

U.S. NUCLEAR REGULATORY COMMISSION OBSERVATION AUDIT
REPORT OAR-07-02, OBSERVATION AUDIT OF OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT, OFFICE OF QUALITY ASSURANCE,
AUDIT OQA-OCRWM-07-19 OF THE SUBMITTAL, CONTROL, AND USE OF
TECHNICAL DATA DEVELOPED FOR THE YUCCA MOUNTAIN PROJECT

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Enclosure

1.0 INTRODUCTION

On March 12–22, 2007, staff from the U.S. Nuclear Regulatory Commission (NRC), Division of High-Level Waste Repository Safety, and the Center for Nuclear Waste Regulatory Analyses (CNWRA) observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Quality Assurance (QA) Audit OQA–OCRWM–07–19 in Las Vegas, Nevada. The auditors evaluated the submittal, control, and use of technical data developed for the Yucca Mountain Project by OCRWM, Bechtel SAIC Company, LLC/Management and Operating Contractor (M&O), and Sandia National Laboratories/Lead Laboratory (Lead Lab).

The primary objective of audit OQA–OCRWM–07–19 was to evaluate the effectiveness of the processes for controlling technical data, evaluate the timeliness of submittal of the data to the Project's Technical Data Management System (TDMS), and ensure that the uses of the submitted data were traceable to the processes and products that reference the data. The objective of the NRC observation was to assess whether the auditors effectively met the objectives of the audit.

2.0 MANAGEMENT SUMMARY

The auditors evaluated technical data developed and used by OCRWM, the M&O, and the Lead Lab in conducting activities for the Yucca Mountain Project. The auditors reviewed data supporting the net infiltration model and identified six potential conditions adverse to quality and determined that overall,

- The quality assurance (QA) program and critical processes were adequately addressed by procedural processes, and
- The QA program and critical processes were implemented effectively except for the conditions identified.

The auditors found that the conditions adverse to quality were minor and generally reflected inattention to detail in submitting information to the TDMS. The auditors identified no technical errors or deficiencies in the data reviewed. The auditors also identified a noteworthy practice and a recommendation for process improvement.

The auditors noted that the Lead Lab had conducted an internal surveillance of data supporting the net infiltration model on February 19 through March 2, 2007, that covered much the same information as planned to be reviewed during this audit. Although the approach of the surveillance differed somewhat from that of the audit, the observers recommend that DOE consider the purpose of performing such pre-audit surveillances and the potential impacts on characterizing subsequent audit results.

The auditors identified a notable practice in that the Lead Lab's Licensing Defense Data Traceability and Qualification organization is reviewing data used to support the License Application and TSPA to ensure data integrity, traceability, and qualification status regardless of the originating organization. This activity is in addition to the processes and procedural controls already in place to produce qualified data. The observers recognized the importance of this effort and recommend continued emphasis in completing the project.

The observers determined that the auditors performed effectively and met the objectives of the audit. The observers agreed with the auditors' conclusions and findings.

3.0 AUDIT PARTICIPANTS

Audit Team Members

Kenneth Gilkerson, OQA, Audit Team Leader

Roxanna Scaglione, Lead Lab, Auditor

Richard Maudlin, M&O, Auditor

Harvey Dove, OQA/Project Enhancement Corporation, Technical Specialist

Observers

Thomas Matula, NRC, Observation Team Leader

Robert Brient, CNWRA, Quality Assurance Specialist

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The auditors conducted the audit in accordance with Line Procedure (LP)–18.3Q–OCRWM, Quality Assurance Internal Audit Program. The auditors identified adverse conditions and recommendations in accordance with Administrative Procedure (AP)–16.1Q, Condition Reporting and Resolution. The observers followed NRC Manual Chapter 2410, Conduct of Observation Audits.

4.1 Scope of the Audit

The scope of the audit covered submission, control, and use of technical data used to support the Total System Performance Assessment (TSPA) for license application and design. The Lead Lab uses technical data to develop science products, and the M&O uses technical data to develop engineering products. The auditors focused on the Lead Lab's role in processing and controlling technical data through the TDMS. The auditors evaluated technical data produced by the M&O and technical data obtained by OCRWM from its suppliers.

The auditors evaluated the adequacy, implementation, and effectiveness of procedures related to technical data, which address applicable elements of, DOE/RW–0333P, Quality Assurance Requirements and Description (QARD); QA–DIR–10, Quality Management Directive (QMD); and QA–PRG–001, Yucca Mountain Project Lead Laboratory Quality Assurance Program Description.

4.2 Conduct and Timing of the Audit

The observers determined that the auditors performed the audit effectively and demonstrated sound knowledge of the applicable implementing procedures and QA program requirements. The auditors conducted the audit primarily through records reviews and interviews. During interviews the auditors challenged and questioned responses when appropriate and effectively employed their checklists. The auditors caucused daily with the observers to discuss the current audit status and potential issues. The auditors met periodically with management from OCRWM, M&O, and Lead Lab and the observers to review the audit status and any new and developing issues.

The auditors noted that the Lead Lab had conducted an internal surveillance of data supporting the net infiltration model on February 19 through March 2, 2007, that covered much the same information as planned to be reviewed during this audit. In addition, the observers learned that DOE provided the audit checklist to the Lead Lab on March 9, 2007, the day before the start of the audit. The auditors determined that the Lead Lab conducted the surveillance to support review activities associated with the net infiltration model, tracing the first tier direct inputs to the TSPA while, during this audit, the auditors examined selected inputs to the data sources. The auditors determined that the audit and surveillance approaches differed sufficiently so that the surveillance and the audit both met their respective objectives. Although the approach of the surveillance differed somewhat from that of the audit, the observers recommended that DOE consider the purpose of performing such pre-audit surveillance and the potential impacts on characterizing subsequent audit results. The observers also recommended that DOE clarify and document its policy for conducting surveillances on intended audit topics immediately before the conduct of audits and provide audit checklists to the organization being audited.

4.3 Auditor Qualifications and Independence

The observers reviewed the qualifications of the auditors with respect to LP-18.4Q, Audit Personnel Qualification. Each of the auditors has been qualified as a lead auditor, and the observers verified their independence of the areas reviewed. The audit technical specialist had also been appropriately qualified.

4.4 Examination of Quality Assurance Elements

The auditors employed checklists based on procedures and critical process steps or key elements applicable to data submission, control, and use. The critical process steps and key elements evaluated by the auditors included the following:

- 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 the TDMS
- Data qualification
- Selection and use of technical data
- Data revision and change control
- Data input verification
- Record submittal

The auditors also reviewed data-related nonconformances by examining Condition Reports (CRs) initiated over the past year.

4.4.1 OCRWM Data Management

OCRWM obtains a limited amount of data from suppliers outside of the M&O and Lead Lab participants. The auditors reviewed data management processes involved with data obtained from the University of Nevada at Las Vegas (UNLV) and audited data controls at the UNLV campus. The auditors also evaluated control of data obtained under the Science and Technology (S&T) program from Los Alamos National Laboratory and the U. S. Geologic Survey.

4.4.2 M&O Data Management

The auditors reviewed controls for data that the M&O used for preclosure analyses and calculations. These data, in general, had been developed or acquired through postclosure investigations, analysis, and modeling managed by the Lead Lab. Requests to a Technical Management Review Board and Interface Exchange Drawings control the transmittal of data between postclosure and preclosure functions.

The auditors also reviewed controls and resolution of assumptions used in preclosure calculations and analyses. All assumptions must be verified for calculations and analyses to be classified as confirmed and ready for use.

The auditors evaluated a sample of data used in preclosure activities to verify data qualification status, traceability, and completeness of supporting documentation.

4.4.3 Lead Lab Data Management

The auditors evaluated a sample of data used to support the net infiltration model being prepared by the Lead Lab, which was in draft during the audit. The auditors selected this model for audit because it is one of the most recent technical activities and has high importance to repository performance. The Lead Lab has responsibility for the TDMS so a significant portion of the audit included examination of TDMS functions.

The auditors discussed TSPA Data Input Packages (TDIPs) with Lead Lab staff. TDIPs contain the input data from source technical documents needed for TSPA compliance calculations, for which initial runs are scheduled to begin in April 2007. About 20 percent of the output data from technical documents providing input to TSPA are direct inputs, so the TDIPs provide an important role in identifying TSPA inputs that support compliance calculations.

The auditors traced several data sets to their sources and identified several errors in their qualification status. Specifically, several data items previously identified as unqualified should have been reclassified as qualified; however, the TDMS had not been updated.

The auditors also met with Lead Lab personnel working on a project to improve the ability of technical products and supporting documentation to support the defensibility of the TSPA. The current TDMS function does not support explicit traceability to data sources, so a new system currently in beta testing is being developed to assure the following:

- Calculations and software used in direct support of TSPA are traceable and qualified;

- Direct input parameters used in compliance calculations are traceable to source information;
- Models used directly in TSPA compliance calculations are validated; and
- Existing review comments from various internal and external sources have been considered and addressed.

The observers recognized the importance of this effort and recommended continued emphasis in completing the project.

4.5 Potential Audit Findings

The auditors presented the following potential findings during the postaudit meeting.

Notable Practice Identified

- The Lead Lab's Licensing Defense Data Traceability and Qualification organization is reviewing data used to support the License Application and TSPA to ensure data integrity, traceability, and qualification status regardless of the originating organization. This activity is in addition to the processes and procedural controls already in place to produce qualified data.

The observers recognized the importance of this effort and recommended continued emphasis in completing the project.

Conditions Adverse to Quality

- Identification of the data originator in Technical Data Input Forms as required by AP-SIII.3Q, Submittal and Incorporation of Data to the Technical Data Management System, for quality-affecting Science and Technology program data and for data submitted by UNLV was incorrect.
- AP-SIII.3Q (as the governing project procedure) and Lead Lab and other external organizations' procedures differed on the data submittal process.
- A CR that effectively invalidated data values (i.e., the original data were incorrect) did not result in actions causing the TDMS to change the qualification status of the subject data. The Lead Lab implemented remedial action during the audit to correct this issue.
- The qualification status of data was not updated in the TDMS when the data qualification status had changed (i.e., when unqualified data becomes qualified as Analysis and Model Reports are approved or as data reviews are completed). Also, data was classified as qualified, but the TDMS did not contain an approved data qualification report.
- Records Road Maps had not been reviewed for completeness and accuracy. Some

road maps were incomplete or inaccurate.

- Some information in the TDMS was inaccurate, misleading, or nonexistent.

Auditors' Recommendation

- UNLV should submit data in accordance with AP-SIII.3Q to address concerns regarding cyber security and the threat of "hacking" that could compromise data integrity from the UNLV practice of using a publicly accessible website to submit data to OCRWM.

The auditors also noted that a follow-up surveillance is necessary to evaluate process changes that may affect the adequacy and effectiveness of TST-PRO-001, the Lead Lab's procedure for submittal and incorporation of data to the TDMS. The Lead Lab implemented the changes at the end of the audit. The auditors expressed concern about changes that eliminated impact reviews for data that are changed.

5.0 NRC STAFF FINDINGS

5.1 NRC Observation Summary

The observers determined that the auditors conducted the audit effectively and demonstrated sound knowledge of the applicable implementing procedures and QA requirements. The auditors conducted thorough reviews and interviews, challenged and questioned responses when appropriate, and effectively employed their checklists. The observers agreed with the auditors' conclusions and findings.

5.2 NRC Audit Observer Inquiry

The observers initiated no Audit Observer Inquiries during this audit.