

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

AUDIT REPORT

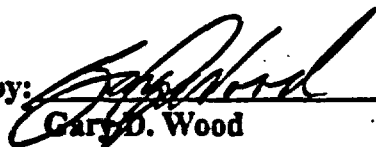
OF THE

**U. S. DEPARTMENT OF ENERGY
OFFICE OF WASTE MANAGEMENT
OFFICE OF EASTERN OPERATIONS
AND
OFFICE OF PROGRAM INTEGRATION**

GERMANTOWN, MARYLAND

**AUDIT NUMBER EM-ARC-97-18
JUNE 2 THROUGH JUNE 5, 1997**

Prepared by:

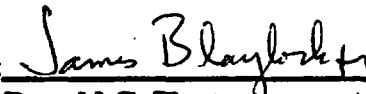


**Gary D. Wood
Audit Team Leader
Office of Quality Assurance**

Date:

6/24/97

Approved by:



**Donald G. Horton
Director
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Date:

7/2/97

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Enclosure

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit EM-ARC-97-18, the audit team determined that the Department of Energy (DOE), Office of Waste Management, Office of Eastern Operations (EM-32) and Office of Program Integration (EM-37), with the exception of areas where deficiencies exist, are satisfactorily implementing applicable portions of the QA Program described in the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 5, and EM-32 Standard Practice Procedures (SPP) for High-Level Waste. QA Program Elements 1.0, 2.0, 5.0, 6.0, 16.0, 17.0, 18.0, and Appendix A were found satisfactory by the audit team. QA Program Elements 3.0, 4.0, 7.0, 8.0, 9.0, 10.0, 11.0, 12.0, 13.0, 14.0, 15.0, Supplements I, II, III, IV, V, Appendix B and C were determined not to be applicable to EM-32/37 headquarters high-level waste activities.

EM-32/37 have performed an impact evaluation and have determined that QARD, Revision 6, has no impact on EM-32/37 headquarters high-level waste activities.

The audit team identified four deficiencies during the course of the audit that resulted in the issuance of three Deficiency Reports described in Section 5.5.2 of this report. There was one deficiency identified by the audit team that was corrected prior to the post-audit meeting. This condition is described in Section 5.5.4 of this report. Additionally, there were two 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, compliance, and the effectiveness of EM-32/37 in implementing the QA Program as described in the QARD and the EM-32 SPPs for high-level waste activities.

The following QA Program Elements/Requirements were evaluated during the audit, in accordance with the approved audit plan.

QA PROGRAM ELEMENTS/REQUIREMENTS

1.0	Organization
2.0	Quality Assurance Program
5.0	Implementing Documents
6.0	Document Control
16.0	Corrective Action

- 17.0 Quality Assurance Records
- 18.0 Audits
- Appendix A High-Level Waste Form Production

The following QA Program Elements/Requirements were not reviewed during the audit because they are not applicable to the EM-32/37 headquarters scope of work.

- 3.0 Design Control
- 4.0 Procurement Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Items
- 9.0 Control of Special Processes
- 10.0 Inspection
- 11.0 Test Control
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Storage and Shipping
- 14.0 Inspection, Test and Operating Status
- 15.0 Nonconformances
- Supplement I Software
- Supplement II Sample Control
- Supplement III Scientific Investigation
- Supplement IV Field Surveying
- Supplement V Control of the Electronic Management of Data
- Appendix B Storage and Transportation
- Appendix C Mined Geologic Disposal System

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members and observers and their assigned areas of responsibility:

<u>Name/Title/Organization</u>	<u>QA Program Elements/Requirements, Technical Areas, Processes, Activities or End-Products</u>
Gary D. Wood, Audit Team Leader, OQA	QA Program Elements 1.0, 2.0, and 17.0
Charlie C. Warren, Auditor, OQA	QA Program Elements 5.0, 6.0, 16.0, 18.0, and Appendix A.
Trieu Troung, Observer, RW-51.	

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The pre-audit meeting was held at the EM-32/37 offices in Germantown, Maryland on June 2, 1997. A daily debriefing and coordination meeting was held with the EM-32/37 management, and daily audit team meetings were held to discuss issues and potential deficiencies. The audit was concluded with a post-audit meeting on June 5, 1997. Personnel contacted during the audit are listed in Attachment 1. The list includes those who attended the pre-audit and post-audit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall, for the program elements that have been implemented, the QA Program is adequate and is being satisfactorily implemented by EM-32/37 for the scope of this audit. The results for each program element evaluated are contained in Attachment 2, Summary Table of Audit Results.

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

A summary table of audit results is provided in Attachment 2. The audit checklists contain the details of the audit evaluation along with identification of the objective evidence reviewed. The checklists are maintained as QA Records.

5.4 Technical Audit Activities

There were no technical activities evaluated during the audit.

5.5 Summary of Deficiencies

The audit team identified three deficiencies during the audit for which three Deficiencies Reports (DR) have been issued. One additional deficiency was identified and corrected prior to the post-audit meeting.

Synopses of deficiencies documented as DRs and the one corrected during the audit are detailed below. The DRs have been transmitted under a separate letter.

5.5.1 Corrective Action Requests (CAR)

None

5.5.2 Deficiency Reports

YM-97-D-062

A memorandum designating the reviewers and review criteria for Issue 16 of the SPPs was not issued by the Project Manager as required by SPP 4.16, Revision 4. Consequently, the auditors could not verify that revised procedures in Issue 16 were reviewed by all required disciplines and organizations.

YM-97-D-063

A QA Specialist, designated by memorandum as being responsible for implementing four SPPs, performed as the Lead Auditor for an internal audit that evaluated the work performed under the four SPPs. SPP 4.02 requires that the Lead Auditor and Auditors be independent of any responsibility for the performance of activities they audit.

YM-97-D-064

Five instances of procedure noncompliance are documented in this DR. The noncompliances consisted of records that were missing, authenticating signatures, a training and qualification file that could not be located, documentation missing from training record files, and failure to process QA records in a timely fashion into the records center.

5.5.3 Performance Reports

None.

5.5.4 Deficiencies Corrected During the Audit

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

The controlled document index, controlled distribution lists, and receipt acknowledgments for the EM Waste Acceptance Process Specification were not on file at the Central Records Facility (CRF) as required by SPP 6.01, Revision 0.

This condition was corrected by the CRF obtaining the missing documents from the previous records contractor and entering them into the records file.

6.0 RECOMMENDATIONS

The following recommendations resulted from the audit and are presented for consideration by the EM-32/37 management:

1. It is recommended that the Fiscal Year (FY) 1997 Evaluation and Assessment Schedule be revised in accordance with SPP 4.01 to reflect changes/postponements of assessment activities from those identified at the start of FY 1997.
2. It is recommended that distribution of SPPs be expanded to include individuals in organizations that have implementation responsibilities for any portion of the SPPs. For example, SPP 6.01 requires individuals designated by controlled document assignment pages and assigned controlled document transmittals to inform the Central Records Facility of distribution changes within the assignee's organization. RW-51 personnel who are on controlled distribution for the EM Waste Acceptance Process Specification (WAPS) cannot be aware of this responsibility because they are not on distribution for the SPPs.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Summary Table of Audit Result

ATTACHMENT 1

PERSONNEL CONTACTED DURING THE AUDIT

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
James Conway	HLW QAPM	X	X	X
Gerry Camasta	CRF Supervisor	X	X	X
Kris Grisham	QA Specialist	X	X	X
Mark Rawlings	WV Team Leader		X	X
Ralph Erickson	Director, EM-32	X	X	
Steve Ayres	SRS Team Leader	X	X	X
Louis Sirianni	QA Specialist		X	X
James Antizzo	Director, EM-37		X	
Maria Vignone	Records Manager		X	
Ken Picha	HLW-Type Manager		X	X
Ray Hempler	Safety and Health		X	

**ATTACHMENT 2
AUDIT EM-ARC-97-18 DETAIL SUMMARY AUDIT RESULTS**

QA ELEMENT/ ACTIVITIES	DOCUMENT REVIEW	CHECKLIST PAGES	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
1.0	SPP 1.02, REV. 0	pgs. 1-2			SAT	SAT	SAT
2.0	SPP 2.01 REV. 0	pgs. 5-6	YM-97-D-064		SAT	SAT	SAT
	SPP 3.01 REV. 0	pgs. 7-12			SAT	SAT	
	SPP 3.02 REV. 0	pgs. 13-15			SAT	SAT	
	SPP 8.01 REV. 0	pgs. 3-4			SAT	NI	
5.0	SPP 4.04 REV. 0; SPP 4.16 REV. 4	pgs. 22-26	YM-97-D-62		SAT	SAT	SAT
6.0	SPP 6.01 REV. 0	pgs. 27-29	CDA #1	#2	SAT	SAT	SAT
16.0	SPP 5.01 REV. 0	pgs. 30-33			SAT	SAT	SAT
	SPP 5.02 REV. 0	pg. 34			SAT	NI	
17.0	SPP 7.01 REV. 0	pgs. 35-37			SAT	SAT	SAT
18.0	SPP 4.01 REV. 0	pgs. 38-39		#1	SAT	SAT	SAT
	SPP 4.02 REV. 0	pgs. 40-43	YM-97-D-063		SAT	SAT	
	SPP 4.03 REV. 0	pgs. 16-21			SAT	SAT	
APPEND. A	WAPS REV. 1	pgs. 22-26			SAT	SAT	SAT

LEGEND:

CDA	Corrected During Audit
NI	Not Implemented
SAT	Satisfactory

cc w/encl:

L. H. Barrett, DOE/HQ (RW-1) FORS
R. A. Milner, DOE/HQ (RW-2) FORS
Ram Murthy, DOE/HQ (RW-3) FORS
S. E. Gomberg, DOE/HQ (RW-51) FORS
J. T. Conway, DOE/HQ (EM-37) TREV
J. O. Thoma, NRC, Washington, DC
W. L. Belke, NRC, Las Vegas, NV
R. R. Loux, NWPO, Carson City, NV
S. W. Zimmerman, NWPO, Carson City, NV
Jim Regan, Churchill County Commission, Fallon, NV
D. A. Bechtel, Clark County, Las Vegas, NV
Susan Dudley, Esmeralda County, Goldfield, NV
Sandy Green, Eureka County, Eureka, NV
Tammy Manzini, Lander County, Austin, NV
Kim Packard, Mineral County, Hawthorne, NV
P. A. Niedzielski-Eichner, Nye County, Chantilly, VA
L. W. Bradshaw, Nye County, Tonopah, NV
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B. R. Mettam, County of Inyo, Independence, CA
Mifflin and Associates, Las Vegas, NV
R. W. Clark, DOE/OQA, Las Vegas, NV