QA: QA

U.S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

OFFICE OF QUALITY ASSURANCE

AUDIT REPORT EM-ARC-01-09

OF THE

U.S. DEPARTMENT OF ENERGY

OFFICE OF ENVIRONMENTAL MANAGEMENT

OFFICE OF SAFETY, HEALTH AND SECURITY

GERMANTOWN, MARYLAND

JUNE 5-7, 2001

Prepared by: _____ **Date:** _____
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Audit Team Leader
Office of Quality Assurance/
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Approved by: _____ **Date:** _____
Robert W. Clark
Director
Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit EM-ARC-01-09, the audit team determined that the U.S. Department of Energy (DOE), Office of Safety, Health and Security (EM-5), with the exception of the deficient conditions identified herein is satisfactorily implementing the Office of Civilian Radioactive Waste Management (OCRWM) QA Program in accordance with the OCRWM DOE/RW-0333P, Revision 10, *Quality Assurance Requirements and Description* (QARD) document, and Standard Practice Procedures (SPPs) for the High-Level Waste (HLW) Program.

QA Program Sections 1.0, 2.0, 5.0, 6.0, 16.0, 17.0, 18.0, and Appendix A were determined to be effectively implemented based on the activities evaluated during the audit, except as noted on Deficiency Reports (DR) summarized below. Sections 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; and Appendices B and C are not implemented by EM-5.

The audit team identified conditions adverse to quality that were addressed in three DRs, EM-01-D-089, EM-01-D-090, and EM-01-D-091.

DR EM-01-D-089 addresses EM's current organizational structure not reflected in controlled documents (i.e., Memorandums of Agreements between HLW and OCRWM and between HLW and HLW sites) that establish internal and external interfaces, organizational structure requirements, and responsibilities for work.

DR-EM-01-D-090 was written to address the lack of a process to review, evaluate and trend deficiencies at the HLW EM-5 level. Due to organizational restructuring, the passing down of trending to sites without a method to trend conditions adverse to quality identified at EM-5 and to trend the HLW program overall is not adequate. Further, conditions identified at the HLW EM-5 level are not being fully evaluated for significant condition adverse to quality should a trend occur as required by the SPPs.

DR-EM-01-D-091 addresses a recurring condition whereby EM failed to document deficient conditions as Deviation and Corrective Action Requests (DCARs), instead identifying them as observations, potential deficiencies or problems. Procedures require that a DCAR will be initiated when identifying a deviation (defined as a condition adverse to quality and a departure from specified requirements). This practice was cited as an isolated incident in an audit performed of the HLW program last year and corrected during the audit (reference corresponding audit report EM-ARC-00-09). However, the philosophy continued after the correction and was discovered this audit to be a routine practice.

Additionally, the DR addresses EM's failure to complete committed corrective action to DR EM-00-D-101. EM committed to assign a full-time federal employee with experience commensurate with the position description for QA Specialist. The audit team is concerned overall by the continuance of a practice identified as deficient in the past and the apparent disregard for completion of committed corrective action. Indication to the audit team was that current management support is lacking and attention to certain quality matters is weak. Personnel interviewed confirmed that previous management was in fact, more quality-oriented and supportive. The need for immediate management attention to these matters is emphasized.

Follow-up of DR EM-00-D-100, issued during last year's EM compliance-based OCRWM audit (EM-ARC-00-009), was performed and corrective actions were found to be effectively implemented. However, DR EM-00-D-101, from the same audit was reviewed and not found to be have been corrected as committed. This concern is documented in DR EM-01-D-091.

2.0 SCOPE

Auditors representing the DOE's Office of Quality Assurance (OQA) conducted a compliance audit to evaluate EM-5 implementation of the OCRWM QA Program, as described in the QARD, and implementing procedures for HLW activities. The audit team, through interviews of cognizant personnel, reviews of documentation, and evaluation of procedures, assessed implementation, adequacy, and effectiveness of EM's implementation of the QA program.

The audit team reviewed the status of open and closed OCRWM deficiency documents that may have been generated during previous OQA audits and surveillances to determine the effectiveness of in-process and completed corrective actions by EM.

In accordance with the approved audit plan, the following QA program Sections were evaluated:

QA PROGRAM SECTIONS

1.0	Organization
2.0	QA Program
5.0	Implementing Documents
6.0	Document Control
16.0	Corrective Action
17.0	QA Records
18.0	Audits
Appendix A	High-Level Waste Form Production

The following QA program sections were not evaluated, since EM-5 is not currently implementing them:

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	Monitored Geologic Repository

3.0 AUDIT TEAM AND OBSERVERS

Name/Title/Organization	**QA Program Element**
Marilyn A. Kavchak, Audit Team Leader, OQA/Navarro Quality Systems (NQS)	1.0, 2.0, 16.0,18,0 and Appendix A
Lester W. Wagner, Auditor, OQA/NQS	2.0, 5.0, 6.0, 17.0, and 18.0

Observers

Larry L. Campbell, Senior QA Engineer
Nuclear Regulatory Commission (NRC)
Jeff Ciocco, Project Manager, NRC
Thomas Matula, Senior QA Engineer, NRC

4.0 AUDIT TEAM MEETINGS

The pre-audit meeting was held in Germantown, Maryland, on June 5, 2001. Daily debriefings as needed were held to apprise EM's management and staff of the progress of the audit and any potential conditions adverse to quality. A post-audit meeting was held with EM on June 7, 2001. Personnel contacted during the audit, including those who attended the pre-audit and post-audit meetings, are listed in Attachment 1, "Personnel Contacted During the Audit."

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall EM's implementation of the QA program is adequate and effective. The results for each QA program section 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 or immediate corrective actions as a result of the audit.

5.3 QA Program Implementation

Attachment 2, "Summary Table of Audit Results" provides results for each QA program section audited. The details of the audit, including the objective evidence reviewed, are documented in the audit checklists. The checklists are maintained as QA records.

5.4 Technical Audit Activities

There were no technical areas evaluated during this audit.

5.5 Summary of Conditions Adverse to Quality

Three DRs with conditions adverse to quality were issued as a result of the audit. Details of these DR's are documented in Section 5.5.2 of this report. Noteworthy are conditions described in DR EM-01-D-091 that were recurring and included a failure to take committed corrective action to previously issued DR EM-00-D-101.

5.5.1 Corrective Action Request

None.

5.5.2 Deficiency Reports

EM-01-D-089
Memorandums of Agreement for "Coordination of QA Activities between the Office of Waste Management and the Office of Radioactive Waste Management (OCRWM)" have not been revised to reflect the current organization structure. Likewise, MOAs for the coordination and implementation of QA activities between the HLW Sites with the Office of Waste Management are also outdated.

EM-01-D-090
No process is in place at the EM-5 level to evaluate trends even though conditions adverse to quality are identified. Conditions identified at this level can not be fully evaluated for a significant condition adverse to quality as required by the SPPs should a trend occur. Further, in the QARD Matrix, EM Headquarters is sited as performing an oversight function and delegating trending to the field (i.e. sites) stating that there is a lack of trending data available. However, the passing down of this requirement in total is considered inappropriate since there is no method to review, integrate or evaluate HLW program trends. Trending data should be made available to EM-5 and a process established to trend conditions adverse to quality identified at the EM-5 level and to conduct trending as an oversight function for the entire program.

EM-01-D-091
Internal Audit Report 01VP-SR-AU-01 and Surveillance Report OOVP-RL-S-01 documented a number of conditions adverse to quality as observations or problems, which is contrary to the requirement of SPP-5.01, Revision 2, "Deviations and Corrective Actions/ Tracking System." SPP-5.01 requires that a Deviation and Corrective Action Report (DCAR) be initiated when identifying a deviation defined as a condition adverse to quality, which is defined as a departure from specified requirements. This practice was wide spread and observed to be a philosophy rather than an individual practice or related to severity of the condition. An identical adverse condition considered to be isolated was identified during OCRWM audit EM-ARC-00-09 conducted May 23-26, 2000.

Further, during the follow-up to DR EM-00-D-101, it was discovered that committed corrective action, scheduled for completion in March 2001, had not been completed. A full-time federal position was committed to be filled with an individual who had experience commensurate with the position description for QA Specialist. Instead additional contractor support was made available, and a federal employee was being utilized through an informal agreement between managers from separate organizations.

5.5.3 Deficiencies Corrected During the Audit

None.

5.5.4 Follow-up of Previously Issued Deficiency Documents

DR EM-00-D-100. This deficiency was related to EM's failure to reflect recent organizational changes related to the interfaces between the HLW QA Program Manager and the Office of River Protection in SPP-1.02, Revision 2, "Organization." Corrective action was taken as committed and was found to be effective. This audit identified a problem with revisions to organizational interfaces rather than the establishment of an interface. The audit team concluded that the deficiency identified last year and one issued during this audit are similar, but differ in the specific problem.

DR EM-00-D-101 was reviewed and not found to be have been corrected as committed. This concern is documented in DR EM-01-D-091.

6.0 RECOMMENDATIONS

EM should consider conducting more frequent surveillances specifically of HLW sites where audits indicate the need for more oversight and more in-depth evaluations. Currently, audits conducted are annual at HLW sites, and each site audit is intended to meet the requirement for an audit from several entities.

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	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Bren, Stephen A.	SAIC/QA Specialist	X	X	X
Camasta, Gerry	EM-5, Records Coordinator	X	X	
Fisher, Kurt W.	EM-42, Savannah River Team Leader	X	X	
Grisham, Kriss K.	EM-42, QA Specialist	X	X	X
Koutsandreas, Denis	EM-22, Program Manager			X
Lightner, Ralph G.	EM-44, Director			X
Majumdar, Chandra	EM-43, Program Manager and QA Support to HLW QA		X	X
Newberry, William R.	EM-5, Program Manager	X	X	X
Picha, Kenneth A.	EM-22, Program Manager		X	
Rawlings, Mark	EM-31, Program Manager	X		
Scott, Randall	EM-5, Director			X
Thomas, Cheryl	THA/Coordinator	X		
Toro, Robert	THA/QA Specialist	X	X	X
Vaughan, Larry D.	EM-5, HLW QA Program Manager	X	X	X
Weber, Carl E.	RW-3, QA Specialist			X
Worley, Michael	EM-41, Program Manager	X		X
Wright, Thomas	EM-44, Program Manager	X		X

HLW - High-Level Waste
QA - Quality Assurance
SAIC - Science Application International Corporation
THA - Turner Harper Associates

ATTACHMENT 2

SUMMARY TABLE OF AUDIT RESULTS

QA SECTIONS/ ACTIVITIES	DOCUMENT REVIEW	CHECKLIST PAGES	DEFICIENCIES	RECOMMEND-ATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
1.0	SPP 1.02, REV. 5	Pgs. 1-3	EM-01-D-089		SAT	UNSAT	SAT
2.0	SPP 2.01 REV. 3	Pgs. 6-8			SAT	SAT	SAT
	SPP 3.01 REV. 3	Pgs. 9-10			SAT	SAT	
	SPP 3.02 REV. 3	Pgs. 11-13			SAT	UNSAT	
	SPP 8.01 REV. 2	Pgs.4-5			SAT	NI	
5.0	SPP 4.04 REV. 4	Pgs. 19-23	EM-01-D-090		UNSAT	N/A	SAT
6.0	SPP 6.01 REV. 3	Pgs. 24-26			SAT	SAT	SAT
16.0	SPP 5.01 REV. 2	Pgs. 27-29	EM-01-D-091		SAT	UNSAT	SAT
	SPP 5.02 REV. 2	Pgs. 17-18			SAT	NI	
17.0	SPP 7.01 REV. 3	Pgs. 30-33			SAT	SAT	SAT
18.0	SPP 4.01 REV. 2	Pgs. 34-35			SAT	SAT	SAT
	SPP 4.02 REV. 5	Pgs. 36-40		REC 1	SAT	SAT	
	SPP 4.03 REV. 2	Pgs. 14-16 And 41-44			SAT	SAT	
APPEND. A	MOA with OCRWM 12/23/98 MOA with ORP 6/23/99	Pg. 45	(EM-01-D-089)		SAT	UNSAT	SAT
Follow-up DRs EM-00-D-100 EM-00-D-101		Pgs. 46-47	(EM-01-D-091)		SAT	UNSAT	SAT
TOTAL	PAGES 47		3 DRs	1 REC	SATISFACTORY		

LEGEND:

NI	Not Implemented
SAT	Satisfactory
UNSAT	Unsatisfactory
REC	Recommendation
DRs	Deficiency Reports