U.S. NUCLEAR REGULATORY COMMISSION STAFF OBSERVATION OF THE FISCAL YEAR 2018 CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE AUDIT 2018-1 OBSERVATION

AUDIT REPORT NO.: OAR-18-01

/RA/

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) of the Southwest Research Institute (SwRI) provides technical support to the U.S. Nuclear Regulatory Commission (NRC) staff through current NRC Contracts 31310018D0001 and 31310018D0002. These contracts require CNWRA to meet the quality assurance (QA) requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities;" Part 63, "Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada;" 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 December 11-12, 2018, QA auditors and technical specialists from SwRI (auditors) conducted the CNWRA Audit 2018-1 of two projects (one NRC funded) 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 auditors and NRC observer on December 13, 2018.

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 January 4, 2019, SwRI report for CNWRA, "Quality Assurance Audit Report for Center for Nuclear Waste Regulatory Analyses Audit, CNWRA 2018-1" (ML19079A205).

2.0 MANAGEMENT SUMMARY

The auditors evaluated the adequacy of applicable QA program elements and two technical tasks during this full-scope audit. During the audit, the auditors identified one minor nonconformance and four recommendations for improvements (see Section 9.0, Results). The observer verified that the auditors were qualified and independent of the activities and technical areas they audited.

The auditors determined that: (1) the CNWRA QA program continues to be effectively implemented and provides adequate controls over technical product development and related quality affecting activities; (2) the CNWRA staff continues to operate in accordance with the CNWRA 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

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

3.2 Technical Specialists

Roland Benke, PhD	Nuclear Engineering and Radiation Safety Independent Consultant
Dave Turner, PhD	Environmental Assessment Saint Mary's University, San Antonio

3.3 NRC Observer

Jon Woodfield	Observer (NMSS/DSFM/IOB Inspector)

4.0 REVIEW OF AUDIT AND AUDITED ORGANIZATION

The CNWRA provides technical support to NRC staff under NRC Contracts 31310018D0001 and 31310018D0002. These contracts require CNWRA to meet the QA requirements of 10 CFR Parts 50, 63, 71, and 72. CNWRA had the audit performed 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 11 (QAP-011), "Internal Audits." The observer evaluated the audit using the guidance of NRC Inspection 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 auditors achieved the audit scope.

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, one QA auditor, and two 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:

QA Programmatic Elements	Corresponding QA Manual Chapter
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:

- Proof of Concept Biosphere Model to Calculate Human Radon Doses Applicable to Buried Radioactive Waste Exposure Scenarios (This was an internal CNWRA Research & Development Project) (CNWRA IR&D Project R8775)

- Environmental Assessment Development (Task Order NRC-HQ-50-15-T-0005 Under Previous NRC Contract NRC-HQ-50-14-E-0001) (CNWRA Project 19942)

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 one minor nonconformance and four recommendations for improvement.

The minor nonconformance identified by the auditors was:

- QAP-019, Control of Measuring and Test Equipment

  Nonconformance Condition Report (NCR) NCR 2018-NCR-0553. Calibrated equipment within Building 57 was observed to be readily available for use beyond its calibration due date (i.e., items were not physically segregated). A thermometer (AN 011675) in the Corrosion Laboratory L111 had a due date of 5/19/2018, while a thermometer (AN 001997) in the Materials laboratory L113 had a due date of 8/16/2018.

The four recommendations for improvements identified by the auditors are:

- Proof of Concept Biosphere Model Project R8775

  Recommendation 1: Full verification and validation testing of the model developed on IR&D project R8775 should be performed prior to use.

- Review of the current project 23700 should be performed to ensure the verification and validation testing is adequately addressed. (Reference Preventive Action Request 2018-PAR-0188)

Recommendation 2: Evaluate if lung dose would be advantageous to consider during future radon dose modeling work in light of performance objectives that address doses to individual organs. (Reference 2018-PAR-0188)

- Environmental Assessment Development Project 19942

Recommendation 3: Environmental Assessment Projects should specifically identify a closeout consistency check between the Safety Review and Environmental Review teams.

- Consideration should be given to formalizing the consistency check process. (Reference 2018-PAR-0189)

Recommendation 4: Mitigation measures described in Chapter 6 of the Environmental Assessment that are enforceable through license conditions should be clearly identified.

- Additionally, document those mitigations that are used in making impact (SMALL, MODERATE, LARGE) determinations.
- Finally, identify those mitigation measures that are best management practices (BMPs), but not enforced by license conditions or used in impact determinations. (Reference 2018-PAR-0189)

The auditors determined that the QA program applied by the CNWRA continues to be adequate and effectively implemented and the recommendations identified provide opportunities for improvements, which may reduce the potential to adversely affect products in the future.

10.0 NRC STAFF FINDINGS/CONCLUSIONS

The NRC staff 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 NRC staff to provide comments and ask questions throughout the audit process. The auditors and NRC staff discussed findings with CNWRA management during the post-audit meeting.

The NRC staff 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 NRC staff determined that the audit was effective in reviewing, evaluating, and determining compliance with procedural requirements in the areas controlled by the QA program. The NRC staff agreed with the auditors' conclusion that the QA program was effectively implemented.