

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT 95-04
OF THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE
AUDIT HQ-ARC-95-04
OF OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
MANAGEMENT AND OPERATING CONTRACTOR

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1.0 INTRODUCTION

During February, 1995, members of the U.S. Nuclear Regulatory Commission Division of Waste Management quality assurance (QA) staff observed a U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, audit of the quality assurance (QA) program of the Civilian Radioactive Waste Management System Management and Operating Contractor (M&O). The audit, HQ-ARC-95-04, was conducted from February 7-10, 1995 at the M&O offices in Vienna, Virginia, and from February 21-24, 1995 at the M&O offices in Las Vegas, Nevada. The audit evaluated portions of the M&O QA program compliance with applicable requirements of OCRWM's "Quality Assurance Requirements and Description" document (QARD - DOE/RW-0333P). This audit, in conjunction with audit HQ-94-02 and other DOE audits and surveillances, completed DOE's "Baseline Audit" of the M&O in meeting the applicable requirements of the QARD. There were no other observers at this audit.

This report addresses the effectiveness of the DOE audit and the adequacy of implementation of QA controls in the audited areas of the M&O QA program. Previous corrective action requests (CARs) from earlier baseline audits, identified by the audit team as open issues, were also evaluated. NRC staff observations at Vienna and Las Vegas are presented separately in this report. NRC staff conclusions are presented for the audit overall.

2.0 OBJECTIVES

The objectives of this audit by DOE were to determine whether the M&O QA program and its implementation meet the applicable requirements and commitments of the QARD and M&O procedures.

The NRC staff's objective was to gain confidence that DOE and its 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 based its evaluation of the audit process and the M&O QA program on direct observations of the audit team members; discussions with audit team and M&O personnel; and reviews of the audit plan, audit checklists, and pertinent M&O documents. The NRC staff has determined that DOE Audit HQ-ARC-95-04 was useful and effective. The audit was 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, overall, implementation of the M&O QA program will not be considered fully effective until the open issues, described in Section 5.10 of this report, and the CARs identified during this audit are satisfactorily resolved. Within the scope of this audit, the M&O QA program implementation is considered effective. However, earlier audits and surveillances identified the open issues where resolution of previous CARs is required.

DOE should continue to closely monitor implementation of the M&O QA program to ensure that the open issues are resolved in a timely manner, that the deficiencies identified during this audit 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 M&O implementation of its QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

John G. Spraul	Observer	Center for Nuclear Waste Regulatory Analyses
Bruce Mabrito	Observer	

4.2 DOE/OCRWM

Marlin Horseman	Audit Team Leader (ATL)	Headquarters QA Division (HQAD)/ Quality Assurance Technical and Support Services Contractor (QATSS)
Hugh Lentz	Audit Team Coordinator	HQAD/QATSS
Charles Betts	Auditor	HQAD/QATSS
Walter Coutier	Auditor	HQAD/QATSS
Vance Cannaday	Auditor	HQAD/QATSS
John Pelletier*	Auditor	HQAD/QATSS
Emily Reiter**	Auditor	HQAD/QATSS
Amy Arceo	Auditor	Yucca Mountain QA Division (YMQAD)/QATSS

* Las Vegas, Nevada, only.

** Vienna, Virginia, only.

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This DOE audit of the M&O 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

The QA programmatic elements listed below were audited:

- 1 Organization
- 2 Quality Assurance Program
- 3 Design Control
- 12 Control of Measuring and Test Equipment

16 Corrective Action
17 Quality Assurance Records
SI Software
SII Scientific Investigation
Appendix C: Mined Geologic Disposal System

The M&O Policy Statement, the impact of CARs, and the impact of procedure revisions were also audited.

The implementation of QA Programmatic Elements 4, 5, 6, 7, 15, and 18 had been audited previously and found to be satisfactory except for the open issues discussed in Section 5.10 of this report. The remaining QA programmatic elements, QARD supplements, and QARD appendices were determined by the audit team to be not applicable because the M&O has no responsibilities in those areas.

No technical activities of the M&O organization were audited.

This audit concentrated on evaluating the compliance of the M&O activities to applicable requirements. It also served as part of the overall baseline audit process, that is, it determined whether the M&O QA program and procedures adequately addressed the QARD and whether the procedures were being effectively implemented.

5.2 Timing of the Audit

The NRC staff believes the general timing of this audit was appropriate to evaluate the pertinent QA activities of M&O and for the NRC staff to evaluate the audit process and implementation of the M&O QA program.

5.3 Examination of QA Programmatic Elements

The NRC staff noted that each of the auditors observed reviewed related documentation and interviewed a representative sample of M&O personnel to determine their understanding of and the degree of implementation of the procedures. The auditors observed were well prepared and knowledgeable of the QA program requirements. They used their checklists effectively and pursued issues beyond the checklists when appropriate. They solicited comments and questions from the NRC observers appropriately. The audit team was divided into sub-teams. The NRC staff observations regarding the audit and the implementation of each of the QA programmatic elements observed are discussed below.

5.3.1 Design Control (QA Programmatic Element 3)

Vienna, Virginia

The audit sub-team evaluated the development of the multi-purpose canister (MPC) specifications and supporting analyses, from which the bidders received the "MPC Transportation Cask Subsystem Design Procurement Specification, Revision 04." The auditors identified the steps in the MPC Design Procurement Specification development, including implementation of Quality Administrative

Procedure (QAP)-3-2, "Design Verification;" QAP-3-8, "Specifications;" and QAP-3-9, "Design Analysis." Checklists had been previously developed based primarily on the requirements of these procedures. Both auditors of the sub-team were observed; working together as a team and working separately when it was required.

To evaluate the first steps of the MPC specification development process, the following documentation was reviewed by the auditors: Specification Review Summaries, Specification Cover Sheets, Design Analysis Review Summaries, Design Analysis Cover Sheets, and Review Notices. Numerous M&O supervisors and managers were interviewed at the Vienna offices during this portion of the audit. The M&O managers explained the processes as they understood and implemented them. Responses, consistent between managers, indicated a generally good understanding of the processes. The same approach of interviews by the auditors with M&O appropriate staff was used throughout the audit, with similar results.

The auditors on the sub-team also reviewed the On-Site Transfer (OST) and On-Site Storage (OSS) Subsystem segments of the Design Procurement Specification to verify compliance with QAP-3-8 and, to the extent the segments had been completed, verified adequate compliance.

The audit sub-team found that three draft specifications were not marked "Preliminary Draft" as required by QAP-3-8. A preliminary CAR, described in Section 5.10 of this report, was generated by the audit team to address this condition.

The evaluation of the Vienna design control process was thorough. Except for the CAR condition, implementation was satisfactory.

Las Vegas, Nevada

One of the auditors who had been reviewing design specifications at the M&O Vienna offices continued the review in the Records Processing Center (RPC) at the Las Vegas M&O offices, utilizing the requirements of QAP-3-8. Three record segment packages which contained Design Package 2C specifications were selected for review. The auditor familiarized himself with the record segment packages and then interviewed the Records Coordinator, who stated that the segment packages had not been formally submitted to RPC, were only being stored there, and were not yet considered complete QA Record packages. An M&O Office of Product Integrity Engineer verified that the three segment packages had not been formally submitted to the RPC as QA Records. Regardless, the audit sub-team made a thorough review of the three record segment packages. A detailed review of two additional record package segments was accomplished by the audit sub-team and, although several minor discrepancies were noted, no procedural violations were identified.

The audit of the design control programmatic element in Las Vegas was effective. The NRC staff agrees with the audit team conclusion that this element was being implemented satisfactorily in Las Vegas. There were no new significant deficiencies found in design control. However, resolution of the

previously identified design-related CARs is required before the M&O QA Program can be considered completely effective.

5.3.3 Records Control (QA Programmatic Element 17)

Vienna, Virginia

Limited observation of the DOE audit of QA Records took place. The following relatively minor deficiencies were identified during this portion of the audit: legibility problems with a small number of surveillance record packages, an incomplete Position Description for one individual, an incomplete Qualification Record for a different individual, an unclear Record Deficiency Notice in the QA Records, the final acceptance test of the QA Records Room fire protection system not completed, and five electronic media diskettes incorrectly identified. All these deficiencies required only remedial corrective action. They were corrected and verified before the post-audit meeting in Las Vegas.

The audit of the QA records in Vienna was effective and the NRC staff agrees with the audit team conclusion that implementation of this QA programmatic element was satisfactory in Vienna.

Las Vegas Nevada

Although not directly observed by an NRC observer, the audit sub-team noted that records and record packages associated with drawings, specifications, and analyses were deficient in the areas of accuracy, completeness, protection, submission to records center, and indexing for retrievability. This prompted the issuance of a CAR in the Records Control element. The CAR was considered significant by the audit team, and this brings into question the adequacy of implementation of the records QA program element.

5.3.4 Software (QARD Supplement I)

The checklists used for auditing software were developed by the auditor primarily from the requirements in the M&O Quality Administrative Procedures (QAPs) listed below:

- QAP-19-1, "Computer Software Verification and Validation," Revision 3 with Procedure Change Notice 1
- QAP-19-2, "Software Configuration Management," Revision 3
- QAP-19-4, "Software Management," Revision 1,

These procedures were in effect while the work being audited was accomplished, but they had been superseded, effective January 31, 1995. The new procedures, as well as the old, have been reviewed, found acceptable, and incorporated into the Requirements Traceability Network matrix by DOE.

The checklists were used at both locations, with the software codes audited and personnel interviewed being site specific.

Vienna, Virginia

The auditor reviewed documentation and interviewed personnel involved with the two qualified scientific and engineering software codes controlled from Vienna and useable in support of work subject to QARD requirements. These were a point-source heating code called "Heating" and a shielding code called "QAD-CGGP." Previous DOE auditors in Vienna had not audited these codes because they had not been qualified for quality affecting work at the time of the audits.

The checklists were complete, the auditor was thorough, this portion of the audit was effective, and implementation of this portion of the QA program was adequate.

Las Vegas, Nevada

The auditor reviewed the documentation and interviewed the personnel involved with five scientific and engineering software codes controlled from Las Vegas and useable in support of work subject to QARD requirements. These five codes had not been audited during previous DOE audits because they had not been qualified for quality affecting work at the time of the audits. The codes audited during this audit - "3DEC," "UNWEDGE," "DIPS," "LYNX," and "FLAC3D" - are for use in subsurface design and analysis.

The checklists were complete, the auditor was thorough, this portion of the audit was effective, and implementation of this portion of the QA program was adequate.

5.3.9 Conclusions

The auditors adequately evaluated activities and objective evidence. The audit was effective in determining the adequacy and degree of current implementation of the M&O QA program.

5.4 Conduct Of Audit

The audit was performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the M&O QA program. The interview method of auditing, combined with checking of objective evidence, allowed for thorough responses to the questions and permitted many additional questions to be answered. In general the audit team personnel were persistent in their interviews, challenged responses when necessary, and performed an effective audit. A caucus of auditors and observers was held at the close of each work day, and a meeting of the ATL and M&O management (with an NRC observer present) was held each morning to discuss the audit status and preliminary findings.

At the pre-audit meeting in Vienna, Virginia, M&O personnel made a comprehensive presentation of the project organization and status to the audit team and observers, but this did not occur at the pre-audit meeting in Las Vegas. This slowed the initiation of the audit process. However, at the first daily ATL-M&O Management meeting in Las Vegas, an M&O representative

described the M&O organization, changes made by the M&O to improve QA program implementation, and technical work completed by the M&O since the previous DOE audit.

During the daily ATL-M&O Management meetings and the daily interfaces between audit team members and M&O personnel, potential audit findings generally appeared to be viewed as a means of improving the program rather than as an indication of poor job performance or punitive action. There still appeared to be a tendency by the M&O to immediately correct a problem without adequate root cause analysis in order to avoid a CAR, but there has been improvement in this regard. The NRC staff indicated to the M&O staff that this is positive change that is beneficial to the program.

5.5 Qualification Of Auditors

The qualifications of the ATL and auditors were found to be acceptable in that each auditor and the ATL met the requirements of QAAP 18.1, "Qualification of Audit Personnel."

5.6 Audit Team Preparation

The auditors were well prepared in the areas they were assigned to audit and were knowledgeable of the applicable procedures. The Audit Plan for this audit included the audit scope, the audit schedule, a list of audit team personnel, a list of the activities to be audited, and audit checklist references.

5.7 Audit Team Independence

Audit team members did not have prior responsibility for performing the activities they audited. The audit team members had sufficient independence to carry out their assigned functions without adverse pressure or influence.

5.8 Review of Previous Audit Findings

Implementation of corrective actions for CARs issued as a result of the last DOE audit of M&O was a special audit item with its own checklists. The ATL was diligent in ensuring that auditors verified CAR corrective actions at both M&O locations.

5.9 Summary of NRC Staff Findings

The NRC staff agrees with the preliminary DOE audit team finding that within the scope of the audit, implementation of the M&O QA program is generally satisfactory. However, before the M&O QA program can be assessed to be fully satisfactory, the CARs and five open issues identified in Section 5.10 must be acceptably resolved.

5.9.1 Observations

The NRC staff did not identify any Observations relating to deficiencies in either the audit process or the M&O QA program.

5.9.2 Good Practice

At both Vienna and Las Vegas, the ATL took special effort to emphasize that this audit was one of compliance with the QARD and implementing documents as opposed to a programmatic audit.

5.10 Summary of DOE Audit Findings

The following two preliminary CARs were discussed at the post-audit meeting.

5.10.1 Revisions to the MPC and OST/OSS design procurement specifications were not marked "Preliminary Draft" as required by QAP-3-8.

5.10.2 The records process for specifications, drawings, and engineering analyses was found to be deficient in the areas of:

- accuracy
- completeness
- protection
- submission to records center
- indexing for retrievability.

Ten deficiencies, found by the audit team and requiring only remedial action, were acceptably resolved by the M&O organization prior to the post-audit meeting in Las Vegas. In addition, the audit team presented twelve recommendations for consideration by the M&O.

At the completion of this audit, the audit team concluded that 1) M&O QA Program implementation is satisfactory with the exception of the above CARs and the five open issues listed below and 2) that the QA Program should not be considered completely effective by DOE until these are acceptably resolved.

Open Issues:

1. Re-evaluation of work activities
2. Effective preparation of design control procedures
3. Effective implementation of the design control procedures
 - Overall tracking process of items to be verified or to be determined
 - Checking/review process
 - Control of design input data transmittals
4. Effective implementation of the corrective action process
5. Effective control of the QA records process