

**QA: QA**

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

**AUDIT REPORT OQA-ARC-00-20**

**OF THE**

**OFFICE OF QUALITY ASSURANCE**

**AT**

**LAS VEGAS, NEVADA**

**SEPTEMBER 18-22, 2000**

**Prepared by:** \_\_\_\_\_

**Lawrence W. McGrath  
Audit Team Leader**

**Date:** \_\_\_\_\_

**Approved by:** \_\_\_\_\_

**Robert W. Clark  
Director  
Office of Quality Assurance**

**Date:** \_\_\_\_\_

## 1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit OQA-ARC-00-020, the audit team determined that the Office of Civilian Radioactive Waste Management (OCRWM) Office of Quality Assurance (OQA) in Las Vegas, Nevada, is satisfactorily implementing the OCRWM Quality Assurance (QA) Program in accordance with the U.S. Department of Energy (DOE) OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 10, and implementing procedures.

QA Program elements 1.0, 2.0, 4.0, 6.0, 7.0, 9.0, 10.0, 12.0, 15.0, 16.0, 17.0, and 18.0 were determined to be effectively implemented based on the activities evaluated during the audit. QA Program elements 3.0, 5.0, Supplement I, and Supplement III were included in the audit plan; however, during preparation for the audit it was noted that OQA activities supporting these elements had been evaluated during the Fiscal Year 2000 performance-based audits. Additionally, QA Program elements 8.0, 11.0, 13.0, 14.0, Supplements II, IV, V, and Appendices A, B, and C are not implemented by the OQA.

The audit team identified conditions adverse to quality which are documented on Deficiency Reports (DR) OQA-01-D-001, DR OQA-01-D-002, and Deficiency Identification and Referral (DIR)-00-24 to open DR OQA-00-D-144 for resolution. Six conditions adverse to quality were identified that were considered isolated and were Corrected During the Audit (CDA).

DR OQA-01-D-001 addresses the failure of the OQA/Quality Assurance Technical Services Support (QATSS) managers to verify required education and experience of personnel performing tasks under their direction, as required by Administrative Procedure (AP)-2.2Q, Revision 0, ICN 0, "Establishment and Verification of Required Education and Experience of Personnel."

DR OQA-01-D-002 addresses the failure of the Quality Assurance Representatives (QAR) to enter the revision level of the cited document in Block 1 of the DR form as required by AP-16.1Q, Revision 4, ICN 1, "Management of Conditions Adverse to Quality."

DIR-00-24 addresses the failure of the QAR to assure that the root cause codes submitted in Corrective Action Report (CAR) LVMO-00-C-001 were in accordance with AP-16.4Q, Revision 0, ICN 0, "Root Cause Determination."

CDA 1 addresses the failure of the QAR to include the record of the Verification of Technical Specialist Qualification in one supplier audit record package for Supplier Audit OQA-SA-00-020, as required by AP-18.3Q, Revision 2, ICN 1, "Supplier Survey/Audits," Attachment 6.

CDA 2 addresses the failure of an OQA/QATSS auditor to document, in the audit checklist, personnel contacted during the audit for Supplier Audit OQA-SA-00-013, as required by AP-18.3, Revision 2, ICN 1, "Supplier Survey/Audits."

CDA 3 addresses the failure of an OQA/QATSS auditor to document, and include in the record package, the required Deficiency Document Encoding Form (DDEF) for Supplier Audit OQA-SA-00-013, as required by AP-18.3, Revision 2, ICN 1, "Supplier Survey/Audits."

CDA 4 addresses two instances of failure of the OQA/QATSS personnel to control obsolete documents identified as controlled in their work areas, in violation of AP-6.1Q, Revision 5, ICN 0, "Controlled Documents."

CDA 5 addresses the failure of the Corrective Action Coordinator (CAC) to forward a copy of the closed DR to the Lessons Learned Program Manager in accordance with AP-16.1Q.

CDA 6 addresses the failure of the CAC to forward a copy of a DR amended response to the record package in accordance with AP-16.1Q.

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

The audit team evaluated the effectiveness of corrective actions for previously issued deficiency documents. The audit team determined that one deficiency document, DIR-99-5, was issued during the last compliance-based audit, OQA-ARC-99-014. This DIR, issued to YMSCO-99-D-101, was subsequently cancelled. Therefore, follow-up of previously identified deficiencies was not required.

## **2.0 SCOPE**

A compliance-based audit was conducted to evaluate the OQA/QATSS implementation of the OCRWM QA Program, as described in the QARD and implementing procedures. The audit team, through interviews of cognizant personnel, reviews of documentation, and evaluation of procedures, assessed adequacy, and effectiveness of OQA/QATSS implementation of the QA Program.

The audit team reviewed the status of open and closed deficiency documents that may have been generated during the previous OQA audit to determine the effectiveness of in-process and completed corrective actions by OQA/QATSS. No deficiencies were identified in this area.

In accordance with the approved audit plan, the following QA Program elements were evaluated:

**QA PROGRAM ELEMENTS**

1.0	Organization
2.0	QA Program
4.0	Procurement Document Control
6.0	Document Control
7.0	Control of Purchased Items and Services
9.0	Control of Special Processes
10.0	Inspection
12.0	Control of Measuring and Test Equipment
15.0	Nonconformances
16.0	Corrective Action
17.0	Quality Assurance Records
18.0	Audits

In preparation for this audit it was noted that the quality functions associated with Elements 3.0, Design Control; 5.0, Implementing Documents; Supplement I, Software; and Supplement III, Scientific Investigations; are activities that support the quality engineering support function of the CRWMS M&O. The OQA/QATSS functions associated with these elements have been evaluated during performance-based audits of the CRWMS M&O throughout the year and are not included in this audit.

The following QA Program elements were not evaluated.

3.0	Design Control
5.0	Implementing Documents
8.0	Identification and Control of Items
11.0	Test Control
13.0	Handling, Storage, and Shipping
14.0	Inspection, Test, and Operating Status
Supplement I	Software
Supplement II	Sample Control
Supplement III	Scientific Investigation
Supplement IV	Field Surveying
Appendix A	High-Level Waste Form Production
Appendix B	Storage and Transportation
Appendix C	Monitored Geologic Repository

### 3.0 AUDIT TEAM

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

<u>Name/Title/Organization</u>	<u>QA Program Element</u>
Lawrence W. McGrath, Audit Team Leader, CRWMS M&O	1.0
Donald J. Harris, Auditor, OQA/QATSS	6.0, 17.0, 18.0
Richard L. Weeks, Auditor, OQA/QATSS	2.0, 4.0, 6.0, 17.0
Hugh F. Lentz, Auditor, OQA/QATSS	2.0, 6.0, 17.0, 18.0
Donna J. Sinks, Auditor, OQA/QATSS	2.0, 6.0, 16.0, 17.0
Victor J. Barish, Auditor, OQA/QATSS	6.0, 7.0, 9.0, 10.0, 12.0, 15.0
Samuel E. Archuleta, Auditor, OQA/QATSS	6.0, 7.0, 9.0, 10.0, 12.0, 15.0

### 4.0 AUDIT TEAM MEETINGS

A pre-audit meeting was conducted at OQA on September 18, 2000. Daily briefings were held to apprise OQA management and staff of the progress of the audit and identify any conditions adverse to quality. A post-audit meeting was conducted at the OQA on September 22, 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 the QA Program is adequate and is being effectively implemented by OQA/QATSS. 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**

Three deficiency documents with conditions adverse to quality were issued as a result of the audit. Details are documented in Section 5.5.2 of this report. Six deficient conditions identified required only remedial actions and were corrected prior to the post-audit meeting. Details of the CDAs are documented in Section 5.5.3 of this report.

##### **5.5.1 Corrective Action Request (CAR)**

None.

##### **5.5.2 Deficiency Reports (DR)**

###### **OQA-01-D-001**

AP-2.2Q, Revision 0, "Establishment and Verification of Required Education and Experience of Personnel," requires the manager to establish a position description that includes verification of required education and experience for personnel working on tasks under their direction. Contrary to this requirement, there was no objective evidence, in two instances cited, that this requirement had been implemented.

###### **OQA-01-D-002**

AP-16.1Q, Attachment 4, requires the QAR to enter the document and revision that has been violated in Block 1 of the DR form. Contrary to the above, of the sample examined, nine closed DRs did not include the document revision number for the controlling document that was violated.

###### **DIR 00-24**

AP-16.1Q requires the QAR to ensure that the content of the DR is in accordance with Attachment 8. Attachment 8 requires that when the cause is unknown or significant, a root cause shall be determined in accordance with AP-16.4Q. Contrary to this requirement, the root cause that was accepted by the QAR was conducted in accordance with "Tap Root," a commercially available software program, which was not in accordance with the approved AP-16.4Q procedure. This condition was referred to DR OQA-00-D-144.

### 5.5.3 Deficiencies Corrected During the Audit (CDA)

Deficiencies that are considered isolated in nature and require only remedial action can be CDA. The following deficiencies were identified and CDA:

1. QAP 18.3, Revision 2, ICN 1, "Supplier Survey/Audits," Attachment 3, requires the Verification of Technical Specialists Qualification for an audit by indoctrination and orientation, reviewing the background experience or training of the technical specialist and ensuring completion of Attachment 6, "Audit Guide for Technical Specialist."

Contrary to the requirement, the record package for Supplier Audit OQA-SA-00-020 did not contain the required technical specialist qualification, Attachment 6. Attachment 6 was completed and supplemented to the record package before audit completion. This was found to be an isolated incident.

2. QAP 18.3 requires that the auditor identify personnel contacted during the audit on the audit checklist.

Contrary to the requirement, the checklist for Supplier Audit OQA-SA-00-013 did not document persons contacted during the audit. The record package was supplemented to correct this condition. This was found to be an isolated incident.

3. QAP 18.3 requires that the Audit Team Leader assemble the QA records, which includes the DDEF, for any identified deficiency documents issued.

Contrary to the requirement, Supplier Audit OQA-SA-00-003 did not contain the required DDEF for DRs. The record package was supplemented to correct this condition. This was found to be an isolated incident.

4. AP-6.1Q requires that the document holder contact in writing, or by e-mail, the Document Control Center (DCC), to be decontrolled from the distribution of a controlled document and for the disposal of the obsolete document.

Contrary to the requirement, two controlled document holders had obsolete documents identified as controlled in their work areas. The DCC was notified and these documents were destroyed or identified as Information Only in accordance with AP-6.1Q. In lieu

of the number of controlled documents in use, this was considered to be an isolated incident.

5. AP-16.1Q requires that the CAC forward a copy of the closed DR/CAR to the Lessons Learned Program Manager and the Initiator, if not from the OQA.

Contrary to this requirement, in February 2000, the Lessons Learned Program Manager requested that OQA remove them from distribution of closed DR/CARs. OQA granted this request resulting in a violation of AP-16.1Q. Subsequently, all closed DR/CARs have been distributed as required, and the Lessons Learned Program Manager has been notified of this requirement.

6. AP-16.1Q requires that the CAC collect and submit the records listed in Paragraph 6.1. These records include completed DR/CAR changes.

Contrary to this requirement, DR LANL-99-D-074 record package did not contain the approved DR amended response. This was determined to be an isolated incident.

#### **5.5.4 Follow-up of Previously Issued Deficiency Documents**

There was one DIR issued to DR YMSCO-99-D-101. DIR-99-05 was retracted on December 8, 1999. Therefore, no additional follow-up of previously identified audit deficiencies was required.

## **6.0 RECOMMENDATIONS**

The following two recommendations resulted from the audit and are presented for OQA/QATSS management's consideration:

1. The OQA should revise the existing audit and surveillance procedures, QAP 18.1, "Auditor Qualification"; QAP 18.2, "Internal Audit Program"; QAP 18.3, "Supplier Survey/Audits"; and QAP 2.8, "Surveillance," to incorporate AP-5.1Q, Revision 1, ICN 2, "Plan and Procedure Preparation, Review, and Approval," format, outstanding Document Action Requests, and Recommendation 8 delineated in Audit Report OQA-ARC-99-014.
2. LP-4.1Q-OCRWM, Revision 0, ICN 1, "Procurement Actions," should be revised to incorporate a method to document mandatory comments on a form similar to the Comment Review Record included in AP-5.1Q.

**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	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Alred C. D.	OQA/QATSS		X	
Bevan, Glenna	ALPHA Services		X	
Blaylock, James	DOE/OQA	X	X	X
Callier, Dorothy	DOE/YMSCO		X	
Clark, J. E.	OQA/QATSS		X	
Clark, R. W.	DOE/OQA	X	X	X
Cox, H. R. Cox	OQA/QATSS		X	
Dana, S. R.	OQA/QATSS		X	
Devers, J. K.	OQA/QATSS		X	
Dove, F. H.	OQA/QATSS		X	
Fitch, E. F.	M&O, Office Engineering		X	
Gilkerson, K. O.	OQA/QATSS		X	
Glasser, W. J.	OQA/QATSS	X	X	X
Habbe, R. D.	OQA/QATSS		X	
Harper, G. T.	OQA/QATSS		X	
Hartstern, R. F.	OQA/QATSS		X	
Hasson, R. P.	OQA/QATSS	X	X	X
Hodges, K. A.	OQA/QATSS		X	
Hopkins, Kay	OQA/QATSS		X	
Humphries-Alder, C. A.	OQA/QATSS		X	
James, R. R.	DOE/YMSCO		X	
Johnson, W. H.	OQA/QATSS		X	
Kavchak, M. A.	OQA/QATSS		X	
Keele, R. P.	OQA/QATSS	X	X	X
Klimas, D. A.	OQA/QATSS	X	X	X
Martin, J. S.	OQA/QATSS	X		X
Mattimoe, J. C.	OQA/QATSS			X
Maudlin, R. L.	OQA/QATSS		X	
Murthy, Ram	DOE/OQA	X	X	X
Noel, R. L.	OQA/QATSS		X	
Osborne, C. D.	OQA/QATSS		X	
Ricks, S. S.	OQA/QATSS		X	
Schmit, J. T.	OQA/QATSS		X	
Salter, N. G.	OQA/QATSS		X	
Schuermann, S. F.	OQA/QATSS		X	
Spangler, E. L.	M&O, Training		X	
Sult, D. G.	OQA/QATSS		X	
Taylor, C. T.	OQA/QATSS	X	X	X
Therien, J. E.	OQA/QATSS	X		X
Thompson, Kathleen	M&O, Records		X	
Threatt, D. C.	OQA/QATSS		X	
Tunney, D. J.	OQA/QATSS		X	

Name	Organization	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Westgarth, C. M.	OQA/QATSS		X	
Williams, E. K.	OQA/QATSS		X	

## ATTACHMENT 2

### Summary Table of Audit Results

QA Element	Implementing Document	Checklist Pages	Deficiencies	Recommendations	Program Adequacy	Procedure Compliance	Overall
1	QAP 1.1, R 5	1 & 2			SAT	SAT	SAT
2	AP-2.1Q, R 1 AP-2.2Q, R 0 QAP 2.4, R 3 QAP 2.8, R 2	3 – 12	DR OQA-01-D-001	1	SAT SAT SAT SAT	SAT UNSAT SAT SAT	SAT
4	LP-4.1Q-OCRWM, R 0, ICN 1 LP-16.1Q-OCRWM, R 0	15 - 21		2	SAT SAT	SAT SAT	SAT
6	AP-6.1Q, R4,	26 –26	CDA 4		SAT	SAT	SAT
7	YLP-7.1Q-OQA, R 1, ICN 2 AP-7.4Q, R 4	27 – 38			SAT SAT	SAT SAT	SAT
9	YAP-9.1Q, R 1	39 – 40			SAT	SAT	SAT
10	AP-10.1Q, R 0 AP-10.2Q, R 0 AP-10.3Q, R 0 NWI-ESF-044Q, R1, ICN 2 YAP-10.2Q, R 0, ICN 1 AP-OM-006Q, R 0, ICN 1 LP-10.1Q-OCRWM, R 0	41 – 63, 69			SAT SAT SAT SAT SAT SAT SAT	SAT SAT SAT SAT SAT SAT SAT	SAT
12	YAP-12.3Q, R 0, ICN 1 LP-CAL-002Q-OCRWM, R 0	64 – 68			SAT SAT	SAT SAT	SAT
15	YAP-15.1Q, R 5	70 – 74			SAT	SAT	SAT
16	AP-16.1Q, R 4, ICN 1  AP-16.2Q, R 0	75 – 89	DR OQA-01-D-002 CDA 4 CDA 5 CDA 6 DIR 00-24		SAT    SAT	UNSAT    SAT	SAT
17	AP-17.1Q, R 1, ICN 2	90 – 92	0		SAT	SAT	SAT
18	QAP 18.1Q, R 6 QAP 18.2Q, R 8 QAP 18.3Q, R 2, ICN 1	93 - 105	0 0 CDA 1 CDA 2 CDA 3	1 1 1	SAT SAT SAT SAT SAT	SAT SAT SAT SAT SAT	SAT
<b>TOTALS</b>		<b>105 Pages</b>	<b>2 DRs 1 DIR 6 CDAs</b>	<b>2 Recom</b>	<b>SATISFACTORY</b>		

Checklist pages 13-15 and 22-25 developed per audit plan for program elements 3.0 and 5.0; however, the QA elements were not reviewed during the audit.