

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 June 9-11, 2009, QA and technical staff from Southwest Research Institute (SwRI) (auditors) conducted the Fiscal Year 2009 CNWRA, Geosciences and Engineering Division (GED), QA Audit 2009-1 at CNWRA facilities in San Antonio, Texas. NRC staff from the Office of Nuclear Material Safety and Safeguards (observers) observed the audit.

The objective of this audit was to evaluate the GED QA program to verify that 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 QA program.

Details of the scope, conduct, findings, and conclusion of the audit are available in the July 7, 2009, CNWRA report, Quality Assurance Audit Report for Geosciences and Engineering Division Audit 2009-1 of NRC-Funded Programs Conducted by the Center for Nuclear Waste Regulatory Analyses. (ML091900351)

2.0 MANAGEMENT SUMMARY

The audit team comprised qualified SwRI auditors and technical specialists trained by GED in auditing techniques. The NRC observers found the auditors to be independent of the activities and technical areas being audited. The auditors identified eight nonconformances with GED QA program requirements, six of which were corrected during the course of the audit, seven recommendations to improve implementation of the QA program, and one good practice. The auditors determined that the eight identified nonconformances are unlikely to have an adverse impact on the quality of CNWRA technical products. The auditors concluded that the GED QA program was being effectively implemented and provided adequate controls over technical product development.

The NRC observers determined that the auditors achieved their objective. The audit was effective in verifying compliance with procedural controls in the areas examined and that the GED QA program was being implemented adequately. The observers also determined that the technical adequacy of the work products and procedures used to govern and control work was satisfactory. The observers agreed with the auditors' conclusion that the CNWRA has effectively implemented its QA program.

The observers recommended that CNWRA management and staff maintain a focus on attention to detail in quality-affecting activities. Due to changed activities resulting from CNWRA's transition from preapplication activities to the review of the Yucca Mountain license application, less CNWRA work is currently subject to formal QA controls. A decrease in repetition and familiarity with previously more frequently performed quality-affecting activities could increase the potential for errors.

3.0 PARTICIPANTS

3.1 Auditors

Thomas Trbovich	Audit Team Leader, Institute Quality Systems (IQS)
Donald Dunavant	QA Auditor, IQS
Ashley Smith	QA Auditor, IQS
Dr. Richard Page	Technical Specialist, Materials Engineering, SwRI
Dr. Leonardo Caseres	Technical Specialist, Materials Engineering, SwRI
Dr. Nicholas Mueschke	Technical Specialist, Engineering Dynamics, SwRI

3.2 NRC Observers

Frank Jacobs	Observation Team Leader
Deborah DeMarco	NRC 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 must meet the QA requirements of 10 CFR Part 63. The CNWRA conducted the annual 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 QA audit to determine the adequacy of the audit process and the effectiveness of the QA program implementation. The auditors performed the audit following GED Quality Assurance Procedure (QAP)-011, "Audits," and the NRC staff observed the audit using the guidance of NRC Manual Chapter 2410, "Conduct of Observation Audits."

5.0 SCOPE OF AUDIT

The scope of this audit was to determine whether the GED QA program meets 10 CFR Part 63 QA requirements and is being effectively implemented for NRC-funded technical activities. The observers determined that the audit scope was achieved.

6.0 CONDUCT AND TIMING OF THE AUDIT

A performance-based approach to the audit was applied to the extent possible. The technical and QA program aspects of the audit were integrated to the extent practicable. The NRC observers determined that the auditors were thorough, effective, and performed in a professional manner. The observers determined that the timing, length, and application of resources to complete this annual QA audit were appropriate for the current level and type of activities.

7.0 AUDIT TEAM QUALIFICATION AND INDEPENDENCE

The audit team comprised an Audit Team Leader, two QA auditors, and three technical specialists. The NRC observers found the qualifications of the Audit Team Leader and QA auditors to be acceptable and in compliance with the GED QA program. The observers also found the audit team technical specialists to be qualified through training and experience. The QA auditors and technical specialists were 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 GED QA Manual Chapter</u>
Organization	1
QA Program	2
Design Control	*
Scientific Engineering Investigation and Analysis Control	3
Procurement Document Control	4
Instructions, Drawings, and Procedures	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.

All QA Manual chapters were addressed in the audit. QA programmatic checklists were used during the technical audits and for the assessment of the programmatic elements. Activities not effectively auditable by the performance-based approach were evaluated for programmatic compliance. The auditors reviewed and evaluated material and documentation related to the QA programmatic elements and interviewed responsible CNWRA personnel to determine the effectiveness of implementing procedures and technical processes.

Details of the scope and conduct of the audit are available in the July 7, 2009, CNWRA Audit Report.

8.2 Technical Activities

CNWRA management applied a risk-informed approach in selecting technical activities to be evaluated during the GED QA program audit. Technical and programmatic risks and the time since the previous audit of an activity were considered in selecting the areas for the audit. The auditors evaluated the following technical activities:

- Analysis of Road Tunnel Surfaces Exposed to a Severe Fire Environment
- Performance of Grouted Systems for Radioactive Waste Disposal
- Potential Drying and Sealing Issues with TAD Designs

The auditors used a performance-based approach to evaluate the effectiveness of the QA program by interviewing technical personnel responsible for the development of technical products, evaluating selected scientific activities, assessing products, and analyzing documentation supporting the underlying engineering and scientific processes for compliance with associated procedural requirements.

The auditors evaluated the qualifications of personnel performing technical work in the areas reviewed by reviewing the training, education, and experience records of personnel who conducted the scientific studies. The auditors concluded that the technical personnel reviewed were qualified for the work they performed and their qualification records supported their individual position descriptions.

Details of the scope and conduct of the audit are available in the July 7, 2009, CNWRA Audit Report.

8.3 Results

The auditors identified the following nonconformances with QA program requirements and determined that they are minor in significance and unlikely to have an adverse impact on the quality of CNWRA technical products:

1. Quality indoctrination and training did not occur within the ten-working-day window for one person as required by QAP-005, "Quality Indoctrination and Training," Rev 4 Chg 4, Section 3.1.2(a). Quality Reporting System (QRS) report 2009-NCR-0160.
2. Six of six scientific notebooks (SNs) reviewed had the Form QAP-01, "Scientific Notebook Checklist," completed and placed loosely in the folder instead of attached as the last page of the notebook as required by QAP-001, "Scientific Notebook Control," Rev 9 Chg 4, Section 3.3.7. QRS report 2009-NCR-0161.
3. One GED Division Procurement Plan was not completed as required by QAP-016, "Procurement," Rev 9 Chg 3, Section 3.1.2, for requisition number 08041576 to the Advanced Combustion Synthesis Laboratory. QRS report 2009-NCR-0162. (Nonconformance corrected during the audit.)
4. The QA logbook for drawings contained three drawings entered in September 2008 for which no log had been generated as required by QAP-017, "Drawing Control," Rev 1 Chg 0, Section 3.1.1. QRS report 2009-NCR-0163. (Nonconformances corrected during the audit.)
5. Scientific Notebooks: (1) minor corrections were required for three SNs reviewed concerning line-out and initial corrections as required by QAP-001, "Scientific Notebook Control," Rev 9 Chg 4, for SN #963, 971, 788; and (2) calibration data for the Sartorius balance (serial number 12809099) used in weighing samples prior to testing was not identified in SN #924E. QRS report 2009-NCR-0164. (Nonconformances corrected during the audit.)
6. Review of Documents, Reports, and Papers: (1) one document reviewed (Q200904210005) had no date for manager's approval on Form QAP-6, "Document Review Request and Transmittal Control;" (2) one Form QAP-19, "Calculation

Verification Worksheet” (Q200904210005), for verification of calculations had no header information; and (3) date entered for processing Form QAP-16, “QA Records Processing Worksheet,” for one document (Q200906020004) was dated 6/10/09 rather than 6/9/09. QRS report 2009-NCR-0165. (Nonconformances corrected during the audit.)

7. M&TE Calibration: (1) three pressure gauges in Building 51 (AN #002419, 002863, 002862) were found with calibration labels out of date; and (2) the Vaisala humidity meter (AN #10700) in Building 57 was being used in an ongoing experiment after the calibration had expired, the principal investigator was aware of the condition but had not prepared the documentation needed to continue the experiment as required by QAP-019, “Control of Measuring and Test Equipment,” Rev 1 Chg 2, Section 3.4.2. QRS report 2009-NCR-0166. (Nonconformances corrected during the audit.)
8. Software Release Notice (SRN) #386 for ABAQUS v6.5 and SRN #458 for ABAQUS v6.8 did not have the checkbox checked indicating the passing of installation testing as required by TOP-018, “Development and Control of Scientific and Engineering Software,” Rev 10 Chg 2, Section 5.7.3. QRS report 2009-NCR-167. (Nonconformances corrected during the audit.)

The auditors identified the following QA program implementation improvement recommendations:

1. The use of the Quality Requirements Application Matrix (QRAM) as a means of implementing QA requirements and the need to update the QRAM as projects change should be reviewed in light of the present practice of generating QRAMs during early planning and proposal stages and not revisiting them.
2. Form QAP-12, “Instructions to Technical Reviewers,” should be revised to change “Reability” to “Readability.”
3. Remove reference to “Sample Control Database” from records of TOP-012, “Identification and Control of Samples and Chemical Reagents and Standards,” Rev 5 Chg 0, since there is no database actually used.
4. GED should review and determine what is needed to document passing of installation testing for controlled software applications.
5. QAP-004, “Surveillance Control,” Rev 5 Chg 0, should be updated to reflect the use of QRS for documenting surveillances.
6. GED should evaluate the ten-working-day requirement to verify and close NCRs/CARs and for completion of Quality Indoctrination and Training by new CNWRA staff.
7. TOP-022 should be revised to update reference to calibration labels generated by the SwRI Cal Lab; in addition, other GED calibration procedures should also be checked and revised.

The auditors identified the following good practice:

1. SN #942E was done professionally containing excellent descriptions of the activities performed with the reasoning behind decisions and the conclusions developed.

Details of the findings and conclusion of the audit are available in the July 7, 2009, CNWRA Audit Report.

9.0 NRC STAFF FINDINGS/CONCLUSIONS

The NRC observers concluded the audit process was well-planned, thorough, effective, and performed in a professional manner. Audit checklists developed and used by the auditors 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 daily caucuses, audit debriefs, and at the post-audit conference.

The observers determined that CNWRA Audit 2009-1 achieved its objectives of evaluating the GED QA program to verify that it met applicable requirements and was being effectively implemented. The NRC observers determined that the CNWRA 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 technical product development and related quality-affecting activities.

Due to changed activities resulting from the transition from preapplication activities to the review of the Yucca Mountain license application, less CNWRA work is currently subject to formal QA controls. For example, there was only one quality-affecting procurement during the past year. Such a decrease in repetition and familiarity with previously more frequently performed activities has the potential to increase the number of errors made in quality-affecting activities. The observers recommended that CNWRA management and staff maintain a focus on attention to detail in quality-affecting activities.