

U.S. NUCLEAR REGULATORY COMMISSION STAFF OBSERVATION OF THE  
FISCAL YEAR 2020 CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES  
QUALITY ASSURANCE AUDIT 2020-1

OBSERVATION AUDIT REPORT NO.: OAR-20-01

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Jon Woodfield, Primary Observer  
Division of 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 Contract 31310018D0001. Contract 31310018D0001 requires 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 1-2, 2020, QA auditors and technical specialists from SwRI (auditors) conducted the CNWRA Audit 2020-1 of two NRC funded projects performed by CNWRA in San Antonio, Texas. An NRC staff member from the Office of Nuclear Material Safety and Safeguards (NMSS) observed the whole audit virtually and was the primary observer. Other NRC staff observed virtually only parts of the audit sessions. The CNWRA held a post-audit virtual meeting with the auditors, NRC primary observer, NRC Contracting Officer Representative and other NRC staff on December 3, 2020.

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 primary 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 18, 2020, SwRI report for CNWRA, "Quality Assurance Audit Report for Center for Nuclear Waste Regulatory Analyses Audit, CNWRA 2020-1" (ML21007A387).

## **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 two minor nonconformances and nine recommendations for improvements (see Section 9.0, Results). The primary 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, contracts, task-orders, project 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 primary 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 primary observer to provide comments and ask questions throughout the audit process. The auditors and primary observer discussed potential findings with CNWRA management during caucuses, audit debriefs, and at the post-audit meeting.

The primary 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 primary 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 primary 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**

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

Jon Woodfield	Primary observer – all sessions (NMSS/DFM/IOB Inspector)
Maurice Heath	Secondary observer – select sessions (NMSS/DUWP/LLWPB Project Manager)
Jin-Ping Gwo	Secondary observer – select sessions (NMSS/DFM/MCAB System Performance Analyst)

### **4.0 REVIEW OF AUDIT AND AUDITED ORGANIZATION**

The CNWRA provides technical support to NRC staff under NRC Contract 31310018D0001. This contract requires 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 primary 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 regarding risk insights. The primary observer determined that the auditors achieved the audit scope.

## 6.0 CONDUCT AND TIMING OF THE AUDIT

The primary observer determined that the auditors were thorough, effective, and performed in a professional manner. The primary 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 NRC contract. The primary 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 additional QA auditor, and two technical specialists. The primary observer found the qualifications of the auditors to be acceptable and in compliance with the CNWRA QA program. The primary 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

\*QAM - CNWRA *Quality Assurance Manual*

\*\*CNWRA does not perform design-related activities.

The auditors addressed all 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 auditors 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:

- BDOSE, Biosphere Dose Assessment Code. The objective of this task was to incorporate a radon exposure submodel into GoldSim-based BDOSE. The enhanced BDOSE code is intended to be of use for NRC reviews of dose assessments of radioactive waste sites and locations of high-level waste tank closure at U.S. Department of Energy sites. Recent activities have focused on refining the radon submodel, subjecting it to validation testing, and preparing the BDOSE Version 3.0 code with an updated BDOSE user's manual. (Task Order 31310018F0077 Task Area 2 Under NRC Contract 31310018D0001) (CNWRA Project 23700.04.020)
- Non-HLW Determinations; Grout Laboratory Studies. The objective of this task was to perform tests exploring the effects on water chemistry from interaction with blast furnace slag-bearing grouts that simulate those emplaced in closed high-level waste tanks at the Savannah River Site (SRS). One intended function of the grouts at the SRS is to impede the release from the tanks of redox-sensitive radioelements such as technetium and plutonium. In particular, the tests look at changes in solution Eh and pH imposed by the grout and attempt to understand the chemical processes driving these changes. (Task Order 31310018F0077 Task Area 3 Subtask 1 Under NRC Contract 31310018D0001) (CNWRA Project 23700.04.031)

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 and nine recommendations for improvement.

The two minor nonconformances identified by the auditors were:

- TOP-012, Identification and Control of Samples, Chemical Reagents, and Standards  
Corrective Action Request (CAR) 2020-CAR-0639. Expired chemicals in Building 65 were not identified with a required *Expired* label and were not located in a designated storage area.
- QAP-016, Procurement  
2020-CAR-0640. Physical identification of accepted items with the purchase order number, purchase requisition number, or appropriate sample identification number was not consistently performed. Numerous chemical containers were observed without the appropriate identification in both Building 57 and 65.

The nine recommendations for improvements identified by the auditors are:

- Programmatic

Recommendation 1: QAP-011, *Internal Audits* should be updated to state that all audit findings will be entered into the Quality Report System (QRS) as Corrective Action Requests (CARs) rather than Nonconformance Reports (NCRs). This change will meet the requirements of ISO 9001. (Reference Preventive Action Request 2020-PAR-0178)

Recommendation 2: The CNWRA should review QAP forms that are no longer being used and determine if they should be made inactive or obsolete.

- QAP-3, *Report Review/Comment Resolution Record*, is no longer required since comments are entered directly in MS Word documents.

- QAP-13, *Instructions to Peer Reviewers*, is not being used.

(Reference 2020-PAR-0179)

- CNWRA Project 23700.04.020 – BDOSE, Biosphere Dose Assessment Code

Recommendation 3: The CNWRA should consider adding the following clarifying statement to the BDOSE User Guide so that users would not need to investigate the technical basis for each referenced dose coefficient:

*In BDOSE Version 3.0, inhalation dose coefficients for radon, which are available for user selection, incorporate contributions from short-lived decay products.*

(Reference 2020-PAR-0180)

Recommendation 4: Author(s) of the BDOSE Radon Submodel Validation Report should consider seeking approval from the NRC to publish atmospheric transport test results on wind speed variations in the peer-reviewed literature. The observed behaviors depicted in Figure 14 would be beneficial to a broader audience.

(Reference 2020-PAR-0181)

- CNWRA Project 23700.04.031 – Non-HLW Determinations: grout laboratory studies

Recommendation 5: The chain of custody forms and Analytical and Environmental Chemistry Department reports are currently captured on individual staff computers. Consideration should be given to ensuring these are stored centrally for easy retrieval.

(Reference 2020-PAR-0182)

Recommendation 6: For future work, the project should consider including:

- An evaluation of the effects of sample aging on results

- Pre-test characterization of the materials

- Pre-test evaluation of pulverized samples to characterize, and perhaps rule out, the presence of crushing debris (e.g., steel fragments) that may affect redox conditions

(Reference 2020-PAR-0183)

Recommendation 7: The project should consider including the following recommended language regarding Jade 3.1/Jade Pro software in reports.

- *Jade is commercial software that is not installed on CNWRA systems, and Jade software validation was not required in the statement of work of the project.*

(Reference 2020-PAR-0184)

Recommendation 8: The project should consider developing and using a project-specific chain of custody form for solids analysis (e.g., XRD analysis) similar to the form used for water analysis. (Reference 2020-PAR-0185)

Recommendation 9: The project should capture the results of interactions with the DOE (e.g., teleconferences) since these may be used to determine future CNWRA experiments in the series and for future experimental design. (Reference 2020-PAR-0186)

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.

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