OBSERVATION OF DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE AUDIT HQ-ARP-95-03 OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM AND OPERATING CONTRACTOR (M&O) CONTROL OF THE DEVELOPMENT/REVISION PROCESS FOR TECHNICAL DOCUMENTS

Prepared for

Nuclear Regulatory Commission
Contract NRC-02-93-005

Prepared by

Bruce Mabrito

Center for Nuclear Waste Regulatory Analyses
San Antonio, Texas

January 1995

This report was prepared to document work performed by the Center for Nuclear Waste Regulatory Analyses (CNWRA) for the Nuclear Regulatory Commission (NRC) under contract No. NRC-02-93-005. The activities reported here were performed on behalf of the NRC Office of Nuclear Material Safety and Safeguards (NMSS), Division of Waste Management (DWM). The report is an independent product of the CNWRA and does not necessarily reflect the views or regulatory position of the NRC.

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PDR WASTE
WM-11 PDR

Mr. Ronald A. Milner, Acting Director
Office of Program Management and Integration
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, D.C. 20585

Dear Mr. Milner:

SUBJECT: OBSERVATION AUDIT OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM (CRWMS) MANAGEMENT AND OPERATING CONTRACTOR (M&O) CONTROL OF DEVELOPMENT/REVISION PROCESS

I am transmitting the Nuclear Regulatory Commission (NRC) Observation Audit Report 95-02 of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) audit of the Civilian Radioactive Waste Management System and Operating Contractor (M&O). The audit, HQ-ARP-95-03, was conducted from December 5-8, 1994, at the M&O offices in Vienna, Virginia. The limited-scope, performance-based audit evaluated the effectiveness of the M&O activities performed under the quality assurance (QA) system associated with the control of the development and revision of M&O technical requirements documents. No other organizations participated as observers of this audit.

The NRC staff observed the audit to evaluate the DOE audit process and to gain confidence that the M&O organization is properly implementing its controls for the development and revision of technical requirements documents. The NRC staff based its evaluation on direct observations of the audit team members; discussions with the audit team and M&O personnel; and reviews of the audit plan, the audit checklists, and pertinent M&O documents.

The NRC staff has determined that Audit HQ-ARP-95-03 was useful and effective. The audit was well organized and conducted in a thorough and professional manner.

The NRC staff agrees with the preliminary audit team finding that the overall implementation of the M&O control processes for developing and revising the technical requirements documents are effective, however, the M&O management should closely monitor implementation. The audit team considered the process for developing and controlling the technical requirements documents to be complicated, and urged M&O management to maintain oversight of its implementation. One preliminary Corrective Action Request (CAR) was discussed by the audit team at the post-audit meeting, and one potential CAR was corrected during the audit by the M&O organization. Six recommendations were also made.

The NRC staff expects to participate in monitoring the corrective actions of the M&O and may perform its own independent audits at a later date to assess the M&O implementation of its QA program.

A written response to this letter or the enclosed report is not required. If you have any questions, please call Jack Spraul of my staff at (301) 415-6715.

Sincerely,

Joseph J. Holonich, Chief
High-Level Waste & Uranium Recovery
Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc: R. Loux, State of Nevada
T. J. Hickey, Nevada Legislative Committee
J. Meder, Nevada Legislative Counsel Bureau
R. Nelson, YMSCO
M. Murphy, Nye County, NV
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
D. Weigel, GAO
P. Niedzielski-Eichner, Nye County, NV
B. Mettam, Inyo County, CA
V. Poe, Mineral County, NV
F. Mariani, White Pine County, NV
R. Williams, Lander County, NV
L. Fiorenzi, Eureka County, NV
J. Hoffman, Esmeralda County, NV
C. Schank, Churchill County, NV
L. Bradshaw, Nye County, NV
W. Barnard, NWTRB

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NAME	JGSpraul/jk		RLJohnson		JJHolonich					
DATE	01/12/95		01/ /95		01/ /95					

U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT 95-02

OF THE

U.S. DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

AUDIT HQ-ARP-95-03

OF THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM

MANAGEMENT AND OPERATING CONTRACTOR

(TRW Environmental Safety Systems, Inc.)

1/ /95
Bruce Mabrito (per telephone)
Center for Nuclear Waste
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John T. Buckley
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Robert L. Johnson, Section Leader
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1.0 INTRODUCTION

During December 5-8, 1994, members of the U. S. Nuclear Regulatory Commission (NRC) Division of Waste Management Quality Assurance staff observed the U. S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) audit of the Civilian Radioactive Waste Management System (CRWMS), Management and Operating (M&O) Contractor QA Program. The audit, HQ-95-ARP-03, was conducted at the M&O offices in Vienna, Virginia. The focus of the audit was a performance-based evaluation of the effectiveness of the M&O QA program with regard to the control of the development and the revision of technical requirements documents. The technical requirements documents identify the requirements necessary to develop the design bases for systems of the High Level Waste repository program. There were no other interested organizations observing in this audit.

This report addresses the effectiveness of the audit and the adequacy of QA controls in the audited area of the CRWMS M&O QA program.

2.0 OBJECTIVES

The objectives of the audit team were to determine whether the CRWMS M&O QA program for the development and the revision of the technical requirements documents and its implementation meet the applicable requirements and commitments of the OCRWM "Quality Assurance Requirements and Description" document (QARD, DOE/RW-0333P) and associated implementing procedures.

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

3.0 MANAGEMENT SUMMARY AND CONCLUSIONS

The NRC staff has determined that audit HQ-ARP-95-03 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 the overall implementation of the M&O QA program relative to technical documents is effective. The audit team also correctly cautioned that the M&O process controls appear to be complicated, and that "If M&O management does not maintain oversight of user implementation, the process could possibly break down." One preliminary Corrective Action Request (CAR) was discussed by the audit team at the post-audit meeting, and one deficiency was acceptably resolved by the M&O organization during the audit. Six recommendations were also provided to the M&O.

The M&O QA program should continue to be monitored 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 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

Hugh Lentz	Audit Team Leader (ATL)	Headquarters Quality Assurance Division (HQAD)/Quality Assurance Technical Support Services (QATSS)
Fred Bearham	Auditor	HQAD/QATSS
Charles Betts	Auditor	HQAD/QATSS
Jim George	Auditor	HQAD/QATSS
Bob Holliday	Auditor	HQAD/QATSS
Dennis Threatt	Auditor	HQAD/QATSS
Gary Wood	Auditor	HQAD/QATSS
Arul Mozhi	Tech Specialist	Roy F. Weston, Inc.
James Doman	Tech Specialist	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, "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 HQ-ARP-95-03 was a performance-based audit, which evaluated the effectiveness of selected processes associated with M&O activities performed under several QA program elements involved with the development and revision of technical requirements documents. Although not specified in the audit plan, the QA program elements involved included 3.0, Design Control, 5.0, Instructions, Procedures and Drawings, 6.0, Document Control, and 17.0, QA Records.

5.1.2 Technical Areas

The audit included evaluations by technical specialists, who reviewed input to the requirements documents for the transportation cask and the multipurpose canister (MPC).

5.1.3 Observations

The NRC staff observed the majority of the audit team evaluations.

5.2 Timing of the Audit

The NRC staff believes the timing of this audit was appropriate for HQAD to evaluate the pertinent technical requirement documents development and revision controls established by the M&O and for the NRC staff to evaluate the OCRWM audit process because of the relatively early stage of

development and the quality problems that other divisions of the M&O have experienced.

5.3 Examination of Process Steps

5.3.1 General Observations

In conducting this audit in a performance-based manner, the CRWMS M&O technical requirements document development and revision process was characterized into seven critical process steps by the audit team. These process steps included:

1) Identify Need/Scope for Technical Requirements
2) Define/Plan Process for Developing Technical Requirements
3) Develop Technical Requirements Document or Revision
4) Perform Technical Document Review and Comment Resolution
5) Approve, Release, and Issue Technical Document
6) Implement Technical Requirements (Including Flowdown Documents)
7) Perform Baseline Change Control

Meeting each of these steps should result in adequate M&O technical requirements documents.

The audit team was divided into three sub-teams of two auditors each, with each sub-team assigned to cover specific process steps. The two technical specialists assisted each sub-team when the subject matter required their expertise.

Prior to the audit, the ATL met with M&O representatives to clearly identify the process steps in a flowchart, along with the objective of each step, and the measurement criteria that the audit team would apply. The measurement criteria for each process step was issued in a Performance Based Audit Flowchart. This flowchart was beneficial in clarifying the accepted minimum requirements to both the audit team and the auditees.

During the course of the audit, all three sub-teams were observed at one time or another by the NRC representatives, as were both technical specialists. Good interviewing techniques were utilized and the audit sub-teams were effective.

Throughout the audit, each auditor worked his way through the appropriate checklists interviewing the affected M&O Managers or key personnel. Utilization of the technical specialists in specific areas was determined the day prior to their use. Potential CARs or concerns were brought to the audit team caucus each afternoon and logged on the status board. All auditors went beyond their checklist questions when it was warranted. "Objective Evidence Reviewed" forms were completed by each auditor and, where necessary, a matrix chart was drawn up to provide clarity and organization to the checking process.

The auditors followed the prepared and approved checklists, deviating when necessary and appropriate to assure complete understanding of the process. Interviews were conducted in a professional manner, with questioning continuing until the auditor felt confident that the personnel were familiar with and understood the process. In addition, CRWMS M&O departmental interfaces were also evaluated. A recommendation was made by the audit team, related to design interface control, that the Quality Assurance Procedures be reviewed to assure all interface requirements have been adequately identified.

5.3.2 Specific Observations

The audit consisted of the review of design analyses, system and subsystem requirements, design input data transmittals, data requests, input logs, assumption rationale sheets, records packages, personnel records, configuration management plans, document control action requests, controlled document instructions, distribution reports, memos and correspondence, and other appropriate documents, as well as interviews with various CRWMS M&O personnel involved with all phases of technical requirement documents related to the transportation cask and the multipurpose canister (MPC). The M&O staff explained the inputs required to produce a design procurement specification: in sequence, (i) the Work Authorization Document (WAD), (ii) the Technical Document Preparation Plan (TDPP), (iii) the CRWMS Requirements (CRD), (iv) the Systems Requirements Documents (SRD) for Waste Acceptance, Transportation, Monitored Retrievable Storage (MRS) and the Mined Geologic Disposal System (MGDS), (v) the Design Requirements Document (DRD), and (vi) the Design Procurement Specification. Each of these documents feeds to its successor.

One audit sub-team, composed of an auditor and both technical specialists, reviewed the planning and crossflow of requirements as they related to design inputs. During interviews with the Waste Acceptance Storage & Transportation Design Manager and an assistance engineer, Design Input Data Transmittals were reviewed and found to be thorough and complete. The Multipurpose Canister (MPC) Subsystem Design Requirements Document was in an early stage of development, Revision 00, but the auditor and technical specialist were able to obtain satisfactory answers to checklist questions. No findings were identified in this area and the audit was effective.

Another sub-team was assigned the responsibility of evaluating the technical document review and comment resolution process. The auditor began the investigation by discussing the Design Requirements Document (DRD) review process with the M&O staff present. Through the interviews, it was determined that the Design Procurement Specification (DPS) is produced and reviewed independently from the Design Requirements Document (DRD) review. Further, it was noted that the review criteria used by the reviewers of the DRD was located in the TDPP. The auditors then examined the review package for the DRD and DPS associated with the MPC. No findings were identified in this area and the audit was effective.

The same sub-team also performed detailed and thorough checks of the document distribution system and the DRD review comments utilizing a matrix chart. The sample size was sufficiently large and during the audit it was noted that the Document Control organization had distributed a controlled MGDS Annotated Outline to seven individuals in error, instead of the requested MGDS Requirements Document. The correct document was distributed during the audit, however a CAR was written because individuals needing the Controlled Requirements Document did not officially have access to it in a timely manner. The audit of this process step was effective.

One deficiency that was considered isolated by the audit team in nature was corrected by CRWMS M&O personnel during the audit. It covered 5 of 11 analyses which referenced a preliminary draft Systems Requirements Issue Resolution Plan. Charts in the draft document were necessary for traceability and the audit team verified that references to the preliminary draft were deleted from the analyses.

The M&O procedures governing development/revision of technical documents appeared to be adequate; however, the audit team considered the process to be complicated and urged M&O management oversight to ensure implementation. The M&O QA personnel had a good understanding of requirements and assisted as informative escorts during the audit. Individual M&O engineering staff personnel appear to perform their function well and promptly responded to the auditor/technical specialist questions acceptably.

5.4 Qualification of Audit Personnel

The qualification of the ATL and auditors were previously found to be acceptable, each having met the requirements of QAAP 18.1, "Qualification of Audit Personnel." One of the technical specialists was relatively new to the program and his resume was reviewed by the NRC Observer and determined to be acceptable.

5.5 Audit Team Independence

The audit team was composed of QATSS personnel who support HQAD and were familiar with the CRWMS procedures on the development/revision process for technical requirement document control. However, the HQAD/QATSS 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 HQAD audit team findings that the overall implementation of the CRWMS M&O technical requirements documents development and revision process is being effectively implemented for the areas identified in the audit scope. This determination is based on the audit checklist results and responses provided to the audit team during the course of the audit.

The NRC staff observed that each of the auditors reviewed an appropriate amount of documentation and interviewed sufficient CRWMS M&O personnel to make valid judgments on the adequacy of each critical process step. The audit team was thorough and carefully reviewed a wide spectrum of objective evidence before drawing their conclusions.

The audit findings were minor in nature and the M&O management showed interest and responsiveness to items identified by the audit team regarding the technical requirement documents.

5.6.1 Good Practices

The audit team was thoroughly prepared and understood the programmatic and technical aspects of performance-based auditing. The auditors were thorough, persistent, and professional in their approach. The ATL was effective in the performance of his function. When there was additional work and details to be covered by one of the audit sub-teams, he was prompt to reassign another sub-team to the area that needed to be covered. His use of a comprehensive status board in the audit team meeting room included the process steps, with potential CARs, items corrected during the audit, recommendations, percent complete, and concerns led to excellent caucus discussions and effective tracking of concerns throughout the audit process.

The ATL scoping visit to pre-establish clear measurement criteria for each of the process steps in this performance based audit was instrumental to the success of the audit. This was an important and crucial planning step in the audit process.

5.6.2 Weakness

There were no weaknesses in the audit process identified.

5.7 Audit Team Findings

The audit team determined that the M&O process controls are being effectively implemented for the areas identified in the scope of the audit. The audit team emphasized during their post-audit summary

that the process for developing and controlling the technical requirements documents is complicated and that without continual management oversight, the implementation of the process may not be effective.

The one preliminary CAR issued at the close of the audit regarded the inadequate distribution of technical documents. Specifically, the Document Control organization distributed the wrong controlled document. The distribution error was identified during the audit. The M&O distributed the correct document during the audit as remedial action.

A deficiency, considered isolated by the audit team and which dealt with analyses, was corrected during the audit.

Six recommendations for improvements to the process control system were also presented to CRWMS M&O management for consideration, and are listed below.

1) The audit team recommended that the difference in MPC design requirements (the document had existing To Be Verified items) and the Waste Package Conceptual requirements be resolved using the QAP-3-9 Design Analyses procedure.

2) The audit team recommended that the M&O allocate, where possible, technical requirements to specific flowdown documents so that all requirements are assured to be included (the SRD flowdown to the DRDs).

3) A positive process for verifying that document preparers complete their self study assignments (per the TDPP) should be established. A similar recommendation was made during the Audit HQ-94-02 in June, 1994.

4) The audit team recommended that a method for tracking commitments made during the comment resolution process be developed.

5) The System Engineering Management Plan in combination with similar QA processes was recommended to be revised to improve control of technical requirement documents.

6) The audit team recommended that the QAPs related to design interface controls be reviewed to assure all interface requirements have been identified.