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

June 9-11, 2009

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EXECUTIVE SUMMARY

The annual internal quality assurance (QA) audit for the Geosciences and Engineering Division (GED) of NRC-funded programs conducted by the Center for Nuclear Waste Regulatory Analyses (CNWRA) was performed June 9-11, 2009. The audit team, comprised of technical specialists and QA auditors, determined that the GED QA program continues to be effectively implemented and provides adequate controls over technical product development and related quality affecting activities. U.S. Nuclear Regulatory Commission (NRC) observers (QA and program management) observed the audit.

The GED staff was operating in accordance with the GED *Quality Assurance Manual* (QAM), operations plans, technical operating procedures (TOPs), QA procedures (QAPs), and applicable administrative procedures (APs). The technical staff was judged to be appropriately qualified through education, experience, and training. The technical work was being conducted in a satisfactory manner.

The results of the audit were discussed with the GED management and staff during daily management briefings and in the post-audit meeting held on June 11, 2009. Two (2) minor nonconformance reports (NCRs) were initiated and six (6) minor nonconformances corrected during the audit (CDAs) were also documented as NCRs for trending purposes. In addition, one (1) good practice was documented as an example of an exemplary work practice. All findings were issued in the *SwRI® Quality Reporting System (QRS)*. The nature of the nonconformances identified was determined by the audit team to pose minimal risk to the quality of GED products. In addition, seven (7) recommendations were identified that may facilitate the maintenance and improvement of GED's quality program and technical products.

1 AUDIT SCOPE

The audit evaluated the GED QA program to determine whether it continues to meet contractually mandated QA program requirements and is being effectively implemented for NRC-funded activities of the CNWRA. In addition, the corrective action process was reviewed to determine its effectiveness.

2 PROGRAMMATIC ELEMENTS AUDITED

QA Program Criteria	Corresponding QAM* Chapter
Organization	1
QA Program	2
Design Control	Not Applicable
(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

*QAM—GED *Quality Assurance Manual*

Design-related activities are not performed by CNWRA; therefore, design control requirements are not applicable. All QAM sections were addressed in the audit. A performance-based approach to auditing was applied to the extent possible. Activities not effectively auditable by the performance-based approach were evaluated for programmatic compliance. The technical and QA program aspects of the audit were integrated to the fullest extent practicable.

3 AUDIT APPROACH

A performance-based approach to auditing was accomplished to the extent possible by direct evaluation of selected technical activities, assessment of products, discussions with key project staff, and the contributions of these processes to product quality. Interview teams composed of a programmatic QA auditor and the assigned technical specialist performed the technical audits of the activities.

In preparation for the audit, technical specialists and QA auditors reviewed applicable operation plans, procedures, quality planning documents, and technical products. Technical checklists were prepared based on these reviews appropriate to each scope of work. QA programmatic checklists were prepared for application during the technical audits and for the assessment of the programmatic elements, (e.g., Document Control, QA Records Control, Nonconformance Control, Corrective Actions, etc.).

The audit sessions were conducted through discussions with project management and technical staff and review of objective evidence, including review packages and scientific notebooks (SNs). Technical and programmatic results were compiled for discussion and reporting. Programmatic activities were also conducted through review of objective evidence, evaluation of reports and SNs through the *Electronic Library Facility* (ELF) database and paper records, discussions with project staff, and observation of laboratory activities.

Daily caucuses for the audit team and NRC observers and daily meetings between the audit team leader and CNWRA management were conducted.

4 TECHNICAL ACTIVITIES AUDITED

A risk-informed approach was applied in selecting the technical activities to audit. Technical and programmatic risks and the time since the previous audit of an activity were considered in selecting the areas for this audit, as follows:

- Analysis of Road Tunnel Surfaces Exposed to a Severe Fire Environment - 14004.03.001
- Performance of Grouted Systems for Radioactive Waste Disposal - 14003.01.007
- Potential Drying and Sealing Issues with TAD Designs - 14004.02.002

5 AUDIT TEAM

Thomas Trbovich	Audit Team Leader (ATL)	Institute Quality Systems (IQS)
Donald Dunavant	QA Auditor	IQS
Ashley Smith	QA Auditor	IQS
Dr. Richard Page	Technical Specialist Institute Scientist; Materials Engineering	Mechanical and Materials Engineering Division (18)
Dr. Leonardo Caseres	Technical Specialist Research Engineer; Materials Engineering	Mechanical and Materials Engineering Division (18)
Dr. Nicholas Mueschke	Technical Specialist Research Engineer; Engineering Dynamics	Mechanical and Materials Engineering Division (18)

6 APPLICABLE REQUIREMENTS DOCUMENTS

The following criteria formed the basis of the audit conduct and generation of audit checklists:

- Title 10 CFR Part 50, Appendix B [by reference in 10 CFR 70.22(f)]
- Title 10 CFR Part 63, Subpart G
- Title 10 CFR Part 71, Subpart H
- Title 10 CFR Part 72, Subpart G
- ANSI/ASME NQA-1-1986
- GED QAM
- GED QA Procedures (QAPs)
- GED Technical Operating Procedures (TOPs)
- GED Administrative Procedures (APs)

7 U.S. NUCLEAR REGULATORY COMMISSION (NRC) OBSERVERS

Frank Jacobs	Observer Team Lead
Deborah DeMarco	Program Management Observer

8 AUDITED ACTIVITIES

8.1 Analysis of Road Tunnel Surfaces Exposed to a Severe Fire Environment - 14004.03.001

Audit Team
Dr. Richard Page (technical specialist)
Thomas Trbovich (QA auditor)

Task Description
The primary objective of this technical task was to evaluate the thermal conditions that developed during the Newhall Pass tunnel fire. Thermal conditions that developed during the fire were estimated by two (2) independent techniques. The first technique involved modeling the tunnel fire using the Fire Dynamics Simulator, Version 5.0 computational fluid dynamics model to compute gas and wall temperatures during the fire. The second technique used melting points, solid-state transformations and thermally-induced degradation of materials removed from vehicles involved in the fire to obtain information about the thermal conditions experienced during the fire.

Products and Associated Documents Reviewed

- *Operations Plan for Technical Assistance for Analysis of Road Tunnel Surfaces Exposed to a Severe Fire Environment* delivered to the NRC in January 2008
- *Numerical Simulations and Structural Materials Analyses of the Newhall Pass Tunnel Fire, 2007* (Q200904010001) delivered to the NRC in April 2009

8.2 Performance of Grouted Systems for Radioactive Waste Disposal - 14003.01.007

Audit Team
Dr. Leonardo Caseres (technical specialist)
Donald Dunavant (QA auditor)

Task Description
This task focused on evaluating the formation of potential fast pathways for radionuclide migration in the grout to be used in vault systems for isolation and containment of radioactive wastes. The primary objective of this evaluation was to determine whether the technical approach of the test program was adequate. In particular, the technical specialist probed the approach used in preparing and testing the cast grouts and evaluated the significance of the test results obtained from the investigation.

It is recommended that if work is continued in the future that chemical composition of the grout be provided, including all significant ingredients.

Products and Associated Documents Reviewed

- *Conceptual Design for Small-Scale Grout Monolith Tests* (Q200804010003) delivered to the NRC in April 2008

8.3 Potential Drying and Sealing Issues with TAD Designs - 14004.02.002

Audit Team
Dr. Nicholas Mueschke (technical specialist)
Thomas Trbovich (QA auditor)

Task Description
The purpose of this task was to evaluate potential drying and sealing issues associated with transportation, aging, and disposal (TAD) canister designs. This was accomplished by reviewing pertinent open literature sources, reviewing individual manufacturer's designs and procedural recommendations, and communicating directly with NRC counterparts.

It was recommended that, in the discussion of the competing cladding phenomena, that comments be added to the report that discuss the conditions under which individual phenomena could be expected to dominate. It is noted that this recommendation does not represent an inadequacy in the quality or accuracy of the work performed, but does represent an opportunity for improvement.

Products and Associated Documents Reviewed

- *Letter Report-Survey and Recommendations for Potential Drying and Sealing Issues with TAD Designs* (Q200902100003) delivered to the NRC in February 2009

8.4 Programmatic QA

QA Auditors
Donald Dunavant, Thomas Trbovich, Ashley Smith

Audit Approach
Those elements that were not likely to be covered in the technical sessions or project reviews (topics including nonconformance control, document control, purchasing, QA records control, etc.) were assigned to the QA auditors. Applicable programmatic elements were also evaluated in each technical session, including Scientific Notebook Control, Review of Documents, Reports, and Papers, Quality Planning, Documentation and Verification of Scientific and Engineering Calculations, etc. Following are the QA procedures evaluated during the audit and the results that corresponded to that programmatic element.

Quality Procedures Reviewed

- **QAP-001**, *Scientific Notebook Control*
  The entire audit team was involved in reviewing the SNs in each technical session and in the evaluation of laboratory activities. In addition, six (6) archived notebooks were reviewed in the ELF database during scheduled programmatic activities. One (1) good practice, one (1) minor nonconformance and one (1) minor nonconformance CDA were identified under this programmatic element. Each notebook was evaluated to determine conformance with the requirements of the procedure.

- **QAP-002**, *Review of Documents, Reports, and Papers*
  The entire audit team was involved in reviewing documents associated with their assigned technical areas. Each technical document was verified to have the proper form completed and comment/resolution sheets with appropriate signatures and approval. Project reviews performed by all audit team members included verifying conformance with the QAP. One (1) minor nonconformance CDA and one (1) recommendation were identified under this programmatic element concerning documentation errors.

- **QAP-004**, *Surveillance Control*
  The surveillance schedule was reviewed during the evaluation of this programmatic element. A sample of scheduled surveillances evaluated had been performed and the associated documentation was complete and thorough. The surveillance program implemented by GED continues to be a value-added process to identify actual and potential nonconforming conditions followed by implementation of corrective actions. One (1) recommendation was identified under this programmatic element.

- **QAP-005**, *Quality Indoctrination and Training*
  Records of training, training notifications, and the database were reviewed during the technical sessions for the personnel involved in the activities. One (1) minor nonconformance and one (1) recommendation were identified under this programmatic element.

- **QAP-007**, *Professional Personnel Qualification*
  Qualification records were being effectively managed; files were complete and readily available. The position descriptions, qualifications, and other information, as required by the QAP were complete and appropriate in the records reviewed. Reviews were performed to ensure personnel meet the requirements of the position and annual reviews were being conducted and documented accordingly.

- **QAP-008**, *Document Control*
  Evaluation of this programmatic topic included control of documents, issue of controlled and uncontrolled documents, control of documents of external origin, and control of sensitive/ proprietary information. Documents were being maintained and controlled effectively through the use of the ELF database. Files are being maintained in an environmentally protected storage vault with access limited. Sensitive and proprietary information is identified in ELF and controlled. Uncontrolled copies generated by the document control clerk are being stamped as uncontrolled.

- **QAP-009**, *Nonconformance Control*
  A sample of NCRs generated since the previous audit were reviewed and found to be thorough, complete, and the corrections were deemed effective. The trend analysis was reviewed. The SwRI® QRS is now being utilized to capture nonconforming conditions. NCRs reviewed were found to be processed in accordance with QAP requirements.

- **QAP-010**, *Corrective Action*
  The one (1) CAR generated since the last audit was reviewed. The actions taken to address the documented findings were appropriate and thorough. Follow-up action included verification by QA personnel that actions taken addressed all proposed corrective actions. QRS is now being utilized to capture corrective action requests. One (1) recommendation was identified under this programmatic element.

- **QAP-011**, *Audits*
  The results of GED 2008-1 annual audit were reviewed. The corrective actions were determined to have been adequately addressed and closed. Recommendations were addressed and each had either been implemented or a justification provided as to why the recommendation was not accepted. The recommendations were also documented and tracked to closure. Planning and conduct of the audit, including qualification of auditors and technical specialists, was accomplished in accordance with QAP requirements.

- **QAP-012**, *Quality Assurance Records Control*
  All QA records reviewed included a completed Form QAP-016, QA Records Processing Worksheet, with retention period marked, verified by manager, and were stored in a 2-hour rated vault, as required. Out cards were being used for all records requested by the audit team. Examination of the quality records archived verified conformance to this procedure. The use of ELF facilitates the archival process. One (1) minor nonconformance CDA was identified under this programmatic element.

- **QAP-013**, *Quality Planning*
  Quality planning was considered by each member of the audit team during the review of the technical documentation as well as through the project reviews. The Quality Requirements Application Matrix (QRAM) was used to verify implementation and conformance to this procedure. One (1) recommendation was identified under this programmatic element.

- **QAP-014**, *Documentation and Verification of Scientific and Engineering Calculations*
  The entire audit team was involved in reviewing scientific and engineering calculations associated with each SN generated for the technical areas audited and the project reviews. Verification of the calculations was determined to be in conformance with the requirements based on the justification identified in the review comments of each technical report, as applicable.

- **QAP-016**, *Procurement*
  Although very few quality-affecting purchases were initiated in the last twelve months, purchase requisitions generated electronically in the Forms Manager application were reviewed. One (1) minor nonconformance CDA was identified under this programmatic element.

- **QAP-017**, *Drawing Control*
  Drawings and drawing logs were reviewed in QA records. One (1) minor nonconformance CDA was identified under this programmatic element.

- **QAP-018**, *Procedure for Confirmatory Analysis*
  No occurrence of the performance of confirmatory analysis was noted for this audit period.

- **QAP-019**, *Control of Measuring and Test Equipment*
  Measuring and test equipment was evaluated in the laboratories of Buildings 51 and 57. Calibration of equipment in use was verified to be current or evidence of calibration verification was documented in the SNs. One (1) minor nonconformance CDA was identified under this programmatic element.

- **AP-001**, *Source Selection and Evaluation*
  No instance of use of subcontractors was noted for the projects evaluated.

- **TOP-012**, *Identification and Control of Samples and Chemical Reagents and Standards*
  Laboratory controls implemented in Buildings 51 and 57 were reviewed. Various metallic samples from the tunnel fire were reviewed and found identified in the sample notebook and located in a clearly marked storage box. One (1) recommendation was identified for this programmatic element.

- **TOP-018**, *Development and Control of Scientific and Engineering Software*
  A sampling of controlled software was evaluated. All applications reviewed were controlled as required. One (1) minor nonconformance CDA and one (1) recommendation were identified under this programmatic element.

9 SUMMARY OF RESULTS

Each technical activity was audited by a team of at least one technical specialist knowledgeable in the field of study and a programmatic QA auditor. Based on review of deliverables produced in the period since the last audit in April 2008, checklists were created specific to each technical task in addition to a general programmatic checklist addressing the QA requirements. As the technical specialist evaluated the qualification of involved personnel, rigor of the science or engineering involved, and thoroughness of supporting documentation, the programmatic auditor confirmed the presence of required documentation supporting the processes involved and their conformance to QA procedural requirements, including review and approval of quality documents, SN controls, and training and qualification of the personnel involved in the activity. The following is a detailed description of the audit results including the technical task or programmatic topic from which the results were noted. One (1) good practice; two (2) minor nonconformances, six (6) minor nonconformances CDA; and seven (7) recommendations are described below.

9.1 Good Practice

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

9.2 Minor Nonconformances

1. **Programmatic Topics—*Indoctrination and Training***
   Quality indoctrination and training did not occur within the ten (10) working day window for one (1) person as required by QAP-005, *Quality Indoctrination and Training*, Rev 4 Chg 4, Section 3.1.2(a).
   See attached QRS report 2009-NCR-0160.

2. **Programmatic Topics—*Scientific Notebooks***
Six (6) of six (6) 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.
See attached QRS report 2009-NCR-0161.

9.3 Corrected During the Audit

1. **Programmatic Topics-*Purchasing***
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.
See attached QRS report 2009-NCR-0162.

2. **Programmatic Topics—*Drawing Control***
QA logbook for drawings contained three (3) 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.
See attached QRS report 2009-NCR-0163.

3. **Programmatic Topics—*Scientific Notebooks***
   - Minor corrections made to three (3) 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.
   - Calibration data for the Sartorious balance (SN 12809099) used in weighing samples prior to testing was not identified in SN #924E.
   See attached QRS report 2009-NCR-0164.

4. **Programmatic Topics-*Review of Documents, Reports, and Papers***
   - One (1) document reviewed (Q200904210005) had no date for manager's approval on Form QAP-6, Document Review Request and Transmittal Control.
   - One (1) Form QAP-19, Calculation Verification Worksheet (Q200904210005), for verification of calculations had no header information.
   - Date entered for processing Form QAP-16, QA Records Processing Worksheet, for one (1) document (Q200906020004) was dated 6/10/09 rather than 6/9/09.
   See attached QRS report 2009-NCR-0165.

5. **Programmatic Topics-*M&TE-Calibration***
   - Three (3) pressure gauges in Building 51 (AN #002419, 002863, 002862) with calibration labels out of date; "Cal Before Use" labels were added.
   - The Vaisala (AN #10700) humidity meter in Building 57 was being used in ongoing experiment after 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.
   See attached QRS report 2009-NCR-0166.

6. **Programmatic Topics-*Software Control***
   - Software Release Notices (SRN) #386 for ABAQUS v6.5 and SRN #458 for ABAQUS v6.8 did not have the checkbox for installation testing passed as required by TOP-018, *Development and Control of Scientific and Engineering Software*, Rev 10 Chg 2, Section 5.7.3.
     See attached QRS report 2009-NCR-167.

9.4 Recommendations

During the course of the audit activities, seven (7) recommendations were made, which if acted upon, may prevent future nonconformances or will support continuous improvement of the GED quality program. These recommendations include the following:

1. The use of the QRAM as a means of implementing QA requirements and the need to update the QRAM as projects change should be reviewed in light of 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 as evidence of 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 (10) 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.

10 QUALITY ASSURANCE PROGRAM EFFECTIVENESS

As determined by this annual audit, the QA program applied by the GED continues to be adequate and effectively implemented. 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. However, the recommendations identified provide opportunities for improvements and, if implemented, may reduce the potential to adversely affect products in the future.

11 PERSONS CONTACTED

	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
GED Staff and Consultants			
Axler, K.	X	X	X
Bannon, D.		X	
Beverly, E.		X	
Bird, G.		X	
Brient, R.	X	X	X
Das, K.	X	X	
He, X.		X	
Mackin, P.	X		X
Mintz, T.	X	X	X
Mohanty, S.			X
Myers, J.		X	
Padilla, M.	X	X	
Patrick, W.	X		X
Pearcy, E.	X	X	X
Sagar, B.	X		X
Walter, G.	X	X	X
Wilt, T.		X	X
Winterle, J.	X		
Wittmeyer, G.	X		X
NRC Observers			
DeMarco, D.	X		X
Jacobs, F.	X		X
Kokajko, L.			X (via teleconference)
Matula, T.			X (via teleconference)
Mohseni, A.			X (via teleconference)
Audit Team and Others			
Caseres, L.	X		X
Dunavant, D.	X		X
Holt, A.			X
Mueschke, N.	X		X
Page, R.	X		X
Trbovich, T.	X		X
Smith, A.	X		X

APPROVAL SIGNATURES

Thomas Trbovich
Audit Team Leader (ATL)

6/29/09
Date

for Donald Dunavant
QA Auditor

6/29/09
Date

Ashley Smith
QA Auditor

6/29/09
Date

Dr. Richard Page
Technical Specialist, Materials Engineering

6/29/09
Date

Dr. Leonardo Caseres
Technical Specialist, Materials Engineering

06/30/09
Date

Dr. Nicholas Mueschke
Technical Specialist, Engineering Dynamics

6/29/09
Date

Robert Brient
Director of Quality Assurance, GED

7/1/2009
Date

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