

U.S. NUCLEAR REGULATORY COMMISSION OBSERVATION AUDIT REPORT OAR-07-01,
OBSERVATION AUDIT OF OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT,
OFFICE OF QUALITY ASSURANCE, AUDIT OQA-BSC-07-03 OF ASSESSMENT
ACTIVITIES, CORRECTIVE ACTIONS, AND TRENDING PROGRAMS

Thomas O. Matula 11/18/07

Thomas Matula
Division of High-Level Waste
Repository Safety
Office of Nuclear Material
Safety and Safeguards

Melanie Wong 11/18/07

Melanie Wong
Division of High-Level Waste
Repository Safety
Office of Nuclear Material
Safety and Safeguards

for Thomas O. Matula 11/18/07

Robert Brient
Center for Nuclear Waste
Regulatory Analyses

Reviewed and Approved by:

AGD 11/19/07

Aby Mehseini, Deputy Director
Licensing and Inspection Directorate
Division of High-Level Waste
Repository Safety
Office of Nuclear Material
Safety and Safeguards

1.0 INTRODUCTION

On December 11–20, 2006, 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 Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), quality assurance (QA) audit OQA–BSC–07–03 in Las Vegas, Nevada. The audit team evaluated assessment activities, corrective actions, and trending programs of OCRWM, Bechtel SAIC Company, LLC (BSC), and Sandia National Laboratories (SNL) Lead Laboratory organizations.

The objectives of this audit were to determine the adequacy, implementation, and effectiveness of the requirements and activities associated with assessments, corrective actions, and trending. 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 procedures for compliance with QA program requirements and their implementation. This included review of selected assessment reports, Condition Reports (CRs), trend reports, and related documentation. The auditors identified five conditions adverse to quality relating to the audit scope, one of which is a significant condition, and determined that, overall, assessment activities, corrective actions, and trending programs were ineffective. The auditors also identified two conditions adverse to quality unrelated to the scope of the audit, several notable (i.e., good) practices, and recommendations for improvements. The observers determined that the auditors performed effectively and met the objectives of the audit.

The observers agreed with the auditors' conclusions and findings. In particular, the observers agreed with the identification of a significant condition adverse to quality (CR 9774) regarding the overall Corrective Action Program (CAP), which includes trending. The observers noted that DOE issued a Process Improvement Plan (PIP) to improve the effectiveness of the CAP in October 2006. The observers consider the PIP to be a quality-affecting activity that should be controlled under CR 9774.

3.0 AUDIT PARTICIPANTS

Auditors

Kenneth Gilkerson, OQA, Audit Team Leader
William Glasser, OQA, Auditor
Marilyn Kavchak, OQA, Auditor
Lester Wagner, Project Enhancement Corporation, Auditor
Roxanna VanDillen, SNL, Auditor

Observers

Thomas Matula, NRC, Observation Team Leader
Melanie Wong, NRC, Observer
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 assessment activities, corrective actions, and trending programs conducted by OCRWM, BSC, and SNL. The observers noted that the Audit Plan included evaluation of the implementation of assessment activities at SNL. However, since SNL had assumed the role of lead laboratory in October 2006, SNL had not yet implemented that portion of its program. As a result of the observers' comments, the Audit Team Leader initiated CR 9670 to address this discrepancy in the Audit Plan.

The auditors evaluated the adequacy, implementation, and effectiveness of procedures related to the audit scope addressing applicable elements of DOE/RW–0333P, Quality Assurance Requirements and Description (QARD), Sections 2, 5, 16, and 17, and applicable sections of DOE/RW–0565, Augmented Quality Assurance Program (AQAP). The AQAP describes requirements for self-assessment and independent assessment.

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 thorough records reviews and interviews, 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, OCRWM, BSC, SNL management, and the observers met periodically to review the audit status and any new and developing issues. While issues with the CAP and trending program had been previously identified, the observers determined that this audit of the CAP was valuable because it identified additional significant issues requiring attention that may not have been addressed in existing CRs.

4.3 Audits Qualifications and Independence

The observers reviewed the qualifications of the auditors with respect to LP–18.4Q, Audit Personnel Qualification. Each of the auditors had been qualified as lead auditor, and the observers verified their independence of the areas reviewed as part of this audit.

4.4 Examination of Quality Assurance Elements

4.4.1 Corrective Action Program

The auditors utilized checklists based on the QARD, BSC and SNL top-tier quality system descriptions, and AP-16.1Q, Condition Reporting and Resolution. One portion of the audit of the CAP focused on procedural compliance and involved reviews of existing CRs to determine whether various activities had been conducted according to AP-16.1Q. Another component of this audit involved evaluation of the judgments used in the corrective action process, such as screening decisions, downgrading or upgrading CR significance levels, the adequacy of the extent of condition and causal analyses, and timeliness of corrective actions. The auditors evaluated ongoing corrective actions relating to the CAP, including CRs initiated as a result of the December 2005 CAP audit and other CRs initiated before and after that audit, including some closed CRs. The auditors identified issues in many corrective action processes including timeliness and repeat occurrences of the same or similar conditions.

The auditors found that numerous CRs had been initiated by various organizations identifying CAP deficiencies. In October 2006, OCRWM management approved a PIP for the CAP that sets expectations, identifies success measures, and provides individual actions for improvement. The auditors determined that, while the PIP appears to be comprehensive, it may not accurately identify the extent of condition and may not adequately address all previously identified conditions. In the aggregate, the auditors determined that previously identified conditions in existing CRs and those identified during this audit reflect the ineffectiveness of the overall CAP. The auditors concluded that corrective action procedures did not adequately provide controls, the organizations did not effectively implement the procedures, and overall, the CAP was not effective. As a result, the auditors identified a significant condition adverse to quality and initiated CR 9774. The auditors noted that the PIP should be controlled under the QARD because it is a quality-affecting activity. Further, the auditors noted that it is appropriate to place the development and execution of the PIP under the CAP because it provides for many of the necessary improvements in the effectiveness of the overall CAP.

4.4.2 Trending Program

The auditors employed a checklist based on QARD and OCRWM, BSC, and SNL trending procedures. The auditors focused on corrective actions planned for the level A (i.e., a significant condition adverse to quality) CR 7458, initiated as a result of the December 2005 CAP audit. The auditors also reviewed and discussed actions planned for other CRs related to the trending process as well as the integrated trending report for the fourth quarter of fiscal year 2006. The fourth quarter 2006 report covered OCRWM, BSC, and SNL trending results in an integrated fashion, while previously, OCRWM and BSC prepared separate trend reports.

The auditors gathered information through interviews with OCRWM, BSC, and SNL personnel responsible for trending activities and with the lead author of the integrated trend report. The auditor determined that

- Corrective actions for level A CR 7458 had been planned, but none had been completed at the time of the audit.

- Trending processes had been significantly improved in comparison to the findings of the December 2005 CAP audit; however, some fundamental changes had been identified as necessary to improve these processes.
- Process improvements will be reflected in a new integrated procedure to be applied to all three organizations. This procedure will include the use of improved event and cause codes and will rely on a Trend Working Group, representing the line organizations, to analyze and report trends. Improvement plans also recognize the importance of accurate CR problem statements, which impact the accuracy of corrective actions as well as trending accuracy.

Since corrective actions for CR 7458 and related CRs had not been completed on a timely basis, the auditors concluded that trending processes were ineffective. CR 7458 is expected to be covered by the new significant condition adverse to quality (see Section 4.4.1) addressing the overall corrective action process (CR 9774).

4.4.3 Assessments

The auditors used checklists based on OCRWM, BSC, and SNL procedures for management assessment, self-assessment, and independent assessment. Management assessment is required by the QARD, and self-assessment and independent assessment are required by the AQAP. The auditors interviewed OCRWM, BSC, and SNL staff and reviewed and evaluated assessment schedules, assessment completion status, and selected assessment reports. The auditors determined that assessment procedures identified adequate controls; however, implementation had been lacking in several areas. Overall, the auditors determined assessment activities to be ineffective.

4.5 Potential Audit Findings

The auditors presented the following potential findings during the post-audit meeting:

Notable Practices Identified

- Trending Program-related conditions continued to be self-identified and addressed through the CAP.
- The BSC Self-Assessment process had thorough guidance for fiscal year 2007, a desktop instruction provided excellent process detail, an evaluation tool provided continuous feedback, and self-identified areas of weakness had been selected for assessment.

Significant Condition Adverse to Quality including trending

- Corrective action processes were ineffective

Conditions Adverse to Quality

- An OCRWM Self-Assessment Program Coordinator had not been designated.
- The OCRWM Self-Assessment Program planning and scheduling requirements had not been implemented.
- Of 58 scheduled self-assessments, independent assessments, and program assessments, only 11 had been completed. The annual management assessment for fiscal year 2006 had not been performed.
- The BSC Self-Assessment program did not assess key critical areas in fiscal year 2006, and a high percentage of assessments had been delayed, cancelled, or not performed.

The auditors identified two additional conditions adverse to quality not directly related to the audit scope:

- QARD Sections 15 (nonconforming items) and 16 (corrective action) lacked an interface.
- A QARD requirement was not met.

Auditors' Recommendation

- The SNL Self-Assessment Program should provide training for assessment leaders, develop a method for evaluating reports, and document recommendations in the CAP.

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 interviews, challenged responses when appropriate, and effectively employed their checklists.

The observers agreed with the auditor's conclusions and findings. In particular, the observers agreed with the identification of a significant condition adverse to quality (CR 9774) regarding the ineffectiveness of the CAP, which includes trending. The observers consider the PIP to be a quality-affecting activity that should be controlled under the CAP and CR 9774.

5.2 NRC Audit Observer Inquiry

The observers did not initiate any Audit Observer Inquiries during this audit and did not present any recommendations.