U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. 93-06

FOR THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM)

QUALITY ASSURANCE DIVISION

AUDIT NO. HQ-93-03 OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM

MANAGEMENT AND OPERATING CONTRACTOR (M&O) HEADQUARTERS

2/18/93
John G. Spraul
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste
Management

2/18/93
John T. Buckley
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste
Management

for 2/18/93
Robert D. Brient (per telephone)
Center for Nuclear Waste
Regulatory Analysis (CNWRA)

Reviewed and approved by:

2/18/93
Kenneth R. Hooks
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste
Management

1.0 INTRODUCTION

During February 1 through 5, 1993, members of the quality assurance (QA) staff of the NRC Division of High-Level Waste Management (HLWM) observed an OCRWM compliance-based QA audit of the M&O Headquarters at the TRW Environmental Safety Systems, Inc. offices in Vienna, Virginia. This was the first audit of M&O Headquarters to be performed by OCRWM and observed by the NRC. The audit, HQ-93-03, evaluated the adequacy and effectiveness of the M&O Headquarters QA program. The audit scope included the 11 applicable QA programmatic elements. No technical areas were evaluated by the audit team.

This report addresses the effectiveness of the OCRWM audit, the adequacy of M&O Headquarters QA procedures, and the implementation of the M&O Headquarters QA program.

2.0 OBJECTIVES

The objective of the OCRWM audit was to determine whether the M&O Headquarters QA program and its implementation meet the applicable requirements of the OCRWM Quality Assurance Requirements Document (QARD), the M&O Quality Assurance Program Description (QAPD), and associated implementing procedures and to assess the extent and effectiveness of implementation of the program.

The NRC staff's objective was to gain confidence that OCRWM and M&O Headquarters are properly implementing the requirements of their QA programs in accordance with the QARD 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 NRC staff based its evaluation of the OCRWM audit process and the M&O QA program on direct observations of the auditors; discussions with audit team and M&O Headquarters personnel; and reviews of the audit plan, the audit checklists, and pertinent M&O documents. The NRC staff has determined that OCRWM QA Audit No. HQ-93-03 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 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 audit team findings that the M&O Headquarters QA procedures need to be upgraded and that implementation of the QA program is marginally effective even though Corrective Action and Audits were preliminarily assessed by the audit team to be ineffective. Nine preliminary Corrective Action Requests (CARs) were discussed by the OCRWM audit team at the post-audit meeting with the M&O. Also, several other preliminary CARs were acceptably resolved by the M&O organization during the audit. None of the preliminary CARs identified by the OCRWM audit team is significant in terms of the overall M&O QA program.

OCRWM should closely monitor the M&O QA program to ensure that the deficiencies identified during this audit are corrected in a timely manner and future implementation is carried out effectively. The NRC staff expects to

participate in this monitoring as observers and may perform its own independent audits later to assess the M&O QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

John G. Spraul	Observation Audit Team Leader	
John T. Buckley	Observer	
Robert D. Brient	Observer	Center for Nuclear Waste Regulatory Analyses

4.2 DOE

Dennis Brown	Audit Team Leader (ATL)	CER Corporation
Fred Bearham	Auditor	CER Corporation
Pete Chomentowski	Auditor	Roy F. Weston, Inc.
Leonard Gordon	Auditor	Roy F. Weston, Inc.
Hank Greene	Auditor	CER Corporation
Marlin Horseman	Auditor	CER Corporation
Robert Howard	Auditor	Roy F. Weston, Inc.
Hugh Lentz	Auditor	CER Corporation
Lester Wagner	Auditor	CER Corporation
Sam Horton	Observer	Science Applications International Corp.

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 M&O Headquarters was based on the NRC procedure, "Conduct of Audits," issued October 6, 1989.

5.1 Purpose/Scope of Audit

The objective of the OCRWM audit was to determine whether the M&O Headquarters QA program and its implementation meet the applicable requirements of the OCRWM Quality Assurance Requirements Document (QARD), the M&O Quality Assurance Program Description (QAPD), and associated implementing procedures and to assess the extent and effectiveness of implementation of the program. The audit scope included the 11 applicable QA programmatic elements that are listed below. Programmatic Elements 8-15 were also considered, but they were identified in the audit plan as not applicable to current M&O Headquarters activities.

1 Organization
2 QA Program
3 Design Control
4 Procurement Document Control
5 Instructions, Procedures, and Drawings

6 Document Control
7 Control of Purchased Items and Services
16 Corrective Action
17 QA Records
18 Audits
19 Computer Software

The audit team developed and utilized checklists based on the requirements in the M&O Headquarters implementing procedures for these programmatic elements. The auditors were instructed to consider the implementation of the M&O QAPD, the DOE QARD, and the newly issued DOE QA Requirements and Description document in their evaluations of the programmatic adequacy of the M&O QA program. Individual auditors or audit sub-teams of two or three auditors were assigned to audit compliance with specific M&O Headquarters Quality Administrative Procedures (QAPs).

5.2 Timing of the Audit

The NRC staff believes the timing of this audit, February 1 through 5, 1993, was appropriate for OCRWM to audit the pertinent QA activities of M&O Headquarters and for the staff to evaluate the OCRWM audit process and the M&O QA program. OCRWM had conditionally approved the M&O QAPD in mid-1991, and unconditional approval was in the fall of 1992. M&O Headquarters is preparing to begin significant quality-affecting activities in high-level waste areas such as cask acquisition and systems engineering for transportation and storage.

5.3 Examination of QA Programmatic Elements

Before the audit, the audit team prepared checklists to use during the audit. The checklists, based on the requirements of the QAPs listed below, also included items to determine the programmatic adequacy of the QAPs. During the audit, the checklists were used by the auditors to guide their interviews with M&O personnel. "Flow down" of the requirements of the QARD and QAPD to the QAPs was also probed.

The NRC staff observed all or a portion of the OCRWM audit covering the listed QAPs that have an asterisk.

QAP 1-1 Escalation of Quality Disputes (Rev. 1)
QAP 2-1 Indoctrination and Training (Rev. 2)
QAP 2-2 Verification of Personnel Qualifications (Rev. 1)
QAP 2-3 Establishing QA Program Controls (Rev. 3)
QAP 2-4* QA Program Status and Trend Reporting (Rev. 1)
QAP 2-5* QA Surveillance (Rev. 1)
QAP 2-6 Readiness Reviews (Rev. 1)
QAP 2-9 Conduct of Training (Rev. 0)
QAP 3-1* Technical Document Review (Rev. 2)
QAP 3-2* System Conformance Reviews (Rev. 2)
QAP 3-5* Development of Technical Documents (Rev. 2)
QAP 3-6* Configuration Identifiers (Rev. 1)
QAP 3-7* Interface Controls (Rev. 1)

QAP 3-8* Procurement Specifications (Rev. 1)
QAP 3-9* Engineering Calculations and Analyses (Rev. 1)
QAP 3-13* Assignment of Document Identifiers (Rev. 1)
QAP 3-14* Project Milestone Reviews (Rev. 0)
QAP 4-1* Procurement Document Reviews (Rev. 0)
QAP 5-1* Preparation of M&O Quality Administrative and Implementing Line Procedures
QAP 6-1 Document Control (Rev. 1)
QAP 7-1* Control of Purchased Items and Services Procurement (Rev. 0)
QAP 16-1* Corrective Action Reports (Rev.0)
QAP 16-2* Stop Work (Rev. 0)
QAP 17-1* Program Records Management: Record Source Responsibilities (Rev. 2)
QAP 17-2* Program Records Management: Receipt and Handling of Program Records and Records Packages (Rev. 0)
QAP 17-4 Program Records Management: Microfilming Program Records (Rev. 0)
QAP 17-5 Program Records Management: Indexing Program Records (Rev. 0)
QAP 17-6 Program Records Management: Storage, Retrieval, and Disposition of Program Records (Rev. 0)
QAP 18-1 Certification of Audit Personnel (Rev. 0)
QAP 18-2* Audits (Rev. 1)
QAP 19-1* Computer Software Verification and Validation (Rev. 1)
QAP 19-2* Software Configuration Management (Rev. 1)

The staff observed that, for each of the auditors/audit sub-teams observed, the auditors reviewed related documentation and interviewed at least a representative sample of M&O Headquarters personnel to determine their understanding and degree of implementation of the QAPs. The auditors observed were well prepared and knowledgeable of the M&O QA program requirements. They used their checklists effectively and pursued issues beyond the checklists when appropriate. They solicited participation by and comments and questions from the staff observers in an acceptable manner. Further staff observations regarding the audit and the implementation of each of these QAPs are provided under the appropriate QA programmatic element discussed below.

5.3.1 QA Program (Programmatic Element 2)

Observations regarding QAP 2-4 and QAP 2-5 are discussed below under Programmatic Elements 16 and 18, respectively.

5.3.2 Design Control (Programmatic Element 3)

Design-related procedures were developed by M&O's Systems Integration Group of the Systems Engineering Division, and design-related activities are to be conducted by the Storage and Transportation Division as well as the Systems Engineering Division. The only actual design performed prior to the audit at Headquarters and the Charlotte, NC office was the Monitored Retrievable Storage system conceptual design at Charlotte. The Manager of that activity was available at Headquarters during this audit. The audit sub-team took great care to be sure that representatives from each activity performing design-related activities were included in its evaluations.

A draft Request for Proposal (RFP) for a cask for transporting used fuel elements from commercial nuclear power plants was reviewed for implementation of QAP 3-1. Implementation appeared effective, however, the RFP was in its infancy and comment resolution had not started.

QAP 3-2 had not been implemented after a significant change in scope in its current revision.

QAP 3-5 had been partially implemented by development of two Technical Document Preparation Plans (TDPPs) for the Transportation System Requirements Document and the Interface Specification. The M&O considers TDPPs to be not quality-affecting since they do not identify QA or technical requirements that are not specified elsewhere. Therefore, TDPPs are not approved at the same level as other instructions and procedures (such as QAPs) and are not controlled in accordance with QAP 6-1. The audit team recommended that the QA status of documents related to a QAP, such as the TDPPs, be identified.

QAP 3-6 applies to the configuration control of both hardware and software. Since the OCRWM procedure for hardware configuration management had not been issued, QAP 3-6 had been used only to issue a block of configuration item numbers for M&O software. The auditor found that the number assigned to an individual software item was not being communicated back to M&O's configuration management (CM) organization. The auditor met with the M&O's CM and software control staff, and a modification to the software QAP 19-2 was proposed to rectify the situation.

QAP 3-7 describes the activities of the M&O's Interface Control Working Group, whose charter had not yet been approved by OCRWM. Hence there had been no implementation of this QAP. Interface control documents will be a product of this group when it becomes active. The auditor questioned managers of each design activity to determine how and at what stage of the process that formal interface controls would be applied.

QAP 3-8 addresses the technical specification portion of procurement documents. This QAP had been implemented to a limited extent on the RFP mentioned above for a transportation cask which was a preliminary draft.

QAP 3-9 was found to be inadequate because it did not address analyses and no requirements were established for documenting the calculation and analysis reviews. QAP 3-9 was one of ten QAPs referenced in a preliminary CAR for not adequately addressing qualitative and quantitative criteria for determining the acceptability of prescribed activities. This procedure had not been implemented for the M&O design activities at either M&O Headquarters or Charlotte, NC.

QAP 3-13 was cancelled until the corresponding OCRWM procedure is issued, after which QAP 3-13 will be revised and re-issued.

Activities at M&O Headquarters had not progressed sufficiently for project milestones to be formally reviewed in accordance with QAP 3-13.

The audit of this programmatic element was effective. Due to the very low level of M&O Headquarters design activity, the effectiveness of the implementation of these procedures could not be ascertained.

5.3.3 Procurement Document Control (Programmatic Element 4)

QAP 4-1 was used to develop the OCRWM audit checklists. The auditors reviewed two purchase orders and the preliminary RFP discussed in Section 5.3.2 to evaluate compliance with QAP 4-1. The checklist was extensive, and the auditors were well prepared. However, implementation was limited to these examples, so the effectiveness could not be fully determined.

5.3.4 Instructions, Procedures, and Drawings (Programmatic Element 5)

The audit of Programmatic Element 5 entailed an examination of record packages for QAPs 2-3, 16-1, and 17-1 to determine whether they were prepared in accordance with QAP 5-1. Deficiencies were identified with the adequacy of QAP 5-1, and QAP 5-1 was referenced in the preliminary CAR for not adequately addressing qualitative and quantitative criteria for determining the acceptability of prescribed activities.

The auditors also identified seven adverse conditions with regard to the implementation of QAP 5-1. They were identified as follows on one preliminary CAR:

- No objective evidence that QAP's are revised when upper tier documents are revised
- Inadequate review instruction and criteria
- Change bars missing
- An expedited Procedure Change Notice (PCN) was written to replace an expired expedited PCN
- Nothing to indicate if a revision review constitutes the complete procedure review required every two years
- Responsibilities identified in the "Responsibilities" section are not addressed in the "Procedure" sections of several QAPs
- No procedure to control the preparation and maintenance of the M&O QAPD.

The audit of M&O Headquarters compliance with Programmatic Element 5 was effective. The NRC staff agrees with the audit team's preliminary assessment that Programmatic Element 5 is marginally effective.

5.3.5 Control of Purchased Material, Equipment, and Services (Programmatic Element 7)

The procurement plan for the transportation cask was the only objective evidence available to review in evaluating implementation of QAP 7-1. Of the 60 checklist items for this procedure, only 3 could be answered; the balance were not yet applicable. While the audit of the procedural requirements was effective, implementation effectiveness was indeterminate.

5.3.6 Corrective Action (Programmatic Element 16)

Corrective actions, stop work actions, and trending were audited under Programmatic Element 16. While auditing to QAP 16-1, the auditors found that the CAR status log was not up to date and had several errors. The CAR status log was updated and corrected during the audit. Shortly before this audit, M&O reviewed 35 CARs issued by the M&O in fiscal year 1992 (FY-92). As a result of this review, the M&O had issued a new CAR (93-QL-C-004) that listed six adverse conditions. The majority of the FY-92 CARs were reported to have one or more discrepancies. The staff recommended that this new CAR be independently tracked and followed to completion by OCRWM, and the ATL agreed that this would be done. In addition, the audit team issued a preliminary CAR after it concluded that M&O audit and surveillance reports show items of concern (that should be tracked) not reported as CARs and, thus, not required to be tracked. Finally, QAP 16-1 was referenced in the preliminary CAR for not adequately addressing qualitative and quantitative criteria for determining the acceptability of prescribed activities.

Regarding QAP 16-2, the M&O has neither issued nor received a stop work order.

The auditors auditing QAP 2-4 found that the first QA trend report had been signed by the M&O QA Manager but had not been issued. The QA trend report was issued during the audit. The auditors commended the M&O for the quality and thoroughness of the trend report. QAP 2-4 was also referenced in the preliminary CAR for not adequately addressing qualitative and quantitative criteria for determining the acceptability of prescribed activities.

The OCRWM audit of M&O Headquarters compliance with the procedural requirements of the QAPs discussed above was effective. The NRC staff agrees with the audit team's preliminary assessment that M&O Headquarters implementation of QA Programmatic Element 16 is ineffective.

5.3.7 QA Records (Programmatic Element 17)

Implementation of QAP 17-1 was evaluated by interviewing the staff of the Central Records Facility (CRF) and examining a sample of closed record packages. Based on interviews with the CRF staff, it is evident that there was some confusion within the M&O technical staff with regard to the difference between "records" and "records package." This confusion has led to improperly prepared record transmittals and untimely submittal of documents to the CRF. For instance, the auditors found that one completed record package contained reports of three different audits. The intent of the procedure is for each record package to contain documents on only one activity. In another instance, the auditors found that one surveillance report (93-SRS-01) was located in two different packages. In addition to these implementation problems, the auditors determined that QAP 17-1 also did not adequately address qualitative and quantitative acceptance criteria for determining the acceptance of prescribed activities.

The requirements of QAP 17-2 were evaluated by examining the records storage facilities and QA record packages submitted to the CRF. The auditors did not identify any deficiencies with this portion of the audit.

Overall, the audit of Programmatic Element 17 was thorough and effective. The NRC staff agrees with the audit team's preliminary finding that implementation of Programmatic Element 17 was marginally effective.

5.3.8 Audits (Programmatic Element 18)

M&O Headquarters had completed a number of internal audits and surveillances during FY-92. No external audits have been deemed necessary to date. The OCRWM auditors evaluated the activities associated with the M&O Headquarters audits to see whether they were performed in accordance with QAP 18-1 and QAP 18-2. QAP 18-2 requires that the effectiveness of the overall QA program be periodically assessed; but, as stated in a preliminary CAR, no evidence was found to show that this had ever been done. Another preliminary CAR was generated when the auditors found that the audit reports they reviewed did not consistently include a statement of effectiveness and a summary of the personnel interviewed and documents reviewed as required by the M&O QAPD. These QAPD requirements were not adequately addressed in QAP 18-2. While auditing QAP 18-2, the auditors noted that the QAP did not adequately specify a distribution for audit reports. Since prior M&O audit reports had been acceptably distributed, the OCRWM audit report will indicate this QAP 18-2 shortcoming as an example of the need for M&O to upgrade its procedures. QAP 18-2 was also referenced in the preliminary CAR for not adequately addressing qualitative and quantitative criteria for determining the acceptability of prescribed activities.

While auditing QAP 2-5 to assess the M&O surveillance program, the auditors noted that the QAP did not adequately specify a distribution for surveillance reports. As with the M&O audit reports, prior M&O surveillance reports had also been acceptably distributed. Additionally, QAP 2-5 did not adequately specify a timeliness requirement for issuing surveillance reports, and the report of a November 1992 surveillance was unissued at the time of the OCRWM audit. The OCRWM audit report will indicate these QAP 2-5 shortcomings as additional examples of the need for M&O to upgrade its procedures.

The audit of Programmatic Element 18 was effective. The NRC staff agrees with the audit team's preliminary finding that implementation of Programmatic Element 18 is ineffective.

5.3.9 Computer Software (Programmatic Element 19)

Based on the checklists for QAPs 19-1 and 19-2, the auditors reviewed documents and software related to the six database programs that the M&O had baselined and released for quality-affecting work. These programs had been approved and accepted by OCRWM. The M&O had developed, "verified," and "validated" the installation packages and users' manuals and issued the software qualification letters for these programs. The M&O now has the responsibility for the configuration management of these programs. QAPs 19-1 and 19-2 were referenced in the preliminary CAR for not adequately addressing qualitative and quantitative criteria for determining the acceptability of prescribed activities. In addition, a preliminary CAR was issued because:

- The quality-affecting software products were not identified in accordance with QAP 19-2. (They were identified in accordance with other QAPs.)

- The programs did not indicate "Quality Affecting Work" on the computer screen when they were run.

- The software identification had not been fed-back to the M&O's overall configuration management function. (This was corrected during the audit.)

The audit of M&O Headquarters software control was effective. Because the items noted above were the only software QA deficiencies noted by the auditors, the NRC staff agrees with the audit team's preliminary finding that M&O Headquarters implementation of Programmatic Element 19 is effective.

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 M&O QA program. Audit team personnel were persistent in their interviews, challenged responses when necessary, and performed an acceptable audit. Daily audit team caucuses were held between auditors and observers, and daily audit status meetings were held between M&O Headquarters management and the ATL (with an NRC observer present) to discuss the preliminary findings. After the first status meeting, the auditors who identified concerns were not included in these meetings, and the ATL adequately presented the audit status and preliminary findings to M&O Headquarters management personnel who attended these meetings.

5.5 Qualification Of Auditors

The qualifications of the OCRWM ATL and auditors had been previously reviewed by the NRC staff and found to be acceptable.

5.6 Audit Team Preparation

The auditors were prepared in the areas they were assigned to audit and were knowledgeable of the M&O Headquarters 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 did not have prior responsibility for performing the activities they audited. Members of the team had sufficient independence to carry out their assigned functions in a correct manner without adverse pressure or influence.

5.8 Review of Previous Audit Findings

OCRWM did not have any open CARs from previous audits relating to this audit.

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 M&O Headquarters QA program implementation.

5.9.2 Good Practices

- M&O upper management demonstrated its interest in the M&O QA program by the M&O General Manager and the two Assistant General Managers' attendance at the daily audit status meetings (in addition to the M&O QA manager).

- A representative from the Yucca Mountain Site Characterization Project Office (YMPO) observed this audit as part of the preparation for a YMPO audit of the M&O in Las Vegas in early March, 1993. The NRC believes this was worthwhile and that DOE should encourage this type of interaction to enhance consistency in its auditing process.

5.9.4 Summary

The QAPs appear to address the QA program elements applicable to the M&O activities, and the M&O staff appears to be generally familiar with the QA program requirements. However, some M&O staff did not appear to be highly knowledgeable of specific procedural requirements or when procedures should be implemented. This is probably due to a number of factors, among them the newness of the M&O organization and the QA program, the recent issue of procedures and lack of experience with them, and the limited amount of quality-affecting activities that have been conducted to date. Both the M&O staff and the M&O procedures appear to need more maturing for the M&O to have a completely effective QA program.

The NRC staff agrees with the preliminary audit team findings that the M&O Headquarters QA procedures need to be upgraded and that implementation of the QA program is marginally effective even though Corrective Action and Audits were preliminarily assessed by the audit team to be ineffective.

5.10 Summary of OCRWM Audit Findings

As a result of this audit, the audit team developed nine preliminary CARs against the M&O Headquarters QA program. Several other preliminary CARs were acceptably resolved by the M&O Headquarters organization during the audit. In addition, the audit team developed nine recommendations to improve the M&O QA program. The audit team concluded that the M&O Headquarters QA procedures

need to be upgraded and that implementation of the QA program is marginally effective.

A summary of the nine preliminary CARs which were not closed during the audit is presented below.

Programmatic Element	Summary of Preliminary CARs
2	Approximately 20% of the personnel records reviewed did not contain acceptable evidence of the verification of education and experience.
2	Training and qualification records of auditing personnel not in accordance with requirements.
2	Six personnel were found to have performed quality-affecting work without being trained to the latest revision of the applicable procedure.
5	Ten QAPs did not adequately address qualitative and quantitative acceptance criteria. (See Sections 5.3.2, 5.3.4, 5.3.6, 5.3.7, 5.3.8, and 5.3.9.)
5	Six adverse conditions noted which indicate that QAP 5-1 had not been adequately implemented during QAP development and revision. (See Section 5.3.4.)
16	Audit and surveillance reports show item of concern (that should be tracked) not reported as CARs and, thus, not required to be tracked. (See Section 5.3.6.)
18	Periodic summaries of the effectiveness of QA program elements not developed. (See Section 5.3.8.)
18	Audit reports did not consistently include a statement of effectiveness and a summary of personnel interviewed and documents reviewed. (See Section 5.3.8.)
19	Quality-affecting software not identified in accordance with QAP 19-2, did not indicate "Quality Affecting Work" on the computer screen, and lacked software configuration feedback to the overall configuration management function. (See Section 5.3.9.)