

U.S. NUCLEAR REGULATORY COMMISSION STAFF OBSERVATION OF THE  
FISCAL YEAR 2016 CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES  
QUALITY ASSURANCE AUDIT 2016-1

OBSERVATION AUDIT REPORT NO.: OAR-16-01

/RA/ 2/22/17  
Jon Woodfield, Observer  
Division of Spent Fuel Management  
Office of Nuclear Material Safety  
and Safeguards

Enclosure

## **1.0 INTRODUCTION**

The Center for Nuclear Waste Regulatory Analyses (CNWRA), Geosciences and Engineering Division (GED), of Southwest Research Institute (SwRI) provides technical support to the U.S. Nuclear Regulatory Commission (NRC) staff through NRC Charter Contract NRC-HQ-12-C-02-0089 and the Enterprise Wide Contract (EWC) NRC-HQ-50-14-E-0001. These contracts require CNWRA to meet the quality assurance (QA) requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 63, "Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada;" Part 50, "Domestic Licensing of Production and Utilization Facilities;" Part 60, "Disposal of High-Level Radioactive Wastes in Geologic Repositories;" Part 71, "Packaging and Transportation of Radioactive Material;" and Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste." On November 29-30, 2016, QA auditors and technical specialists from SwRI (auditors) conducted the GED Audit 2016-1 of one NRC funded program and two non-NRC funded programs conducted by CNWRA in San Antonio, Texas. One NRC staff member from the Office of Nuclear Material Safety and Safeguards (observer) observed the audit. The CNWRA held a post-audit meeting with the NRC on December 1, 2016.

The scope of the audit was to evaluate the CNWRA QA program to determine whether it meets contractually mandated QA program requirements and is being effectively implemented for NRC sponsored activities by the CNWRA. The objective of the NRC observer was to evaluate the effectiveness of the audit process and the implementation of the CNWRA QA program.

Details of the audit are available in the December 14, 2016, CNWRA report, "Quality Assurance Audit Report for Geosciences and Engineering Division Consolidated Audit, GED 2016-1" (ML17027A170).

## **2.0 MANAGEMENT SUMMARY**

The auditors evaluated the adequacy of applicable QA program elements and three technical tasks during this full-scope audit. The observer found the auditors to be qualified and independent of the activities and technical areas audited. During the audit, the auditors identified two minor nonconformances; one minor nonconformance corrected during the audit, and six recommendations for improvements (see Section 9.0, Results).

The auditors determined that: (1) the GED QA program continues to be effectively implemented and provides adequate controls over technical product development and related quality affecting activities, (2) the GED staff continues to operate in accordance with the GED Quality Assurance Manual, operations plans, technical operating procedures, QA procedures, and applicable administrative procedures, and (3) the technical staff was appropriately qualified through education, experience, and training with the technical work executed in a satisfactory manner.

The observer concluded that the audit process was well-planned, thorough, effective, and performed in a professional manner. The auditors developed and used audit checklists that were comprehensive and effective in providing guidance to the auditors. The Audit Team Leader provided ample opportunities for the observer to provide comments and ask questions throughout the audit process. The auditors and observer discussed potential findings with CNWRA management during caucuses, audit debriefs, and at the post-audit meeting.

The observer determined that the audit achieved its objectives of evaluating the CNWRA QA program to verify that it met applicable requirements and was effectively implemented. The observer determined that the audit was effective in reviewing, evaluating, and determining compliance with procedural requirements in the areas controlled by the QA program. The observer agreed with the auditors' conclusion that the QA program was effectively implemented.

### **3.0 PARTICIPANTS**

#### **3.1 Auditors**

Faye Bockwell	Institute Quality Systems (IQS) – Audit Team Leader
Ross Cantu	IQS – Auditor
Mark Ehnstrom	IQS – Auditor

#### **3.2 Technical Specialists**

Thomas Gardner, PhD	Trinity University, San Antonio
Dave Turner, PhD	St. Mary's University, San Antonio
John McFarland, PhD	SwRI Mechanical Engineering Division (18)

#### **3.3 NRC Observer**

Jon Woodfield	Observer
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### **4.0 REVIEW OF AUDIT AND AUDITED ORGANIZATION**

The CNWRA provides technical support to NRC staff under NRC Contracts NRC-HQ-12-C-02-0089 and NRC-HQ-50-14-E-0001. These contracts require CNWRA to meet the QA requirements of 10 CFR Parts 63, 50, 60, 71, and 72. CNWRA performed the audit to determine whether its QA program meets contractually mandated QA program requirements and was effectively implemented for NRC sponsored activities at the CNWRA. The observer evaluated the conduct of the audit to determine the adequacy of the audit process and the effectiveness of the QA program implementation. The auditors performed the audit following CNWRA Quality Assurance Procedure (QAP)-011, "Internal Audits." The observer evaluated the audit using the guidance of NRC Manual Chapter 2410, "Conduct of Observation Audits."

### **5.0 SCOPE OF AUDIT**

The CNWRA audit was both compliance and performance based. The auditors reviewed selected QA program elements to determine compliance with applicable procedures. The audit was also performance based in that the auditors reviewed completed technical products to determine compliance with CNWRA QA control processes and procedures. CNWRA risk-informed its selection of the technical topics for the audit based on the time since the previous audit of the areas and the importance of the activity, particularly in regard to risk insights. The observer determined that the audit scope was achieved.

### **6.0 CONDUCT AND TIMING OF THE AUDIT**

The observer determined that the auditors were thorough, effective, and performed in a professional manner. The observer determined that the timing, length, and application of resources to complete this audit were appropriate for the current level and type of activities

performed by CNWRA under the contracts. The observer also determined that the auditors achieved the purpose of the audit.

## 7.0 AUDIT TEAM QUALIFICATION AND INDEPENDENCE

The audit team was composed of an Audit Team Leader, two QA auditors, and three technical specialists. The observer found the qualifications of the auditors to be acceptable and in compliance with the CNWRA QA program. The observer also found the auditors to be independent of the activities they reviewed.

## 8.0 AREAS OF EXAMINATION AND RESULTS

### 8.1 QA Elements

The auditors evaluated the following QA programmatic elements:

<u>QA Programmatic Elements</u>	<u>Corresponding QA Manual Chapter</u>
Organization	1
QA Program	2
Design Control	*
Scientific/Engineering Investigation and Analysis Control	3
Procurement Document Control	4
Instructions, Procedures, and Drawings	5
Document Control	6
Procurement Control	7
Identification and Control of Items, Software, and Samples	8
Control of Processes	9
Inspection	10
Test Control	11
Control of Measuring and Test Equipment	12
Handling, Storage, and Shipping	13
Inspection and Test Status	14
Nonconformance Control	15
Corrective Action	16
Records Control	17
Audits	18

\*CNWRA does not perform design-related activities.

The auditors addressed all of the QA Manual chapters during the audit except for Design Control. The auditors used checklists during the audit for the assessment of the QA programmatic and technical elements. The auditors reviewed and evaluated material and documentation related to the QA programmatic and technical elements and interviewed responsible personnel to determine the effectiveness of implementing procedures and technical processes.

## 8.2 Technical Activities

The CNWRA selected the technical products for the audit based on the level of activity, technical and programmatic risks involved, and the time since each technical area was last audited. The auditors evaluated the following technical products:

- Mechanical Stratigraphy and Natural Deformation in the Austin Chalk (This was not an NRC sponsored task) (R8637)
- Analysis of Missile Impact Probability for Generic Tornado Hazard Assessments, Task Order NRC-HQ-20-16-T-0001 Under Contract NRC-HQ-50-14-E-0001 (19943.01)
- Electrical Resistivity Survey Bulverde Transmission Line (This was not an NRC sponsored task) (19674.01.002)

The auditors used a performance-based approach to evaluate the effectiveness of the QA program in ensuring product quality. The auditors implemented the performance-based approach by using sub-teams of technical specialists and QA auditors who evaluated activities from their individual technical perspectives and evaluated implementation of procedures and plans associated with product development.

## 9.0 Results

As listed below, the auditors identified two minor nonconformances; one minor nonconformance corrected during the audit, and six recommendations for improvement.

The first minor nonconformance identified by the auditors was:

- Electrical Resistivity Survey Bulverde Transmission Line (This was not an NRC sponsored task) (19674.01.002)

Nonconformance Condition Report (NCR) NCR 2016-NCR-0460. Conflict of interest determinations were not current for the IQS auditors and for one subcontractor used on technical project 19674.

Requirement: AP-001, Evaluating, Selecting, and Engaging Labor Resources

The second minor nonconformance identified by the auditors has two examples which are:

QA records are not being submitted and are not being examined to ensure completeness.

- Analysis of Missile Impact Probability for Generic Tornado Hazard Assessments, Task Order NRC-HQ-20-16-T-0001 Under Contract NRC-HQ-50-14-E-0001 (19943.01)

NCR 2016-NCR-0459. Form QAP-012 available through QA records missing editorial review completion date and evidence of technical review for several required areas. Note: a completed version of the form was presented by the Principle Investigator. Also, Form QAP-019 is missing the signature and date for the person performing the calculation verification.

- Electrical Resistivity Survey Bulverde Transmission Line (This was not an NRC sponsored task) (19674.01.002)

NCR 2016-NCR-0459. Hard copy review comments were not submitted as a record. Also, scanned pages from notebook 1188, covering the period from February 2016 to May 2016 were not available for review.

Requirement: QAP-012, Quality Assurance Records Control, sections 3.4.1 and 3.4.4.

The minor nonconformance identified by the auditors that was corrected during the audit is:

- No specific project.

No NCR written. The calibration date listed on the certificate of calibration was not consistent with the date on the equipment status label for balance, AN 010225. The calibration certificate stated the calibration was performed 31 October 2016 yet the calibration sticker showed calibration on 28 October 2016. The date of calibration was verified and the certificate revised to include the correct date. Data for all 8 balances calibrated on 28 October 2016 was reviewed and no other errors were noted.

Requirement: QAP-019, Control of Measuring & Test Equipment

The six recommendations for improvements identified by the auditors are:

- Analysis of Missile Impact Probability for Generic Tornado Hazard Assessments, Task Order NRC-HQ-20-16-T-0001 Under Contract NRC-HQ-50-14-E-0001 (19943.01)

Recommendation 1: The basis and/or limitations for claims made in the report to support the conclusions should be clearly stated.

- Section 2.1 of the report states: "differences are most likely statistical artifacts," but does not provide any basis for this.
  - Additional qualitative and/or quantitative evidence for claims, such as a simple numerical example (even with hypothetical numbers) to illustrate the points being presented should be included.
  - Address or note potential limitations/assumptions associated with the conclusion based on the nature of the models/data used in the analysis.
- Electrical Resistivity Survey Bulverde Transmission Line (This was not an NRC sponsored task) (19674.01.002)

Recommendation 2: Consider including references in the report to previous successful applications of the methodology, approach and likelihood ranking to provide a more sound technical basis.

Recommendation 3: Capture important technical expert reasoning in the scientific notebook. Areas to address include reasoning used in establishing the survey area and electrode spacing, and in establishing the contouring of the data.

- QAP-012, Quality Assurance Records Control

Recommendation 4: The QAP-012, Quality Assurance Records Control, Section 3.4.4, should be revised to allow the division's QA Representative to sign Form QAP-16 when processing quality planning documents such as the Quality Requirements Application Matrix (QRAM). Additionally, form QAP-16 should be revised to add a QA signature block.

- QAP-001, Scientific Notebook Control

Recommendation 5: Evaluate the requirement for scanning hard copy notebook information. Consider adding “as soon as practicable at the end of a project or not to exceed 6-months.” Currently the requirement is “not to exceed 6-month intervals.”

- QAP-008, Document Control & QAP-012, Quality Assurance Records Control

Recommendation 6: Review procedures to ensure references to Electronic Library Facility (ELF) are still appropriate and accurately describe the processes being followed within the Division. Consider implementing a procedure describing the process for electronic record retention and retrieval.

The auditors determined that: (1) the QA program applied by the GED continues to be effectively implemented and provides adequate controls over technical product development and related quality affecting activities, (2) the technical work was determined to have been executed in a satisfactory manner, and (3) the recommendations provide opportunities for improvements of the GED quality program and technical products.

## **10.0 NRC STAFF FINDINGS/CONCLUSIONS**

The observer concluded that the audit process was well-planned, thorough, effective, and performed in a professional manner. The auditors developed and used audit checklists that were comprehensive and effective in providing guidance to the auditors. The Audit Team Leader provided ample opportunities for the observer to provide comments and ask questions throughout the audit process. The auditors and observer discussed potential findings with CNWRA management during caucuses, audit debriefs, and at the post-audit meeting.

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