QA: QA

U.S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

OFFICE OF QUALITY ASSURANCE

AUDIT REPORT EM-ARC-00-09

OF THE

U.S. DEPARTMENT OF ENERGY

OFFICE OF ENVIRONMENTAL MANAGEMENT

GERMANTOWN, MARYLAND

MAY 23-26, 2000

Prepared by: _____ **Date:** _____
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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-00-09, the audit team determined that the U.S. Department of Energy (DOE), Office of Environmental Management (EM)-5/20/30/40, with the exception of the deficient conditions identified, is satisfactorily implementing the Office of Civilian Radioactive Waste Management (OCRWM) QA Program in accordance with the DOE OCRWM *Quality Assurance Requirements and Description* document (QARD), DOE/RW-0333P, Revision 10, and EM-5/20/30/40 implementing procedures.

QA Program Elements 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. Currently 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; and Appendices B and C are not implemented by the EM-5/20/30/40.

The audit team identified conditions adverse to quality that were addressed in two Deficiency Reports (DR), EM-00-D-100 and EM-00-D-101, and one condition adverse to quality that was considered isolated and was Corrected During the Audit (CDA).

DR EM-00-D-100 addresses EM's failure to reflect the recent organizational changes related to the interfaces between the High-Level Waste (HLW) QA Program Manager and the Office of River Protection (ORP) in Standard Practice Procedure (SPP)-1.02, Revision 2, "Organization."

DR EM-00-D-101 addresses EM's failure to assign QA Specialists to support HLW QA who have the requisite experience in QA disciplines.

The following deficient conditions found during the audit were CDA:

EM failed to include or reference information on the "Controlled Distribution Request" for the distribution of controlled documents or maintain the distribution memorandum as a lifetime record.

EM failed to maintain as a QA record the content of the HLW Lead Auditor Qualification/Certification examination.

EM failed to document a deficiency as a Deviation and Corrective Action Request (DCAR) in lieu of an observation. The procedure states that a DCAR will be initiated when identifying a deviation, defined as a condition adverse to quality, which is a departure from specified requirements.

EM failed to provide objective evidence to ensure that the Program Manager reviewed and concurred with the audit report prior to issuance.

EM failed to provide objective evidence to ensure that RW provided concurrence to the Waste Form Compliance Plans.

EM failed to provide objective evidence to ensure that the Records Support personnel were performing an annual inventory of records.

In addition, there were four recommendations resulting from the audit as documented in Section 6.0 of this report.

Follow-up of OCRWM DR EM-99-D-061, issued during last year's EM compliance-based audit, was found to be effectively implemented.

2.0 SCOPE

Auditors representing the DOE's Office of Quality Assurance (OQA) conducted a compliance audit to evaluate EM-5/20/30/40's 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 elements were evaluated:

QA PROGRAM ELEMENTS

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 elements were not evaluated, since EM-5/20/30/40 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	Mined Geologic Disposal System

3.0 AUDIT TEAM

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

Name/Title/Organization	**QA Program Element**
Richard L. Maudlin, Audit Team Leader, OQA	1.0 and 18,0
Linda L. Galyon, Auditor,OQA	5.0, 6.0, 17.0, and 18.0
James V. Voigt, Auditor, OQA	2.0, 16.0, and Appendix A

4.0 AUDIT TEAM MEETINGS

The pre-audit meeting was held in Germantown, Maryland, on May 23, 2000. 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 May 26, 2000. 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 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 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 element 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

Two 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. One deficient condition identified required only remedial action and was corrected prior to the post-audit meeting. Details of this CDA is documented in Section 5.5.3 of this report.

5.5.1 Corrective Action Request (CAR)

None.

5.5.2 Deficiency Reports (DR)

EM-00-D-100

Procedure SPP-1.02 did not reflect the recent organizational changes related to the interfaces between the HLW QA Program Manager and the ORP.

EM-00-D-101

EM staff assigned as QA Specialists to support HLW QA do not have the requisite experience in QA disciplines.

5.5.3 Deficiencies Corrected During the Audit (CDA)

Deficiencies that are isolated in nature and require only remedial action can be CDA. The following deficiency was identified as CDA:

Internal Audit Report 00-EA-IN-AU-01 documented a deficiency as an observation (Section 6.2.3.1), which is contrary to the requirement of SPP-5.01, Revision 1, "Deviations and Corrective Actions/ Tracking System." SPP-5.01 requires that a DCAR be initiated when identifying a deviation defined as a condition adverse to quality. Prior to the completion of the audit, DCAR 00-EA-IN-AU-01-D03 was generated to document the adverse condition identified in the audit report. The action taken satisfactorily resolves the deficiency.

5.5.4 Follow-up of Previously Issued Deficiency Documents

DR EM-99-D-061 was issued during the audit of EM last year. This deficiency was related to the organizational structure in the SPPs not accurately reflecting the current organization. The results of this audit identified a problem with organizational interfaces rather than the structure itself. The audit team concluded that the deficiency identified last year and the one issued during this audit are similar, but differ in the specific problem.

6.0 RECOMMENDATIONS

The following recommendations resulted from the audit of EM and are presented for EM's consideration:

1. The memorandum from EM-30, dated October 29, 1999, titled "FY 2000 High-Level Waste Quality Assurance Requirements," directing Savanna River, West Valley, and the ORP to implement the requirements of the QARD, should be updated to reflect direction from the responsible organizations under the new organizational structure established in November 1999.

2. The completed audit checklists should be maintained as a quality record or the audit report should detail all pertinent checklist information. During the reviews of various audit reports, it was unclear if the information denoted on the approved checklist was evaluated during the audit.

3. Although the time period to issue DCARs meets internal EM procedural requirements, the time after the problem is discovered to time of issuance appears excessive (71 to 88 days was observed – time to issue). It is recommended that DCARs be issued in a more timely manner, sometime prior to the issuance of the audit report.

4. During the audit it was noted that there was not an awareness of the problems with implementation of the British Nuclear Fuels, Ltd., Inc. (BNFL) Quality Program at Richland, Washington, by the assigned HLW QA Program Manager. The HLW QA Program Manager should review the ORP Audit Report as a result of the audit of BNFL on October 18-20, 1999, and assess needed over-site by HLW QA.

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
Kriss K. Grisham	EM-42, QA Specialist	X	X	X
Geraldine A. Camasta	EM-72, A Records Specialist	X	X	X
Ralph G. Lightner	EM-44, Office Director		X	
Mark Rawlings	EM-32, West Valley Team Leader	X	X	
Ralph E. Erickson	EM-42, HLW Team Leader	X	X	X
Kurt W. Fisher	EM-42, Savannah River Team Leader	X	X	
Robert Goldsmith	EM-5, Deputy Director		X	X
William R. Newberry	EM-5, QA Specialist	X	X	
Stephen A. Bren	EM-32, SAIC/QA Specialist	X	X	X
Kenneth A. Picha	EM-22, HLW Waste-Type Manager	X	X	X
Carl E. Weber	RW-3, QA Specialist			X
Larry D. Vaughan	EM-5, HLW QA Program Manager	X	X	X
Denis J. Koutsandreas	EM-22, HLW Vitrification Engineer	X		X
Barry A. Smith	EM-42, Office Director		X	X
Jay E. Rhoderick	EM-22, Office Director		X	
William E. Murphie	EM-31, Office Director		X	
Mark W. Frei	EM-40, Deputy Assistant Secretary		X	
Sally A. Robinson	EM-41, Office Director		X	

HLW – High-Level Waste
QA – Quality Assurance

ATTACHMENT 2

SUMMARY TABLE OF AUDIT RESULTS

QA ELEMENT/ ACTIVITIES	DOCUMENT REVIEW	CHECKLIST PAGES	DEFICIENCIES	RECOMMEND-ATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
1.0	SPP 1.02, REV. 4	Pgs. 1-2	DR EM-00-D-100		UNSAT	SAT	SAT
2.0	SPP 2.01 REV. 2	Pgs. 5-7		Rec 4	SAT	SAT	SAT
	SPP 3.01 REV. 2	Pgs. 8-12			SAT	SAT	
	SPP 3.02 REV. 2	Pgs. 13-15	DR EM-00-D-101		SAT	UNSAT	
	SPP 8.01 REV. 1	Pgs. 3-4			SAT	NI	
5.0	SPP 4.04 REV. 3	Pgs. 23-27			SAT	SAT	SAT
6.0	SPP 6.01 REV. 2	Pgs. 28-30			SAT	SAT	SAT
16.0	SPP 5.01 REV. 1	Pgs. 31-33			SAT	SAT	SAT
	SPP 5.02 REV. 1	Pgs. 21-22			SAT	NI	
17.0	SPP 7.01 REV. 2	Pgs. 34-37			SAT	SAT	SAT
18.0	SPP 4.01 REV. 1	Pgs. 38-39			SAT	SAT	SAT
	SPP 4.02 REV. 4	Pgs. 40-43		Recs 2 & 3	SAT	SAT	
	SPP 4.03 REV. 1	Pgs. 16-20			SAT	SAT	
APPEND. A	MOA 05/23/95	Pg. 44		Rec 1	SAT	NI	SAT
TOTAL	PAGES 44		2 DRs 1 CDA	4 Recs	SATISFACTORY		

LEGEND:

CDA	Corrected During Audit
NI	Not Implemented
SAT	Satisfactory
UNSAT	Unsatisfactory
REC	Recommendation
DRs	Deficiency Reports