

QA: QA

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

**REPORT FOR AUDIT OQAC-OQA-03-09**

**OF THE**

**OFFICE OF QUALITY ASSURANCE**

**LAS VEGAS, NEVADA**

**AUGUST 11-15, 2003**

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## EXECUTIVE SUMMARY

A quality assurance (QA) audit was conducted at the Office of Civilian Radioactive Waste Management (OCRWM) on activities performed by the Office of Quality Assurance (OQA) in Las Vegas, NV from August 11, 2003, through August 15, 2003. 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 the Department of Energy (DOE) staff, OQA's Technical Support contractor, Navarro Quality Services (NQS) and Bechtel SAIC Company (BSC). A total of seventeen (17) procedures were audited for compliance.

Five Deficiency Reports (DR) were issued during the 2002 audit of OQA. This audit determined that the actions taken to preclude recurrence for four of those deficiencies were effective. DR OQA(O)-03-D-064 from the last audit is still open and was not evaluated.

After conducting personnel interviews and reviews of supporting documents used to verify conformance to implementing procedures, the audit team has determined that the Office of Quality Assurance is adequately implementing its Quality Assurance Program.

The audit identified three (3) Conditions Adverse to Quality (CAQ), two (2) were Corrected During the Audit (CDA) and six (6) recommendations for improvement. DRs issued are summarized below:

### Deficiency Reports:

1) OQA(O)-03-D-240 – AP-16.1Q, Revision 6 ICN 0, *Management of Conditions Adverse to Quality* does not describe a process to lift a Stop Work order.

**Program Impact:** Without a process in place, it could be possible to lift a “Stop Work” order without verifying that the conditions that prompted the Stop Work have been corrected.

### Deficiency Reports Corrected During the Audit:

1) OQA(O)-03-D-238 – A Stop Work Order was issued to a prior revision (5) of AP-16.1Q. When the Stop Work was lifted, the Stop Work Order form was not completed and several signature blocks were blank leaving an incomplete quality record. The stop work order blanks were marked as not applicable (N/A) to complete the record.

**Program Impact:** An incomplete quality record can raise questions on the how the stop work order was lifted.

2) OQA(O)-03-D-239 – During a review of Delegation of Authority memos, one memo “OQA:RDB-0887, Dennis Brown to Margaret Chu, dated March 26, 2003 Subject: Standing Delegation of Authority” was identified with an incorrect QA

designator. A designation of QA: NA was noted on the memo. The memo was revised to indicate a designation of QA: QA.

**Program Impact:** If a quality record is miscategorized as QA: NA, the record will not be stored in accordance with the requirements of the QARD.

Recommendations for Improvement:

1) AP-18.3Q Revision 0 ICN 1, *Internal Audit Program* does not define a timeline for completion of the audit report. Develop a timeline for completion of OQA audit reports.

**Program Impact:** The Quality Assurance Requirements and Description (QARD) require that requirements be established to ensure conditions adverse to quality are promptly identified and corrected as soon as practical. Without a defined timeline for completion of audit reports, there could be delays in distributing the audit report.

2) Although self assessments are being conducted as required by AP-2.20Q Revision 1 ICN 1, *Self Assessments*, the scope of OQA self assessments lacks rigor and focuses on only one aspect, "Procedure Compliance." Self-assessments conducted by OQA over the past year were based on procedure compliance, with very few problems found. The self-assessment process should be expanded to include critical evaluations of: prior audit findings, lessons learned, effectiveness of corrective actions, adequacy of procedures, and areas of concern that have been identified.

**Program Impact:** An aggressive OQA self-assessment process can identify problem areas, provide continuous improvement, and improve the effectiveness of the Quality Program.

3) The QARD requires that each Affected Organization evaluate and assess the need for additional indoctrination and training as implementing documents change. The process of evaluating and assessing the need for additional indoctrination and training when implementing documents change is not being documented. A process needs to be developed to document these reviews.

**Program Impact:** Without a system for documenting the evaluation for the need of additional indoctrination and training, it cannot be determined if this requirement of the QARD is being met.

4) During the review of records associated with plan and procedure preparation, review and approval, transcription errors were found in the official signed and dated Requirements Traceability Network (RTN) "014" Reports. While procedure AP 5.1Q, Revision 3/ICN 4 specifies the use of RTN "012" reports for the requirements matrix, the "014" report was also used, marked up and subsequently

sent to the Document Control organization. The corrected data from the “014” reports was subsequently entered into the RTN by the document control staff. As a result, RTN database was electronically updated with the incorrect data. While the errors were found in the signed and dated “014” forms, the actual implementation of the QARD requirements in the applicable QA-related procedures were found to have been properly flowed down and implemented based upon this review. It is recommended that a comprehensive review of the RTN database(s) and/or the official signed and dated RTN Reports, either the “012” or “014” reports of record, be completed to ensure that no other errors exist in the OQA version of the official requirements matrix required by QARD Section 2.2.1.

**Program Impact:** It is important to ensure that the requirements matrix is current and up to date to ensure that the requirements of the QARD are being implemented.

5) Section 5.4.1 (b) of Procedure AP-2.2Q Revision. 1 ICN 2, *Establishment and Verification of Required Education and Experience of Personnel* allows for justification of a personnel assignment when education and experience cannot be verified, but the procedure does not provide criteria as to what constitutes adequate justification. The justifications in place seem adequate, but without specific criteria, the evaluation is subjective and can be challenged. It is recommended that criteria for acceptable justification be added to procedure AP-2.2Q.

**Program Impact:** Personnel qualifications may be in question if inadequate justifications are used.

6) Section 5.2.3 (a) of procedure AP-16.3Q, Revision. 3 ICN 1, *Trend Evaluation and Reporting* requires a periodic review and analysis of deficiency data using guidelines in Attachment 3. After review of Attachment 3 and discussions with NQS staff, it was noted that Attachment 3 provides very little guidance and is ineffective in guiding the reviewer on how to analyze the deficiency data. It is recommended that OQA revise Attachment 3 and provide meaningful guidance or remove the attachment from the procedure.

**Program Impact:** With inadequate guidance for the analysis of deficiency data, the causes of deficiencies may be inaccurate resulting in inadequate corrective actions.

## 1.0 INTRODUCTION

### 1.1 PURPOSE AND 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 scope of the audit also included a review of the status of deficiency documents identified during the previous audit of the OQA (Audit OQA-ARC-02-14) 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 OQA personnel in the following procedures:

- LP-1.1Q-OCRWM, Revision 0 ICN 0, *Organization*
- AP-2.1Q, Revision 2 ICN 2, *Indoctrination and Training of Personnel*
- AP-2.2Q, Revision 1 ICN 2, *Establishment and Verification of Required Education and Experience of Personnel*
- LP-2.2Q-OCRWM, Revision 1, ICN 0, *Maintenance of the QARD and Quality Assurance Program Clarifications*
- AP-2.20Q, Revision 1 ICN 1, *Self-Assessments*
- AP-2.26, Revision 0 ICN 0, *Quality Assurance Surveillance*
- LP-4.1Q-OCRWM, Revision 3 ICN 0, *Procurement Actions*
- LP-4.2Q-OCRWM, Revision 0 ICN 1, *Procurement of Services*
- AP-5.1Q, Revision 3 ICN 4, *Procedure Preparation, Review, and Approval*
- AP-6.28, Revision 0 ICN 2, *Document Review*
- AP-7.4Q, Revision 5 ICN 3, *Supplier Evaluation and Qualified Supplier List (QSL) Maintenance*
- AP-16.1Q, Revision 6 ICN 0, *Management of Conditions Adverse to Quality*
- AP-16.3Q, Revision 3 ICN 1, *Trend Evaluation and Reporting*
- AP-17.1Q, Revision 2 ICN 5, *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 1, *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

All criteria of the audit plan were addressed during the audit.

**1.2 AUDIT TEAM**

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

<b>1.2.1.1 Name – Title – Organization</b>	<b>Assigned QA Program Sections</b>
Randolph T. Kay – Audit Team Leader  Quality Assurance Specialist, Idaho Operations Office	Section 1.0, Organization  Section 18.0, Audits
Elver D. Robbins – Auditor  Quality Assurance Specialist, Rocky Flats Environmental Technology Site	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
Sam A. Vega – Auditor  Quality Assurance Specialist, Office of River Protection	Section 2.0, Quality Assurance Program  Section 16.0, Corrective Action  Section 17.0, Quality Assurance Records

**2.0 SUMMARY OF AUDIT RESULTS**

**Organization (QARD Criterion 1.0)**

The QARD Criterion 1.0 establishes the requirements for the Quality Assurance Organization. The audit team verified OQA compliance with the procedures that implement Criterion 1.0 requirements that control the Quality Assurance Organization by reviewing records and interviewing personnel.

The OQA procedure that implements QARD criterion are LP-1.1Q-OCRWM, Revision 0 ICN 0, *Organization*. During the audit, it was found that LP-1.1Q-OCRWM is out of date and does not reflect the current organizational structure. The Office of Quality Assurance has identified this CAQ on DR OCRWM (O)-03-D-075. This DR requires that the out-of-date procedure LP-

1.1Q-OCRWM be canceled and that the QARD be used to describe the organizational structure and interfaces for the Office of Quality Assurance.

OQA(O)-03-D-239 was issued and closed during the audit. Paragraph 5.2.c.3 of Procedure AP-17.1Q Revision 2 ICN 5 states: "Provide the following information on the first page of each record: QA designator of "QA: QA" for a QA Record." Memo OQA:RDB-0887, Dennis Brown to Margaret Chu, dated March 26, 2003 Subject: Standing Delegation of Authority, was not designated as a QA record. The memo was revised to indicate a designation of QA: QA.

Based on these reviews and interviews, the audit team determined that the Quality Assurance Organization is **effectively implemented**.

### **Quality Assurance Program (QARD Criterion 2.0)**

The QARD Criterion 2.0 establishes the requirements for the Quality Assurance Program. The audit team verified OQA compliance with the procedures that implement Criterion 2.0 requirements that control the Quality Assurance Program activities by reviewing records and interviewing personnel.

The OQA procedures that implement QARD Criterion 2.0 requirements reviewed by the audit team are AP-2.1Q, Revision 2 ICN 2, *Indoctrination and Training of Personnel*; AP-2.2Q, Revision 1 ICN 2, *Establishment and Verification of Required Education and Experience of Personnel*; AP-2.26Q, Revision 0 ICN 0, *Quality Assurance Surveillance*; and LP-2.2Q-OCRWM, Revision 1 ICN 0, *Maintenance of the QARD and Quality Assurance Program Clarifications*. The audit team interviewed the staff responsible for implementing these procedures and reviewed the required documentation to verify the procedures were properly implemented. The audit team identified one recommendation for improvement associated with training.

The audit team reviewed OQA and NQS support staff position descriptions, verification of education and experience forms, the training requirements matrix, and training documentation records. The audit team found that procedure AP-2.1Q, Revision 2 ICN 2, *Indoctrination and Training of Personnel* and the associated activities performed did not meet the intent of the QARD Section 2.2.12 (A.). (see recommendation for improvement 3)

Problems with training identified by the audit team were previously documented in DR-YMSCO-(O)-02-D-180. OQA and is currently in the process of implementing corrective actions that will revamp the indoctrination and training process. These corrective actions should resolve the issues identified in this audit.

The self-assessment process needs to be strengthened to include other subjects beside procedure compliance. (see recommendation for improvement 2)

Section 5.4.1 (b) of procedure AP-2.2Q, Rev. 1, ICN 2, *Establishment and Verification of Required Education and Experience of Personnel* allows for a justification of a personnel assignment when education and experience cannot be verified, but the procedure does not

provide criteria as to what constitutes adequate justification. The justifications in place seem reasonable, but without specific criteria, the evaluation is subjective and can be challenged. It is recommended that criteria for acceptable justification be added to procedure AP-2.2Q. (see recommendation for improvement 5)

Based on these reviews and interviews, the audit team determined that the Quality Assurance Program is **effectively implemented**.

#### **Procurement Document Control (QARD Criterion 4.0)**

The QARD Criterion 4.0 establishes the requirements for the Quality Assurance Program. The audit team verified OQA compliance with the procedures that implement Criterion 4.0 requirements that control the Procurement Document Control activities by reviewing records and interviewing personnel.

The OQA procedures that implement QARD Criterion 4.0 requirements reviewed by the audit team are LP-4.1Q-OCRWM Revision 3 ICN 0 *Procurement Actions* and LP-4.2Q-OCRWM Revision 0 ICN 1 *Procurement of Services*. The audit team evaluated the implementation of the requirements for Procurement Document Control associated with the OQA. Review of procurement actions since November 2002 was conducted based on interviews with OQA staff, support staff from NQS and a review of records. There were no new procurement actions initiated by the OQA during the timeframe in question. Examples of task orders initiated by other organizations within OCRWM during the timeframe, were reviewed to ensure OQA actions were completed as required. The procurement document review actions performed by OQA have been performed in accordance with the governing procedure.

Based on the fact that no new procurement of services activities had occurred during the timeframe, this procedural aspect of the QARD was not reviewed for compliance.

Based on these reviews and interviews, the audit team determined program requirements for Procurement Document Control are **effectively implemented**.

#### **Implementing Documents (QARD Criterion 5.0)**

The QARD Criterion 5.0 establishes the requirements for Implementing Documents. The audit team verified OQA compliance with the procedures that implement Criterion 5.0 requirements that control Implementing Documents by reviewing records and interviewing personnel.

The OQA procedures that implement QARD Criterion 5.0 requirements reviewed by the audit team are AP-5.1Q Revision 4 ICN 1 *Procedure Preparation, Review and Approval*. The audit team reviewed procedures for the control of document changes and records of procedure changes, and found no concerns with OQA's performance of procedure preparation, review and approval.

During the review of records associated with plan and procedure preparation, review and approval, transcription errors were found in the official signed and dated Requirements Traceability Network (RTN) "014" Reports. While procedure AP 5.1Q, Revision 4 ICN 1 specifies the use of RTN "012" reports for the requirements matrix, the "014" report was also

used, marked up and subsequently sent to the Document Control organization. The corrected data from the “014” reports was subsequently entered into the RTN by the document control staff. As a result, the other RTN database was electronically updated with the incorrect data. The errors were found in the signed and dated 014 forms; actual implementation of the QARD requirements in the applicable QA related procedures were found to have been properly flowed down and implemented based upon this review. It is recommended that a comprehensive review of the RTN database(s) and/or the official signed and dated RTN Reports, either the “012” or “014” reports of record, be completed to ensure that no other errors exist in the OQA version of the official requirements matrix required by QARD Section 2.2.1. (see recommendation 4)

Based on these reviews and interviews, the audit team determined that program requirements for Implementing Documents are **effectively implemented**.

#### **Document Control (QARD Criterion 6.0)**

The QARD Criterion 6.0 establishes the requirements for Document Control. The audit team verified OQA compliance with the procedures that implement Criterion 6.0 requirements that control Implementing Documents by reviewing records and interviewing personnel.

The OQA procedures that implement QARD Criterion 6.0 requirements reviewed by the audit team are AP-6.28Q Revision 0 ICN 2 *Document Review*. The audit team reviewed procedures for the control of document changes and records of procedure changes. A sample of QA records was retrieved from the Records Processing Center (RPC) to ensure that the sampled records were retrievable and legible. The audit team found no concerns with OQA’s performance with respect to Document Control.

Based on these reviews and interviews, the audit team determined that program requirements for Document Control are **effectively implemented**.

#### **Control of Purchased Items and Services (QARD Criterion 7.0)**

The QARD Criterion 7.0 establishes the requirements for Control of Purchased Items and Services. The audit team verified OQA compliance with the procedures that implement Criterion 7.0 requirements that control Purchased Items and Services by reviewing records and interviewing personnel.

The OQA procedures that implement QARD Criterion 7.0 requirements reviewed by the audit team are AP-7.4Q Revision 5 ICN 2 *Supplier Evaluation and Qualified Supplier List (QSL)*. The team reviewed records of completed evaluations based on one or more of the following purposes: supplier history, records review, surveys audits and annual evaluations. The Qualified Supplier List (QSL) and supporting records were also reviewed to ensure that the List was accurate and properly maintained and controlled. All supplier evaluation activities reviewed have been properly performed and met the requirements identified in the QARD. The QSL was found to be accurate and up to date.

Based on these reviews and interviews, the audit team determined that program requirements for the Control of Purchased Items and Services are **effectively implemented**.

### **Corrective Actions (QARD Criterion 16.0)**

QARD Criterion 16.0 establishes the requirements for Corrective Actions. The audit team verified OQA compliance with the procedures that implement criterion 16.0 requirements and control activities associated with corrective actions by reviewing documents and implementing procedures, sampling work activities, and interviewing personnel.

The OQA procedures that implement QARD criterion 16.0 requirements reviewed by the audit team were AP-16.1Q, Revision 6 ICN 0, *Management of Conditions Adverse to Quality* and AP-16.3Q, Revision 3 ICN 1, *Trend Evaluation and Reporting*. The audit team interviewed the staff responsible for implementing the trending procedure, and reviewed trending reports and the process for identifying trend codes. No CAQs were identified.

The audit team interviewed the individuals responsible for processing corrective action documentation, reviewed the stop work order process, and the process for generating, processing, and managing condition reports to verify these activities were performed in accordance with the procedures. The audit team identified one condition adverse to quality DR OQA(O)-03-D-240 associated with stop work instructions in AP-16.1Q. This procedure provided direction for initiating a stop work and documenting the conditions needed to be met to remove a stop work, but fails to discuss who performs verification of the required conditions and rescinds the stop work.

Section 5.13.1.b of AP-16.1Q, Revision 5 States: “The Quality Assurance Representative (QAR) shall: 1) Sign and date the Stop Work Order (SWO) form in Block 15 accepting verification of total restart. 2) Prepare restart approval notification correspondence indicating full closure of the SWO. 3) Sign and date the SWO form Block 16 recommending total restart of work. Contrary to this requirement, Stop Work Order BSC(O)-03-C-097 was not closed after the contractor received written notice from DOE rescinding the stop work. This condition was documented on OQA(O)-03-D-238, this CAQ was corrected during the audit. NOTE: Revision 6 of AP-16.1Q was in affect at the time the stop work order was rescinded. Revision 6 does not require the use of a SWO but an incomplete quality record can raise questions on the how the stop work order was lifted.

Section 5.2.3 (a) of procedure AP-16.3Q, Rev. 3, ICN 1, *Trend Evaluation and Reporting* requires a periodic review and analysis of deficiency data using guidelines in Attachment 3. After review of Attachment 3 and discussions with NQS staff, it was noted that Attachment 3 provides very little guidance and is ineffective in guiding the reviewer on how to analyze the deficiency data. It is recommended that OQA revise Attachment 3 and provide meaningful guidance or remove the attachment from the procedure. (See recommendation for improvement 6)

Based on these reviews and interviews, the audit team determined that the program requirements for Corrective Actions are **effectively implemented**.

### **Quality Assurance Records (QARD Criterion 17.0)**

The QARD Criterion 17.0 establishes the requirements to ensure quality assurance records are specified, prepared and maintained. The audit team verified OQA compliance with the procedures that implement Criterion 17.0 requirements and the activities associated with quality assurance records by reviewing documents and implementing procedures, sampling work activities, and interviewing personnel.

The OQA procedure that implements QARD Criterion 17.0 requirements reviewed by the audit team was AP-17.1Q, Revision 2 ICN 5, *Record Source Responsibilities for Inclusionary Records*. The audit team interviewed the staff responsible for generating and processing QA records from various QA activities to assure QA records were properly identified and processed. The audit team verified that signature and initial lists were in place and maintained, that in-process QA records were properly protected and maintained, and that QA records were properly transmitted to the Records Processing Center (RPC). The audit team also verified QA records were retrievable electronically via the intranet. There were no concerns identified.

During the review of “Delegation of Authority” memos, one memo, “OQA:RDB-0887, Dennis Brown to Margaret Chu, dated March 26, 2003 Subject: Standing Delegation of Authority” was identified with an incorrect QA designator. A designation of QA:NA was noted on the memo. CAQ OQA(O)-03-D-239 was corrected during the audit by revising the memo to indicate a designation of QA: QA.

Based on these reviews and interviews, the audit team determined that the program requirements for Quality Assurance Records are **effectively implemented**.

### **Audits (QARD Criterion 18.0)**

The QARD Criterion 18.0 establishes the requirements for Quality Assurance Audits. The audit team verified OQA compliance with the procedures that implement Criterion 18.0 requirements that control the QA Audit Process by reviewing records and interviewing personnel.

The OQA procedures that implements QARD Criterion 18.0 requirements reviewed by the audit team are AP-18.1Q Revision 0 ICN 0 *Audit Personnel Qualification*, AP-18.2Q Revision 0 ICN 1, *Supplier Surveys/Audits*, and AP-18.3Q Revision 0 ICN 1 *Internal Audit Program*.

Certification files were sampled for Lead Auditors, Auditors, and Technical Specialists to verify that required indoctrination, training and experience were documented, verified and that the documentation required by AP-18.1Q was complete and retrievable from the RPC. All required documents were available and complete for the sample reviewed.

A sample of supplier audits conducted over the past year was reviewed to ensure that the requirements of AP-18.2Q were met. Lead Auditor/Auditor qualifications were verified for the sampled audits and the required documentation for each audit was verified complete and retrievable from the RPC.

A sample of internal audits was reviewed to ensure that the requirements of AP-18.3Q were met and that the audit reports and checklist were complete. All required documentation was included in the sample reviewed and was retrievable from the RPC.

AP-18.3Q Revision 0 ICN 1 does not define a timeline for the completion of the audit report. A timeline for the completion of OQA audit reports needs to be developed. (see recommendation 1)

Based on these reviews and interviews, the audit team determined that the program requirements for Audits are **effectively implemented**.

### 3.0 AUDIT FINDINGS

#### 3.1 *CONDITIONS ADVERSE TO QUALITY IDENTIFIED DURING THE AUDIT*

##### 3.1.1 Corrective Action Reports

No Corrective Action Reports were generated during the audit.

##### 3.1.2 Deficiency Reports

###### 1) OQA(O)-03-D-240

**Requirement:** DOE/RW 0333P, Revision 13 Section 2.2.1 (B) states: “Affected organizations shall establish implementing documents applicable to their scope of work that translate Quality Assurance Requirements and Description (QARD) requirements into work processes.”

**Description of Deficiency:** AP-16.1Q, Revision 6 ICN 0, *Management of Conditions Adverse to Quality* Paragraph 5.3.2 (b) describes the process for issuing a Stop Work, but does not define the process to restart work. (Note: The restart of work is a critical step, important to safety, which should include a process to verify that the condition, which caused the stop work, has been resolved.)

##### 3.1.3 Recommendations for Improvement

1) AP-18.3Q Revision 0 ICN 1 does not define a timeline for the completion of the audit report. A timeline for the completion of OQA audit reports needs to be developed.

2) Although self assessments are being conducted as required by AP-2.20Q Revision 1 ICN 1, *Self Assessments*, the scope of OQA self assessments lacks rigor and focuses on only one process, Procedure Compliance. Self-assessments conducted by OQA over the past year were based on procedure compliance, with very few problems found. The self-assessment process should be expanded to include critical evaluations of: prior audit findings, lessons learned,

effectiveness of corrective actions, adequacy of procedures, and other areas of concern which have been identified.

3) The QARD requires that each Affected Organization evaluate and assess the need for additional indoctrination and training as implementing documents change. The process of evaluating and assessing the need for additional indoctrination and training when implementing documents change is not being documented and a process needs to be developed to document these reviews.

4) During the review of records associated with plan and procedure preparation, review and approval, transcription errors were found in the official signed and dated Requirements Traceability Network (RTN) "014" Reports. While procedure AP 5.1Q, Revision 4 ICN 1 specifies the use of RTN "012" reports for the requirements matrix, the "014" report was also used, marked up and subsequently sent to the Document Control organization. The corrected data from the "014" reports was subsequently entered into the RTN by the document control staff. As a result, the other RTN database was electronically updated with the incorrect data. The errors were found in the signed and dated "014" forms, actual implementation of the QARD requirements in the applicable QA related procedures were found to have been properly flowed down and implemented based upon this review. It is recommended that a comprehensive review of the RTN database(s) and/or the official signed and dated RTN Reports, either the "012" or "014" reports of record, be completed to ensure that no other errors exist in the OQA version of the official requirements matrix required by QARD Section 2.2.1.

5) Section 5.4.1 (b) of procedure AP-2.2Q, Rev. 1, ICN 2, *Establishment and Verification of Required Education and Experience of Personnel* allows for a justification of a personnel assignment when education and experience cannot be verified, but the procedure does not provide criteria as to what constitutes adequate justification. The justifications in place seem reasonable, but without specific criteria, the evaluation is subjective and can be challenged. It is recommended that criteria for acceptable justification be added to procedure AP-2.2Q.

6) Section 5.2.3 (a) procedure AP-16.3Q, Rev. 3, ICN 1, *Trend Evaluation and Reporting* requires a periodic review and analysis of deficiency data using guidelines in Attachment 3. After reviewing Attachment 3 and from discussions with NQS staff, it was noted that Attachment 3 provides very little guidance and is ineffective in guiding the reviewer on analyzing the deficiency data. It is recommended that OQA revise Attachment 3 and provide meaningful guidance or remove the attachment from the procedure.

### **3.2 CONDITIONS CORRECTED DURING THE AUDIT**

#### **1) OQA(O)-03-D-238**

**Requirement:** Section 5.13.1.b of AP-16.1Q, Rev. 5 States: "The Quality Assurance Representative (QAR) shall: 1) Sign and date the SWO form in Block 15 accepting verification of total restart. 2) Prepare restart approval notification correspondence indicating full closure of the SWO. 3) Sign and date the SWO form Block 16 recommending total restart of work.

**Description of Deficiency:** Steps 1 and 3 were not performed prior to the lifting the stop work.

**Note:** Revision 6 of AP-16.1Q was released prior to the lifting of the stop work order. Revision 6 of AP-16.1Q does not require the use of the Stop Work Order form, but the Stop Work Order form had been utilized to Stop Work in accordance with Revision 5 of AP-16-1Q. Revision 6 of AP-16-1Q was used to lift the Stop Work order but the Stop Work Order form used to Stop Work was never completed, resulting in an incomplete record with no explanation of why the signature blocks were blank.

2) **OQA(O)-03-D-239**

**Requirement:** Paragraph 5.2.c.3 of Procedure AP-17.1Q Revision 2 ICN 5 states: "Provide the following information on the first page of each record : QA designator of "QA: QA" for a QA Record."

**Description of Deficiency:** Memo OQA:RDB-0887, Dennis Brown to Margaret Chu, dated March 26, 2003 Subject: Standing Delegation of Authority, was not designated as a QA record. The memo was revised to indicate a designation of QA: QA.

### 3.3 ***FOLLOW-UP OF PREVIOUSLY ISSUED DEFICIENCY REPORTS***

1) **OQA(O)-03-D-063**

Deficiency Report OQA(O)-03-D-063 dated January 16, 2003 was issued against the program for the failure of the Director of OQA determine the need for training on QARD revisions. Procedure LP-2.2Q-OCRWM was revised as required by the DR's corrective action plan. The revision transferred the responsibility for the determination of training to the Training Manager. As a result, the OQA closed the deficiency report.

Based upon a follow up review, the Training Manger is now implementing his responsibilities as required by procedure LP-2.2Q-OCRWM but is not documenting his evaluation of the need for additional training. (see recommendation for improvement #3)

2) **OQA(O)-03-D-065**

Deficiency Report OQA(O)-03-D-065 dated January 16, 2003 was issued against the program for vague auditor and prospective lead auditor training requirements. As a result, the OQA training matrix was reviewed and revised to include auditor and lead auditor training requirements.

Based upon a follow-up review, the revised training matrix provides sufficient clarification to determined training requirements for auditors and lead auditors.

3) **OQA(O)-03-D-066**

Deficiency Report OQA-(O)-03-D-066 dated January 16, 2003 was issued against the program for failure to implement requirements from the Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Rev. 5. The OQA response stated that the QARD requirements had in fact been implemented and that the reference to the Requirements Traceability Network (RTN) database as the source of the concern was in fact incorrect, since the RTN is identified as a non-Q system. As a result, the OQA closed the deficiency report.

Based upon a follow up review, the QARD requirements are in fact properly implemented and the fact that the RTN is a non-Q system was substantiated. The DR is considered closed.

4) **OQA(O)-03-D-071**

Deficiency Report OQA(O)-03-D-071 dated January 16, 2003 was issued against the program for failing to issue ad DR for a CAQ but instead, a Quality Observation (QO) was issued. During a self-assessment (OQA-2002-SA-02) a CAQ was identified where the lead auditor did not sign the audit checklist. Fourteen separate instances were discovered where the checklists were not signed as required. As a result, procedure AP16.1Q *Management of Conditions Adverse to Quality* was revised to delete QOs. Upon further investigation, it was determined that having the Lead Auditor's signature on the audit checklist was an administrative measure and did not affect the outcome or quality of the audit.

Based upon a follow-up review, it has been determined that the revision to AP-16.1Q will prevent this from occurring in the future.

#### **4.0 ATTACHMENTS**

Attachment A - Personnel Contacted During the Audit

Attachment B - Summary of Audit Results

**ATTACHMENT 1**

**4.1.1.1 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>
Aleman-Kozai, Mirna	BSC		X	
Auer, Pat	NQS	X	X	
Bennington, Mary	OQA	X		X
Brown, Denny	OQA	X	X	X
Capshaw, Roy	OQA	X		
Clemensen, K.	DOE/CMD		X	
DeKlever, R.	NQS		X	
Diaz, Mario	OQA			X
Dyer, Russ	DOE/ORD			X
Flaherty, Jim	NQS			X
Glasser, William	NQS	X	X	
Glover, M.	DOE/CMD		X	
Grooms, Kerry	OQA	X	X	X
Habbe, Robert	BSC	X	X	X
Harris, Donald	NQS		X	
Harris-Womack, Sharon	BSC		X	
Hasson, Robert	NQS	X		X
Hopkins, Kay	NQS		X	
Kavchak, Marilyn	NQS	X		X
Kettell, Richard	NQS	X	X	
Latta, Robert	NRC	X		X
Murthy, Ram	OQA	X		X
Opelski, Ed	NQS		X	X
Petersen, Spencer.	DOE/CMD		X	
Quinnell, Kim	BSC		X	
Schmit, James	NQS	X	X	
Scott, Bobby	NQS			X

<b>Name</b>	<b>Organization</b>	<b>Pre-Audit Meeting</b>	<b>Contacted During Audit</b>	<b>Post-Audit Meeting</b>
Thompson, Kathleen	BSC		X	
Threatt, Dennis	NQS		X	
Tiesenhausen, E. V.	Clark County			X
Wagner, Les	NQS		X	
Westgarth, Cheryl	NQS			
West-Thompson, Pam	BSC		X	
Williams, Albert	OQA			X

**ATTACHMENT 2**  
**Summary Table of Audit Results**

<b>QA Element</b>	<b>Implementing Document</b>	<b>Checklist Pages</b>	<b><u>Deficiencies</u></b>	<b>Procedure Compliance</b>
<b>1.0</b>	LP-1.1Q-OCRWM	1-5	None	SAT
<b>2.0</b>	AP-2.1Q	5-7	None	SAT
	AP-2.2Q	7-19	None	SAT
	LP-2.2Q-OCRWM	10-14	None	SAT
	AP-2.20Q	3	None	SAT
	AP-2.26Q	14-17	None	SAT
<b>4.0</b>	LP-4.1Q-OCRWM	18-22	None	SAT
	LP-4.2Q-OCRWM	22-24	None	N/A
<b>5.0</b>	AP-5.1Q	25-29	None	SAT
<b>6.0</b>	AP-6.28Q	30-33	None	SAT
<b>7.0</b>	AP-7.4Q	33-38	None	SAT
<b>16.0</b>	AP-16.1Q	39-46	OQA(O)-03-D-238 (CDA)	SAT
	AP-16.3Q	47-52	None	SAT
	DOE/RW 0333P	52	OQA(O)-03-D-240	UNSAT
<b>17.0</b>	AP-17.1Q	52-58	OQA(O)-03-D-239 (CDA)	SAT
<b>18.0</b>	AP-18.1Q	58-63	None	SAT
	AP-18.2Q	64-67	None	SAT
	AP-18.3Q	68-77	None	SAT