U.S. NUCLEAR REGULATORY COMMISSION STAFF OBSERVATION OF THE CALENDAR YEAR 2024 CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE AUDIT, CNWRA 2024-1

OBSERVATION AUDIT REPORT NO.: OAR-24-01

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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 Charter Contract 31310023D0004 and Work-For-Others Contract 31310023D0005. 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 3 through December 5, 2024, QA auditors from SwRI and technical specialists (auditors) conducted the audit CNWRA 2024-1 of two NRC funded projects performed by CNWRA at the SwRI facility in San Antonio, Texas. An NRC staff member (observer) from the Office of Nuclear Material Safety and Safeguards (NMSS) observed the audit at the SwRI facility and was the primary observer. The CNWRA held a preaudit meeting on December 3, 2024, on site with the auditors and NRC primary observer, and with NRC contract staff who participated virtually. The CNWRA also held a postaudit meeting on December 5, 2024, on site with the auditors and NRC primary observer, and with NRC contract staff who participated virtually.

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 January 10, 2025, SwRI report for CNWRA, "Quality Assurance Audit Report for Center for Nuclear Waste Regulatory Analyses (CNWRA) Audit, CNWRA 2024-1" (Agencywide Documents Access and Management System Accession No. ML25043A083).

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 three good practices, two minor nonconformances and four 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, and applicable 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 postaudit 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

Colby Tate	Institute Quality Systems (IQS) – Audit Team Leader
Mark Ehnstrom	IQS – QA Auditor
Angel Samanjego	IQS – Auditor-In-Training

3.2 Technical Specialists

David Turner, PhD	Professor of Environmental Science St. Mary's University, San Antonio, Texas
Roland Benke, PhD	Director – Technologies Division Renaissance Code Development, LLC, Corvallis, Oregon
3.3 NRC Observer	
Jeremy Tapp	Primary observer (NMSS/Division of Fuel Management/ Inspection and Oversight Branch Inspector)

4.0 REVIEW OF AUDIT AND AUDITED ORGANIZATION

The CNWRA provides technical support to the NRC staff under NRC Contracts 31310023D0004 and 31310023D0005. These contracts require CNWRA to meet the QA requirements of 10 CFR Parts 50, 63, 71, and 72. The 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 IQS procedure IQS–P081, "Audit and Surveillance Program Management," revision 5. The observer evaluated the audit using the guidance of NRC Inspection Manual Chapter 2410, "Conduct of Observation Audits."

5.0 SCOPE OF AUDIT

The audit of CNWRA was both compliance and performance-based. The auditors reviewed selected QA program elements to determine procedural compliance, as applicable. The audit was also performance-based in that the auditors reviewed technical activities to determine compliance with CNWRA QA control processes and procedures. The auditors risk-informed their selection of the technical topics for the audit based on technical risk, programmatic risk, and the time since an activity was last audited. 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, an auditor-intraining, and two technical specialists. The primary observer found the qualifications of the auditors to be acceptable and in compliance with SwRI quality system procedures. The primary observer also found the auditors to be independent of the activities they reviewed.

8.0 AREAS OF EXAMINATION

8.1 QA Elements

The auditors evaluated the following QA programmatic elements:

QA Programmatic Elements QA Manual*	Corresponding Chapter
Organization	1
QA Program	2
Design Control	Not Applicable**
Scientific/Engineering Investigation and Analysis Control	3
Procurement Document Control	4
Instructions, Procedures, and Drawings	5
Document Control	6
Control of Purchased Items and Service	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, interviewed responsible personnel, and observed laboratory activities to determine the effectiveness of programmatic and technical processes.

8.2 Technical Activities

The auditors selected the technical products for the audit based on the technical and programmatic risks involved and the time since an activity was last audited. The auditors evaluated the following technical products:

- <u>Technical Assistance for Review of the U.S. Department of Energy's Non-High Level</u> <u>Waste Determinations</u> The project task concerns updating and summarizing work performed by CNWRA during Fiscal Years 2022 through 2024 involving laboratory studies to evaluate potential radionuclide release rates from saltstone. (CNWRA Project 28500.02)
- <u>MELCOR Accident Consequence Code System (MACCS) Code Assessment: Testing,</u> <u>Benchmarking, Verification, Validation, and Confirmatory Analyses</u> This project details a comprehensive process of evaluating the accuracy and reliability of the MACCS computer code, used to analyze the potential offsite consequences of a nuclear power plant accident, by conducting various tests including benchmarking against real-world data, verifying its internal logic, validating its results against known scenarios, and performing confirmatory analyses to ensure its suitability for regulatory applications. (CNWRA Project 24013)

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

For the CNWRA 2024-1 audit as listed below, the auditors identified three good practices, two minor nonconformances and four recommendations for improvement.

The three good practices are:

• Programmatic

Good practice 1: The programmatic approach taken with Scientific Notebook #1347 captures the thinking process and key discussion points in project development. Unexpected conditions are clearly identified, and remedial actions are generally described in detail.

Good practice 2: The use of track changes in Microsoft Word and the capture of inprocess documents in the SharePoint system is implemented very effectively. Comments in particular use full names to clearly identify all participants. This approach is effective in capturing the thought process throughout the planning and conduct of the work, and the development of the deliverable. Good practice 3: CNWRA project execution with NRC engagement resulted in clear documentation, well-supported conclusions, and excellent communication of numerical information in graphical plots.

The two minor nonconformances identified by the auditors are:

• Programmatic

Minor nonconformance 1: Signature/initials were missing for line-outs and employees initials were not listed in the Abbreviations Table within Scientific Notebook #1343. This was corrected during the audit. (Reference 2024-CAR-0636 written to address this issue)

Minor nonconformance 2: Employee quality indoctrination and training completion was not documented by email per TAP-01-0702-002, "Quality Indoctrination and Training," section 4.3.2. The Division training system automatically documents completion of training for Division 01 personnel, but non-Division personnel still need to send Division Quality Assurance an email confirming training is complete. (Reference 2024-CAR-0637)

The four recommendations for improvement identified by the auditors are:

• Programmatic

Recommendation 1: The department should assess spreadsheets containing formulas to verify that cells used for calculations are safeguarded against any unauthorized adjustments. (Reference 2024-PAR-0168)

Recommendation 2: CNWRA should evaluate the use of chain of custody forms even when SwRI employees are performing testing at 3rd party laboratories. (Reference 2024-PAR-0169)

Recommendation 3: CNWRA should evaluate data management for long projects to ensure preservation and access to information is maintained. (Reference 2024-PAR-0170)

Recommendation 4: For CNWRA Project 24013, the 50-year time frame for estimating offsite cost could be emphasized in the report as it further supports the concluded underestimation of offsite costs in MACCS analyses. (Reference 2024-PAR-0171)

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

10.0 NRC STAFF FINDINGS/CONCLUSIONS

The NRC observer concluded that the audit process was thoroughly planned, effective, and performed in a professional manner. The NRC observer also concluded that the auditors developed and used audit checklists that were comprehensive and effective in providing guidance to the auditors. The SwRI audit team leader provided ample opportunities for the NRC staff to provide comments and ask questions throughout the audit process. The auditors and NRC observer discussed findings with CNWRA management during the postaudit meeting.

The NRC 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. In addition, the NRC 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 NRC observer agreed with the auditors' conclusion that the QA program was effectively implemented.