

United States Government

Department of Energy

Memorandum

QA: QA

DATE: JAN 09 2002

REPLY TO:

ATTN OF: RW-3 (Ram Murthy/(702) 794-5549)

SUBJECT: U.S. DEPARTMENT OF ENERGY (DOE) OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM) OFFICE OF QUALITY ASSURANCE (OQA) AUDIT EM-ARC-02-01 OF THE OFFICE OF ENVIRONMENTAL MANAGEMENT, OFFICE OF SAFETY, HEALTH AND SECURITY (EM-5), HIGH-LEVEL WASTE (HLW) QUALITY ASSURANCE (QA) PROGRAM

TO: EM-5 (P. M. Golan)

Enclosed is the Audit Report EM-ARC-02-01 conducted by representatives of the OQA on December 11-14, 2001, at Germantown, Maryland. The compliance-based audit was performed to: evaluate EM-5's implementation of the HLW QA Program; determine whether it meets the requirements of OCRWM DOE/RW-0333P, Revision 10, *Quality Assurance Requirements and Description* (QARD) document; and commitments of Standard Practice Procedures (SPP).

The audit team determined that with the exception of the deficient conditions identified, EM-5 is satisfactorily and effectively implementing applicable portions of the QA program described in the QARD and the SPPs.

The audit team identified conditions adverse to quality that are addressed in two Deficiency Reports (DR); DR EM-02-D-055, which addresses lack of revision histories to Memorandums of Agreements, and DR EM-02-D-056 that documents the lack of training documentation. Details of these DRs are discussed in Section 5.5.2 of the report.

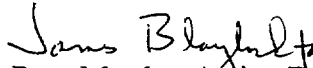
During the audit, a review of objective evidence associated with committed corrective actions for open DRs EM-01-D-089, EM-01-D-090, and EM-01-D-091 was conducted. Portions of corrective action were acceptable; however, all three DRs remain open and are discussed in Section 5.5.4 of the report.

The audit is considered completed and closed as of the date of this letter. However, the open DRs will continue to be tracked until they are closed to the satisfaction of the Quality Assurance Representative and the Acting Director, OQA.

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WM-11

JAN 09 2002

If you have any questions, please contact either James Blaylock at (702) 794-1420 or John R. Doyle at (702) 794-5021.


Ram Murthy, Acting Director
Office of Quality Assurance

OQA:JB-0486

Enclosure:
Audit Report EM-ARC-02-01

cc w/encl:

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QA: QA

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

AUDIT REPORT EM-ARC-02-01

OF THE

**U.S. DEPARTMENT OF ENERGY
OFFICE OF ENVIRONMENTAL MANAGEMENT
OFFICE OF SAFETY, HEALTH AND SECURITY
HIGH-LEVEL WASTE QUALITY ASSURANCE PROGRAM**

AT

GERMANTOWN, MARYLAND

DECEMBER 11 THROUGH DECEMBER 14, 2001

Prepared by: John R. Doyle Date: 01/07/2002
John R. Doyle
Audit Team Leader
Navarro Quality Services

Approved by: Ram Murthy Date: 1/9/02
Ram Murthy
Acting Director
Office of Quality Assurance

ENCLOSURE

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Compliance-Based Audit EM-ARC-02-01, the audit team determined that the U.S. Department of Energy (DOE), Office of Environmental Management (EM) Office of Safety, Health and Security (EM-5), with the exception of the deficient conditions herein identified is satisfactorily and effectively 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) QA 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 DR EM-02-D-055, which identifies three Memorandums of Agreements (MOA) that do not contain revision histories as required by SPP-4.04, Revision 4, *Technical and QA Documents*, and DR EM-DR-D-056 that was issued to address several related conditions adverse to quality in the area of training. Details of these DRs are discussed in Section 5.5.2 of this report.

Follow-up of open DRs EM-01-D-089, 090, and 091 from the previous Office of Quality Assurance (OQA) compliance-based audit (EM-ARC-01-09) was performed and corrective actions were found to be incomplete. A summary of the review and status are provided in Section 5.5.4 of this report.

2.0 SCOPE

Auditors representing the DOE's OQA conducted a compliance-based 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 the implementation, adequacy, and effectiveness of EM's implementation of the QA program.

The audit team also reviewed the status of open OCRWM DRs that had been generated during previous OQA audits to determine the effectiveness of EM's implementation of the corrective actions.

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, Shipping and Storage
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

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

<u>Name/Title/Organization</u>	<u>QA Program Sections</u>
John R. Doyle, Lead Auditor, Navarro Quality Services (NQS)	5.0
James E. Flaherty, Auditor, NQS	6.0, 17.0, Appendix A
Marilyn A. Kavchak, Auditor, NQS	1.0, 2.0, 16.0, 18.0

Observers

Larry Campbell, Senior QA Engineer, U.S. Nuclear Regulatory Commission (NRC)
Kamal R. Naidu, Senior Reactor Engineer, NRC
Jack Parrott, Yucca Mountain On-Site Representative, NRC
Wilkins R. Smith, QA Scientist, NRC

4.0 AUDIT TEAM MEETINGS AND PERSONNEL CONTACTED

The pre-audit meeting was held in Germantown, Maryland, on December 11, 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 December 14, 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 satisfactory 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 the audit.

5.5 Summary of Conditions Adverse to Quality

Two DRs with conditions adverse to quality were issued as a result of the audit and the details are documented in Section 5.5.2 of this report.

5.5.1 Corrective Action Request

None.

5.5.2 Deficiency Reports

EM-02-D-055

MOAs, when revised, are required by SPP 4.04, paragraph 4 c.(4), to contain a revision history to document historical changes made to the document. A review of three MOAs concerning EM and the River Protection Office (EM-44), Savannah River Office and the Ohio Project Office, reveal that revisions histories were not contained in the documents.

EM-02-D-056

A review of selected personnel training files and qualifications revealed the following inter-related conditions adverse to quality:

The following conditions were identified:

- Contrary to the requirements of SPP 3.02, Revision 3, *Qualification and Certification Records*, verification of education and experience documentation was not available for the EM-5 and EM-44 Project Managers.
- The HLW QA Program fails to require a description of job responsibilities when position descriptions are required by SPP 3.02, Section 4 a.1.c. A review of position descriptions confirmed the job responsibilities are undefined for specific quality functions performed.
- A review of training documentation indicated that functional responsibilities were not identified for each individual nor did the documentation meet the requirements of SPP 3.02 paragraph 4 a. 1 e.

5.5.3 Deficiencies Corrected During the Audit (CDA)

None.

5.5.4 Follow-up of Previously Issued Deficiency Documents

During the audit, a review of objective evidence associated with committed corrective actions for open DRs, EM-01-D-089, EM-01-D-090, and EM-01-D-091, was conducted. Portions of corrective action were acceptable; however, all three DRs remain open.

The audit team noted that during the annual internal audit, 02EA-IN-AU-01, of EM HLW QA Program conducted December 3 through 7, 2001, Deviation and Corrective Action Report (DCAR), 02EA-IN-AU-D02, was initiated.

The DCAR identifies that corrective actions to prevent recurrence to conditions adverse to quality have not been performed in a timely manner. At the time of this audit report, this DCAR had been approved by the HLW QA Program Manager for issuance. OQA will monitor the resolution of the DCAR.

A summary of the DRs reviewed and their status is as follows:

DR EM-01-D-089

MOAs between EM HLW Headquarters and HLW Sites were to have been revised by October 26, 2001.

MOAs revisions were completed, pending EM management final review and signature. During the audit EM's senior management indicated that organizational changes could impact the finalization of the MOAs.

Corrective actions are not complete; therefore, this DR remains open.

DR EM-01-D-090

A review of deficiencies and observations over the past two years was conducted as committed, according to EM-HLW QAPM; however, no objective evidence of this activity was available during the audit. The QAPM was advised that this objective evidence was required for closure.

Revisions to SPP 5.01, *Deviations and Corrective Actions/Tracking System*, were to include a process for evaluating trends. Changes were not sufficient to process deficiencies since the procedure does not provide the necessary detail relative to defining a trend or a system for processing a trend, should one be identified. In addition, the QARD Matrix, Revision 4, which currently takes exception to EM-HLW HQ trending, needs to be revised to remove the exception.

Corrective actions are not complete; therefore, this DR remains open.

DR EM-01-D-091

1. Since the original commitment to provide a full time federal person was retracted, EM has frozen contract support funds. Currently, the EM-HLW QAPM and other EM management are evaluating staffing

and displayed confidence that resources would be made available to support required RW Yucca Mountain Project (YMP) activities. Rational provided in the DR response that the EM-HLW QA Program has been performed satisfactorily does not provide sufficient evidence that adequate QA support will be available in the future under the current resource constraints.

2. The definitions of “condition adverse to quality,” “deviation,” and “observation” were not revised in the glossary as committed and additional procedural details are still required to show sufficient corrective action.

This DR will remain open pending evidence of continued management support to provide staffing to YMP activities and completion of corrective actions.

6.0 RECOMMENDATIONS

None.

7.0 List of Attachments

Attachment 1 - Personnel Contacted During the Audit
Attachment 2 - Summary Table of Audit Results
Attachment 3 - Acronyms/Abbreviations

ATTACHMENT I

PERSONNEL CONTACTED DURING THE AUDIT

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Camasta, Gerry	EM-5/Records Coordinator	X	X	
Toro, Robert	EM-5/Turner Harper Associates, QA Specialist			X
Smith, Barry	EM-42/Senior Office Director			X
Weber, Carl	RW-3/Senior QA Engineer	X		X
Vaughan, Larry	EM-5/HLW QA Project Manager	X	X	X
Worley, Michael	EM-41/Idaho HLW Program Manager	X		X
Greenberg, Ray	EM-31/Ohio Representative			X
Fischer, Kurt	EM-42/Senior HLW Project Manager			X
Picha, Ken	EM-22/Program Manager	X	X	
Koutsandres, Denis	EM-22/Program Manager	X	X	X
Grisham, Kriss	EM-42/Senior QA Specialist	X		
Golan, Paul	EM-5/Project Manager		X	
Murray, Robert	EM-5/Team Lead		X	

ATTACHMENT 2

SUMMARY OF AUDIT RESULTS

QA Section/ Activities	Document Review	Reference to Checklist Pages	Deficiencies/ DIR	CDA	Recommendations	Program Adequacy	Procedure Compliance	Over-all
1.0	SPP 1.02, Rev. 5	Pgs. 1 - 3				SAT	SAT	SAT
2.0	SPP 2.01, Rev. 3 SPP 3.01, Rev. 3 SPP 3.02, Rev. 3 SPP 8.01, Rev. 2	Pgs. 6 - 8 Pgs. 9 - 10 Pgs. 11 - 13 Pgs. 4 - 5	EM-02-D-056			UNSAT	UNSAT	UNSAT
5.0	SPP 4.04, Rev. 4	Pgs. 19 - 23	EM-02-D-055			SAT	UNSAT	SAT
6.0	SPP 6.01, Rev. 3	Pgs. 24 - 26				SAT	SAT	SAT
16.0	SPP 5.01, Rev. 2 SPP 5.02, Rev. 2	Pgs. 27 - 29 Pgs. 17 - 18, Pg. 45				SAT	UNSAT*	UNSAT*
17.0	SPP 7.01, Rev.3	Pgs. 30 - 33				SAT	SAT	SAT
18.0	SPP 4.01, Rev. 2 SPP 4.02, Rev. 5 SPP 4.03, Rev. 2	Pgs. 34 - 35 Pgs. 36 -40 Pgs. 41-43 Pgs. 14 - 16				SAT	SAT	SAT
Appendix A		Pg. 44				SAT	SAT	SAT
TOTAL	PAGES = 45		2 DRs	0 CDA	0 REC	SATISFACTORY		

Legend:

CDA Corrected During the Audit
 NI Not Implemented
 DIR Deficiency Identification and Referral
 DR Deficiency Report
 REC Recommendation
 SAT Satisfactory
 UNSAT Unsatisfactory

* UNSAT based on lack of timely corrective action to resolve previously issued OQA DRs.
EM HLW QA initiated internal deficiency document DCAR 02EA-IN-AU-D02.

ATTACHMENT 3

ACRONYMS / ABBREVIATIONS

CDA	Corrected During the Audit
DCAR	Deviation and Corrective Action Report
DOE	U.S. Department of Energy
DR	Deficiency Report
EM-5	U.S. Department of Energy Office of Safety, Health and Security
HLW	High Level Waste
MOA	Memorandum of Agreement
NI	Not Implemented
NQS	Navarro Quality Services
NRC	U.S. Nuclear Regulatory Commission
OCRWM	Office of Civilian Radioactive Waste Management
OQA	Office of Quality Assurance
QA	Quality Assurance
QARD	Quality Assurance Requirements and Description
REC	Recommendations
SAT	Satisfactory
SPP	Standard Practice Procedure
UNSAT	Unsatisfactory
YMP	Yucca Mountain Project

ATTACHMENT 2

SUMMARY OF AUDIT RESULTS

QA Section/ Activities	Document Review	Reference to Checklist Pages	Deficiencies/ DIR	CDA	Recommendations	Program Adequacy	Procedure Compliance	Over-all
1.0	SPP 1.02, Rev. 5	Pgs. 1 - 3				SAT	SAT	SAT
2.0	SPP 2.01, Rev. 3 SPP 3.01, Rev. 3 SPP 3.02, Rev. 3 SPP 8.01, Rev. 2	Pgs. 6 - 8 Pgs. 9 - 10 Pgs. 11 - 13 Pgs. 4 - 5	EM-02-D-056			UNSAT	UNSAT	UNSAT
5.0	SPP 4.04, Rev. 4	Pgs. 19 - 23	EM-02-D-055			SAT	UNSAT	SAT
6.0	SPP 6.01, Rev. 3	Pgs. 24 - 26				SAT	SAT	SAT
16.0	SPP 5.01, Rev. 2 SPP 5.02, Rev. 2	Pgs. 27 - 29 Pgs. 17 - 18, Pg. 45				SAT	UNSAT*	UNSAT*
17.0	SPP 7.01, Rev.3	Pgs. 30 - 33				SAT	SAT	SAT
18.0	SPP 4.01, Rev. 2 SPP 4.02, Rev. 5 SPP 4.03, Rev. 2	Pgs. 34 - 35 Pgs. 36 -40 Pgs. 41-43 Pgs. 14 - 16				SAT	SAT	SAT
Appendix A		Pg. 44				SAT	SAT	SAT
TOTAL	PAGES = 45		2 DRs	0 CDA	0 REC	SATISFACTORY		

Legend:

CDA Corrected During the Audit
 NI Not Implemented
 DIR Deficiency Identification and Referral
 DR Deficiency Report
 REC Recommendation
 SAT Satisfactory
 UNSAT Unsatisfactory

* UNSAT based on lack of timely corrective action to resolve previously issued OQA DRs.
EM HLW QA initiated internal deficiency document DCAR 02EA-IN-AU-D02.

ATTACHMENT 3

ACRONYMS / ABBREVIATIONS

CDA	Corrected During the Audit
DCAR	Deviation and Corrective Action Report
DOE	U.S. Department of Energy
DR	Deficiency Report
EM-5	U.S. Department of Energy Office of Safety, Health and Security
HLW	High Level Waste
MOA	Memorandum of Agreement
NI	Not Implemented
NQS	Navarro Quality Services
NRC	U.S. Nuclear Regulatory Commission
OCRWM	Office of Civilian Radioactive Waste Management
OQA	Office of Quality Assurance
QA	Quality Assurance
QARD	Quality Assurance Requirements and Description
REC	Recommendations
SAT	Satisfactory
SPP	Standard Practice Procedure
UNSAT	Unsatisfactory
YMP	Yucca Mountain Project