

1.0 INTRODUCTION

On August 7–15, 2006, staff from the U.S. Nuclear Regulatory Commission (NRC), Division of High-Level Waste Repository Safety; Division of Nuclear Material Safety, Region IV; and the Center for Nuclear Regulatory Analyses (CNWRA) (observers) observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) audit OCRWM–OQA–06–15, on the implementation of the Quality Assurance (QA) program at Las Vegas, Nevada, and Washington, DC. The objective of this audit was to evaluate the adequacy, implementation, and effectiveness of the QA program, as defined in DOE/RW–0333P, Revision 17, “Quality Assurance Requirements and Description” (QARD) as applicable to DOE activities. The audit also assessed the status of procedures, training, and documentation associated with the transition to the new OCRWM organization; the readiness to review project-related documents and products; and the development and implementation of corrective actions for condition reports (CRs) identified during the 2005 OQA audit of the Office of Repository Design and selected OCRWM Condition Reports issued during the past year.

2.0 MANAGEMENT SUMMARY

The DOE Audit Team evaluated seven sections of the QARD applicable to OCRWM activities, including: (1) organization; (2) QA program; (3) design; (4) procurement, (5) document control; (6) corrective action; and (7) quality records. Two QARD supplements dealing with sample control and control of the electronic management of data, and the QARD Appendix C, “Monitored Geologic Repository,” were also evaluated.

The Audit Team was well-prepared and effectively used its previously developed checklists to interview various OCRWM management and staff and to perform required record reviews. Sixteen issues and two recommendations were identified and will be entered in the Corrective Action Program as CRs. The Audit Team characterized the QA program as being ineffectively implemented.

The NRC observers determined the DOE audit was performed effectively and agreed with the team’s issues and conclusions.

3.0 AUDIT PARTICIPANTS

Auditors

Elver Robbins, Audit Team Leader
James Blaylock, Auditor
Nancy Voltura, Auditor
Carl Weber, Auditor (Washington, DC)
Lam Xuan, Auditor

NRC Observers

Paul Bell, Observer Team Lead, NRC
Wilkins Smith, NRC, Washington, DC
Robert Latta, On-Site Representative, NRC
Thomas Trbovich, CNWRA

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The DOE auditors conducted the audit in accordance with Line Procedure (LP)–18.3Q–OCRWM, Quality Assurance Internal Audit Program. The auditors reported conditions adverse to quality in accordance with Administrative Procedure (AP)–16.1Q, “Condition Reporting and Resolution”, which describes four levels of CRs:

- Level A—Significant Adverse Condition
- Level B—Adverse Condition
- Level C—Minor Adverse Condition
- Level D—Opportunity for Improvement

The NRC Observer Team followed the NRC Manual Chapter 2410, “Conduct of Observation Audits”, July 12, 2000, while observing the audit.

4.1 Scope of the Audit

The DOE Audit Team evaluated the adequacy, implementation, and effectiveness of programmatic quality requirements applicable to OCRWM activities. The Audit Team evaluated documents and records in relation to DOE/RW–0333P, Revision 17, QARD, and its implementing LP and AP procedures. The team evaluated various engineering, purchasing, training, and qualification documents and interviewed responsible management to determine procedural application and compliance.

The following procedures were included within the scope of the audit:

- LP–1.1Q–OCRWM, “Organization”
- LP–2.13Q–OCRWM, “Verification of Education and Experience of Personnel”
- LP–2.19Q–OCRWM, “Personnel Training and Qualification”
- LP–PMC–011–OCRWM, “Program Assessments”
- LP–PMC–006–OCRWM, “Independent Assessments”
- LP–PMC–001–OCRWM, “Self Assessment”
- LS–PRO–0203–OCRWM, “Q-List and Classification of Structures, Systems, and Components”

- LP–2.16–OCRWM, “Readiness Review”
- LP–2.5Q–OCRWM, “Management Assessments”
- LP–2.4Q–OCRWM, “Quality Assurance Program Controls”
- LP–3.1Q–OCRWM, “Preparation, Review, and Approval of Office of National Transportation Level 2 Baseline Requirements”
- LP–3.35Q–OCRWM, “Preparation, Review, and Approval of Monitored Geologic Repository System Requirements Documents”
- AP3.9Q, “Interface Management Process”
- LP–4.1Q–OCRWM, Procurement Actions
- LP–4.2Q–OCRWM, “Processing Agreements with Other Federal Entities and Acceptance of Management and Operating Contractor Deliverables”
- LP–4.7Q–OCRWM, “Controls for Use of Guidance Criteria to Obtain Services”
- LP–5.1Q, “Procedure Preparation Review and Approval”
- LP–6.2Q–OCRWM, “Document Control”
- LP–6.1Q–OCRWM, “Document Review”
- LP–7.5Q, “Establishing Deliverable Acceptance Criteria and Submitting and Reviewing Deliverables”
- AP–16.1Q, “Condition Reporting and Resolution”
- AP–17.1Q, “Records Management”
- Procedure–PRO–0803, “Requesting, Transferring, and Returning Yucca Mountain Project Specimens from the Sample Management Facility”
- LP–SV.2Q–OCRWM, “Control of Electronic Management of Information”
- QARD, Appendix C, “Monitored Geologic Repository—Expert Elicitation”

4.2 Conduct and Timing of the Audit

The auditors prepared checklists based on applicable procedure requirements and applied their checklists effectively during interviews and while reviewing documents and records. The auditors expanded their questioning, as appropriate, to resolve identified questions or issues or to obtain further clarification.

The timing of the audit was appropriate because a recent reorganization of the Yucca Mountain Project required revision to existing procedures, updating of qualification and training of personnel, and rearranging of responsibilities and duties. In addition, this was the annual DOE audit of programmatic compliance and follow-up of CRs from the 2005 audit.

4.3 Audit Team Qualifications and Independence

The observers reviewed the qualifications of the Audit Team Leader and auditors and determined they were qualified by education, experience, and training, and, being part of OQA, were independent of the areas reviewed.

4.4 EXAMINATION OF QA ELEMENTS

4.4.1 Quality Assurance Program

The DOE auditors interviewed various DOE staff and discussed the requirements of the QARD, Section 2, QA program, and eight implementing line procedures at the Las Vegas, Nevada, and Washington, DC, offices. The auditors paid particular attention to the performance of the readiness review for lifting a contractor suspension regarding the performance of certain design reporting activities.

The audit team identified four discrepancies related to QARD Questionnaire Form completion, personnel qualifications, readiness review performance, and job function matrices completion. Two recommendations were noted concerning the self-assessment program and the timeliness of Document Action Requests (DARs).

The observers determined that audit was effective in this element and agreed with the auditors' conclusion's.

4.4.2 Design Control

OCRWM staff representing the Office of Chief Engineer were interviewed. Two issues were identified: necessary controlled implementing procedures for the Office duties and responsibilities as described in the QARD have not been developed – and the Project Director position remains vacant. It was evident the auditor(s) had reviewed considerable background documentation before conducting the interviews.

The observers determined the audit was effective in this element and agreed with the auditors conclusions.

4.4.3 Procurement Document Control

The auditors reviewed procurement agreements, proposals, and supplier deliverables and discussed the content of the documents with purchasing staff at both the Las Vegas, Nevada, and Washington, DC, offices. Issues were noted regarding the identification of QARD requirements in the reviewed agreement, "FY2006 Program Guidance and Funding to the Oak Ridge Operations Center", dated March 21, 2006. These issues were lack of OQA involvement in a specific proposal review, and lack of documentation of the engineering review of a particular supplier deliverable.

The observers determined the audit was effective in this area and agreed with the auditors' conclusions.

4.5 IDENTIFIED ISSUES/RECOMMENDATIONS

The Audit Team identified the following issues and recommendations at the post-audit conference held August 17, 2006.

4.5.1 Issue Summary

- A process to manage organizational change and to evaluate and address its impacts on quality-affecting activities, as required by QARD Section 1.2, is lacking.
- OCRWM lacks procedures to fully implement the responsibilities addressed in Section 1.3.1 of the QARD and the QARD Requirements Matrix.
- The Office of Chief Engineer has not formally designated Project Director(s) to address the responsibility identified in QARD Section 1.3.1.D.1.
- OCRWM Office Record File Plans have not been updated to reflect the current organization, as required by QARD Section 17.2.1 and AP-17.1Q, Section 5.1.2.
- Work processes involving questionnaire completion lacked attention to detail; OQA was not assigned for document review; and four technical documents did not have instructions for the completion of Document Review Records nor Comment Sheet forms, as required by QARD Sections 2.0, 5.0, and 6.0.
- The Office of Project Controls had developed a training matrix for the organization, but it had not been formally approved. This was subsequently approved and this issue was considered Closed During the Audit.
- OCRWM has not addressed CRs in a timely manner, as required by QARD Section 16.2.3.B. The Audit Team identified numerous CRs for which OCRWM personnel have direct responsibility that have been in the "plan corrective action," "supervisor review plan," or "oversee implementation stages" for periods of time that do not provide evidence of timely corrective action.
- One agreement, "FY2006 Program Guidance and Funding to the Oak Ridge Operations Center", was not processed in accordance with LP-4.2Q-OCRWM, for evaluation with the QARD Applicability Checklist and other relevant provisions of the procedure.
- The technical review of a vendor proposal did not include OQA, as required by QARD Section 4.2.2 and LP-4.1Q-OCRWM.
- The acceptance review of three deliverable vendor packages did not identify the reviewers nor the qualitative and quantitative review criteria, and the review package record was not available to support the acceptance letters forwarded to the vendors, as required by LP-4.1Q-OCRWM.

- OCRWM reorganized and assigned one Federal staff member to perform QARD-controlled work, before that person had an approved position description and an updated Verification of Education and Experience form on file, contrary to the requirements of QARD Section 2.1.12.
- The OCRWM technical evaluation and independent review activities of two technical reports were not accomplished in accordance with a controlled quality-rated procedure, as required by QARD Section 5.0.
- OCRWM management closed three Level A CRs without having all actions completed; thus causing new CRs to be issued.
- DOE performed a Readiness Review in accordance with the requirements of LP-2.16Q-OCRWM, to ensure design processes were in place for the resumption of preliminary design activities. The Contracting Officer sent a release letter allowing preliminary design to proceed before release from the review chair and before verification of completion of items identified during the review.
- One records package from the Office of Chief Scientist could not be located in the Records Processing Center, to determine whether the 60-day requirement for submission had been met, as required by AP-17.1Q.
- The Office of Director, Regulatory Authority and Regulatory Authority—Preclosure Offices, did not have approved employee-to-job function matrices, as required by QARD Section 2.2.12.

4.5.2 Recommendation Summary

- The Washington, DC, office should be made aware of the commitments made in CR responses, to ensure timely corrective action at all DOE locations.
- Some DARs have been open for a significant amount of time. They should be reviewed to determine whether they are still necessary. OQA should perform a comprehensive surveillance to evaluate whether any open DARs should be expedited to address adverse quality conditions.

5.0 NRC STAFF FINDINGS

5.1 NRC OBSERVATION SUMMARY

The NRC observers determined that the Audit Team was well-prepared and effective in evaluating the QA program adequacy and implementation. The observers agreed with the Audit Team issues and conclusions. The observers determined that the Audit Team members were qualified, independent of the areas being audited, and had a good knowledge of OCRWM and appropriate understanding of the QARD and procedure requirements.

5.2 NRC AUDIT OBSERVER INQUIRIES

No audit observer inquiries were submitted during this audit.