

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 93-02
FOR THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM)
QUALITY ASSURANCE DIVISION
AUDIT NO. HQ-93-01 OF THE OCRWM QA PROGRAM

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1.0 INTRODUCTION

During November 30 through December 10, 1992, the quality assurance (QA) staff of the Division of High-Level Waste Management (HLWM) observed a limited scope internal QA audit of the U.S. Department of Energy's Office of Civilian Radioactive Waste Management (OCRWM). The Yucca Mountain Quality Assurance Division (YMQAD) activities in Las Vegas were audited November 30-December 4, 1992, and the OCRWM Headquarters (HQ) activities were audited December 7-10, 1992, at the Forrestal Building in Washington, D.C. This OCRWM audit, HQ-93-01, evaluated the OCRWM QA program to determine whether it meets the OCRWM requirements and commitments. The audit scope included seven QA programmatic elements. No technical areas were evaluated by the audit team.

This report addresses the effectiveness of the OCRWM audit and the adequacy of implementation of QA controls in the audited programmatic areas of the OCRWM QA program.

2.0 OBJECTIVES

The objective of the OCRWM audit was to evaluate the implementation and effectiveness of the OCRWM QA program in meeting the applicable requirements of the OCRWM Quality Assurance Requirements Document (QARD), the OCRWM Quality Assurance Program Description (QAPD), and associated implementing procedures.

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

3.0 SUMMARY AND CONCLUSIONS

The U.S. Nuclear Regulatory Commission staff based its evaluation of the OCRWM audit process and the OCRWM QA program on direct observations of the auditors; discussions with audit team personnel, with other contractor personnel, and with OCRWM personnel; and reviews of the audit plan, the audit checklists, and other pertinent OCRWM documents. The NRC staff has determined that OCRWM QA Audit HQ-93-01 was useful and effective. The audit was well organized and conducted in a thorough and professional manner with minimal logistic delays. The audit team was well qualified in the QA discipline, and its assignments and checklist items were adequately described in the audit plan.

The staff had concerns regarding the independence of the audit team during the HQ portion of the audit. During the audit, the Audit Team Leader (ATL) took action to provide more audit team independence by having auditors from YMQAD assume some of the audit team and ATL's responsibilities regarding the audit of work performed by the ATL's employing organization. While the staff believes that acceptable independence was provided in this way, we recommend that the planning for future internal audits of OCRWM provide for more audit team independence.

On Tuesday, December 8, 1992, the Director of the HQ QA Division joined the daily audit team debriefing meeting while it was in session. Although this individual had a primary responsibility for the audit, he and his organization were also being audited. These meetings are generally limited to the audit

team and observers, and they provide a forum for an open discussion of findings. The presence of this individual appeared to stifle some of the ongoing discussion, and the NRC staff recommends that attendance at these meetings be limited to the audit team and observers.

The NRC staff agrees with the preliminary OCRWM audit team finding that the OCRWM QA program has adequate procedural controls in place. The NRC staff also agrees that QA program implementation in the areas audited is generally adequate even though Corrective Action was judged by the audit team to be marginally effective at YMQAD. A total of eight preliminary Corrective Action Requests (CARs) were discussed by the OCRWM audit team at the post-audit meeting. Also, several other potential CARs were acceptably resolved by the audited OCRWM organization during the audit. None of the CARs identified by the OCRWM audit team is significant in terms of the overall OCRWM QA program.

OCRWM management should closely monitor the OCRWM QA program to ensure that the deficiencies identified during this audit and earlier audits and surveillances are corrected in a timely manner and future implementation is effective. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits later to assess the OCRWM QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

John G. Spraul	Observation Audit Team Leader (HQ only)
John T. Buckley	Observer (HQ only)
John W. Gilray	Observer (YMQAD only)
Kenneth R. Hooks	Observer (HQ only - Part time)

4.2 DOE

Dennis Brown	Audit Team Leader (ATL)	CER Corporation
Michael Donovan	Auditor (HQ only)	CER Corporation
Marlin Horseman	Auditor	CER Corporation
Hank Greene	Auditor	CER Corporation
Lester Wagner	Auditor (YMQAD only)	CER Corporation
Hugh Lenz	Auditor (HQ only)	CER Corporation
Stephen Dana	Auditor (HQ only)	Scientific Applications International Corporation (SAIC)
Sam Horton	Auditor (HQ only)	SAIC
Robert Howard	Auditor	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, Rev. 5, "Audit Program," and QAAP 16.1, Rev. 4, "Corrective Action." The NRC staff observation audit of this audit of OCRWM was based on the NRC procedure, "Conduct of Audits," issued October 6, 1989.

5.1 Purpose/Scope of Audit

The purpose of the OCRWM audit was to determine whether the OCRWM QA program at YMQAD and at HQ meets the requirements imposed by the QARD and to assess the extent and effectiveness of implementation of the program. The audit scope was limited to the seven QA programmatic elements listed below. The audit team developed and utilized checklists based on the requirements in the OCRWM QAPD and associated implementing procedures.

- 1 Organization (HQ only)
- 2 QA Program
- 5 Instructions, Procedures, and Drawings (HQ only)
- 6 Document Control (HQ only)
- 16 Corrective Action
- 17 QA Records
- 18 Audits

Individual auditors or audit sub-teams of two or three auditors were assigned to audit compliance with specific OCRWM procedures. Two of the three teams assigned to audit HQ activities included an auditor from YMQAD, while the audit teams at YMQAD included personnel from HQ only.

5.2 Timing of the Audit

The NRC staff believes the timing of this audit, November 30-December 10, 1992, was appropriate to re-audit the pertinent QA activities and to verify corrective actions from previous internal OCRWM audits and surveillances and for the staff to evaluate the OCRWM audit process and the OCRWM QA program. Approximately a year had elapsed since these programmatic elements had been last audited by an OCRWM HQ audit team.

5.3 Examination of QA Programmatic Elements

Before the audit, the audit team prepared checklists to use during the audit. The checklists were based on the requirements of the procedures covered by the audit. The NRC staff observed all or a portion of the OCRWM audit covering the following procedures:

- QAAP 2.3, Rev. 0, "Establishing Quality Assurance Program Controls" (HQ only)
- QAAP 2.7, Rev. 1, "Management Assessment" (HQ only)
- QAAP 2.10, Rev. 0, "Hold Points" (HQ only)
- QAAP 5.1, Rev. 3, "Preparation and Revision of QAAPs" (HQ only)
- QAAP 17.1, Rev. 2, "QA Records Management" (HQ only)
- Implementing Line Procedure (ILP) 12.17.01, Rev. 2, "Quality Records Center Implementing Line Procedure" (HQ only)
- Administrative Procedure (AP) 1.18Q, Rev 1 and ICN 10, "Records Management" (YMQAD only)
- QAAP 18.1, Rev. 3, "Qualification of Audit Personnel" (YMQAD only)
- QAAP 18.2, Rev. 5, "Audit Program" (Both locations)
- QAAP 18.3, Rev. 5, "Surveillance Program" (Both locations)
- Quality Management Procedure (QMP) 02-01, Rev. 6, "Indoctrination and Qualification Training" (YMQAD only)

The NRC staff's observations regarding the audit and the implementation of each of these QA procedures are provided under the appropriate QA programmatic element discussed below.

5.3.1 QA Program (Programmatic Element 2)

- OCRWM HQ

To audit performance to QAAPs 2.3, 2.7, and 2.10, the auditors interviewed involved OCRWM personnel. The auditors also interviewed the team leader for the ongoing OCRWM QA management assessment while auditing to QAAP 2.7. For QAAPs 2.7 and 2.10, the auditors also reviewed related documentation.

In auditing to QAAP 2.3, the auditor interviewed various OCRWM Associate Directors and Office Directors involved in the QA program to determine whether the organizational functions and work activities described in the Quality Assurance Controls Document (QACD - issued October 1990) were correct. QAAP 2.3 requires the QACD to describe all functions and work activities of each OCRWM organizational unit and identify the QA controls which apply. In general, the descriptions in the QACD were verified as accurate and in conformance with approved mission and function statements by the interviewees. Although there have been no organizational changes since the QACD was issued, activities associated with QA training have been reassigned (from the Office of Quality Assurance to the Office of Program and Resource Management) and the activities associated with the Occurrence Reporting and Processing System (ORPS) have been added to the responsibilities of the Office of Systems and Compliance.

The descriptions in the QACD concerning responsibility for training are sufficiently general that QA training could be interpreted to be covered in the receiving organization's function and work activities. It was noted, however, that the QACD descriptions may not consistently meet the QAAP requirement for level of detail. A preliminary CAR was issued by the auditor concerning the lack of any description in the QACD of activities associated with the ORPS.

Neither QAAP 2.7 nor the QARD requires verification or tracking to closure of recommendations from a management assessment team. In light of this, follow-up to the 1991 management assessment was deemed acceptable by the auditors. However a preliminary recommendation was made to incorporate such a requirement into QAAP 2.7 so that it better reflects the overall intent of management assessments.

In auditing to QAAP 2.10, the auditors found no CAR conditions, but recommendations were made regarding minor changes in work practices and QAAP 2.10 such that the work practices and procedure would be in better agreement.

The auditors used the checklists effectively to guide their interviews and were persistent in their questioning when necessary. The audit of OCRWM compliance with the procedural requirements of the QAAPs discussed above was effective. The NRC staff agrees with the audit team finding that OCRWM HQ implementation of QA Programmatic Element 2 is generally adequate.

5.3.2 Instructions Procedures, and Drawings (Programmatic Element 5)

- OCRWM HQ

The auditors examined four QAAP record packages to verify that the QAAPs were prepared in accordance with QAAP 5.1. This procedure requires that QAAP reviewers identify mandatory comments and justify the designation with one of four criteria specified in the QAAP. During the audit it was determined that not all reviewers of the draft QAAPs had identified the mandatory comments in accordance with this requirement. In spite of this deficiency, there is evidence that adequate comment resolution was achieved. Therefore, the auditor prepared a recommendation rather than a CAR on this issue.

For the area observed, the audit of Programmatic Element 5 was effective. Based on the limited amount of evidence available for review, the NRC staff agrees with the audit team finding that Programmatic Element 5 is being adequately implemented.

5.3.3 QA Records (Programmatic Element 17)

- OCRWM HQ

Twenty-five checklist items were developed from QAAP 17.1 and thirteen from ILP 12.17.01. Based on these items, the auditors reviewed pertinent documents and interviewed involved OCRWM personnel. No areas of concern were identified during this portion of the audit, and no CARs were generated.

The auditors used the checklist effectively to guide their document reviews and interviews, and they were persistent in their questioning when necessary. The audit of OCRWM compliance with the procedural requirements of QAAP 17.1 and ILP 12.17.01 was effective. The NRC staff agrees with the audit team finding that OCRWM HQ implementation of Programmatic Element 17 is generally adequate.

- YMQAD

The auditors reviewed and evaluated selected record packages to determine that these record packages had been properly reviewed for completeness and clarity and that they were being protected and stored in accordance with AP-1.18Q. The auditors also verified that the personnel involved in generating and storing QA records were properly trained and familiar with the pertinent program requirements.

The auditors used the checklist effectively to guide their document reviews and interviews, and they were persistent in their questioning when necessary. The audit of YMQAD compliance with the procedural requirements of AP-1.18Q was effective. The NRC staff agrees with the auditors' findings that YMQAD control of records is in compliance with QA program requirements, that the personnel involved were adequately trained, and that implementation of Programmatic Element 17 is generally adequate.

5.3.4 Audits (Programmatic Element 18)

- OCRWM HQ

OCRWM HQ had completed two audits (one internal and one external) during fiscal year 1992 (FY92). Auditors from the current audit team evaluated the activities associated with these audits to see whether they were performed in accordance with QAAP 18.1, Rev. 3, "Qualification of Audit Personnel," and QAAP 18.2. The NRC staff did not observe the portion of the audit associated with QAAP 18.1.

For QAAP 18.2, the auditor successfully addressed the checklist questions by reviewing the audit planning documents and the record packages for the completed audits. Contrary to the requirements of QAAP 18.2, it was determined that Revisions 3 and 4 of the FY92 audit schedule had not been distributed to the OCRWM Technical Project Officers (TPOs) and QA Managers as required. In addition, there was no evidence that the FY93 audit schedule had been transmitted to the TPOs.

The evaluation of QAAP 18.3 was conducted by reviewing the surveillance schedule and the document packages for surveillances HQ-SR-92-04, 05, and 06. QAAP 18.3 requires that the Director of OCRWM's Office of Quality Assurance review the surveillance schedule at least quarterly. However, since the initial surveillance schedule for FY92 was not issued until June 4, 1992, this requirement was not met.

The audit of Programmatic Element 18 was effective. Although a CAR resulted from the discrepancies noted above, the NRC staff agrees with the audit team finding that implementation of Programmatic Element 18 is adequate.

- YMQAD

The auditors verified that YMQAD auditors were properly qualified based upon experience, audit skills, and supporting documentation and that the qualification and training record packages contained the necessary objective evidence demonstrating qualification certification of training and maintenance of proficiency.

The yearly Audit and Surveillance Schedules were reviewed to determine whether the planned internal and external audit intervals were being identified properly relative to the organization to be audited, location and date of audit, and the QA programmatic elements to be audited. Completed audit and surveillance packages were reviewed and evaluated to determine that the audit and surveillance reports including any identified deficiencies were being properly documented and approved by the appropriate YMQAD and Yucca Mountain Project Office staff.

The audit of Programmatic Element 18 was effective. The NRC staff agrees with the audit team finding that the YMQAD audit process is acceptable, the qualification and experience of audit personnel are acceptable and in accordance with QA program requirements, and that implementation of Programmatic Element 18 is adequate.

5.4 Conduct Of Audit

The audit was productive and performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the OCRWM QA program. Two perceived weaknesses, one concerning audit team independence of HQ QA activities being audited and the other concerning the Director of the HQ QA Division's presence at a daily audit team debriefing meeting, are discussed in Section 5.9.2 below. Despite these weaknesses, the OCRWM audit team personnel were persistent in their interviews, challenged responses when necessary, and performed an acceptable audit. Daily audit team debriefing meetings were held between auditors and observers, and daily audit status meetings were held between OCRWM management and the ATL to discuss the preliminary findings. Although the auditors who identified concerns were not included in the daily status meetings, the ATL adequately presented the audit status and preliminary findings to OCRWM management personnel who attended these meetings.

5.5 Qualification Of Auditors

The qualifications of the auditors on the OCRWM audit team were reviewed by the NRC staff during the audit and found to be acceptable. Certifications and qualifications were either in the OCRWM HQ file or, having been completed relatively recently, in the process of being sent there for filing.

5.6 Audit Team Preparation

The auditors were prepared in the areas they were assigned to audit and were knowledgeable of the OCRWM procedures. The audit plan for this audit included (1) the audit scope, (2) the audit schedule, (3) a list of audit team personnel, (4) a list of the activities to be audited, and (5) audit checklist references.

5.7 Audit Team Independence

The audit team members generally did not have prior responsibility for performing the activities they audited. However, a staff concern regarding the independence of the audit team performing the audit at HQ is discussed in Section 5.9.2 below.

5.8 Review of Previous Audit Findings

5.8.1 OCRWM did not have any open CARs from previous audits requiring review during this audit.

5.8.2 The NRC staff did not have any open observations from previous observation audits relating to this audit.

5.9 Summary of NRC Staff Findings

5.9.1 Observations

The NRC staff did not identify any observations relating to deficiencies in either the audit process or the OCRWM QA program implementation.

5.9.2 Weaknesses

The staff had concerns regarding the independence of the audit team during the HQ portion of the audit. During the audit, the ATL took action to provide more audit team independence by having auditors from the Las Vegas office assume some of the audit team's responsibilities regarding the audit of work performed by his employing organization. While we believe that acceptable independence was provided in this way, we recommend that the planning for future internal audits of OCRWM provide for more audit team independence.

On Tuesday, December 8, 1992, the Director of the HQ QA Division joined the daily audit team debriefing meeting while it was in session. Although this individual had a primary responsibility for the audit, he and his organization were also being audited. These meetings are generally limited to the audit team and observers, and they provide a forum for an open discussion of findings. The presence of this individual appeared to stifle some of the ongoing discussion, and the NRC staff recommends that attendance at these meetings be limited to the audit team and observers.

5.9.3 Summary

The NRC staff has determined that OCRWM QA Audit HQ-93-01 was useful and effective. The NRC staff agrees with the preliminary audit team findings that the OCRWM QA program has adequate procedural controls in place and implementation in the areas audited is satisfactory.

5.10 Summary - OCRWM Audit Findings

As a result of this audit, the audit team developed 8 preliminary CARs against the OCRWM QA program. Also, several other potential CARs were acceptably resolved by the OCRWM audited organization during the audit. In addition, the audit team developed 13 recommendations to improve the OCRWM QA program. None of the preliminary CARs identified or the recommendations developed by the OCRWM audit team is significant in terms of the overall OCRWM QA program. Generally, they represent a fine-tuning of an acceptable program. A summary of the 8 preliminary CARs which were not closed during the audit is presented below.

Programmatic

Element CAR

- | | |
|---|--|
| 2 | A procedure review was performed by an individual whose record of required training for reviewing procedures could not be found. |
|---|--|

- 2 The indoctrination and training records of three individuals were missing a required update.
- 2 Thirteen individuals performing quality-affecting activities were not on the "List of Employees Performing Assignments Against the QARD" as required.
- 2 An assigned activity (though not subject to QA program controls) is not identified in the QACD as required.
- 6 A QA Manual, used by several personnel performing quality-affecting activities, was not updated as required.
- 16 In some of the audit samples, corrective action documentation and follow-up do not meet all requirements.
- 17 Six lead auditor certification files did not contain objective evidence of examination contents as required.
- 18 Audit/surveillance schedules were not reviewed/issued within the allowed time.