

U. S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 91-13
FOR THE OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
AUDIT NO. 91-003
ENVIRONMENTAL RESTORATION AND WASTE MANAGEMENT,
WASTE VITRIFICATION BRANCH

John T. Buckley 10/8/91
John T. Buckley
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste
Management

James T. Conway 10/8/91
James T. Conway
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste
Management

Reviewed and Approved by James T. Conway 10/8/91
Kenneth R. Hooks
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management

1.0 INTRODUCTION

From August 26 through 30, 1991, members of the U.S. Nuclear Regulatory Commission (NRC) staff participated as observers on the U.S. Department of Energy (DOE)/Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Audit No. 91-003 of the DOE Office of Environmental Restoration and Waste Management (EM) Vitrification Projects Branch (EM-343) in Germantown, Maryland. EM is responsible for the management and operation of facilities, operations, or site for storage, treatment or disposal of radioactive, hazardous, mixed and sanitary waste materials. Specifically, EM-343 is responsible for administration and overview of the site field offices to ensure the acceptability of high-level radioactive canistered waste forms. This report addresses the NRC staff's assessment of the effectiveness of the OCRWM audit and, to a lesser extent, the adequacy of the EM-343 QA program.

2.0 OBJECTIVES

The objective of the OCRWM audit was to determine the effectiveness of the EM-343 QA program in meeting the applicable requirements of the OCRWM Quality Assurance Requirements Document (QARD, DOE/RW-0214), Revision 4, for the Civilian Radioactive Waste Management Program. The NRC staff's objective was to gain confidence that OCRWM and EM-343 are properly implementing the requirements of their QA programs by evaluating the effectiveness of the OCRWM audit process and determining whether the EM-343 QA program is in accordance with the applicable requirements of the OCRWM QARD and Title 10 Code of Federal Regulations (10 CFR) Part 50, Appendix B.

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the OCRWM audit process and the EM-343 QA program on direct observations of the auditors, discussions with the audit team and EM-343 personnel, and reviews of the pertinent audit information (e.g., audit plan, checklists, and EM-343 documents). The NRC staff has determined that, overall, OCRWM Audit No. 91-003 of EM-343 was of appropriate scope and achieved its purpose of determining the adequacy and effectiveness of the EM-343 QA program. The audit of the criteria observed was conducted in a professional manner. The audit team was well qualified in the QA discipline, and their assignment and checklist items were adequately described in the audit plan.

The NRC staff agrees with the audit team's preliminary findings that EM-343 has an inadequate QA program for most of the areas that were audited, and the EM-343 QA program, for the most part has insufficient controls in place to perform work related to the overview of site field offices vitrification projects. The NRC staff also agrees with the OCRWM audit team's conclusion that there was ineffective implementation of the EM-343 QA program in most areas audited by the audit team. In other areas audited, there has been minimal activity, therefore, adequacy of implementation in these areas was indeterminate.

4.0 AUDIT PARTICIPANTS

4.1 NRC

John T. Buckley	Observer
James T. Conway	Observer

4.2 DOE

Robert Clark	Audit Manager	DOE
Norman Frank	Audit Team Leader	CER Corporation (CER)
Clyde Morell	Auditor	CER
Robert Thomas	Auditor	CER
Dennis Brown	Auditor	CER
Craig Walenga	Auditor	CER
Thomas Rogers	Auditor	CER
Louis Wade	Auditor	Roy F. Weston, Inc.
Frank Nash	Observer	Duke Engineering and Services, Inc.

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The OCRWM audit was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18-2, "Audit Program," Revision 1, and QAAP 16.1, "Corrective Action Requests (CAR)," Revision 1. The NRC staff observation of the OCRWM audit was based on the NRC procedure "Conduct of Observation Audits" issued October 6, 1989. NRC staff findings are classified in accordance with the guidelines in this procedure.

The NRC staff findings may also include weaknesses (actions or items which are not deficiencies but could be improved), good practices (actions or items which enhance the QA program) and requests for information required to determine if an action or item is deficient. Written responses to weaknesses identified by the NRC staff will be requested when appropriate.

In general, weaknesses and items related to requests for information will be examined by the NRC staff in future audits or surveillances.

5.1 Scope of Audit

The audit scope was to verify that the EM-343 QA program meets the requirements of the EM QA Program Description (QAPD), Revision 0, dated October 1990 (which is based on the OCRWM QARD), and to verify the adequacy of implementation of the QA program. The audit also determined whether EM-343 had taken effective actions to resolve findings identified during previous audits and surveillances.

The scope of this audit did not include any review of the technical adequacy of technical products and activities. The programmatic audit utilized checklists based on the requirements in the OCRWM QARD, the EM QAPD and associated Standard Practice Procedures (SPPs). The checklists covered QA program controls for 11 of the 18 program elements of the EM QAPD. Criteria VIII, IX, X, XI, XII, XIII, and XIV of 10 CFR Part 50, Appendix B (Sections 8 through 14 of the OCRWM QARD and the QAPD) were not included in the scope of the audit.

5.2 Timing of the Audit

The NRC staff believes the timing of the QA audit was appropriate. Even though implementation was limited, this audit was useful to determine the adequacy of the EM-343 QA program for initiation of quality-affecting activities.

5.3 Examination of Programmatic Elements

The OCRWM programmatic checklists covered the QA program controls for the 11 elements listed below:

- 1.0 Organization
- 2.0 Quality Assurance Program
- 3.0 Design Control
- 4.0 Procurement Document Control
- 5.0 Instructions, Procedures, Plans, and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 15.0 Control of Nonconforming Items
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits

The NRC staff observed the audit team's evaluation of the following selected programmatic elements of the EM-343 program. Since only some elements of the QA program were observed, the details of unobserved program deficiencies identified by the OCRWM audit team will not be addressed in this report.

In addition, the auditors reviewed and evaluated activities related to 1) qualification of technical personnel, and 2) procedural requirements pertaining to development and qualification of waste forms.

(a) Organization (Criterion 1)

The auditors utilized the published audit checklists and were generally thorough in reviewing the associated objective evidence. The auditors

utilized in-depth questioning and interviewed a number of individuals from EM-343. The personnel interviewed included the Branch Chief (BC), Program Manager (PM) and Assistant PM for the Defense Waste Processing Facility (DWPF) and two QA Assistants from BDM International, Inc. (BDM), a contractor to EM-343. BDM, along with the Project Technical Support Office (PTSO) in Richland, Washington, perform support tasks in technical and QA areas.

Currently, EM-343 consists of 21 individuals (10 from DOE/EM and 11 from BDM). Since EM-343 does not have any direct DOE staff in QA positions, it receives all of its QA support from BDM. In discussions with the BC, it was learned that EM-343 is planning on hiring at least four individuals, one for a QA Program Manager position reporting to the BC, and three QA specialists, each reporting to the PM for the three projects for which EM-343 has responsibility. This new organization is also described in the EM/Office of Waste Operations QAPD (DOE/EM/WO/02), Revision 1 which is currently going through management approval. The NRC staff strongly supports direct DOE personnel being in responsible QA positions for activities covered by EM-343.

The audit team verified that the BC was independent from production responsibilities. It was also noted that EM-343 monitors the activities of the Working Group on Waste Acceptance and the DOE field offices located in Richland, Washington (RL), Aiken, South Carolina (SR), Idaho Falls, Idaho (ID), and Chicago, Illinois (CH).

It was noted that the RL Field office was not sending quarterly "QA and Safety Status Reports" to the EM Office of Waste Operations as required by the Program Execution Guidance document. The auditors identified two CARs under Criterion 1. One CAR described the adverse condition as a failure to define organizational interfaces between EM-343 and external organizations such as RL, SR, ID, and CH in DOE/EM/WO/02. In addition, there was no description of the responsibilities or authority of the support contractors. The other adverse condition was that the EM QA Program has not identified the responsibilities or levels of authority for a number of management positions identified in the organizational charts.

Based on the depth of questioning and satisfactory completion of the audit checklist, the auditors adequately reviewed and evaluated the EM-343 organizational structure for compliance to DOE/EM/WO/02 and the OCRWM QARD. Based on the number of checklist items that were found to be unsatisfactory, the NRC staff agrees with the auditors' finding that the implementation of Criterion 1 is ineffective.

(b) Quality Assurance Program (Criterion 2)

The auditors reviewed documentation and interviewed a number of EM-343 personnel to determine overall programmatic implementation with 11 SPPs which contained requirements related to Criterion 2.

It was noted that Revision 1 of the EM QAPD for high-level waste form development and qualification is being reviewed by management. OCRWM recently reviewed and sent comments on the QAPD to EM-343. During the interviews, the auditors learned that a number of activities had not been performed under the existing QA Program. The non-implemented areas included peer reviews; external reviews or evaluations of EM-343; annual assessments to determine QA program effectiveness; allegation system; technical reviews; trending analysis of identified deficiencies; and internal audits.

Although Revision 1 to the QAPD identifies a QA Manager and three QA Specialists, there was no objective evidence of a detailed job description for these QA personnel. It was noted that the status reports of the QA program were prepared monthly as required by an SPP, but it was not clearly defined which organizations were overviewed by EM-343. The Quality Assurance Review Group, which consisted of a number of personnel from BDM, PTSO, and Performance Development Corporation (PDC) reviewed the QA plans for DWPF, West Valley Demonstration Project (WVDP) and the Hanford Waste Vitrification Plant (HWVP).

The Training, Indoctrination and Orientation (TIO) Plan and Schedule for January 1, 1991 through September 30, 1991 was reviewed. The TIO Plan and Schedule, which is reviewed by QA and approved by the BC, applies to all EM-343 personnel (both DOE and contractors) who perform quality-affecting activities. The training to the SPPs is given in three modules by PDC, and the QA orientation is given by BDM. Other training is related to Occupational Safety and Health Administration (OSHA), OCRWM QARD, and project related documentation. The Needs Assessment Worksheet (NAS) document, which is prepared by a Program Manager, reviewed by QA, and approved by the BC was reviewed for all 10 DOE individuals in EM-343. Some of the training dates on the NAS were after the date training was required or completed for several individuals. A document was prepared to identify and track completion of TIO requirements.

There was no documented evidence that individual lesson plans were reviewed and approved by a QA specialist and the individual's supervisor as required by procedure. To date, there has been no project specific indoctrination classes conducted. In addition, one PM has not attended all the training sessions to which he was assigned. Although EM-343 is committed to requirements contained in NQA-1, training covered in "QA orientation" addresses the basic requirements but not the NQA-1 supplements.

The auditors identified deficiencies or conditions adverse to quality in four CARs under Criterion 2. One CAR listed a number of areas where requirements pertaining to the TIO program were not met. A second CAR noted that an annual assessment of the scope, status adequacy, and compliance of the QA program with DOE/RW-0214 was not completed. A failure to review and accept the implementing procedures for SR and RL was identified as a third CAR. No controls being in place to implement the QAPD requirement for a graded QA program resulted in a fourth CAR. The failure to perform a trend analysis on approximately 40 CARs in the system was identified as an observation.

Based on an in-depth utilization of the checklist items, the audit of Criterion 2 appeared to be effective. Because of the numerous instances of procedural non-compliance, the implementation of Criterion 2 is considered inadequate.

(c) Instructions, Procedures, Plans, and Drawings (Criterion 5)

The auditors reviewed SPP's 4.01, 4.02, 4.03, 4.05, 4.06, 4.07, 7.01 and 7.02 to evaluate effectiveness of implementation and whether their development was consistent with SPP 2.01 (procedure for development of procedures).

As a result of interviews with the Deputy QA Manager and Assistant PM and a review of the above stated SPP's, the auditors identified several deficiencies in EM-343's implementation of the procedures (see Section 5.9). In addition to the deficiencies identified, the auditors made the observation that the EM-343 QA program contains several administrative/program management related SPP's which could be deleted and implemented as Administrative Procedures instead. The auditors stated that the following SPP's should be implemented as Administrative Procedures:

1. SPP 6.01 - Official HLW Office Files,
2. SPP 6.02 - Preparation of Correspondence,
3. SPP 6.03 - Incoming Mail,
4. SPP 6.04 - Commitment Control,
5. SPP 9.01 - Preparation and Maintenance of Program Schedules,
6. SPP 9.02 - HLW Monthly Progress Reporting, and
7. SPP 9.03 - Preparation and Maintenance of the Work Breakdown Structures (WBS).

The auditors utilized the published checklist and conducted interviews with the EM-343 staff in a professional manner. The audit of this criterion was effective. The NRC staff agrees with the audit team's preliminary conclusion that in the area of criterion 5, EM-343 has adequate procedural controls in place, but, the implementation of these procedures is ineffective. Further, there

seemed to be a pervasive attitude within EM-343 and supporting contractor personnel that following the procedures is not required. On many occasions the EM-343 and contractor staff acknowledged that procedures were knowingly violated but "the intent was met." The NRC observers are concerned by the auditees attitude displayed during the audit regarding compliance with the implementing procedures.

(d) Document Control (Criterion 6)

The auditor used the published checklists prepared from SPP's 2.04, 6.01, 6.02, 6.03, 6.04, and 6.05 in conducting the audit of this criterion. Interviews with the EM-343 Document Control Clerk indicated that there were several instances of non-compliance with administrative SPP's. For instance:

1. Document numbers associated with the file list are assigned differently than required by SPP 6.01.
2. There is currently no dedicated QA Specialist and thus the SPP's which require QA Specialist review, etc... cannot be complied with.

In an effort to evaluate the control of QA documents, the auditor reviewed the EM QAPD. Again, the auditor identified deviations from these procedures. First, there was no evidence that the QA Manager reviewed the document control system prior to implementation. Second, there was no evidence that the QA Manager verified the adequacy of controlled documents as required by SPP 6.05. Finally, there was evidence that controlled documents were being changed in a manner inconsistent with the implementing procedures.

Although the auditor identified several instances of non-compliance with the SPP's, controlled documents were found to be complete and current. As a result of the evidence reviewed, the NRC staff believes that EM-343 is adequately controlling documents even though the procedures are not being adequately implemented. The audit of this criterion was conducted in a thorough and professional manner. The audit process is considered to be effective.

(e) Corrective Action (Criterion 16)

The auditor evaluated EM-343's program against the requirements of SPP 5.02, 5.03, 5.04, 5.06 and 10.2. A very methodical, professional and thorough interview was conducted with an EM-343 Program Manager.

It was determined through the interview that deficiencies identified during an internal surveillance (report dated June 14, 1991) and an internal management assessment were never written as CARs against EM-343. The auditee could not provide a valid reason for not writing CARs against themselves following these internal evaluations. Only a limited portion of the audit of this criterion was observed. A determination of effectivity of implementation could not be made by the auditors because the working files for the corrective action system were not available for review.

(f) Audits (Criterion 18)

The auditors utilized their checklists for review of both surveillances and audits in an effective manner and solicited responses from the interviewees over and above the checklist items. The Project Manager for WVDP, a DOE project engineer, and two individuals from SAIC were interviewed to determine that surveillances and audits were conducted in accordance with the requirements contained in the QAPD and implementing procedures.

The auditors verified that surveillance plans and schedules were documented. A review of surveillance logs for 1991 indicated that PTSO performed six, four, and two surveillances of DWPF, WVDP, and HWVP, respectively. In addition, five surveillances were conducted of EM-343 in 1991. A sample of surveillance packages was reviewed by the auditors, and the qualifications by education and experience of the surveillance personnel were verified. A file for each surveillance had been established, and the activity status log had been completed. Although surveillance reports are transmitted to the management of the organization being evaluated, the reports are not being retained as quality assurance records.

EM-343 has conducted three external audits - two of SR and one of the West Valley, NY (WV) field office. The auditor reviewed the working files for Audit No. 91EA-WV-AU-001 conducted at WV in June 1991 and Audit No. 91EA-SR-AU-001 conducted at SR in February 1991. The files contained an audit plan and schedule, notes on audit planning meetings, audit team agenda, audit checklists and the audit report which contained an executive summary and CARs. To date, none of the documents have been prepared as quality records.

The auditor determined that the audit report for WV did not contain sufficient information to describe the conduct of the audit and the items and activities reviewed, and a CAR will be written in this area. EM-343 has not conducted any internal audits and a second CAR will be generated addressing this deficiency. The auditor had one observation and noted that objective evidence was not available to

verify that two technical specialists on the WV audit were qualified for specific areas of review to which they were assigned.

The audit of this area was thorough and appeared to be effective. The staff agrees with the auditor's finding that the implementation of Criterion 18 requirements is inadequate.

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 EM-343 program. The audit checklists included the important QA controls addressed in the OCRWM QARD that are applicable to the EM program. The audit team used the comprehensive checklists effectively during the interviews with EM personnel and review of documents. In general, the team was persistent in its interviews, challenging certain EM responses when necessary.

5.5 Qualification of Auditors

The qualifications of the QA auditors on the team were acceptable based on Quality Management Procedure-02-02, the Yucca Mountain Site Characterization Project Office procedure for qualifying auditors.

5.6 Audit Team Preparation

The QA auditors were well prepared in the areas they were assigned to audit and knowledgeable in the EM QAPD and implementing procedures. Overall Audit Plan 91-003 was complete and included: (1) the audit scope; (2) a list of audit team personnel and observers; (3) a list of all the audit activities; (4) the audit notification letter; (5) the QAPD; and (6) the QA and technical checklists.

5.7 Audit Team Independence

The audit team members did not have prior responsibility for performing the activities they investigated. Members of the team appeared to have sufficient independence to carry out their assigned functions in a correct manner without adverse pressure or influence from EM personnel.

5.8 Summary of NRC Staff Findings

(a) Observations

The NRC staff did not identify any observations relating to deficiencies in either DOE/OCRWM audit process or the EM QA program.

(b) Good Practices

The audit team was well prepared and conducted a thorough audit in a professional manner.

(c) Weaknesses

In several instances auditors expressed too much opinion on the philosophy of QA and on possible corrective actions for identified deficiencies. These discussions detracted from the overall efficiency of the audit.

As noted in Section 5.3(c) of this report, the NRC staff is concerned by the auditees attitude regarding compliance with the implementing procedures. This attitude was evident in the EM-343 staff as well as support contractors.

Although the audit rightly included the EM-343 support contractors, it appeared in many cases that the EM-343 staff relied too heavily on the contractors to answer auditors' questions. In many cases it seemed as though the EM-343 staff was not familiar with the procedural requirements and had to rely on the contractors to address the auditors' questions.

5.9 Summary DOE/OCRWM Audit Team Findings

During the course of the audit, the audit team identified deficiencies documented in 10 preliminary CARs. These CARs were well substantiated and reflected issues important to the quality system. In addition, the audit team also identified 10 observations which identify areas of the program which would benefit from improved procedural controls. Although these observations do not represent deficiencies in procedural implementation, they do indicate areas of program weaknesses. Below is a summary of the preliminary CARs developed by the audit team.

- EM-343 demonstrated a general lack of compliance with the issued SSP's. This finding is supported by many examples of non-compliance.
- Inadequate and ineffective training program. The audit team identified seven deficiencies to support this CAR.
- EM-343 has not completed any management assessments or internal QA program audits.
- The QARG-1 (SPP) review process is inadequate and ineffective.
- No procedure is in place to define work that is subject to the EM-343 QA program requirements.
- EM-343 had not designated a person to act as the HLW QA Program Manager.

- Deficiencies identified in Surveillance Report 91EA-VP-S-13 were not documented on deviation reports and no action was taken to correct deficiencies.
- The EM-343 administrative support contract for BDM does not require BDM to perform work in accordance with the SPP's or EM-343 QAPD.
- EM-343 has not reviewed and accepted the West Valley or Richland Operations Office implementing procedures.