

U.S. NUCLEAR REGULATORY COMMISSION STAFF OBSERVATION OF THE
FISCAL YEAR 2017 CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
QUALITY ASSURANCE AUDIT 2017-1

OBSERVATION AUDIT REPORT NO.: OAR-17-01

 /RA/ 2/2/2018
Jon Woodfield, Observer
Division of Spent 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 NRC Charter Contract NRC-HQ-12-C-02-0089 and the Enterprise Wide Contract (EWC) NRC-HQ-50-14-E-0001. These contracts require CNWRA to meet the quality assurance (QA) requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 63, "Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada;" Part 50, "Domestic Licensing of Production and Utilization Facilities;" Part 60, "Disposal of High-Level Radioactive Wastes in Geologic Repositories;" 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 5-6, 2017, QA auditors and technical specialists from SwRI (auditors) conducted the CNWRA Audit 2017-1 of two NRC funded programs conducted by CNWRA in San Antonio, Texas. One NRC staff member from the Office of Nuclear Material Safety and Safeguards (observer) observed the audit. The CNWRA held a post-audit meeting with the auditors and NRC observer on December 7, 2017.

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 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 19, 2017, SwRI report for CNWRA, "Quality Assurance Audit Report for Center for Nuclear Waste Regulatory Analyses Audit, CNWRA 2017-1" (ML18030A563).

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 minor nonconformances and six recommendations for improvements (see Section 9.0, Results). The 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, operations 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 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 observer to provide comments and ask questions throughout the audit process. The auditors and observer discussed potential findings with CNWRA management during caucuses, audit debriefs, and at the post-audit meeting.

The 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 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 observer agreed with the auditors' conclusion that the QA program was effectively implemented.

3.0 PARTICIPANTS

3.1 Auditors

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

3.2 Technical Specialists

Leonardo Caseres, PhD	SwRI Mechanical Engineering Division (18)
Steve Green	SwRI Mechanical Engineering Division (18)

3.3 NRC Observer

Jon Woodfield	Observer
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4.0 REVIEW OF AUDIT AND AUDITED ORGANIZATION

The CNWRA provides technical support to NRC staff under NRC Contracts NRC-HQ-12-C-02-0089 and NRC-HQ-50-14-E-0001. These contracts require CNWRA to meet the QA requirements of 10 CFR Parts 63, 50, 60, 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 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 in regard to risk insights. The observer determined that the auditors achieved the audit scope.

6.0 CONDUCT AND TIMING OF THE AUDIT

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

*CNWRA does not perform design-related activities.

The auditors addressed all of 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 CNWRA 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:

- SOAR: A Model for Scoping of Options and Analyzing Risk version 2.0 User Guide (updating and verification), Part of Task Order NRCT009 Under Contract NRC-HQ-12-C-02-0089 (CNWRA Project 17860.09.705)
- Copper and/or Carbon Steel Corrosion, Also part of Task Order NRCT009 Under Contract NRC-HQ-12-C-02-0089. (CNWRA Project 17860.09.022)

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 three minor nonconformances and six recommendations for improvement.

The first minor nonconformance identified by the auditors was:

- QAP-008, Document Control

Nonconformance Condition Report (NCR) NCR 2017-NCR-0450. 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 Revision 7 was made effective on 2/18/2017, but is missing an approved by signature and date.

The second minor nonconformance identified by the auditors was:

- QAP-001, Scientific Notebook Control

NCR 2017-NCR-0451. 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.

The third minor nonconformance identified by the auditors was:

- QAP-004, Surveillance Control

NCR 2017-NCR-0452. 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.

The six recommendations for improvements identified by the auditors are:

- QAP-008, Document Control

Recommendation 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 Geosciences and Engineering Division and Division should be removed from QAP-018, QAP-011, and Technical Operating Procedure 18 (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 Preventive Action Request 2017-PAR-0206)

- QAP-013, Quality Planning

Recommendation 2: Consideration should be given to preparing individual Quality Requirements Application Matrixes 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

Recommendation 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 the entry in notebook 1312 to show this was a known late entry. (Reference 2017-PAR-0208)

- Copper and/or Carbon Steel Corrosion Project

Recommendation 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)

Recommendation 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)

Recommendation 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)

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 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 observer to provide comments and ask questions throughout the audit process. The auditors and observer discussed findings with CNWRA management during the post-audit meeting.

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