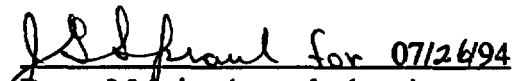
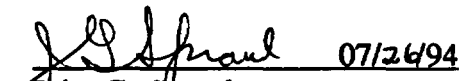




**U.S. NUCLEAR REGULATORY COMMISSION**  
**OBSERVATION AUDIT REPORT 94-08**  
**OF THE U.S. DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT**  
**AUDIT HQ-94-03**  
**OF THE**  
**OFFICE OF WASTE MANAGEMENT HIGH-LEVEL WASTE DIVISION**

  
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ENCLOSURE

## **1.0 INTRODUCTION**

During June 27-July 1, 1994, members of the Nuclear Regulatory Commission Division of Waste Management quality assurance (QA) staff observed a U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance Headquarters audit of the QA program of the Office of Waste Management High-Level Waste Division (EM-323). The audit, HQ-94-03, was conducted at the EM-323 offices in Germantown, Maryland. The audit evaluated the adequacy and effectiveness of the EM-323 QA program in all applicable QA programmatic areas. The State of Nevada did not participate in this audit.

This report addresses the effectiveness of the Headquarters audit and the adequacy of implementation of QA controls in the audited areas of the EM-323 QA program.

## **2.0 OBJECTIVES**

The objectives of the audit by the Headquarters team were to determine whether the EM-323 QA program and its implementation meet the applicable requirements and commitments of the OCRWM "Quality Assurance Requirements and Description" document (QARD - DOE/RW-0333P) and the EM-323 Standard Practice Procedures (SPPs) which comprise the EM-323 QA program.

The NRC staff's objective was to gain confidence that Headquarters and EM-323 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 Headquarters Audit HQ-94-03 was useful and effective. The audit was 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 Headquarters audit team finding that the overall implementation of the EM-323 QA program is indeterminate, awaiting resolution of OCRWM comments regarding the acceptability of the EM-323 QA program description to meet the OCRWM QA program requirements. Four preliminary Corrective Action Requests (CARs) were discussed by the Headquarters audit team at the post-audit meeting. Three other potential CARs were acceptably resolved by the EM-323 organization during the audit. Neither the preliminary nor potential CARs identified by the Headquarters audit team are significant in terms of the overall EM-323 QA program.

Headquarters should continue to closely monitor implementation of the EM-323 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 implementation of the EM-323 QA program.

#### 4.0 AUDIT PARTICIPANTS

##### 4.1 NRC

John G. Spraul	Observer	
Bruce Mabrito	Observer	Center for Nuclear Waste Regulatory Analyses

##### 4.2 DOE/Headquarters

Fred Bearham	Audit Team Leader (ATL)	Quality Assurance Technical and Support Services Contractor - CER (QATSS)
Charles Betts	Auditor	QATSS
Pat Cotter	Auditor	QATSS
Conrad Coulombe	Auditor	QATSS
Jim George	Auditor	QATSS
Rob Howard	Auditor	QATSS
Tom Swift	Auditor	QATSS

#### 5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This Headquarters audit of EM-323 was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program" (Revision 6) and QAAP 16.1, "Corrective Action" (Revision 4). 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

This audit was designed to evaluate the adequacy and implementation of the EM-323 QA Program as defined in its SPPs to meet the OCRWM QARD.

### 5.1.1 QA Programmatic Elements

The audit scope included the applicable QA programmatic elements which are listed below:

- 1 Organization
- 2 Quality Assurance Program
- 4 Procurement Document Control
- 5 Instructions, Procedures, and Drawings
- 6 Document Control
- 7 Control of Purchased Items and Services
- 16 Corrective Action
- 17 Quality Assurance Records
- 18 Audits

However, the EM-323 QA program is not arranged in accordance with these programmatic elements (QA criteria of Appendix B to 10 CFR Part 50). Therefore, the audit team audited and assessed the effectiveness of the EM-323 SPPs which are listed in Table 1.

### 5.1.2 Technical Areas

There were no technical areas audited during the course of this audit of the EM-323 QA program.

### 5.1.3 Observations

The NRC staff observed all or part of the Headquarters audit team evaluation of QA Programmatic Elements 1, 2, 4, 5, 6, 7, 17, and 18; only these QA programmatic areas are discussed in Section 5.3 of this report.

## 5.2 Timing of the Audit

The NRC staff believes the general timing of this audit was appropriate for Headquarters to evaluate the pertinent QA activities of EM-323 and for the NRC staff to evaluate the Headquarters audit process and implementation of the EM-323 QA program. The last OCRWM QA audit of the EM-323 organization was held January 11-15, 1993. The reorganization of the EM-323 organization had been in effect for over two months at the time of the audit. The audit was the first Headquarters audit of the EM-323 organization since the reorganization which created EM-323 and since the EM-323 QA program was revised to meet the requirements of the OCRWM QARD. At the time of the audit, the revised EM-323 QA program had not been accepted by OCRWM. The effectivity of the EM-323 QA program could have been assessed better by the Headquarters audit team if OCRWM comments regarding the EM-323 SPPs had been resolved prior to the audit.

### **5.3 Examination of QA Programmatic Elements**

The NRC staff observations regarding the audit and the implementation of each QA programmatic element observed are discussed below.

#### **5.3.1 Organization (QA Programmatic Element 1)**

The two SPPs pertaining to the organization, SPP 1.01, "Index of High-Level Waste Standard Practice Procedures for Quality Assurance," and SPP 1.02, "EM Organization for Waste Acceptance Process Activities of High-Level Waste Form Production," were utilized as the bases for investigation by the sub-team auditing this QA Programmatic Element. All of the questions by the audit sub-team were satisfactorily answered.

The NRC staff agrees with the Headquarters audit team that EM-323 is adequately implementing QA controls for activities under this QA programmatic element.

#### **5.3.2 Quality Assurance Program (QA Programmatic Element 2)**

By examining applicable SPPs, the auditors determined that the SPPs currently constitute the body of EM-323 organization's QA Program.

The NRC staff agrees with the Headquarters audit team that EM-323 is adequately implementing QA controls for activities under this QA programmatic element.

#### **5.3.3 Procurement Document Control and Control of Purchased Items and Services (QA Programmatic Elements 4 and 7)**

The portion of the audit related to these two programmatic elements involved the audit sub-team questioning exactly what procurements the EM-323 organization would be making for the vitrification projects and discussing the responses. It was determined that the EM-323 organization does not make quality-affecting hardware procurements for the two vitrification projects. The audit sub-team therefore ceased work in this area of the EM-323 organization and went on to audit other portions of the QA program.

The audit sub-team made the decision that the programmatic elements are not applicable based upon the type of work being performed by the EM-323 organization. The NRC staff agrees.

#### **5.3.4 Instructions, Procedures, and Drawings (QA Programmatic Element 5)**

At times during the audit process, the audit sub-teams noted inconsistencies and specific areas in some the EM-323 SPPs which were not clear. This prompted the ATL to combine the relatively minor SPP findings into a single Corrective Action Request (CAR) which

identified the need for the EM-323 staff to complete work which was in progress on the SPPs and publish them as soon as practical.

The NRC staff agrees with the Headquarters audit team that the EM-323 organization needs to address this programmatic area with prompt corrective actions for activities under this QA programmatic element.

#### 5.3.5 Document Control (QA Programmatic Element 6)

This QA programmatic element emphasized compliance with SPP 6.05, "Controlled Documents." A list of current holders of controlled SPPs was reviewed and a sample of nine key project individuals were selected out of 44 total to verify appropriate control over the distributed documents. There were no difficulties in locating all the controlled SPPs, which were in four different buildings in the Germantown area. The audit sub-team utilized a matrix to verify compliance with the SPP requirements. The audit sub-team concluded that the control of documents was adequate. The document control process was found to be effective in controlling EM-323 documents and ensuring that the latest revision is available at the point of use when required. All checklist items were answered and only one minor finding was identified in this QA programmatic area. That item, in SPP 6.05, requires that controlled documents no longer needed by individuals be returned to the QA Program Manager (QAPM). Contrary to that requirement, there had been a memorandum from the QAPM stating that SPP manuals no longer required are to be destroyed.

This portion of the audit was effective, and the QA programmatic element appeared to be satisfactorily implemented, except for the one finding noted above.

#### 5.3.6 Quality Assurance Records (QA Programmatic Element 17)

The audit of the QA records took place immediately after the QA records had been moved into a new location. Attention was given to the housing of QA records in one of the dual-storage facilities. No discrepancies were noted by the audit sub-team during the QA records portion of the audit.

This portion of the audit was effective, and this QA programmatic element appeared to be satisfactorily implemented.

#### 5.3.7 Audits (QA Programmatic Element 18)

The audit sub-team requested the West Valley Vitrification Plant and the Savannah River audit reports by EM-323 to begin its review of the EM-323 audit program. These were the only two audits performed by EM-323 since the last OCRWM Headquarters audit of EM-343. The auditors verified that the appropriate notification letters had been issued prior to the audits with the scope, dates of the audits, and audit team members being identified. The EM-323 audit checklists were reviewed for completeness and compliance to SPP 4.02,

**"Administration and Conduct of Quality Assurance Audits."** The audit sub-team reviewed the completed audit reports for scope, audit manager/auditors/observers, identification of individuals contacted, pertinent data from the checklist, summary of documents reviewed, summary of audit results, effectiveness of the QA program elements, description of conditions adverse to quality, deviation reports, corrective action reports, and observations. All items were acceptably addressed in both audit reports reviewed.

Under SPP 4.04, "Administration and Conduct of Surveillances," there were a total of six surveillances conducted in Fiscal Year 1994, and all six surveillance reports were reviewed by the audit sub-team. The reports were checked for full compliance to the requirements of the SPP, and there was no deviation. Again, a detailed matrix list was utilized by the auditors and it was useful in covering all the items. The audit sub-team requested that another sub-team verify the qualifications of the EM-323 surveillance staff to best maximize resources, and that was accomplished with no inconsistencies noted.

This portion of the audit was effective and this QA programmatic element appeared to be satisfactorily implemented.

#### **5.3.8 Conclusions**

This QA programmatic audit was conducted in a professional manner, and the auditors adequately evaluated activities and objective evidence. The audit was effective in determining the adequacy and degree of implementation of the EM-323 QA program. Four preliminary CARs resulted from the audit.

The auditors generally worked in two-person sub-teams. They were well prepared and demonstrated a sound knowledge of the EM-323 QA program. They interviewed appropriate EM-323 and support staff personnel. They examined the SPPs to verify adequacy and to determine whether the SPP requirements were being met. They were thorough in their questioning, using their checklists effectively and pursuing issues beyond the checklists when appropriate by asking additional follow-up questions. The auditors' questions were sufficient to determine the compliance to the SPPs. They solicited comments and questions from the NRC staff in an appropriate manner. The auditors checked for objective evidence demonstrating compliance to each of the SPPs. The auditors were effective in the audit of each QA programmatic element.

The interview method of auditing, combined with the checking of objective evidence, resulted in an acceptable audit. A caucus of the ATL, the auditors, and the NRC observers was held at the close of each work day, resulting in good sub-team interface and integration. A meeting of the ATL and EM-323 management (with an NRC observer present) was held each morning to discuss the audit status and preliminary findings.

The EM-323 personnel appeared well qualified and properly trained and had an overall understanding of QA requirements. The NRC staff believes that there has been an improvement in the acceptance of the EM-323 QA program and that EM-323 management shows an increased sensitivity to the need for it.

#### **5.4 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."

#### **5.5 Audit Team Independence**

The audit team members did not have prior responsibility for performing the activities they audited. The audit team members had sufficient independence to carry out their assigned functions without adverse pressure or influence.

#### **5.6 Closure of NRC Open Items**

There were three items being held open by the NRC staff as the result of previous observation audits of EM-343. These open items were concerned with 1) deviations from requirements found by EM-343 being reported as observations rather than being documented and tracked to completion as requests for corrective action, 2) preparation of a technical document without a covering procedure, and 3) the scope of the QA program. These open items were resolved during this audit on the bases of (correspondingly) 1) a revision to SPP 5.01 that more clearly defined observations and deviations and verification that the revised SPP 5.01 has been implemented effectively; 2) a revision to SPP 4.16 to address the preparation, review, and comment resolution of technical documents and verification of the correction of the work that resulted in the open item; and 3) a list of items and activities important to safety and/or waste isolation has been prepared, reviewed by the EM-323 Technical Review Group, and will be approved by EM-323.

#### **5.7 Summary of NRC Staff Findings**

The NRC staff agrees with the preliminary Headquarters audit team finding that the overall implementation of the EM-323 QA program is indeterminate, awaiting resolution of OCRWM comments regarding the acceptability of the EM-323 QA program description to meet the OCRWM QA program requirements. The staff does not disagree with the effectivity findings of the audit team for the individual SPPs as shown in Table 1. The NRC staff did not observe any deficiencies in the audit process.



### **5.7.1 Weakness**

The ATL could have presented a more deliberate and focused presentation during the post-audit meeting which would have better benefitted the EM-323 members in attendance.

### **5.7.2 Good Practices**

The integration of the sub-team comments by the ATL at the daily audit team caucus was handled well and there was good use of the potential CAR tracking board. A complete audit notebook with checklists, SPPs, and supporting documentation was available for the observers.

## **5.8 Summary of Headquarters Audit Findings**

Within the scope of this audit, the audit team concluded that the EM-323 SPPs are adequate (but some need to be changed to reflect the reorganization of EM-323) and that EM-323's QA program implementation is adequate. At the post-audit meeting, the ATL gave an explanation of the areas of concern and provided draft CARs to the Division Director and the Quality Assurance Program Manager. The four CARs are summarized as follows.

**5.8.1 Five SPPs were not being fully implemented or complied with to the extent required.**

**5.8.2 Procedures were not in place to describe how minimum education and experience requirements are established and how they are verified. There was no objective evidence that minimum education and experience are being verified based on the requirements for the position and no objective evidence is being retained in the QA records system.**

**5.8.3 A quarterly analysis of adverse quality trends did not include sections required by an SPP.**

**5.8.4 There was no objective evidence existing in the QA records system to show (i) what criteria were considered for SPP reviews and (ii) how independent reviewers are identified for the review process.**

Three other potential CARs were acceptably resolved by the EM-323 organization prior to the post-audit meeting.

**Table 1. EM-323 SPPs and their effectivity as rated by the audit team.**

NO.	TITLE	EFFECTIVITY
1.01	Index of High-Level Waste Standard Practice Procedures for Quality Assurance	Effective
1.02	EM Organization for Waste Acceptance Process Activities of High-Level Waste Form Production	Effective
2.01	Standard Practice Procedures	Marginally Effective
2.03	Quality Assurance Program Description	Effective
3.01	Training Needs Assessment	Effective
3.02	Preparation and Conduct of Training	Effective
3.03	Qualification and Documentation Requirements for Audit, Surveillance, and Review Personnel	Marginally Effective
3.05	Administration of Personnel Certification, Qualification, and Training Records	Not Effective
4.01	Planning and Scheduling of Evaluation Activities	Effective
4.02	Administration and Conduct of Quality Assurance Audits	Effective
4.04	Administration and Conduct of Surveillance	Effective
4.08	Administration and Conduct of Peer Reviews	Indeterminate (No Activity)
4.12	Quality Assurance Input to the Program Execution Guidance Documents	Effective
4.13	Observation of Evaluation Activities Led by External Organizations	Effective
4.14	Administration and Conduct of Operational Readiness Evaluations	Effective
4.15	Administration and Performance of Reviews by Technical Review Groups	Effective
4.16	Document Preparation and Review	Effective
5.01	Deviations and Corrective Actions	Effective
5.03	Stop Work Orders	
5.07	Evaluation and Assessment Commitment Tracking and Reporting System	Effective
6.05	Controlled Documents	Effective
7.01	Preparation, Transfer, and Receipt of Quality Records	Effective
7.02	Quality Records Management	Effective
8.02	Annual Assessment of the Quality Assurance Program	Effective
8.03	Quality Assurance Program Progress and Status Reports	Effective
10.01	Analysis of Adverse Quality Trends	Not Effective
10.03	Differing Staff Opinions and Allegations	Indeterminate (No recent activity)