

U.S. NUCLEAR REGULATORY COMMISSION STAFF OBSERVATION OF THE
FISCAL YEAR 2019 CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
QUALITY ASSURANCE AUDIT 2019-1

OBSERVATION AUDIT REPORT NO.: OAR-19-01

A handwritten signature in black ink, reading "Jon M. Woodfield". The signature is written in a cursive style with a horizontal line underneath the name.

Jon Woodfield, Primary Observer
Division of 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 current NRC Contracts 31310018D0001 and 31310018D002. Contract 31310018D0001 requires 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 10-11, 2019, QA auditors and technical specialists from SwRI (auditors) conducted the CNWRA Audit 2019-1 of three projects (two NRC funded) conducted by CNWRA in San Antonio, Texas. Two NRC staff members from the Office of Nuclear Material Safety and Safeguards (NMSS) observed the audit [one primary observer and the Contracting Officer Representative (COR) as a secondary observer]. The CNWRA held a post-audit meeting with the auditors, NRC primary observer, and COR on December 12, 2019. The NMSS Division of Fuel Management Director and Deputy Director also attended the post-audit meeting since they were at the SwRI that day.

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 7, 2020, SwRI report for CNWRA, "Quality Assurance Audit Report for Center for Nuclear Waste Regulatory Analyses Audit, CNWRA 2019-1" (ML20071F403).

2.0 MANAGEMENT SUMMARY

The auditors evaluated the adequacy of applicable QA program elements and three technical tasks during this full-scope audit. During the audit, the auditors identified two minor nonconformances and six 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, 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 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 and COR to provide comments and ask questions throughout the audit process. The auditors, primary observer, and COR discussed potential findings with CNWRA management during caucuses, audit debriefs, and at the post-audit 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

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

3.2 Technical Specialists

Dave Turner, PhD	Environmental Assessment Saint Mary's University, San Antonio
Roland Benke, PhD	Nuclear Engineering and Radiation Safety Independent Consultant
Florent Bocher, PHD	Senior Research Engineer SwRI Mechanical Engineering Division

3.3 NRC Observers

Jon Woodfield	Primary observer (NMSS/DFM/IOB Inspector)
Caylee Kenny	COR observer (NMSS/DFM/CTCF Mechanical Engineer)

4.0 REVIEW OF AUDIT AND AUDITED ORGANIZATION

The CNWRA provides technical support to NRC staff under NRC Contract 31310018D0001. This contract requires 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 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. The 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 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, two QA auditors, and three technical specialists. The primary observer found the qualifications of the auditors to be acceptable and in compliance with the CNWRA QA program. The primary 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

*The 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 auditors 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:

- Technical Assistance for the Development of an Environmental Impact Statement for Interim Storage Partners LLC's License Application Request for a Consolidated Interim Storage Facility for Spent Nuclear Fuel (Task Order 31310018F0126 Under NRC Contract 31310018D0001) (CNWRA Project 23700.06)
- Reactor Vessel Cladding Investigation for Chubu Electric (This Project was performed for a Japanese Electric Utility that has Nuclear Power Plants) (CNWRA Project 22533)
- Technical Assistance to NRC for Development of Regulatory Analyses Supporting 10 CFR Part 61 (Task Order 31310018F0091 Under NRC Contract 31310018D0001) (CNWRA Project 23700.05)

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 two minor nonconformances and six recommendations for improvement.

The two minor nonconformances identified by the auditors were:

- QAP-019, Control of Measuring and Test Equipment

Nonconformance Condition Report (NCR) NCR 2019-NCR-0686. Nonconformance reports are not consistently written when equipment is found to be out-of-tolerance upon recalibration as required by QAP-019. Since January 2019, five items have been identified as out-of-tolerance by the Institute Calibration Laboratory; however, only two nonconformance reports were issued.

- QAP-011, Audits

NCR 2019-NCR-0687. Audit related documents are not maintained or retained as required by QAP-011. The procedure requires that the following items be retained as permanent records in accordance with QAP-012, Quality Assurance Records Control: audit plans, auditor and technical specialist qualifications, checklists, meeting attendance rosters, and audit reports.

The six recommendations for improvements identified by the auditors are:

- Programmatic

Recommendation 1: It is not clear that the procedure QAP-011, Audits is only applicable to the annual audit of the CNWRA and that the performance of the ISO 9001 audit of Division 01 is addressed in SOP-01-8.2.2, Internal Quality Audits and Surveillances. The CNWRA should consider revision QAP-011 to clarify. (Reference Preventive Action Request 2019-PAR-0268)

Recommendation 2: The CNWRA should consider using the Division 01 training system to track and document training in procedures (e.g.). Administrative Procedures, QA Procedures and Technical Operating Procedures). This would automate the notification, tracking and record keeping for internal Division 01 staff and would also provide options to easily track and document for outside support (Consultants, other non-Division 01 SwRI employees). (Reference 2019-PAR-0269)

Recommendation 3: The use of the “Uncontrolled” watermark on current versions of documents should be evaluated and either updated to state “Uncontrolled copy when printed” or to only apply the “Uncontrolled” water mark at the time of printing. Obsolete (previous versions) of documents should be saved in a limited access folder. (Reference 2019-PAR-0270)

- Technical Assistance for the Development of an Environmental Impact Statement for Interim Storage Partners LLC’s License Application Request for a Consolidated Interim Storage Facility for Spent Nuclear Fuel

Recommendation 4: Good practices should be included in routine training of environmental review staff and external subject matter experts. Training should be documented using existing CNWRA QA practice, including acknowledgement of receipt of training materials, or sign-in sheets for specific sessions. (Reference 2019-PAR-0271) Good practices include:

- Use of the Pacific Northwest National Laboratory developed, NRC sponsored, software-based comment response system (Comment Response Database) to manage more than 29,000 public comments. The CNWRA project management team showed the processing of comments through the system to the Environmental Impact Statement, and described the systems used to delineate, summarize, respond to, and cross check the database for accuracy.
- Use of a Sharepoint system to monitor Requests for Additional Information (RAI) response status with NRC project management. RAI response meetings with the applicant are public meetings and documented using existing NRC practice.
- Use of list-serves, notifications, and coordination with the NRC safety review team to ensure consistency of the environmental review with facility design and licensing.
- Use of incorporation by reference for applicant environmental commitments in developing environmental mitigation measures and monitoring as a part of impact significance determinations.

Recommendation 5: The CNWRA should update the Environmental Impact Statement Scoping Process Summary Report, Section A.2 Background to correct the date referenced in relation to 83 FR 53115 from November 19, 2019 to November 19, 2018. (Reference 2019-PAR-0272)

- Technical Assistance to NRC for Development of Regulatory Analyses Supporting 10 CFR Part 61

Recommendation 6: Because results in Figure 5 were computed from the suite of GoldSim calculations, instead of a separate GoldSim model, explicitly stating this in the report would add clarity. The technical approach is valid, but CNWRA should also replace mention of a single disposal cell with a single disposal facility for this figure. (Reference 2019-PAR-0273)

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

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