

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT OA-95-08
OF THE U.S. DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
AUDIT HQ-ARC-95-08
OF THE
OFFICE OF ENVIRONMENTAL MANAGEMENT HIGH-LEVEL WASTE DIVISION

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1.0 INTRODUCTION

During June 26-30, 1995, members of the U.S. 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 Environmental Management High-Level Waste (HLW) Division (EM-323). The audit, HQ-ARC-95-08, 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, Rev. 2) and the EM-323 Standard Practice Procedures (SPPs) which comprise the EM-323 QA program.

The NRC staff 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 of the Code of Federal Regulations (CFR) Title 10, Part 60 (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-ARC-95-08 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 effective. Three preliminary Corrective Action Requests (CARs) were discussed by the Headquarters audit team at the post-audit meeting. Two 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

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 Rodney M. Weber Observer

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4.2 DOE/Headquarters

Fred Bearham	Audit Team Leader (ATL)	Quality Assurance Technical and Support Services Contractor— CER (QATSS)
Charles Betts	Auditor	QATSS
Emily Reiter	Auditor	QATSS
Conrad Coulombe	Auditor	QATSS
Gary Wood	Auditor	QATSS
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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 (QAP) 18.2, "Audit Program" (Revision 6) and QAP 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

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. Revisions 1 and 2 of the QARD were fully accepted by the NRC on June 6, 1995.

5.1.1 QA Programmatic Elements

EM-323's SPPs are not arranged in accordance with the programmatic elements of the QARD (and similarly the QA criteria of Appendix B to 10 CFR Part 50). A link between the SPPs and the programmatic elements of the QARD is documented in the QARD Requirements Matrix. The QARD Requirements Matrix identifies which SPPs implement the requirements of each QARD programmatic element. The audit team audited and assessed the effectiveness of the EM-323 SPPs which are listed in Table 1. These SPPs are associated with QA programmatic elements which are listed below:

- 1 Organization
- 2 Quality Assurance Program
- 5 Instructions, Procedures, and Drawings
- 6 Document Control
- 16 Corrective Action
- 17 Quality Assurance Records
- 18 Audits.

Only the above QA elements were found to be applicable to EM-323 activities. The audit team utilized the QARD Requirements Matrix document to verify the relationship of the SPPs to the QARD. This document also provides an explanation and justification for those QA elements that are not applicable to the EM-323 activities.

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 the Headquarters audit team evaluation of QA Programmatic Elements 1, 2, 5, 6, 16, 17, and 18; only these QA programmatic areas are applicable to EM-323 and 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 June 26-July 1, 1994.

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)

SPP 1.02, "High-Level Waste Vitrification Program and Spent Nuclear Fuel Program Organization," was utilized as the basis for the checklist questions and the investigation by the sub-team auditing this QA Programmatic Element. The auditors interviewed the QA Program Manager to understand the EM-323 QA program organization and how the QARD is implemented. All of the questions asked by the audit sub-team were satisfactorily answered.

The NRC staff agrees with the 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)

The checklist questions used to evaluate the observed portions of this programmatic element were developed from SPPs 2.01, 3.01, and 8.02. The auditor began the evaluation of this programmatic element by reviewing an index of SPPs required by SPP 2.01, "Standard Practice Procedures and QARD Requirements Matrix." Samples of revised SPPs were reviewed to assure that effectivity dates and training/reading assignments were present. Implementation of SPP 2.01 was found to be acceptable.

The NRC staff also observed the auditors evaluate the EM-323 implementation of SPP 3.01, "Training Needs Assessment." A review of the training matrix for 1994 revealed that the matrix was not produced by September 30 of each year as required by SPP 3.01. The auditor suggested that a memo be placed in the file to provide rationale for the delay. EM-323 placed a memo in the file prior to the audit exit meeting. The deficiency was considered to be an isolated incident with little impact on quality. Therefore, this deficiency was considered "closed during audit."

To evaluate the controls of SPP 8.02, "Annual Management Assessment," the auditor reviewed the August 29-September 2, 1994, Management Assessment Report. From the review and discussions with a QA Specialist, it was determined that EM-323 is not meeting four requirements of SPP 8.02. One CAR was written to document the following adverse conditions:

1. No objective evidence was presented to allow verification that the Director of EM-323 established the Management Assessment Team and documented the basis for the assignment of individual members. The evidence presented indicated that the selection of the team and the basis for assignment was performed by the EM HLW QA Program Manager.
2. No objective evidence was available to establish that the Director of EM-323 reviewed and approved the Management Assessment Report, as required.
3. Neither the Assessment Plan or the Assessment Report addressed all aspects of the program required by the procedure. Further, no justification was provided for excluding aspects of the program from consideration.
4. No objective evidence was available to prove that the Director evaluated the assessment report results and developed plans to address needed areas of improvement. The evidence provided indicates that the plan to resolve the assessment recommendations was prepared by the HLW QA Program Manager and provided to the Director for concurrence.

The NRC staff agrees with the audit team findings. The adverse conditions identified are procedural violations and did not significantly affect the quality of the management assessment. However, due to the number of adverse conditions identified the staff believes that EM-323's implementation of the QA controls for activities under this QA programmatic element is only marginally effective.

5.3.3 Instructions, Procedures, and Drawings (QA Programmatic Element 5)

The audit team evaluated the EM-323 QA program implementing SPPs and the technical document review process through discussions with the QA Specialist for these areas. The SPPs were compared against the applicable requirements of the QARD sections identified in the EM-323 Requirements Matrix for the HLW program. The specific areas evaluated included the planning and scheduling of evaluation and assessment activities and the conduct of those activities. A review of objective evidence was accomplished in all these areas.

The previous years OCRWM audit identified inconsistencies in some the EM-323 SPPs. Specifically, there were no procedures to describe the minimum training and experience requirements. The audit team determined that these deficiencies appear to have been adequately addressed; however, the team identified one additional area where the SPPs failed to address several QARD audit element requirements. This is discussed further under paragraph 5.3.7 below. These deficiencies were not considered serious.

The area described by SPP 4.14, "Administration and Conduct of Readiness Reviews," was judged to be indeterminate. There were no readiness reviews conducted since the last audit.

The NRC staff agrees with the Headquarters audit team assessment that overall this programmatic area is considered effective.

5.3.4 Document Control (QA Programmatic Element 6)

The auditor utilized a checklist developed around the requirements of SPP 6.05, "Controlled Documents." Document distribution lists and transmittal documents were reviewed. A sampling of current holders of controlled SPPs was selected in order to verify currency of the manuals in their possession. During the subsequent audit activities, the manuals of the selected individuals were examined and found to be satisfactory. The QA specialist for this area was interviewed and answered all questions to the auditor's and observer's satisfaction. The distribution of controlled documents to Idaho National Engineering Laboratories (INEL) was discussed with the QA specialist. The auditor asked questions relating to the on-site INEL control of documents and the fact that these were not being controlled to a level equal to that described in the EM-323 SPPs. The process was clarified to the auditor by an INEL representative who was present as an observer. It was determined that distribution had been occurring for six months, was controlled by an INEL "letter procedure," and that EM had plans to audit the activity. Because this was a relatively new activity, EM-323 was controlling the distribution to INEL, and the specialist was planning an audit of the activity, the auditor chose not to address this as a deficiency related to this audit.

It was noted during the audit that the QARD Requirements Matrix was not being controlled as required by SPP 6.05, "Distribution of Controlled Documents." This deficiency was documented in a CAR. Lack of proper control of the QARD requirements matrix is not considered to be a significant condition adverse to quality.

This portion of the audit was effective, and the QA programmatic element appeared to be satisfactorily implemented, with the exception of the one finding listed above.

5.3.5 Corrective Action (QA Programmatic Element 16)

The auditor evaluated SPP 5.07, "Evaluation and Assessment Commitment Tracking and Reporting System," by interviewing the responsible QA Specialist regarding the commitment tracking process. Several quarterly "Commitment Tracking and Reporting System" status reports were reviewed by the auditor. These status

reports list the Deviation and Corrective Action Reports (DCARs) written against EM-323, audit observations requiring response, and recommendations from management assessments. From the status reports, it is evident that the commitment tracking and reporting system had some control problems in the past. However, the newly assigned Tracking System Coordinator appears to be effectively implementing existing procedural controls.

The area described in SPP 5.03, "Stop Work Orders," was judged to be indeterminate. There were no Stop Work Orders issued.

The staff agrees with the assessment that this element is effective.

5.3.6 Quality Assurance Records (QA Programmatic Element 17)

The audit of this programmatic area took place at the offices of the QA specialist responsible for document control and at the Satellite Central Records Facility. During the review of objective evidence, the auditor noted that records were not being annotated in accordance with SPP 7.01. This situation was not considered adverse to quality, and the auditor addressed this with a recommendation to change the procedure to reflect current practices.

Questions related to the identification of records as permanent lifetime or nonpermanent were discussed. Records over three years old were being held awaiting guidance on this matter. The auditor made a recommendation that the application matrix be corrected to reflect the appropriate requirements.

One correction to the WVNS-ORPP-017 document was found to have been made without an initial and date by the person making the change. This was an isolated incident and was corrected during the audit. No other discrepancies were noted by the auditor 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 auditor utilized a checklist derived from the QARD and SPP 4.02, "Administration and Conduct of Quality Assurance Audits." One audit had been performed during the year at the Savannah River site. No audit had been conducted at the West Valley Vitrification Plant facility. The auditor verified that the appropriate notification letter had been issued prior to the audit with the scope, dates of the audit, and audit team members being identified. However, the report transmittal letter did not follow the SPP 4.02 Attachment D example for form and format. This was not considered significant. The 1994 Savannah River audit report was reviewed to verify closeout. The auditor verified that the appropriate closure letter was issued; however, the checklists could not be reviewed because they were not part of the report package and were maintained in another location.

Several questions related to QARD requirements flow down to the SPP documents were asked. It was not clear to the auditor that the requirements of the QARD had been completely and clearly addressed in the EM-323 SPPs. As a result of the number of items occurring on this subject, a CAR was issued. None of the incomplete or unclear QARD flow down requirements represents a significant condition adverse to quality.

Surveillance activities were reviewed for compliance to SPP 4.04, "Administration and Conduct of Surveillance." Using the checklist generated from this document, a thorough review was conducted through an interview with the QA Specialist for this area and a review of documentation. QARD flow down was checked, and no deficiencies were identified. Audit and surveillance schedules were reviewed, and the auditor found them to be reasonable.

This portion of the audit was effective, and this QA programmatic element appeared to be satisfactorily implemented. One CAR was issued to address the issues related to QARD requirements not clearly addressed in the SPPs.

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. Three preliminary CARs resulted from the audit.

The auditors worked individually and in audit sub-teams. They were well prepared and demonstrated a sound knowledge of the EM-323 QA program. They interviewed appropriate EM-323 specialists and support staff personnel. They examined the SPPs to verify adequacy, determined whether the SPP requirements were being met, and verified that the requirements of the QARD were included in the SPPs. 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 compliance to the SPPs. They solicited comments and questions from the NRC staff in an appropriate manner. Objective evidence demonstrating compliance to each of the SPPs was verified by the auditors. The auditors were effective in addressing each of the applicable QA programmatic elements.

The method of auditing which combined interviewing 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 continues to be improvement in the EM-323 QA program and that EM-323 management shows an increased sensitivity to the requirements.

5.5 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 effective to the extent shown for the individual SPPs in Table 1. The audit team was adequately staffed with knowledgeable and experienced auditors. The NRC staff did not observe any deficiencies in the audit process.

5.5.1 Weakness

The audit plan did not provide adequate information in Sections 1.0, Scope, and 4.0, Activities to be Audited, to determine what QARD programmatic elements would be evaluated during the audit. The NRC observers believe a more comprehensive scope should be identified.

5.5.2 Good Practices

The audit team was persistent in tracking down details when questions remained on particular issues. Team intercommunications were good, and the ATL facilitated effective communications among all audit participants.

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

NO.	TITLE	EFFECTIVITY
1.02	EM Organization for Waste Acceptance Process Activities of HLW Form Production	Effective
2.01	Standard Practice Procedures	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	Effective
3.05	Administration of Personnel Certification, Qualification, and Training Records	Effective
4.01	Planning and Scheduling of Evaluation and Assessment Activities	Effective
4.02	Administration and Conduct of Quality Assurance Audits	Effective
4.04	Administration and Conduct of Surveillance	Effective
4.12	Quality Assurance Input to the Program Execution Guidance Documents	Effective
4.14	Administration and Conduct of Readiness Reviews	Indeterminate
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	Indeterminate
5.07	Evaluation and Assessment of Commitment Tracking and Reporting System	Effective
6.05	Distribution of Controlled Documents	Effective
7.01	Preparation, Transfer, and Receipt of Quality Records	Effective
7.02	Quality Records Management	Effective
8.02	Annual Management Assessment	Marginally Effective
8.03	Quality Assurance Program Progress and Status Reports	Effective
10.03	Differing Staff Opinions	Indeterminate