



Center for Nuclear Waste Regulatory Analyses
Chemistry and Chemical Engineering Division
Southwest Research Institute®
6220 Culebra Road
San Antonio, Texas USA 78238-5166
210.522.5157 • F. 210.522.5155

January 10, 2025
Contract No. 31310023D0004
Task Order No. 31310023F0032
Project No. 28500.01

U.S. Nuclear Regulatory Commission
Dr. Jin-Ping Gwo
NMSS/DFM/MSB
Mail Stop: TWFN 4 B34
Washington, DC 20555

Subject: Center for Nuclear Waste Regulatory Analyses Quality Assurance Audit Report
for 2024

Dear Dr. Gwo:

The purpose of this letter is to transmit the subject report for the 2024 Annual Quality Assurance Audit of the Center for Nuclear Waste Regulatory Analyses (CNWRA®). This document was prepared by the Southwest Research Institute® (SwRI®) Institute Quality Systems (IQS) group and is transmitted consistent with the requirements of the Management and Infrastructure task order under the contract for operation of the CNWRA.

The annual quality assurance audit was conducted December 3–5, 2024. The SwRI IQS group developed and transmitted the Audit Plan and Audit Schedule in advance of the audit. In addition to participation in selected portions of the audit by members of the U.S. Nuclear Regulatory Commission (NRC) staff, the audit was observed formally by an NRC staff member, who we understand will provide an audit observation report during the first quarter of calendar year 2025. Details regarding the audit and associated findings are provided in the attached report.

Dr. Jin-Ping Gwo
Page 2
January 10, 2025

Please contact me at david.pickett@swri.org or (210) 522-5582 if you have any questions concerning this matter.

Sincerely yours,

David A. Pickett
Director
Center for Nuclear Waste Regulatory Analyses

DAP/ar
Enclosure

NRC	CNWRA/SwRI
Scott Comeau	Carlos Barberino
Rob Robinson	Faye Brockwell
Rachel Glaros	Colby Tate
Kimyata Morgan-Butler	Angel Samaniego
Diane Jackson	Lane Howard
Kristina Banovac	Michael Lewis
Jeremy Tapp	Joe McDonough
Maurice Heath	
Duane White	
Salman Haq	
Nazila Tehrani	



SOUTHWEST RESEARCH INSTITUTE

QUALITY ASSURANCE AUDIT REPORT

For

**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES (CNWRA) AUDIT,
CNWRA 2024-1**

December 3-5, 2024

CONTENTS

EXECUTIVE SUMMARY	iii
AUDIT SCOPE	1
PROGRAMMATIC ELEMENTS AUDITED	1
AUDIT APPROACH	2
TECHNICAL ACTIVITIES AUDITED	2
AUDIT TEAM	3
APPLICABLE REQUIREMENTS DOCUMENTS	3
AUDIT APPROACH	5
QUALITY PROCEDURES REVIEWED	6
SUMMARY OF RESULTS	7
PERSONS CONTACTED	9
APPROVAL SIGNATURES	10

EXECUTIVE SUMMARY

The annual internal quality assurance (QA) audit for the Center for Nuclear Waste Regulatory Analyses (CNWRA), was performed December 3 – 5, 2024. The audit team, comprising technical specialists and QA auditors, determined that the CNWRA QA program continues to be effectively implemented and provides adequate controls over technical product development and related quality affecting activities. One (1) U.S. Nuclear Regulatory Commission (NRC) representative formally observed the audit.

The CNWRA staff continues to operate in accordance with the CNWRA *Quality Assurance Manual* (QAM), contracts, task-orders, and project plans, and applicable Chemistry and Chemical Engineering Division SOPs, TAPS, and Work Instructions. The technical staff was judged to be appropriately qualified through education, experience, and training. The technical work was determined to have been executed in a satisfactory manner.

The results of the audit were discussed with the CNWRA management and staff, as well as with the NRC audit observer during the post-audit meeting held on December 5, 2024. Three (3) good practices, two (2) minor nonconformance and four (4) recommendations for improvement were identified for the quality program and technical products. The nonconformances and recommendations will be tracked and dispositioned in the SwRI® Quality Reporting System (QRS).

AUDIT SCOPE

This internal audit evaluated the Center for Nuclear Waste Regulatory Analyses (CNWRA) quality assurance program to determine whether it meets contractually mandated QA program requirements and is being effectively implemented for Nuclear Regulatory Commission (NRC) sponsored activities. This was a full-scope audit in which all QA program elements applicable and two (2) technical tasks were evaluated.

PROGRAMMATIC ELEMENTS AUDITED

QA Program Criteria	Corresponding Chapter
Organization	1
Quality Assurance 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*

**Design-related activities are not performed by CNWRA; therefore, design control requirements are not applicable. All other QAM sections were addressed in the audit.

AUDIT APPROACH

A performance-based approach to auditing was accomplished to the extent possible by direct evaluation of selected technical activities, assessment of products, discussions with key project staff, and the contributions of these processes to product quality. Interview teams, composed of a programmatic QA auditor and the assigned technical specialist, performed the technical audits of the activities. The NRC observer was present during the technical sessions.

In preparation for the audit, technical specialists and QA auditors reviewed applicable proposals, the *Quality Requirements Application Matrix* (QRAM) for each project, procedures, other quality planning documents, and technical products. Technical checklists were prepared based on these reviews appropriate to each scope of work. A comprehensive QA programmatic checklist was prepared for application during each of the technical sessions and for the assessment of the programmatic elements.

The technical sessions were conducted through discussions with project management and key technical staff and review of objective evidence, which included document review packages and scientific notebooks (SNs), as appropriate. Programmatic audit activities also were conducted through review of objective evidence, evaluation of reports and SNs, discussions with project staff, and observation of laboratory activities. Technical and programmatic results were compiled for discussion and reporting.

TECHNICAL ACTIVITIES AUDITED

A risk-informed approach was applied in selecting the technical activities to audit by qualified technical specialists. Technical risk, programmatic risk, and the time since an activity was last audited were considered. Key technical topics identified for this audit include the following:

Project	Title
28500.02	Technical Assistance for Review of the U.S. Department of Energy's Non-High Level Waste Determinations.
24013	MELCOR Accident Consequence Code System (MACCS) Code Assessment: Testing, Benchmarking, Verification, Validation and Confirmatory Analyses.

In addition to specific project activities, the audit addressed general QA activities applied to all CNWRA processes, such as Document Control, Records Control, Nonconformance, and Corrective Action.

AUDIT TEAM

QA Auditors

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

U.S. NUCLEAR REGULATORY COMMISSION (NRC) OBSERVER(S)

Jeremy Tapp	Observer
-------------	----------

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

APPLICABLE REQUIREMENTS DOCUMENTS

The following criteria formed the basis of the audit conduct and the generation of audit checklists:

- Title 10 CFR Part 50, Appendix B [by reference in 10 CFR Part 60, Subpart G and 10 CFR 70.22(f)]
- Title 10 CFR Part 51
- Title 10 CFR Part 61
- Title 10 CFR Part 63, Subpart G
- Title 10 CFR Part 71, Subpart H
- Title 10 CFR Part 72, Subpart G
- ANSI/ASME NQA-1-1986
- CNWRA QA Manual (QAM)
- Division 01 Standard Operating Procedures (SOPs)
- CNWRA Test/Analytical Procedure (TAPs)

AUDITED ACTIVITIES

- **Technical Assistance for Review of the U.S. Department of Energy’s Non-High Level Waste Determinations.**

Audit Team

Dr. David Turner (*Technical Specialist*), Colby Tate (*QA Auditor*)

Task Description

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. During the more recent period, CNWRA conducted several activities, including (i) scanning electron microscopy (SEM) observations and energy dispersive spectroscopy (EDS) measurements of subsamples of previously leached saltstone simulants SS2A and SS3A, (ii) X-ray diffraction (XRD) analyses of powdered subsamples of SS2A and SS3A, (iii) attempted re-leaching of a small subsample of specimen SS5, and (iv) preparation of four new saltstone simulant specimens spiked with technetium and radioactive iodine using a new U.S. Department of Energy formula for ordinary Portland cement (OPC)-free saltstone, and (v) continued controlled aging of simulated saltstone specimens 1, 3B, and 4, which were prepared during FYs 2014, 2016, and 2017, respectively, but were never leached.

Products and Associated Documents Reviewed

- Fiscal Years 2022–2024, Saltstone Leaching Experiments Status Report—Draft” (IM 28500.02.032.135)
 - Fiscal Years 2022–2024, Saltstone Leaching Experiments Status Report—Final” (IM 28500.02.032.140)
 - Scientific Notebook #1343
 - Scientific Notebook #1347
- **MELCOR Accident Consequence Code System (MACCS) Code Assessment: Testing, Benchmarking, Verification, Validation and Confirmatory Analyses.**

Audit Team

Roland Benke (*Technical Specialist*), Colby Tate (*QA Auditor*)

Task Description

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

Products and Associated Documents Reviewed

- 24013 MACCS\Report_Task_6B_Level3comparison\Data and Computations\Level 3 PRA
- 24013 MACCS\Report_Task_6B_Level3comparison\Data and Computations\NUREG CR-4467 Inventory
- 24013 MACCS\Report_Task_6B_Level3comparison\Data and Computations\NUREG CR-4551
- 24013 MACCS\Report_Task_6B_Level3comparison\Checks by S Stothoff
- 24013 MACCS\Report_Task_6B_Level3comparison\Data and Computations\NUREG CR-6349
- 24013 MACCS\Report_Task_6B_Level3comparison\Data and Computations\NUREG_BR-0184
- 24013 MACCS\Report_Task_6B_Level3comparison\Report
- Comparing NUREG BR-0184 to Level 3 PRA_R5.pdf
- Comparing NUREG BR-0184 to Level 3 PRA_R5.docx
- Comparing NUREG BR-0184 to Level 3 PRA_R5_MU.docx
- Comparing NUREG BR-0184 to Level 3 PRA and Appendices_R5.pdf
- Comparing NUREG BR-0184 to Level 3 PRA and Appendices_R4.pdf
- Comparing NUREG BR-0184 to Level 3 PRA_R4.pdf
- FRM-923 Document Review Request and Transmittal Control.pdf
- FRM-924 Instructions to Technical Reviewers.pdf
- FRM-925 Calculation Verification Worksheet.pdf
- NRC Comments Updating NUREG BR-0184 tables TGhosh AJN.docx
- Comparing NUREG BR-0184 to Level 3 PRA, AJN, 4-23-2024.docx
- Comparing NUREG BR-0184 to Level 3 PRA_ProgrammaticReview.docx
- Comparing NUREG BR-0184 to Level 3 PRA_TechReview_R2.docx
- UNSCEAR_2020_21_Annex-B_Attach_A-20.pdf

Programmatic QA

Mark Ehnstrom, Angel Samaniego

QA Auditors

Colby Tate

AUDIT APPROACH

Elements that were not likely to be covered in the technical sessions or project reviews (topics including nonconformance control, document control, purchasing, QA records control, etc.) were assigned to the QA auditors. Applicable programmatic elements were also evaluated in each technical session, including *Scientific Notebook Control; Review of Documents, Reports, and Papers; Quality Planning; Documentation and Verification of Scientific and Engineering Calculations*; etc. The following are the QA procedures reviewed during the audit

and the results corresponding to that specific programmatic element.

QUALITY PROCEDURES REVIEWED

- **SOP-01-4.2.3, *Laboratory/ Scientific Notebook Requirements***
Electronic and physical notebooks were reviewed for adherence to the Division wide notebook requirements. One (1) nonconformance was identified under this programmatic element.
- **TAP-01-0701-009, *Records Processing***
Records were reviewed to ensure the proper instructions were followed for preparing, processing, storing, and delivering unclassified CNWRA records. No concerns were identified under this programmatic element.
- **TAP-01.0702-001, *Review of Documents, Reports, and Papers***
The entire audit team was involved in reviewing documents associated with their assigned technical areas. Project reviews performed by all audit team members included verifying conformance with the TAPs. No concerns were identified under this programmatic element.
- **TAP-01-0702-002, *Quality Indoctrination and Training***
Records of training, training notifications, and the database were reviewed during the technical sessions for the personnel involved in the activities. One (1) nonconformance was identified under this programmatic element.
- **TAP-01-0702-003, *Internal Audits***
The results of the 2023 CNWRA annual audit (2023-1) were reviewed prior to this audit under the follow-up surveillance, 2024-SR-0238, and any remaining items were addressed during this audit. There were no concerns identified under this programmatic element.
- **TAP-01-0702-004, *Quality Assurance Records Control***
Examination of archived quality records verified conformance to this procedure. There were no nonconformances identified under this programmatic element.
- **TAP-01-0702-005, *Quality Planning***
Quality planning was considered by each member of the audit team during the review of the technical documentation as well as through the project reviews. The Quality Requirements Application Matrix (QRAM) for each technical topic was used to verify implementation and conformance to this procedure. There were no nonconformances identified under this programmatic element.
- **TAP-01-0702-006, *Documentation and Verification of Scientific and Engineering Calculations***
The entire audit team was involved in reviewing scientific and engineering

calculations associated with technical areas audited and the project reviews. No concerns were identified under this programmatic element.

- **TAP-01-0702-008, *Drawing Control***
A drawing control process is established, and no concerns were identified under this programmatic element.
- **TAP-01-0702-009, *Procedure for Confirmatory Analysis***
The applicability of this procedure was reviewed during each technical session. No concerns were identified under this programmatic element.
- **TAP-01-0701-001, *Source Selection and Evaluation***
The entire audit team was involved in reviewing the applicability of this procedure in each technical session to determine if this process is being followed. No concerns were identified under this programmatic element.
- **TAP-01-0703-002, *Identification and Control of Samples and Chemical Reagents and Standards***
Laboratory controls implemented were reviewed. No concerns were identified under this programmatic element.
- **TAP-01-0703-005, *Control, Development and Modification of Scientific and Engineering Software***
A process for the development and control of scientific and engineering software is established. The requirements were not applicable for the two technical sessions evaluated during the audit.

SUMMARY OF RESULTS

Each technical activity was audited by a team of at least one technical specialist knowledgeable in the field of study and a programmatic QA auditor. Based on review of deliverables produced in the period since the last audit in December 2023, checklists were created specific to each technical task in addition to a general programmatic checklist addressing the QA requirements. Detailed checklists were used containing a total of sixty-three (63) items, which resulted in three (3) good practices, two (2) minor nonconformances, and four (4) recommendations. As the technical specialist evaluated the technical qualifications of involved personnel, rigor of the science or engineering involved, and thoroughness of supporting documentation, the programmatic auditor confirmed the presence of required documentation supporting the processes involved and their conformance to QA procedural requirements. This programmatic evaluation included review and approval of quality documents, SN controls, and training and qualification of the personnel involved in the activity. The following is a detailed description of the audit results, including the technical task or programmatic topic from which the results were noted.

- **Good Practice**

Three (3) good practices were identified during the audit.

Programmatic

- The programmatic approach taken with SN#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.
- The use of track changes in Microsoft Word and the capture of in-process documents in the SharePoint system is very effectively implemented. 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
- CNWRA project execution with NRC engagement resulted in clear documentation, well-supported conclusions, and excellent communication of numerical information in graphical plots.

- **Minor Nonconformance**

During the audit activities, two (2) minor nonconforming conditions were identified.

Programmatic

- Signature/initials were missing for line-outs and employs initials were not listed in the Abbreviations Table within notebook SN#1343 . This was corrected during the audit. See 2024-CAR-0636.
- Employee quality indoctrination and training completion was not documented by e-mail 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 DQA an email confirming training is complete. See 2024-CAR-0637.

- **Recommendations**

During the audit activities, four (4) recommendations were made, which if acted upon, may prevent future nonconformances or will support continuous improvement of the CNWRA quality program. These recommendations include the following.

Programmatic

- The department should assess spreadsheets containing formulas to verify that cells used for calculations are safeguarded against any unauthorized adjustments. (See 2024-PAR-0168)
- CNWRA should evaluate the use of chain of custody forms even when SwRI employees are performing testing at 3rd party laboratories. (See 2024-PAR-0169)

- CNWRA should evaluate data management for long projects to ensure preservation and access to information is maintained. (See 2024-PAR-0170)
- 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. (See 2024-PAR-0171)

QUALITY ASSURANCE PROGRAM EFFECTIVENESS

As determined by this annual audit, the QA program applied by the CNWRA continues to be adequate and effectively implemented. The nonconformances and recommendations identified provide opportunities for improvements and, if implemented, may reduce the potential to adversely affect products in the future or further enhance the products.

PERSONS CONTACTED

	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
CNWRA Staff and Consultants			
Pickett, D.	X	X	X
Howard, L.	X		X
Patrick, W.	X	X	X
Parmenter, D.		X	
NRC			
Tapp, J.	X		X
Gwo, J.	X		X
Glaros, R.	X		X
Jackson, D.	X		X
Morgan-Butler, K.	X		X
Audit Team and Others			
Barberino, C.	X		X
Ehnstrom, M.	X		X
Tate, C.	X		X
Samaniego, A.	X		X
Turner, D.	X		
Benke, R.	X		X
Brockwell, F.			X
Olivarri, J.		X	
Gomez, L.		X	
Dinwiddie, C.		X	
McDonough, J.			X
Gerhardus, J.			X

APPROVAL SIGNATURES

Colby Tate

21-December-2024

Colby Tate
Audit Team Leader (ATL)

Date

David Turner

12/31/2024

Dr. David Turner
Technical Specialist

Date

Roland Benke

Digitally signed by Roland Benke
Date: 2024.12.31 17:20:38 -06'00'

Dr. Roland Benke
Technical Specialist

Date

Carlos Barberino

SWRI

Digitally signed by cbarberino
Date: 2025.01.02 11:21:21 -06'00'

Carlos Barberino
CNWRA QA Staff Support

Date