SOUTHWEST RESEARCH INSTITUTE

QUALITY ASSURANCE AUDIT REPORT

For

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES AUDIT, CNWRA 2020-1

December 1 - 3, 2020

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EXECUTIVE SUMMARY

The annual internal quality assurance (QA) audit for the Center for Nuclear Waste Regulatory Analyses (CNWRA®) was performed December 1 - 3, 2020. A hybrid audit consisting of Webex sessions, file sharing, and physical walk-through of laboratories was conducted due to the COVID-19 pandemic. The audit team, comprised of 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 observed the audit.

The CNWRA staff continues to operate in accordance with the CNWRA *Quality Assurance Manual* (QAM); contracts, task-orders, and project plans; technical operating procedures (TOPs); QA procedures (QAPs); and applicable administrative procedures (APs). 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 and members of NRC senior management, during the post-audit meeting held on December 3, 2020. Two (2) minor nonconformances were identified. The nature of the nonconformances identified were determined by the audit team to pose minimal risk to the quality of CNWRA products. In addition, nine (9) recommendations were identified that may provide opportunities for improving the CNWRA quality program and technical products. All findings were issued and will be tracked and dispositioned in the SwRI® Quality Reporting System (QRS).

1.0 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 were evaluated and two (2) technical tasks with associated reports were audited.

2.0 PROGRAMMATIC ELEMENTS AUDITED

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

3.0 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 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). Technical and programmatic results were compiled for discussion and reporting. 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.

4.0 TECHNICAL ACTIVITIES AUDITED

A risk-informed approach was applied in selecting the technical activities to audit. Technical and programmatic risks and the time since the previous audit of an activity were considered in selecting the areas for this audit, as follows:

Project	Title
23700.04.020	BDOSE, biosphere dose assessment code
23700.04.031	Non-HLW Determinations; grout laboratory studies

5.0 AUDIT TEAM

QA Auditors

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

Technical Specialists

David Turner, PhD	Technical Specialist Environmental Assessment	St. Mary's University, San Antonio, Texas
Roland Benke, PhD	Technical Specialist Nuclear Engineering and Radiation Safety	Renaissance Code Development, LLC, Corvallis, Oregon

6.0 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 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)
- CNWRA QA Procedures (QAPs)
- CNWRA Administrative Procedures (APs)
- CNWRA Technical Operating Procedures (TOPs)

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

Jon Woodfield	Observer

8.0 AUDITED ACTIVITIES

8.1 BDOSE, biosphere dose assessment code

Audit Team
Dr. Roland Benke *(Technical Specialist)*, Ross Cantu (QA Auditor)

Task Description
The objective of this task is 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.

Products and Associated Documents Reviewed

- BDOSE Version 3.0 and Radon Submodel GoldSim player files
- BDOSE Radon Submodel Validation Report
- Associated software change reports and release notices

8.2 Non-HLW Determinations; grout laboratory studies

Audit Team
Dr. David Turner *(Technical Specialist)*, Mark Ehnstrom *(QA Auditor)*

Task Description
The objective of this task is to perform tests exploring the effects on water chemistry of 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.

Products and Associated Documents Reviewed

- IM 23700.04.031.005 Draft Tank Grout Water-Conditioning Tests—Fiscal Year 2019 Status Report
- IM 23700.04.031.010 Final Tank Grout Water-Conditioning Tests—Fiscal Year 2019 Status Report
- Referenced documents (Final Tank Grout Water-Conditioning Tests—Status Report, April 2019)
- Associated scientific notebooks (SN#1289, 1319, and 1332)

8.3 Programmatic QA

QA Auditors
Ross Cantu
Mark Ehnstrom

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. Following are the QA procedures reviewed during the audit and the results that corresponded to that specific programmatic element.

Quality Procedures Reviewed

- **QAP-001**, *Scientific Notebook Control*
  The entire audit team was involved in reviewing the scientific notebooks. No concerns were identified under this programmatic element.

- **QAP-002**, *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 QAP. No concerns were identified under this programmatic element.

- **QAP-004**, *Surveillance Control*
  The surveillance program implemented by CNWRA continues to be a value-added process. No concerns were identified under this programmatic element.

- **QAP-005**, *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. No concerns were identified under this programmatic element.

- **QAP-008**, *Document Control*
  Evaluation of this programmatic topic included control of documents, issue of controlled and uncontrolled documents, control of documents of external origin, and control of sensitive/proprietary information. There were no concerns identified under this programmatic element.

- **QAP-009**, *Nonconformance Control*
  Eleven (11) nonconformances were initiated since the last audit. No concerns were identified under this programmatic element.

- **QAP-010**, *Corrective Action*
  There were no corrective actions initiated since the last audit. No concerns were identified under this programmatic element.

- **QAP-011**, *Audits*
  The results of the 2019 CNWRA annual audit (2019-1) were reviewed prior to this audit under the follow-up surveillance, 2020-SR-0278, and any remaining items were addressed during this audit. There were no concerns identified under this programmatic element.

- **QAP-012**, *Quality Assurance Records Control*
  Examination of archived quality records verified conformance to this procedure. No concerns were identified under this programmatic element.

- **QAP-013**, *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 concerns identified under this programmatic element.

- **QAP-014**, *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.

- **QAP-016**, *Procurement*
  Purchase requisitions initiated in the previous 12 months for quality-affecting material were reviewed. Product received and accepted in the laboratories were also reviewed for proper identification. One (1) minor nonconformance was identified under this programmatic element.

- **QAP-017**, *Drawing Control*
  A drawing control process is established, and no concerns were identified under this programmatic element.

- **QAP-018**, *Procedure for Confirmatory Analysis*
  The applicability of this procedure was reviewed during each technical session. No concerns were identified under this programmatic element.

- **QAP-019**, *Control of Measuring and Test Equipment*
  Measuring and test equipment was evaluated in the laboratories of Building 57. No concerns were identified under this programmatic element.

- **AP-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.

- **TOP-012**, *Identification and Control of Samples and Chemical Reagents and Standards*
  Laboratory controls implemented in Buildings 57 and 65 were reviewed. One (1) minor nonconformance was identified under this programmatic element.

- **TOP-018**, *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 evaluated during one of the technical sessions. No concerns were identified under this programmatic element.

9.0 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 2019, 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 one-hundred and ten (110) items, which resulted in fifty-four (54) satisfactory items, two (2) minor nonconformances, nine (9) recommendations and forty-five (45) judged to be not applicable (NA) or that could not be evaluated (NE) due to lack of use or execution of the particular item. 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. Two (2) minor nonconformances and nine (9) recommendations are described in the following sections.

9.1 Minor Nonconformances

1. ***TOP-012, Identification and Control of Samples, Chemical Reagents, and Standards***

   Expired chemicals in Building 65 were not identified with a required *Expired* label and were not located in a designated storage area. (Reference 2020-CAR-0639)

2. ***QAP-016, Procurement***

   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. (Reference 2020-CAR-0640)

9.2 Recommendations

During the audit activities, nine (9) 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

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

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, *Instruction to Peer Reviewers*, is not being used.

   (Reference 2020-PAR-0179)

23700.04.020 – BDOSE, biosphere dose assessment code

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)

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)

23700.04.031 – Non-HLW Determinations; grout laboratory studies

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)

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)

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)

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)

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)

10.0 QUALITY ASSURANCE PROGRAM EFFECTIVENESS

As determined by this annual audit, with the exception of the nonconformances noted, the QA program applied by the CNWRA continues to be adequate and effectively implemented. The 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			
Patrick, W.	X		X
MacNaughton, M.			X
Pickett, D.	X	X	X
Juckett, M.	X		X
Pensado, O.	X	X	X
Laplante, P.	X	X	X
Dinwiddie, C.	X	X	
Boyd, J.			X
Reyes, M.		X	
Neill, L.	X	X	X
NRC			
Gwo, J.	X		X
Rubenstone, J.	X		X
Regan, C.	X		
Dudek, J.	X		X
Woodfield, J.	X		X
Audit Team and Others			
Barberino, C.	X	X	X
Cantu, R.	X		X
Ehnstrom, M.	X		
Turner, D.	X		X
Benke, R.	X		X
Brockwell, F.	X		X

APPROVAL SIGNATURES

Rosendo Cantu — 12/17/2020

Ross Cantu
Audit Team Leader (ATL)

Date

Mark R. Ehnstrom — 12/18/2020

Mark Ehnstrom
QA Auditor

Date

Approved via Email, per Ross Cantu — 12/18/2020

Dr. David Turner
Technical Specialist

Date

Roland R Benke — 12/18/2020

Dr. Roland Benke
Technical Specialist

Date

Digitally signed by Carlos H. Barberino
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Carlos Barberino
Sr. Quality Scientist, CNWRA QA Staff Support

Date