

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT 95-02
OF THE
U.S. DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
AUDIT HQ-ARP-95-03
OF THE
CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM
MANAGEMENT AND OPERATING CONTRACTOR

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1.0 INTRODUCTION

During December 5-8, 1994, members of the U. S. Nuclear Regulatory Commission Division of Waste Management Quality Assurance (QA) staff observed the U. S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) audit of the QA program of the Civilian Radioactive Waste Management System Management and Operating Contractor (M&O). The audit, HQ-95-ARP-03, was conducted at the M&O offices in Vienna, Virginia. The focus of the audit was a performance-based evaluation of the effectiveness of the M&O QA program with regard to the control of the development and the revision of technical requirements documents. The technical requirements documents identify the requirements necessary to develop the design bases for systems of the High Level Waste repository program. No other organizations observed this audit.

This report addresses the effectiveness of the audit and the adequacy of QA controls in the audited area of the M&O QA program.

2.0 OBJECTIVES

The objectives of the audit team were to determine whether the M&O QA program for the development and the revision of the technical requirements documents and its implementation meet the applicable requirements and commitments of the OCRWM "Quality Assurance Requirements and Description" document (QARD, DOE/RW-0333P) and associated implementing procedures.

The NRC staff's objective was to gain confidence that OQA and the M&O are properly implementing the requirements of their QA programs in accordance with the OCRWM QARD and Title 10 of the Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

3.0 MANAGEMENT SUMMARY AND CONCLUSIONS

The NRC staff has determined that audit HQ-ARP-95-03 was useful and effective. The audit was very well organized and conducted in a thorough and professional manner. Audit team members were independent of the activities they audited. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the preliminary audit team finding that the overall implementation of the M&O QA program relative to technical documents is effective. The audit team also correctly cautioned that the M&O process controls appear to be complicated, and that "If M&O management does not maintain oversight of user implementation, the process could possibly break down." One preliminary Corrective Action Request (CAR) was discussed by the audit team at the post-audit meeting concerning the distribution of a wrong controlled document. The distribution error was identified during the audit, and the M&O distributed the correct document during the audit as remedial action. In addition, one deficiency was acceptably resolved by the M&O organization during the audit. Six recommendations were also provided to the M&O.

DOE should continue to monitor the M&O QA program to ensure that the deficiencies identified during this audit and previous audits are corrected in

a timely manner and that future QA program implementation is effective. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits at a later date to assess implementation of the M&O QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

John T. Buckley	Observer (Part time)	
Bruce Mabrito	Observer	Center for Nuclear Waste Regulatory Analyses

4.2 DOE

Hugh Lentz	Audit Team Leader (ATL)	Headquarters QA Division/QA Technical Support Services (HQAD/QATSS)
Fred Bearham	Auditor	HQAD/QATSS
Charles Betts	Auditor	HQAD/QATSS
Jim George	Auditor	HQAD/QATSS
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Gary Wood	Auditor	HQAD/QATSS
Arul Mozhi	Tech Specialist	Roy F. Weston, Inc.
James Doman	Tech Specialist	Roy F. Weston, Inc.

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This audit was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program" (Revision 6) and QAAP 16.1, "Corrective Action" (Revision 6). The NRC staff observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

5.1 Scope of the Audit and Observations

5.1.1 QA Programmatic Elements

Audit HQ-ARP-95-03 was a performance-based audit, which evaluated the effectiveness of selected processes associated with M&O activities performed under several QA program elements involved with the development and revision of technical requirements documents. Although not specified in the audit plan, the QA program elements involved included 3.0, Design Control, 5.0, Instructions, Procedures and Drawings, 6.0, Document Control, and 17.0, QA Records.

5.1.2 Technical Areas

The audit included evaluations by technical specialists, who reviewed input to the requirements documents for the transportation cask and the multipurpose canister (MPC).

5.1.3 Observations

The audit team activities that the NRC staff observed are discussed below.

5.2 Timing of the Audit

The NRC staff believes the timing of this audit was appropriate for HQAD to evaluate the pertinent technical requirement documents development and revision controls established by the M&O and for the NRC staff to evaluate the OCRWM audit process because of the relatively early stage of development and the QA problems that other divisions of the M&O have experienced.

5.3 Examination of Process Steps

5.3.1 General Observations

In conducting this audit in a performance-based manner, the audit team characterized the M&O technical requirements document development and revision process into the following process steps:

- 1) Identify need/scope for technical requirements,
- 2) Define/plan process for developing technical requirements,
- 3) Develop technical requirements document or revision,
- 4) Perform technical document review and comment resolution,
- 5) Approve, release, and issue technical document,
- 6) Implement technical requirements (including flowdown documents), and
- 7) Perform baseline change control.

Meeting each of these steps should result in adequate M&O technical requirements documents.

The audit team was divided into three sub-teams of two auditors each, with each sub-team assigned to cover specific process steps. The two technical specialists assisted each sub-team when the subject matter required their expertise.

Prior to the audit, the ATL met with M&O representatives to clearly identify the process steps in a flowchart, along with the objective of each step and the measurement criteria that the audit team would apply. The measurement criteria for each process step was issued in a Performance Based Audit Flowchart. This flowchart was beneficial in clarifying the accepted minimum requirements to both the audit team and the auditees.

During the course of the audit, all three sub-teams were observed at one time or another by the NRC observers, as were both technical specialists. Good interviewing techniques were utilized and the audit sub-teams were effective.

Throughout the audit, each sub-team worked its way through the appropriate checklists interviewing the affected M&O Managers and other key personnel. Utilization of the technical specialists in specific areas was determined the day prior to their use. Potential CARs or concerns were discussed at the

audit team caucus each afternoon and listed on the status board. All auditors went beyond their checklist questions when it was warranted. "Objective Evidence Reviewed" forms were completed by each auditor and, where necessary, a matrix chart was drawn to provide clarity and organization to the auditing process.

The auditors followed the prepared and approved checklists, deviating when necessary and appropriate to ensure complete understanding of the process. Interviews were conducted in a professional manner, with questioning continuing until the auditor determined whether that the audited personnel were familiar with and understood the process. In addition, M&O departmental interfaces were also evaluated. A recommendation was made by the audit team, related to design interface control, that the QA procedures be reviewed to assure all interface requirements have been adequately identified.

5.3.2 Specific Observations

The audit consisted of the review of design analyses, system and subsystem requirements, design input data transmittals, data requests, input logs, assumption rationale sheets, records packages, personnel records, configuration management plans, document control action requests, controlled document instructions, distribution reports, memos and correspondence, and other appropriate documents, as well as interviews with various M&O personnel involved with all phases of technical requirement documents related to the transportation cask and the MPC. The M&O staff explained the inputs required to produce a design procurement specification: in sequence, (i) the Work Authorization Document, (ii) the Technical Document Preparation Plan (TDPP), (iii) the Civilian Radioactive Waste Management System Requirements Document, (iv) the Systems Requirements Documents (SRD) for Waste Acceptance, Transportation, Monitored Retrievable Storage and the Mined Geologic Disposal System (MGDS), (v) the Design Requirements Document (DRD), and (vi) the Design Procurement Specification (DPS). Each of these documents feeds to its successor.

One audit sub-team, composed of an auditor and both technical specialists, reviewed the planning and crossflow of requirements as they related to design inputs. During interviews with the Waste Acceptance Storage & Transportation Design Manager and an assistance engineer, Design Input Data Transmittals were reviewed and found to be thorough and complete. The MPC Subsystem DRD was in an early stage of development, Revision 00, but the auditor and technical specialist were able to obtain satisfactory answers to checklist questions. No findings were identified in this area and the audit was effective.

Another sub-team was assigned the responsibility of evaluating the technical document review and comment resolution process. The sub-team began the investigation by discussing the DRD review process with the M&O staff. Through the interviews, it was determined that the DPS is produced and reviewed independently from the DRD review. Further, it was noted that the review criteria used by the reviewers of the DRD was located in the TDPP. The auditors then examined the review package for the DRD and DPS associated with the MPC. No findings were identified in this area and the audit was effective.

The same sub-team also performed detailed and thorough checks of the document distribution system and the DRD review comments utilizing a matrix chart. The sample size was sufficiently large, and during the audit it was noted that the Document Control organization had distributed a controlled MGDS Annotated Outline to seven individuals in error, instead of the requested MGDS Requirements Document. The correct document was distributed during the audit. However, a preliminary CAR was written because individuals needing controlled copies of the MGDS Requirements Document did not officially have access to them in a timely manner. The audit of this process step was effective.

The audit sub-team audited the eleven QAP-3-9 design analyses that the M&O had completed. Five of these eleven analyses referenced a draft Systems Requirements Issue Resolution Plan (SRIRP). Charts in the SRIRP are necessary for traceability from data "to be verified" (TBV) to the appropriate QAP-3-9 design analysis. Because the SRIRP was not issued, the TBV data were not clearly linked to the analyses. The M&O corrected this during the audit by attaching the necessary information from the draft SRIRP to the QAP-3-9 analysis reports. The audit team considered this to be an isolated deficiency.

The M&O procedures governing development/revision of technical documents appeared to be adequate. However, the audit team considered the process to be complicated and urged M&O management oversight to ensure continued adequate implementation. The M&O QA personnel had a good understanding of requirements and assisted as informative escorts during the audit. Individual M&O engineering staff personnel appear to perform their function well and promptly responded to the audit team's questions acceptably.

5.4 Qualification of Audit Personnel

The qualification of the ATL and auditors was previously found to be acceptable by the NRC, each having met the requirements of QAAP 18.1, "Qualification of Audit Personnel." One of the technical specialists was relatively new to the program and his resume was reviewed by an NRC Observer and determined to be acceptable.

5.5 Audit Team Independence

The audit team was composed of QATSS personnel who support HQAD and were familiar with the M&O procedures on the development/revision process for technical requirement document control. The audit team members were assigned to areas where they did not have prior responsibility or involvement. The audit team members had sufficient independence to carry out their assigned functions without adverse pressure and influence.

5.6 Summary of NRC Staff Findings

The NRC staff agrees with the preliminary HQAD audit team findings that the overall implementation of the M&O technical requirements documents development and revision process is being implemented adequately for the areas identified in the audit scope. This determination is based on the audit checklist results and responses provided to the audit team during the course of the audit.