different versions of the HFM, process of leveling and digital referencing to map traces, construction steps of the 3-D HFM and documentation of construction steps in procedure and in scientific notebooks, updating of the potentiometric surface in the HFM, and the processes of clipping versus extrapolation where data do not exist.

The audit team requested and was provided information on each of the above listed items. Based on the review of this information the technical specialists were generally satisfied that the this AMR met the audit evaluation criteria.

The NRC technical observers noted that the water table, which constitutes the upper boundary for the HFM has a large measure of uncertainty in that it is based on water level measurements in different aquifer units including confined aquifers. Although the AMR acknowledges that there are alternative conceptual models for the "water table", the NRC technical observers were concerned that these alternative conceptual models were neither identified nor analyzed. Examination of another AMR (i.e., Water-Level Data Analysis for the Saturated Zone Site-Scale Flow and Transport Model, S-000034), which was cited by the M&O staff as the source for the water table model, confirmed that alternative conceptual models of the water level were not identified or analyzed.

The DOE audit team acknowledged the NRC technical observer's concern which was complementary to the audit team findings and agreed to address this item in their report of the OCRWM QA Audit M&O-ARP-00-10.

4.6.3 Analysis Model Report, Calibration of the Site-Scale Saturated Zone Flow Model (MDL-NSB-HS-000011, Rev 00F)

A total of 17 audit checklist items, pertinent to this AMR, were evaluated by the auditors. The following technical subjects were addressed: completeness of work including references, checking the results of the NETPATH code, proper referencing of software codes, grid resolution, FEHM boundary condition macro, local recharge, sensitivity of estimated parameter values, analysis of weighted residuals, conversion of FEHM code output to TECPLOT code input, effective continuum approach, anisotropy representation in the SZ model, HFM representation in the SZ model, infiltration map and linkage of SZ and UZ models, calibration goal, calibration error, importance of wells in the calibration.

The audit team requested and was provided information on each of the above listed items. Based on the review of this information the technical specialists were generally satisfied that this AMR met the audit evaluation criteria.

The NRC technical observers were concerned that the use of currently available regional SZ flow model in the calibration of the site-scale model might not be appropriate. They pointed out that the current regional model is not in active use, and that if a regional model is to be used in the calibration or validation of the site-scale model, the updated version of the regional model, currently under development by the U.S.G.S., was preferable. The NRC technical observers noted further that the status of the regional model should to be clearly documented in the AMR. The DOE audit team acknowledged the NRC technical observer's concerns which were complementary to the audit team findings and agreed to address these items in their report of the OCRWM QA Audit M&O-ARP-00-10.

4.6.4 Analysis Model Report, Input and Results of the Base Case Saturated Zone Flow and Transport Model for TSPA, (ANL-NBS-HS-00003, Revision 00)

A total of 20 audit checklist items, pertinent to this AMR, were evaluated by the auditors. The following technical areas were specifically addressed: plan and schedule to qualify unqualified software, documentation and referencing of software testing, time conversion factors, relative mass flux, "SZ-CONVOLUT" computer code documentation, validation of software routines, documentation of data transfer from other AMRs and from other sources, explanation for the assumption that the point source for radionuclide transport in the SZ is conservative, assumptions pertaining to the one-dimensional radionuclide transport modeling, rationale for using 100 realizations, applicability of the volcanic aquifer flux to the entire flow path from the repository to the biosphere, controls to avoid propagation of data errors and procedures to check for errors, evaluation of sensitivity of parameters in the stochastic representation in the model, how the SZ model is updated as the UZ site-scale model data changes, verification process of the flux computations, derivation of alluvium uncertainty zone, horizontal anisotropy derivation, determination of impact of climate changes on flow paths, and sources of parameter values used for model comparison.

The audit team requested and was provided information on each of the above listed items. Based on the review of this information the audit team was generally satisfied that the AMR met the audit evaluation criteria.

The NRC technical observers noted that field tests simulating radionuclide transport in the saturated zone have been conducted in the C-well complex. The scale of these tests was on the order of 30 meters, whereas the size of the grid blocks used in the Total System Performance Assessment (TSPA) is 500 meters on a side. Homogeneous material properties are assigned to individual hydrogeologic units in the TSPA. With the possibility that transport parameters are scale dependent, the NRC technical observers were concerned that the data collected in small-scale field experiments may not support the parameter ranges used in TSPA., where the grid size is an order of magnitude larger than the field tests. The NRC technical observers recommended that future revisions to the AMR address this issue and clearly delineate how the field tests support the SZ transport model.

The DOE audit team acknowledged the NRC technical observer's concerns which were complementary to the audit team findings and agreed to address these items in their report of the OCRWM QA Audit M&O-ARP-00-10.

4.7 NUCLEAR REGULATORY COMMISSION STAFF FINDINGS

The NRC staff has determined that OQA Audit M&O-ARP-00-010 was effective in determining the level of compliance of M&O activities associated with the subject AMRs. The NRC staff agrees with the audit team conclusion that the OCRWM QA program had been satisfactorily implemented. No deficiencies were identified during the audit and the NRC staff concluded that the technical quality and completeness of the scientific products in the SZ PMR and the associated AMRs indicated an improving trend over the products evaluated in the previous six PMR audits conducted in the last quarter of 1999 and the first quarter of 2000.

4.7.1 Closure of Previous NRC Audit Observer Inquiries

a) AOI No. OCRWM-ARC-99-015-1, dated September 22, 1999, requested additional information and clarification on the qualification status and use of the "Waste Stream Profiles" addressed in the "Design Basis Waste Stream for Interim Storage and Repository" and the "Waste Quantity, Mix and Throughput Study" documents. The response provided in DOE's Letter to the NRC (C.W. Reamer) from DOE (R.W. Clark), "U.S. Nuclear Regulatory Commission (NRC) Auditor Observer Inquiries," dated April 4, 2000, provides an acceptable response to this inquiry.

b) AOI No. M&O-ARP-00-02-1, dated November 18, 1999, identified that Procedure AP-3.10Q, "Analysis and Modeling" and the QARD are not specific regarding which calculations/analyses are subject to model validation and the timing of model validation, and that the M&O Environmental, Safety and Regional Programs Office, involved with the Biosphere AMRs, do not appear to have an understanding or strategy for model validation as it applies to the biosphere AMRs/PMRs. The response provided in DOE's Letter to the NRC (C.W. Reamer) from DOE (R.W. Clark), "U.S. Nuclear Regulatory Commission (NRC) Auditor Observation Inquires," dated April 4, 2000, provides an acceptable response to this inquiry.

c) AOI No. M&O-ARP-00-02-2, dated November 18, 1999, was closed during the conduct of this audit/observation. This AOI documented that the resolution of individual comments was not required for checks of analysis and models (AP-3.10Q) and that it was optional for review of technical products (AP-2.14Q). However, the lack of a documented resolution to these issues is inconsistent with the QARD, Section 2.2.10 (F), which requires that mandatory comments shall be documented and resolved before approval of the document.

Based on the review of DOE's Letter to the NRC (C.W. Reamer) from DOE (R.W. Clark), dated April 4, 2000, it was determined that Procedure AP-3.10Q has been revised to require documentation of comment resolution in accordance with Procedure AP-2.14Q and that the staff responsible for the implementation of these procedures had been appropriately trained. Therefore, the NRC observers concluded that appropriate corrective actions had been implemented to resolve this AOI.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 22, 2000

Mr. James H. Carlson, Acting Director
Program Management and Administration
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION OBSERVATION AUDIT REPORT NO. OAR-00-08, "OBSERVATION AUDIT OF THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE DIVISION AUDIT NO. M&O-ARP-00-013"

Dear Mr. Carlson:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report No. OAR-00-08 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 (YMQAD), audit of the processes and activities supporting the Total System Performance Assessment-Site Recommendation (TSPA-SR) performed by the OCRWM Management & Operating Contractor (M&O). The audit, M&O-ARP-00-013, was conducted on July 9–19, 2000, at the M&O facilities in Las Vegas, Nevada.

The purpose of this performance-based audit was to evaluate the quality of TSPA-SR inputs, the adequacy of the TSPA-SR model, and the effectiveness of the TSPA-SR approach in demonstrating compliance with the overall performance objective and applicable regulatory criteria.

The audit team concluded that the OCRWM quality assurance (QA) program had been satisfactorily implemented for the analysis model reports (AMRs) supporting the TSPA-SR with the exception of model validation. Since the TSPA-SR Model Report was in draft during the audit, the report effectiveness will be determined during a second audit. Within the areas evaluated, the audit team identified potential deficiencies for: 1) failure to document the impact of "to be verified" inputs on analysis and models; 2) failure to document rationale for exclusion of uncertainties, assumptions, and alternative conceptual models for process level AMRs; 3) failure to implement appropriate methodology to validate the TSPA-SR model; 4) failure to maintain model information in the Model Warehouse; and 5) failure to follow planning documents or make changes when appropriate. A number of recommendations were offered for improvements and enhancements to the AMRs. The deficiencies are discussed throughout Sections 4.4 and 4.5 of the enclosed report.

The NRC observers (observers) determined that this audit was effective in identifying potential deficiencies in the AMRs and the TSPA-SR Model Report. During the conduct of the audit,

both the audit team and the observers reviewed data, analysis model reports, and software within the scope of the audit to determine whether they were properly qualified. The audit team and the observers determined that the software supporting the AMRs, with a few exceptions, had been qualified. The observers agreed with the audit team's conclusions, findings, and recommendations.

However, the observers noted that, when reviewed collectively, the potential deficiencies may indicate programmatic problems with the implementation of the QA Program. Specifically, the potential deficiencies identified by the audit team included failure to revise planning documents, failure to maintain the Model Warehouse, and failure to properly validate models. These were all examples where the M&O failed to follow procedures.

The observers were concerned that failure to follow procedures continues to be a weakness. This problem was most recently documented by DOE in its "OCRWM QA Trend Report for Quality Program Deficiencies First Semester 2000," dated August 10, 2000. The report reviews trends for deficiencies identified between January 1, and June 30, 2000. In that report DOE concluded that "the majority of this semesters issues continue to be personnel error related to failure to follow procedure and inattention to detail." The observers recommend that DOE management continue to focus attention on procedural compliance.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Timothy J. Kobetz of my staff at (301) 415-7285.

Sincerely,

Janet Schlueter, Chief (Acting)
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: U.S. Nuclear Regulatory Commission Observation Audit Report No. OAR-00-08, "Observation Audit of the Office of Civilian Radioactive Waste Management Quality Assurance Division Audit No. M&O-ARP-00-013"

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within the scope of the audit to determine whether they were properly qualified. The audit team and the observers determined that the software supporting the AMRs, with a few exceptions, had been qualified. The observers agreed with the audit team's conclusions, findings, and recommendations.

However, the observers noted that, when reviewed collectively, the potential deficiencies may indicate programmatic problems with the implementation of the QA Program. Specifically, the potential deficiencies identified by the audit team included failure to revise planning documents, failure to maintain the Model Warehouse, and failure to validate all models which were all examples where the M&O failed to follow procedures.

The observers were concerned that failure to follow procedures continues to be a weakness. This problem was most recently documented by DOE in its "OCRWM QA Trend Report for Quality Program Deficiencies First Semester 2000," dated August 10, 2000. The report reviews trends for deficiencies identified between January 1, and June 30, 2000. In that report DOE concluded that "the majority of this semesters issues continue to be personnel error related to failure to follow procedure and inattention to detail." The observers recommend that DOE management continue to focus attention on procedural compliance.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Timothy J. Kobetz of my staff at (702) 794-7285.

Sincerely,

Janet Schlueter, Chief (Acting)
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: U.S. Nuclear Regulatory Commission Observation Audit Report No. OAR-00-08, "Observation Audit of the Office of Civilian Radioactive Waste Management Quality Assurance Division Audit No. M&O-ARP-00-013"

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both the audit team and the observers reviewed data, analysis model reports, and software within the scope of the audit to determine whether they were properly qualified. The audit team and the observers determined that the software supporting the AMRs, with a few exceptions, had been qualified. The observers agreed with the audit team's conclusions, findings, and recommendations.

However, the observers noted that, when reviewed collectively, the potential deficiencies may indicate programmatic problems with the implementation of the QA Program. Specifically, the potential deficiencies identified by the audit team included failure to revise planning documents, failure to maintain the Model Warehouse, and failure to properly validate models. These were all examples where the M&O failed to follow procedures.

The observers were concerned that failure to follow procedures continues to be a weakness. This problem was most recently documented by DOE in its "OCRWM QA Trend Report for Quality Program Deficiencies First Semester 2000," dated August 10, 2000. The report reviews trends for deficiencies identified between January 1, and June 30, 2000. In that report DOE concluded that "the majority of this semesters issues continue to be personnel error related to failure to follow procedure and inattention to detail." The observers recommend that DOE management continue to focus attention on procedural compliance.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Timothy J. Kobetz of my staff at (301) 415-7285.

Sincerely,

Kevin Stablein
for

Janet Schlueter, Chief (Acting)
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: U.S. Nuclear Regulatory Commission Observation Audit Report No. OAR-00-08, "Observation Audit of the Office of Civilian Radioactive Waste Management Quality Assurance Division Audit No. M&O-ARP-00-013"

Letter to J. Carlson from J. Schlueter dated: 7/22/2000

cc: R. Loux, State of Nevada
S. Frishman, State of Nevada
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A. Brownstein, DOE/Wash, DC
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B. Price, Nevada Legislative Committee
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U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-00-08

OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE DIVISION

AUDIT NO. M&O-ARP-00-013

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Per FAX 09/14/00
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N. King Stablein 09/22/00
N. King Stablein, Chief
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U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-00-08

OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE DIVISION

AUDIT NO. M&O-ARP-00-013

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1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Yucca Mountain Quality Assurance Division (YMQAD) audit of the processes and activities supporting the Total System Performance Assessment-Site Recommendation (TSPA-SR) performed by the OCRWM Management & Operating Contractor (M&O). The audit, M&O-ARP-00-013, was conducted on July 9–19, 2000, at the M&O facilities in Las Vegas, Nevada.

The objective of this audit was to evaluate the implementation of the applicable provisions contained in the OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 9, by reviewing selected analysis model reports (AMRs) supporting the TSPA-SR. During the audit, selected AMRs and the draft TSPA-SR Model Report were subjected to technical reviews as well as reviews to assess whether the applicable programmatic requirements contained in the QARD and implementing procedures were met.

The NRC staff objective was to assess whether the M&O and OQA were 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 Code of Federal Regulations (10 CFR Part 60). Because of the anticipated DOE submittal of the site recommendation (SR) in November 2000, the following observation activities were emphasized: 1) confirming that data, software, and models supporting site recommendation are properly qualified; and 2) reviewing the progress being made by DOE and its contractors in meeting the qualification goals for SR.

2.0 MANAGEMENT SUMMARY

OQA Audit M&O-ARP-00-013 was the first of two audits planned for the TSPA-SR. This audit evaluated the early-phase TSPA-SR activities, particularly inputs to the TSPA-SR. The second audit will evaluate outputs from TSPA-SR. The NRC staff determined that OQA Audit M&O-ARP-00-013 was effective and conducted in a professional manner. Audit team members were independent of the activities they audited and were knowledgeable in the quality assurance (QA) and technical disciplines within the scope of the audit.

The audit team concluded that the OCRWM QA program had been satisfactorily implemented for the AMRs supporting the TSPA-SR with the exception of model validation. Since the TSPA-SR Model Report was in draft during the audit, the report effectiveness will be determined during the second audit. Five potential deficiency reports were initiated during the audit. Specifically, the audit team identified potential deficiencies for: 1) failure to document the impact of "to be verified" inputs on analysis and models; 2) failure to document rationale for exclusion of uncertainties, assumptions, and alternative conceptual models for process level AMRs; 3) failure to implement appropriate methodology to validate the TSPA-SR model; 4) failure to maintain model information in the Model Warehouse; and 5) failure to follow planning documents or make changes when appropriate. A number of recommendations were offered for improvements and enhancements to the AMRs. The deficiencies and recommendations are discussed throughout sections 4.4 and 4.5 of this report.

The NRC observers (observers) determined that this audit was effective in identifying potential deficiencies, and recommending improvements, in the AMRs and TSPA-SR Model Report. During the conduct of the audit, both the audit team and the observers reviewed data, analysis model reports, and software within the scope of the audit to determine whether it was properly qualified. The audit team and the observers determined that the software supporting the AMRs, with a few exceptions, had been qualified. However, some of the data still required verification.

However, the observers noted that, when reviewed collectively, the potential deficiencies may indicate programmatic problems with the implementation of the QA Program. Specifically, deficiencies identified by the audit team included failure to revise planning documents, failure to maintain the Model Warehouse, and failure to validate all models which were all examples where the M&O failed to follow procedures.

The observers were concerned that failure to follow procedures continues to be a weakness. This issue was discussed with the audit team during the audit, however, not specifically discussed at the audit exit meeting. Subsequent to the audit, this problem was documented by DOE in its "OCRWM QA Trend Report for Quality Program Deficiencies First Semester 2000," dated August 10, 2000. The report reviews trends for deficiencies identified between January 1, and June 30, 2000. In that report DOE states "it is concluded that the majority of this semesters issues continue to be personnel error related to failure to follow procedure and inattention to detail." The observers recommend that DOE management continue to focus attention on procedural compliance.

In addition to the above observations, the observers provided detailed observations regarding the implementation of the quality assurance program (see Section 4.6.1 of this report) and a review of the technical adequacy of the AMRs and TSPA-SR (see Section 4.6.2 of this report). These observations cover topics discussed during the audit that are of particular concern regarding the technical adequacy of the AMRs and potential concern over the acceptability of DOE's upcoming site recommendation report.

3.0 AUDIT PARTICIPANTS

3.1 Nuclear Regulatory Commission Observers

Robert Brient	Team Leader (Quality Assurance)	CNWRA
David Esh	Technical Specialist (Performance Assessment)	NRC
Richard Codell	Technical Specialist (Performance Assessment)	NRC
Tim Kobetz	QA Engineer (Quality Assurance)	NRC
Sitakanta Mohanty	Technical Specialist (Performance Assessment)	CNWRA
Michael Smith	Technical Specialist (Performance Assessment)	CNWRA
Osvaldo Pensado	Technical Specialist (Performance Assessment)	CNWRA

3.2 OQA Audit Team

Kristi Hodges	Audit Team Leader	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
James Blaylock	Auditor	OQA/DOE
Harvey Dove	Technical Specialist	OQA/QATSS
Michael Eshleman	Auditor	Yucca Mountain Site Characterization Office (YMSCO)/Management and Technical Services (MTS)
Mark Nutt	Technical Specialist	YMSCO/MTS
Richard Powe	Auditor	OQA/QATSS
James Voigt	Auditor	OQA/QATSS
Alf Wikjord	Technical Specialist	YMSCO/Atomic Energy of Canada, Limited
Frank Wong	Technical Specialist	YMSCO/MTS

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, Revision (Rev.) 6, Interim Change Notice (ICN) 0, "Internal Audit Program," and QAP-16.1Q, Rev. 4, ICN 1, "Performance/Deficiency Reporting." The NRC staff's observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

4.1 Scope of the Audit

The audit team conducted a limited scope, performance based, audit of activities and processes related to the development of the AMRs and the TSPA-SR Model Report supporting the TSPA-SR. AMRs, software, and data were evaluated during the audit process. The audit included review of the programmatic controls governing the AMRs and technical issues discussed in the AMRs. The following procedures and AMRs supporting the TSPA-SR were reviewed by the audit team and the observers during the audit:

Procedures

a) AP-SI.1Q, "Software Management," Revision 2, Interim Change Notice 4

b) AP-SIII.2Q, "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data," Rev. 0, ICN 2

c) AP-2.13Q, "Technical Product Development Planning," Rev. 0, ICN 4

d) AP-2.14Q, "Review of Technical Products," Rev 0, ICN 1

e) AP-3.10Q, "Analysis and Models," Rev. 2, ICN 2

f) AP-3.15Q, "Managing Technical Product Inputs," Rev. 1, ICN 1

Reports

a) MDL-WIS-PA-000002, "Total System Performance Assessment (TSPA) Site Recommendation Model Report" in draft

b) ANL-EBS-PA-000001, "WAPDEG Analysis of Waste Package and Drip Shield Degradation," Revision 00

c) ANL-WIS-MD-000010, "Summary of Dissolved Concentration Limits," Revision 00

d) ANL-NBS-MD-000005, "Abstraction of Drift Seepage," Revision 00

e) ANL-NBS-MD-000007, "Abstraction of BDCF Distribution for Irrigation Period," Revision 00

f) Features, Events, and Processes (FEPs) AMRs: 1) Engineered Barrier System FEPs AMR (ANL-WIS-PA-000002); 2) Waste Package FEPs (ANL-EBS-PA-000002 and ANL-WIS-MD-000008); 3) Waste Form FEPs (ANL-WIS-MD-000009); 4) UZFT FEPs AMR (ANL-NBS-MD-000001); and 5) Biosphere FEPs AMR (ANL-MGR-MD-000009). The FEPs Database (Revision 1)

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 M&O and DOE programs and procedures. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit.

The audit team and observers caucused at the end of each day to discuss new and developing issues. Also, the audit team met with M&O management, with the observers present, each morning to discuss the current audit status and preliminary findings. The observers determined that the timing of the audit was appropriate for the audit team to evaluate ongoing TSPA-SR activities.

4.3 Audit Team Qualification and Independence

The observers determined that the qualifications of the audit team leader and the OQA audit team members met the requirements of QAP-18.1, "Auditor Qualification." The audit team members did not have prior responsibility for performing the activities they audited. Curriculum vitae of the audit team Technical Specialists were reviewed by the observers and found to be acceptable.

4.4 Examination of Quality Assurance Elements

The OQA programmatic and technical audit activities were conducted separately. The limited scope audit focused on the QA elements associated with the development of the AMRs. The observers evaluated the audit team's review of the following QA areas and agreed with the audit team's findings and conclusions in these areas.

4.4.1 AP-2.13Q "Technical Product Development Planning"

The audit team reviewed technical development plans and work product planning sheets applicable to the subject AMRs. The audit team found that, in two instances, the M&O failed to follow AP-2.13, Step 5.3, which requires changes to a plan to be documented. The audit team considered this issue a potential deficiency report siting AP-3.10Q, Steps 5.2 and 5.6, which require a plan to be followed in the development of AMRs and the technical checker to verify that the plan was followed (see Sections 4.5.1 and 4.5.2 for specific findings). The observers agreed with this finding.

4.4.2 AP-SI.1Q "Software Management"

The audit of software management focused on control of software routines. Rather than requiring the full qualification process expected for more complex software, the procedure requires that routines must be verified (usually by hand calculation) for each application. The audit team was concerned that some verification was by calculation using different software (e.g., MATHCAD) rather than hand calculations and some routines may have been complex enough to justify full qualification as a computer code. The observers agreed with this concern.

4.4.3 AP-3.15Q "Managing Technical Product Inputs"

The audit team identified a concern with the tracking of input data. In the iterative performance assessment process, the outputs from lower tier AMRs (such as process and abstraction models) become the inputs for higher tier AMRs and eventually the TSPA-SR model. Outputs were classified under the current procedure as "N/A: Technical Product Output" regardless of any unqualified or TBV input data that may have been used in the lower tier AMR. The audit team identified this concern as a potential deficiency report involving the requirements of AP-3.10Q to evaluate the impact of unqualified data on the validation of a model. The observers agreed with this finding.

4.4.4 AP-SIII.2Q "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data"

The data status and traceability were evaluated, however, the data qualification process was not specifically audited.

4.4.5 AP-3.10Q "Analysis and Models"

Independent of the technical audit, the technical checking process was evaluated for the subject AMRs. The draft TSPA-SR Model Report had not yet been through this verification step. No discrepancies were identified.

However, the audit team identified potential deficiency reports with regard to the following areas of AP-3.10Q:

- The M&O failed to assess the impact of TBV data input to the AMRs, particularly in the impact of unqualified data on model validity (see Section 4.4.3, of this report).

- AMRs did not adequately address model validation, (i.e., validation criteria and methods, validation tests conducted, and results). Specifically, the model validation approach for the TSPA-SR model was taking credit for process level AMR validations which may or may not have occurred, rather than establishing a formal model validation for the TSPA-SR model. The audit team determined this is a potential deficiency report citing AP-3.10Q, Step 5.3. The observers agreed with this finding.

- The audit team identified that AP-SIII.3Q required inputs and outputs of models to have been submitted to a "Model Warehouse." A potential deficiency citing failure to follow AP-3.10Q was identified because, in several examples, certain information required by the procedure was not transferred to the Model Warehouse. The observers agreed with this finding.

4.4.6 AP-2.14Q "Review of Technical Products"

According to the procedure, technical reviews were required when organizations outside of the originating organization, in this case, Performance Assessment, were affected by the report. Since Performance Assessment was the ultimate user of these AMRs, technical reviews were generally not performed on the subject AMRs. The audit team noted that more extensive reviews may improve the products and may have corrected some of the concerns that were found during the audit. The observers agreed with this finding.

4.5 Examination of Technical Activities

The audit team technical specialists prepared detailed checklists for each of the AMRs being evaluated. Technical activities examined by the audit team are summarized below for each of the AMRs.

4.5.1 Total System Performance Assessment Site for Recommendation (MDL-WIS-PA-000002, in draft)

The report on the TSPA-SR documented the model for analyzing the performance of the repository system in isolating waste for long periods of time. The objective of the TSPA-SR model was to integrate information from other process models into one comprehensive model. The individual parts of the TSPA-SR model are called component models. The M&O selected to segment the repository system into the following main component models:

- Unsaturated zone flow and transport
- Thermal hydrology
- In-drift geochemical environment
- Waste package degradation
- Waste form degradation
- Saturated zone flow and transport
- Biosphere
- Disruptive events

The audit of the TSPA-SR included an assessment of whether the quality assurance procedures were followed in the development of the document and whether the technical

content of the product was acceptable. The audit team inquired about numerous technical and procedural areas of the report generation process. These included: 1) planning and implementation; 2) qualification status of data utilized; 3) assumptions used; 4) data acquisition and traceability; 5) data uncertainty; 6) integration of the TSPA-SR model with other components; 7) code verification; and 8) model implementation.

The observers concurred with the audit team that the technical content of the report was appropriate. The audit team determined the M&O had not followed the plans for the AMR. Specifically, the M&O had not updated the AMR to address all of the acceptance criteria provided in the NRC Issue Resolution Status Reports (IRSRs) and the M&O had not addressed Peer Review comments in the AMR. The M&O stated that, in both cases, it had addressed the items implicitly. The audit team noted that these types of comments should have received more explicit treatment. The observers concurred with the audit team that a more explicit treatment of IRSR acceptance criteria and peer review comments was required by the plan and would improve transparency and traceability. The audit team identified this issue as a failure to follow AP-2.13Q, Step 5.3, which requires changes to a plan to be documented. The audit team identified this issue as a potential deviation report citing AP-3.10Q, Steps 5.2 and 5.6, for failure to implement a plan and failure by the technical checker to verify the plan was followed.

The audit team found that the qualification status of the data inputs to the TSPA-SR model were in various states of verification with many data inputs having a TBV quality status. Therefore, the results (output) from this model were also TBV. The audit team found that every major component of the TSPA-SR model produced output that should have been categorized as TBV. The observers noted that a significant amount of data still required verification and that the M&O's schedule for completing data verification appeared ambitious.

GoldSim is a software program used by the M&O to integrate models and collectively evaluate the repository performance for the TSPA-SR. The GoldSim software program was not yet qualified.

The observers concurred with the audit team that, compared to documentation reviewed in past audits, an improved effort has been made by the M&O to explicitly list assumptions that apply to the TSPA-SR model. In addition, the model document lists assumptions that were specifically generated via the component model abstraction process. However, all of the assumptions applying to supporting AMRs (those supporting abstraction AMR's) were not propagated into the higher-level documents. The audit team noted, and the observers agreed, that a complete listing of applicable assumptions and either the technical basis or references to the technical basis supporting the assumptions would improve the document.

The audit team found that verification of calculations had been performed in the TSPA-SR model document. The audit team reviewed a number of the calculations in detail. The audit team was not able to determine the requirements for the number of calculations required to verify a model. In addition, the audit team was unable to identify acceptance criteria for model verification. Specifically, some calculations were exact to two significant digits while other calculations of an identical type were exact to five significant digits. It was not clear to the audit team whether verification to two significant digits was acceptable or if all calculations should be performed to five significant digits. Since the TSPA-SR model was still in draft no technical review had been performed. The audit team commented that, in the future, the technical reviewer should identify and resolve this type of potential discrepancy.

The audit team discussed the component verification of the WAPDEG (see Section 4.5.2 of this report) with the M&O. Specifically, the audit team noted that the WAPDEG calculations and transfer of information to and from the TSPA-SR model should be discussed in the TSPA-SR model document. At the conclusion of the audit this had not been completed.

The audit team identified that some basic steps in model testing were not documented and/or completed. The TSPA model is a mathematical model; therefore, it should be appropriately tested and the results documented. For example, the audit team determined that sensitivity of the TSPA-SR results, with regard to variations in TSPA time-step-size and to variations in resolution at the component-level (i.e., number of infiltration bins, number of thermohydrology bins, number of stream tubes, etc.), had not been presented. The M&O stated that such testing did take place, but the results of the testing were not formally presented at the system-level. The audit team determined, and the observers agreed, that a description of TSPA-SR model stability was essential to achieving confidence in the model.

The audit team identified that data usage by the TSPA-SR model from the component models was appropriate, with one exception. Dissolved concentration limits were generated for a more narrow range of chemical conditions than the expected environments generated by the in-package chemistry component model. Therefore, the TSPA-SR model could potentially generate chemical conditions for which the dissolved concentration limit abstraction does not apply. While these extreme chemical conditions are not expected, they are possible as defined by the in-package chemistry component model. No objective evidence existed that the current procedures were able to identify the aforementioned problem. The observers agreed with this concern.

The audit team discussed the implementation of seismic effects on cladding in the TSPA-SR model. The observers concurred with the audit team that the current implementation in the TSPA model did not appear to be correct. Inclusion of seismic events should be consistent with the implementation of intrusive or extrusive igneous activity in computing risk.

The audit team also identified problems with the implementation of model validation. The QARD states in part that as part of scientific investigation, model validation must be planned and implemented. The QARD provided a number of options to model validation. The TSPA-SR model document outlined an approach to model validation where the component models are validated individually and the transfer of information within the TSPA is verified. The audit team determined, and the observers agreed, that the approach taken by the M&O is not in accordance with the information contained in the QARD. Almost all of the major abstraction AMRs have not been validated. The audit team considered this issue a potential deficiency report for failing to follow AP-3.10Q which implements the requirements of the QARD.

4.5.2 Analysis Model Report WAPDEG Analysis of Waste Package and Drip Shield Degradation (ANL-EBS-PA-000001, Rev 00)

This AMR documented the abstraction of drip shield and waste package (WP) degradation from the code "WAPDEG," for use in DOE's TSPA-SR. The WAPDEG model itself is composed of several sub-models to determine general and localized corrosion of the drip shield, WP outer and inner barriers, manufacturing defects, stress corrosion cracking, material aging, and microbial induced corrosion.

The audit of the WAPDEG AMR included a combination of procedural and technical inquiries to verify whether the quality assurance procedures were followed in the development of the document and the technical quality of the product was acceptable. The audit team inquired about technical areas of the report and procedural areas of the report generation process, including: 1) planning and implementation; 2) qualification status of data utilized; 3) assumptions used; 4) data acquisition and traceability; 5) data uncertainty; 6) integration of this model component with other model components; 7) rationales for the types of abstractions; and 8) use of the generated technical output by other groups or system components.

The observers concurred with the audit team that the technical content of the report was appropriate. However, as with several of the other audits, there appeared to be inadequate tracking of comments generated in DOE's external peer review of the TSPA. The WAPDEG planning document states that they will address the peer review comments, but there was no mention of them in the AMR. This AMR acknowledged the issues from the NRC IRSRs that pertained to waste package degradation, but did not appear to explicitly address them. The audit team identified this issue as a failure to follow AP-2.13Q, Step 5.3, which requires changes to a plan to be documented. The audit team identified this issue as a potential deficiency report citing AP-3.10Q, Steps 5.2 and 5.6, for failure to implement a plan and failure by the technical checker to verify the plan was followed.

The audit team also identified a number of technical problems and inconsistencies with the WAPDEG model:

- The AMR did not provide sufficient detail to demonstrate how stress corrosion cracking (SCC) was incorporated into the model for degradation of the end-cap welds. This included a lack of detail on how stress mitigation techniques were incorporated into the SCC models. This issue was identified as a potential deficiency report for failure to implement Supplement III.2.6B, of the QARD.

- It was not clear how aging effects of the alloy 22 material were taken into account.

- The audit team noted an inconsistency in the way that the corrosion rate was sampled for SCC of the end cap for the WPs. The end cap model has two layers of alloy 22 representing a single layer of material in the as-designed waste package. The WAPDEG code samples the corrosion rate twice even though the corrosion of a single layer of material is being calculated. The audit team felt that there should have been a single corrosion rate to cover both of the layers.

- Failure time is described as the time of first penetration of the WP. However, the penetration time for SCC is orders of magnitude shorter than the time for general corrosion, yet the SCC failure would allow only diffusive release. The audit team felt that the AMR should make this distinction very clear, so that the short times for failure due to SCC are not misinterpreted.

The audit team identified concerns with the use of "Gaussian Variance Partitioning" (GVP) in the AMR. GVP was utilized in an attempt to separate uncertainty and variability in the distributions of parameters used in the WAPDEG model. The concept was that a distribution of a parameter, such as the corrosion rate for alloy 22, contains both variability and uncertainty, and that this dichotomy should be recognized in the performance analysis. For corrosion rate,

"variability" would represent the real differences in corrosion rate from place to place in the repository, or from place to place on the waste package, caused by mechanistic differences in material properties or the environment. This information could be gathered in corrosion experiments by subjecting coupons to a range of chemical environments, and taking coupons for the experiments from potentially different materials such as welds and open areas. Uncertainty, on the other hand, would be random, non-mechanistic variations caused by measurement errors or unquantifiable processes. The AMR author stated that most of the distribution is caused by uncertainty in experimental measurements rather than mechanistic differences in the samples or environments. Randomly sampling the partitioning of uncertainty and variability is not appropriate if the result is a reduction in risk.

The author of the AMR noted that increasing the proportion of the distribution attributed to variability gave conservatively shorter times for the first package breach, but it gave lower peak release rates overall. Therefore, the current application of GVP could result in a significant underestimation of the peak dose if the application of the GVP technique is not statistically supported by the data. The observers commented that the way in which the peak dose is reported (i.e., the peak of the mean dose), makes it unclear whether increased variability or increased uncertainty is more conservative. The observers recommended that the WAPDEG model results should not be looked at in isolation, and that the overall TSPA-SR results would have to be examined to make this determination.

4.5.3 Analysis Model Report Summary of Dissolved Concentration Limits (ANL-WIS-MD-000010, Rev 00)

The AMR for the summary of dissolved concentration limits documented the M&O staff abstraction of solubility limits of radioactive elements from the process-level models provided by Natural Environment Program Operations and Waste Package Operations. The product of the abstraction was to develop solubility limits as functions, distributions, or constants for all transported radioactive elements identified by the Performance Assessment Operation radioisotope screening. The results of the analyses were generated for performance assessment calculations.

The audit of the summary of dissolved concentration limits AMR included a combination of procedural and technical inquiries to verify that the quality assurance procedures were followed in the development of the document and the technical quality of the product was acceptable. The audit team inquired about many technical areas of the report and procedural areas of the report generation process, including: 1) planning and implementation; 2) qualification status of data utilized; 3) assumptions used; 4) data acquisition and traceability; 5) data uncertainty; 6) integration of this model component with other model components; 7) rationales for the types of abstractions [probability distribution functions, response surfaces, constants]; and 8) use of the generated technical output by other groups or system components.

The observers concurred with the audit team that the technical content of the report was appropriate. The audit team determined the plans for the document had been followed with two exceptions. Specifically, NRC IRSR acceptance criteria and TSPA-SR Peer Review comments were not addressed (consistent with all technical documents reviewed for this audit). The document authors stated they did address the aforementioned items but did so implicitly. The audit team was looking for a more explicit treatment. The observers concurred with the audit

team that a more explicit treatment of IRSR acceptance criteria and peer review comments would improve transparency and traceability. This AMR acknowledged the issues from the NRC IRSRs that pertained to waste package degradation, but did not appear to explicitly address them. The audit team identified this issue as a failure to follow AP-2.13Q, Step 5.3, which requires changes to a plan to be documented. The audit team identified this issue as a potential deficiency report citing AP-3.10Q, Steps 5.2 and 5.6 for failure to implement a plan and failure by the technical checker to verify the plan was followed.

The audit team found that the qualification status of the data inputs to the TSPA model were in various states of verification with the main input to the EQ3/6 modeling effort being TBV. Therefore, the results (output) from this abstraction were also TBV.

As discussed in Section 4.5.1 of this report, the observers concurred with the audit team that an improved effort has been made to explicitly list assumptions that apply to an abstraction. However, all of the assumptions applying to supporting AMRs (those supporting abstraction AMRs) are not propagated into the higher-level documents. The audit team and observers agreed that a complete listing of applicable assumptions and either the technical basis or references to the technical basis supporting the assumptions would improve the document.

Some potential technical problems were identified with the integration of this model component with other model components and the use of technical output generated by other groups or system components. For example, solubility limits were generated for a range of potential chemical environments. The in-package chemistry AMR was not completed at the time of preparation of the dissolved concentration limits AMR. Therefore, the dissolved concentration limits AMR developed probability distribution functions (pdfs) and response surfaces based on their best estimate for expected in-package environmental conditions. However, the ranges selected for key chemical variables by the dissolved concentration limits AMR were more narrow than those generated by the in-package chemistry model. Therefore, the result was that the TSPA-SR model would potentially generate chemical conditions for which no data has been produced for the solubility limits. The authors did evaluate the impact of using the response surfaces outside of the ranges for which they were developed but did not do the same for the pdfs. In addition, it was not clearly identified that the dissolved concentration limits were developed based on the assumption of long-package lifetime (J-13 water as the starting fluid concentration). The abstraction would not apply for an under performance-type calculation.

The audit team identified that little technical basis was provided for the decoupling of system components. For example, in-package chemistry is one-way coupled to the dissolved concentration limits abstraction, such that, there is no feedback to in-package chemistry resulting from the solubility limits abstraction. The source-term degradation resulting in the release of uranium was discussed in this context. The uranium will be present in solution potentially up to its solubility limit (and may be deposited as secondary phases). The M&O stated that high uranium concentrations (determined via the solubility limit) could affect pH, thereby creating a fully-coupled system at the abstraction-level.

The audit team also identified problems with the implementation of model validation. The QARD states in part that as part of scientific investigation, model validation must be planned and implemented. The QARD provides a number of options for model validation. The document authors acknowledged that they had not completed model validation but that they

were compiling the information and it should appear in a future revision to the document. The audit team determined, and the observers agreed, that the approach taken by the M&O is not in accordance with the information contained in the QARD. Almost all of the major abstraction AMRs have not been validated. The audit team considered this issue a potential deficiency report for failure to follow AP-3.10Q which implements the requirements of the QARD.

4.5.4 Analysis Model Report Abstraction of Drift Seepage (ANL-NBS-MD-000005, Rev 00)

The AMR documented the M&O's abstraction of the process-level models for drift seepage for use in DOE's TSPA-SR. It was based both on process-model results (CRWMS M&O, 2000s, section 6.1) and calibration of seepage tests from one niche in the Exploratory Studies Facility (CRWMS M&O 2000d). The model also takes into account increased seepage flow to the drift to account for uncertainties in rock mechanics, parameter correlations, and channelized flow in the rock. The abstracted model is needed for the TSPA-SR.

The audit of this AMR included a combination of procedural and technical inquiries to assess whether the quality of the product was acceptable. The audit team inquired about several technical and procedural areas of the report generation process, including:
1) planning and implementation; 2) assumptions used; 3) data acquisition and traceability; 4) data uncertainty; 5) integration of the present model with other models; 6) rationales for the types of abstraction; and 7) use of the generated technical output by other groups or system components.

The audit team commented that the authors did a good job of tracking assumptions. The abstraction model incorporated all of the original assumptions in the background model, and several additional ones made necessary by simplification. The observers agreed with the audit team's assessment that the assumptions were carefully stated.

The audit team assessed how much data used in the models was from expert elicitation and how much was from data collected at YM or an appropriate analog. The author stated that there were problems with the underlying analyses that supported the abstraction. Specifically, the author stated that he was not entirely comfortable with the level of justification of the models. The observers reviewed the results of an audit report on the performance-based QA audit on activities related to the Unsaturated Flow and Transport Process Model Report, conducted by DOE January 24–28, 2000. The observers also reviewed the NRC observation report which discussed that audit. The DOE report identified deficiencies in the bases used to derive the abstraction and the NRC report agreed with this finding. The present AMR did not justify the underlying models, but simply abstracted the behavior into a model suitable for the TSPA code. The observers are concerned that this problem has not been corrected.

The audit team identified several other weaknesses during the audit:

- The report had no explicit mention of any open issues or acceptance criteria relating to seepage from NRC's IRSRs for Container Life and Source Term, Evolution of the Near Field Environment, or Unsaturated/Saturated Flow under Isothermal Conditions.

- There were several recommendations from a DOE peer review conducted on the TSPA-SR, but there was no apparent tracking of these comments.

- The AMR did not mention alternative conceptual models. The author stated that the underlying basis models did not consider alternatives either, and this was basically an abstraction of that work. Other AMRs had alternative conceptual models for seepage, but these were not considered in the abstraction.

The audit team found that the AMR author did not have high confidence in the abstraction, mainly because the underlying AMR contained insufficient justification. The author commented that he felt a need for more seepage tests at the site before they would have sufficient confidence. Some data from air-permeability tests in the niches were used in the model, but the data were taken in close proximity, less than 1 meter, from the drift wall and were likely to be influenced by the mining operations, stress-induced cracking and ventilation effects.

4.5.5 Analysis Model Report Abstraction of BDCF Distribution for Irrigation Period (ANL-NBS-MD-000007, Rev 00)

The AMR for abstraction of biosphere dose conversion factor (BDCF) distributions for irrigation periods documented the M&O staff's derivation of abstractions for the time evolution of the BDCFs due to radionuclide build-up effects in soil. These abstractions are to be used in TSPA-SR. The analyses for radionuclide build-up in soil were conducted using GENII-S, which includes effects from previous irrigation, harvest removal, radioactive decay, and leaching. The M&O investigated and added the effects of soil erosion to their analyses prior to performing distribution fitting to develop the abstractions.

The audit of the abstraction of BDCF distributions for irrigation periods AMR included a combination of procedural and technical inquiries to verify that the quality assurance procedures were followed in the development of the document and that the technical quality of the product was acceptable. The audit team inquired about many technical areas of the report and procedural areas of the report generation process, including: 1) planning and implementation; 2) data acquisition and traceability; 3) assumptions used; 4) rationales for the types of abstractions; 5) qualification status of data utilized; 6) model designation; 7) data uncertainty; and 8) integration of this model component with other model components.

The observers concurred with the audit team that the technical content of the report was appropriate. The audit team determined the plans for the document had been followed. The authors' specific use of NRC's acceptance criteria was noted by the audit team and referred to as a potential model for other AMRs.

The observers concurred with the audit team that improvements could be made in the area of data acquisition and traceability. The audit team focused on the procedures used for notifying affected parties when data had been superceded. The author appeared familiar with the procedure (affected parties would be notified when data used was changed) but had never been informed of such a data change. The audit team was concerned that notification to affected AMRs of superceded data may not be occurring. The auditor noted that the traceability of the mathematical contribution of BDCFs to human dose in TSPA would be verified later.

The observers agreed with the audit team that final assumptions had been clearly stated. Alternate assumptions and options were reported in supporting AMRs, but are not explicitly discussed in the abstraction of BDCF's AMR. The audit team noted that some of the assumptions stated in this AMR were not carried forward into higher-level documents. Specifically, the auditor noted that only one of the two primary assumptions listed in the abstraction of BDCF's AMR was carried forward to the TSPA-SR. No explanation was provided since the AMR author was not scheduled to review the TSPA-SR until after the audit.

The observers concurred with the audit team that the scientific approach appeared sound and defensible but improved documentation in some areas was needed. The author acknowledged that areas needing improvements included selection of distribution types, erosion calculations, and the survey conducted to obtain critical group characteristics.

The observers concurred with the audit team that additional work may be needed in the area of data and model validation, specifically, in the use of GENII. The author was aware of this issue and stated that work had already begun for validating the use of GENII for YM dose assessments. Most of the data used for this AMR have been developed. The use of expert elicitation was minimal, possibly none, and most of the data were accepted. Limited data for soil-to-plant transfer factors is available for the specific conditions at YM (i.e. plants, soil types, pH).

The audit team also reviewed the reporting of this type of work (abstraction of BDCFs) in an AMR rather than in a technical report (TR). The audit team questioned whether this material was a model and warranted the QA scrutiny that is associated with an AMR, or whether the AMR should be reviewed to the lesser requirements of a technical report. The audit team was also satisfied with the subjective nature of the goodness-of-fit used and that the BDCFs utilized for each radionuclide reflected the true nature of uncertainty seen in the biosphere model. The author acknowledged that additional work was required for the parameters related to the critical group and biosphere.

4.5.6 Analysis Model Reports for Features, Events, and Processes (FEPs)

The reports reviewed included: 1) Engineered Barrier System FEPs AMR (ANL-WIS-PA-000002); 2) Waste Package FEPs (ANL-EBS-PA-000002 and ANL-WIS-MD-000008); 3) Waste Form FEPs (ANL-WIS-MD-000009); 4) UZFT FEPs AMR (ANL-NBS-MD-000001); and 5) Biosphere FEPs AMR (ANL-MGR-MD-000009). The FEPs Database (Revision 1) was also audited.

The purposes of these AMR documents and the electronic database are to identify and document the analyses and resolution of the primary FEPs affecting the repository performance. The process-level FEP AMRs identify subject-specific FEPs and provide screening arguments. The overall FEPs AMR contains FEPs identified from various sources and describes screening methodology. DOE prepared these AMRs to aid in the resolution of the FEP inclusion/exclusion process and the screening methodology used in the process. These documents were developed to: 1) identify which FEPs are to be considered explicitly in the TSPA (called included FEPs); and 2) identify FEPs not to be included in the TSPA (called excluded FEPs) and provide justification for why these FEPs do not need to be a part of the TSPA model.

The biosphere AMR for evaluation of the applicability of biosphere-related FEPs had a more expanded scope than the other FEP AMR documents audited. The biosphere FEP AMR documented two areas of work conducted by the M&O staff: 1) the screening analysis for FEPs that are potentially biosphere related; and 2) the adequacy of the scientific bases for the Yucca Mountain Project (YMP) biosphere model. The screening analysis included the screening decision, screening argument, and recommended TSPA utilization for biosphere-related FEPs. Validation of the YMP biosphere model, GENII-S, was performed in accordance with AP-3.10Q to ensure that the model is appropriate and adequate for its intended use for Yucca Mountain. The audit did not cover the second part of the AMR, which discussed the adequacy of the scientific bases for the YMP biosphere model. That section of the AMR described the validation of the YMP biosphere model, GENII-S, to ensure that the model is appropriate and adequate for its intended use for Yucca Mountain.

The scope of all of the FEP AMR audits included the evaluation of the FEPs screening process, screening decision, screening argument, and recommended TSPA utilization. The audit evaluations included a combination of procedural and technical inquiries to verify that the quality assurance procedures were followed in the development of the documents and that the technical quality of the products was acceptable. The procedural inquiry primarily focused on areas of 1) planning and implementation; and 2) integration. The technical areas of inquiry included the 1) assumptions and criteria used; and 2) rationale for inclusion and exclusion of FEPs.

The audit team reviewed the process used to create the FEPs reports. For all process-level AMRs, the existing overall list of FEPs was used from which recommendations for change and modification were made. In several reports, FEPs were added or modified, but in others several FEPs were only shifted to and from other locations (e.g., microbial corrosion moved out of biosphere and soil type moved into biosphere).

The audit team reviewed the qualifications of the document authors and the processes that were followed in identifying included and excluded FEPs in the reports and the database. The team also examined the technical basis/rationale supporting inclusion and exclusion of these FEPs. The audit team also inquired about how the planning document was used in tracing FEPs screening arguments and decisions. The audit team focused the discussions on the M&O's rationale for inclusion and exclusion of various FEPs. The audit team stated that the scope was not to investigate the adequacy of logic used to screen FEPs, since that was reviewed during the review of each individual AMR.

The overall FEPs AMR (ANL-WIS-PA-000002) was audited first, followed by the audit of remaining process-level FEP AMRs. The audit team performed reviews for: 1) assumptions and criteria used and 2) rationale for inclusion and exclusion of FEPs. In doing so, the audit team selected both included and excluded FEPs. Neither the audit team nor the observers identified any problems with the selection of FEPs.

Overall, the audit team was satisfied with the implementation of the process and rationale for inclusion and exclusion of FEPs. The audit team, however, found deficiencies in interaction among various groups to ensure consistency in rationale for inclusion or exclusion of a FEP. For example, there was a lack evidence of interactions among safety, design, and implementation groups. The observers considered the audit to be effective, and concurred with the findings of the audit team.

4.6 Nuclear Regulatory Commission Staff Findings

The observers determined that OQA Audit M&O-ARP-00-013 was effective. The observers agreed with the audit team conclusion that the OCRWM QA program was effectively implemented except for model validation for the AMRs supporting the TSPA-SR, and that the effectiveness of the TSPA Model Report (in draft during this audit) will be determined during the second phase audit. The observers agreed with all other audit team conclusions, potential deficiency reports, findings, and recommendations.

The observers agreed with the technical findings of the audit team. In addition, the observers identified one other issue that was discussed with the audit team but not specifically discussed at the audit exit meeting. The observers noted that, when reviewed collectively, the potential deficiencies indicate a potential programmatic breakdown with the implementation of the QA Program. Specifically, deficiencies identified by the audit team included failure to revise planning documents in accordance with AP-2.13Q and AP-3.10Q, failure to maintain model information the Model Warehouse in accordance with AP-3.10Q, and failure to validate all models in accordance with AP-3.10Q. The observers were concerned that failure to follow procedures continues to be a weakness.

This problem was most recently documented by DOE in its "OCRWM QA Trend Report for Quality Program Deficiencies First Semester 2000," dated August 10, 2000. The report reviews trends for deficiencies identified between January 1, and June 30, 2000. In that report DOE states "it is concluded that the majority of this semesters issues continue to be personnel error related to failure to follow procedure and inattention to detail." The observers recommend that DOE management continue to focus attention on procedural compliance.

The following were technical findings identified by the audit team. These findings relate to technical issues in the documents reviewed and are not reflective of DOE's implementation of its QA program. These items were discussed in Section 4.5 of this report and are being highlighted again in this section to stress the observers' agreement on the importance of the issues.

4.6.1 General Technical Findings

1. Uncertainties and assumptions identified in lower tier TSPA-related level AMRs were not communicated in the successive tier documents, such as the abstraction AMRs and TSPA model report.

2. TSPA-SR model validation has not been completed nor documented with the exception of the seepage model abstraction. Model validation of scientific investigation is a requirement of the QARD.

3. Some TSPA-SR components (e.g., dissolved concentration limits) were not sufficiently integrated into the TSPA-SR model. The reports did not provide an adequate technical basis for not fully coupling the dissolved concentration limits with the in-drift geochemical environment and the in-package chemistry.

4. The conservatism of assumptions and the conservatism of selection among alternative conceptual models did not appear to be based on comparison to the peak mean dose (i.e., the risk metric). The conservative elements of the assumptions were not clearly identified, nor were they always intuitive.

5. Uncertainty was not consistently addressed in performance assessment component models stochastic analyses. When data are limited:

   - uncertainty should be assigned a high value to reflect the statistical uncertainty in the parameter,
   - conservative values should be used, and/or
   - more data should be collected to reduce uncertainty.

   In addition, the confidence in the selection of parameter ranges does not appear to have been statistically tested.

4.6.2 Specific Technical Findings

1. Analysis Model Report—Abstraction of Seepage into Drifts (ANL-EBS-000005)

   Open issues, such as those identified in NRC's IRSR and in DOE's peer review of TSPA, should be directly addressed within the content of the affected AMR.

2. Analysis Model Report—WAPDEG Analysis of Waste Package and Drip Shield Degradation (ANL-EBS-PA-000001)

   The conceptual model of the waste package has a great deal of uncertainty, particularly in terms of material properties and fundamental mechanisms of waste package corrosion. Therefore, the underlying base of data and understanding of the conceptual models may be inadequate for the purposes to which WAPDEG will be applied. The GVP, while a reasonable approach for examining the importance of variability and uncertainty in key data, should be carried through to the final results of the system performance assessment. In addition, the hypothesis of uncertainty and variability should be statistically tested for each set of data where it may be applied for Type I or II errors.

3. FEP AMR Activities

   - The status of whether the FEP database is 'quality-affecting' or not should be resolved. While the database is abstracted data from approved AMRs, appropriate control to assure consistency between the database and contributing AMRs (especially as the AMRs are revised) may be important.
   - Limited interaction between FEP AMR developers from different disciplines and between FEP AMR and 'process' AMR developers may lead to inconsistent criteria applied for including or excluding an FEP.

- The definitions for FEP inclusion and exclusion need to be clearer. Additional FEP inclusion/exclusion categories may be necessary. For example, the FEP 'radiation damage' is excluded; however, radiation damage is used as a basis for selecting amorphous phases for solubility controls.

4.6.3 Audit Observer Inquiries

No audit observer inquiries were issued.

4.6.4 Open NRC Audit Observer Inquires

No NRC audit observer inquiries were open at the conclusion of this observation.

5.0 REFERENCES

DOE/RW-0333P, "Quality Assurance Requirements Document," Revision 9.

October 2, 2000

Mr. James H. Carlson, Acting Director
Program Management and Administration
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- 00-10, "OBSERVATION AUDIT OF OFFICE OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT, QUALITY ASSURANCE DIVISION, AUDIT NO. M&O-ARP-00-07"

Dear Mr. Carlson:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report (No. OAR-00-10), 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 of activities pertaining to the Disruptive Events Process Model Report (DE PMR). The DE PMR was prepared by and the supporting activities performed by the OCRWM Management and Operating Contractor (M&O). This audit was conducted on August 21-25, 2000, at the M&O facilities in Las Vegas, Nevada.

The purpose of this performance-based audit was to evaluate the effectiveness of the implementation of the OCRWM Quality Assurance Program described in the Quality Assurance Requirements and Description document and its implementing procedures for the DE PMR and selected Analysis Model Reports (AMRs) supporting the DE PMR. There are a total of nine PMRs supporting the Site Recommendation Considerations Report (SRCR). The DE PMR was the last PMR to be audited.

The NRC observers (observers) determined that this audit was effective in identifying potential deficiencies and weaknesses, and recommending improvements for the PMR and AMRs reviewed. During the conduct of the audit, both the audit team and the observers independently reviewed applicable analysis reports and supporting data, models, and software.

Further, the observers met with the M&O personnel responsible for the qualification of data and software supporting the SRCR. As a result of these reviews and discussions, the observers determined that significant progress was being made in reaching the DOE/M&O goals of having 80 percent of the data and software fully qualified by mid-January 2001. The observers were informed that on August 25, 2000, 73 percent of the data and 89 percent of the software supporting the SRCR were fully qualified.

Although the DE PMR appeared to satisfactorily compile the results of the supporting AMRs, the OQA audit team (audit team) identified several concerns about the content of the AMRs. The observers agreed with the audit team's conclusions, findings, and recommendations as

presented at the audit exit. Within the areas evaluated, the audit team identified potential deficiencies in: a) verification of the qualifications of personnel performing PMR and AMR activities; b) adequacy of review and checking; c) identification of the conceptual basis for computer codes; and d) clarity of the purpose and intent of the igneous consequence AMR and the clarity of the AMR text interfaces to other documents. In addition, the audit team recommended numerous editorial and technical changes to correct minor errors in the documents it reviewed. The authors of these documents agreed to correct these errors.

As discussed in the attached report, the observers identified and discussed their findings during the course of the audit and at the audit exit. The most significant observer concerns pertained to: a) the need for the authors of audited documents to have appropriate personnel available during the audit to answer questions in the areas of the subject matter being audited; b) author and checker inattention to detail and c) an apparent backlog of procedure changes.

Subsequent to the audit, the NRC staff performed additional reviews of the apparent backlog of procedures and determined that several procedures have outstanding changes that need to be incorporated. Section 5.3 of the attached report provides discussion on the staff's review of the backlog of procedure changes.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Larry L. Campbell at (301) 415-5000.

Sincerely,

/RA/

Janet Schlueter, Chief (Acting)
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report No. OAR-00-10, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. M&O-ARP-00-07"

Letter to J. Carlson from J. Schlueter dated: October 2, 2000

cc: R. Loux, State of Nevada
S. Frishman, State of Nevada
L. Barrett, DOE/Wash, DC
A. Brownstein, DOE/Wash, DC
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A. Kalt, Churchill County, NV
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J. Curtiss, Winston & Strawn

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Subsequent to the audit, the NRC staff performed additional reviews of the apparent backlog of procedures and determined that several procedures have outstanding changes that need to be incorporated. Section 5.3 of the attached report provides discussion on the staff's review of the backlog of procedure changes.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Larry L. Campbell at (301) 415-5000.

Sincerely,
/RA/
Janet Schlueter,(Acting) Chief,
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report No. OAR-00-10, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. M&O-ARP-00-07"

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U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-00-10

"OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

OFFICE OF QUALITY ASSURANCE

AUDIT NO. M&O-ARP-00-07"

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/RA/ 09/29/00
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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 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 of activities pertaining to the Disruptive Events Process Model Report (DE PMR). The DE PMR was prepared by and the supporting activities performed by the OCRWM Management & Operating Contractor (M&O). This audit was conducted on August 21–25, 2000, at the M&O facilities in Las Vegas, Nevada.

The purpose of this audit was to evaluate the implementation of the applicable provisions contained in the OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 9, by evaluating the DE PMR and selected Analysis Model Reports (AMRs) supporting the DE PMR. During the audit, the PMR and selected AMRs were subjected to a technical evaluation as well as evaluation to ensure that the applicable programmatic requirements contained in the QARD and implementing procedures were met.

The NRC observers' (observers') objective was to assess whether the M&O and OQA 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 Code of Federal Regulations (10 CFR Part 60). Because of the anticipated DOE submittal of the Site Recommendation Considerations Report (SRCR) in December 2000, the following observation activities were emphasized: 1) confirming that data, software, and models supporting the SRCR are properly qualified; 2) evaluating the progress being made by DOE and its contractors in meeting the data and software qualification goals for SRCR: and 3) ensuring the technical adequacy of the PMR and AMRs within the scope of the OQA audit.

This report addresses the observers' determination of the effectiveness of the OQA audit and the adequacy of implementation of QARD controls by the M&O in the audited areas of DE PMR and AMR development.

2.0 MANAGEMENT SUMMARY

The observers generally agreed with the OQA audit team's (audit team's) conclusions, findings, and recommendations. The observers determined that OQA Audit M&O-ARP-00-07 was well planned and effectively implemented. The audit team members were independent of the activities they audited and were generally knowledgeable in the quality assurance (QA) and technical disciplines within the scope of the audit. The audit team qualifications were reviewed and the members were found to be generally qualified. However, the observers believed that certain technical aspects of the audit such as evaluating the development and content of the AMRs could have been enhanced if the individuals assigned as the technical specialists on the audit team had greater expertise in the subject matter of the AMRs. Because of the well-prepared audit checklist and experience of the technical specialists, this situation did not appear to impact the overall effectiveness of the audit.

Overall, the audit team concluded that the OCRWM QA program had been satisfactorily implemented in the areas evaluated. As a result of reviews and discussions, the observers determined that significant progress was being made in reaching the DOE/M&O goals of having 80 percent of the data and software fully qualified by mid-January 2001. The observers were informed that on August 25, 2001, 73 percent of the data and 89 percent of the software supporting the SRCR were fully qualified.

Within the areas evaluated, the audit team identified potential deficiencies in: a) verification of the qualifications of personnel performing PMR and AMR activities; b) adequacy of review and checking; c) identification of conceptual basis for computer codes; and d) clarity of the purpose and intent of the igneous consequence AMR were unclear and the clarity of the AMR text interfaces to other documents. In addition, the audit team recommended numerous editorial and technical changes to correct minor errors in the documents reviewed. The authors of these documents agreed to correct the errors.

The observers identified and discussed their findings during the course of the audit and at the audit exit. The most significant observer concerns pertained to: a) the need for the authors of audited documents to have appropriate personnel available during the audit to answer questions in the areas of the subject matter being audited (the principal authors of some of the documents reviewed did not appear to be subject-matter experts in the subject of their documents); b) author and checker inattention to detail; and c) an apparent backlog of procedure changes (several of the identified changes appear to be the results of recommendations and deficiencies identified during the conduct of the nine PMR audits).

3.0 AUDIT PARTICIPANTS

3.1 Nuclear Regulatory Commission Observers

Larry Campbell	Team Leader	NRC
John Trapp	Technical Specialist	NRC
Timothy Kobetz	QA Engineer	NRC
Brittain Hill	Technical Specialist	CNWRA
Mike Miklas	Technical Specialist	CNWRA

3.2 OQA Audit Team

Michael Goyda	Audit Team Leader	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
Robert Hartstern	Auditor	OQA/QATSS
Lester Wagner	Auditor	OQA/QATSS
Kenneth McFall	Auditor	OQA/QATSS
Chet Wright	Auditor	OQA/QATSS
James Voigt	Auditor	OQA/QATSS
Keith Kersch	Technical Specialist	SAIC
Levy Kroitoru	Technical Specialist	Golder Associates, Inc.
Eric Zwahlen	Technical Specialist	Golder Associates, Inc.

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 performed in accordance with NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

4.1 Scope of the Audit

The audit team conducted a limited-scope, performance-based audit of activities and processes related to the development of the AMRs supporting the DE PMR. Audit activities included evaluation of the DE 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. The implementation of the following procedures for the audited activities, and the preparation of the following AMRs and the DE PMR were evaluated by the audit team and the observers during the audit:

Procedures

a) AP-2.1Q, "Indoctrination and Training of Personnel," Revision 0, with Interim Change Notice (ICN) No. 0

b) AP-2.2Q "Establishment and Verification of Required Educational and Experience of Personnel," Revision 0, with ICN No. 0

c) AP-2.13Q, "Technical Product Development Planning," Revision 0, with ICN No. 3

d) AP-2.14Q, "Review of Technical Products," Revision 0, with ICN No. 1

e) AP-2.15Q, "Work Package Planning Summaries," Revision 0, ICN No. 1

f) AP-3.4Q, "Level 3 Change Control," Revision 1, ICN No. 3

g) AP-3.10Q, "Analysis and Models," Revision 2, with ICN No. 2

h) AP-3.11Q, "Technical Reports" Revision 1, with ICN No. 1

i) AP-3.14Q, "Transmittal of Input" Revision 0, with ICN No. 0

j) AP-3.15Q, "Managing Technical Product Inputs," Revision 1, with ICN No. 1

k) AP-3.17Q, "Impact Reviews," Revision 0, with ICN No. 0

l) AP-SI.1Q, "Software Management," Revision 2, with ICN No. 4

m) AP-SIII-1Q, "Scientific Notebooks," Revision 0, with ICN No. 1

n) AP-SIII.2Q, "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data," Revision 0, with ICN No. 2

o) AP-SIII.3Q, "Submittal and Incorporation of Data to the TDMS," Revision 0, with ICN No. 3

p) AP-SV.1Q, "Control of the Electronic Management of Data," Revision 0, with ICN No. 1

q) QAP-2.0, "Conduct of Activities," Revision 0

r) QAP 16.1Q, "Management of Conditions Adverse to Quality," Revision 4, with ICN No. 1

s) QAP-18.1Q, "Auditor Qualification," Revision 6, with ICN No. 0

t) QAP-18.2Q, "Internal Audit Program," Revision 8, with ICN No. 0

PMR

a) TDR-NBS-MD-000002, "Disruptive Events Process Model Report," Revision 00, with ICN No. 1

AMRs

a) ANL-WIS-MD-000005, "Disruptive Events Features, Events, and Processes" (T00010), Revision 00

b) ANL-WIS-MD-000017, "Igneous Consequence Modeling for Total System Performance Assessment for Site Recommendation" (T0070), Revision 00

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 DE 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 each morning 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, experience, and annual evaluation records of the audit team members. As a result of these reviews, one item was identified and discussed with the audit team regarding the subject matter experience of the technical specialists on the audit team.

For some aspects of the audit, certain technical specialists appeared to have difficulty in evaluating the sufficiency of the technical basis for much of the data and models presented in the audited documents. In these areas, a number of the quality-affecting technical questions were asked by the observers and not by the technical specialists. The observers noted that

several of the previous PMR audits used technical specialists who had in-depth experience and education regarding the audited subjects.

For example, the audit team technical specialist assigned to AMR T0070 had no documented education or experience in modeling igneous processes. On occasion, the observers needed to explain or clarify many fundamental processes and data associated with igneous processes outlined in the AMR. The scope of audit team's questions, however, included the primary QA concerns of the NRC audit team.

The observers concluded that the inclusion of technical specialists on the audit team with specific in-depth subject-matter expertise and education or experience in the audited subjects would have enhanced the focus of questions and resulted in a better audit team evaluation of the responses given. The observers recommend that for future performance-based audits, OQA attempt to obtain the services of technical specialists having greater experience in the subject matter being audited.

4.4 Examination of QA Elements

The OQA programmatic and technical audit activities were conducted simultaneously using sub-audit teams consisting of at least one technical specialist and one QA auditor. The limited-scope audit focused on the QA elements closely associated with the development of the AMRs. The observers evaluated the audit team's review of the following QA elements.

4.4.1 AP-2.13Q, "Technical Product Development Planning"

The audit team reviewed technical development plans and work product planning sheets applicable to the subject AMRs. In addition, the audit team reviewed the methodology for the product development, including the tracking of unresolved issues such as inputs requiring qualification, to be verified (TBV). The audit team determined that Technical Development Plan, TDP-WIS-MD-000023, for AMR T0070, was unclear if the ASHPLUME code (a code used for volcanic eruption and transport of ash and radioactive waste particles in a plume to a specified location) work was to be performed in AMR T0070 or somewhere else. The text of the technical development and AMR T0070 implied that it would control the development of the code, but it was found that the development of the code was outside the scope of the AMR. The relationship between AMR T0070 and related activities was not clearly defined for the AMR. Further, because the AMR T0070 purpose was unclear relative to the activities performed, the audit team concluded that AMR T0070 did not comply with several of the provisions contained in AP-3.10Q and identified this condition as a potential deficiency. The observers agreed with this potential deficiency.

4.4.2 AP-SI.1Q, "Software Management"

Software controls associated with the DE PMR and AMRs were discussed during each of the technical interviews. The audit team reviewed qualification documentation and determined that the requirements of the software management procedure had been met for the ASHPLUME code. However, the audit team identified that the conceptual basis for ASHPLUME needed to be established. The audit team identified this as a potential deficiency. The observers agreed with the audit team's finding. In addition, during the conduct of the audit, the observers provided the following discussion on the qualification status of the ASHPLUME code:

There was a lack of demonstrable validation for key models that will support the DOE Total System Performance Assessment-Site Recommendation (TSPA-SR). Specifically, there was no documentation available to indicate that the tephra-dispersion model ASHPLUME 1.4LV can reasonably represent dispersal of tephra from an erupting basaltic volcano representative of the Yucca Mountain region (YMR). A review of AMR T0070 indicated that the current DOE implementation of ASHPLUME 1.4LV and associated parameters may underestimate the dispersal capabilities of YMR-type volcanoes. Subsequent to the audit, these topics were discussed with appropriate staff during the August 29–31 Technical Exchange on Igneous Activity.

Informal discussions between the observers and the M&O staff revealed that work toward model validation was ongoing for the tephra-dispersion model. This work focused on comparing results from the current version of ASHPLUME with data from the 1995 Cerro Negro eruption, Nicaragua. The M&O staff also acknowledged the need to validate the high-level waste (HLW) incorporation model, although additional effort is needed to develop an effective work plan for this validation.

The M&O stated that it considered ASHPLUME 1.4LV a validated code. The observers discussed a significant concern because the DOE procedures appear to allow a software code to be considered validated without demonstration that the model used to develop the software has been validated. Information obtained during this audit demonstrated that the models used by ASHPLUME 1.4LV for the dispersal of volcanic tephra containing high-level waste have not been validated as required by DOE AP-3.10Q. The lack of model and software validation is a continuing concern raised by the audit team and observers during previous PMR audits.

The lack of a conceptual model to support the validation of ASHPLUME 1.4LV was identified as a potential deficiency by the audit team. The observers agreed with the audit team findings in this area. However, the observers believed that the procedural controls for determining when a computer code, such as ASHPLUME, is validated needs to be assessed based on the above discussion.

4.4.3 AP-3.15Q, "Managing Technical Product Inputs"

Each of the AMRs examined included document input reference sheets that list the inputs to and references cited in the AMR. The document input reference sheets also identify the status of the input (e.g., qualified, TBV). The audit team examined the TBV status and determined that it generally included the appropriate statements in accordance with the Analysis/Model Documentation Outline. The audit team identified one potential deficiency in this area that addressed a noncompliance with AP-3.15Q: the Document Information Retrieval System (DIRS) input was inconsistent with the Automated Technical Data Tracking (ATDT) data base information (e.g., TBVs were identified as open when they were closed). Editorial errors found in AMRs caused additional confusion during the audit relative to data identification. These errors were addressed and resolved during the audit. The observers agreed with the audit team findings in this area.

4.4.4 AP-3.10Q, "Analysis and Models"

Procedure AP-3.10Q was used by the audit team to evaluate the activities covered during the audit. By definition, 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.

The audit team generally concluded that the requirements of Procedure AP-3.10Q had been appropriately implemented for AMR T00010. However, a potential deficiency was identified because several examples were identified where AMR T0070 failed to meet the provisions contained in AP-3.10Q. Specifically, the audit team determined that the AMR T0070 failed to comply with AP-3.10 Q because: a) there was inadequate review and checking; b) there was a lack of a conceptual basis for the ASHPLUME code; c) the relationships between the AMR and related activities were not clearly defined; and d) the AMR purpose was unclear relative to the activities performed. The observers agreed with the audit team findings.

4.4.5 AP-2.14Q, "Review of Technical Products"

The observers held discussions with cognizant individuals in the Data/Software Qualification Department and reviewed selected data tracking number (DTN) sets to gain insights into the verification methodology to resolve TBVs. As a result of reviews and discussions, the observers determined that significant progress was being made in reaching the DOE/M&O goals of having 80 percent of the data and software fully qualified by mid-January 2001. The observers were informed that on August 25, 2000, approximately 73 percent of the data and 89 percent of the software supporting the SRCR were fully qualified.

4.5 Examination of Technical Activities

The technical specialists on the audit team performed detailed reviews of the technical adequacy of the subject DE PMR and AMRs. The observers assessed the audit team's performance of these reviews and were provided an opportunity to perform a review of the technical adequacy of the documents subject to the audit.

As discussed in the following paragraphs, the observers identified and discussed a concern with the audit team about the qualifications of the PMR and AMR authors and checkers. The audit team investigated the observers' concern regarding the qualification of the authors and checkers.

The audit team determined that there was no objective evidence that the responsible manager for the AMRs and PMR ensured that position descriptions were established for the author and checkers. Thus, the qualifications for these individuals were not verified by the M&O, as required by AP-2.2Q. This condition was identified as a potential deficiency.

The technical specialists on the audit team evaluated activities and processes supporting the development of the DE PMR. The technical specialists used a combination of technical questioning and programmatic compliance checks to verify AMR technical adequacy and QA program effectiveness. The technical activities were evaluated using three evaluation criteria pertaining to transparency; traceability; and defensibility.

In addition to the audit team findings, the observers identified concerns related to the PMR and AMRs, which are described in Sections 4.5.1 through 4.5.3, of this report. The observers presented and discussed their concerns with the audit team during the conduct of the audit and certain concerns were discussed again during the audit exit. Section 5.2 of this report identifies the concerns that the observers presented during the audit exit.

4.5.1 Process Model Report, PMR No. TDR-NBS-MD-000002, "Disruptive Events Process Model Report," Revision 00 with ICN No 01

The DE PMR is a summary document having the primary purpose of collecting information from various supporting AMRs into one document. In addition, the DE PMR provides the DOE's evaluation of the status of the various NRC key technical issues (KTIs) that relate to disruptive processes and events.

Throughout the audit process, it was evident to the observers that the primary author for the DE PMR was more of a project manager than a technical expert in the subject matters contained in the DE PMR. The observers informed the audit team that one of their primary concerns was that neither the author nor the checker had their primary training and experience in the disruptive events featured in the DE PMR. The audit team asked several questions about the technical content of the DE PMR and in certain instances the person responding was unable to answer questions. The following are examples where the response indicated an unfamiliarity in the subject matter being discussed.

a) The audit team asked questions about the use of the Phi grain-size scale, and the DE PMR author was unable to provide a meaningful response.

b) The DE PMR author was asked about an apparent contradiction between Figure 3-2, the text [on various topics, including volcanism and seismic activity, the author deferred to the original authors of the technical discussion contained in the features, events, and processes (FEP) analysis, as the persons who should be queried for responses to various technical questions], and Table 3-4; the author's response indicated that the author did not fully understand the subject matter.

c) Pages 3-5 and 3-6 of the PMR discussed the number of subsurface intrusions associated with a volcano, which is summarized from the "Characterize Framework for Igneous Activity" AMR. This report concluded that essentially one intrusion was associated with each new volcano in the Yucca Mountain Region (YMR). On Page 3-16, however, information summarized from the "Characterize Eruptive Processes at Yucca Mountain, Nevada" AMR, stated that the number of dikes associated with formation of a new volcano should follow a log normal distribution with a minimum of 1, mean of 3 and 95th percentile of 10. Neither the author nor checker recognized this contradiction.

As discussed in Section 4.5 of this report, the audit team determined that no objective evidence could be found to indicate that M&O management had reviewed the qualifications of the primary author and checker assigned to the DE PMR. The observers concluded that the quality of the PMR may have been impacted because of this omission. Further, as discussed in various sections of this report, the audit team found that the technical reviewer for the DE PMR had overlooked several administrative errors. The technical reviewer acknowledged that he had

overlooked several changes made to the document in the late stages of its development. In addition, the responsibilities of the document checker, which included assuring the technical adequacy of the document, did not appear to have been satisfied. The observers concluded that the checker's failure to recognize and correct these types of errors may have been the result of an inappropriate technical background in the subject area. The audit team discussed its belief that the presence of such mistakes should have been identified and corrected by the checking process. Further, the audit team discussed that although it was not entirely clear, it appeared some errors found by the designated checker were either not corrected, or were incorrectly incorporated, into the DE PMR. The observers concurred with the audit team suggestion that the checking process was deficient.

The observers and the audit team discussed their belief that either the procedure, which governs the selection of authors and checkers based on technical competencies, was flawed or that the proper implementation of an acceptable procedure did not occur.

The audit team noted that although several computer codes were listed in Section 1.3 of the DE PMR, the analyses contained in the document used none of these codes. The observers suggested that only codes actually used by the author(s) in their analysis should be included in Section 1.3.

The observers concurred with the audit team that reference to basalt in the YMR as being no older than 11 million years is erroneous and should be corrected to account for older basalts that are found in the region.

The audit team found that although TSPA-Viability Assessment (VA) workshops were mentioned in the DE PMR, the workshops were not referenced. The observers agreed with the audit team finding that when information from workshops was used to produce information contained in the DE PMR, the use of the workshop should be documented in the DE PMR. Of particular interest was the documented rationale for the selection of certain FEPs to be included and analyzed in the DE PMR document

The audit team identified a concern with the reliance of certain exclusion arguments on the presence of backfill. The observers accepted the author's response that ICN No. 02 of the DE PMR will evaluate the "no-backfill" case, whereas DE PMR, Revision 00, with ICN No. 01, will remain the same and be considered the "backfill" case. The observers agreed with the audit team that the M&O should clarify in each document what design is used to support the conclusions contained in the documents.

The audit team identified a significant concern with the screening and exclusion of post-closure seismic FEPs at inappropriate levels of annual probabilities of recurrence. Numerous FEPs were excluded based on peak ground accelerations for an earthquake with an annual recurrence of only 10^{-4}. In contrast, 10 CFR Part 60 and 10 CFR Part 63 as proposed, both require performance evaluation of events with annual probabilities $\geq 10^{-8}$. It was discussed that peak ground accelerations are likely to increase significantly as the annual probability of recurrence decreases from 10^{-4} to 10^{-8}. Thus, consequences were evaluated and FEPs excluded using peak ground acceleration values that were inappropriately low. Although this topic will be discussed in detail at the next technical exchange involving seismicity, the observers briefly discussed that more explicit linkage is needed between the results of that technical exchange and updates to the FEPs' screening arguments and documentation.

The audit team and the observers found that the executive summary of the DE PMR contained the following statement: "The Disruptive Events PMR outputs are adequate for the intended use as input to TSPA-SR." However, the conclusions stated: "This Disruptive Events Process Model Report provides support for the conclusion that the analyses and calculation supporting this report were conducted and documented under the appropriate QA procedures and other project requirements and that they produced results that are adequate for the intended purpose of supporting analysis of the potential hazards of disruptive events during the TSPA-SR modeling." The NRC observers agreed with the audit team that it was not clear what conclusions and outputs were derived from the DE PMR, nor how these outputs will be incorporated in and used by the TSPA.

The observers identified a concern about incorrect quoting of previously documented NRC statements contained in the DE PMR. For example, page 4-17 of the DE PMR contains the following quote from the Igneous Activity Issue Resolution Status Report (IRSR): " . . . the staff repeated the observation that the use of both a $1.5X10^{-8}$ and a 10^{-7} annual probability for volcanic eruption in calculations would be acceptable." The exact quote in the IRSR was "While the staff consider that this value ($1.5x10^{-8}$) is at the low end of the range of acceptable probability values, if used by the DOE in performance assessment, along with analysis at 10^{-7} that would demonstrate the effect that this range in probability values has on the overall risk, the NRC would have a basis to resolve its questions concerning this acceptance criterion." Another example was found on page 4-23, where the DE PMR states "In summary comments on this criterion, the NRC staff stated that the expert elicitation supporting the PVHA (CRWMS M&O 1996) was consistent with the Branch Technical Position . . . ." In the Igneous Activity IRSR, the statement is "While there were areas of weakness, the probability hazard assessment elicitation (Geomatrix, 1996) is generally consistent with the BTP . . . ." The observers were concerned that such quotes in the DE PMR are incorrect, and that ineffective checks were performed to assure that material quoted was correct in content.

4.5.2 Analysis Model Report, AMR No. ANL-WIS-MD-000005, "Disruptive Events Features, Events and Processes," (T0010)

The observers assessed the audit team interviews of the technical reviewers for AMR T0010. Many of the concerns of the audit team were acknowledged by the author, who explained that most of the audit team's concerns were already addressed in the ICN 01 version of the AMR that is currently in internal review. Some of the suggestions of the audit team, which were new to the author, led the author to note that he would make a significant effort to respond to technical comments and suggestions in the ICN 01 revision of AMR T0010. The observers' discussion of ICN 01 with the author indicated that ICN 01 will be a significant improvement over the current document.

The audit team found that there were originally 26 disruptive event FEPs included in the AMR T0010. Five of these FEPs were subsequently assigned to other areas. The audit team questioned the basis for these reassignments and the basis for the selection of the original 26 FEPs. The author did not know if there was a document that described the FEPs' selection and assignment process. Subsequent questioning revealed that it there seems to be no documentation for these selections and reassignment. This lack of transparency and traceability represents a potential deficiency in the document production and review process provided in AP-3.10Q.

The audit team found that the technical basis for many of the screening arguments lacked sufficient depth. The audit team and the observers believed that this condition may be the result of combining several different authors' work into a single document. The observers concurred with the audit team in suggesting that document integration procedures require that the level of technical discussion be similar throughout the document.

Several computer codes, such as WAPDEG, DRKBA, and UDEC were discussed in AMR T0010. The author had not used the codes in his analyses but merely reported on other authors' use of the codes. AMR T0010 did not list the codes in Section 1.3, "Quality Assurance for Disruptive Events Analyses and the Disruptive Events Process Model Report". The observers concurred with the audit team in recommending that the DOE be consistent in its description and incorporation of codes and computer-generated information in summary documents such as this AMR.

There was some confusion generated by AMR T0010 (also in the DE PMR) on the meaning of "low consequence" when used in a screening argument. The author's definition of "low consequence" included the notion of risk where the probability of an event is multiplied by the expected consequence and the resulting small change in dose is used as a consequence argument to screen out some FEPs from further consideration. The "low-consequence," argument relied on a qualitative rather than a quantitative assessment of the likely risk for the FEP. In addition, the author, at times, used low-probability and low-consequence concepts interchangeably for some FEPs' screening arguments. The observers agreed with the audit team that the "low-consequence" definition, and perhaps the name, itself, should be clarified such that low consequence is explicitly related to dose and not to the usual definition of consequence (e.g., the actual effect of some significant geologic event such as a major earthquake). The audit team and observers suggested that "low consequence" might be renamed "low-dose consequence" to affirm the relationship of the particular exclusion argument to dose. The author committed to clarifying the confusion in proposed ICN No. 01 to AMR T0010 that is currently in review.

The audit team identified a concern with some FEP exclusion arguments depending on the presence of backfill in the screening argument. The observers accept the author's response that ICN 01 to AMR T0010 will be the document that evaluates the "no-backfill case," whereas AMR T0010, Revision 00, with ICN 00, will remain the same and will be considered the "backfill case." The observers agreed with the audit team that it should be made clear in each document what design is in place for the document conclusions to be valid.

The audit team noted that there is an implication, in AMR T0010, that geothermal activity is not present at or near Yucca Mountain. Recent shallow drill holes about 15 km from Yucca Mountain contained water at elevated temperatures (20-35°C). The author indicated he would revise the discussion in this section. The observers concurred with the need for revision.

The audit team found that there were a few TBV items, in the screening arguments, that were not complete. The author was not clear on how the information from the completed TBVs will be integrated into future revisions (if any) of the screening arguments, or if a screening argument was substantially affected, how that effect will be integrated through the system.

The audit team questioned the status of the update of the FEPs' IRSR issues. The author indicated that he would be placing a table in the proposed ICN No. 1 to AMR T0010, which will

update the IRSR issues. The observers concurred with the placement of IRSR issue-resolution updates in this AMR revision. The audit team also identified many editorial corrections for the AMR. The observers agreed with the audit team findings.

4.5.3 Analysis Model Report, AMR No. ANL-WIS-MD-000017, "Igneous Consequences Modeling for Total System Performance Assessment for Site Recommendation," T0070

This AMR described the conceptual models and associated parameters used to evaluate the consequences of igneous events that interact with the proposed repository systems. The primary emphasis of this report was to describe the model and parameters used to represent airborne transport of high-level waste in a volcanic eruption. This AMR relies heavily on data derived from the Characterize Eruptive Processes at Yucca Mountain, Nevada AMR.

The following sections of this report provided additional discussion on the audit team's and observers' findings in their review of AMR T0070: a) Section 4.4.2 of this report discusses the qualification of the ASHPLUME software; b) Section 4.3 discusses the qualification of the technical specialists on the audit team assigned to review this AMR; c) Section 4.4.1 discusses the technical planning; and d) Section 4.5 discusses the qualification of the authors and checkers.

The observers assessed the audit team interviews of the technical reviewers for AMR T0070. With respect to AMR T0070, the audit team found that the reviewer had missed several technical, as well as administrative, errors. The technical reviewer acknowledged that the errors were the result of oversight. In addition, the technical reviewer stated that he was not able to confirm that all Data Tracking Numbers (DTNs) had been entered in the Technical Data Tracking System (TDMS), because he was located remotely from the contractor's office and did not have access to the TDMS. However, the technical reviewer acknowledged that he could have reviewed the TDMS at the Sandia National Laboratory near his office.

In this instance, access to the TDMS would not have provided useful information to the technical reviewer because the data for that ARM were still being controlled in accordance with AP-3.14Q, "Transmittal of Input." The technical reviewer acknowledged that he had confirmed that the appropriate DTNs were being controlled by AP-3.14Q. However, the audit team was concerned that this may not be an isolated issue. There are numerous technical reviewers working at remote locations who may also have problems accessing the TDMS. The observers agreed with this concern.

A calculation document, "Number of Waste Packages Hit by Igneous Intrusion," CAL–WIS–PA–000001, Rev 00, was added later to the audit to evaluate the implementation of QA requirements for documentation of calculations. NRC did not observe the checking of the spreadsheet calculations contained in this AMR.

As a result of reviewing AMR T0070, the audit team and the observers identified the following significant concerns:

a) The AMR planning document and Section 1 of the AMR stated that a primary goal of this AMR was to develop models for igneous-activity consequence modeling. The AMR contained little documentation on the development of the ASHPLUME 1.4LV tephra-

dispersion model, and no evidence that DOE AP 3.10Q requirements for model development and validation had been implemented for the tephra-dispersion model in the AMR. Section 4.4.2 of this report provides additional observer discussion on the validation of ASHPLUME 1.4LV.

b) Modeling assumptions regarding the incorporation and dispersal of HLW into an erupting volcano also appeared to be inadequately supported in the AMR. There was no evidence presented that the AP 3.10Q requirements for development and validation for the HLW incorporation model were implemented.

c) This AMR author's technical background and experience appeared to be insufficient to answer a number of the audit team's questions. These questions included basic information on igneous processes, function of parameters in models, and possible modifications to the ASHPLUME 1.4LV model.

d) Wind-speed characteristics used to model eruption plumes were inappropriate for the altitudes of concern and may have significantly underestimated the extent of eruption dispersion. In addition, readily available data more appropriate for modeling these events were not used in the AMR.

e) Numerous editorial problems persisted in this AMR, including incorrect DTN references, lack of DTNs for some data, figures inconsistent with statements in text, vague statements in support of model or parameter conservatism, and lack of support for some conclusive statements.

As a result of the numerous technical and administrative errors in AMR T0070, the audit team considered the errors, collectively, to be a potential deficiency for failure to effectively implement DOE/RW-0333P, "Quality Assurance Requirements and Description," Revision 10, Step 2.2.10 (A). Among other things, this step required the technical reviewers to review the PMR and AMR for correctness, technical adequacy, completeness, and accuracy. The observers agreed with this finding.

5.0 NUCLEAR REGULATORY COMMISSION STAFF FINDINGS

The observers determined that OQA Audit M&O-ARP-00-07 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 observers concluded that the technical quality and completeness of the scientific products contained in the AMRs are areas that need to continue to improve. The following sections address the observers' findings.

5.1 NRC Audit Observer Inquiries

No NRC audit observation inquiries (AOIs) were generated during this audit. Presently, there are no open AOIs.

5.2 NRC Observer Findings

In addition to the audit team's findings, the observers presented the following during the audit exit meeting:

a) The observers found that certain technical aspects of the development and content of the AMRs, as well as the audit process, could have been enhanced if the individuals involved had been subject matter experts in the areas audited.

b) There appeared to be a backlog of procedure changes to address problems and recommendations identified during the previous eight PMR audits. The significance and impact of this backlog should be assessed by the DOE and M&O.

c) There were a considerable number of verbal agreements made during the conduct of the audit to correct technical and editorial errors in the documents reviewed by the audit team. The authors of these documents agreed to correct several of the identified errors. The observers expressed a concern about the method used to capture, track, and bring to closure these agreements because it was unclear how this would be accomplished.

d) As a result of audit team concerns with editorial comments being made on all the documents being reviewed, the M&O acknowledged that recently a Performance Enhancement Review Group (PERG) process had been initiated and employed by the M&O to provide additional review of documents before they are released. The PERG performs technical and editorial reviews to correct errors. This attempt by the M&O to enhance the quality of their final products is strongly encouraged by the NRC observers.

5.3 Backlog of Procedure Changes

During the conduct of the previous eight PMR audits, the audit teams and the observers identified concerns with the need for clarification and the lack of detail in administrative procedures. Again, during Audit M&O-ARP-00-07, the observers discussed similar concerns with M&O management and the OQA staff. During these discussions, both the M&O and OQA stated that they were aware of the problems with several administrative procedures and were in the process of revising them.

The observers specifically discussed concerns that, AP-3.10Q, "Analysis and Models," and AP-3.11Q, "Technical Reports," did not have a direct reference to AP-3.17Q, "Impact Reviews." The M&O and OQA both acknowledged that these procedures should clearly state that all AMR and PMR changes are to receive impact reviews. In addition, the M&O stated that its staff was currently preparing revisions to AP-3.10Q and AP-3.11Q to address this issue. OQA further stated that a Document Action Request (DAR) may have been generated to update AP-3.17Q to clarify when impact reviews should be performed.

The observers reviewed the DAR database and found three DARs (DAR 22761, dated 9/1/99; DAR 24373, dated 1/25/00; and DAR 24983, dated 2 /25/00) to update AP-3.17Q. The observers noted that one of the DARs pertained to the issue discussed above. However, the observers were concerned that, although the DARs were identified as "Accept for Immediate Action," two were approximately six months old and one was 1 year old.

AP-3.17Q was originally issued on June 16, 1999, and has not been revised since its initial issue date. In addition, the observers found several DARs for AP-3.10Q and AP-3.11Q. However, none discussed revisions to clarify the need to perform impact reviews.

During the conduct of the nine PMR audits, OQA identified numerous recommendations related to the technical completeness and adequacy of administrative controls associated with the analytical modeling and process model development programs. These recommendations, which required responses from the audited organizations, typically involved procedural implementation and/or technical adequacy issues. For those recommendations that resulted in proposed procedural changes, DARs were initiated in accordance with procedure AP-5.1Q, "Plan and Procedure Preparation, Review, and Approval."

Subsequent to the audit, the NRC staff performed additional reviews of the apparent backlog of procedure changes by reviewing the DAR log, and determined that several procedures have outstanding changes that need to be incorporated. To evaluate the effectiveness of the corrective actions associated with the resolution of the OQA audit recommendations, the NRC observers reviewed the outstanding DARs for a selected sample of administrative procedures identified in Section 4.1 of this report. As a result of this review, the NRC observers noted several examples of DARs which, although they had been accepted for immediate action, remained open for a prolonged period of time (e.g., 6-12 months). The results of this review were as follows:

> The NRC On-Site Representatives (ORs) reviewed the status of approximately 30 additional DARs associated with an expanded sample of 12 administrative procedures. As a result of this review, the ORs determined that numerous DARs that had been approved for immediate action, concerning substantive revisions to administrative procedures, had remained unincorporated for extended periods of time, with some remaining open for over a year. Examples of these DARs included: a) software qualification (DAR-23718, dated 1/26/00); b) tracking of inputs for TBV/To Be Determined assignments, (DAR-22866, dated 9/21/99); c) conflicting terminology related to accepted data (DAR-24395, dated 1/25/00); d) coordination of impact reviews (DAR-22761, dated 9/8/99); e) electronic data management control, (DAR-22576, dated 8/25/99); f) control of scientific notebooks (DAR-22374.dated 8/10/99); g) and the submittal of data as QA records (DAR-24368, dated 2/10/00).
>
> The ORs discussed the status of these DARs with representatives from OQA. Based on these discussions it was ascertained that the DAR data base incorrectly identified at least two of the DARs as being open (i.e., DAR-24667 and DAR-22769) when, in fact, the required actions had been completed and the DARs should have been closed. Nevertheless, the failure to address these DARs in a timely manner is of concern because the effective remediation of these issues, many of which directly impact the quality of technical products, may also impact the viability of the site recommendation process.

The observers are concerned that when DARs are initiated, the procedural changes do not appear to be made in a timely manner. The lack of timeliness, in making changes, to administrative procedures, appeared to be a generic issue.

5.4 Audit Team Findings Presented at the Audit Exit Meeting

The observers agreed with the results of the audit as identified by the audit team at the exit meeting. Three Potential Deficiency Reports were identified as follows:

a) DIRS inputs were inconsistent with the ATDT database (i.e., TBVs open vs closed);

b) There was no evidence that the responsible manager ensured that position descriptions were established and qualifications verified for certain authors and checkers;

c) The igneous consequence modeling for the AMR T0070 did not comply with AP–3.10Q because: 1) there was inadequate review and checking; 2) the conceptual basis for ASHPLUME is needed; 3) the relationships between the AMR T0070 and related activities were not clearly defined; and 4) the AMR T0070 purpose was unclear relative to the activities performed.

The audit team made the following three recommendations:

a) Assure that individuals performing checking at remote locations have access to the M&O Intranet (TDMS) during reviews.

b) In AMR T0010, the documentation for FEPs' selection basis and the discussion on screening decisions needs to be improved.

c) DE PMR should be revised to reflect a more accurate statement regarding the beginning of Basaltic Volcanism activity.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 17, 2000

Mr. James H. Carlson, Acting Director
Program Management and Administration
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- 00-09, "OBSERVATION AUDIT OF OFFICE OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT, QUALITY ASSURANCE DIVISION, AUDIT NO. M&O-ARP-00-08"

Dear Mr. Carlson:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report No.OAR-00-09 of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), audit of the Near Field Environment (NFE) Process Model Report (PMR) activities performed by the OCRWM Management and Operating Contractor (M&O). The audit, M&O-ARP-00-08, was conducted on July 24-28, 2000, at the M&O facilities in Las Vegas, Nevada.

The scope of the audit was limited to evaluating the effectiveness of the implementation of the OCRWM Quality Assurance Program described in the "Quality Assurance Requirements and Description" and its implementing procedures for selected analysis model reports (AMRs) supporting the NFE PMR.

The NRC observers determined that OQA Audit M&O-ARP-00-08 was effective in determining the level of compliance of M&O activities associated with the NFE PMR. The NRC observers agreed with the audit team's conclusions, findings, and recommendations as presented at the audit exit. Within the areas evaluated, the audit team identified potential deficiencies in: a) software routines not containing sufficient information; b) input data and assumptions not being clearly stated and justified; and c) the scope of the CAL (Calculation) document exceeded that allowed by the procedure.

As discussed in the attached report, the observers identified and discussed their findings during the course of the audit. The most significant observer concern is that certain aspects of the two AMRs and the one CAL audited were found to be technically insufficient for either the intended purpose or for supporting the stated conclusions. The specific potential deficiencies and/or recommendations are detailed in the sections pertaining to the individual AMRs and CAL. The DOE audit team Technical Specialists identified these potential deficiencies and/or recommendations and brought them to the attention of the originators, and the NRC staff concurred with those findings. The NRC observers generated no audit observer inquiries (AOIs) during this audit.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Ted Carter of my staff at (301) 415-6684.

Sincerely,

/RA/

Janet Schuleter, Chief (Acting)
High-Level Waste and Performance
Assessment Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report No. OAR-00-09, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. M&O-ARP-00-08"

cc: See attached list.

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2) This document is related to the HLW program. It should be placed in the LSS THC 9-22-00 (Initials) (Date)

Letter to J. Carlson from J. Schlueter dated: October 17, 2000

cc: R. Loux, State of Nevada
S. Frishman, State of Nevada
L. Barrett, DOE/Wash, DC
A. Brownstein, DOE/Wash, DC
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J. Kessler, EPRI
D. Duncan, USGS
R. Craig, USGS
W. Booth, Engineering Svcs, LTD
J. Curtiss, Winston & Strawn
J. Curtiss, Winston & Strawn

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Ted Carter of my staff at (301) 415-6684.

Sincerely,

Janet Schlueter, Chief (Acting)
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report No. OAR-00-09, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. M&O-ARP-00-08"

cc See attached list.

U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-00-09

OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE DIVISION

AUDIT NO. M&O-ARP-00-08

10/16/00
Ted Carter
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

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Lauren Browning
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Reviewed and Approved by:

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Enclosure

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), Yucca Mountain Quality Assurance Division performance-based audit of the Near Field Environmental (NFE) Process Model Report (PMR) activities performed by the OCRWM Management & Operating Contractor (M&O). The audit, M&O-ARP-00-08, was conducted on July 24-28, 2000, at the M&O facilities in Las Vegas, Nevada.

The objective of this audit was to evaluate the implementation of the applicable provisions contained in the OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 8, by reviewing selected Analysis Model Reports (AMRs) and other documents supporting the NFE PMR. During the audit, selected AMRs and a Calculation (CAL) document were subjected to a technical and programmatic review to ensure that the applicable requirements contained in the QARD were met.

The NRC staff objective was to gain confidence that the M&O and OQA 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 Consideration Report (SRCR) in December 2000, the following observation activities were emphasized: (1) confirming that data, software, and models supporting the SRCR are properly qualified; and (2) reviewing the progress being made by DOE and its contractors in meeting the qualification goals for SRCR.

This report addresses the NRC staff determination of the effectiveness of the OQA audit and the adequacy of implementation of QARD controls by the M&O in the audited areas of AMR development.

2.0 MANAGEMENT SUMMARY

The NRC staff has determined that OQA Audit M&O-ARP-00-08 was useful, effective, and conducted in a professional manner. Audit team members were independent of the activities they audited and appeared to be knowledgeable in the quality assurance (QA) and technical disciplines within the scope of the audit. The audit team members' qualifications were reviewed and the members were found to be qualified in their respective disciplines.

The audit team concluded that the OCRWM QA program had been satisfactorily implemented in the areas evaluated. However, five potential deficiencies were identified during the audit, and approximately 27 recommendations were offered for improvements and enhancements to the AMRs. Within the areas evaluated, the audit team identified potential deficiencies in: a) software routines not containing sufficient information; b) input data and assumptions not being clearly stated and justified; and c) the scope of the CAL document exceeded that allowed by the procedure. The NRC staff determined that this audit was effective in identifying the deficiencies and recommending improvements in the AMRs. The NRC staff also agrees with the audit team conclusions, findings, and recommendations.

3.0 AUDIT PARTICIPANTS

3.1 Nuclear Regulatory Commission Observers

Ted Carter	Observer (Team Leader-NRC)
Debra Hughson	Observer (Technical Specialist-CNWRA)
Lauren Browning	Observer (Technical Specialist-CNWRA)
Goodluck Ofoegbu	Observer (Technical Specialist-CNWRA)

3.2 OQA Audit Team

Robert Hartstern	Audit Team Leader	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
Steve Harris	Auditor	OQA/QATSS
Richard Weeks	Auditor	OQA/QATSS
Chet Wright	Auditor	OQA/QATSS
William Roberds	Technical Specialist	DOE/MTS
David Sassani	Technical Specialist	DOE/MTS

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 the NRC draft procedure, "Conduct of Observation Audits," issued October 6, 1989 (Draft).

4.1 Scope of the Audit

The audit team conducted a limited-scope, performance-based audit of activities and processes related to the development of the AMRs supporting the NFE PMR. AMRs, software, and data were evaluated during the audit process. The audit included review of the programmatic controls governing the AMRs and technical issues discussed in the AMRs. Specifically, the following two AMRs and one CAL supporting the NFE PMR were reviewed by the audit team and the NRC observers during the audit:

Analysis Model Reports

- N000 Thermal Tests Thermal-Hydrological (TH) AMR (ANL-NBS-TH-000001), Rev 00
- N0120 Drift-Scale Coupled Processes Models (Drift Scale Test (DST) and TH-Chemical Seepage) (MDL-NBS-HS-000001), Rev 00

Calculation

- CAL-NBS-MD-000002-00: Premeability Change Due To Coupled TH-Mechanical Effects, Rev 00 (Tracking Number - N0C30)

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 M&O and DOE programs and procedures. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit. The NRC staff believes the timing of the audit was appropriate for the auditors to evaluate the effectiveness of the analyses and models process for the NFE PMR and the quality of resultant end products.

The DOE audit team and NRC observers caucused at the end of each day. Also, meetings of the audit team and M&O management (with the NRC observers present) were held each morning to discuss the current audit status and preliminary findings.

4.3 Audit Team Qualification and Independence

The qualifications of the DOE audit team leader and the OQA audit team members were found to be acceptable in that they met the requirements of QAP 18.1, "Auditor Qualification," as verified by the NRC observation audit lead. The audit team members did not have prior responsibility for performing the activities they audited. In addition, training, education, and experience records for audit team members were reviewed and found acceptable. Further, the NRC observer reviewed the technical specialists' qualifications (resumes) and found that the technical specialists had sufficient technical education, training, and experience related to the AMRs reviewed.

4.4 Examination of QA Programmatic Elements

The OQA programmatic and technical audit activities were conducted simultaneously, using sub-audit teams consisting of a technical specialist and a QA auditor. The limited-scope audit focused on the QA elements closely associated with the development of the AMRs. The NRC staff observed that each of the auditors reviewed related documentation and interviewed a representative sample of M&O personnel to determine their understanding of implementing procedures and processes. Training, education, and experience records were reviewed to assure M&O personnel were in compliance with their individual position descriptions. Objective evidence was provided and reviewed by the auditor and it was determined that all personnel were in compliance.

4.5 Examination of Technical Activities

The DOE audit team prepared detailed checklists for the CAL and each of the AMRs. Technical activities examined by the audit team, and in some cases those questions forwarded to the audit team, are summarized below for the CAL and each of the AMRs.

AMR N0000, Thermal Tests Thermal-Hydrological Analyses/Model Report (Rev 00, 04/00)

As stated in the AMR, the report had two purposes. First, the AMR was to evaluate the drift scale TH property set derived from the unsaturated zone (UZ) flow and transport analyses for thermally perturbed conditions. Second, the AMR was to conduct sensitivity studies of other TH property sets, including the mountain scale TH property set, and investigate modifications that would result in adequate agreement between simulated and measured TH data. However, the AMR did not

fulfill all the purposes as defined in the AMR development plan (CRWMS M&O, 1999). The development plan requires the AMR to recommend a property set for thermally perturbed flow and transport in the UZ.

The DOE Technical Specialist/auditor (hereafter referred to as the DOE auditor) found that this purpose as stated in the development plan had not been met. The NRC observer concurred with this finding. Specifically, the DOE auditor noted that quantitative comparisons between simulations and test results were made only for temperature data while simulated hydrological responses for thermally perturbed flow and saturations detected by geophysical techniques in the test environments were characterized in the AMR only subjectively as being in "good agreement." In addition, the significantly differing moisture distributions simulated using the various property sets indicated to the DOE auditor that this AMR did not succeed in discriminating between various TH property sets for predicting hydrological responses to thermal perturbations for use in PA. The DOE auditor pointed out that measured and simulated temperatures were compared quantitatively by weighted statistical measures but the criteria by which the comparisons were deemed acceptable were subjective and not adequately justified. Finally, the DOE auditor noted, and the NRC observer concurred, that the criteria for acceptable matches between simulations and temperature data were set so that all the property sets were found to be acceptable.

The DOE auditor also found the following additional potential deficiencies and/or recommendations in this AMR during the audit.

- Although the purpose of this AMR was to evaluate property sets for thermally perturbed flow and transport in the UZ, only one unit, the middle non-lithophysal unit of the Topopah Spring Tuff which comprises about 10 percent of the proposed repository, was investigated.

- Assumptions about boundary and initial conditions were not clearly stated nor justified and appeared to be inconsistent.

- Focusing of condensate drainage and preferential flow in fractures is observed in the thermal tests and is acknowledged to be the source of water collecting in several boreholes at the DST. This phenomenon is a mechanism by which water may enter drifts during the thermal period and may be important to performance, yet this AMR neglects spatial heterogeneity. The water collected and removed from boreholes in the DST is not included in the models.

- Leakage through the thermal bulkhead of the DST was not well represented by the models. The AMR acknowledged that leakage through the bulkhead remains one of the largest uncertainties in the DST results.

The NRC observer agreed with these findings as they were conveyed to the AMR originators during the audit. NRC recommends that DOE more thoroughly evaluate thermally driven moisture redistribution, such as focused condensate drainage through fractures, that are important to repository performance.

CRWMS M&O 1999, *Thermal Test Thermal-Hydrological Analysis and Models Report, DI#ANL–NBS–TH–000001.* TDP–NBS–TH–000002, Rev. 0 ICN 0. Las Vegas, Nevada, CRWMS M&O. ACC: MOL.20000124.0319.

AMR N0120, Drift-Scale Coupled Processes (DST and THC Seepage) Models, Rev 00

This report evaluated coupled thermal-hydrologic-chemical (THC) processes associated with the DST, and then extended the model calculations to time frames appropriate for the evaluation of a potential waste-emplacement drift at Yucca Mountain, NV. Analytical data from the DST were used to appraise the conceptual and numerical models. Results from this study will be used as input for the performance assessment, "UZ Flow and Transport PMR," and the NFE PMR.

Although this AMR used state-of-the-art techniques, several limitations and areas for improvement were identified by the DOE auditor. The NRC observer concurred with all technical recommendations made by the DOE auditor/technical specialist. The following paragraphs summarize those technical recommendations.

The following model assumptions should be explicitly stated and supported by stronger technical bases:

- Reaction rates of most minerals in the systems described by Cases 1 and 2 of this AMR are known to be pH dependent. However, the DOE observer/technical specialist noted that this AMR employs a simplified version of the rate law that does not account for non-linear variations in effective reaction rates due to H+ dependency. The intrinsic rate constants were calculated assuming a fixed pH of 7. It is assumed in this AMR that these simplifications will have negligible effects on the model results. The NRC observer concurs with the DOE auditor/technical specialist that this assumption should be explicitly stated, and that technical bases should be given to support a specific pH range under which these assumptions are valid.

- Current design specifications require 70 percent heat removal by ventilation, but the DOE auditor/technical specialist noted that this AMR assumes 50 percent heat removal in calculations of effective thermal conductivities. The DOE auditor/technical specialist recommended that this discrepancy in heat loss be clearly indicated in the text, and that an impact analysis should be performed to evaluate the effects on the model results. The NRC observers agree with this recommendation, and also noted that the discussion of heat removal in this AMR lacks appropriate references. The DOE auditor/technical specialist recommended that appropriate references be included.

- The following model assumption should be explicitly stated: Aqueous fluid properties may be affected by changes in dissolved constituent concentrations over a range of temperatures. In this AMR, these effects are assumed to be negligible. The DOE auditor/technical specialist recommended that this assumption be explicitly stated in Section 5, and the NRC technical observer agreed.

Several modifications should be made to the text to improve its transparency. These are explained below.

- The DOE auditor noted that modifications to the rate law given in Equation 8 are likely to have a significant effect on the model results, and recommended that these modifications be explicitly described in the AMR (not just the scientific notebook). The NRC observer concurred.

- The DOE auditor identified incorrect values of the fracture reactive surface area for the units "ptnf3" and "tswf7" in Table III-I of this AMR. Although these errors were not propagated into the model input files, the DOE technical specialist and the NRC observer agreed that these values must be corrected in the AMR.

- The DOE auditor recommended that direct linkage to data derivation be improved by adding input Tables and Data Tracking Numbers to DIRS and then removing the Data Tracking Numbers and Input Tables from the list of model outputs in Section 8.4. These modifications were requested for Table 4 and Attachments II-IV. The NRC observer agreed with this recommendation.

This AMR addressed model validation by comparing model predictions with measured parameters from the DST. Several recommendations were made to strengthen this comparison and increase confidence in long-term predictions of the THC Seepage model. These recommendations are explained below.

- The NRC observer noted that a number of water and gas samples from the DST were analyzed, but many of these were not used as benchmarks for comparison with model predictions. The NRC observer was concerned that the measurements used in this AMR may not be representative. Alternatively, measurements that were not used in this AMR may reflect important processes that need to be considered. The DOE auditor agreed, and recommended that the full range of water and gas samples be evaluated to determine which measurements, if any, should be excluded from further consideration. Both the DOE auditor and the NRC observer emphasized that all assumptions used in the evaluation of water analyses should be stated explicitly and supported by technical bases.

- The DOE auditor/technical specialist and the NRC observer agreed that additional data for uncertainty analyses are needed to strengthen the Case 2 comparison against DST measurements. Because model validation relies on a comparison with analytical water and gas compositions, the DOE auditor recommended that the reliability of these data be assessed in a quantitative fashion. This AMR included some discussion of data uncertainties and limitations, but more comprehensive evaluations should be performed to strengthen the validation of the THC Seepage model. Uncertainties may stem from the analytical measurements themselves or from incomplete knowledge about the physical location(s) and condition(s) that contributed to the measured values. Data uncertainties should be evaluated, and corresponding bounds should placed on model results.

- Both the DOE auditor and the NRC observer were concerned that simulations performed using extended (Case 1) and abbreviated (Case 2) sets of minerals led to incongruous results. The NRC observer concurs with the DOE auditor that stronger technical bases are needed to support the conclusion that Cases 1 and 2 approaches are well-suited to predict THC processes over different time frames. Case 2 provides a closer match with the DST measurements than Case 1, and is used to validate the model over short time frames. However, the NRC observer noted that the explanation given for excluding Case 1 as a benchmark for comparison with the DST measurements p. 57(i.e. uncertainties in thermodynamic and kinetic data) can be applied equally well to Case 2. The DOE auditor and the NRC observer agreed that additional work is needed to reconcile differences between Case 1 and Case 2 results. The DOE auditor/technical specialist recommended that additional sensitivity studies be performed to identify the input parameters that contribute most significantly to model uncertainties, and to place bounds on the model results. The NRC observer concurred with these recommendations.

Calculation CAL–NBS–MD–000002–00: "Permeability Change Due To Coupled Thermal-Hydrological-Mechanical Effects" (Tracking Number - N0C30)

This report described a calculation performed to provide a bounding estimate of fracture permeability change owing to thermal-mechanical effects at the proposed Yucca Mountain repository. The estimate would be used to support PA abstractions of drift seepage and the NFE PMR. Results from the calculation were used to suggest that thermal-mechanical effects on permeability would be limited to a permeability increase by a factor of 10 or less within a zone extending up to two drift diameters from a drift wall. However, the NRC observer concurred with the DOE auditor that the calculation is inadequate to support such a conclusion for the following reasons.

The mechanical model used for the calculation did not represent the anticipated mechanical environment at the proposed repository. The model used for the calculation consisted of a rectangular prism 60m-high (vertically), 30m-wide, in the drift direction, and 50m-wide in the drift-normal direction. The emplacement drift was represented by a horizontal circular opening, 5.5m in diameter and 30m-long, which is located at the mid-height of the prism. The applied mechanical boundary conditions consisted of zero vertical displacement at the base (i.e., at 30m below the emplacement-drift axis) and zero stress change on all other surfaces. The value of fixed stress at the stress boundary surfaces was set equal to the initial *in-situ* stress (i.e., before thermal loading) for the repository depth. These boundary conditions permitted free thermal expansion of the heated domain and, consequently, the resulting stress states are substantially different from the anticipated stress states during the thermal regime at Yucca Mountain. For example, the maximum principal compressive stress calculated from the model remained vertical throughout a 1000-year simulation period. On the other hand, the maximum principal compressive stress was expected to be horizontal during the thermal regime at Yucca Mountain because of higher restraint in the lateral than vertical direction. The document originator explained that the boundary conditions were chosen to promote rock loosening and, therefore, maximum permeability increase, in the roof area of the emplacement drift. However, thermal-mechanical models of the repository, with boundary conditions that appropriately represented the anticipated mechanical environment, indicated that stress-driven slip on subhorizontal fractures is an important mechanism of permeability change. The NRC observer concurred with the DOE auditor that, because of focusing on a mechanism that is inconsistent with the anticipated mechanical environment at Yucca Mountain, the calculation may produce nonconservative conclusions regarding the magnitude of potential permeability change and the geometrical characteristics of the zones of such change.

The fracture pattern at Yucca Mountain was represented in the model as three orthogonal (i.e., two vertical and one horizontal) fracture sets. This fracture pattern was different from the pattern used in previous DOE analyses of thermal-mechanical effects. The analyses presented in each of the following previous DOE documents were based on nonorthogonal fracture sets with dips of about 80 degrees for each of two subvertical sets and about 20 degrees for a subhorizontal set: "Exploratory Studies Facility (ESF) Ground Support Design" (BABEE0000–01717–0200–00002–00D); "Seismic Topical Report II" (YMP/TR–003–NP–2); "Drift Ground Support Design Guide" (BCAA00000–01717–2500–00001–00); "Repository Ground Support Analysis for Viability Assessment" (BCAA00000–01717–0200–00004–01); and the "Drift Degradation Analysis AMR (ANL–EBS–MD–000027–00). The NRC observer concurred with the DOE auditor that the use of a fracture pattern that is not representative of the fracture pattern at Yucca Mountain may result in nonconservative conclusions regarding the magnitude of potential permeability change.

The thermal-mechanical property values used in the analyses were inconsistent with values in the DOE database. For example, the calculation used a thermal expansivity of 3×10^{-6}/K, whereas thermal expansivity varies with temperature from about 7×10^{-6}/K at 25–50 degrees C, to about 20×10^{-6}/K at 225–250 degrees C, based on information in the "Yucca Mountain Site Geotechnical Report" (B00000000–01717–5705–00043–01). Smaller values of thermal expansivity gave smaller values of thermal stress. Therefore, the use of a value of thermal expansivity that is small compared with values in the DOE database would lead to calculated thermal stress that is small compared with the anticipated thermal stress based on information from the DOE database. Smaller stresses imply reduced magnitudes of inelastic response and, therefore, permeability change. Therefore, the NRC observer concurred with the DOE auditor that the potential deficiencies in the audited calculation may produce nonconservative conclusions regarding the magnitude of potential permeability change.

4.6 NRC Staff Findings

The NRC staff has determined that OQA Audit M&O-ARP-00-08 was effective in determining the level of compliance of M&O activities associated with the subject AMRs. The NRC staff agreed with the audit team conclusion that the OCRWM QA program had been satisfactorily implemented. The NRC staff also determined the following:

- The NRC staff found the OQA Audit M&O-ARP-00-08 to be thorough, comprehensive, technically detailed, and professional.

- Specific aspects of the two AMRs and the one CAL audited were found to be technically insufficient for either the intended purpose or for supporting the stated conclusions. The specific potential deficiencies are detailed in the sections pertaining to the individual AMRs and CAL. The DOE audit team Technical Specialists identified these potential deficiencies and recommendations for improvement and brought them to the attention of the originators, and the NRC staff concurred with those findings.

- The NRC staff found this audit to be effective in identifying deficiencies and recommending improvements in the audited documents. However, the DOE OQA should verify that the recommendations of this audit are satisfactorily addressed by the originators of the AMRs and the CAL.

4.6.1 Audit Observer Inquiries

There were no audit observer inquires opened during this audit and all previous audit observer inquiries are closed.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 21, 2000

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-01-02, "OBSERVATION AUDIT OF OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT, QUALITY ASSURANCE DIVISION, AUDIT NO. OQA-SA-01-006"

Dear Mr. Milner:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report (OAR) No. OAR-01-02, of the U.S. Department of Energy's (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) supplier audit of Beta Analytic Inc. (BAI). The audit, OQA-SA-01-006, was conducted on November 16-17, 2000, at BAI's facility in Miami, Florida.

The scope of the audit evaluated the effectiveness of the BAI Quality Assurance Program for Yucca Mountain Project Activities, as delineated in U.S. Geological Survey Purchase Order 99CRSA1014 and associated implementing procedures. BAI prepares USGS samples for the Accelerated Mass Spectrometry (AMS) analysis for the purpose of Carbon-14 age dating of the samples. The AMS is performed by LLNL Center for Accelerator Mass Spectrometry which is on the OCRWM approved suppliers list.

The NRC observers concluded that Audit No. OQA-SA-01-006 was effective in determining the level of compliance of BAI activities associated with the Yucca Mountain Project. Within the areas evaluated, the DOE audit team identified a minor potential deficiency which was corrected and verified prior to the writing of the DOE audit report.

The NRC staff determined that this DOE audit was effective in conducting the audit. The NRC staff also agrees with the audit team conclusions, findings, and recommendations, as presented at the audit exit. The NRC observers generated no audit observer inquiries during this audit.

NMSS07
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A written response to this letter and the enclosed report is not required. If you have any questions, please contact Ted Carter of my staff at 301-415-6684.

Sincerely,

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-01-02, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. OQA-SA-01-006"

cc See attached list.

Letter to J. Carlson from C. W. Reamer dated: December 21, 2000

cc: R. Loux, State of Nevada
S. Frishman, State of Nevada
L. Barrett, DOE/Wash, DC
A. Brownstein, DOE/Wash, DC
S. Hanauer, DOE/Wash, DC
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J. Lyznicky, AMA
R. Clark, EPA
F. Marcinowski, EPA
R. Anderson, NEI
R. McCullum, NEI
S. Kraft, NEI
J. Kessler, EPRI
D. Duncan, USGS
R. Craig, USGS
W. Booth, Engineering Svcs, LTD
J. Curtiss, Winston & Strawn

U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-01-02

OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE DIVISION

AUDIT NO. OQA-SA-01-006

12/18/00

Ted Carter
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

12/18/00

Bruce Mabrito
Center for Nuclear Waste
Regulatory Analyses

Reviewed and Approved by:

12/21/00

N. King Stablein, Chief
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

Enclosure

1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission (NRC), Division of Waste Management, observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) supplier audit of Beta Analytic Inc. (BAI). Audit No. OQA-SA-01-006, was conducted on November 16-17, 2000, at the facility in Miami, Florida.

The objective of this audit was to evaluate the implementation of the applicable provisions contained in the BAI Quality Assurance Program, by reviewing documentation and interviewing BAI staff supporting BAI work activity.

The NRC staff objective was to gain confidence that BAI and OQA are properly implementing the applicable provisions contained in the Quality Assurance Requirements and Description 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).

2.0 MANAGEMENT SUMMARY

The NRC staff has determined that OQA Audit No. OQA-SA-01-006 was useful, effective, and conducted in a professional manner. Audit team members were independent of the activities they audited and appeared to be knowledgeable in the quality assurance (QA) and technical disciplines within the scope of the audit. The audit team members' qualifications were previously reviewed and the members were found to be qualified earlier in their respective disciplines.

The audit team concluded that the BAI QA program had been satisfactorily implemented in the areas evaluated. The NRC staff determined that this audit was effective. The NRC staff also agrees with the audit team conclusions and recommendations.

3.0 AUDIT PARTICIPANTS

3.1 NRC Observers

Ted Carter	Team Leader	NRC
Bruce Mabrito	Team Member	Center for Nuclear Waste Regulatory Analyses)

3.2 OQA Audit Team

Richard Maudlin	Audit Team Leader	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
F. Harvey Dove, Ph.D., P.H.	Technical Specialist	OQA/QATSS

3.3 Observer

Bruce Parks	Observer	U.S. Geological Survey (USGS), Denver, CO

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This OQA audit of BAI 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 the NRC Manual Chapter 2410, dated July 12, 2000.

4.1 Scope of the Audit

The scope of the audit was to evaluate the effectiveness of the BAI QA program, Revision QA_5.00, dated January 2000, and associated implementing procedures as delineated in USGS Purchase Order 99CRSA1014 . BAI prepares USGS samples for the Accelerated Mass Spectrometry (AMS) analysis for the purpose of Carbon-14 age dating of the samples. The AMS is performed by LLNL Center for Accelerator Mass Spectrometry which is on the OCRWM approved suppliers list.

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 M&O and DOE programs and procedures. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit. The NRC staff believes the timing of the audit was appropriate for the auditors to evaluate the pertinent BAI activities associated with the past and on-going activities and implementation of the QA Program.

The DOE audit team and NRC observers caucused at the end of each day of auditing. Also, meetings of the audit team and BAI management (with the NRC observers always present) were held to discuss the audit status and preliminary findings.

A USGS staff member was present during most of the audit to observe and assist in information transfer and to respond to questions pertaining to the USGS Purchase Order to BAI.

4.3 Audit Team Qualification and Independence

The qualifications of the DOE audit team leader and the OQA audit team member had been reviewed earlier and were then found to be acceptable in that they met the requirements of QAP 18.1, "Auditor Qualification," as verified by an NRC observation audit lead. The audit team members did not have prior responsibility for performing the activities they audited. In addition, training, education, and experience records for the two DOE audit team members were previously reviewed and found acceptable. NRC observers had previously reviewed the technical specialist's qualifications and found that the technical specialist had sufficient technical education, training, and experience.

4.4 Examination of QA Programmatic Elements

The NRC staff observed that each of the audit team members reviewed appropriate documentation and interviewed key BAI personnel to determine their understanding of implementing procedures and processes. Training, education, and experience records were reviewed to assure BAI personnel met

the requirements of their individual position descriptions. Objective evidence was provided and reviewed by the auditor and it was determined that all personnel were in compliance.

4.5 Examination of Technical and Programmatic Activities

After an introductory BAI explanation of the general processes used to determine radiocarbon dating information, the DOE auditors used their checklists as a tool to determine if the QA program was being effectively implemented. In addition to specific questions from the prepared programmatic and technical checklists, the auditors used acceptable sampling techniques to determine if traceability of prepared radiocarbon dating specimens was adequate.

Various "Beta numbers" were identified as discrete tasks specifically for the USGS and those were traced back through the BAI documentation chain. These included USGS water samples and other samples submitted in Fiscal Year (FY) 2000, which were traced from initial receipt through to final age determination. Specifically, the DOE audit team tracked 15 water samples that were prepared for the Yucca Mountain program during the FY and found the documentation complete, including the sampling bags, labels, forms, and paperwork. No inconsistencies were noted by the audit team and this was concurred in by the NRC observers.

The BAI management explained that the calibration of radiocarbon dating of samples is accomplished by regular and periodic "round robin" testing at eight Accelerated Mass Spectrometric laboratories worldwide. The DOE audit team and NRC observers were shown documentation to explain how the round robin radiocarbon (or 14C) consortium system functions and how it maintains an age dating calibration control on the labs performing such work.

Preparation of radiocarbon samples in the BAI laboratory was observed by the DOE technical specialist and one of the NRC observers. The sample preparation process is now commercialized by BAI and the technicians followed a standard procedure which was developed in a university laboratory setting by 1970. BAI claims to be the largest radiocarbon dating laboratory in the world now, having produced over 120,000 analyses. The BAI technicians answered the DOE audit team technical specialist questions while performing the preparation activities. The DOE technical specialist also checked the qualifications of the BAI technicians and stated they were well qualified for their positions. The NRC observer concluded that the sample-preparation technicians used approved procedures.

During the programmatic portion of the audit, the DOE audit team leader checked the current BAI QA Program and the applicable criteria for the tasks being performed. The areas of concentration included: the qualification of personnel; certification and documentation; procurement issues; application of appropriate quality requirements in accordance with the USGS Purchase Order; generated nonconformance reports and related corrective actions; calibration of equipment; electronic and hard copies of records; software used; traceability of samples; and use of scientific notebooks when developing new processes. There were no areas of noncompliance noted by the DOE team leader.

The audit team leader's investigations were watched by an NRC observer and there was agreement in the line of questions and concurrence with the stated results.

The DOE audit team technical specialist reviewed sample tracking sheets for USGS/Yucca Mountain program work, along with those for a national museum. The documentation was readily available, easily presented, and well kept according to the DOE audit team member. The NRC observer agreed with the assessment.

During the first day of the audit, it was mentioned by the DOE audit team leader that the latest version of the BAI proprietary implementing procedures, which are part of the QA manual, had a problem of incorrect headers on some of the manual sections. This item was specifically covered in the second day of the audit. Due to the specific text software program in use at BAI and the age of some of the QA manual sections, making the header changes so that the manual was consistent throughout, was not an easy process. In the post-audit meeting the DOE audit team leader stated that if the BAI QA implementing procedures could be made consistent through manipulation of software within approximately 10 days, he would not carry that over as an open item to audit OQA-SA-01-006. BAI management agreed to this arrangement and the DOE audit team leader confirmed that the corrections were made to the BAI proprietary implementing procedures within the time frame. NRC observers were present to see this method of securing compliance and concurred in its application.

The NRC observers concluded that the methods used by the audit team members provided an adequate approach and was effective in determining the level of compliance of the BAI activities.

4.6 NRC Staff Findings

The NRC staff has determined that OQA Audit No. OQA-SA-01-006 was effective in determining the level of compliance of BAI activities associated with the radiocarbon dating services. The NRC staff agreed with the audit team conclusion that the BAI QA program had been satisfactorily implemented. The NRC staff also determined the following:

- The NRC staff found OQA Audit No. OQA-SA-01-006 thorough, comprehensive, technically detailed, and professional.

- The DOE audit team technical specialist did an acceptable job with the technical portion of the audit. He demonstrated an acceptable level of understanding of the technical methods that were the subject of the audit. The radiocarbon dating services BAI was offering were determined to be traceable and acceptable.

- The NRC observers were allowed to question the BAI technical staff as needed.

- The NRC observers were present when the commitment was made by BAI management to correct the BAI implementing procedure header inconsistency.

4.6.1 Audit Observer Inquiries

There were no audit observer inquires issued during this audit observation, and there were no previous audit observer inquiries at BAI to be closed.

A written response to this letter and the enclosed report is not required. If you have any questions, please contact Ted Carter of my staff at 301-415-6684.

Sincerely,

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-01-02, "Observation Audit of the Office of Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. OQA-SA-01-006"

cc: See attached list.

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 5, 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-01-03, "OBSERVATION AUDIT OF THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT, QUALITY ASSURANCE DIVISION, AUDIT NO. M&O-ARP-01-02"

Dear Mr. Milner:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report (No. OAR-01-03), of the U.S. Department of Energy's (DOE's), Office of Civilian Radioactive Waste Management (OCRWM), Quality Assurance Division's,(OQA's), audit of activities regarding to the "Unsaturated Zone Flow and Transport Model Process Model Report" (UZ PMR). The UZ PMR was prepared by, and the supporting activities performed by, the OCRWM Management and Operating Contractor (M&O), and the U.S. Geological Survey. This audit was conducted on February 5 through 9, 2001, at the M&O facilities in Las Vegas, Nevada.

UZ PMR activities and selected Analysis Model Reports (AMRs) were previously audited on January 24 through 28, 2000, and at that time, several of the documents audited were in the process of being developed. The purpose of this performance-based audit was to evaluate the effectiveness of the implementation of the OCRWM Quality Assurance Program described in the Quality Assurance Requirements and Description document, and its implementing procedures for the UZ PMR and selected AMRs supporting the UZ PMR. Also, the audit evaluated action taken as a result of the findings and recommendations from the January 2000 UZ 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.

Within the areas evaluated, the audit team identified four potential deficiencies, of which two were corrected during the conduct of the audit. Subsequent to the audit, one potential deficiency was resolved. The remaining potential deficiency identified procedure compliance problems with processing input transmittals for UZ PMR and AMR activities.

Although the UZ PMR appeared to satisfactorily compile the results of the supporting AMRs, the audit team made 20 recommendations regarding the content of AMR No. ANL-NBS-HS-000017 (U0085), "Analysis of Geochemistry Data," Revision 0, with Change Notice No. 1. Except for AMR No. U0085, there were very few audit team recommendations. Although not discussed during the audit nor the audit exit, the Division of Waste staff is concerned that the number of audit team recommendations for AMR No. U0085 may reflect some inattention to detail by the AMR preparers and reviewers.

As discussed in the attached report, the observers submitted four audit observer inquiries (AOIs) requesting clarification and information on audited documents. The AOIs addressed outstanding recommendations identified in the NRC observation report from the January 2000 UZ PMR audit activities.

Although the audit team identified some potential deficiencies, and four AOIs requesting clarification and information were generated, the observers believe that the AMRs and PMR reviewed during the audit were technically sound and that these products indicated an improving trend over several AMRs and PMRs audited during the past year. The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit.

During the audit, the observers met with the M&O personnel responsible for the qualification of data and software supporting the potential DOE site recommendation for a high-level waste repository. The observers were informed that as of January 30, 2001, 85 percent of the data and 97 percent of the software supporting site recommendation were fully qualified.

A written response to this letter and the enclosed report is not required; however, we do request that you respond to the four AOIs. The responses to the AOIs should be entered on the appropriate AOI form and forwarded either to the NRC Onsite Representatives or to Larry L. Campbell at NRC headquarters. If you have any questions, please contact Larry L. Campbell at (301) 415-5000.

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-01-03, "Observation Audit
of the Office of Civilian Radioactive
Waste Management, Quality Assurance
Division, Audit No. M&O-ARP-01-02"

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A written response to this letter and the enclosed report is not required; however, we do request that you respond to the four AOIs. The responses to the AOIs should be entered on the appropriate AOI form and forwarded either to the NRC Onsite Representatives or to Larry L. Campbell at NRC headquarters. If you have any questions, please contact Larry L. Campbell at (301) 415-5000.

Sincerely,

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-01-03, "Observation Audit
of the Office of Civilian Radioactive
Waste Management, Quality Assurance
Division, Audit No. M&O-ARP-01-02"

Letter to R. Milner from C.W. Reamer dated: March 5, 2001

cc:

R. Loux, State of Nevada
S. Frishman, State of Nevada
L. Barrett, DOE/Washington, DC
A. Brownstein, DOE/Washington, DC
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S. Mellington, YMPO
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T. Gunter, YMPO
K. Hess, BSC
D. Krisha, BSC
S. Cereghino, BSC
M. Voegele, BSC/SAIC
S. Echols, Winston & Strawn
B. Price, Nevada Legislative Committee
J. Meder, Nevada Legislative Counsel Bureau
D. Bechtel, Clark County, NV
E. von Tiesenhausen, Clark County, NV
A. Kalt, Churchill County, NV
G. McCorkell, Esmeralda County, NV
L. Fiorenzi, Eureka County, NV
A. Johnson, Eureka County, NV
A. Remus, Inyo County, CA
M. Yarbro, Lander County, NV
R. Massey, Lander County, NV
J. Pitts, Lincoln County, NV
M. Baughman, Lincoln County, NV
A. Funk, Mineral County, NV
J. Shankle, Mineral County, NV
L. Bradshaw, Nye County, NV
M. Murphy, Nye County, NV
J. McKnight, Nye County, NV
D. Weigel, GAO
W. Barnard, NWTRB
R. Holden, NCAI
A. Collins, NIEC
R. Arnold, Pahrump County, NV
J. Larson, White Pine County
R. Clark, EPA
F. Marcinowski, EPA
R. Anderson, NEI
R. McCullum, NEI
S. Kraft, NEI
J. Kessler, EPRI
D. Duncan, USGS
R. Craig, USGS
W. Booth, Engineering Svcs, LTD
J. Curtiss, Winston & Strawn
N. Rice, NV Congressional Delegation
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U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. OAR-01-03

"OBSERVATION AUDIT OF THE

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

OFFICE OF QUALITY ASSURANCE

AUDIT NO. M&O-ARP-01-02"

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Enclosure

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 (OCRWM), Quality Assurance Division's (OQA's), audit of activities regarding to the "Unsaturated Zone Flow and Transport Model Process Model Report" (UZ PMR). The UZ PMR was prepared by and the supporting activities performed by the OCRWM Management & Operating Contractor (M&O) and the U.S. Geological Survey (USGS). This audit, M&O-ARP-01-02, was conducted on February 5-9, 2001, at the M&O facilities in Las Vegas, Nevada.

The UZ PMR activities and selected Analysis Model Reports (AMRs) were previously audited on January 24-28, 2000 (OQA Audit No. M&O-ARP-00-04), 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 Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 10, by evaluating the UZ PMR and selected AMRs supporting the UZ PMR. Also, the audit evaluated action taken as a result of the findings and recommendations from the January 2000 UZ audit. During the audit, the PMR and four AMRs were subjected to a technical evaluation as well as evaluation to ensure that the applicable programmatic requirements contained in the QARD and implementing procedures were met.

The NRC observers' (observers') objective was to assess whether the M&O, USGS, and OQA 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 SR are properly qualified; 2) evaluating the progress being made by DOE and its contractors in meeting the data and software qualification goals for SR; and 3) ensuring the technical adequacy of the PMR and 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 in the audited areas of the UZ PMR and the adequacy of implementation of QARD controls by the M&O in the audited areas of UZ PMR and AMR development.

2.0 MANAGEMENT SUMMARY

The observers agreed with the audit team's (audit team's) conclusions, findings, and recommendations. The observers determined that OQA Audit M&O-ARP-01-02 was well-planned and effectively implemented. The audit team members were independent of the activities they audited and were knowledgeable in the quality assurance (QA) and technical disciplines within the scope of the audit. The audit team qualifications were reviewed and were found acceptable.

Within the areas evaluated, the audit team identified four potential deficiencies. Two deficiencies were corrected during the audit; one was determined, subsequent to the audit, not to be a deficiency; and the following potential deficiency remained open: input transmittals were not processed in accordance with procedure. The audit team made several recommendations about the content of the documents reviewed including: a) justification for selection of base-case models over alternative models; b) exemption of a software package from procedure requirements; and c) several recommendations, for the AMR, addressing the analysis of geochemistry data, including changes in text of the AMR to improve traceability, transparency, justification of assumptions, clarity of the AMR purpose, and the need for additional discussion of alternative models (see Section 4.5.3 of this report).

As discussed in the attached report, the observers submitted four audit observer inquiries (AOIs) requesting clarification and information on audited documents. The AOIs addressed outstanding recommendations identified in the NRC observation report from the January 2000 UZ audit.

Although the audit team identified some potential deficiencies, and four AOIs requesting clarification and information were generated, the observers believe that the AMRs and PMR reviewed during the audit were technically sound and that these products indicated an improving trend over several AMRs and PMRs audited during the past year.

Overall, the audit team concluded that the OCRWM QA program had been satisfactorily implemented in the areas evaluated. The observers generally agreed with the audit team's conclusion.

3.0 AUDIT PARTICIPANTS

3.1 Observers

Robert Latta	Team Leader	NRC
Hans Arlt	Technical Specialist	NRC
James Winterle	Technical Specialist	CNWRA

3.2 OQA Audit Team

Robert Hartstern	Audit Team Leader	OQA/Quality Assurance Technical Support Services (OQA/QATSS)
Samuel Archuleta	Auditor	OQA/QATSS
Robert Hasson	Auditor	OQA/QATSS
Richard Powe	Auditor	OQA/QATSS
Richard Weeks	Auditor	OQA/QATSS
Keith Kersch	Technical Specialist	SAIC
Thomas Doe	Technical Specialist	Management & Technical Services
Levy Kroitoru	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 UZ PMR activities and selected AMRs were previously audited on January 24-28, 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 UZ PMR. Audit activities included evaluation of the UZ PMR, four 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 January 2000 UZ PMR audit.

The implementation of the following procedures for the audited activities, and the preparation of the following AMRs and the UZ PMR were evaluated by the audit team and the observers during the audit:

Procedures

a) AP-2.1Q, "Indoctrination and Training of Personnel," Revision 0, with Interim Change Notice (ICN) No. 0

b) AP-2.2Q "Establishment and Verification of Required Education and Experience of Personnel," Revision 0, with ICN No. 0

c) AP-2.13Q, "Technical Product Development Planning," Revision 0, with ICN No. 4

d) AP-2.14Q, "Review of Technical Products," Revision 1, with ICN No. 1

e) AP-2.15Q, "Work Package Planning Summaries," Revision 0, with ICN No. 1

f) AP-3.4Q, "Level 3 Change Control," Revision 2, with ICN No. 0

g) AP-3.10Q, "Analysis and Models," Revision 2, with ICN No. 3

h) AP-3.11Q, "Technical Reports," Revision 1, with ICN No. 1

i) AP-3.14Q, "Transmittal of Input," Revision 0, with ICN No. 2

j) AP-3.15Q, "Managing Technical Product Inputs," Revision 2, with ICN No. 0

k) AP-3.17Q, "Impact Reviews," Revision 1, with ICN No. 0

l) AP-SI.1Q, "Software Management," Revision 2, with ICN No. 4, ECN No. 1

m) AP-SIII-1Q, "Scientific Notebooks," Revision 1, with ICN No. 0

n) AP-SIII.2Q, "Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data," Revision 0, with ICN No. 2

o) AP-SIII.3Q, "Submittal and Incorporation of Data to the TDMS," Revision 0, with ICN No. 3

p) AP-SV.1Q, "Control of the Electronic Management of Data," Revision 0, with ICN No. 2

q) QAP-2.0, "Conduct of Activities," Revision 0

r) QAP 16.1Q, "Management of Conditions Adverse to Quality," Revision 4, with ICN No. 1

s) QAP-18.1Q, "Auditor Qualification," Revision 6, with ICN No. 0

t) QAP-18.2Q, "Internal Audit Program," Revision 8, with ICN No. 0

u) AP-2.21, "Quality Determinations and Planning for Scientific, Engineering, and Regulatory Compliance Activities," Revision 0

PMR

a) TDR-NBS-HS-000002, "Unsaturated Zone Flow and Transport Process Model Report," Revision 00, with ICN No. 02

AMRs

a) U0010 (ANL-NBS-HS-00032), "Simulation of Net Infiltration for Modern and Potential Future Climates," Revision 00, with ICN No. 01

b) U0085 (ANL-NBS-HS-000017), "Analysis of Geochemistry Data," Revision 00, with ICN No. 01

c) U0110/N0120 (MDL-NBS-HS-000001), "Drift Scale Coupled Processes (DST and THC Seepage) Models," Revision 01

d) U0175 (MDL-NBS-GS-000011), "Future Climate Analysis - 10,000 Years To 1,000,000 Years After Present," Revision 00

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 UZ 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 PMR and AMRs.

4.4 Examination of QA Elements

The OQA programmatic and technical audit activities were conducted simultaneously using sub-audit teams generally consisting of at least one technical specialist and one QA auditor. Often during the audit, certain programmatic aspects of the documents audited were independently reviewed by a audit team member. The observers determined that the limited-scope audit focused on the QA elements closely associated with the development of the AMRs. The observers evaluated the audit team's review of the following QA elements.

4.4.1 AP-2.13Q, "Technical Product Development Planning"

The audit team reviewed technical development plans and work product planning sheets applicable to the subject AMRs. In addition, the audit team reviewed the methodology for the product development, including the tracking of unresolved issues such as inputs requiring qualification, to be verified (TBV). The observers agreed with the audit team's findings in this area and made no additional findings nor observations.

4.4.2 AP-SI.1Q, "Software Management"

Software controls associated with the UZ PMR and AMRs were discussed during each of the technical interviews. The audit team reviewed qualification documentation and determined that the requirements of the software management procedure had been met, with the exception of computer software package ARCINFO, Version 6.1.2, for AMR No. U0010, on infiltration. However, the audit team concluded, that use of the ARCINFO software was limited to visual display of data. Therefore, the audit team recommended that the use of the ARCINFO software be evaluated to determine if it is exempt from AP-SI.1Q because of its use in the AMR. Notwithstanding this recommendation, the audit team made a positive comment that software routines in the AMR No. U0010 were well-documented. The observers agreed with the audit team findings in this area and made no additional observations nor inquiries.

4.4.3 AP-3.15Q, "Managing Technical Product Inputs"

Each of the AMRs examined included document input reference sheets that list the inputs to and references cited in the AMR. The document input reference sheets also identify the status of the input (e.g., qualified, TBV). The audit team examined the TBV status and determined that it generally included the appropriate statements in accordance with the "Analysis/Model Documentation Outline." The observers agreed with the audit team findings in this area and made no additional findings nor observations.

4.4.4 AP-3.10Q, "Analysis and Models"

The audit team used Procedure No. Ap-3.10Q to evaluate the activities covered during the audit. By definition, 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.

The audit team generally concluded that the requirements of Procedure AP-3.10Q had been appropriately implemented for AMR Nos. U0010, U0085, U0175, and U0110/N0120. The observers agreed with the audit team findings in this area and made no additional findings nor observations.

4.4.5 AP-2.14Q, "Review of Technical Products"

The observers held discussions with cognizant individuals in the Data/Software Qualification Department and reviewed selected data tracking number (DTN) sets to gain insights into the verification methodology to resolve TBVs. As a result of reviews and discussions, the observers determined that significant progress was being made. The observers were informed that on January 31, 2001, approximately 85 percent of the data and 97 percent of the software supporting site recommendation were fully qualified.

4.4.6 Potential Deficiencies

The audit team identified the following potential deficiencies:

One potential deficiency identified that the Technical Data Management System (TDMS) database access list was not being submitted to the Records Processing System, as required by Procedure No. AP-S.III.3Q. Subsequent to the audit exit, the audit team determined that the TDMS access list was maintained electronically and that Procedure No. AP-S.III.3Q had been satisfied because the access list was being electronically submitted.

The second potential deficiency identified two examples where the responsible M&O manager failed to follow the provisions contained in Paragraph 5.4.3 of Procedure No. AP-3.14Q. Specifically, the responsible manager failed to sign a copy of the PMR and AMR input transmittal and forward the completed transmittal to the Input Tracking Coordinator. These two examples of this deficiency were corrected during the conduct of the audit. However, as a result of these two examples, the audit team performed additional reviews and identified additional examples of the apparent failure to follow procedure. As a result of the investigation of the input transmittals referenced in the UZ PMR, the audit team issued a potential deficiency to evaluate the extent of this condition.

4.5 Examination of Technical Activities

The technical specialists on the audit team performed detailed reviews of the technical adequacy of the UZ PMR and 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.

As discussed in the following paragraphs, the observers generally agreed with the audit team findings in this area; however, the observers identified and discussed a few areas of concern, as discussed in the following sections, with the audit team.

4.5.1 PMR No. TDR-NBS-HS-000002, "Unsaturated Zone Flow and Transport Model," Revision 00, ICN 02

The UZ PMR documents the integration of outputs from submodels for climate, infiltration, unsaturated flow, drift seepage, and radionuclide transport to develop a simplified, yet robust approach for considering these processes in total-system performance assessments.

The audit team technical specialist assigned to review the UZ PMR was well-prepared to conduct the audit. The PMR originator and cognizant PMR-development staff were available to answer the audit team's technical questions and provide information about software, data, and model documentation. The audit team technical specialist emphasized the importance of understanding how data outputs from the various submodels are treated to become input for the process model and other submodels. The audit team made two recommendations in this area: 1) justification should be provided for selecting the transport model with matrix diffusion over an alternative model with no matrix diffusion, because the use of matrix diffusion over no matrix diffusion in the transport models is not justified either in the PMR or in the supporting AMRs; and 2) review other alternative models in the PMR and add statements of justification for their exclusion, as necessary. The NRC observers agreed with the audit team recommendations.

Several questions were focused on understanding how the "active fracture" concept is used to scale the effective fracture-matrix interface area as a function of percolation flux. An observer noted that since fracture-matrix interface area is greatly reduced by the active-fracture model, it seemed surprising that sensitivity studies show the process of matrix diffusion significantly delays transport of radionuclides to the water table. The observers discussed that since matrix diffusion is emerging as an important process, there is a strong need to verify that the active-fracture and matrix-diffusion models are properly integrated. During ensuing discussions, the audit team technical specialist suggested that a study of the sensitivity of the transport model to the active fracture parameter would be a useful. Also, the observers suggested that a sensitivity study be carried out showing that the active-fracture and matrix-diffusion models are properly integrated. The PMR authors agreed that this sensitivity study would enhance confidence in the model.

4.5.2 AMR No. U0010 (ANL-NBS-HS-000032), "Simulation of Net Infiltration for Modern and Potential Future Climates," Revision 00, ICN 01

This AMR produces spatially heterogeneous infiltration maps of average, high, and low infiltration rates for modern, monsoonal, and glacial transition climates for Yucca Mountain. The estimates of net infiltration are used for defining the upper boundary condition for the site-scale 3-dimensional flow model for the unsaturated zone.

The audit team technical specialist assigned to review this AMR was well-prepared to conduct the audit. The AMR checker and cognizant AMR-development staff were available to answer the audit team's technical questions and provide information about software, data, and model documentation. The technical specialist's questions were focused on the editorial changes that had been made since the last revision, and on the method of tracking the changes. The audit team did not identify any technical deficiencies in this AMR. The observers agreed with the audit team's findings.

The observers evaluated whether recommendations made during a previous audit (NRC's Observation Audit Report No. OAR-00-04) were adequately addressed. The observer concluded that all but four of the previous recommendations were incorporated into the Infiltration AMR. The four exceptions are summarized as follows: 1) provide a technical basis for predicting how future climate might affect vegetation cover, and therefore infiltration, at Yucca Mountain; 2) validate assumptions stated in the distributed-parameter water-balance model to ensure that mean annual shallow infiltration estimates are not under-predicted; 3) provide a justification for not using time-steps smaller than 24 hours when performing surface-water flow routing and calculating daily net infiltration; and 4) describe how a previous infiltration model report (Flint et al., 1996, as identified in Section 6.0 of this report) was used in the Infiltration AMR. The audit team identified, as a concern, the unqualified nature of the Flint, et al. (1996) report during the previous audit of this particular AMR, in January 24-28, 2000. This concern was identified, as such, in the OCRWM QA Audit Report M&O APR-00-04. The AMR checker commented that the revised AMR supplants the Flint, et al. (1996) report entirely; however, the stated purpose in the AMR is that it "...describes enhancements made to the infiltration model documented in Flint, et al. (1996) and documents an analysis using the enhanced model." Further, it was discussed that Flint, et al. (1996) is also used as a reference for many assumptions asserted in the revised Infiltration AMR. The observers generated four AOIs to document these omitted recommendations. Section 5.1 of this report provides additional detailed discussion on these four AOIs.

At the time of the AMR revision, an analysis of model sensitivity to uncertainty in input parameters and of the impact of parameter accuracy on model results, for this AMR, was not complete. Considering the relatively high level of uncertainty associated with the infiltration model results, the observers emphasized that this analysis needs to be completed and documented as provided for on Page 77 of the AMR.

4.5.3 AMR No. U0085 (ANL-NBS-HS-000017), "Analysis of Geochemistry Data," Revision 00, ICN 01

This AMR provides a summary of geochemistry data for the UZ at Yucca Mountain that are derived from a variety of sources. None of the data in this AMR is used as direct input to other AMRs or the UZ PMR. Rather, the data are used for model validation or to support conceptual model development.

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

During the audit, the observers raised a concern regarding infiltration estimates, in the AMR, that are based on the chloride mass balance (CMB) method. Specifically, Assumption No. 19 in Table 2 of the AMR states that the CMB approach is assumed to be valid for flow in a fractured-rock system. This assumption was listed as TBV, but the observer questioned whether this assumption can be verified since the CMB approach is applicable to plug flow in a homogenous porous medium. In ensuing discussion it was agreed that this assumption results in a limitation that the CMB infiltration estimates in this AMR represent lower-bounds. This limitation was acknowledged in the text of the AMR. Also, the observer found that the CMB infiltration estimates in this AMR were not used for input to, or validation for, any other AMR or PMR. This was a discussion of whether it may be possible to close the TBV status of Assumption No. 19, because the resulting limitations are acknowledged and made clear to potential end users of the CMB analysis. The audit team technical specialist recommended that an approach should be developed to address the TBV status of assumptions in this AMR. The observer asked how the TBV status of this assumption is tracked; an M&O staff member demonstrated how assumptions are tracked through the DIRS system. The observer found that Assumption No. 19 from this AMR was listed in the DIRS system with the identifier TBV-4766, and appropriate points of contact were listed.

No deficiencies were identified in this AMR; however, the technical specialist made several formal recommendations for improving the traceability, transparency, defensibility, and reproducibility of the analyses in this AMR. Although the UZ PMR appeared to satisfactorily compile the results of the supporting AMRs, the audit team made 20 recommendations regarding the content of AMR No. U0085. Except for AMR No. U0085, there were very few audit team recommendations. Although not discussed during the audit nor the audit exit, the DWM staff is concerned that the number of audit team recommendations for AMR No. U0085 may reflect some inattention to detail by the AMR preparers and reviewers. The observers agree with the audit team findings and recommendations.

4.5.4 AMR No. U0110/N0120 (MDL-NBS-HS-000001), "Drift-Scale Coupled Processes (DST and THC Seepage) Models," Revision 01

The purpose of this AMR is to provide the framework to evaluate THC coupled processes at the drift scale, to predict flow and transport behavior for specified thermal loading conditions, and predict the chemistry of waters and gases entering potential waste-emplacement drifts.

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

For this AMR, the scope of the audit team review was limited to evaluating whether recommendations made during a previous audit (OCRWM Audit Report M&O-ARP-00-08) were adequately addressed. The technical specialist concluded that most of the previous recommendations have been incorporated into the current AMR and he complimented the originator on a much improved document. The technical specialist made some minor suggestions, such as incorporation of an additional reference and confirmation of an assumption regarding the percentage of heat removal for modeling the drift-scale heater test.

An observer asked if confirmation of this assumption is being tracked. The AMR originator was able to show the observer that the assumption in question is listed in the DIRS as TBV and will be closed on completion of an ongoing study.

The audit team did not identify any deficiencies in this AMR. The observers agree with the audit team's findings.

4.5.5 AMR No. U0175 (ANL-NBS-GS-000011), "Future Climate Analysis - 10,000 Years To 1,000,000 Years After Present," Revision 00

The purpose of this AMR is to provide input to the infiltration model of Yucca Mountain for the period from 10,000 to 1,000,000 years after closure of the proposed repository. Key inputs include calcite mineral data from Devil's Hole, south of Yucca Mountain, and fossil records from lake-bed sediments from Owen's Lake, CA. The technical approach taken for this AMR is patterned after a similar AMR developed for the postclosure period from zero to 10,000 years.

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

The AMR was in draft form at the time of the audit, undergoing the late stages of the technical review process. This gave the audit team an opportunity to evaluate the technical review and revision processes as specified in AP-3.10Q.

The technical specialist's questions were focused on the traceability, transparency, defensibility, and reproducibility of model inputs and outputs. One concern the audit team technical specialist raised was that the AMR did not address how future climate might affect vegetation cover at Yucca Mountain. The audit team questioned whether there is sufficient technical basis for the parameters in the infiltration model that are used to account for vegetation changes during future climates. The AMR originator answered that climate-induced changes in vegetation were beyond the scope of this AMR. The effects of climate on vegetation, and hence, infiltration, are addressed in the AMR on infiltration, which was also reviewed during the audit (see Section 4.5.2 of this report).

The audit team did not identify any deficiencies for this AMR that had not already been noted during the technical review process. The audit team commended the originators and checkers for compliance with the AP-3.10Q technical review process. Specifically, the auditors were impressed with the word-processing approach that provided color-coded reviewer comments, made it easy to see which portions of AMR text were affected, and also provided a convenient summary of all comments. The observers agree with the audit team's findings.

5.0 NRC STAFF FINDINGS

The observers determined that OQA Audit M&O-ARP-01-02 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 Audit Observer Inquiries

The following AOIs were generated during the audit:

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 were qualified and assumptions verified. NRC requests additional information and details. (Refer to U.S. NRC's Observation Audit Report No. OAR-00-04)."

5.2 NRC Audit Exit Summary

During the audit exit, the observers expressed appreciation for the excellent cooperation and responsiveness provide to them during their observation activities. Also, the observers stated that they agreed with the audit team findings and recommendations, as presented at the audit exit. Also, the observers identified that they had provided the audit team four audit observer inquiries. Further, it was explained that these inquiries related to the subject of net infiltration as discussed in AMR No.U0010, and that these inquiries had been discussed with the audit team and cognizant technical leads.

Although not directly within the scope of the UZ PMR audit, the observers became aware of a project initiative that may roll up technical information related to the consideration of cool repository design referred to as an "Integrated AMR." The observers stated that DWM staff would appreciate a presentation to better understand the proposed Integrated AMR and proposed that this presentation be discussed at the next quarterly management meeting in March 2001.

Except for AMR No. U0085, there were very few audit team recommendations. Although not discussed during the audit nor the audit exit, the Division of Waste Management staff is concerned that the 20 audit team potential recommendations for AMR No. U0085, identified by the audit team and discussed in Section 4.5.3 of this report, may reflect some inattention to detail by the AMR preparers and reviewers.

6.0 References

Flint, A.L.; J.A. Hevesi, and L.E. Flint, *Conceptual and Numerical Model of Infiltration for the Yucca Mountain Area, Nevada*, Milestone 3GUI623M, 1996. Denver, Colorado: U.S. Geological Survey, ACC: MOL.19970409.0087

U.S. Nuclear Regulatory Commission's Observation Audit Report No. OAR-00-04, "Observation of the Office of the Civilian Radioactive Waste Management, Quality Assurance Division, Audit No. M&O-ARP-00-004," March 20, 2000

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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