

**QA: QA**

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

**AUDIT REPORT OQA-ARC-02-14**

**OF THE**

**OFFICE OF QUALITY ASSURANCE**

**AT**

**LAS VEGAS, NEVADA**

**NOVEMBER 18–21, 2002**

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

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

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

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

**James Blaylock  
Office of Quality Assurance**

## 1.0 EXECUTIVE SUMMARY

A quality assurance (QA) audit was conducted on the Office of Civilian Radioactive Waste Management (OCRWM) activities performed by the Office of Quality Assurance (OQA) in Las Vegas, NV. The purpose of the audit was to verify OQA's compliance with the procedures that control their quality related activities. The audit included quality related activities performed by OQA's technical Support contractor, Navarro Quality Services (NQS). A total of eighteen (18) procedures were audited for compliance.

The audit identified seven (7) nonsignificant, conditions adverse to quality and three (3) recommendations for improvement. Deficiency Reports (DR) and Quality Observations (QO) were issued for the following CAQ:

- a) The Training Manager, rather than the Director, OQA, was determining the need for training on revisions to the DOE/RW-0333P, *Quality Assurance Requirements and Description* (QARD) document.
- b) The QARD had not been updated to reflect the QA criteria of Title 10 CFR 63, Subpart G, "Quality Assurance."
- c) A condition adverse to quality was not properly classified. The condition should have been classified as a DR rather than a less significant QO. In addition, the same individual generated, evaluated, and closed the QO.
- d) Procedure AP-181Q, *Audit Personnel Qualification*, did not provide sufficient detail to consistently and effectively determine the required training for auditors and prospective Lead Auditors.
- e) Procedure LP-4.1Q, *Procurement Actions*, did not implement the QARD requirements as shown by the Detailed Requirements Matrix.
- f) Procedure AP-16.3Q, *Trend Evaluation and Reporting*, did not include the unique document identifier for the "Trend Analysis Codes" a referenced document.
- g) The approved OQA organization chart did not reflect the current OQA organizational structure.

Two DRs were issued during the 2001 audit of OQA. This audit determined that the actions taken to preclude recurrence of those deficiencies were effective.

## 2.0 SCOPE

The scope of the audit was to verify that OCRWM QA personnel located in Las Vegas, NV, were effectively implementing the OCRWM QA Program and related procedures. The audit was limited to those activities performed by the OQA and its technical support contractor NQS.

The scope of the audit also included a review of the status of deficiency documents identified during the previous audit of the OQA (audit number OQA-ARD-01-15) to determine the effectiveness of corrective actions, as well as the status of any open deficiency documents.

The audit scope specifically covered those activities performed by QA personnel in the following procedures:

- LP-1.1Q, Revision 0, ICN 0, *Organization*
- AP-2.1Q, Revision 2, ICN 0, *Quality Assurance Program*
- AP-2.2Q, Revision 1, ICN 0, *Establishment and Verification of Required Education and Experience of Personnel*
- LP-2.2Q-OCRWM, Revision 0, ICN 1, *Maintenance of the QARD and ISMQAP*
- LP-2.4Q-OCRWM, Revision 0, ICN 0, *Quality Assurance Program Controls*
- AP-2.26, Revision 0, ICN 0, *Quality Assurance Surveillance*
- LP-4.1Q, Revision 2, ICN 0, *Procurement Actions*
- LP-4.2Q, Revision 0, ICN 1, *Procurement of Services*
- LP-16.1Q-OCRWM, Revision 0, ICN 0, *Review of Procurement Records for use in the Verification Confirmation of Data or Technical Information*
- AP-5.1Q, Revision 3, ICN 2 *Plan and Procedure Preparation, Review, and Approval*
- AP-6.28, Revision 0, ICN 1, *Document Review*
- AP-7.4Q, Revision 5, ICN 2, *Supplier Evaluation and Qualified Suppliers List (QSL) Maintenance*
- AP-16.1Q, Revision 5, ICN 0, *Management of Conditions Adverse to Quality*
- AP-16.3Q, Revision 3, ICN 0, *Trend Evaluation and Reporting*
- AP-17.1Q, Revision 2, ICN 3, *Record Source Responsibilities for Inclusionary Records*
- AP-18.1Q, Revision 0, ICN 0, *Audit Personnel Qualification*
- AP-18.2Q, Revision 0, ICN 1, *Supplier Surveys/Audits*
- AP-18.3Q, Revision 0, ICN 0, *Internal Audit Program*

The audit covered requirements from the following sections of the QARD:

Section 1.0	Organization
Section 2.0	Quality Assurance Program
Section 4.0	Procurement Document Control
Section 5.0	Implementing Documents
Section 6.0	Document Control
Section 7.0	Control of Purchased Items and Services
Section 16.0	Corrective Action
Section 17.0	Quality Assurance Records
Section 18.0	Audits

### 3.0 AUDIT TEAM MEMBERS

The following identifies the audit team and their assigned areas of responsibility:

<b>Name – Title – Organization</b>	<b>Assigned QA Program Sections</b>
Robert L. Blyth – Audit Team Leader Program Manager, Quality Assurance National Spent Nuclear Fuel Program	Section 1.0, Organization Section 4.0, Procurement Document Control Section 7.0, Control of Purchased Items and Services Section 16.0, Corrective Action Section 17.0, Quality Assurance Records
Wayne E. Booth, P.E. - Auditor Program Manager Quality Service Associates, Inc.	Section 2.0, Quality Assurance Program Section 5.0, Implementing Documents Section 6.0, Document Control Section 17.0, Quality Assurance Records Section 18.0, Audits

### 4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

A pre-audit meeting was conducted with OQA staff on November 18, 2002. 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 with OQA staff on November 21, 2002. Personnel contacted during the audit, including those who attended the pre-audit conference and post-audit meetings, are listed in Attachment 1, "Personnel Contacted During the Audit."

### 5.0 SUMMARY OF AUDIT RESULTS

#### 5.1 Implementation Effectiveness

Five (5) DRs and two (2) QOs were identified during the audit. Several of the deficiencies were directly attributed to QA procedures that needed improvement. For example: a procedure(s) that lacked detail to ensure consistent and adequate implementation; a procedure(s) that had not been kept current with actual work practices; and a procedure that did not contain upper tier requirements. The audit team identified one condition adverse to quality that was attributed to ineffective implementation of a procedure. That condition dealt with the misclassification of a deficiency, i.e., a QO should have been classified as a DR. Based on these results, the audit team concluded that procedure implementation was effective overall.

#### 5.2 Stop Work or Immediate Corrective Actions Taken

The identified conditions adverse to quality did not warrant issuance of a stop work order or the need to take immediate corrective actions.

### 5.3 Audit Activities

Attachment 2, “Summary Table of Audit Results” provide an overview of the results for each procedure audited and the applicable QA program element. The details of the audit, including the objective evidence reviewed, are documented in the audit checklists. The checklists are maintained as QA records as required by AP-18.3Q, *Internal Audit Program*.

### 5.4 Technical Audit Activities

The audit was a compliance-based audit of activities performed by QA personnel. The audit did not include an evaluation of technical work products.

### 5.5 Summary of Conditions Adverse to Quality

Seven (7) conditions adverse to quality were identified during the audit. These conditions were evaluated against the criteria specified by AP-16.1Q, *Management of Conditions Adverse to Quality*, for significance. As a result of the evaluation, five (5) conditions were classified as DRs and two (2) were classified as QOs (all were nonsignificant conditions adverse to quality). The QO has the least significant impact on quality.

The following sections summarize each DR and QO.

#### 5.5.1 OQA(O)-03-D-063

**Requirement:** LP-2.2Q-OCRWM, *Maintenance of the QARD and/or ISMQAP*, Revision 0, ICN 1, Section 5.2.2, states that the Responsible Individual (in this case it is the Director OQA) is required to determine the need for training on QARD revisions.

**Description of Adverse Condition:** This step is not being implemented by the Director, OQA. The need for conducting QA training is determined by the Training Manager. The Training Manager reviews the change to the QARD and determines if a change is needed to the QARD Lesson Plan. The procedure, LP-2.2Q, was not kept current with the actual work process.

#### 5.5.2 OQA(O)-03-D-064

**Requirement:** QARD Section 1.3.2, (B.1.a), states that the OQA is responsible for “Ensuring that a QA program that meets regulatory and management requirements is established, maintained, and effectively executed.”

**Description of Condition:** The QARD has not been updated to reflect the QA requirements of 10 CFR 63, Subpart G, “Quality Assurance.” The current QARD is based on 10 CFR 60, which is no longer applicable to the Yucca Mountain repository.

### 5.5.3 OQA(O)-03-D-065

**Requirement:** AP-5.1Q, *Plan and Procedure Preparation, Review, and Approval*, Section 5.1, and 5.1, (a), Process Steps. “Provide sequential action steps necessary to complete the process controlled by the procedure.” “Include details on how to complete a specific action. . . .”

**Description of Deficiency:** The required training for Auditors and prospective Lead Auditors is vague and the process is not clearly defined.

Procedure AP-18.1Q, *Audit Personnel Qualification*, was developed to describe the requirements and process for training and qualification of Auditors and Lead Auditors.

Sections 5.1.1 and 5.2.1 of AP-18.1Q require Verification Management to determine appropriate training required for Auditors and prospective Lead Auditors rather than specifying the actual training required for these functions. Interviews with three QA individuals identified three different interpretations of the same requirement.

### 5.5.4 OQA(O)-03-D-066

**Requirement, Part A:** QARD requirements shall be traceable to the lower tier implementing procedure via the Detailed Requirements Matrix. Section 7.2.1, paragraph C, of the QARD states that an element of procurement planning is to “Identify and document the sequence of actions and milestones needed to effectively complete the procurement.” The Detailed Requirements Matrix shows OCRWM LP-4.1Q-OCRWM, 5.1.5b) as implementing this requirement.

**Part B:** Detailed Requirements Matrix shows QARD Section 4.2.2B as being implemented by OCRWM LP-4.1Q-OCRWM Sections 5.2.6, 5.2.7, 5.2.8 and 5.2.9. In accordance with OCRWM LP-4.1Q-OCRWM Sections 5.2.6 and 5.2.8 are performed by the CO (contracting Officer).

**Description of Deficiency, Part A:** OCRWM LP-4.1Q-OCRWM, 5.1.5b) does not address the sequence of actions and milestones needed to effectively complete the procurement.

**Part B:** Interviews with project personnel indicate that Sections 5.2.7 and 5.2.9 are performed by the procurement organization, not Technical Organization and OQA reviewers.

#### 5.5.5 OQA(O)-03-D- D-071

**Requirement:** AP-16.1, *Management of Conditions Adverse to Quality*, Section 3.12, provides the definition for a QO. The definition, in part, states that the condition adverse to quality is isolated, and has no impact if not corrected. Attachment 8 of AP-16.1 states the requirements for processing a QO. The process requires, in part, a review of the condition adverse to quality by the QA representative to ensure that it meets the definition of a QO .

**Description of Deficiency:** A QO was written (OQA-02-O-058) to document a condition adverse to quality identified during a self-assessment. The self-assessment (OQA-2002-SA-02) identified where audit checklists were not signed nor dated by the Audit Team Leader (ATL) (indicating that a review had been performed) on 14 audits over the past two years. (The review by the ATL is performed to ensure that the checklists are pertinent to the scope of work and that they are sufficiently adequate to evaluate the work.)

The condition adverse to quality should have been classified as a DR.

The QO evaluation by the QA representative determined that “this procedure noncompliance revealed that the need for a signature is administrative only and that there is no impact on the acceptability or usability of the information contained within these checklists due to the missing signatures.”

**The QO was initiated and evaluated by the same individual.**

#### 5.5.6 OQA(O)-03-O-038

**Requirement:** QARD Section 5.2, “Requirements” states that work shall be performed in accordance with controlled implementing documents.

**Description of Deficiency:** AP 16.3Q, *Trend Evaluation and Reporting*, makes numerous mention of a document titled “Trend Analysis Codes”. AP-16.3Q does not include this document’s unique identifying number (QAR-CRW-QA-000001) as a means of retrieval.

#### 5.5.7 OQA(O)-03-039

**Requirement:** QARD Section 1.2, “Requirements,” states that “Each affected organization shall prepare one or more controlled documents, accepted by the OCRWM Office of Quality Assurance (OQA), that describes internal and external interfaces, organizational structures, requirements, and responsibilities for its scope of work.”

**Description of Deficiency:** The current organization chart for OQA does not accurately represent the current organization structure. This condition was corrected during audit.

## 5.6 Follow-up of Previously Issued Deficiency Documents

This section provides the results of the evaluation of the corrective action effectiveness on the deficiencies issued during the previous audit (OQA-ARC-01-15).

### 5.6.1 QA-01-D-146

This deficiency was issued to report conditions adverse to quality regarding the determination of training requirements and the submittal and retrieval of training records for QA personnel.

This audit sampled training records of QA personnel to verify that the corrective actions taken for D-146 were effective. No deficiencies were identified. The audit team did however, have a recommendation related to the implementation of QARD training requirements.

### 5.6.2 OQA-01D-147

This deficiency was issued to report that block 9 on Deficiency/Corrective Action Report form was not completed for several deficiency reports. This audit sampled several completed Deficiency/Corrective Action Report forms to ensure block 9 was properly completed. No deficiencies were identified; corrective action was effective.

## 6.0 RECOMMENDATIONS

The audit identified areas where the QA program could potentially be improved.

### 6.1 Recommendation No. 1 (CIRS No. 003752)

**Observed Condition:** Although procedurally compliant, the five NQS job functions do not correspond to the QA functions specified by OCRWM procedures. For example, NQS does not have a job function of Auditor, Lead Auditor, Verification Management, and Certification Coordinator; therefore, there is no requirement to provide training to these individuals who carry out these procedure functions.

Training that is assigned to the various job functions, QA Specialist for example, does not seem to be logical, based on the individual's actual roles and responsibilities as described by QA program procedures. For example, QA Specialists are required to be trained in AP-16.1, *Management of Conditions Adverse to Quality*. However, QA Specialists are not required to be trained in AP-18.3Q, *Internal Audit Program*, even though performing QA audits is a major activity of QA Specialists.

This method of implementation by NQS is not inconsistent with that of other OCRWM affected organizations.

**Recommendation:** OCRWM/OQA should evaluate the methods being used by the commercial nuclear industry to comply with QARD Section 2.2.12 (NQA-1) for personnel qualification requirements. An element of the evaluation should include the relative cost of implementation for comparison purposes.

## 6.2 Recommendation No. 2 (CIRS No. 003753)

**Observed Condition:** The self-assessments conducted by OQA did not include the effectiveness of the corrective actions for DR numbers OQA-01-D-146 and 147.

AP-2.20Q, *Self-Assessments*, Section 5.2 (b) (1) states that the scope of self-assessments should include the effectiveness of corrective actions from DRs, CARs, QAMAs, etc.

**Recommendation:** During the planning of future self-assessments, OQA should ensure that the scope of self-assessments include an element to verify the effectiveness of corrective actions for previous conditions adverse to quality.

## 6.3 Recommendation No. 3 (CIRS No. 003754)

**Observed Condition:** Interviews with program personnel indicate that completion of “Deficiency Report / Corrective Action Report” form, block 10 “Recommended Actions” has been informally discontinued.

**Recommendation:** If the program has decided to not include recommended actions when issuing deficiency / corrective action reports, AP-16.1Q should be revised accordingly.

## 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**

<b>Name</b>	<b>Organization</b>	<b>Pre-Audit Meeting</b>	<b>Contacted During Audit</b>	<b>Post-Audit Meeting</b>
Auer, Pat	NQS	X	X	X
Blaylock, James	OQA	X	X	X
Brown, Denny	OQA	X	X	X
Dove, Harvey	NQS		X	
Glasser, William	NQS	X	X	X
Harper, George	NQS		X	
Harris, Donald	NQS		X	
Hasson, Robert	NQS	X	X	X
Hodges, Kristi	NQS	X		X
Hopkins, Kay	NQS		X	
Kavchak, Marilyn	NQS		X	
Murthy, Ram	OQA		X	X
Opelski, Ed	NQS	X	X	X
Palay, Christian	NQS		X	
Schmidt, James	NQS		X	
Scott, Bobby	NQS		X	
Threatt, Dennis	NQS		X	
Wagner, Les	NQS	X	X	
Westgarth, Cheryl	NQS		X	

## ATTACHMENT 2

### Summary Table of Audit Results

<b>QA Element</b>	<b>Implementing Document</b>	<b>Checklist Pages</b>	<b>Deficiencies</b>	<b>Procedure Compliance</b>
<b>1.0</b>	LP-1.1Q	1-5a	O-039	SAT
<b>2.0</b>	AP-2.1Q	6-7	None	SAT
	AP-2.2Q	8-10	None	SAT
	LP-2.2Q-OCRWM	11-14	D-063 D-064	UNSAT
	LP-2.4Q-OCRWM	15-16	None	SAT
	AP-2.26Q	17-20	None	SAT
<b>4.0</b>	LP-4.1Q	21-26	D-066	UNSAT
	LP-4.2Q	27-29	None	SAT
	AP-16.1Q-OCRWM	41-46	None	SAT
<b>5.0</b>	AP-5.1Q	30	D-065	UNSAT
<b>6.0</b>	AP-6.28Q	31-34	None	SAT
<b>7.0</b>	AP-7.4Q	35-40	None	SAT
<b>16.0</b>	AP-16.1Q	41-46		UNSAT
	AP-16.3Q	47-51	O-038	UNSAT
<b>17.0</b>	AP-17.Q	52-57	None	SAT
<b>18.0</b>	AP-18.1Q	58-63	None	SAT
	AP-18.2Q	64-67	None	SAT
	AP-18.3Q	68-76	None	SAT