

U.S. NUCLEAR REGULATORY COMMISSION STAFF OBSERVATION OF THE
FISCAL YEAR 2015 CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
QUALITY ASSURANCE AUDIT 2015-1

OBSERVATION AUDIT REPORT NO.: OAR-15-01

/RA/

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and Environmental Review
Office of Nuclear Material Safety
and Safeguards

Enclosure

1.0 INTRODUCTION

The Center for Nuclear Waste Regulatory Analyses (CNWRA), Geosciences and Engineering Division (GED), of 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. This contract requires 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." On December 15-17, 2015, QA auditors and technical specialists from SwRI (auditors) conducted the GED Audit 2015-1 of NRC-funded programs conducted by CNWRA (audit) in San Antonio, Texas. NRC staff from the Office of Nuclear Material Safety and Safeguards (observer) observed the audit. The CNWRA held a post-audit meeting with the NRC on December 17, 2015.

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 of 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 January 13, 2016, CNWRA report, "Quality Assurance Audit Report for Geosciences and Engineering Division Audit 2015 of NRC-Funded Programs Conducted by the Center for Nuclear Waste Regulatory Analyses" (ML16071A068).

2.0 MANAGEMENT SUMMARY

The auditors evaluated the adequacy of applicable QA program elements and three technical tasks during this full-scope audit. The observer found the auditors to be qualified and independent of the activities and technical areas audited. During the audit, the auditors identified one good work practice and six recommendations for improvements (see Section 9.0, Results).

The auditors determined that: (1) the QA program applied by the GED continues to be effectively implemented and provides adequate controls over technical product development and related quality affecting activities, (2) the technical work was determined to have been executed in a satisfactory manner, and (3) the recommendations provided opportunities for improvements of the GED quality program and technical products.

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 Bockewell	Institute Quality Systems (IQS) – Audit Team Leader
Thomas Trbovich	IQS – Auditor
Mark Ehnstrom	IQS – Auditor

3.2 Technical Specialists

Augusto Garcia Hernandez	SwRI Mechanical Engineering Division (18)
Leonardo Caseres, PhD	SwRI Mechanical Engineering Division (18)
Dave Turner, PhD	St. Mary's University, San Antonio

3.3 NRC Observer

Thomas Matula	Observer
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4.0 REVIEW OF AUDIT AND AUDITED ORGANIZATION

The CNWRA provides technical support to NRC staff under NRC Contract NRC-HQ-12-C-02-0089. This contract requires CNWRA to meet the QA requirements of 10 CFR Part 63. CNWRA performed the audit to determine whether its QA program meets contractually mandated QA program requirements and was effectively implemented for NRC sponsored activities of 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 (QAP)-011, "Audits." The observer evaluated the audit using the guidance of NRC 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 audit scope was achieved.

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 contract. The observer also determined that the auditors achieved the purpose of the audit.

7.0 AUDIT TEAM QUALIFICATION AND INDEPENDENCE

The audit team comprised an Audit Team Leader, two QA auditors, and three 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 in 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:

- Technical Assistance for Independent Cost Estimation (ICE) Under Contract No.: NRC-HQ-50-14-E-0001, Task Order No.: NRC-HQ-20-15-T-0012 – Task Order 37 (19934.01)
- Disposal-Related Integrated Spent Nuclear Fuel Regulatory Activities - Identification and Analysis of Key Regulatory and Technical Issues for Disposal of Spent Nuclear Fuel and High-Level Waste, Task Order 9 Under Contract NRC-HQ-12-C-02-0089, Subtask 3 - Waste Package; Experiments on Corrosion of Copper and Carbon Steel Waste Containers – Progress Report (17860.09.013)
- Technical Assistance for the Development of an Environmental Impact Statement (EIS) for Termination of NRC Materials License SUB-1435 for the Depleted Uranium Impact Area at Jefferson Proving Ground, Madison, Indiana – Task Order No.: 9 (19921.01)

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 one good work practice and six recommendations for improvements.

The good work practice identified by the auditors is:

- Disposal-Related Integrated Spent Nuclear Fuel Regulatory Activities - Identification and Analysis of Key Regulatory and Technical Issues for Disposal of Spent Nuclear Fuel and High-Level Waste, Task Order 9 Under Contract NRC-HQ-12-C-02-0089, Subtask 3 - Waste Package; Experiments on Corrosion of Copper and Carbon Steel Waste Containers – Progress Report (17860.09.013)

Good Word Practice: The CNWRA Principal Investigator sent known concentration (blind) samples to the analytical laboratories to confirm the accuracy of the testing performed.

The six recommendations for improvements identified by the auditors are:

- Technical Assistance for ICE Under Contract No.: NRC-HQ-50-14-E-0001, Task Order No.: NRC-HQ-20-15-T-0012 – Task Order 37 (19934.01)

Recommendation 1: The CNWRA should identify a method to capture the following items that were identified in the final report:

- The Short Term Replacement power calculation presented on Pages 2-9 of the final report should be reviewed and clarified;
 - A clarification should be provided to address the difference between the cost presented in Tables 3-4 and Tables 3-6 for the One-Time cost per reactor for the reactors that are currently in operation (previously identified and discussed with NRC);
 - For document consistency, the recurring cost amount or time for the expected recurring cost in Table 3-10, SI No 4, Pages 3-10, should be incorporated;
 - The correct equation should be provided in Tables 3-11, Pages 3-12, as used in the calculation of the average number of alternatives.
- Disposal-Related Integrated Spent Nuclear Fuel Regulatory Activities - Identification and Analysis of Key Regulatory and Technical Issues for Disposal of Spent Nuclear Fuel and High-Level Waste, Task Order 9 Under Contract NRC-HQ-12-C-02-0089, Subtask 3 - Waste Package; Experiments on Corrosion of Copper and Carbon Steel Waste Containers – Progress Report (17860.09.013)

Recommendation 2: The CNWRA should consider the following items for any future work in the area of corrosion analysis:

- The deionized water used for the source solutions should be checked to ensure there is no contamination;
 - Potassium and sodium ions should be included in the concrete pore solution since these ions could promote hydrogen induced cracking of carbon steel;
 - The test setup for the corrosion of carbon steel should be improved in order to mitigate conspicuous crevice corrosion in undesirable areas;
 - Ensure the hydrogen concentration in metals is measured shortly after the test is completed to avoid any hydrogen loss;
 - Document all periodic verification and maintenance of the oxygen probe.
- Technical Assistance for the Development of an EIS for Termination of NRC Materials License SUB-1435 for the Depleted Uranium Impact Area at Jefferson Proving Ground, Madison, Indiana – Task Order No.: 9 (19921.01)

Recommendation 3: Section 4.4 of the Draft EIS states “NRC conducted independent review of the models and supporting data developed by the Army to evaluate their validity and developed its own assessment of potential impacts to water resources”. This wording may imply that NRC staff have performed independent confirmatory calculations; therefore, wording should be clarified that no independent calculation verifications have been performed at this time as part of the confirmatory analysis, and should be addressed in future submissions.

- QAP-005, Quality Indoctrination and Training

Recommendation 4: The CNWRA should revise QAP-005 to remove the use of Form QAP-2, Document Transmittal, Training, and Acknowledgement Records, since this form is no longer used. The auditors noted that training is documented through e-mail notification.

- QAP-013, Quality Planning

Recommendation 5: All sections of Form QAP 17, Quality Requirements Application Matrix (QRAM), should be completed to show that a review and evaluation of each area and question has been performed. The auditors observed that several QRAM areas or questions were not marked for Project 19934.01. In addition, the auditors observed that questions on the QRAM should be reviewed and reworded, where necessary, to allow for a “Yes” or “No” response, and to capture all required information.

- QAP-002, Review of Documents, Reports, and Papers

Recommendation 6: The technical review requirements for an EIS report should be evaluated to ensure Form QAP-012, Instructions to Technical Reviewers, identifies the following “Technical Correctness” review criteria, when appropriate:

- Critical information obtained from cited sources is accurately described and correctly interpreted;
- Data are appropriate and are properly referenced;
- Conclusions are properly supported by correctly interpreted data;
- Calculations require verification.

The auditors determined that: (1) the QA program applied by the GED continues to be effectively implemented and provides adequate controls over technical product development and related quality affecting activities, (2) the technical work was determined to have been executed in a satisfactory manner, and (3) the recommendations provided opportunities for improvements of the GED quality program and technical products.

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 potential findings with CNWRA management during caucuses, audit debriefs, and at the post-audit meeting.

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