

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

John T. Buckley 3/9/95
Bruce Mabrito (per telephone)
Center for Nuclear Waste
Regulatory Analyses

John T. Buckley 3/8/95
John T. Buckley
High-Level Waste & Uranium
Recovery Projects Branch
Division of Waste Management

Reviewed and approved by:

Reviewed and approved by:

J. G. Spraul 3/15/95
John G. Spraul, QA Lead
High-Level Waste & Uranium
Recovery Projects Branch
Division of Waste Management

John O. Thoma 3/16/95
John O. Thoma, Section Leader
High-Level Waste & Uranium
Recovery Projects Branch
Division of Waste Management

1.0 INTRODUCTION

During January 9-13, 1995, 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 audit of the Civilian Radioactive Waste Management System, Management and Operating (M&O) Contractor QA Program. The audit, YM-AR-95-02, was conducted at the M&O offices in Las Vegas, Nevada, and at the Nevada Test Site. The audit included both a compliance-based audit on QA Program Elements 5.0, "Implementing Documents;" 15.0, "Nonconformances;" 16.0, "Corrective Action;" and 17.0, "QA Records" and a performance-based evaluation of the corrective action process. A State of Nevada representative participated as an observer, and a Clark County representative attended the audit exit meeting.

This report addresses the effectiveness of the audit and the adequacy of the M&O QA program.

2.0 OBJECTIVES

The objectives of the audit team were to determine whether M&O QA Program Elements 5.0, 15.0, 16.0, and 17.0 were being effectively implemented and met the applicable requirements of the OCRWM "Quality Assurance Requirements and Description" (QARD, DOE/RW-0333P) and associated implementing procedures. Additionally, the performance-based portion of the audit focused on the M&O corrective action process.

The NRC staff's objective was to gain confidence that DOE and the M&O are effectively implementing the requirements of their QA programs in accordance with the 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 YM-AR-95-02 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 QA Program Elements 5.0, 15.0, and 17.0 were satisfactorily implemented by the M&O. The staff also concurs with the audit team's assessment that QA Program Element 16.0, "Corrective Action," was unsatisfactorily implemented. M&O management should take immediate actions to effectively implement a Corrective Action system which is capable of achieving the desired results. The audit team identified deficiencies with the M&O's Corrective Action process specifically in the areas of timeliness of Corrective Action responses, the adequacy of those responses, and the lack of objective evidence for actions taken. Two preliminary Corrective Action Requests (CARs) were drafted at the conclusion of the audit and discussed in the post-audit meeting, and one potential CAR was corrected during the audit by the M&O organization. One recommendation was also made by the audit team.

The M&O QA program should continue to be monitored by DOE 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 or verifications at a later date to assess implementation of the M&O QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

John T. Buckley	Observer	
Bruce Mabrito	Observer	Center for Nuclear Waste Regulatory Analyses

4.2 DOE

Steven Nolan	Audit Team Leader (ATL)	Yucca Mountain QA Division (YMQAD)/QA Technical Support Services (QATSS)
Walt Coutier	Auditor	Headquarters QA Division (HQAD)/QATSS
Stephen Dana	Auditor	YMQAD/QATSS
Kenneth Gilkerson	Auditor	YMQAD/QATSS
Frank Kratzinger	Auditor	YMQAD/QATSS

4.3 Other Observers

Susan Zimmerman	Observer	State of Nevada
Engelbrecht V. Tiesenhausen	Observer	Clark County (exit meeting only)

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 YM-AR-95-02 was both a programmatic compliance-based and a performance-based audit which evaluated the effectiveness of selected processes associated with M&O activities performed under the identified QA program elements. As specified in the audit plan, the QA program elements evaluated for programmatic compliance included 5.0, "Implementing Documents;" 15.0, "Nonconformances;" 16.0, "Corrective Action;" and 17.0, "QA Records." The performance-based portion of the audit concentrated on the M&O's corrective action process.

For the performance-based portion of the audit, the M&O's corrective action process was divided into five steps by the audit team. These steps were:

- 1) Satisfactory completion of the critical process steps
- 2) Providing an acceptable end product
- 3) Documentation and objective evidence that substantiates product quality
- 4) Performance of trained and qualified personnel
- 5) Implementation of the applicable QA program elements

Prior to the audit, the ATL met with M&O personnel to discuss these process steps, the objective of each step, and the measurement criteria that the audit team would apply. This was beneficial in clarifying the accepted minimum requirements to both the audit team and the auditees. As noted by the ATL, meeting each of the measurement criteria should result in adequate M&O implementation of the corrective action process.

5.1.2 Technical Areas

There were no technical areas evaluated during this audit.

5.2 Timing of the Audit

The NRC staff believes that the timing of this audit was appropriate considering previous audit results and because of quality problems that the M&O has experienced.

5.3 Examination of Programmatic Elements

5.3.1 General Observations

The audit team was divided into four sub-teams, with each sub-team assigned to cover specific QA Program Elements. The NRC observers noted that good interviewing techniques were utilized and conclude that the audit sub-teams were effective.

Throughout the audit, auditors utilized the appropriate checklists when interviewing M&O personnel or reviewing objective evidence. Potential CARs or concerns were discussed at the audit team caucus each afternoon and logged on a status board. "Objective Evidence Reviewed" forms were completed by each auditor. When appropriate, matrix charts were used to provide clarity and organization to the auditing process.

The auditors went beyond checklists when necessary to assure complete understanding of the QA program elements and processes.

5.3.2 Specific Observations

- Implementing Procedures (Program Element 5.0). The auditor began his work by discussing the procedure development method and the formal review process with a M&O QA specialist. The auditor reviewed a sample of M&O Procedure Action Requests and Procedure Review Records to determine whether implementing procedures were being developed and revised in accordance with Quality

Administrative Procedures (QAP)-5-1 and QAP-5-2. Numerous interviews were held with key M&O staff members relative to their input to implementing procedures. During these discussions, the auditor determined that M&O specifications and drawings were not referenced in the M&O Requirements Traceability Network (RTN) Matrix as implementing documents. After further investigation, the auditor determined that QARD Section 5.0 requirements are met in M&O procedures QAP-3-8 (Specifications) and QAP-3-10 (Engineering Drawings). A preliminary CAR was written (see Section 5.7), including the recommendations that QAP-3-8 and QAP-3-10 be added to the RTN Matrix and that QAP-3-8 and QAP-3-10 be revised to meet the QARD Section 5.0 requirements.

The audit of this program element was effective, and the element was determined to be satisfactorily implemented, with the exception of the CAR described above.

- **Nonconformances (Program Element 15.0).** This portion of the audit was conducted at the Nevada Test Site (NTS). The purpose for auditing at the NTS was to obtain a copy of the most current field Nonconformance Report (NCR) Log and to review the condition of the records at the site. The auditor reviewed the NCR Log, obtained NCRs from a field M&O representative, reviewed each of the NCRs, and recorded pertinent information such as dates, justification, disposition, personnel who provided disposition, and reportable/non-reportable condition. A detailed matrix was utilized to track this information. The ATL also verified that those who had worked on NCRs in any capacity had taken Yucca Mountain Administrative Procedure (YAP)-15-1Q, "Control of Nonconformances" training. No discrepancies were noted in the audit of the NCRs and associated activities. It was recommended by the audit team that a broad-based surveillance should be made to determine the effectiveness of YAP-15-1Q, which spans the work of many organizations at the Yucca Mountain site. The auditor determined that the Program Element 15.0 was being satisfactorily implemented. The audit of this program element was effective.

- **Corrective Action (Program Element 16.0).** Program Element 16.0 was evaluated from both compliance and performance-based standpoints. The auditor began the compliance-based portion of the audit by examining the M&O's internal Weekly CAR Action Status Report and the Monthly CAR Status Summary Report for the previous period, concentrating on those CARs dealing with Design Package 2C. A total of 14 CARs were examined, and numerous deficiencies were identified. The auditor determined that each of the 14 CARs had problems related to one or more of the following areas: timeliness to complete action, inadequate root cause investigation, and inadequate corrective action. In addition, the M&O had rejected 4 of the 14 CARs on initial verification of corrective action. Further, the auditors found no evidence that six Design Package 2C early release CARs had verification of remedial action prior to release. Early release CARs are those which affected the first 40 feet of tunnel boring machine operation. A list of the deficiencies associated with this program element is in Section 5.7 of this report.

The performance-based evaluation of this program element was conducted by requesting documents from the Local Records Center (LRC) which pertained to the start of construction and by examining selected documents. Of specific

interest was the records package for the "Readiness Review for the Start of the ESF Using the TBM," Revision 0, dated 11/21/94. The auditor noted that the record package had been accepted as being delivered to the LRC, but had not been reviewed and accepted for adequacy by the LRC at the time of the audit. Appendix C of the Readiness Review Report documented open items, including hold points which were to be tracked to closure. Six open items were reviewed for content pertaining to identification, tracking between the Open Item List and the Open Item Report, assignment of responsibilities, status, and dates for closure. Additionally, six open items were selected and compared to the Status Tracking List management tool. Each item was found to be properly identified on the Status Tracking List, including the appropriate dates, as noted in Appendix C of the Readiness Review Report.

When reviewing the signature sheet of the "Readiness Review for Start of Construction of the ESF Using the TBM" that formally documents the approvals of the report, the auditor noted that some of the signatures had been cut from other pages and taped onto the signature page submitted with the document. This "objective evidence" raised more questions than it answered and was identified as a concern. During the course of the audit, the M&O organization was able to have the signature page of the document properly re-signed by each individual. Therefore, this potential CAR was considered corrected during the audit.

The auditors were thorough in their approach, selecting appropriate sample sizes, and utilizing approved checklists to note discrepancies. Audit team members effectively integrated the findings from the programmatic and performance-based portions of the audit into one significant preliminary CAR. The NRC staff believes the audit process was effective and concurs with the audit team finding that implementation of the corrective action process is unsatisfactory.

5.4 Qualifications of Audit Personnel

The qualifications of the ATL and auditors were previously found to be acceptable, each individual having met the requirements of QAAP 18.1, "Qualification of Audit Personnel."

5.5 Audit Team Independence

The audit team was composed of YMQAD and HQAD personnel who support DOE and who were familiar with the M&O procedures under evaluation. The auditors 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 YMQAD audit team finding that M&O QA Program Elements 5.0, 15.0, and 17.0 are being effectively implemented. The NRC staff also agrees with the audit team finding that QA Program Element 16.0, Corrective Action, is being ineffectively implemented.

Each of the auditors reviewed an appropriate amount of documentation and interviewed sufficient M&O personnel to make valid judgments on the adequacy of each QA program element in both the programmatic compliance and the performance-based parts of the audit. The audit team was thorough and carefully reviewed a wide spectrum of objective evidence before drawing its conclusions. There were critical discussions during the audit team caucuses which ultimately resulted in the ineffective implementation evaluation of the M&O corrective action process.

The audit findings were important because of the negative results of past M&O audits.

5.6.1 Good Practices

The scoping visit to establish clear measurement criteria for the performance-based portion of the audit was important to the success of the audit.

5.6.2 Weakness

One auditor had to depart the audit for an important conference prior to completing the assigned checklist for the evaluation of Program Element 16.0 because of an airline scheduling problem. The premature departure of the auditor resulted in a substantial duplication of effort and a lack of continuity in the evaluation of this program element. Better audit team personnel planning and utilization is desirable.

5.7 Audit Team Findings

The audit team determined that M&O QA Program Elements 5.0, 15.0, and 17.0 were effectively implemented. The team determined that QA Program Element 16.0, "Corrective Action," was not effectively implemented. It was emphasized during the post-audit meeting that M&O management attention and involvement in the corrective action process is important, especially because of past findings in this area.

The two preliminary CARs issued at the close of the audit are described below:

One preliminary CAR identifies the fact that M&O specifications and drawings are not shown as implementing documents in the M&O RTN Matrix as procedures are. The audit team emphasized that procedures, specifications, and drawings are all implementing M&O documents and should be so identified by the RTN Matrix.

The second preliminary CAR, supported by a list of adverse conditions, stated that the corrective action process is not being adequately implemented at the M&O facilities in Las Vegas, Nevada, with regard to timeliness of corrective action responses, the adequacy of the responses, and the supporting objective evidence for the corrective actions. This CAR was considered significant by the audit team, and the preliminary CAR identified numerous examples of an inadequate corrective action process. The specific adverse conditions are listed below with information supplied by the audit team from the preliminary CAR:

- CAR 94-QN-C-042. Significant, original response due date 8/2/94. Response due date was not met, two reminder inter-office communications (IOCs) were issued (8/4/94 and 8/11/94), extending due date to 8/30/94. Extension request received and granted for due date of 8/30/94. Three amended responses (10/31/94, 11/7/94, and 1/10/95). Response of 10/31/94 rejected on 11/3/94. Response of 11/7/94 accepted on 11/7/94, with completion date of 12/31/94. Extension request of 1/10/95 to extend the completion date to 2/24/95 — open.
- CAR 94-QN-C-049. Significant, original response due date 8/15/94. Extension request (8/18/94) accepted (8/29/94) for due date of 8/31/94. Response (9/14/94) accepted (9/22/94) with a completion date of 1/31/95. Amended response (1/3/95) accepted (1/4/95) requesting extension to 3/31/95.
- CAR 94-QN-C-055. Non-significant, original response due date 8/19/94. Amended response (10/25/94), no objective evidence of QA acceptance, completion date of 12/31/94. Amended response (12/22/94) accepted 1/6/95 with new completion date of 2/28/95.
- CAR 94-QN-C-039. Non-significant, original response due date 7/18/94. Transferred responsibility to Mined Geologic Disposal System (6/24/94), completion date of 10/31/94. Extension request 10/20/94 accepted on 10/25/94, new completion date of 12/31/94. Corrective action was determined unsatisfactory on 1/3/95.
- CAR 94-QN-C-035. Non-significant, original response due date 6/21/94. Response received (6/14/94) and accepted with completion date of 1/6/95. As of 1/12/95, no response or extension request received.
- CAR 94-QN-C-023. Non-significant, original response due date 4/8/94. Response (4/14/94) accepted with completion date of 6/30/94. Amended response with new completion date of 8/1/94; CAR file missing amended response information for 8/94. Amended response (10/21/94) accepted with new completion date of 12/30/94.
- CAR 94-QN-C-053. Non-significant, original response due date 8/17/94. Accepted response with completion date of 9/30/94. Extension request (9/27/94) accepted with a new completion date of 11/30/94. Corrective action determined as unsatisfactory (12/2/94) with completion required by 12/16/94. Amended response (no date) requesting new completion date of 2/28/95 accepted.
- CAR 94-QN-C-040. Significant, original response due date 7/18/94. Extension request (7/19/94) accepted with completion date of 8/5/94. IOC (8/11/94) response due. CAR reclassified (8/15/94) as significant, extended completion date to 9/16/94. Response (9/14/94) accepted with new due date for preventative action at 4/1/95. An extension (10/25/94) for remedial action with a completion date of 12/31/94. CAR Log reflects completion date of 4/1/95, but did not show earlier completion date for remedial actions.
- CAR 94-QN-C-001 and 002. These CARs were closed by IOC dated 12/21/94. The closure IOC does not identify or define the objective evidence that was verified by QA to justify the closure of these two CARs.

- The audit team noted that the M&O had identified 14 internally generated CARs as impacting Design Package 2C. A review of those CARs indicated that all CARs had problems relative to timeliness, adequate root cause investigation, adequate corrective action, or a combination of these items. All of the CARs were initiated prior to August 1994, and at the time of the audit, six of the CARs were still open and had dates into April 1995 for corrective action. Four of the 14 CARs were rejected on initial verification of corrective action by the M&O. The audit team noted that no objective evidence was found that verification of remedial action for Design Package 2C early release CARs were performed prior to that release.
- CAR 94-QN-C-044 — Non-significant, initiated 7/14/94, CAR response received 8/25/94, closed 11/4/94. Determined to have impact on Design Package 2C early release.
- CAR 94-QN-C-025 — Non-significant, initiated 3/10/94, CAR response received 4/8/94, closed 9/20/94. Determined to have impact on Design Package 2C early release.
- CAR 94-QN-C-058 — Non-significant, initiated 7/28/94, CAR response received 8/29/94, closed 10/7/94. Determined to have impact on Design Package 2C early release.
- CAR 94-QN-C-038 — Non-significant, initiated 6/17/94, CAR response received 9/14/94, several QA letters requesting response with only one extension approved by QA, closed 10/5/94.
- CAR 94-QN-C-056 — Significant, initiated 7/26/94, CAR response received 8/26/94, closed 10/3/94. Determined to have an impact on Design Package 2C early release.
- CAR 94-QN-C-032 — Significant, initiated 5/12/94, CAR response received 6/14/94, upgraded to significant on 8/15/94 requiring a new response dated 9/16/94. YMQAD review during this audit found the root cause to be inadequate and not addressed by the action to prevent recurrence but accepted by the M&O QA; corrective action was rejected on 12/15/94 by M&O QA, and a new response requested by 1/5/95. Response was not received until the M&O was questioned during the audit as to its status. New response for M&O QA evaluation was submitted on 1/12/95 during the audit. CAR has been open seven months. Determined to have impact on Design Package 2C early release.
- CAR 94-QN-C-050 — Non-significant, initiated 7/15/94, CAR response received 9/7/94 (due 8/15/94). Ten-day extensions approved on 10/6/94 and 11/17/94 until 10 days after completion of Design Package 2C (2C was submitted in segments and was still not complete at the time of this audit, thus the status of this corrective action commitment could not be determined). Considered Open Indeterminately by audit team.
- CAR 94-QN-C-046 — Non-significant, initiated 7/14/94, CAR response received 7/18/94, amended on 8/17/94, 8/18/94, and 10/14/94. Closed 10/20/94. Determined to have impact on Design Package 2C early release.

- CAR 94-QN-C-051 — Non-significant, initiated 7/19/94, CAR response received 9/9/94 (was due 8/16/94). The response takes exception to the CAR condition; provides no commitments for remedial action and refers to the YMQAD CAR YM-94-065 for addressing any actions. This CAR should have been closed.
- CAR 94-QN-C-040 — Significant, initiated 6/17/94, CAR response was received 9/14/94 (it was due 7/18/94 with one extension request granted and establishing an 8/5/94 due date). The response accepted by M&O QA did not address root cause, nor establish recurrence control, but did establish a corrective action date of 4/1/95; however, on that date, corrective action will still not be complete because the commitment was only to provide an amended response to address this problem as determined by a working group. Considered Open Indeterminately by audit team.
- CAR 94-QN-C-047 — Non-significant, initiated 7/15/94, CAR response received 8/18/94 (due date was 8/2/94) with one extension request changing the corrective action due date from 12/31/94 to 2/28/95. Determined to have impact on Design Package 2C early release. The CAR has been open six months with another two months expected for closure.
- CAR 94-QN-C-057 — Non-significant, initiated 7/27/94, CAR response received 9/7/94 (it was due 8/25/94). The CAR was closed 9/13/94.
- CAR 94-QN-C-049 — Significant, initiated 7/15/94, CAR response received 9/14/94 (it was due 8/15/94 and extended to 8/31/94 after missing the due date, no extension was approved to the 9/14/94 response date). Root cause is not adequate to address the described condition. Amended response does not address root cause determination. Amended response has a completion date of 3/31/95. CAR has been open six months as of the audit.
- CAR 94-QN-C-054 — Non-significant, initiated 7/19/94, CAR response received 9/15/94 (it was due 8/18/94 and there was no extension request). The CAR was closed 9/13/94.
- The audit team further identified these general CAR conditions: The present method of not identifying the next sequential page number, the author's name, and the date on CAR responses and amended responses during the development of the CAR record files fails to maintain adequate objective evidence and traceability of actions taken during the corrective action process. There is insufficient objective evidence to support the determination of the root cause or compliance with DOE Guideline DOE-NE-STD-1004-92 for significant CARs as committed to in Paragraph 5.6.3 of M&O QAP-16-1 (Revision 1).

One potential CAR was corrected during the audit. It involved the objective evidence of a Readiness Review which had been constructed by cutting and pasting approval signatures onto a single page. Before the post-audit meeting, a complete record of the Readiness Review approval signatures was assembled and shown to the auditors.

One recommendation was presented by the audit team to M&O management. The audit team recommended that a performance-based surveillance of all Yucca

- 10 -

Mountain Project participants be conducted to determine their compliance to YAP-15.1Q, "Control of Nonconformances."