SOUTHWEST RESEARCH INSTITUTE

QUALITY ASSURANCE AUDIT REPORT

For

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES AUDIT, CNWRA 2017-1

December 5 - 6, 2017

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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 5 - 6, 2017. 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. A 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), operations 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 representative during the post-audit meeting held on December 7, 2017. Three (3) minor nonconformances were identified. All findings were issued in the SwRI® Quality Reporting System (QRS). The nature of the nonconformances identified was determined by the audit team to pose minimal risk to the quality of CNWRA products. In addition, six (6) recommendations were identified that may provide opportunities for improving the CNWRA quality program and technical products.

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
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*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 activities were also 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
17860.09.705	SOAR: A Model for Scoping of Options and Analyzing Risk version 2.0 User Guide (updating and verification)
17860.09.022	Copper and/or carbon steel corrosion

5.0 AUDIT TEAM

QA Auditors

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

Technical Specialists

Leonardo Caseres, PhD	Technical Specialist SwRI Sr. Research Engineer Materials Engineering	Mechanical Engineering (18)
Steven Green	Technical Specialist SwRI Institute Engineer Fluids & Machinery Engineering	Mechanical Engineering (18)

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
- Title 10 CFR Part 60, Subpart G
- Title 10 CFR Part 63, Subpart G
- Title 10 CFR Part 71, Subpart H
- Title 10 CFR Part 72, Subpart G
- 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

Jon Woodfield	Observer

8.0 AUDITED ACTIVITIES

8.1 SOAR: A Model for Scoping of Options and Analyzing Risk version 2.0 User Guide (updating and verification)

Audit Team
Steven Green *(Technical Specialist)*
Ross Cantu *(QA Auditor)*

Task Description
- The purpose of this task was to revise the SOAR performance assessment model from version 1.0 to 2.0.This included revisions to functional expressions to enhance flexibility of use and changes to a number of corrosion models, such as consolidation of the general corrosion model into one with fewer model elements. It was noted that the SOAR model is not used for regulatory decision making.

Products and Associated Documents Reviewed

- SOAR: A Model for Scoping of Options and Analyzing Risk Version 2.0 User Guide: Final Report, June 2017
- QAP-006 for 17860.09
- QRAM for 17890.09

8.2 Copper and/or carbon steel corrosion

Audit Team
Dr. Leonardo Caseres *(Technical Specialist)*
Mark Ehnstrom *(QA Auditor)*

Task Description
The purpose of this task was to determine the corrosion behavior of copper in various anaerobic solutions. The study also investigated hydrogen induced carbon steel cracking behavior in simulated concrete pore solutions.

Products and Associated Documents Reviewed

- Report: Effects of Chloride on Copper Corrosion and Cathodic Charging of Carbon Steel for Nuclear Waste Disposal Application, September, 2017
- QAP-006 for 17860.09
- QRAM for 17890.09

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, including books related to one (1) of the technical sessions. Each notebook was evaluated to determine conformance with the requirements of the procedure. One (1) minor nonconformance and one (1) recommendation 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 GED continues to be a value-added process. One (1) minor nonconformance was 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. One (1) minor nonconformance and one (1) recommendation were identified under this programmatic element.

- **QAP-009**, *Nonconformance Control*
  A sample of NCRs generated since the previous audit were reviewed and found to be thorough, complete, and the corrections were deemed effective. 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 2016 GED annual audit (2016-1) were reviewed prior to this audit under the follow-up surveillance, 2016-SR-0447, and any remaining items were addressed during this audit. No concerns were 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. One (1) recommendation was 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 each SN generated for the technical areas audited and the project reviews. No concerns were identified under this programmatic element.

- **QAP-016**, *Procurement*
  Purchase requisitions initiated in the previous twelve months for quality-affecting material were reviewed. No concerns were 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. Calibration of equipment in use was verified to be current or evidence of calibration verification was documented in the scientific notebooks. 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 Building 57 were reviewed. No concerns were identified under this programmatic element.

- **TOP-018**, *Control, Development and Modification of Scientific and Engineering Software*
  A sampling of controlled software was evaluated. These requirements were also 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 2016, 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 seventeen (117) items, which resulted in eighty three (83) satisfactory items, three (3) minor nonconformances and thirty one (31) 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,

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. Three (3) minor nonconformances and six (6) recommendations are described below.

9.1 Minor Nonconformances

1. ***QAP-008, Document Control***

   Documents were made effective prior to being approved which is in conflict with QAP-008, Document Control, section 3.3.4. Several documents were noted to have effective dates of 2/18/2017 which was prior to their approval date of 2/20/2017. In addition QAP-005, Rev 7 was made effective on 2/18/2017 but is missing an approved by signature and date.
   (Reference 2017-NCR-0450)

2. ***QAP-001, Scientific Notebook Control***

   There was no project manager review documented on form QAP-001 for a completed scientific notebook as required by QAP-001, Scientific Notebook Control, section 3.5.2. This issue was observed for scientific notebook 1250 which was completed in May 2017.
   (Reference 2017-NCR-0451)

3. ***QAP-004, Surveillance Control***

   The identifying number of a nonconformance report was not listed on the surveillance report as required by QAP-004, Surveillance Control, section 3.4.2. There was no reference to 2017-NCR-0267 provided on surveillance report 2017-SR-0488. Note: This instance was corrected at the time of the audit.
   (Reference 2017-NCR-0452)

9.2 Recommendations

During the course of the audit activities, six (6) 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:

QAP-008, Document Control

1. The following procedures should be revised following updates to the organization or to other documentation.
   - QAP-016 refers to obsolete IQS procedures and should be updated with the current procedures.
   - References to GED and Division should be removed from QAP-018, QAP-011 and TOP-018.
   - An incorrect form (TOP-6-2) is referenced in TOP-018, section 5.7.3. The correct form (TOP-6-1) should be referenced instead.
     (Reference 2017-PAR-0206)

QAP-013, Quality Planning

2. Consideration should be given to preparing individual QRAMs for each task within larger projects. This would allow the individual task QA requirements to be identified. (Reference 2017-PAR-0207)

QAP-001, Scientific Notebook Control

3. When late entries or corrections are made to records as a result of a nonconformance or corrective action report, the corresponding reference should be included in the record. For example the nonconformance reference (2017-NCR-0267) could have been added to entry in notebook 1312 to show this was a known late entry.
(Reference 2017-PAR-0208)

Copper and/or carbon steel corrosion

4. Consideration should be given to simultaneously exposing three or four specimens to each solution to provide reproducibility data for the copper and/or carbon steel corrosion experiments. Current data provides the execution of single test experiments in four solutions, using a single copper specimen for each test, but a minimum of duplicate test specimens are typically required to warrant that the test approach is valid with some degree of reproducibility.
(Reference 2017-PAR-0211)

5. Consider using alternative electrochemical impedance spectroscopy (EIS) equivalent circuits to model the EIS data since these alternative circuits may better fit the data for all the solutions used in the project. Circuits that contain Warburg impedance to represent diffusional controlled reactions or a series combination of Randles circuits to represent the passive oxide and any corrosion of the underlying oxide layer could be considered.
(Reference 2017-PAR-0211)

6. A summary report to draw all of the corrosion experiments and their conclusions together should be prepared. This would provide all the pertinent data and conclusions from several tasks, performed over a number of years, in one report and allow summary conclusions to be presented.
(Reference 2017-PAR-0211)

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.

PERSONS CONTACTED

	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
GED Staff and Consultants			
Patrick, W.	X		X
Pickett, D.	X	X	X
Pensado, O.	X	X	X
Howard, L.	X		X
He, X.		X	X
Neill, L.		X	X
Werling, B.		X	
NRC Observer			
Woodfield, J.			X
Audit Team and Others			
Barberino, C.	X	X	X
Brockwell, F.	X		X
Cantu, R.	X		X
Ehnstrom, M.	X		X
Caseres, L.	X		X
Green, S.	X		X
Lewis, M.	X		

APPROVAL SIGNATURES

Faye Brockwell
Audit Team Leader (ATL)

18 Dec 2017
Date

Ross Cantu
QA Auditor

12/19/2017
Date

Mark Ehnstrom
QA Auditor

12/18/17
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Dr. Leonardo Caseres
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18 DEC 2017
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15 DEC 2017
Date

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