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
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A. Brownstein, DOE/Wash, DC
S. Hanauer, DOE/Wash, DC
C. Einberg, DOE/Wash, DC
J. Carlson, DOE/Wash, DC
N. Slater, DOE/Wash, DC
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J. Curtiss, Winston & Strawn

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.

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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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DOCUMENT NAME: S/DWM/HLWB/llc/disruptive events obs audit report.wpd ***See Previous concurrence**

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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"

/RA/ 09/25/00
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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:

<u>Procedures</u>

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.