CNWRA®

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September 23, 2011
Contract No. NRC–02–07–006
Account No. 20.14002.01.011
06300001

ATTN: Document Control Desk
U.S. Nuclear Regulatory Commission
ATTN: Mrs. Deborah DeMarco
Office of Nuclear Material Safety and Safeguards
Division of High-Level Waste Repository Safety
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Washington, DC 20555

Subject: 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 (IM 14002.01.011.140)

Dear Mrs. DeMarco:

This letter transmits the subject report to fulfill the requirements of intermediate milestone 14002.01.011.140, which is titled Annual Internal Quality Assurance Audit Report in the Center for Nuclear Waste Regulatory Analyses (CNWRA®) Operations Plan for the High-Level Waste Repository Safety Program.

This audit was planned, executed, and reported in accordance with the Geosciences and Engineering Division Quality Assurance Manual and associated quality assurance procedures. We appreciate the observation of this audit by the U.S. Nuclear Regulatory Commission (NRC) representatives. This audit confirms that the CNWRA is implementing an effective quality assurance program, adequate controls are placed on technical product development, and the integrated quality program continues to address the needs of NRC. Several recommendations developed during the audit were broadly characterized as stemming from a "lack of attention to detail." We plan to examine each recommendation individually for its cause and develop appropriate resolution. Furthermore, we thank the NRC staff for providing their valuable observations during the audit.

Please contact me at (210) 522-5252 or Mr. Fred Hawkins at (210) 522-5824, if you have any questions concerning this matter.

Sincerely,

Budhi Sagar
President

BS/FH/ln

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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

AUGUST 23 – 25, 2011

CONTENTS

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 August 23 – 25, 2011. 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. The U.S. Nuclear Regulatory Commission (NRC) representatives, QA and program management, observed the audit.

The GED staff continues to operate 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 determined to have been executed in a satisfactory manner.

The results of the audit were discussed with the GED management and staff, with the NRC representatives present, during daily management briefings and in the post-audit meeting held on August 25, 2011. One (1) major nonconformance (CAR) and three (3) minor nonconformances (NCRs) were initiated, including one (1) minor nonconformance corrected during the audit (CDA). 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. Although it was noted in the audit closing statements that many of the items identified may be attributed to *a lack of attention to detail*, it could be an oversimplification to group these discrepancies into such a broad category. The CNWRA should evaluate discrepancies of this type and discern a precise root cause upon which effective corrective action can be taken to prevent recurrence.

In addition, ten (10) recommendations were identified that may provide opportunities for the improvement of the GED quality program and technical products. The recommendations were classified as such as determined by the QA auditors based on the consideration of the sample taken at the time of the audit.

1 AUDIT SCOPE

This internal audit evaluated the GED quality assurance program to determine whether it meets contractually mandated QA program requirements and is being effectively implemented for Nuclear Regulatory Commission (NRC) sponsored activities of the Center for Nuclear Waste Regulatory Analyses (CNWRA). This was a full-scope audit in which all QA program elements applicable were evaluated and five (5) technical tasks were audited. In addition, the corrective action process was reviewed to determine its effectiveness.

2 PROGRAMMATIC ELEMENTS AUDITED

QA Program Criteria	Corresponding QAM* Chapter
Organization	1
Quality Assurance 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.

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, the *Quality Requirements Application Matrix* (QRAM) for each project, procedures, other 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.

The audit sessions were conducted through discussions with project management and key 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 as well as daily meetings between the audit team leader and the 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:

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

5 AUDIT TEAM

QA Auditors

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

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

6 APPLICABLE REQUIREMENTS DOCUMENTS

The following criteria formed the basis of the audit conduct and the 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 Quality Assurance Manual (QAM);
- GED QA Procedures (QAPs);
- GED Technical Operating Procedures (TOPs); and
- GED Administrative Procedures (APs).

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

Tom Matula	Observer Team Lead
Deborah DeMarco	Program Management Observer

8 AUDITED ACTIVITIES

8.1 14003.01.007 Column Experiment on Technetium-99 Leaching from Simulated Saltstone Grout

Audit Team
Michael Dammann *(Technical Specialist)*
Thomas Trbovich *(QA Auditor)*
Ross Cantu *(QA Auditor-in-Training)*

Task Description
The purpose of this task was to evaluate the process used to execute a column leaching experiment conducted to determine the release behavior of Technetium-99 initially sequestered in reducing grout as water interacts with the grout and changes the system chemistry. Note that the report provided discussed the materials and methods used in the experiment and presented preliminary data on the evolution of system chemistry and technetium release. The experiment is ongoing, and additional results and data interpretation will be presented in a future final report.

There was one good practice identified in this session regarding the porosity value of the grout

solution which was calculated and subsequently verified experimentally. One minor nonconformance was noted because the rationale for not requiring calculation over-checks was not available, as required by QAP-014, *Documentation and Verification of Scientific and Engineering Calculations*.

For this session, it was recommended that the collected *transformed spectral index of external standards (tsie)* data should be recorded to demonstrate constant quench. The report should also include information on the actual solution composition identified in the draft progress report, Table 2-3, which was not verified against Table 2-2; specifically, the addition of Cl^- and HCO_3^- were not accounted for, plus there was a significant error in the difference between the actual solution used versus the target, which was not described in the report. In addition, several duplicate tests of grout should be included to prove a homogenous mixture is present. Finally, the traceability information for the standards used should be included in the scientific notebook.

Products and Associated Documents Reviewed

- Draft Progress Report: *Column Experiment on Technetium Release From Reducing Grout* (Deliverable 14003.01.007.460)
- QRAMS for 14003.01.007

8.2 14005.01.001 Scoping of Options and Analyzing Risk (SOAR) Model and Users Guide

Audit Team
Ashley Smith *(Technical Specialist)*
Faye Brockwell *(QA Auditor)*

Task Description
This task focused on evaluating the collaborated effort between the CNWRA and the NRC regarding the development of a generic performance assessment model for geologic disposal of high-level nuclear waste using the GoldSim Version 10.11 modeling environment. The Scoping of Options and Analyzing Risk (SOAR) model provides a platform for gaining risk insights into various potential configurations of geologic media, waste form types, and repository designs. This session was conducted to determine the technical approach taken in the model development. Although TOP-018, *Development and Control of Scientific and Engineering Software*, was not required, many aspects were used to control the development and ensure traceability for each version up to the release of V1.0.

For this session, it was recommended to ensure folder access on the *N drive* is controlled to prevent inadvertent changes or deletions by others not on the project.

Products and Associated Documents Reviewed

- *14005.01.001.110 The GoldSim Model: SOAR Version 1.0 / Draft Users Guide*
- Deliverable – Intermediate Milestone 14005.01.001.110, *The GoldSim Model: SOAR Version 1*, Letter dated March 30, 2011
- QRAM for 14005.01.001

8.3 15555.01.023 Effect of Wet and Dry Cycling on Aging of Medium Voltage Electric Cables

Audit Team

Sterling Kinkler, Jr. *(Technical Specialist)*
Mark Ehnstrom *(QA Auditor)*

Task Description

This task focused on the experimental plan regarding accelerated aging of medium-voltage electrical power cables of a type found in safety circuits at nuclear power facilities. Particular failure symptoms called *"water trees"* were to be evaluated in terms of physical presence, density, length, and other characteristics in samples under test conditions at planned intervals. Aging accelerant modalities including elevated voltage and frequency were applied to one subset of the cables while only elevated voltage was applied to another subset. Additionally, some cables of each population were exposed to constant submergence in salt water, while some were cycled between submergence and dry conditions. The postulated failure mechanism for water tree formation in cable insulation included water intrusion and subsequent formation of faults (water trees) due to interaction of constant rapid "switching" of electric field polarity, in the cable insulation (due to AC power frequency and voltage), and the dipolar nature of the molecular structure of water. This session was conducted to evaluate the technical approach used to execute this experiment.

During conduct of the experiments, failures of test equipment and certain cable samples under test were encountered, resulting in adjustments to planned experimental processes. In reacting to and overcoming unexpected technical problems, it should be noted that during the course of the task scientific discipline was strictly maintained—this effort should be commended. If similar work is to continue for future tasks, the experimental plan should be revised based on lessons learned in order to achieve optimal results.

There was one nonconformance identified in this session regarding calibration documentation from Grubb Engineering, which did not identify traceability to NIST, as identified in the procurement plan as required by QAP-016, *Procurement*.

It was also recommended that QAP-018, *Procedure for Confirmatory Analyses*, Section 4, be revised to remove the reference to the *"confirmatory analysis logbook"*, as no such logbook is currently used.

Products and Associated Documents Reviewed

- *Programmatic Review of Paper for the 13th International High-Level Radioactive Waste Management Conference (AI 15555.01.023.100)*, dated November 3, 2010
- *Experimental Plan to Study the Effect of Wet and Dry Cycling on Electrical Cable*
- *Insulation Material Aging* (Intermediate Milestone 15555.01.002.020), dated May 28, 2010
- Statement of Work, *Technical Assistance for Corrosion/Materials Review of the Effect of Boric Acid on Concrete, Structures and Effect of Moisture on Electrical Cables Materials for License Renewal*
- *Literature Review Reports on Boric Acid Degradation of Concrete Structures* (Intermediate Milestone 15555.01.001.010) and Electrical Cable Corrosion (IM 15555.01.002.010), dated April 9, 2010
- QRAM for 15555

8.4 14002.01.441.170 Knowledge Management/Capture: History and Value of Uncertainty and Sensitivity Analyses Acquired In-House Over Past 20 Years

Audit Team

Dr. Robert Mason *(Technical Specialist)*

Faye Brockwell *(QA Auditor)*

Task Description

This task focused on evaluating the technical efforts put forth in the documentation of the uncertainty and sensitivity analysis knowledge acquired over the past 20 years by the NRC and the CNWRA staff during preparations to develop site-specific regulations for disposal of high-level radioactive waste (HLW) at the proposed Yucca Mountain repository. This documentation is intended to serve the needs of future performance assessors or risk analysts at NRC and CNWRA who may be engaged in future HLW-related regulatory activities.

For this session, it was recommended to ensure that a precautionary note be added to the documents that they are only knowledge-capture summaries and do not include judgment on the usefulness or accuracy of chosen methods.

Products and Associated Documents Reviewed

- Intermediate Milestone 14002.01.441.170 – *History and Value of Uncertainty and Sensitivity Analyses at the Nuclear Regulatory Commission and Center for Nuclear waste Regulatory Analyses*, dated July 28, 2011
- QRAM for 14002.01.441

8.5 15948.01.001/.002/.003 Verification and Validation of Fracture Analysis of Vessels (FAVOR) and Extremely Low Probability of Rupture (xLPR) and xLPR Codes Comparison

Audit Team

Carl Polelar *(Technical Specialist)*
Mark Ehnstrom *(QA Auditor)*

Task Description

This task focused on evaluating the technical approach used in the verification and validation of the FAVOR *(Fracture Analysis of Vessels—Oak Ridge)* and xLPR *(extremely low probability of rupture)* codes. The cooperative program between the NRC and the Electric Power Research Institute (EPRI) resulted in the development of a modular-based, probabilistic fracture mechanics code capable of determining the probability of failure for reactor coolant system components, referred to as xLPR. The xLPR code comes in two forms, one developed by Sandia National Laboratories (SNL) in GoldSim *(a commercial product)* and another developed by ORNL in Python *(Python is open source, the Python interface is referred to as SIAM by the ORNL software developers)*. There were two xLPR tasks, (i) verification of FORTRAN modules common to the Sandia and ORNL codes, and (ii) comparison of the Sandia and ORNL codes. The NRC also sponsored development at Oak Ridge National Laboratory (ORNL) of the computer code FAVOR. The CNWRA performed verification of the FAVOR code Version 09.1, focusing on changes since Version 06.1.

For this session, one nonconformance was identified because no conflict of interest (COI) / Source Evaluation Committee (SEC) review was performed for non-GED staff utilized on the project, as required by AP-001, *Source Selection and Evaluation*.

For intermediate milestone 15948.01.001.100, *Technical Letter Report – Verification and Validation of FAVOR Version 09.1 Code (Task 1)*, it was recommended to maintain strict adherence to the terminology used in the report for *software verification* and *software validation* as these terms were

used interchangeably in Section 2.3, Subsection 2.3.2 of the final report.

Products and Associated Documents Reviewed

- Intermediate Milestone 15948.01.001.100, *Technical Letter Report – Verification and Validation of FAVOR Version 09.1 Code (Task 1)*, dated February 18, 2011
- Intermediate Milestones 15948.01.002.200 (Task 2) and 15948.01.003.300 (Task 3), *Technical Letter Report – Assessment of Capabilities of Extremely Low Probability of Rupture (xLPR) Software, GoldSim and SIAM Version 1.0*, dated May 26, 2011
- QRAM for 15948

8.6 Programmatic QA

QA Auditors
Faye Brockwell, Ross Cantu, Mark Ehnstrom

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 reviewed 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 scientific notebooks in each technical session and in the evaluation of laboratory activities. Each notebook was evaluated to determine conformance with the requirements of the procedure. One (1) recommendation was identified under this programmatic element with three specific items to consider.

- **QAP-002**, *Review of Documents, Reports, and Papers*
  The entire audit team was involved in reviewing documents associated with their assigned technical areas. Technical documents were 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) recommendation was identified under this programmatic element with two specific items to consider.

- **QAP-004**, *Surveillance Control*
  The surveillance schedule was reviewed during the evaluation of this programmatic element. The surveillance program implemented by GED continues to be a value-added process, though recommendations identified in the surveillances should be tracked to closure. One (1) recommendation was identified under this programmatic element with two specific items to consider.

- **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. No concerns 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. One (1) recommendation was identified under this programmatic element with two specific items to consider.

- **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. No concerns were identified under this programmatic element.

- **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. No concerns were identified under this programmatic element.

- **QAP-010**, *Corrective Action*
  No CARs had been generated since the last audit. No concerns were identified under this programmatic element.

- **QAP-011**, *Audits*
  The results of GED 2010-1 annual audit were reviewed prior to this audit under the follow-up surveillance, 2011-SR-0290 and any remaining items were addressed during this audit. No concerns were identified under this programmatic element.

- **QAP-012**, *Quality Assurance Records Control*
  Examination of archived quality records verified conformance to this procedure. The use of ELF facilitates the archival process. No concerns were 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. No concerns were 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. One (1) minor nonconformance was identified under this programmatic element in the technical session, *Column Experiment on Technetium-99 Leaching from Simulated Saltstone Grout*.

- **QAP-016**, *Procurement*
  Purchase requisitions initiated in the previous twelve months for quality-affecting material were reviewed. One (1) minor nonconformance was identified under this programmatic element in the session, *Effect of Wet and Dry Cycling on Aging of Medium Voltage Electric Cables*. In addition, one (1) minor nonconformance corrected during the audit and one (1) recommendation were identified during the programmatic reviews under this element.

- **QAP-017**, *Drawing Control*
  Drawings and drawing logs were reviewed in QA records and during technical sessions, where applicable. No concerns were identified under this programmatic element.
- **QAP-018**, *Procedure for Confirmatory Analysis*
  The applicability of this procedure was reviewed during each technical session. One (1) recommendation was identified under this programmatic element during the session, *Effect of Wet and Dry Cycling on Aging of Medium Voltage Electric Cables*.

- **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 scientific notebooks. No concerns were identified under this programmatic element.

- **AP-001**, *Source Selection and Evaluation*
  The entire audit team was involved in reviewing the applicability of this procedure in each technical session to determine if this process is being followed. One (1) major nonconformance was identified under this programmatic element in the session, *Verification and Validation of Fracture Analysis of Vessels (FAVOR) and Extremely Low Probability of Rupture (xLPR) and xLPR Codes Comparison*.

- **TOP-012**, *Identification and Control of Samples and Chemical Reagents and Standards*
  Laboratory controls implemented in Buildings 51 and 57 were reviewed. No concerns were identified under this programmatic element.

- **TOP-018**, *Development and Control of Scientific and Engineering Software*
  A sampling of controlled software was evaluated. Although not a specific requirement, these requirements were addressed in the session, *Scoping of Options and Analyzing Risk (SOAR) Model and Users Guide*. No concerns 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 July 2010, 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; one (1) major and three (3) minor nonconformances, including one (1) minor nonconformance CDA; and ten (10) recommendations are described below.

9.1 Good Practice

1. ***Column Experiment on Technetium-99 Leaching from Simulated Saltstone Grout***

   The porosity value of the grout solution was calculated and subsequently verified experimentally.

9.2 Major Nonconformance

1. ***Verification and Validation of Fracture Analysis of Vessels (FAVOR) and Extremely Low Probability of Rupture (xLPR) and xLPR Codes Comparison***

   There was no conflict of interest (COI) / Source Evaluation Committee (SEC) review of Division 18 staff utilized on the project. Three (3) nonconformance reports have been issued for the same condition during the past year, as identified in the *Trend Analysis Report for CY 2010*. Requirement: AP-001, *Source Selection and Evaluation* (Reference 2011-CAR-0282)

9.3 Minor Nonconformances

1. ***Column Experiment on Technetium-99 Leaching from Simulated Saltstone Grout***

   The rationale for not requiring calculation over-checks was not available in the records provided. QAP-002 review of the report for project 14003.01.007 did not require any verification of calculations; no justification was provided as to why over-checks were not required. Requirement: QAP-014, *Documentation and Verification of Scientific and Engineering Calculations*, Section 3.2.3 (Reference 2011-NCR-0286)

2. ***Effect of Wet and Dry Cycling on Aging of Medium Voltage Electric Cables***

   Calibration documentation obtained from Grubb Engineering did not identify traceability to NIST, as required by the procurement plan. Requirement: QAP-016, *Procurement*, Section 5.2 (Reference 2011-NCR-0287)

9.4 Corrected During the Audit

1. **Programmatic Topics – *QAP-016, Procurement***

   No procurement plan had been prepared documenting the purchase of quality-affecting material (cables) procured from a non-ASL supplier. The procurement plan was generated during the audit. Requirement: QAP-016, *Procurement*, Section 5.2 (Reference 2011-NCR-0288)

9.5 Recommendations

During the course of the audit activities, ten (10) 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. ***Column Experiment on Technetium-99 Leaching from Simulated Saltstone Grout***

   The collected *transformed spectral index of external standards (tsie)* data should be recorded to demonstrate constant quench. The report should also include information on the actual solution composition identified in the draft progress report, Table 2-3, which was not verified against Table 2-2; specifically, the addition of Cl^- and HCO_3^- were not accounted for, plus there was a significant error in the difference between the actual solution used versus the target, which was not described in the report. In addition, several duplicate tests of grout should be included to prove a homogenous mixture is present. Finally, the traceability information for the standards used should be included in the scientific notebook. (Reference 2011-PAR-0256)

2. ***Scoping of Options and Analyzing Risk (SOAR) Model and Users Guide***

   Folder access on the *N drive* should be controlled to prevent inadvertent changes or deletions by others not on the project. (Reference 2011-PAR-0257)

3. ***Effect of Wet and Dry Cycling on Aging of Medium Voltage Electric Cables***

   QAP-018, *Procedure for Confirmatory Analyses*, Section 4, should be revised to remove the reference to the *"confirmatory analysis logbook"*, as this logbook is not currently used. (Reference 2011-PAR-0258)

4. ***Knowledge Management/Capture: History and Value of Uncertainty and Sensitivity Analyses Acquired In-House Over Past 20 Years***

   A precautionary note should be added to the documents indicating that they are only knowledge – capture summaries and do not include judgment on the usefulness or accuracy of chosen methods. (Reference 2011-PAR-0259)

5. ***Verification and Validation of Fracture Analysis of Vessels (FAVOR) and Extremely Low Probability of Rupture (xLPR) and xLPR Codes Comparison***

   The terms for *software verification* and *software validation*; as defined in this report, were used interchangeably in Section 2.3, Subsection 2.3.2 of the Intermediate Milestone 15948.01.001.100, *Technical Letter Report – Verification and Validation of FAVOR Version 09.1 Code (Task 1)*. Strict adherence to the terminology defined should be maintained. (Reference 2011-PAR-0260)

6. ***QAP-001, Scientific Notebook Control***

   A mechanism should be established for version control of electronic scientific notebooks when changes are required to original entries. A transfer notebook should also be used for recording data to maintain a record and verification of hand-developed notes. In addition, the process for electronic notebooks should be evaluated, including how to handle blank pages, references to other scientific notebooks, etc., and ensure personnel are aware of these requirements. (Reference 2011-PAR-0261)

7. ***QAP-002, Review of Documents, Reports, and Papers***

Form QAP–12, *Instructions to Technical Reviewers*, should identify the reviewer and the applicable review section when more than one individual is conducting the review. Also, Form QAP–6, *Document Review Request and Transmittal Control*, should identify all authors that contribute to the report or paper. (Reference 2011-PAR-0265)

8. *QAP-004, Surveillance Control*

Consider showing the correlation between the surveillance schedule and the surveillance activity/scope identified in QAP-004, *Surveillance Control*, Table 1. In addition, a process should be introduced for tracking recommendations made during surveillance activities to conclusion. (Reference 2011-PAR-0269)

9. *QAP-007, Professional Personnel Qualification*

QA records for NRC personnel under the staff exchange program should include resumes indicating qualifications for particular jobs as well as indoctrination into the QA program. In addition, Form QAP-11, *Professional Personnel Qualification Records*, should reference professional titles, as recommended in the procedure, rather than payroll titles. Several forms reviewed identified the payroll titles for the employees. (Reference 2011-PAR-0274)

10. *QAP-016, Procurement*

QAP-016, *Procurement*, Section 5.1 should be evaluated to determine what receiving inspection documentation such as the approved purchase requisition or receipt traveler (green sheet) is to be maintained as a QA record as required by QAP-012, *Quality Assurance Records Control*. (Reference 2011-PAR-0275)

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. 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			
Pearcy, E.	X		X
Patrick, W.	X		X
Sagar, B.	X		X
Pickett, D.	X	X	X
Pabalan, R.	X	X	
Mackin, P.	X		X
Axler, K.	X		X
Mohanty, S.	X	X	X
Wilt, T		X	X
Shukla, P.			X
McMurry, J.		X	X
Nes, R.			X
Lenhard, R.		X	X
Padilla, M.		X	X
Waiting, D.		X	X
Wittmeyer, G.			X
Bannon, D.		X	X
Norman, G.			X
Janetzke, R.		X	X
Pensado, O.		X	X
Pan, Y.			X
Myers, J.			X
Mintz, T.		X	
Gonzalez, J.		X	
Folk, O.			
Stothoff, S.		X	
Tipton, E.		X	
NRC Observers			
DeMarco, D.	X		X
Matula, T.	X		X
Kokajko, L.			X (via teleconference)
Davis, J.			X (via teleconference)
Stablein, K.			X (via teleconference)
Guttman, J.			X (via teleconference)
Benney, B.			X (via teleconference)
Kim, Y.			X (via teleconference)
Rubenstone, J.			X (via teleconference)
Jackson, R.			X (via teleconference)
Audit Team and Others			
Hawkins, F.	X	X	X
Ehnstrom, M	X		X
Brockwell, F.	X		X
Popelar, C.	X		X
Mason, R.	X		
Kinkler, S.	X		X
Cantu, R.	X		X
Smith, A.	X		X
Dammann, M.	X		X
Hobson, C.	X		X
Trbovich, T.	X		X

APPROVAL SIGNATURES

Thomas Trbovich — 9/20/11
Thomas Trbovich
Audit Team Leader (ATL)
Date

Faye Brockwell — 9.20.11.
Faye Brockwell
QA Auditor
Date

Mark R. Ehnstrom — 9/20/11
Mark Ehnstrom
QA Auditor
Date

Rosendo Cantu — 9/20/2011
Ross Cantu
QA Auditor-in-Training
Date

for S.C. Tilovich — 9/21/11
Michael Dammann
Technical Specialist
Date

for S.C. Tilovich — 9/21/11
Carl Popelar
Technical Specialist
Date

E. Sterling Kinkler, Jr. — 9/21/11
Sterling Kinkler, Jr.
Technical Specialist
Date

for S.C. Tilovich — 9/21/11
Robert Mason
Technical Specialist
Date

Ashley Smith — 9/19/11
Ashley Smith
Technical Specialist
Date

Fred Hawkins — 9/21/2011
Fred Hawkins
Principal QA Engineer, GED QA Staff Support
Date

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