U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT OAR-98-05

OF THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION

AUDIT M&O-ARP-98-20

OF THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM
MANAGEMENT AND OPERATING CONTRACTOR

10/30/98
Ted Carter
Quality Assurance Specialist
Performance Assessment & HLW
Integration Branch
Division of Waste Management

11/2/98
Latif Hamdan,
Engineering and Geosciences
Branch
Division of Waste Management

11/4/98
Sandra Wastler, Section Chief
Performance Assessment & HLW
Integration Branch
Division of Waste Management

11/2/98
David Brooks, Section Chief
Engineering and Geosciences
Branch
Division of Waste Management

Enclosure

1.0 INTRODUCTION

Members of the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management Quality Assurance (QA) staff 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) performance based audit of the Civilian Radioactive Waste Management System Management and Operating (M&O) Contractor. The audit, ARP-98-20, was conducted on September 28 through October 7, 1998.

The NRC staff objective was to gain confidence that OQA and the M&O are properly implementing the requirements of their QA programs in accordance with OCRWM Quality Assurance Requirements and Description (QARD): DOE/RW-0333P) and Title 10 of the Code of Federal Regulations (10CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

This report addresses the effectiveness of the OQA audit and the adequacy of implementation of QA controls in the audited areas of the M&O QA program.

2.0 MANAGEMENT SUMMARY

The NRC staff has determined that the OQA Audit ARP-98-20 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 and technical disciplines, and its assignments and checklist items were adequately described in the audit plan.

The audit resulted in issuing a Corrective Action Report (CAR) (*see Attachment 1*). The NRC staff agrees with the audit team finding and recommended actions.

3.0 AUDIT PARTICIPANTS

3.1 NRC

Ted Carter	QA Observer
Latif Hamdan	QA Observer

3.2 AUDIT TEAM

Kenneth Gilkerson	OQA/QATSS, Las Vegas, NV	Audit Team Leader
Robert Hasson	OQA/QATSS, Las Vegas, NV	Auditor
James Blaylock	OQA, Las Vegas, NV	Auditor
Jefferson McCleary	CRWMS M&O, Moab, UT	Auditor

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*," QAP 16.1Q, "*Performance/Deficiency*

Reporting" and AP 16.2Q, "*Corrective Action and Stop Work.*" 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 performance based audit of the technical data activities associated with the following deliverables:

- WBS 1.2.3.31.2.9 - SP24BM3, The Site Scale Unsaturated Zone Model of Yucca Mountain, Nevada, for the Viability Assessment, dated June 1997 (LBNL)
- WBS 1.2.3.4.1.5.1 - SP25BM3, The Site-Scale Unsaturated Zone Transport Model of Yucca Mountain, Revision 1 (LANL)
- WBS 1.2.3.1.2.5 - SP3000M3, Near-Field and Altered-Zone Environment Report, Volume 1: Technical Basis for EBS Design, Revision 1 (LLNL)

Additional data was evaluated from reports/deliverables randomly selected during the audit. The critical process steps which were evaluated are listed below:

- Data Submittal
- Data Traceability
- Use of Technical Data
- Record Submittals

A performance based audit evaluates products and associated processes to determine the degree to which they meet program requirements and management commitments and expectations. This evaluation of process effectiveness and product acceptability will be based upon:

- Satisfactory completion of the critical process steps
- Documentation that substantiates quality of data
- Performance of trained and qualified personnel
- Implementation of applicable QA program elements

4.2 Conduct of the Audit

The audit was performed in a professional manner and the audit team was well prepared and demonstrated a sound knowledge of the M&O and DOE QA programs. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit.

The DOE audit team and NRC observers caucused at the end of each day during the week of September 28, 1998. 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 Timing of the Audit

The NRC staff believes the timing of the audit was critical. This audit was a follow-up to concerns identified during a previous audit (M&O-ARP-98-16) on the Technical Data Management System

(TDMS). It should be recognized that the OQA staff responded quickly in their follow-up and planning of this audit.

4.4 Examination of QA Programmatic Elements

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. Checklists were used effectively and the NRC observer was provided ample opportunities to provide comments and ask questions.

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 focus of this performance-based audit was on the TDMS. At issue is whether or not the TDMS meets the requirements specified in DOE's QA program, with regard to scientific investigations resulting in data, models and scientific reports. More specifically, the issue is whether or not the TDMS meets the following specific program requirements: (1) data identification is conducted in a manner that facilitates traceability to associated documentation as well as the data qualification status; (2) identification and traceability are maintained throughout the lifetime of the data; (3) technical reports are reviewed in accordance with document review criteria that include applicability, correctness, technical adequacy, and compliance with established requirements; and (4) pertinent background information is made available to the reviewers (DOE/RW-0333P QARD, Supplement III).

The current audit involved reviewing 18 deliverables, including technical reports from the viability assessment supporting documents. The audit resulted in a finding that 9 of the 18 documents audited did not fully satisfy the QA program requirements. Specifically, the following deficiencies have been identified by the auditors: (1) some of the data referenced in the reports were not traceable to their origins; (2) data referenced could not always be traced as to their qualification status; and (3) overall, identification and traceability of the data were not being maintained.

In addition, the audit also disclosed that the technical reviews did not satisfy the review criteria specified in the QA requirements, and that this resulted in issuing technical reports that do not meet the QA program requirements.

The audit recommended conducting remedial action, root cause analysis, and action to preclude recurrence; an impact review; and administrative controls that provide for a detailed explanation in the reports as to how the data was modified or manipulated for analysis and/or support of technical findings.

The staff agrees with the audit findings, and recommendations. In addition, the staff made the following additional observations:

1. The technical reviews cannot be limited to reviewing the technical reports; the technical reviews should involve careful examination of the data provided in the reports as well as the data sources.

2. Many of the technical deficiencies identified in the audit report can and should be corrected at the report preparation stage, by careful identification of the data sources and their Data Tracking Numbers or DTNs, and by providing satisfactory explanations in the reports for all deviations from the source data. Correcting the reports at the review stage would be cumbersome, and highly inefficient.

3. Some of the technical deficiencies identified in the audit report can be easily corrected by prompt and timely updates of the technical database in the TDMS.

4. Deficiencies in the technical reports should not be construed as deficiencies in the electronic TDMS system itself, which seems to be operating very well.

5. The QA office uses a trending analysis code to track deficiencies by category, including technical and non-technical categories (e.g., organization, document control, inspection, records, software, design, scientific investigation, etc.). The code can also track deficiencies to specific departments, contractors, laboratories etc. This is a valuable code that should be used to identify, rank, and ultimately remedy the technical deficiencies, but the program is not available to the M&O, and therefore underutilized. A read-only version of the code should be made accessible to all of the senior M&O managers. The availability of the information generated by the trending code to the M&O managers on a daily basis should greatly improve communication between the QA and M&O senior staffs, and prompt the M&O senior staff to take remedial action to prevent potential deficiencies and/or to correct deficiencies soon after they are uncovered.

6. The auditors noted that a large number of outstanding deficiencies have been identified by previous audits (reportedly about 120 deficiencies). Every effort should to be made to examine the technical deficiencies identified by previous audits, to critically evaluate their significance, and to undertake necessary remedial action as may be warranted.

4.6 Audit Team Qualification and Independence

The qualifications of the Audit Team Leader (ATL) and audit team members were found to be acceptable in that they each met the requirements of QAP 18.1, "Auditor Qualification." The audit team members did not have prior responsibility for performing the activities they audited. 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.

4.7 Summary of OQA Findings

The audit team issued one Corrective Action Report: **CAR NO. LVMO-99-C-001** (*see Attachment* 1).

Requirement:

DOE/RW-0333P QARD, Supplement III, *SCIENTIFIC INVESTIGATION*, addresses controls for scientific investigations that result in data, models and technical reports.

Section III.2.3 requires that: A) Data shall be identified in a manner that facilitates traceability to associated documentation; B) Data shall be identified in a manner that facilitates traceability to its qualification status; and C) identification and traceability shall be maintained throughout the life of the data.

Section III.2.5 requires that "Technical reports shall be reviewed in accordance with the requirements of Subsection 2.2.10, Document Review."

Section 2.2.10 requires that review criteria include "applicability correctness, technical adequacy, and compliance with established requirements" and that "pertinent background information of data shall be made available to the reviewers."

Description of Condition:

Contrary to the above, a review of selected Technical Reports from Viability Assessment documents evaluated during Audit M&O-ARP-98-20 disclosed that: 1) some data referenced in the reports were not traceable to its origin; 2) data referenced could not always be traced to its qualification status; and 3) overall, identification and traceability of the data was not being maintained. The technical reviews performed per the requirements of QARD, Section 2.2.10, by the data source (i.e., CRWMS M&O, National Laboratories, and USGS) did not ensure the applicability, correctness, technical adequacy nor compliance with requirements for the technical reports reviewed. As a result, technical reports have been issued which do not meet QA program requirements. The deficiency identified suggests that rigor in the preparation and review process is ineffective.

Recommendations:

1. Provide remedial actions, root cause analysis, and action to preclude recurrence.
2. Perform an impact review of the extent of condition and take appropriate actions.
3. Establish administrative controls that provide for a detailed explanation in the respective reports as to how the data was used and what manipulation of conversion was done to it, to get to the presentation in the report. Without this information, the technical report reviewers and users will be guessing about what was done, and coming to different opinions as to whether the data supports the technical report or not.

4.8 NRC Staff Findings

The NRC staff determined that the audit was effective in assessing M&O compliance with requirements in the areas examined. The audit was conducted in a professional manner and the audit team adequately evaluated activities and objective evidence. The ATL was extremely effective in his daily presentation to the M&O management and staff in providing guidance to the audit team. The checklist questions provided a sound basis to conduct the audit. Both the auditors and M&O staff were knowledgeable in their respective disciplines. The M&O management suggested that less OQA involvement is needed to implement the QA process and that M&O staff should be made accountable for adequate implementation of the QA process. The NRC staff agrees with QA accountability at the M&O staff level. In addition, OQA involvement is necessary to maintain adequate implementation of safety and health policy.

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

8
CAR NO. LVMO-98-C-001

PAGE 1 OF ___

QA: L

CORRECTIVE ACTION REQUEST

1 Controlling Document:	2 Related Report No.
Quality Assurance Requirements and Description (QARD) Document	M&O-ARP-98-20
3 Responsible Organization:	**4 Discussed With:**
Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) / U.S. Geological Survey (USGS)	Dan Wilkins, CRWMS M&O; Bob Craig, USGS.

5 Requirement:

DOE/RW-0333P QARD, Supplement III, *SCIENTIFIC INVESTIGATION*, addresses controls for scientific investigations that result in data, models and technical reports.

Section III.2.3 requires that "A. Data shall be identified in a manner that facilitates traceability to associated documentation. B. Data shall be identified in a manner that facilitates traceability to its qualification status. C. Identification and traceability shall be maintained throughout the lifetime of the data."

Section III.2.5 requires that "Technical reports shall be reviewed in accordance with the requirements of Subsection 2.2.10, Document Review."

Section 2.2.10 requires that review criteria include "applicability, correctness, technical adequacy, and compliance with established requirements" and that "pertinent background information or data shall be made available to the reviewers."

6 Description of Condition:

Contrary to the above, a review of selected Technical Reports from Viability Assessment documents evaluated during Audit M&O-ARP-98-20 disclosed that: 1) some data referenced in the reports were not traceable to its origin; 2) data referenced could not always be traced to its qualification status; and 3) overall, identification and traceability of the data was not being maintained. The technical reviews performed per the requirements of QARD, Section 2.2.10, by the data source (i.e., CRWMS M&O, National Laboratories, and USGS) did not ensure the applicability, correctness, technical adequacy nor compliance with requirements for the technical reports reviewed. As a result, technical reports have been issued which do not meet quality assurance program requirements. The deficiency identified suggests that rigor in the preparation and review process is ineffective.

7 Initiator	9 Does a Stop Work condition exist?
Robert P. Hasson for Kenneth O. Gilkerson Date 10/8/98	Yes ___ No X ; If Yes, Attach copy of SWO If Yes, Check One: A☐ B☐ C☐ D☐

10 Recommended Actions:

1. Provide remedial actions, root cause analysis, and action to preclude recurrence. (including assessment of potential use of incorrect data) RWC 10/9/98
2. Perform an impact review of the extent of condition and take appropriate actions.
3. Establish administrative controls that provide for a detailed explanation in the respective reports as to how the data was used and what manipulation or conversion was done to it, to get to the presentation in the report. Without this information, the technical report reviewers and users will be guessing about what was done, and coming to different opinions as to whether the data supports the technical report or not.

11 QA Review	12 Response Due Date:
Robert P. Hasson Date 10/8/98	20 Working Days From Issuance

13 DOQA Issuance Approval:

Printed Name Robert W. Clark Signature R.W. Clark Date 10/9/98

22 Corrective Action Verified	23 Closure Approved by:
QAR Date	DOQA Date

Attachment

CAR/SWO CONTINUATION PAGE

Discussion

The deficient conditions found during the audit can be characterized in one or a combination of the following ways:

1. Some of the data disconnects that were identified can be traced to a report reflecting an incorrect Data Tracking Number (DTN) that points to the wrong supporting data set. This was found in several cases for Lawrence Berkeley National Laboratory (LBNL) and Lawrence Livermore National Laboratory (LLNL) reports.

2. Data traceability problems exist in the preparation and format of the reports themselves, wherein, due to numerous references to DTNs and other report references, there is no way to track the technical conclusions or data depicted in the reports back to the data source. A number of USGS and Los Alamos National Laboratory (LANL) technical reports reflect this condition.

3. Data that can be found within the referenced DTN but other data from the same tables cannot be found in any of the referenced DTNs is another issue. For example, a chapter in the Total-System Performance Assessment (TSPA) Technical Basis Document prepared by Sandia National Laboratories (SNL) provides data that is both inconsistent with the data reflected in the supporting DTN but also provides data that is nonexistent in the DTNs referenced (i.e., they come from somewhere else).

4. Data and conclusions that are produced in a report cannot be reproduced from the referenced data.

The specific documents that were reviewed during the audit and a brief description of any anomalies identified during this review follows. It should be kept in mind that in order for a definitive conclusion to be reached (the data in the Technical Data Management System (TDMS) does or does not support the report being examined), several conditions had to exist: 1) There had to be data in the report; 2) There had to be data in the TDMS that was clearly related to the report (same dates, same location [G-2], same type of data [pump test], etc.); and, 3) The data in the two locations (report and TDMS) had to be presented in formats that were similar enough that it was possible to make a comparison (usually by performing some simple calculations on one data set or the other). In many instances these conditions did not exist and no evaluation was possible.

Report 1

Single Heater Test Final Report, SPY148M4, SNL

Tables in Appendix C were examined. These tables present (among other data) the x,y,z locations of gauges in the Single Heater Test (SHT) block. While the report identifies an SNL DTN number (SNF35110695001.009), it was not in the TDMS. Data found in the Records Center for the SHT, First Quarter Results (SNF35110695001.003), disclosed discrepancies in locations of some gauges relative to the Appendix C tables of this report. Additionally, upon checking with LLNL, the locations of many of LLNL RTDs and Temp Gauges were not consistent with LLNL documents (i.e., DTN LL970805504244.043). The SNL document did not reference any LLNL DTN or Technical Data Information Form (TDIF) numbers for the source of LLNL data that was included in this report resulting in the Q-status of gauge locations supplied to SNL by LLNL being indeterminate.

CAR/SWO CONTINUATION PAGE

Report 2

TSPA-VA Technical Basis Document, Unsaturated Zone Hydrology Model, SLX0M3, SNL

Chapter 2, table 2-34, was examined. The table provides "alpha" and "k" values for model layers and references DTNs SNT05091597001.003, LB970801233129.001, and LB9711000012S4.004. The SNL DTN entry in the TDMS does contain most of the "alpha" values. However, the report contains values for model layers that do not exist on the SNL DTN, and the report inverts the *chz* and *chv* values relative to the SNL DTN. Values for "k" referenced to the SNL DTN do not exist on that DTN. Mean values of "alpha" and "k" are referenced to the LBNL DTNs. These DTNs are large model warehouse or system performance entries that could not be accessed for comparison.

Report 3

Administrative Report: Integrated Fracture Data in Support of Process Models, Yucca Mountain, Nevada, SPG32M3, USGS

Table B of the report provides DTNs and associated titles that are apparently applicable to the subject of the report, but no specifics as to which DTNs support which report sections. Despite several attempts, it was not possible to specifically relate data in the TDMS to data in the report.

Report 4

Results of Hydraulic and Conservative Tracer Tests in Miocene Tuffaceous Rocks at the C-Hole Complex, 1995 to 1997, Yucca Mountain, Nye County, Nevada, SP23PM3, USGS

Table B provides a list of DTNs and associated titles used in the report. These are apparently appropriate to the report topic, but specific DTNs are not referenced to specific report sections. Based on similarities in titles and dates, it was possible to associate DTN GS970308312314.002 (Water-level altitude data from four wells in the continuous network, May through December 1996) with Figure 26 of the report (Drawdown in UE-25 ONC-1, UE-25 WT#3, USW H-4, and UE-25 WT#14, May 6, 1996, to March 26, 1997). By performing a series of calculations on the data in the TDMS (correlating dates of measurement to time in minutes since the start of pumping, and calculating differences in water-level altitudes between start dates and dates of measurement) it was possible to confirm that selected points on Figure 26 were supported by data in the TDMS.

In the same report, chemical data on Table 11 were checked against data on DTN GS970708312314.004 (also selected based on similarities in title and date), and the data in the TDMS were found to support the report table.

Report 5

Preliminary Saturated-Zone Flow Model, SP24CBM3, USGS

Table B of the report lists DTNs and associated titles that are apparently appropriate to the topic of the report and the data provided on Table 1 of the report. However, despite several attempts, it was not possible to associate any specific Table 1 data entries with a specific data entry on a DTN. In conjunction with this deliverable, two TDIFs were submitted on C-Hole complex pump tests, TDIF 305143 on the 280 GPM pump test, and TDIF 305142 on the 356 GPM pump test. When DTNs for these TDIFs were called up from the TDMS, they were obviously data from the pump tests. However, differences in titles/parameters (pump test Vs pneumatic pressure), format, and units, precluded evaluation by the audit team.

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

8

☑ Corrective Action Request
☐ Stop Work Order

NO. LVMO-99-C-001

PAGE 4 OF ____

QA: L

CAR/SWO CONTINUATION PAGE

Report 6

The Site-Scale Unsaturated Zone Model of Yucca Mountain, Nevada, for the Viability Assessment, SP24BM3, LBNL

Figure 10.4-1 of the report shows pneumatic pressure data from borehole NRG-7a. Based on Table 10.3-1, this information came from DTN GS960308312232.001. When this DTN was pulled from the TDMS, it was found that there was no overlap in dates. Therefore, the data on the figure came from some other source.

Table 11.3 of the report provides thermal conductivity data (miss-labeled as thermal conditions) and references the Reference Information Base (RIB). When the RIB entry was pulled from the TDMS, it was found that three values (of the five presented in the report) matched. The other two apparently came from another (unidentified) source.

Figure 11.3 of the report provides a plot of temperature Vs depth for borehole SD-12, and compares observed and calculated data. Based on Table 11.2, the observed temperature data came from DTN GS960308312232.001. While the temperature data on the report figure is plotted as a single line, the TDMS entry provides tabular data collected over a period of several months (therefore, a range of temperatures was recorded at each depth of measurement). When the temperature ranges from the DTN in the TDMS were plotted by the audit team on figure 11.3 of the report, it was found that they did not match (fell to the left of) the temperature profile on the figure.

Table 13.3.2 of the report provides data on chloride concentration in pore and perched water from Yang et al 1996. Based on table 13.2.1, the DTN associated with this reference is GS961108312271.006. This DTN does not appear to exist in the TDMS. The audit team did a search on author name but was unable to locate the supporting data.

Figure 13.6.6.3 of the report provided data on a pump test at G-2. Table 13.2.1 indicates that this data came from DTN GS960508312312.006. When this DTN was pulled from the TDMS, it was found to contain only a few days of data rather than the 250 days of data shown on the figure. The audit team did a search on the author and was able to locate the correct DTN (GS970208312312.003) which did support the report figure.

Report 7

Near Field and Altered Zone Environment Report, Volume 1: Technical Basis for Engineered Barrier System Design, SP3000M3, LLNL

On page 95 of the report, DTN LL960201004241.011 is cited and reference is made to Table 10.4-4. This table (as is clear from the referencing) appears on page 10.4-94 of another related deliverable (M0L305). When the DTN was pulled from the TDMS, it was found that the data in the TDMS did not match the data in the report. While all the data were from the same area (natural analog studies at the Wairakei geothermal field), the report presented more information both in duration and in number of parameters reported.

Report 8

The Site-Scale Unsaturated Zone Transport Model of Yucca Mountain, SP25BM3, LANL

Figure 6-2 of the report presents information on Chlorine-36/total Chloride ratios in infiltrating water. A table in the report provides a listing of applicable DTNs by category, but does not provide titles for the DTNs. In the category of Chlorine-36 studies, the table provided 34 DTNs. The audit team pulled five DTNs that were apparently not directly applicable to infiltrating water before concluding that this tact was too time consuming. The team then did a search by author and located a few titles that appeared to be potentially applicable. These were pulled from the TDMS, but no data directly applicable to Figure 6-2 could be located.

CAR/SWO CONTINUATION PAGE

Report 9

The Technical Site Suitability Synthesis Report (Site Description Document), Section 4, M&O

Section 4.1.3 of the Site Description Document discussed Regional and Site Climatology, and Section 4.1.3.1 provides data sources. Section 4.1.4 discussed the Meteorological Monitoring Network. Data is presented in a series of summary tables (4.1-11 through 4.1-20). The Site Description Document does not provide DTNs for the data in the summary tables but a CRWMS M&O document that was referenced in Section 4.1.3.1.was pulled *(Engineering Design Climatology and Regional Meteorological Conditions Report*, B00000000-01717-5707-00066, Revision 00). This report is clearly the correct source for the summary tables presented in the Site Description Document: however, there is no link to the DTNs that would have provided the source data for the summary tables.

It should be noted that recent audits have identified deficiencies at LANL, LBNL and LLNL relative to a lack of appropriate preparation and review of technical reports (e.g., LANL-98-D-108 and D-109; LBNL-98-D-030; and LLNL-98-D-086 and D-087).