U.S. NUCLEAR REGULATORY COMMISSION STAFF OBSERVATION OF THE FISCAL YEAR 2012 CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE AUDIT 2012-1

OBSERVATION AUDIT REPORT NO. OAR-12-01

/RA/
Thomas Matula, Observation Team Leader
Division of Spent Fuel Alternative Strategies
Office of Nuclear Material Safety
and Safeguards

/RA/
Deborah DeMarco, NRC Center Deputy
Program Manager
Division of Spent Fuel Alternative Strategies
Office of Nuclear Material Safety
and Safeguards

Enclosure

1.0 INTRODUCTION

The Center for Nuclear Waste Regulatory Analyses (CNWRA) Geosciences and Engineering Division (GED) 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 28-30, 2012, QA auditors and technical specialists from Southwest Research Institute (SwRI) (auditors) conducted the Fiscal Year 2012 CNWRA, Geosciences and Engineering Division, QA Audit 2012-1 (audit) at CNWRA facilities in San Antonio, Texas. Two NRC staff from the Office of Nuclear Material Safety and Safeguards 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.

Details of the audit are available in the September 25, 2012 CNWRA report, "Quality Assurance Audit Report for Geosciences and Engineering Division Audit 2012-1 of NRC-Funded Programs Conducted by the Center for Nuclear Waste Regulatory Analyses" (ML12299A162).

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 three technical tasks. The audit team comprised qualified auditors. The observers found the auditors to be independent of the activities and technical areas audited. The auditors identified two minor nonconformances and 11 recommendations for improvements. The auditors also identified one good practice.

The auditors determined that: (1) the QA program applied by the GED continues to be adequate and effectively implemented; (2) 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; and (3) 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 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 observers agreed with the auditors' conclusions that the QA program was being effectively implemented and provided adequate controls over quality-affecting activities.

3.0 PARTICIPANTS

3.1 Auditors

Thomas Trbovich	Institute Quality Systems (IQS) – Audit Team Leader
Faye Brockwell	IQS – Auditor
Ashley Smith	IQS – Auditor
Ross Cantu	IQS – Auditor

3.2 Technical Specialists

Darius Daruwalla	SwRI Division 01
Steve Green	SwRI Division 18
Barry Badders	SwRI Division 01

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. CNWRA performed 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, three IQS auditors, three SwRI 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:

- Quantitative Hazards Development in Support of Department of Energy/Nuclear Regulatory Commission (DOE/NRC) Interagency Agreement (14014.01.001)

- Key Regulatory and Technical Issues: Numerical Simulations and Analysis of Lava Flow Cooling (14005.02.001.201)

- Technical Review and Safety Evaluation of the National Fire Protection Association (NFPA) 805 License Amendment Request for the Donald C. Cook Nuclear Plant Unit 1 and 2 Covering Fire Modeling and Fire Protection (16607.02.002)

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, two nonconformances, and 11 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.

The good practice identified is as follows:

- Key Regulatory and Technical Issues: Numerical Simulations and Analysis of Lava Flow Cooling: The use of SharePoint for reviews of the report easily shows document revisions and comments and approvals by individuals.

The two minor nonconformances identified are follows:

Programmatic topics:

- Technical Operating Procedures (TOP)-012, Identification and Control of Samples and Chemical Reagents and Standards: A bottle of pH 5.0 buffer solution in the Geochemistry group laboratory had expired.

- QAP-019, Control of Measuring and Test Equipment: No entry was found in the scientific notebook confirming that a performance verification of a Solartron SI1287 Electrochemical Interface was performed.

The 11 recommendations identified are as follows:

Quantitative Hazards Development in Support of DOE/NRC Interagency Agreement

- Consider explaining the radionuclide inventory change during spent nuclear fuel storage.

- Consider using Selective Catalytic Reduction for nitrogen oxide abatement.

- Sections in the report should be reviewed that reference iodine isotopes I-131 and I-129.

Key Regulatory and Technical Issues: Numerical Simulations and Analysis of Lava Flow Cooling

- Consider revising the report to make conclusions sound less general.

- Consider revising the Quality Requirements Application Matrix (QRAM) or issuing a new QRAM that is task specific.

- Consider reviewing control of software to determine if minor versions of software should be controlled (i.e., ANSYS_/FLUENT Versions 12.1, 12.1.2, 12.1.4).

Tech Review and Safety Evaluation of NFPA 805 License Amendment Request for the Donald C. Cook Nuclear Plant Unit 1 and 2 Covering Fire Modeling and Fire Protection

- Consider reviewing control of software to determine if Fire Dynamics Tool and FIVE-Rev1 in Excel should be controlled under TOP-018 as they are used as “applications” developed by the NRC.

- Where entries are made in the scientific notebooks for clarification, ensure it is clear who actually performed the task/work.

QAP-019, Control of Measuring and Test Equipment

- A review of the weekly balance verification performed in lab L106 should be completed. The acceptable tolerance should be reviewed to ensure it is suitable. The values used to calculate the acceptance limits should be based on the certified value of the calibration weights. In addition, the actions to take in the event a value is obtained outside the acceptance limits should be stated.

QAP-004, Surveillance Control

- Consider updating Section 3.2.3 to remove the requirement to revise the annual surveillance schedule when the timing of programmatic surveillances is changed.

QAP-005, Quality Indoctrination and Training

- Division QA should review and clarify the procedure for QA program indoctrination for the audit team technical specialists.

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.

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 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 observers agreed with the auditors' conclusions that the QA program was being effectively implemented and provided adequate controls over quality-affecting activities.