U.S. NUCLEAR REGULATORY COMMISSION STAFF OBSERVATION OF THE FISCAL YEAR 2011 CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE AUDIT 2011-1

OBSERVATION AUDIT REPORT NO. OAR-11-01

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Enclosure

1.0 INTRODUCTION

The Center for Nuclear Waste Regulatory Analyses (CNWRA) provides technical support to U.S. Nuclear Regulatory Commission (NRC) staff under NRC Contract NRC-02-07-006. Under this contract, CNWRA is required to meet the quality assurance (QA) requirements of 10 CFR Part 63. On August 23-25, 2011, QA auditors and technical specialists from Southwest Research Institute (SwRI) (auditors) conducted the Fiscal Year 2011 CNWRA, Geosciences and Engineering Division, QA Audit 2011-1 (audit) at CNWRA facilities in San Antonio, Texas. NRC staff from the Office of Nuclear Material Safety and Safeguards (observers) observed the audit.

The scope of audit was to evaluate the CNWRA QA program to determine whether it met applicable requirements and was being effectively implemented. The objective of the NRC observers 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 September 23, 2011 CNWRA report, "Quality Assurance Audit Report for Geosciences and Engineering Division Audit 2011-1 of NRC-Funded Programs Conducted by the Center for Nuclear Waste Regulatory Analyses" (ML112660523).

2.0 MANAGEMENT SUMMARY

The audit was full-scope in which the auditors evaluated the adequacy of applicable QA program elements and the acceptability of five technical tasks. The audit team comprised qualified SwRI auditors. The NRC observers found the auditors to be independent of the activities and technical areas being audited. The auditors identified one major nonconformance, three minor nonconformances, and 10 recommendations for improvements. The auditors also identified one good practice as an example of an exemplary work practice.

The auditors determined that the nature of the nonconformances identified in the audit does not pose a significant potential to adversely affect products or the overall effectiveness of the program. The auditors concluded that the CNWRA QA program continues to be adequate and effectively implemented. The auditors determined that the recommendations identified provide opportunities for improvements and, if implemented, may reduce the potential to adversely affect products in the future.

The observers 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 observers to provide comments and ask questions throughout the audit process. The auditors and observers discussed potential findings with CNWRA management during caucuses, audit debriefs, and at the post-audit conference.

The observers determined that the audit achieved its objectives of evaluating the CNWRA QA program to verify that it met applicable requirements and was being effectively implemented. The NRC observers determined that the audit was effective in reviewing, evaluating, and determining risks and the associated compliance with procedural requirements in the areas controlled by QA program requirements. The NRC observers agreed with the auditors' conclusions that the QA program was being effectively implemented and provided adequate controls over quality-affecting activities.

The observers noted at the conclusion of the audit that the identified nonconformances and

recommendations could be generally attributed to inattention to detail. The observers recommended that CNWRA management and staff continue to emphasize the focus on attention to detail in performing quality-affecting activities. The observers will review CNWRA's examination of the identified discrepancies and the effectiveness of its actions.

3.0 PARTICIPANTS

3.1 Auditors

Thomas Trbovich	Institute Quality Systems (IQS) - Audit Team Leader
Faye Brockwell	IQS, QA Auditor
Mark Ehnstrom	IQS, QA Auditor
Ross Cantu	IQS – Auditor-in-Training

3.2 Technical Specialists

Michael Dammann	SwRI Division 01
Carl Popelar	SwRI Division 18
Sterling Kinkler	SwRI Division 10
Robert Mason	SwRI Division 08
Ashley Smith	SwRI IQS

3.3 NRC Observers

Thomas Matula	Observation Team Leader
Deborah DeMarco	Center Deputy Program Manager

4.0 REVIEW OF AUDIT AND AUDITED ORGANIZATION

The CNWRA provides technical support to NRC staff under NRC Contract NRC-02-07-006. In performing work under this contract, CNWRA is required to meet the QA requirements of 10 CFR Part 63. The CNWRA conducted the audit to determine whether its QA program continues to meet contractually mandated QA program requirements and is effectively implemented for NRC-funded activities. The NRC staff observed 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 NRC staff observed the audit using the guidance of NRC Manual Chapter 2410, "Conduct of Observation Audits."

5.0 SCOPE OF AUDIT

The 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 observers determined that the audit scope was achieved.

6.0 CONDUCT AND TIMING OF THE AUDIT

The observers determined that the auditors were thorough and effective, and performed in a professional manner. The observers also 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 observers 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, one QA auditor-in-training, and five technical specialists. The NRC observers found the qualifications of the audit team members to be acceptable and in compliance with the CNWRA QA program. The observers 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:

QA Programmatic Elements	Corresponding GED QA Manual Chapter
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. 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 CNWRA personnel to determine the effectiveness of implementing procedures and technical processes.

8.2 Technical Activities

The CNWRA determined the technical areas for the audit based on the level of activity, technical risks involved, programmatic risks involved, and the time since each area had last been audited. The auditors evaluated the technical activities listed below:

- Column Experiment on Technetium-99 Leaching from Simulated Saltstone Grout (14003.01.007)
- Scoping of Options and Analyzing Risk (SOAR) Model and Users Guide (14005.01.001)
- Effect of Wet and Dry Cycling on Aging of Medium Voltage Electric Cables (15555.01.023)
- Knowledge Management/Capture: History and Value of Uncertainty and Sensitivity Analyses Acquired In-House Over Past 20 Years (14002.01.441.170)
- Verification and Validation of Fracture Analysis of Vessels (FAVOR) and Extremely Low Probability of Rupture (xLPR) and xLPR Codes Comparison (15948.01.001/.002/.003)

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 QA auditors and technical specialists who evaluated activities from their individual perspectives, and evaluated implementation of procedures and plans associated with product development.

9.0 Results

As listed below, the auditors identified one good practice, one major nonconformance, three nonconformances, and 10 recommendations. The auditors determined that the nonconformances identified do not have a significant potential to adversely affect products or the overall effectiveness of the program.

- Good Practice – Column Experiment on Technetium-99 Leaching from Simulated Saltstone Grout: The porosity value of the grout solution was calculated and subsequently verified experimentally

- Major Nonconformance – Verification and Validation of FAVOR and xLPR and xLPR Codes Comparison: There was no conflict of interest/Source Evaluation Committee review of Division 18 staff utilized on the project; three nonconformance reports have previously been issued for the same condition during the past year

- Minor Nonconformance 1 – Column Experiment on Technetium-99 Leaching from Simulated Saltstone Grout: Justification for missing calculation over-checks was not available

- Minor Nonconformance 2 – Effect of Wet and Dry Cycling on Aging of Medium Voltage Electric Cables: Calibration documentation from Grubb Engineering did not identify required traceability to National Institute of Standards and Technology

- Minor Nonconformance 3 – Effect of Wet and Dry Cycling on Aging of Medium Voltage Electric Cables (Procurement Control): The required procurement plan for quality-affecting cables purchased from a supplier who was not on the Approved Supplier List was not available

- Recommendation 1 – Column Experiment on Technetium-99 Leaching from Simulated Saltstone Grout: Record the collected transformed spectral index of external standards data to demonstrate constant quench; verify the actual solution composition in Table 2-3 against the solution in Table 2-2 to account for differences and errors; provide duplicate tests to prove homogenous grout mixture; and provide traceability information for standards used

- Recommendation 2 – SOAR Model and Users Guide: Control folder access on the N-drive to prevent inadvertent changes or deletions

- Recommendation 3 – Effect of Wet and Dry Cycling on Aging of Medium Voltage Electric Cables: Revise the Procedure for Confirmatory Analyses (QAP-018) to remove reference to the Confirmatory Analysis Logbook which is not currently used

- Recommendation 4 – Knowledge Management/Capture: History and Value of Uncertainty and Sensitivity Analyses Acquired In-House Over Past 20 Years: Add a note indicating that documents are knowledge-capture summaries only and do not describe usefulness or accuracy of chosen methods

- Recommendation 5 – Verification and Validation of FAVOR and xLPR and xLPR Codes Comparison: Maintain adherence to proper use of terms for software verification and software validation

- Recommendation 6 – Scientific Notebook Control (QAP-001): Establish version control for scientific notebooks (SNs) when original entries are changed; use transfer SNs to maintain records and verification of hand-developed notes; and evaluate the electronic SNs process to address the use of blank pages and references made to other SNs

- Recommendation 7 – Review of Documents, Reports, and Papers (QAP-002): Modify Instructions to Technical Reviewers (Form QAP-12) to identify the reviewers for each section reviewed; and modify Document Review Request and Transmittal Control (Form QAP-6) to identify all report contributors

- Recommendation 8 – Surveillance Control (QAP-004): Correlate the surveillance schedule and surveillance activity/scope in Table 1 of Surveillance Control (QAP-004); and track recommendations made during surveillance activities to conclusion

- Recommendation 9 – Professional Personnel Qualification (QAP-007): Include resumes for NRC personnel under staff exchange indicating qualifications and indoctrination into the CNWRA QA program; reference professional titles rather than payroll titles in Professional Personnel Qualification Records (Form QAP-11)
- Recommendation 10 – Procurement (QAP-016): Determine what receiving inspection

documentation (e.g., purchase requisition, receipt traveler) is to maintained as QA records as required by Quality Assurance Records Control (QAP-012)

The auditors determined that the nature of the nonconformances identified in the audit does not pose a significant potential to adversely affect products or the overall effectiveness of the program. The auditors concluded that the CNWRA QA program continues to be adequate and effectively implemented. The auditors determined that the recommendations identified provide opportunities for improvements and, if implemented, may reduce the potential to adversely affect products in the future.

9.0 NRC STAFF FINDINGS/CONCLUSIONS

The observers 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 observers to provide comments and ask questions throughout the audit process. The auditors and observers discussed potential findings with CNWRA management during caucuses, audit debriefs, and at the post-audit conference.

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