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Washington, DC 20585

QA: QA

APR 11 2007

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REPORT FOR AUDIT OQA-OCRWM-07-19 OF THE SUBMITTAL, CONTROL, AND USE OF TECHNICAL DATA DEVELOPED FOR THE YUCCA MOUNTAIN PROJECT (YMP)

Representatives of the YMP conducted a limited scope audit of the submittal, control, and use of technical data developed for the YMP by Office of Civilian Radioactive Waste Management (OCRWM), Bechtel SAIC Company, LLC /Management and Operating Contractor (M&O), and the OCRWM Lead Laboratory (Sandia National Laboratories). The audit was performed from March 12 to 22, 2007, in Las Vegas, Nevada.

As a result of this audit, the audit team documented six condition reports (CR) categorized as conditions adverse to quality, and one CR documenting a recommendation. Specific details are described in Section 2.0 of the enclosed report.

The audit team determined that the processes and procedures for OCRWM, the M&O, and the Lead Lab were adequate for control and use of data. Overall, implementation was determined to be satisfactory with the exception of the identified conditions adverse to quality. The team also determined the overall effectiveness of the processes implemented by the project to be satisfactory.

The identified conditions will be followed to closure. The audit is complete and closed and no response to this letter is necessary.

If you have any questions, please contact me at (702) 821-8448 or Kenneth O. Gilkerson at (702) 821-8407.

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OQA:EDR-0874

Enclosure:
Report Plan OQA-OCRWM-07-19



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QA: QA

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

**REPORT FOR AUDIT OQA-OCRWM-07-19
OF
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT,
BECHTEL SAIC COMPANY, LLC (MANAGEMENT AND OPERATING
CONTRACTOR), AND THE OCRWM LEAD LABORATORY
(SANDIA NATIONAL LABORATORIES)**

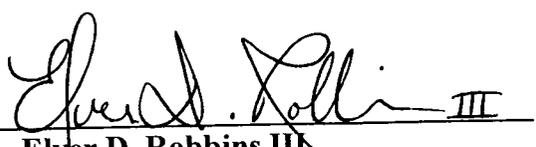
**FOR SUBMITTAL, CONTROL, AND
USE OF DATA ON THE YUCCA MOUNTAIN PROJECT**

AT LAS VEGAS, NEVADA

MARCH 12 - 22, 2007

Prepared by: 
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Office of Quality Assurance

Date: 05 April 2007

Approved by: 
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Date: 4/5/2007

EXECUTIVE SUMMARY

Representatives of the Yucca Mountain Project (YMP) conducted a limited scope audit of the submittal, control, and use of technical data developed for the YMP by the Office of Civilian Radioactive Waste Management (OCRWM), Bechtel SAIC Company, LLC/Management and Operating Contractor (M&O), and the OCRWM Lead Lab (Sandia National Laboratories) organizations in Las Vegas, Nevada, from March 12 to 22, 2007. This audit was conducted to evaluate the adequacy, implementation, and effectiveness of these processes.

The scope of the audit included reviewing the processes that address the submission, control and use of the data maintained in the Technical Data Management System (TDMS) in relation to the latest revisions of DOE/RW-0333P, *Quality Assurance Requirements and Description (QARD)*; QA-DIR-10, *Quality Management Directive (QMD)*; QA-PRG-001, *Yucca Mountain Project Lead Laboratory Quality Assurance Program Description*; and applicable procedures implemented by each organization. A primary objective of this audit was to evaluate the effectiveness of the processes for controlling technical data, the timeliness of submittal of the data to the Project's TDMS, and ensuring that the uses of the submitted data are traceable to the processes and products that reference the data. The audit team developed and used critical process steps for assessing the data control processes and determining program adequacy, process implementation, and effectiveness of these processes.

In addition, the audit team examined corrective actions for condition reports (CR) identified from previous audits and surveillances of these activities.

The audit team documented six CRs categorized as conditions adverse to quality (CAQs), and one CR documenting a recommendation as a result of this audit. One noteworthy practice was also identified relating to Licensing Defense activities.

CRs 10300 and 10315 identified CAQs associated with the qualification status data being maintained correctly in the TDMS, while CRs 10298 and 10301 identified CAQs associated with maintaining traceability from the data to its associated documentation. CR 10295 identifies an issue with the Technical Data Information Form (TDIF) being correctly completed for OCRWM suppliers of data. CR 10302 addresses an OCRWM document hierarchy issue wherein AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System*, a project level procedure, is not being followed by all personnel submitting project data into the TDMS. The Lead Lab and the University and Community College System of Nevada (UCCSN) program use different data control processes. Since data from University of Nevada Las Vegas (UNLV) is obtained from a public website, a concern was noted that data integrity could be compromised. CR 10303 documents a recommendation to address this.

A noteworthy practice was identified relative to the activities being performed by the Lead Lab's Licensing Defense organization. Licensing Defense Data Traceability and Qualification personnel are performing data traces and data reviews to ensure the integrity of all data and Analysis and Model Reports (AMR) used to support the License Application and Total System Performance Assessment (TSPA). This data is being traced to its source to ensure integrity, traceability, qualification status, and transparency in the cited documents. A software tool has

been developed to perform and capture this trace. This effort is performed subsequent to the quality processes and controls already in place at YMP for the initial submission, control and use of data in reports. This effort provides an additional assurance of the integrity of the data developed or acquired for use at YMP.

Additionally, the Lead Lab presented to the audit team and observers an insight to the next generation TDMS database structure that they are developing. The current TDMS database is founded on older software and database technology. The Lead Lab is developing a new database using technology that ties all sources of data, databases, and supporting information to the TDMS. This new system should be in place by June 2008.

The Audit Team observed just prior to the audit, that the Lead Lab had completed Surveillance LLQA-IS-07-16 of control of data in the TDMS for the model report MDL-NBS-HS-000023, Revision 01B, *Simulation of Net Infiltration for Present-Day and Potential Future Climates*. While similar in scope to the audit, the focus of this surveillance was on the quality assurance (QA) compliance review of the draft document and dealt with all inputs to the AMR. This surveillance identified two CRs characterized as CAQs and two process recommendations. One CAQ addressed an incomplete data review (i.e., checklist not completed) and the other addressed an incomplete reference for a data set (i.e., records package). These CRs cite additional issues to those identified in this audit.

Although the procedures and processes for OCRWM, the M&O, and the Lead Lab were adequate for control and use of data, the CRs cited in the audit and surveillance depict some implementation issues. Overall, implementation for procedures and processes were determined to be effective with the exception of the identified CAQs.

1.0 PURPOSE AND SCOPE

The audit team reviewed the adequacy, implementation, and effectiveness of the QA program procedures and critical process steps applicable to the submission, control, and use of data developed or acquired for YMP and maintained in the TDMS. The critical process steps reviewed included:

- Sources of technical information
- Identification of information as data
- Data reduction
- Data review and submittal
- Data traceability and transparency
- Data receipt and input into the TDMS
- Status of data in TDMS
- Data qualification
- Selection and use of technical data
- Data revision/change control
- Data input verification
- Record submittals

Audit team activities consisted of technical and QA reviews of selected data from the TDMS, the documentation supporting the data and technical products that cite the selected data. Data used as direct inputs in model report MDL-NBS-HS-000023, Revision 01B, *Simulation of Net Infiltration for Present-Day and Potential Future Climates*, Science & Technology (S&T) data from Los Alamos National Laboratory (LANL), recent data from U.S. Geological Survey (USGS), selected data from M&O pre-closure science activities and data from UNLV were used to perform this assessment. The primary focus of this audit was to evaluate the effectiveness of the processes for controlling technical data, the timeliness of submittal of the data to the Project's TDMS, and ensuring that the uses of the submitted data are traceable to the processes and products that reference the data. QA reviews were conducted in the areas of submittal of data into the TDMS, control of data in the TDMS, maintaining correct qualification status of the data and ensuring the traceability of the data to its documentation (sources). Review activities consisted of examination of documents and records, retrieval of information from various databases that support TDMS, software qualification, document development activities, and interviews with responsible OCRWM and OCRWM external agencies, M&O, and Lead Lab personnel.

2.0 AUDIT DETAILS

The Audit Team Leader held a pre-audit meeting at Las Vegas, Nevada, on March 12, 2007. The audit team and observers met each afternoon to review audit status and potential issues. An e-mail documenting progress of the audit and any potential issues was sent out each evening to affected organizations. Additionally, the Audit Team Leader met, as needed, with management of OCRWM, the M&O, and the Lead Lab to communicate audit status and discuss issues. The Audit Team Leader held a post-audit briefing on March 22, 2007, to report the overall results of the audit.

Attachment A lists the personnel contacted during the audit, including meeting attendees. Attachment B provides a summary of the audit results.

The completed audit checklist developed from the critical process steps provides specific detail for the data sets and technical products assessed during the audit.

Audit Team and Observers

Kenneth O. Gilkerson	Office of Quality Assurance /Audit Team Leader
Roxie L. Scaglione	Lead Lab/Audit Team Member
Richard L. Maudlin	BSC/Audit Team Member
Floyd H. Dove	Project Enhancement Corporation/Technical Specialist
Thomas O. Matula	U.S. Nuclear Regulatory Commission (NRC)/Observer
Robert D. Brient	NRC, Center for Nuclear Waste Regulatory Analyses/Observer

2.1 Data Submittal to the TDMS for OCRWM Suppliers

A review was performed of the processes in place for the submittal of data to the TDMS for OCRWM suppliers supporting the Office of Chief Scientist in accordance with the requirements of the following procedures to determine that the process for data submittals was effective. The audit team also interviewed personnel from USGS, LANL, UNLV and OCRWM relative to the processes and data assessed.

- AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System*
- LANL-OSTI-QP-SIII.3, *Transfer of Data and Technical Information*
- YMPB-USGS-QMP-SIII.02, *Data Identification and Review*
- UCCSN QAP-3.6, *Submittal of Data*

The requirements for the submittal of data are referenced in the applicable U.S. Department of Energy (DOE) procurement documents. The procurement documents require that the supplier implement the requirements of their approved QA program for the specified scope of work. A review of the data submittals and processes for LANL, USGS, and UCCSN, (i.e., UNLV) were found to be satisfactory and effective except for the noted CAQs identified during the audit. CR 10295 identifies an issue with the TDIF being correctly completed for OCRWM suppliers of data. The originator/preparer for data on the TDIF was incorrectly identified in the TDMS for LANL S&T data submittals as well as UNLV data submittals. CR 10302 identified that AP-SIII.3Q requires all organizations developing or acquiring data for use on YMP to comply with the processes in this procedure. The UCCSN does not follow AP-SIII.3Q as required but posts its data on a public web site. OCRWM approved a change to the cooperative agreement to allow UCCSN to put data on the web site. The AP-SIII.3Q was not revised to reflect this change (see CR 10302). A process recommendation was proposed with regards to refraining from obtaining data from a public website that may be subject to data manipulation. UNLV data should be submitted to the TDMS in accordance with AP-SIII.3Q. This recommendation was documented in CR 10303.

Overall, data from OCRWM suppliers was found to be submitted to the YMP TDMS Coordinator, with the exception of the UCCSN, which maintains the data on their public web site.

2.2 Control of Data from TDMS by the Lead Lab

A review of the processes that address the submission, control, and use of the data by the Lead Lab was evaluated by examining a selection of data in the TDMS in regards to the critical process steps identified in Section 1.0 as well as governing QA program requirements and implementing procedures. Direct input data [20 of 54 data tracking numbers (DTN)] from the model report MDL-NBS-HS-000023, Revision 01B, *Simulation of Net Infiltration for Present-Day and Potential Future Climates*, and new data identified in Lead Lab TSPA Data Input Package (TDIP) Reports were selected to perform this assessment. Interviews of Lead Lab personnel as well as documentation reviews were also conducted.

The following procedures were also examined in evaluating the processes being implemented by the Lead Lab relative to the critical process steps:

- AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System*
- TST-PRO-001, *Submittal and Incorporation of Data to the Technical Data Management System*
- LS-PRO-001, *Technical Reports*
- SCI-PRO-004, *Managing Technical Product Inputs*
- SCI-PRO-005, *Scientific Analysis and Calculations*
- SCI-PRO-006, *Models*
- PA-PRO-001, *Technical Reports*

The audit team review of sampled data sets and associated AMRs/Technical Reports resulted in the following findings relative to data qualification status and maintaining it throughout the lifetime of the data, data traceability to its associated documentation and consistency in the control of data with particular concern on change control. The team reviewed the draft Surveillance LLQA-IS-07-16 on data and interviewed the Lead Lab surveillance personnel. Two CAQs were identified by the Lead Lab, which reflected similar issues found by the audit team. A noteworthy practice was also identified during the audit.

Qualification Status

In a review of 20 Net Infiltration DTNs, the audit team identified four data sets that had been categorized in the TDMS as Unqualified with a note that upon approval of a specific AMR (ANL-NBS-HS-000055 R00) the data qualification status would change to qualified. The qualification status changed on March 8, 2007, six months after approval of the AMR. The Lead Lab Surveillance LLQA-IS-07-16 had identified one of these four data sets as being incorrect, but did not initiate a CR. It was corrected by TDMS during the surveillance. An additional Net Infiltration DTN categorized in the TDMS as Unqualified should have been changed to Qualified based on completed technical reviews that had been previously performed. In these cases, the change control processes were not implemented as required to reflect the accurate qualification status of this data. During review of new Lead Lab data being referenced in a TDIP, an additional DTN was identified in the TDMS as being Qualified; but a subsequent review of the associated documentation disclosed that the data qualification report making it "Q" was never approved. An additional issue was identified during the follow-up of CR 9781 on data values being incorrect. It was noted that the DTN status of this incorrect data was still characterized as Qualified in the TDMS and the M&O used this data in engineering products without knowledge of its changed qualification status. Again the initiators failed to use the Impact Review Action Notice (IRAN) as required. In all of this, it was observed that there are no checks and balances in the TDMS system to ensure that the information being depicted is correct, accurate or complete. The audit team documented these CAQs in CRs 10300 and 10315.

Data Traceability to Associated Documentation

In the review of the sampled data, the audit team noted numerous inconsistencies in the depiction of data information in the TDMS [Automated Technical Data Tracking (ATDT) database]. The

ATDT depicts the DTN information on a TDIF. A review of 20 Net Infiltration DTNs disclosed numerous cases of inaccurate, incomplete, or misleading information. Many TDIFs indicated 'no Records Roadmaps found.' A review of the associated records package in Record Information System (RIS) would often disclose the existence of one. Other TDIFs were incomplete and did not reference the associated documentation (i.e., records packages) and in one case the records package cited did not exist. The TDIF has a quality control check block on it, but interviews with TDMS personnel disclosed that they only verified that information was in certain blocks on the form. There was no verification of the accuracy or completeness of this information or that it even exists. The audit team documented these CAQs in CR 10301.

Interview and procedure reviews disclosed another traceability issue. During the reviews of Net Infiltration Data and interviews of Licensing Defense Data Traceability and Qualification personnel, it was noted that reviews of the Records Roadmap are no longer required. As part of the corrective actions to the data CARs (LVMO 98-C-002 and LVMO 99-C-001), a commitment was made to produce these records roadmaps. Reviews of data as well as the roadmaps was part of the qualification status verification effort. A requirement to review these roadmaps and assure that they were correct has existed in the project program procedures up through the issuance of LP-3.15Q-BSC, Revision 3, ICN 1, *Managing Technical Product Inputs*. Although the requirement for the originator to produce the roadmaps still exists in current procedures, there is no requirement for a review of this information along with the data review to ensure completeness and accuracy of the source trace. CR 6491 depicted a failure of the process to maintain traceability of data to its sources in roadmaps that are not reviewed. Licensing Defense Data Traceability and Qualification personnel are currently identifying errors in the roadmaps in the data re-review effort that they are doing. Roadmaps developed for current DTNs need to be reviewed for accuracy and completeness to meet the QARD requirement to provide traceability to data's documentation and quality status on YMP. The audit team documented these CAQs in CR 10298. It should be noted that a revision to the Lead Lab procedure TST-PRO-001 effective on March 19, 2007, appears to have addressed this issue, but the AP-SIII.3Q and BSC procedures do not.

Consistency in the Control of Data

AP-SIII.3Q is a project procedure that established consistent controls for all project personnel developing or acquiring data for use on the YMP. The Lead Lab procedure TST-PRO-001, Revision 0, was developed for use by Lead Lab personnel and duplicated the processes and controls in AP-SIII.3Q. The audit team viewed that as long as the procedure reflected the administrative procedure (AP) process controls, their lower-level implementing procedure was appropriate to use. Near the end of the audit the audit team found that the TST-PRO-001 had been revised (effective March 19, 2007) and no longer reflected the requirements and processes of the controlling project AP. A cursory review of the new procedure disclosed changes in processes that were improvements in many areas, but discarded the IRAN used to address changes in data and document actions taken relative to impacts on documents. The process established for change control in the new TST-PRO-001 is not adequate. Similarly, it was identified previously in the OCRWM portion of the assessment that the UCCSN program no longer implements AP-SIII.3Q as required. This OCRWM document hierarchy issue is documented in CR 10302.

Noteworthy Practice

A noteworthy practice was identified relative to the activities being performed by the Lead Lab's Licensing Defense organization. Licensing Defense Data Traceability and Qualification personnel are performing data traces and data reviews to ensure the integrity of all data and AMR used to support the License Application and TSPA. This data is basically being traced to its source to ensure integrity, traceability, qualification status, and transparency in the cited documents. A software tool has been developed to perform and capture this trace. A demonstration on the use of this tool was performed during the audit for the audit team and NRC observers and was well received. This effort is performed subsequent to the quality processes and controls already in place at YMP for the initial submission, control and use of data in reports. This effort provides an additional assurance of the integrity of the data developed or acquired for use at YMP.

Technical Adequacy

The technical review began with the selection of 54 DTNs from Section 4 of the draft model report MDL-NBS-HS-000023, Revision 01B, *Simulation of Net Infiltration for Present-Day and Potential Future Climates*. Because of the depth of the review, 20 DTNs from the initial field of 54 DTNs were evaluated in detail. In general, the controls to ensure that data are identified in such a manner that facilitates traceability to associated documentation are adequate. However, some additional checks and balances are necessary to maintain the integrity of technical data entered into the TDMS. As noted previously, a CAQ was written for 7 DTNs (of 20 reviewed) that were not consistent with this QARD requirement (Section III.2.3.A). The technical adequacy and transparency for data use, data reduction, and data qualification was satisfactory for the 20 DTNs reviewed. It was not necessary to contact the originator of any data documentation to explain technical issues. Examples include the following:

TDR-NBS-HS-000019, *Technical Evaluation and Review Results, Technical Procedures, and Methods Related to the Collection of Moisture Monitoring Data Using Neutron Probes in Shallow Boreholes* (evaluated using LP-3.11Q-BSC, *Technical Reports*, for DTN MO0601SEPNEULG.002).

ANL-NBS-HS-000055, *Data Analysis for Infiltration Modeling: Development of Soil Units and Associated Hydraulic Parameter Values* (evaluated using LP-SIII.9Q-BSC, *Scientific Analyses*, for DTNs MO0605SEPDEVSH.002, MO0605SPASOILS.005, MO0605SEPFCSIM.000, and MO0605SEPALTRN.000).

DTN MO0603SEPSTREA.000 containing mean streamflow data (classified as existing data) was qualified using LP-SIII.2Q-BSC, *Qualification of Unqualified Data*.

Various types of data encountered during the audit were developed data, acquired data (both qualified and unqualified), and existing data. No accepted data were associated with the 20 DTNs reviewed. In general, the DTNs were traced to the actual data in the data source documentation unless the source files were simply too large. The 20 DTNs evaluated during the audit could be traced to their data source.

Data that is superseded, revised or otherwise modified receives a new DTN. Objective evidence of this process can be seen on the TDIF and in the RPC records packages for the following eight DTNs:

MO0606SEPRECIP.001, MO0605SPASOILS.005, MO0601SEPNEULG.002,
MO0305SEP01MET.002, MO0206SEPQ1998.001, MO0302METMON99.001,
MO0209SEPQ2000.001, and MO0305SEP02MET.002.

If data is changed, superseded, or modified, impacts for data use in technical products are determined using the IRAN process (AP-SIII.3Q). Some concern is expressed by the audit team that this IRAN impact process has been removed from the latest version of TST-PRO-001 and proposed to be removed from AP-SIII.3Q. This concern is captured in CR 10302.

The removal of the IRAN process from both procedures appears to be counter productive and should be reconsidered. Objective evidence for the IRAN process can be seen on the TDIF and in the RPC records packages for the following DTNs:

MO0606SEPRECIP.001 (IRAN 5589 A-C and IRAN 5632-A),
MO9907GCESPYMN.000 (IRAN 5417-A), and
MO0605SPAFABRP.004 (IRAN 5584-A).

In general, controls to ensure that data is traceable to its qualification status are adequate. However, some additional checks and balances in the TDMS are necessary to maintain data integrity.

2.3 Control of Data from TDMS by the M&O for Pre-Closure Science and Engineering

The audit team conducted a review of the M&O processes that address the submission, control, and use of the data maintained in the TDMS in relation to program requirements and the critical process steps identified in Section 1. Additionally, the team evaluated applicable procedures implemented by each M&O organization, Nuclear Facilities Engineering (Seismic), and Design Engineering.

The audit team assessed the adequacy, implementation, and effectiveness of the requirements and activities to evaluate the effectiveness of the processes for controlling technical data, the timeliness of submittal of the data to the Project's TDMS, and ensuring that the uses of the submitted data are traceable to the processes and products that reference the data. While the audit team assessed data and associated documentation, the team also interviewed cognizant personnel relative to these processes. The Lead Lab is the focus for processing and control of data through the TDMS, but the M&O produces and submits data as well. Data is used by both the Lead Lab in developing science products and the M&O in developing engineering products.

The procedures and program document implemented by the M&O in addressing the critical process steps include the following:

- AP-SIII.3Q, *Submittal and Incorporation of Data to the Technical Data Management System*
- PA-PRO-0301, *Managing Technical Product Inputs*
- CC-PRO-2001, *Technical Interface Control*
- EG-PRO-3DP-G04B-00037, *Calculations and Analyses*
- EG-PRO-3DP-G04B-00058, *Supplier Engineering and Quality Verification Documents*
- QA-DIR-10, *Quality Management Directive*

Nuclear Facilities Engineering (Seismic):

The audit team evaluated data selection and use for data considered in developing velocity profiles for updated ground motion site-response modeling. The data evaluated are being used as direct input. Some of the data evaluated are unqualified.

The audit team found that for the data evaluated, the processes in place adequately ensure:

- external source data that are not identified as established fact and are used as direct input to scientific analysis or performance modeling are qualified for its intended use;
- unqualified data used in scientific investigation provides traceability to its status as unqualified data;
- unqualified data developed from scientific investigation activities that are used as direct input to site characterization, scientific analysis or performance modeling that address safety and waste isolation will be qualified; and
- for those qualification methods requiring a review to determine the technical correctness of the data, review criteria have been determined and established.

Design Engineering:

The processes in place ensure:

- development of design input control processes for determining how data from scientific investigation activities used as design input shall be qualified prior to use in the design product (additionally, the processes adequately describe the interface between the lead laboratory and the M&O);
- alternate or simplified calculations or analyses developed to verify correctness of the original calculation or analyses, design verification methods adequately describe the review process for determining the appropriateness of input data used;
- the method of acceptance of supplier generated documents that include the acquisition, processing, and recording of test data; and

- the process for performing a technical verification of data produced by a service provider is adequate.

With the exception of supplier generated data (there was no supplier generated data received by Engineering for use in design products), the audit team determined satisfactory implementation and effectiveness of the requirements for controlling technical data, the timeliness of submittal of the data to the Project's TDMS, and ensuring that the uses of the submitted data are traceable to the processes and products that reference the data.

3.0 PROGRAM ADEQUACY, IMPLEMENTATION, AND EFFECTIVENESS

The audit team determined that the processes and procedures for OCRWM, the M&O and the Lead Lab were adequate for control and use of data. Overall, implementation was determined to be satisfactory with the exception of the identified conditions adverse to quality that were processed as CRs. The team also determined the overall effectiveness of the processes implemented by the project to be satisfactory. The technical adequacy for documentation associated with 20 Net Infiltration DTNs was satisfactory.

4.0 FOLLOW-UP ON PREVIOUS CONDITION REPORTS

The audit team conducted follow-up reviews for audit OQA-BSC-06-04 on the TSPA performed last year. Only one CR (CR 8837) was identified and subsequently appropriately resolved. This same issue regarding depiction of data values (impacted by the rounding methodology during a conversion process) was not found during this audit.

The audit team interviewed Lead Lab QA personnel that conducted surveillance LLQA-IS-07-16 on Data Submittal into the TDMS for the Net Infiltration Study. This surveillance was conducted February 19 to March 2, 2007, just prior to this audit and resulted in two CAQs (CRs 10187 and 10188) and two process recommendations (CR 10183 and 10186). These issues are addressed in the executive summary and in Section 2.1. They depict similar conditions found during this audit. The surveillance report was still in draft during the writing of this report.

In addition, the audit team reviewed and performed follow-up to data CRs 9781 regarding incorrect data values and CR 9979 relative to data not being submitted into the TDMS. The audit team initiated CR 10315 because the data qualification status was not changed to unqualified as a result of CR 9781.

5.0 ATTACHMENTS

- Attachment A – Personnel Contacted
- Attachment B – Summary of Audit Results

Attachment A – Personnel Contacted

Organization	Name	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
BSC/L&NS	William Watson	X	X	X
BSC/L&NS	Richard Quittmeyer	X	X	
BSC/L&NS Deputy Manager	S. J. Cereghino	X		
BSC/L&NS Technical Interface	Roger Keller	X	X	
BSC/L&NS Engineering	J.D. Cloud	X		
BSC/L&NS Engineering	Richard Foster		X	
BSC/L&NS Engineering	Pierre Macharet		X	
BSC/L&NS Engineering	Peter Noel		X	
BSC/L&NS Engineering	Mary Woods		X	
BSC/L&NS Engineering	David Rhodes		X	
BSC/OA Audit Liaison	Pam West-Thompson	X	X	X
BSC/Post Closure Safety Analysis	Mark Weisenburg	X		
BSC/Licensing	Federico Perdomo	X		
BSC/Licensing	Brent Pogue	X		X
BSC/OA Manager	C.D. Sorensen	X		
BSC/ES&H	Ed McCann	X		
BSC/ES&H	Ken Wolverton	X		
BSC/QA Manager	Mike Carmichael			X
BSC/IT Configuration Management	Frank Bibler		X	
DOE/Contracting Officer	Birdie Ray Hamilton		X	
DOE/Procurement	Bertha Terrell		X	
DOE/OCE	Jon White	X		X
DOE/OCS S&T Program Manager	John Wengle		X	
DOE/OCS, Chief Scientist	Russ Dyer			X
DOE/OCS Repository Science	Claudia Newberry		X	X
DOE/OCS	Mark Tynan	X	X	X
DOE/OCS	Drew Coleman		X	X
DOE/RAO Sr. Tech Advisor	Neal Hunemuller	X		
DOE/OQA Assessment Team Lead	Elver Robbins	X		X
DOE/OQA Director	Larry Newman			X
DOE/OQA Assessments	James Blaylock		X	
NRC/QA CNWRA	Robert Brient	X		X
NRC/OSR	Robert Latta	X		
NRC/QA Engineer	Tom Matula			X
NRC/OSR	Jack Parrott	X		X
LANL QA Manager	Larry Maasson		X	
LANL Graduate Research Assistant	Cynthia Scism		X	
Lead Lab PA Deputy Manager	Paul Dixon		X	
Lead Lab PA	Pamela Dahl		X	X
Lead Lab TSPA	Palmer Vaughn		X	
Lead Lab Quality Compliance	Bryan Mitchelltree		X	
Lead Lab Quality Compliance	John Devers			X
Lead Lab Quality Compliance	Robert Spencer		X	
Lead Lab Quality Compliance	Peter Persoff		X	
Lead Lab Organizational Assurance	Fifine Brightman		X	
Lead Lab, TDMS	Alice Thompson		X	

Attachment A – Personnel Contacted (continued)

	Name	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Lead Lab, TDMS Supervisor	Dave Seamans		X	
Lead Lab (LBNL) PA	Jim Houseworth, Lead	X		
Lead Lab Manager	Andrew Orrell	X		
Lead Lab CAP Lead, Acting	Michael Russell		X	- X
Lead Lab License Defense	Michael Jaeger		X	
Lead Lab License Defense	Mary-Alena Martell		X	
Lead Lab License Defense	James Raleigh	X		X
Lead Lab License Defense Manager	E.J. Tito Bonano	X	X	
Lead Lab License Defense	Martha Pendelton			X
Lead Lab Technical Support Manager	Raymond Shaum	X	X	X
Lead Lab Technical Support	Sunita Moonka		X	
Lead Lab Technical Support	Walter Walkow		X	
Lead Lab QA Manager	Ronald Stevens	X	X	X
Lead Lab QA	James Maupin	X	X	X
Lead Lab QA	Bruce Foster			
UCCSN, Project Manager	Raymond Keeler		X	
USGS YMP Deputy Mgr	Martha Mustard		X	X
USGS, Data Coordinator	Clay Hunter		X	X
USGS QA Manager	Pam Motyl		X	X
USGS Software Coordinator	Cynthia Miller-Corbett		X	

Legend:

CAP	Corrective Action Program	OCE	Office of Chief Engineer
CNWRA	Center for Nuclear Waste Regulatory Analyses	OA	Organizational Assurance
ES&H	Environmental, Safety and Health	OCS	Office of Chief Scientist
IT	Information Technology	OQA	Office of Quality Assurance
LANL	Los Alamos National Laboratory	OSR	On Site Representative
L&NC	License & Nuclear Safety	PA	Performance Assessment
Lead Lab	Lead Laboratory (SNL)	QA	Quality Assurance
TSPA	Total System Performance Assessment		

Attachment B – Summary of Audit Results

Assessment QARD Section	Critical Process Steps Implementing Documents	Condition Reports	Noteworthy Practices	Program Adequacy	Implementation	Overall Effectiveness
SIII.2.3	Data traceability and transparency	CR 10298, CR 10301	1	SAT	SAT*	SAT
	Identification of information as data					
	Status of data in TDMS (Q vs NON-Q)	CR 10300, CR 10315				
	Data revision/change control	CR 10300, CR 10315, CR 10302				
SIII.2.4	Data review and submittal	CR 10295, CR 10302**		SAT	SAT*	SAT
	Data input verification					
	Data Reduction					
	Data Qualification (qualification of unqualified data)	CR 10300				
SIII.2.4	Selection and use of technical data					
5.0	AP-SIII.3Q, TST-PRO-001, QA-PRO-0301, SCI-PRO-004, SCI-PRO-005, SCI-PRO-006, LS-PRO-001, LANL-OSTI-QP-SIII.3, LANL-OSTI-QP-SIII.3, UCCSN QAP-3.6, CC-PRO-2001	CR 10295, CR 10302		SAT	SAT*	SAT
17.0	Record submittals			SAT	SAT	SAT
Previously Issued CRs	CRs 8837, 9781, 9979, 10187, 10188			N/A	N/A	N/A

Program Adequacy = whether the implementing documents meet the applicable requirements (including critical process steps); Implementation = whether the instructions and processes were followed correctly; Overall Effectiveness = whether the previous two elements combined to meet the realistic intent of the requirements.

*Implementation is adequate overall except as described in listed CRs.

** CR 10302- is a process recommendation