

U.S. NUCLEAR REGULATORY COMMISSION OBSERVATION AUDIT REPORT OAR-07-03,
OBSERVATION AUDIT OF THE U.S. DEPARTMENT OF ENERGY,
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT,
OFFICE OF QUALITY ASSURANCE AUDIT OQA-SNL-07-06,
OF THE INFILTRATION MODEL REPORT

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Enclosure

1.0 INTRODUCTION

On June 4-18, 2007, staff from the U.S. Nuclear Regulatory Commission's (NRC's), 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-SNL-07-06, in Albuquerque, New Mexico, and Las Vegas, Nevada. The DOE audit team evaluated the infiltration model developed by the Sandia National Laboratory, OCRWM's Lead Laboratory (Lead Lab) for the Yucca Mountain Project. The DOE audit team transmitted its report on this audit to the Lead Lab Program Director by letter dated August 15, 2007. It is available on NRC's Licensing Support Network (accession numbers DN2002454003 and DN2002456224).

The primary objective of the DOE audit was to evaluate the MDL-NBS-HS-000023, "Simulation of Net Infiltration for Present-Day and Potential Future Climates" (Infiltration Model Report) relative to defensibility in the potential license application process. The DOE audit team performed an overall assessment of the technical adequacy, product quality, and implementation effectiveness of the "Quality Assurance Requirements and Description" (QARD), DOE/RW-0333P, requirements for the Infiltration Model Report. The objective of the NRC observation was to assess whether the audit team effectively met the objectives of the audit.

2.0 MANAGEMENT SUMMARY

The DOE auditors evaluated the Infiltration Model Report through staff technical interviews and examination of quality records. They identified nine conditions adverse to quality and eight technical issues but determined that overall, the Infiltration Model Report is adequate for its intended purpose and meets established criteria for overall effectiveness in QARD implementation, technical adequacy, and product quality. The DOE audit team also identified three noteworthy (i.e., good) practices and eight recommendations for improvement.

The NRC observers determined that the DOE audit team performed effectively and met the objectives of the audit. However, the NRC observers identified five areas where the objective of the audit may have been better achieved. In accordance with the "Agreement Between DOE/OCRWM and NRC/Office of Nuclear Material Safety and Safeguards (NMSS) Regarding Prelicensing Interactions," five NRC recommendations for these areas are summarized below:

The primary NRC recommendation is to:

- 1) Avoid grouping multiple audit-identified technical issues into one condition report (CR), [see Section 4.2.3].

Of secondary importance are NRC recommendations to:

- 2) Conduct audits earlier in the model development process, so that audit-identified issues can be addressed before the final revision of the technical product is produced, [see Section 4.2.1];

- 3) Have the most current version of the technical products being audited available to performance-based audit teams before the audit, [see Section 4.2.2];
- 4) Include, in the initial scope of performance-based audits of technical products, any subordinate model input reports that discuss the collection, qualification, reduction, and manipulation of input data critical to the technical products, [see Section 4.1]; and,
- 5) More effectively use the NRC's Yucca Mountain Review Plan (YMRP) acceptance criteria, as performance-based audit criteria, at the beginning of the audit of technical products that support the license application, [see Section 4.1].

3.0 AUDIT PARTICIPANTS

DOE Audit Team Members

Marilyn Kavchak, OQA, Audit Team Leader
Patrick Auer, Project Enhancement Corporation (PEC), Audit Team Member
Christian Palay, OQA, Audit Team Member
Mark Kachun, PEC, Audit Team Member
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Harvey Dove, PEC, Technical Specialist
Thomas Doe, Golder and Associates, Technical Specialist
John McCray, Management and Technical Support Services (MTS), Technical Specialist
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NRC Observers

Jack Parrott, NRC, Observation Team Leader
Randall Fedors, NRC, Technical Observer
Eugene Peters, NRC, Technical Observer
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Rodney Weber, CNWRA, Quality Assurance Specialist
Stuart Stothoff, CNWRA, Technical Observer

Affected Units of Local Government Observers

Susan Lynch, State of Nevada
Engelbrecht Von Teisenhausen, Clark County, Nevada

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The DOE auditors conducted the audit in accordance with Line Procedure 18.5Q-OCRWM, "OCRWM Contractor Surveys/Audits." They identified adverse conditions and recommendations in accordance with Administrative Procedure 16.1Q, "Condition Reporting and Resolution." The NRC observers followed NRC Manual Chapter 2410, "Conduct of Observation Audits," and/or the "Agreement Between DOE/OCRWM and NRC/NMSS Regarding Prelicensing Interactions," in the conduct and documentation of the audit observation.

4.1 Scope of the Audit

The DOE auditors evaluated the Infiltration Model Report in regard to the requirements of the QARD. The DOE audit team evaluated the technical adequacy and product quality against critical process steps that include planning and procedural compliance, control of data and input, validity of calculation and calculation documentation, document checking and comment resolution, and document accuracy and compliance.

The DOE audit focused on reviewing the hydrological aspects and critical process steps applied in the development of the Infiltration Model Report. The DOE audit also evaluated use of material from report ANL-NBS-HS-000027, Revision 1, "Analysis of Infiltration Uncertainty," to determine whether inputs (i.e., data) were adequately integrated into the Infiltration Model Report.

Although the planned scope of the audit addressed the Infiltration Model Report and the "Analysis of Infiltration Uncertainty" report, the NRC observers noted that there were nine other key subordinate input reports that discussed the collection, qualification, reduction, and manipulation of input data critical to the infiltration model (e.g., soil thickness and bedrock hydraulic properties). The NRC observers noted that the objective of the audit would have been better achieved if the original scope had included these nine subordinate input reports. The NRC observers recommend that, for similar technically focused audits, the scope be expanded to include these types of key supporting documents, particularly documents like these that were created for the sole purpose of supporting, and providing input to, the audited document. The subordinate input reports for the Infiltration Model Report are particularly significant in that they seek to substantiate the quality of the data used in the original U.S. Geological Survey net infiltration modeling report.

The NRC observers also noted that the audit plan stated, "Overall the Model Report, MDL-NBS-HS-000023, will be evaluated relative to the defendability [defensibility] in the license application process." However, the performance-based audit criteria identified in the audit plan and initially used in the audit were not specifically tied to NRC's YMRP acceptance criteria, which NRC will use in the potential license application review process. During the audit, the DOE audit team recognized the utility of evaluating the Infiltration Model Report against the applicable criteria in the YMRP, to help determine the report's defensibility as a support document in a potential licensing process. The NRC observers recommend that the YMRP acceptance criteria be used in future performance-based audits of technical products used to support the licensing basis of a potential license application.

4.2 Conduct and Timing of the Audit

The DOE audit team members conducted the audit through records reviews and interviews, challenged and questioned responses when appropriate, and effectively employed their checklists. The DOE auditors caucused daily with the NRC observers to discuss the current audit status and identified issues.

The NRC observers determined that the DOE audit team performed the audit effectively and demonstrated adequate knowledge of the applicable implementing procedures and QA program requirements. However, NRC observers identified three issues related to the conduct and timing of the audit as discussed in the following three sections.

4.2.1 Audit Scheduling

Attachment 3 of Procedure LP-18.5Q-OCRWM, "OCRWM Contractor Surveys/Audits," under the section, "Scheduling and Planning OCRWM Contractor Surveys/Audits," states, "Audits of OCRWM contractors shall be scheduled in a manner to provide coverage, consistency, and coordination with ongoing work as follows: Begin the audit as early in the life of the work as practical and at a frequency commensurate with the status and importance of the work."

The work on the Infiltration Model Report originally began on September 22, 2005; however, the June 2007 audit was the first audit of this activity. Conducting this audit when work is essentially complete impacts the objective of a performance-based audit because it becomes more difficult to incorporate the findings to improve the quality (i.e., defensibility) of the product.

Also, a DOE audit team finding, that several QA program requirements were not effectively implemented during the development of the Infiltration Model Report, indicates that auditing of this work should have been done sooner, or that additional audits or surveillances of this work should have been done while the work was in progress. NRC recommends that OQA evaluate the timing of performance-based audits so as to be able to more effectively use the results to improve the quality of the products audited.

4.2.2 Coordination Between the Auditing and Audited Organization

The checklist the DOE auditors used was developed using a draft version of the Infiltration Model Report, with the understanding that this would be the audited product. However, as described in the DOE audit report, the finalized version was approved on May 24, 2007, but not provided to the DOE audit team until the audit started. This led to inefficient use of the checklist and some delay at the beginning of the audit. NRC recommends that better coordination between the auditing and the audited organizations be undertaken before audits begin so that the audited version of products is available to the auditing team somewhat before the audit begins.

4.2.3 Processing of Technical Issues Identified

The NRC observers noted that, as described in the DOE audit report, the eight technical issues identified by the DOE technical specialists were combined into a single CR, after the audit, and described as "recommendations." However, the uniqueness of each individual technical issue, the potential significance of each issue relative to the objective of the audit plan, its potential impact on the quality of the document, and the ability to trend the individual issues in the Corrective Action Program, or track them in other programs, demonstrate that these issues should have been identified as individual CRs. NRC recommends that distinct technical issues with potentially different levels of significance not be grouped together into one CR.

4.3 Audit Team Qualifications and Independence

The NRC observers reviewed the qualifications of the auditors with respect to LP-18.4Q, “Audit Personnel Qualification.” Each of the DOE auditors had been qualified as lead auditor, and the NRC observers verified their independence from the areas reviewed in this audit. The DOE technical specialists had also been appropriately qualified. The DOE audit team leader identified several discrepancies with the qualification documentation in the auditor qualification records before presenting them to the NRC observers for review. However, these represented documentation discrepancies—not actual qualification discrepancies. These documentation discrepancies were documented in a CR.

4.4 Examination of QA Elements

The DOE auditors prepared checklists to evaluate adherence to QARD requirements for the development of the Infiltration Model Report. The checklists were organized according to the critical process steps identified in the audit plan as follows: (1) planning and procedural compliance; (2) control of data and input; (3) validity of calculation and calculation documentation; (4) document checking and comment resolution; and (5) document accuracy and compliance. The QA auditors also followed up on previously closed CRs related to the Infiltration Model Report and identified one CR as having inadequate completion of corrective action. In addition, the DOE auditors reviewed online records to assess areas such as: (a) contracting; (b) purchasing; (c) training documentation; (d) data inputs; (e) checking and review; (f) approvals; and (g) change control. They identified areas where the Lead Lab had failed to effectively implement some QA program elements.

The NRC observers agreed with the audit results in these areas. However, the NRC observers noted that a DOE auditor review of the Lead Lab audit, surveillance, and self-assessment schedules for the Infiltration Model Report work indicated that scheduled audit and self-assessment activities had not been conducted (see Section 4.2.1). Had they been conducted, the issues regarding implementation of some QA program elements might have been identified earlier.

4.5 Examination of Technical Activities

The DOE technical specialists prepared checklists based on detailed reviews of the Infiltration Model Report and associated technical work plans, before the audit. During the audit, the nine subordinate input reports were identified and also reviewed, and further audit questions were generated. The NRC observers noted that these nine subordinate input reports are integral for supporting input values used in the net infiltration model and should have been reviewed before the audit to facilitate the objective of the audit. During the audit, the DOE audit team interviewed a primary contributor and other key contributors to the Infiltration Model Report, as needed.

With a view toward defensibility of the Infiltration Model Report in a potential repository licensing process, two areas of focus for the DOE audit team were: (1) control of data and inputs; and (2) validity of calculation and calculation documentation. For the control of data and inputs, the DOE technical specialists identified the sensitive parameters for the net infiltration estimates and focused questions during the audit accordingly. For the validity of calculation and

calculation documentation, the DOE technical specialists focused on traceability of supporting bases for inputs and models, including both software validation and validation of results.

Within these focus areas, the DOE technical specialists identified eight technical issues, which were summarized in one CR as recommendations. The NRC observers noted that the recommendations, if implemented, will improve confidence in the model results and therefore the quality of the Infiltration Model Report. However, the NRC observers noted that technical recommendation 6 discussed a bias in the calculations towards an overestimation of infiltration, caused by the tendency to select conservative parameters or assumptions. It should be noted that biases in assumptions and model inputs can lead to overestimates or underestimates. The YMRP acceptance criteria leads NRC reviewers to ensure that parameter values and modeling results provide a conservative estimate of risk or do not cause an overall reduction of the risk estimate. Therefore, technical evaluations of risk inputs should focus on reducing the uncertainty of parameters or assumptions, or on providing enough information to evaluate the effects of biases on results, rather than highlighting conservative inputs or assumptions.

5.0 NRC STAFF FINDINGS

The NRC observers determined that the DOE audit team conducted the audit effectively and demonstrated acceptable knowledge of the applicable implementing procedures and QA requirements. The DOE auditors conducted thorough interviews, challenged and questioned responses when appropriate, and effectively employed their checklists.

The NRC observers agreed with the DOE audit team's conclusions and findings, but note that the objectives of the audit would have been better achieved had:

- The original scope of the audit identified, for review, the nine subordinate documents that provide support for direct inputs to the model;
- The YMRP acceptance criteria been more effectively used as audit criteria at the beginning of the audit, to help determine model defensibility;
- The timing of the audit relative to document finalization been better coordinated to allow for pre-audit review and checklist development on the version of the document that was actually audited;
- The technical issues not been grouped into one CR as that might have masked the uniqueness and significance of the issues and might have precluded model quality improvement;
- An audit been conducted earlier in the model development process, since at least some of the issues identified in this audit could have been addressed before the Lead Lab's final revision of the Infiltration Model Report.

The observers also identified several good practices during the audit. These included:

- Good issue discovery through review of objective evidence, even in areas that were not strictly compliance issues;

- Willingness of QA auditors to use conservative judgments regarding interpretation of requirements; and
- Improved facilitation of NRC's observation by the presence of observers from QA and licensing.