U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT 93-10

OF THE HEADQUARTERS QUALITY ASSURANCE DIVISION

AUDIT HQ-93-05

OF THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

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1.0 INTRODUCTION

During May 10-13, 1993, members of the quality assurance (QA) staff of the NRC Division of High-Level Waste Management (HLWM) observed a U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, Headquarters Quality Assurance Division (HQAD) audit of OCRWM. The audit, HQ-93-05, was conducted at the OCRWM offices, Forrestal Building, in Washington, DC. The audit evaluated the adequacy and effectiveness of the OCRWM QA program in three programmatic areas.

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

2.0 OBJECTIVES

The objectives of the audit by HQAD were to determine whether the OCRWM QA program and its implementation meet the applicable requirements and commitments 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 program in accordance with the QARD, the QAPD, 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 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the HQAD audit process and implementation of the OCRWM QA program on direct observations of the auditors; discussions with audit team and OCRWM personnel; and reviews of the audit plan, the audit checklists, and other pertinent documents. The NRC staff has determined that QA Audit HQ-93-05 was useful and effective. The audit was well organized and conducted in a thorough and professional manner with minimal logistic delays. Audit team members were generally independent of the activities that 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 HQAD audit team finding that implementation of the OCRWM QA program in the areas audited is generally adequate. Five preliminary Corrective Action Requests (CARs) were discussed by the HQAD audit (exit) team at the post-audit meeting. Several other potential CARs were acceptably resolved by the OCRWM organization during the audit. None of the preliminary CARs identified by the HQAD audit team is significant in terms of the overall OCRWM QA program.

OCRWM should continue to closely monitor implementation of its QA program to ensure 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 OCRWM implementation of its QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

Pauline P. Brooks	Observer	
Kenneth R. Hooks	Observer	
Bruce Mabrito	Observer	Center for Nuclear Waste Regulatory Analyses

4.2 DOE

Thomas Rodgers	Audit Team Leader (ATL)	CER Corp. (CER)
Fred Bearham	Auditor	CER
Hugh Lentz	Auditor	CER
Marlin Horseman	Auditor	CER
Robert Howard	Auditor	Weston
Richard Maudlin	Auditor	MAC Technical Services Company
Trieu Truong	Technical Specialist	OCRWM
Tim Johnson	Auditor-in-Training	OCRWM

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This HQAD audit of OCRWM was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program" (Revision 5 plus Interim Change Notice 1) and QAAP 16.1, "Corrective Action" (Revision 4). The NRC observation audit of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

5.1 Scope of Audit

This audit was designed to be performance-based to the maximum extent possible. The auditors were directed to focus on work products rather than programmatic requirements.

The audit scope included the three QA programmatic elements listed below:

3.0   Design Control
4.0   Procurement Document Control
7.0   Control of Purchased Items and Services

The work products to be reviewed and evaluated were the Waste Acceptance Systems Requirements Document (WA-SRD), Revision 0; selected fiscal year 1993 Programmatic Funding and Guidance Letters (PGLs); and selected Work Authorization Directives (WADs).

The audit team developed and utilized checklists based on the requirements in the QARD, specific QAAPs, Quality Administrative Procedures (QAPs), and the Technical Document Preparation Plan (TDPP). Programmatic Element 3.0 and the WA-SRD were audited simultaneously. Auditing of QA Programmatic Element 4.0

was conducted simultaneously with auditing of QA Programmatic Element 7.0, PGLs, and WADs.

This audit, and Audit HQ-93-01 which was conducted from November 30 through December 9, 1992, together cover all the applicable programmatic elements of the OCRWM QA program in which there is any activity.

5.2 Timing of the Audit

The NRC staff believes the timing of this audit was appropriate for HQAD to audit the pertinent QA activities of OCRWM and for the NRC staff to evaluate the HQAD audit process and implementation of the OCRWM QA program. This audit was scheduled in conformance with OCRWM's practice of auditing each applicable QA programmatic element at least annually.

5.3 Examination of QA Programmatic Elements

The NRC staff observed that each of the auditors reviewed related documentation and interviewed at least a representative sample of OCRWM personnel to determine their understanding and 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 in an appropriate manner. The NRC staff observations regarding the audit and the implementation of each appropriate QA programmatic element are discussed below.

5.3.1 Design Control (Programmatic Element 3.0)

A sub-team composed of two auditors and a technical specialist evaluated Criterion 3 as implemented in the preparation, review, approval and issuance of the WA-SRD, which is intended to establish system-level requirements for waste acceptance. The team examined the Quality Records Package for the preparation and review of the WA-SRD, determined whether the WA-SRD was prepared and reviewed in accordance with the TDPP and, using an Indoctrination and Training (I&T) matrix, examined the I&T records for preparers and reviewers of of the WA-SRD.

Although the TDPP calls for reviewer qualifications to be placed in the records package for the WA-SRD, several had been put into System 80 Personnel Records System without so annotating the records. The auditors reviewed a sample of the System 80 qualification records of the personnel who had reviewed the WA-SRD. The NRC observers also reviewed a sample of the qualification records. Some records, such as resumes and transcripts, are not part of the System 80 record packages; however, the existence and adequacy of such documents were verified for a sample of the reviewers by an HQAD auditor.

Document Review Records (DRRs) were reviewed technically and programmatically to determine whether QAP 6.2, Document Review, was followed. A sample of reviewers were interviewed to determine their familiarity with review requirements.

The audit sub-team determined that the WA-SRD was based on a draft version of the Civilian Radioactive Waste Management System Requirements Document (CRD). OCRWM personnel stated that the draft and final versions of the CRD had been compared, and no variations which would affect the WA-SRD were found; however, documentation of this review had not been submitted to the Local Records Center. A preliminary CAR was written concerning the use of a draft, unapproved document as the basis for the WA-SRD. The audit team also determined that some requirements in the WA-SRD were not adequately documented on Issue Clarification and Derived Requirements Documentation forms, and wrote a preliminary CAR on this deficiency.

The audit sub-team reviewed the flow-down of requirements from the WA-SRD to the Waste Acceptance Preliminary Specification (WAPS) issued by DOE Office of Environmental Restoration and Waste Management, Office of Waste Management to the waste form producers. The sub-team determined that some requirements could not be traced, and that OCRWM had not reviewed and approved the WAPS. Since OCRWM procedures do not require OCRWM review and approval of the WAPS, no CAR was written; however, the audit team recommended that a surveillance be performed of the WAPS to verify the flow down of requirements from the WA-SRD.

The auditor reviewed a sample of the qualification records of the personnel who had reviewed the WA-SRD, and compared the list of reviewers against the list of preparers of the WA-SRD to verify independence. The NRC observers also reviewed a sample of the qualification records, which are part of System 80. Some records, such as resumes and transcripts, are not part of the System 80 record packages; however, the existence and adequacy of such documents were verified for a sample of the reviewers by an HQAD auditor.

The audit of Programmatic Element 3.0 and the WA-SRD was effective, and the NRC staff agrees with the audit team that QA program implementation under this program element is generally adequate.

5.3.2 Procurement Document Control and Control of Purchased Items and
Services (Programmatic Elements 4.0 and 7.0)

The two auditors assigned to these sections began their portion of the audit by interviewing each of the key OCRWM staff associated with procurements. In these discussions, the variations in different procurements were discussed, specifically work involving contractors versus work by government organizations and how those differences are handled to ensure quality requirements are passed through to the performing entity.

Audit interviews were held with the following personnel/offices: Director of Contract Management Division; Director of Transportation and Logistics; Associate Director for Storage and Transportation; Chief of the Systems Engineering Branch; and Chief of the Systems Planning and Integration, Director of Management and Operating Contractor (M&O) Management Division. Following the initial interviews, the auditors worked separately to complete checklist items by verifying objective evidence obtained from the Quality Records Center (QRC) or from the individual OCRWM offices. When necessary, follow-up interviews were conducted with the appropriate person to clarify or obtain additional objective evidence.

This method of auditing allowed for thorough responses to the questions, as both general and specific questions were asked. The auditors' familiarity with ongoing OCRWM activities was particularly beneficial in scheduling the appropriate management personnel to be available for questioning.

PGLs to the Oak Ridge National Laboratory and Idaho National Engineering Laboratory, which are performing work for OCRWM were checked to ensure that management and technical review criteria in accordance with the Document Review Procedure had been met. Procurement documents for the Energy Information Administration and the WAD to the M&O were also closely checked. The WAD provided direction and resources to support the Transportation element of the OCRWM program, which included systems engineering, transportation casks, support systems, regulatory interfaces, project management, QA, environmental, safety and health, and institutional activities.

Although the two auditors worked separately at times, they coordinated their work well and were thorough and meticulous in reviewing objective evidence. They worked effectively with the OCRWM QRC in obtaining referenced documents and created matrix checklists when required to verify multiple requirements in a series of procurement documents. The indoctrination and training records of key OCRWM staff were reviewed by the auditors, and when they identified that the records were not complete, the audited organization performed remedial action by locating most of the documents which had not been submitted to the QRC.

Throughout the audit in the procurement area, concerns were identified by the two auditors which were either substantiated and elevated to a CAR condition, or, objective evidence was presented which completely responded to the concern and it was dropped. This process occurred a number of times during the audit and resulted in one CAR being written. The adverse condition identified was a procedural violation in that there was no objective evidence that a required document review, as required by QAP 3.5, "Technical Document Preparation," was performed on a direct-support contract, and also that personnel who prepared the direct-support contract were not trained in the Procurement of Services procedure.

Overall, the audit was effective and the implementation of procurement document controls appeared to be effective, except in the area in which the CAR was issued.

5.3.3 Conclusions

The audit was performed in determining the adequacy and degree of implementation of the OCRWM QA program. The audit team appropriately identified areas of weakness by issuing five CARs: four in the WA-SRD process and one in the direct-support process. The deficiencies do not indicate serious programmatic inadequacies, but reflect the need to make adjustments in the OCRWM quality system to make it internally consistent and up-to-date in its approach.

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 OCRWM QA program. In general the audit team personnel were persistent in their interviews, challenged responses when necessary, and performed an acceptable audit. Daily caucuses were held between auditors and observers, and daily audit status meetings were held between OCRWM management and the ATL (with an NRC observer present) to discuss the preliminary findings.

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 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

The audit team members did not have prior responsibility for performing the activities they audited. Although most of the audit team had worked on other parts of the OCRWM program, members of the team had sufficient independence to carry out their assigned functions in a correct manner without adverse pressure or influence. An auditor from the Yucca Mountain Quality Assurance Division was included in the audit team to be available to review any items which had been worked on by the ATL, but no such items were reviewed during the course of the audit.

5.8 Summary of NRC Staff Findings

5.8.1 Observations

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

5.8.2 Good Practices

Including an auditor from the Yucca Mountain Quality Assurance Division to serve as ATL, should it have become necessary to review items that had been worked on by the ATL, was good contingency planning.

5.8.3 Weaknesses

- Although the audit was intended to be performance-based, the process seemed to be mainly a programmatic, compliance-based audit. This was at least partly due to the nature of, and scarcity of, work products.

- Compared to other OCRWM audits observed by the NRC staff the auditors had more problems in reaching agreement with the auditees on the rationale for findings.

- Some of the deficiencies identified appeared to result from lack of understanding of the OCRWM QA program by the OCRWM staff, particularly concerning applicability of procedures and the need to document and retain records of decisions. The NRC observers did not detect the across-the-board awareness of the QA program requirements that now seems to generally prevail at long-time program participants.

- Although many of the personnel are genuinely striving to improve their quality system and their resulting products, in a few areas of the OCRWM HQ organization, key staff did not seem too interested in the audit until it was apparent that a CAR would be written.

5.9 Summary of HQAD Audit Findings

Within the scope of this audit, the audit team concluded that the OCRWM QA procedures are adequate and that OCRWM's QA program implementation in the areas audited is adequate except where corrective action is required as discussed in Section 5.3. At the audit Exit Meeting, the audit team provided 12 observations of the OCRWM QA program, and five preliminary CARs resulting from the audit. Two other preliminary CARs were acceptably resolved by the OCRWM organization prior to the Exit Meeting.

The preliminary CARs reported at the Exit Meeting were:

- Source input evaluation information for the WA-SRD was not transmitted to the Configuration Management Branch.

- The CRD used as a source document in preparing the WA-SRD was a draft document (see Section 5.3.1).

- The rationale and bases for some derived requirements in the WA-SRD were not adequately documented (see Section 5.3.1).

- QAP 3.5, Technical Document Preparation, does not address requirements for a QA review of the TDPP.

- There was no objective evidence that procurement document preparers for the Asta Engineering contract had been trained in QAAP 7.1, Procurement of Services, or that a QAP 6.2 review of the documents was performed (see Section 5.3.2).