

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

AUDIT REPORT OF
THE OFFICE OF WASTE MANAGEMENT (EM-30)
OFFICE OF EASTERN WASTE MANAGEMENT OPERATIONS (EM-32)
GERMANTOWN, MD

AUDIT NO. HQ-ARC-96-02
JUNE 17 THROUGH JUNE 20, 1996

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Date: 7/11/96

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Date: 7/19/96

1.0 EXECUTIVE SUMMARY

Audit HQ-ARC-96-02 was conducted to review and assess the effectiveness of EM-32 compliance with the QARD and implementation of EM-32 Standard Practice Procedures (SPPs) and was planned and scheduled as a compliance audit.

As a result of Quality Assurance (QA) Audit HQ-ARC-96-02, the audit team determined that EM-32 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 4, and EM-32 implementing procedures for QA Program Elements 1, 2, 5, 6, 16, 17, 18 and QARD Appendix A.

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

2.0 SCOPE

The audit was a compliance-based evaluation of the effectiveness of the EM-32 quality assurance (QA) program and associated EM-37 quality assurance activities.

Follow-up of open OCRWM initiated deficiencies identified during previous QA audits were included in the scope of the audit to determine the effectiveness of EM-32 corrective actions. Additionally, SPPs 8.02 and 8.03 which were not baselined during the FY95 audit (HQ-ARC-95-08) were reviewed and accepted for baseline approval during this audit.

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
Appendix A	High-Level Waste Form Production

The following QA Program Elements were not evaluated during the audit because those activities identified below are not applicable to EM Headquarters activities. Activities identified below are delegated to the field offices with the exception of Supplement IV(S IV) and Appendix B which are not applicable to waste form production.

3	Design Control
4	Procurement Document Control
7	Control Of Purchased Items And Services
8	Identification And Control Of Items
9	Control Of Special Processes
10	Inspection
11	Test Control
12	Control of Measuring And Test Equipment
13	Handling, Storage, And Shipping
14	Inspection, Test And Operating Status
15	Nonconformances
S I	Software
S II	Sample Control
S III	Scientific Investigation
S IV	Field Surveying
App. B	Transportation, And Appendix C, Mined Geologic Disposal System

Checklists developed from the OCRWM QARD (DOE/RW/0333P) and EM-32 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 the observers.

<u>Title</u>	<u>Name</u>	<u>Organization</u>	<u>SPPs Audited</u>
ATL	Charles E. Betts	QATSS	3.01, 3.02, 3.03, 3.05, 5.03, & 10.03
Auditor	James George	QATSS	1.02, 2.01, 4.12, 4.14, 4.15, & Appendix A
Auditor	Don Hendrix	QATSS	5.01, 5.07, 6.05, 7.01, & 7.02
Auditor	Jack Walsh	QATSS	4.01, 4.02, 4.04, 4.16, 8.02, & 8.03
Observer	Ram Murthy	RW-3.1	

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The preaudit conference was held at EM-32 offices in Germantown, MD on June 17, 1996. A daily debriefing and coordination meeting was held with EM-32 management and staff. Daily audit team meetings were also held to discuss issues and concerns. The audit concluded with a postaudit conference held on June 20, 1996. 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 the EM-32 QA program is adequate and is satisfactorily being implemented for the scope of the audit.

5.1.1 Program Elements

The EM-32 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 elements identified in the scope of the audit. In addition, Attachment 2 of this report addresses the adequacy of EM-32 SPPs.

5.1.2 QA Program Audit Activities

Of the QA Program Elements audited, implementation for seven was determined to be satisfactory and one was unsatisfactory. Twenty-three (23) SPPs were included in the audit sample and implementation for twenty-two (22) was determined to be satisfactory. Implementation of SPP 2.01 was determined to be unsatisfactory. SPPs 5.03 and 10.03 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	Satisfactory
5 Instructions, Procedures, and Drawings	Unsatisfactory
6 Document Control	Satisfactory
16 Corrective Action	Satisfactory
17 Quality Assurance Records	Satisfactory
18 Audits	Satisfactory
Appendix A High-Level Waste Form Production	Satisfactory

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 deficiencies during the audit, one of which was corrected during the audit, two were processed as Performance Reports (PRs) 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.

5.5.2 Deficiency Reports (DRs)

HQ-96-D-009

SPP 2.01, Revision 5, "Standard Practice Procedures," and the QARD Requirements Matrix state in part that: "Work performed by EM-32 is properly planned and accomplished under controlled conditions. The SPPs provide positive control over external interfaces between affected organizations and internal interfaces with the various EM organizations. The procedure preparation process prescribed by SPP 2.01 applies to both new procedures and subsequent revisions."

Contrary to this requirement, SPPs were being changed via DOE Memorandum and not through the SPP revision process.

5.5.3 Performance Reports (PRs)

HQ-96-P-004

SPP 1.02, Revision 1, "Organization" does not reflect the current EM-32 organization due to a re-organization within EM-30. In addition, all of the responsibilities and reporting functions are not correctly defined as required by the QARD, Section 1.2.

HQ-96-P-005

Quality Assurance Records, generated as a result of the implementation of SPP 4.15, Revision 5, "Administration and Performance of Reviews by Technical Review Groups," are not identified within the procedure as either lifetime (L) or non-permanent (N) records as required by the QARD, Section 5.2.2.

5.5.4 Deficiencies Corrected During the Audit (CDAs)

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

SPP 3.05, Revision 5, "Administration of Personnel Certification, Qualification, and Training Records," Section 4.a(1)d states that: "The QAS maintains and provides access to the following documents for each person in accordance with applicable portions of the DOE-28 Training Records System".... "Position descriptions identifying the minimum education and experience requirements for each position." Contrary to this requirement, the minimum education & experience requirements were not defined for (1) federal EM employee. This item was corrected during the audit by placing, into the individual's Qualification and Certification file, a copy of the Federal Qualification Standard which identifies the minimum education and experience requirements for the position currently held by the employee.

6.0 RECOMMENDATIONS

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

- 6.1** The audit team recommends that SPP 2.01 be revised to provide a mechanism to allow for a controlled "quick change process" for procedures.

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. Antizzo	EM-37	Office Director	X		X
C. Betts	QATSS/ CER	Lead Auditor	X		X
G. Camasta	EM-14/SFI	Central Records Facility Supervisor		X	
J. Conway	EM-37	Quality Assurance Manager	X	X	X
S. Crawford	EM-67 SAIC	Waste Management Specialist	X		X
R. Erickson	EM-32	Director	X		
K. Fisher	EM-32	Program Manager			X
J. George	QATSS/ CER	Auditor	X		X
K. Grisham	EM-32	QA Specialist	X	X	
B. Hartstern	EM-37/ MACTEC	QA Specialist	X	X	X
D. Hendrix	QATSS/ CER	Auditor	X		X
J. LeVea	EM-37/ BDM	QA Specialist	X	X	X
T. McIntosh	EM-32	Program Manager	X		X
N. Moreau	EM-37 MACTEC	QA Specialist	X	X	X
R. Murthy	DOE/ RW 3.1	Observer	X		X
K. Picha	EM-32	Team Leader	X	X	X
M. Rawlings	EM-32	Vitrification Engineer		X	X
L. Sirianni	EM-32 SAIC	QA Specialist	X		X
J. Smith	EM-37 MACTEC	QA Specialist	X	X	X
D. Strother	EM-37 MACTEC	QA Specialist	X	X	X

NAME	ORGAN.	TITLE	PRE	CONTACT	POST
B. Toro	BDM	QA Specialist	X		X
L. Wade	EM-37 MACTEC	QA Specialist	X	X	X
J. Walsh	QATSS/ CER	Auditor	X		X

ATTACHMENT 2
Summary Table of Audit Results

COMPLIANCE AUDIT NO. HQ-ARC-96-02 DETAIL SUMMARY							
QARD ELEMENT	DOCUMENTS REVIEWED	DETAILS (Checklist)	DRs	PRs	CDA	RECOMMEND	PROCEDURE COMPLIANCE
6.0	*SPP 1.01	Pgs. 1-4*					SATISFACTORY
1.0	SPP 1.02	Pgs. 1-3		HQ-96-P-004 #2			SATISFACTORY
5.0	SPP 2.01	Pgs. 1-3	HQ-96-D-009 #1			#5	UNSATISFACTORY
2.0	SPP 3.01	Pgs. 1-6	HQ-96-D-009 #1				SATISFACTORY
2.0	SPP 3.02	Pgs. 1-5					SATISFACTORY
2.0	SPP 3.03	Pgs. 1-6					SATISFACTORY
2.0	SPP 3.05	Pgs. 1-5			#3		SATISFACTORY
18.0	SPP 4.01	Pgs. 1-5					SATISFACTORY
18.0	SPP 4.02	Pgs. 1-5					SATISFACTORY
2.0	SPP 4.04	Pgs. 1-4					SATISFACTORY
N/A	SPP 4.12	Pgs. 1-2					SATISFACTORY
2.0	SPP 4.14	Pgs. 1-2					SATISFACTORY
N/A	SPP 4.15	Pgs. 1-3		HQ-96-P-005 #4			SATISFACTORY
6.0	SPP 4.16	Pgs. 1-5					SATISFACTORY
16.0	SPP 5.01	Pgs. 1-3					SATISFACTORY

ATTACHMENT 2
Summary Table of Audit Results

COMPLIANCE AUDIT NO. HQ-ARC-96-02 DETAIL SUMMARY							
QARD ELEMENT	DOCUMENTS REVIEWED	DETAILS (Checklist)	DRs	PRs	CDA	RECOMMEND	PROCEDURE COMPLIANCE
16.0	SPP 5.03	Pgs. 1-5					<i>Lack of Activity</i>
16.0	SPP 5.07	Pgs. 1-3	HQ-96-D-009 #1				SATISFACTORY
6.0	SPP 6.05	Pgs. 1-4					SATISFACTORY
17.0	SPP 7.01	Pgs. 1-4					SATISFACTORY
17.0	SPP 7.02	Pgs. 1-4					SATISFACTORY
2.0	SPP 8.02	Pgs. 1-4	HQ-96-D-009 #1				SATISFACTORY
2.0	SPP 8.03	Pgs. 1-4					SATISFACTORY
1.0	SPP 10.03	Pgs. 1-3					<i>Lack of Activity</i>
APPENDIX A	APPENDIX A	Pgs. 1-2					SATISFACTORY
TOTAL		94	1	2	1	1	SATISFACTORY

* 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
- CAR Corrective Action Report
- DR Deficiency Report
- PR Performance Report
- RECOMMEND Recommendations
- COMPLIANCE Procedures Implemented
- N/A No cross reference to the QARD
- LOA Lack of Activity