

**U.S. DEPARTMENT OF ENERGY**  
**OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT**  
**OFFICE OF QUALITY ASSURANCE**

**AUDIT REPORT OF**  
**ENVIRONMENTAL RESTORATION AND WASTE MANAGEMENT (EM)**  
**VITRIFICATION PROJECTS DIVISION (EM-323)**  
**GERMANTOWN, MD**

**AUDIT NO. HQ-ARC-95-08**

**JUNE 26 THROUGH JUNE 30 1995**

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Date: 9/29/95

Approved by: Carl E. Horton for  
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Director  
Office of Quality Assurance

Date: 10/18/95

## 1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit HQ-ARC-95-08, the audit team determined that EM-323 is satisfactorily implementing an effective QA program in accordance with the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD), DOE/RW/0333P, Revision 2, and EM-323 implementing procedures for QA Program Elements 1, 2, 5, 6, 16, 17, and 18.

Audit HQ-ARC-95-08 was conducted to review and assess the effectiveness of EM-323 compliance with the QARD and implementation of EM-323 Standard Practice Procedures (SPPs) and was planned and scheduled as a compliance audit. However, it was conducted as a baseline audit for the Office of Quality Assurance (OQA) acceptance of EM-323's QA program. The change in the audit scope was made possible based on the fact that the audit team reviewed previous revisions in addition to current revisions of the SPPs and did not identify any significant adverse conditions. A weakness in the EM-323 Annual Management Assessment program was identified as a deficiency and SPP. 8.02, "Annual Management Assessments," was determined to be marginally effective and unacceptable for baseline approval. SPP 8.03, "Quality Assurance Program Progress and Status Report," was determined to be unacceptable for baseline approval because the EM-323 QARD Implementation Matrix did not address the applicable requirements of the QARD. With the exception of SPPs, 8.02 and 8.03, all remaining SPPs were determined to be acceptable for baseline approval by OQA. The QA Program elements audited were considered to be satisfactory with the exception of Organization. EM-323 Management Assessment (MA) was audited under Organization and categorized as marginal.

Significant changes to the EM-323 QA Program have been initiated since the last OCRWM audit in June 1994. These include the revision of all EM-323 Standard Practice Procedures to reflect the revised EM-323 organization and the requirements of the QARD, and the preparation of the EM-323 QARD Implementation Matrix, which is the input document to the Requirements Traceability Network (RTN) database.

The audit team identified five deficiencies during the audit that resulted in issuance of one Deficiency Report (DR) and one Performance Report (PR) in accordance with AP-16.1Q, Revision 0. The remaining deficiencies required only remedial action and were corrected prior to the postaudit meeting. These conditions are described in Section 5.5.2 of this report. Additionally, there were four recommendations resulting from the audit, which are detailed in Section 6.0 of this report.

## 2.0 SCOPE

The audit was conducted to evaluate the adequacy of, compliance to, and the effectiveness of EM-323's QA program as described in the QARD and EM-323 SPPs. In addition, the completion of Corrective Action Requests (CARs) issued as a result of previous OCRWM audit was evaluated for verification of implementation.

### 2.1 QA PROGRAM ELEMENTS

The following QA Program Elements were evaluated during the audit in accordance with the approved audit plan:

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

Checklists developed from the OCRWM QARD (DOE/RW/0333P) and EM-323 Standard Practice Procedures (SPPs) were used to conduct the audit.

### 2.2 TECHNICAL AREAS

Technical areas were not reviewed and a Technical Specialist was not assigned because the audit was a compliance audit.

## 3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members, with their assigned area of responsibility, and observers.

<u>Title</u>	<u>Name</u>	<u>Organization</u>	<u>SPPs Audited</u>
ATL	Fred Bearham	QATSS	All Areas
Auditor	Norm Frank	QATSS	4.01, 4.02 & 4.04
Auditor	Gary Wood	QATSS	5.01, 5.03, 5.07, 8.02 & 10.3
Auditor	Emily Reiter	QATSS	6.05, 7.01, 7.02, & 8.03
Auditor	Charles Betts	QATSS	3.01, 3.02 & 3.03
Auditor	Conrad Coulombe	QATSS	4.12, 4.15, & 4.16
Auditor	Vance Cannaday	QATSS	1.02, 2.01 & 3.05
Observer	John Buckley	USNRC	
Observer	Rod Webber	USNRC	
Observer	Earl Bradford	EM-37	

#### 4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The preaudit conference was held at EM-323 contractors' offices at 20010 Century Boulevard in Germantown, MD. on June 26, 1995. A daily debriefing and coordination meeting was held with EM-323 management and staff. Daily audit team meetings were also held to discuss issues and concerns. The audit concluded with a postaudit conference held in the Century Boulevard Building on June 30, 1995. Personnel contacted during the audit, including those attending the preaudit and postaudit conferences, are listed in Attachment 1.

#### 5.0 SUMMARY OF AUDIT RESULTS

##### 5.1 PROGRAM EFFECTIVENESS

The audit team concluded that, in general, the EM-323 QA program is adequate and is satisfactorily implemented for the scope of the audit.

##### 5.1.1 Program Elements

The EM-323 SPPs do not exactly correspond to the 18 criteria of the QARD. Therefore, Section 5.1.2 of this report addresses the adequacy of the SPPs in addition to the seven elements identified in the scope of the audit.

##### 5.1.2 QA Program Audit Activities

Of the seven QA Program Elements audited, implementation of six was determined to be satisfactory and one was marginal. Twenty-three (23) SPPs were included in the audit sample and implementation of nineteen (19) was determined to be satisfactory. Implementation of SPP 8.02 was determined to be marginal. SPPs 5.03, 10.03 and 4.14 were not evaluated due to a lack of activity in the applicable areas.

<u>QA Program Element</u>	<u>Results</u>
1 - Organization	Satisfactory
2 - Quality Assurance Program	Marginal
5 - Instructions, Procedures, and Drawings	Satisfactory
6 - Document Control	Satisfactory
16 - Corrective Action	Satisfactory
17 - Quality Assurance Records	Satisfactory
18 - Audits	Satisfactory

**STATEMENT OF RESULTS FOR SPPs**

<b><u>PROCEDURE</u></b>	<b><u>REVISION</u></b>	<b><u>RESULTS</u></b>
SPP 1.01	13	Satisfactory
SPP 1.02	1	Satisfactory
SPP 2.01	5	Satisfactory
SPP 3.01	4	Satisfactory
SPP 3.02	4	Satisfactory
SPP 3.03	5	Satisfactory
SPP 3.05	4	Satisfactory
SPP 4.01	4	Satisfactory
SPP 4.02	6	Satisfactory
SPP 4.04	4	Satisfactory
SPP 4.12	4	Satisfactory
SPP 4.14	2	Lack of Activity
SPP 4.15	4	Satisfactory
SPP 4.16	3	Satisfactory
SPP 5.01	4	Satisfactory
SPP 5.03	5	Lack of Activity
SPP 5.07	3	Satisfactory
SPP 6.05	4	Satisfactory
SPP 7.01	6	Satisfactory
SPP 7.02	4	Satisfactory
SPP 8.02	5	Marginal
SPP 8.03	4	Satisfactory
SPP 10.03	4	Lack of Activity

**5.2 Stop Work or Immediate Corrective Actions Taken**

There were no Stop Work Orders, immediate corrective actions, or related additional items resulting from this audit.

**5.3 Audit Activities**

A summary table of the audit results is provided in Attachment 2. The details of the audit evaluation, along with the objective evidence reviewed, are contained within the audit checklists. The checklists are maintained as QA records.

**5.4 Technical Activities**

No technical activities were evaluated during the audit.

## 5.5 Summary of Deficiencies

The audit team identified five deficiencies during the audit, three of which were corrected during the audit, one was processed as a Performance Report (PR) and one was processed as a Deficiency Report (DR). A synopsis of the deficiencies documented as a PR/DR and those corrected during the audit (CDA) is detailed below. The PRs/DRs will be issued under a separate cover letter.

### 5.5.1 Corrective Action Requests (CARs)

No CARs were issued as a result of the audit.

#### PR-HQ-95-001

Eight entries in the EM-323 QARD matrix do not adequately reflect the QARD requirements. This deficiency is a PR because only remedial action is necessary, and there is no adverse impact on the activities addressed in the references. The audit team considers that the EM-323 matrix reference to QARD requirement 16.2.6B should be addressed as a priority. The subject paragraph requires the evaluation of nonconformances and significant conditions adverse to quality, and the EM-323 QARD matrix cross references the requirement to SPP 5.01 Section 4.a(4). This paragraph is limited to the evaluation of Deviation and Corrective Action Reports (DCARs) prior to issue and does not address the periodic evaluation of adverse conditions reported from each affected organization to determine the impact on other organizations. The QARD requirement is adequately addressed in SPP 8.03, which provides instructions for the QA Program Progress and Status Report, and requires the Quality Assurance Specialist (QAS) to review, analyze, and report significant trends. The FY 95 second quarter QA Program and Status report contained evidence of a review of significant trends but was incomplete because data from Defense Waste Processing Facility (DWPF) was not available to the QAS. In summary the procedures and personnel are in place to satisfactorily evaluate trend analyses or data and should be fully utilized.

#### DR-HQ-95-001

Four adverse conditions were reported regarding the EM-323 Management Assessment (MA) performed in the period August/September 1994. Two of these conditions referenced to the lack of objective evidence to support the involvement of the Director, EM-323 in the MA as required by SPP 8.02. The remaining two conditions referred to the lack of objective evidence that the MA team fully complied with two of the SPP requirements.

### **5.5.2 Deficiencies Corrected During the Audit**

Deficiencies that are considered isolated in nature and only require remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit:

Contrary to SPP 2.01, Paragraph 4.k, the EM-323 QARD Implementation Matrix was not maintained as a nonpermanent QA record. During the audit, the EM-323 Quality Assurance Program Manager (QAPM) added the matrix to the controlled document register.

Contrary to SPP 7.01, Paragraph 4.a(b), one QA document had corrections that were not properly annotated. It was determined that this was an isolated occurrence and the correction was properly annotated during the audit.

Contrary to SPP 3.01, Paragraph 4.a(9), the training needs matrix for FY94 was not completed by September 30, 1993. This was a conscious decision by EM-323 management but it was not documented. The justification for delaying the issue of the matrix was documented during the audit.

## **6.0 RECOMMENDATIONS**

The following recommendations resulted from the audit and are presented for consideration by the EM management.

- 6.1** SPP 3.02, Rev. 4, Section 4, paragraph 4.b(6) requires the training instructor to ensure that each participant completes an evaluation form for the classroom presentation. The purpose of the evaluation form is to obtain important feedback to improve the training process. It should be recognized that non compliance with QA requirements during training sessions is unacceptable because of the poor example to the trainees. It is therefore recommended that this requirement be rigidly implemented or deleted.
- 6.2** SPP 3.02 , Rev. 4 does not address the preparation and conduct of training when training material is provided by sources outside EM. The audit team recommends that such material be controlled in accordance with the requirements of SPP 3.02. A lesson plan should be prepared and a QAS should be assigned to conduct training.
- 6.3** Letters issued by the High Level Waste Program Manager to the Waste Form Producer, accepting the Waste Form Producer's Waste Form Qualification Report (WQR) Packages, should identify any unresolved concerns identified in the Waste

Acceptance Technical Review Group's Final Report ("Conclusions and Recommendations") for the associated WQR Package to assure that any concerns are totally resolved prior to final acceptance of the Waste Form Producers WQR. A letter indicating that the resolution of the concerns identified in the WQR Package Final Report should be placed in each of the affected WQR packages to assure the closure of the concerns identified in recommendation 6.3.

### **Background**

The Final Reports for three of the West Valley Demonstration Projects (WVDP) Waste Qualification Report Packages (Package 1, 2, & 3) all state that "It should be noted, however, that this conclusion and recommendation are contingent upon successful resolution of VQ/TRG-0479 concerns and DCAR #94EA-WV-AU-02-D03 as discussed in Section 2 above." The concern deals with the qualification of existing data used in the WVDP Data Packages that are referenced in the WQR Packages.

- 6.4 The EM Requirements Traceability Matrix lists the implementation link for QARD 17.2.1.A5 to SPP 7.01, Section 3b. The audit team recommends that the Matrix be corrected to reflect N/A because EM-323 does not retain any records pertaining to waste form production.

## **7.0 LIST OF ATTACHMENTS**

- Attachment 1: Personnel Contacted During the Audit  
Attachment 2: Summary table of Audit Results

**ATTACHMENT 1**  
**Personnel Contacted During the Audit**

NAME	ORGAN.	TITLE	PRE	CONTACT	POST
E. Bradford	INEL	Observer	X	X	X
J. Yocum	BDM	Tech. Support			X
G. Camasta	BDM	Records Task Mgr.	X	X	X
J. Conway	EM-323	QA Prog. Mgr.	X	X	X
S. Crawford	SAIC	Sr. Quality Engineer	X	X	X
M. Vignone	EM-141	Records Mgr.	X		
R. Erickson	EM-323	Director		X	
J. Flaherty	SAIC	QA Specialist			X
K. Grisham	EM-323	QA Specialist		X	
R. Hartstern	MACTEC	QA Specialist	X	X	X
C. Hunter	MACTEC	QA Specialist	X	X	
R. Jakubik	BDM	Sr. Staff Member			X
R. Webber	USNRC	Observer	X	X	
J. LeVea	BDM	Sr. Staff Member	X	X	X
R. Lowder	MACTEC	Sr. Consultant	X	X	
RJ. Buckley	USNRC	Observer	X	X	
W. McClanahan	BDM	Sr. QA Engineer	X	X	
T. McIntosh	EM-323	WVDP Program Mgr.	X	X	
N. Moreau	MACTEC	QA Specialist		X	X
K. Picha	EM-323	DWPF Prog. Mgr.		X	
L. Sirianni	SAIC	QA Specialist	X	X	X
J. Smith	MACTEC	QA Specialist	X	X	X
D. Strother	MACTEC	Training Specialist	X	X	X
R. Toro	BDM	Sr. Staff Member	X		X
L. Wade	MACTEC	QA Specialist	X	X	X
C. Weber	RW-3.1	QA Specialist	X	X	

**ATTACHMENT 2**  
**Summary Table of Audit Results**

Audit Report  
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<b>COMPLIANCE AUDIT NO. HQ-ARC-95-08 DETAIL SUMMARY</b>							
<b>QARD ELEMENT</b>	<b>DOCUMENTS REVIEWED</b>	<b>DETAILS ( Checklist)</b>	<b>DRs</b>	<b>PRs</b>	<b>CDA</b>	<b>RECOMMEND</b>	<b>PROCEDURE COMPLIANCE</b>
6.0	SPP 1.01	pgs 1-8*					<i>Satisfactory</i>
1.0	SPP 1.02	pgs 1-4					<i>Satisfactory</i>
5.0	SPP 2.01	pgs 1-10		1	1		<i>Satisfactory</i>
2.0	SPP 3.01	pgs 1-8			1		<i>Satisfactory</i>
A2.0	SPP 3.02	pgs 1-11				2	<i>Satisfactory</i>
2.0	SPP 3.03	pgs 1-7					<i>Satisfactory</i>
2.0	SPP 3.05	pgs 1-3					<i>Satisfactory</i>
18.0	SPP 4.01	pgs 1-7					<i>Satisfactory</i>
18.0	SPP 4.02	pgs 1-8					<i>Satisfactory</i>
2.0	SPP 4.04	pgs 1-8					<i>Satisfactory</i>
N/A	SPP 4.12	pgs 1-3					<i>Satisfactory</i>
2.0	SPP 4.14	pgs 1-3					<i>Lack of activity</i>
N/A	SPP 4.15	pgs 1-7				1	<i>Satisfactory</i>
6.0	SPP 4.16	pgs 1-5					<i>Satisfactory</i>
18.0	SPP 5.01	pgs 1-9					<i>Satisfactory</i>

**ATTACHMENT 2**  
**Summary Table of Audit Results**

Audit Report  
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<b>COMPLIANCE AUDIT NO. HQ-ARC-95-08 DETAIL SUMMARY</b>							
<b>QARD ELEMENT</b>	<b>DOCUMENTS REVIEWED</b>	<b>DETAILS ( Checklist)</b>	<b>DRs</b>	<b>PRs</b>	<b>CDA</b>	<b>RECOMMEND</b>	<b>PROCEDURE COMPLIANCE</b>
16.0	SPP 5.03	pgs 1-5					<i>Lack of activity</i>
16.0	SPP 5.07	pgs 1-4					<i>Satisfactory</i>
6.0	SPP 6.05	pgs 1-8					<i>Satisfactory</i>
17.0	SPP 7.01	pgs 1-9			1	1	<i>Satisfactory</i>
17.0	SPP 7.02	pgs 1-8					<i>Satisfactory</i>
2.0	SPP 8.02	pgs 1-6	1				<i>Marginal</i>
2.0	SPP 8.03	pgs 1-4					<i>Satisfactory</i>
1.0	SPP 10.03	pgs 1-3					<i>Lack of activity</i>
<b>TOTAL</b>		<b>148</b>	<b>1</b>	<b>1</b>	<b>3</b>	<b>4</b>	<b>Satisfactory</b>

\* SPP 1.01 is the SPP index and was included in the audit of SPP 6.05

"DOCUMENTS REVIEWED" includes the referenced procedure or process step and the associated records/objective evidence

CDA ..... Corrected During Audit

DR ..... Deficiency Report

PR ..... Performance Report

RECOMMEND Recommendations

COMPLIANCE Procedures Implemented

N/A ..... No cross reference to the QARD