

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

AUDIT REPORT OF
OFFICE OF ENVIRONMENTAL MANAGEMENT (EM)
HIGH LEVEL WASTE DIVISION (EM-323)
GERMANTOWN, MD

AUDIT NO. HQ-94-03
JUNE 27 THROUGH JULY 1 1994

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Date: 8/31/94

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Date: 9/7/94

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit HQ-94-03, the audit team concluded that the overall implementation of the EM-323 QA program in accordance with the OCRWM QARD (DOE/RW/0333P) and EM-323 implementing procedures is effective.

This audit was conducted to review and assess the effectiveness of implementation of EM-323 SPPs (Standard Practice Procedures) prepared in accordance with DOE/RW/0333P requirements.

The audit team examined ten QA Program Elements: Organization, QA Program, Procurement Document Control, Instructions, Procedures, and Drawings, Document Control, Control of Purchased Items, Corrective Action, QA Records, Audits, and Appendix A to DOE/RW/0333P.

Implementation of six of the ten QA Program Elements audited were determined to be satisfactory, two were unsatisfactory, one was marginal, and one had a lack of activity.

Four Corrective Action Requests (CARs) were written to document those deficiencies which could not be corrected during the course of the audit.

Two deficiencies, requiring only remedial action, were corrected during the audit. One deficiency was not processed as a CAR since resolution of a QARD Requirements Matrix comment is tracking the condition.

Four recommendations were written for EM-323 management consideration.

Progress has been made towards full compliance with DOE/RW/0333P. OCRWM comments to the EM-323 QARD Requirements Matrix are currently in the process of resolution; implementing procedures are being revised to reflect the new EM-323 organization, and the transition from DOE/RW/0214 to DOE/RW/0333P.

The audit team concluded that significant improvement has been made in the implementation of and compliance with the High Level Waste Division (EM-323) QA Program since the last OCRWM audit in January 1993. The principal areas of improvement noted were in the areas of Records Management, Audits, and Training.

The EM oversight of vitrification processes could be further enhanced by conducting performance based audits of processes, activities, and items identified as important to waste production and acceptance. In addition, increased focus should be placed on the technical adequacy of the end products being produced.

2.0 SCOPE

2.1 QA Program Elements

The following QA Program Elements were evaluated during the audit in accordance with the published audit schedule:

- 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
- DOE/RW/0333P Appendix A

Requirements were drawn from the OCRWM QARD (DOE/RW/0333P) and EM-323 Standard Practice Procedures.

2.3 Technical Areas

No Technical Specialist was assigned because the audit was classified as 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>ORGANIZATION</u>	<u>QA PROGRAM ELEMENT/REQUIREMENT</u>
AUDITORS		
Fred Bearham	QATSS	Audit Team Leader
Rob Howard	QATSS	1,2, & Appendix A
Jim George	QATSS	1,2, & Appendix A
Tom Swift	QATSS	6,16, & 18
Charles Betts	QATSS	6,16, & 18
Conrad Coulombe	QATSS	4,5,7, & 17
Pat Cotter	QATSS	4,5,7, & 17
OBSERVERS		
Jack Spraul	USNRC	
Bruce Mabrito	USNRC	

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 27, 1994. 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 potential deficiencies. The audit was concluded with a postaudit conference held in the Century Boulevard Building on July 2, 1994. 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, EM-323 is effectively implementing the EM-323 QA Program in accordance with the OCRWM QARD and the associated EM-323 implementing procedures.

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 addresses implementation of the SPPs in addition to the 10 elements identified in the scope of the audit

5.1.2 QA Program Audit Activities

Of the ten QA Program Elements audited, implementation of six Elements was determined to be satisfactory, two were determined to be unsatisfactory, one was marginal, and one had a lack of activity. Twenty-seven SPPs were included in the audit sample. Implementation of nineteen (19) SPPs was determined to be satisfactory. Implementation of two SPPs was determined to be unsatisfactory and two were determined to be marginal. Four SPPs were not evaluated due to a lack of activity in the applicable areas.

RESULTS BY ELEMENT

<u>QA PROGRAM ELEMENT</u>	<u>RESULTS</u>
1 - Organization	Satisfactory
2 - Quality Assurance Program	Unsatisfactory
4 - Procurement Document Control	Satisfactory
5 - Instructions, Procedures, and Drawings	Marginal
6 - Document Control	Satisfactory
7 - Control of Purchased Items and Services	Lack of activity
16 - Corrective Action	Unsatisfactory
17 - Quality Assurance Records	Satisfactory
18 - Audits	Satisfactory
Appendix A	Satisfactory

RESULTS BY SPPs

<u>PROCEDURE</u>	<u>REVISION</u>	<u>RESULTS</u>
SPP 1.01	10	Satisfactory
SPP 1.02	0	Satisfactory
SPP 2.01	4	Marginal
SPP 2.03	3	Satisfactory
SPP 3.01	3	Satisfactory
SPP 3.02	3	Satisfactory
SPP 3.03	3	Marginal
SPP 3.05	3	Unsatisfactory
SPP 4.01	3	Satisfactory
SPP 4.02	4	Satisfactory
SPP 4.04	3	Satisfactory
SPP 4.08	3	Lack of Activity
SPP 4.12	3	Satisfactory
SPP 4.13	3	Satisfactory
SPP 4.14	1	Lack of Activity
SPP 4.15	2	Satisfactory
SPP 4.16	1	Satisfactory
SPP 5.01	3	Satisfactory
SPP 5.03	4	Lack of Activity
SPP 5.07	2	Satisfactory
SPP 6.05	3	Satisfactory
SPP 7.01	5	Satisfactory

<u>PROCEDURE</u>	<u>REVISION</u>	<u>RESULTS</u>
SPP 7.02	3	Satisfactory
SPP 8.02	3	Satisfactory
SPP 8.03	3	Satisfactory
SPP 10.01	3	Unsatisfactory
SPP 10.03	3	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 QA Program Audit Activities

Details of the audit activities along with the objective evidence reviewed are contained within the audit checklists. The checklists are processed as QA Records. A summary table of results is provided in Attachment 2.

5.4 Technical Activities

No technical activities were evaluated during the audit.

5.5 Summary of Deficiencies

The audit team identified seven deficiencies. Two of these were corrected during the audit and one was deferred to the QARD Requirements Matrix review process. Four deficiencies were documented on Corrective Action Reports (CARs).

A synopsis of the deficiencies documented as CARs and those corrected during the audit are detailed below.

5.5.1 Corrective Action Requests (CARs)

As a result of the audit, the following CARs were issued:

CAR-HQ-94-021

Procedures do not describe how education and experience are verified. There is no objective evidence that the verification is based on position description requirements and there is no evidence to indicate the method of verification.

CAR-HQ-94-022

There is no objective evidence to indicate the review criteria considered during the review of SPPs.

CAR-HQ-94-023

The analysis of Adverse Quality Trends Report for the second quarter of FY94 does not include inputs required by SPP 10.01 Section 4b-Analyzing Trend Data, paragraphs (1), (2), and (3).

CAR-HQ-94-024

Several SPPs contain requirements that are not being implemented:

SPP 3.03. The Master Surveillance and Review Personnel Qualification List is not maintained.

SPP 4.02. The titles of personnel contacted during the audit are not being recorded in audit reports.

SPP 6.05. Conflict regarding the disposition of SPP manuals which are no longer required by manual holders. The SPP requires the manuals to be returned to the QA Program Manager for reassignment and a subsequent memo directs them to be destroyed.

SPP 4.15. Does not address the personnel qualification records to be transmitted to the Document Control Center and does not adequately describe the qualification requirement for TRG personnel.

SPP 4.14. Section 2 addresses out of date references.

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:

1. An SPP manual assigned to a Program Manager did not include recent SPP revisions. The revised SPPs were in the PMs office and placed in the manual immediately.
2. A surveillance report requiring the signature of the Program Manager was unsigned. The report was signed during the audit and it was determined that the lack of a signature had no adverse impact on the activity.

3. Verification of Education and experience for EM-323 staff and contractors and documentation of certification of Lead Auditors does not adequately comply with DOE/RW/0333P. This deficiency is being tracked through the QARD Requirements Matrix process.

6.0 RECOMMENDATIONS

The following recommendations resulted from the audit and are presented for consideration by EM-323 management.

1. SPP 2.01, Rev. 4, Section 4, paragraphs f.(1) and g.(1)(c), respectively, require the OAPM to "Review SPPs within one year of the latest revision" (and) "processes . . . (the review) documentation . . . into the quality records system."

To date, this annual review has not been accomplished nor documented in accordance with the SPP but the SPPs have been revised more frequently than annually. The audit team believes that this meets the intent of the requirement, however, the audit team recommends that the SPP be revised to include provisions for an "either/or" requirement. The requirement, as written, is not strictly being implemented.
2. SPP 1.02, Rev. 0, Section 3, third paragraph, last sentence, states in part that "the MOA, dated 10/30/91, --- Appropriate technical and QA requirements be incorporated into the MOA." The chronology of the MOA is past tense (the MOA is from 1991 and the SPP was written in 1993). This appears to be a mistake and/or typo and EM did not intend to revise the MOA. This item is addressed in the new proposed draft SPP 1.02, Rev. 1. The recommendation of the audit team is that the technical and QA requirements be clarified or deleted from the proposed revised SPP.
3. SPP 2.01, Rev. 4, Attachment C, Review Comment Record (RCR) does not include provisions for a continuation sheet. Consequently, when SPP reviewers have more than one page of comments, each page is the same format as the lead page. The audit team recommends that SPP 2.01 be revised to require that the RCR forms be completed or provisions included for a continuation sheet.
4. SPP 2.01, Rev. 4, Section 3.a., paragraph 3, requires the change transmittal memorandum accompanying a new or revised SPP to include the effective date as well as the training or reading assignment necessary. Currently training assignment is specified in a separate memo to be issued within ten days of the effective date. The audit team recommends that the specified training be included on the memorandum with the initial transmittal.

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
J. Allison	EM-323	Engineer		X	
R. Blaney	EM-33	Deputy Director	X		X
G. Camasta	BDM	Records Task Manager		X	X
J. Conway	EM-323	QA Prog. Mgr.	X	X	X
S. Crawford	SAIC	Sr. Quality Engineer		X	X
A. Dasti	BDM	Staff Member		X	X
R. Erickson	EM-323	Director	X	X	X
J. Flaherty	SAIC	QA Specialist			X
C. Good	SAIC	Sr. Records Mgt. Specialist		X	
K. Grisham	EM-323	QA Specialist	X	X	X
R. Hartstern	MACTEC	QA Specialist	X	X	X
J. Hennessey	EM-361	HWVP Acting Prog. Mgr.	X		X
C. Hunter	MACTEC	QA Specialist	X	X	X
R. Jakubik	BDM	Sr. Staff Member		X	X
R. Johnson	USNRC	Observer	X		X
L. Ledingham	MACTEC	QA Specialist	X	X	X
J. Lefman	SAIC	QA Group Manager			X
J. LeVea	BDM	Sr. Staff Member	X	X	X
R. Lowder	MACTEC	Sr. Consultant	X	X	X
R. Mabrito	USNRC	Observer	X	X	X
W. McClanahan	BDM	Sr. QA Engineer	X	X	X
T. McIntosh	EM-323	WVDP Program Manager		X	
J. Mikolajezak	BDM	SR. Staff Member			X
C. Miller	EM-323	TRG Program Manager		X	

ATTACHMENT 1

Personnel Contacted During the Audit

NAME	ORGAN.	TITLE	PRE	CONTACT	POST
W. Moreau	MACTEC	Specialist	X	X	X
R. Murthy	RW-3.1	QA Specialist		X	X
K. Picha	EM-323	DWPF Prog. Mgr.	X	X	X
L. Sirianni	SAIC	QA Specialist - DWPF	X	X	X
J. Smith	MACTEC	QA Specialist	X	X	X
J. Spraul	USNRC	Observer	X	X	X
D. Strother	MACTEC	Training Specialist	X	X	X
R. Toro	BDM	Sr. Staff Member			X
Ha Vu	EM-323	DWPF Program Integration			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

DISCUSSION

For the ten QA Program Elements evaluated during the audit, the implementation of six was determined to be satisfactory. Those elements were: 1.0, 4.0, 6.0, 12.0, 17.0, and 18.0. Among these seven elements, three deficiencies corrected during the audit are reported in paragraph 5.5.2. Element 7.0 was not evaluated due to a lack of activity.

The implementation of Element 5.0 was determined to be marginal due to the adverse conditions addressed in CAR HQ-94-022. Section 6.0 includes three recommendations relative to Element 5.0.

The implementation of Elements 2.0 and 16.0 were determined to be unsatisfactory. Element 2.0 is the subject of two CARs; HQ-94-021 and HQ-94-024. Element 16.0 is determined to be unsatisfactory because of the adverse condition addressed in CAR HQ-94-023. Elements 4.0 and OCRWM QARD Appendix A are subject to acceptance of the EM-323 QARD Requirements Matrix.

Although the audit team determined that the Element 4 and OCRWM QARD Appendix A are being satisfactorily implemented, it is not established that these areas are in compliance with OCRWM QARD resolution of comments to the QARD Requirements Matrix.

ATTACHMENT 2 (Continued)

Summary Table of Audit Results

AUDIT HQ-94-03 DETAIL SUMMARY								
ELEMENT	DOCUMENTS REVIEWED	DETAILS (✓ List)	CARs	CDA	RECOMMEND	ADEQUACY	COMPLIANCE	OVERALL
1	SPP 1.02, R0	Pgs. 1-5			2		SAT	SAT
	SPP 10.03, R3	Pgs. 1-3					lack of activity	
	SPP 2.03, R3	Pgs. 1-3					SAT	
2	SPP 3.01, R3	Pgs. 1-6					SAT	UNSAT
	SPP 3.02, R3	Pgs. 1-5					SAT	
	SPP 3.03, R3	Pgs. 1-3	HQ-94-024				Marginal	
	SPP 3.05, R3	Pgs. 1&2	HQ-94-021	3			UNSAT	
	SPP 4.04, R3	Pages 1&2		2			SAT	
	SPP 4.08	Pgs. 1-4					lack of activity	
	SPP 4.14, R1	Pgs. 1-6	HQ-94-024				lack of activity	
	SPP 4.15, R2	Pgs. 1-6	HQ-94-024				SAT	
	SPP 4.16, R1	Pgs. 1-5					SAT	
	SPP 8.02, R3	Pgs. 1-6					SAT	
	SPP 8.03, R3	Pgs. 1-3					SAT	
4	SPP 4.12, R3	Pgs. 1-3					SAT	SAT
5	SPP 2.01, R4	Pgs. 1-6	HQ-94-022		1, 3, 4		Marginal	Marginal

ATTACHMENT 2 (Continued)

Summary Table of Audit Results

AUDIT HQ-94-03 DETAIL SUMMARY								
ELEMENT	DOCUMENTS REVIEWED	DETAILS (✓ List)	CARs	CDA	RECOMMEND	ADEQUACY	COMPLIANCE	OVERALL
6	SPP 1.01, R10	Pgs. 1-5		1			SAT	SAT
	SPP 6.05, R3	Pgs. 1-7	HQ-94-024				SAT	
7	N/A	Pgs. 1&2					lack of activity	
16	SPP 5.01, R3	Pgs. 1-5					SAT	UNSAT
	SPP 5.03, R4	Pgs. 1-4					lack of activity	
	SPP 5.07, R2	Pgs. 1-4					SAT	
	SPP 10.1, R3	Pgs. 1-5	HQ-94-023				UNSAT	
17	SPP 7.01, 5	Pgs. 1&2					SAT	SAT
	SPP 7.02, R3	Pgs. 1-4					SAT	
18	SPP 4.01, R3	Pgs. 1-4					SAT	SAT
	SPP 4.02, R4	Pgs. 1-5	HQ-94-024				SAT	
	SPP 4.13, R3	Pgs. 1-3					SAT	
	APPENDIX A	Pgs. 1-3					SAT	SAT
TOTAL		122	4	3	4			Effective

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

CARs..... Corrective Action Requests
CDA..... Corrected During Audit
RECOMMEND..... Recommendations
ADEQUACY..... Requirements in Procedures
COMPLIANCE..... Procedures Implemented
OVERALL..... Summary of Element