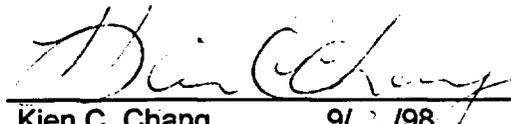
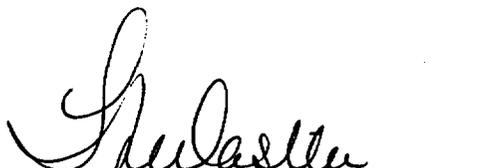


U.S. NUCLEAR REGULATORY COMMISSION  
OBSERVATION AUDIT REPORT OA-98-02  
OF THE OFFICE OF QUALITY ASSURANCE  
AUDIT M&O-ARP-98-15  
OF THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT  
SYSTEM MANAGEMENT AND OPERATING CONTRACTOR

  
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## **1.0 INTRODUCTION**

Members of the U.S. Nuclear Regulatory Commission (NRC) 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 (OQA) performance-based audit of the Civilian Radioactive Waste Management System Management and Operating Contractor (M&O). The audit, M&O-ARP-98-15, was conducted on August 17 through August 20, 1998, for work being performed at the M&O offices in Las Vegas, NV. A representative from the DOE/OCRWM participated as an observer at this audit.

The objective of this performance-based audit by OQA was to evaluate the implementation of the M&O QA program requirements associated with the System Description Document (SDD) process.

The NRC staff's objective was to gain confidence that OQA and the M&O are properly implementing the requirements of their QA programs in accordance with the OCRWM Quality Assurance Requirements and Description (QARD: DOE/RW-0333P) and Title 10 of the Code of Federal Regulations (10CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

This report addresses the effectiveness of the OQA audit and the adequacy of implementation of QA controls in the audited areas of the M&O QA program.

## **2.0 MANAGEMENT SUMMARY**

The NRC staff has determined that OQA Audit ARP-98-15 was useful and effective. The audit was organized and conducted in a professional manner. Audit team members were independent of the activities they audited. The audit team was well qualified in the QA and technical disciplines, and its assignments and checklist items were adequately described in the audit plan.

The audit team found that the M&O QA program had been satisfactorily implemented. Deficiencies noted in training were added to an existing Discrepancy Report by the audit team in addition to providing six recommendations. The NRC staff agrees with these conclusions and determined that the M&O QA program implementation for the SDD effort was effective.

## **3.0 AUDIT PARTICIPANTS**

### **3.1 NRC**

William L. Belke  
Kien C. Chang

QA Observer  
QA Observer

Enclosure

### **3.2 DOE/YMQAD**

Lawrence W. McGrath	Audit Team Leader, OQA/Quality (ATL) Assurance and Technical Support Services(QATSS)/MACTECH
Patrick V. Auér	Auditor, OQA/QATSS/MACTECH
Raymond A. Mele	Technical Management and Technical Specialist Support/Booze Allen Hamilton

### **3.3 OCRWM Headquarters**

Mark Senderling	Observer
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## **4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION**

The OQA audit of the M&O was conducted in accordance with OCRWM Quality Assurance Procedure (QAP) 18.2, "Internal Audit Program" and QAP 16.1Q., "Performance/Deficiency Reporting." The NRC staff observation of this audit was based on the NRC procedure, "Conduct of Observation Audits," issued October 6, 1989.

### **4.1 Scope of the Audit**

The performance-based audit was to evaluate the critical process steps required to produce SDDs that meet management objectives and expectations. The following documents were considered in the development of the checklist questions for this audit:

- o QARD: DOE/RW-0333P
- o CRWMS M&O QA Program Procedures
- o Technical Procedures
- o Surface License Application Design (LAD) Work Breakdown Structure (WBS) 1.2.4.6
- o Subsurface LAD WBS 1.2.4.7, "Facilities System Design Descriptions"

### **4.2 Conduct of Audit**

The audit was performed in a professional manner and the audit team was well prepared and demonstrated a sound knowledge of the M&O and DOE QA programs. Audit team personnel were persistent in their interviews, challenged responses when appropriate, and performed an acceptable audit. The audit plan identified this as a performance-based audit in which the evaluation process effectiveness and product acceptability would be based on: 1) satisfactory completion of the critical process steps; 2) acceptable results and quality of the end product; 3) documentation that substantiates quality of products; 4) performance of trained and qualified personnel; and 5) implementation of applicable QA program elements.

The DOE audit team and NRC observers caucused at the end of each day. Also, meetings of the audit team and M&O management (with an NRC observer present) were held each morning to discuss the then-current audit status and any preliminary findings.

#### **4.3 Timing of the Audit**

The NRC staff believes the general timing of the audit was appropriate for OQA to evaluate the pertinent M&O activities associated with the ongoing SDD process and implementation of the respective QA program. The OQA believed it would be prudent to perform this audit early enough in the process to determine that this activity did not have any serious deficiencies during its development.

#### **4.4 Examination of QA Programmatic Elements**

The NRC staff observed that each of the auditors reviewed related documentation and interviewed a representative sample of M&O personnel to determine their understanding of implementing procedures. Checklists were used effectively and issues were pursued beyond the checklists when appropriate. NRC observers were provided ample opportunities to provide comments and ask questions.

Training, education, and experience records were reviewed for personnel conducting SDD activities to assure such personnel were in compliance with their individual position descriptions. Objective evidence was provided and reviewed; and it was determined that all personnel were in compliance with the exception of one individual that did not have objective evidence for verification of experience.

The SDD process was initiated in mid-1997 and identifies the specific design criteria and shows how these criteria are satisfied by the design. Enclosure 1 provides a schematic of the SDD process. In the SDD, design criteria are categorized under system performance, safety (nuclear and non-nuclear), environmental, system interfacing, operational, codes and standards.

Presently, 31 SDDs have been developed for the waste package, surface, and subsurface systems. Through this process, criteria are established with the intent to incorporate these criteria into the design as early as possible. This will facilitate improved integration between the project requirements and design activities/products. Each design criteria identifies the appropriate 10 CFR Part 60 and DOE Mined Geologic Disposal Requirement.

The audit team evaluated the critical process for SDD development including requirements flowdown, personnel training, design input selection, design analysis, review and checking process, comment resolution, revisions and changes, and associated records.

#### **4.5 Examination of Technical Activities**

The audit's emphasis was on the effectiveness of QA program controls in the M&O's development of SDD's. Technical activities were discussed and audited from the standpoint of how effective and harmonized the technical activities are documented in the SDD to allow the

SDD to facilitate design and management of technical information needed for all phases of the repository project.

Technical activities on the engineered barrier system (EBS) operations including waste package design operations were examined and discussed by auditing team members. The team members examined procedures of how design requirements flow down for the design process, and the consistency of funding level and management's direction on work priority. The M&O's fiscal year 1998 technical activities have been concentrated on the preparation analyses and documentation to support the Viability Assessment (VA). Specific technical topics discussed include EBS and waste package features and design alternatives being considered and analyzed for VA. These activities will continue for the License Application commencing in September 1998.

#### **4.6 Audit Team Qualification and Independence**

The qualifications of the ATL and audit team members were found to be acceptable in that they each met the requirements of QAP 18.1, "Auditor Qualification."

The audit team members did not have prior responsibility for performing the activities they audited. The audit team members were prepared in the areas they were assigned to audit and were knowledgeable in applicable procedures. The checklist was adequately formulated and covered the subject matter well.

#### **4.7 NRC Staff Findings**

For this performance-based audit, the QA programmatic and technical portions of the audit were conducted in a professional manner and the audit team adequately evaluated activities and objective evidence. The ATL was effective in his daily presentations to the audited and in providing guidance to the audit team.

The checklist questions provided a sound basis from which to conduct this performance-based audit and reach an accurate conclusion on the three-dimensional modeling process. Both the auditors and audited were knowledgeable in their respective disciplines. The various contributors to the SDD development demonstrate that there is adequate coordination for the preparation of SDD's.

In the NRC On-site Representative Report dated December 22, 1995, and in several NRC Audit Observation Audit reports, it was noted that the previous design document hierarchy was a multi-tiered system, complex, and difficult to use, especially for flowdown of requirements. With the revised improved system for the SDD development process flow (See Enclosure 1), it represents a significant improvement as opposed to the prior document hierarchy. Flowdown of requirements now appears to be more readily visible and traceable. In addition, the document hierarchy is less complex and easier to comprehend. The NRC audit observers indicated that this improved document hierarchy will assist in its review of potential licensing documentation should DOE become authorized to submit an application for licensing.

#### **4.8 Summary of YMQAD Findings**

The application of QA controls was determined to be effective for the SDD process. The NRC staff agrees with this conclusion.

At the post audit meeting, the audit team presented six preliminary recommendations summarized below. A recommendation does not require a response unless requested by the auditor.

- 1) The management technical process is not clearly defined for requirements flowdown and interface control. The audit team recommended that the M&O define, control, integrate, and approve these processes in a management review plan.
- 2) There does not appear to be a comprehensive method to verify all the 10 CFR Part 60 requirements. The M&O should develop a matrix equivalent to that used for the VA.
- 3) Recommendations that a structured method be developed to verify all the Controlled Design Assumptions have been addressed.
- 4) It is unclear whether certain documents were used as input to the Criteria basis Statements. The audit team recommended that these documents be evaluated to determine whether these documents were used as inputs.
- 5) There was no method to control duplication of the items "To be Verified/To be Determined (TBX)." It was recommended that a procedure be developed to control these TBX's.
- 6) There were several procedures for the comment and resolution process. It was recommended that an effort be initiated to consolidate these procedures.