



# **QUALITY ASSURANCE AUDIT REPORT**

For

**GEOSCIENCES AND ENGINEERING DIVISION AUDIT 2008-1  
OF NRC-FUNDED PROGRAMS CONDUCTED BY THE  
CENTER FOR NUCLEAR WASTE  
REGULATORY ANALYSES**

April 14-18, 2008

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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 April 14-18, 2008. 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. U.S. Nuclear Regulatory Commission (NRC) observers (QA, technical, and program management) observed the audit.

The GED staff was operating in accordance with the GED QA 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.

Concerns from the previous audit were adequately addressed and closed as determined by the follow-up surveillance, 2007-SR-0261, conducted in December 2007. Good practices and improvements identified during the audit included the seamless integration of the *Infiltration Tabulator for Yucca Mountain (ITYM)* code team into the TPA effort; two exceptionally well-documented scientific notebooks (SNs); changes incorporated into the BDOSE product that resulted in greater functionality; meticulously documented verification of equipment before use; and a very thorough and complete software validation report.

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 April 18, 2008. One (1) minor nonconformance report (NCR) was initiated and five (5) minor nonconformances corrected during the audit (CDA) were also documented as NCRs for trending purposes. All findings were issued in the *SwRI<sup>®</sup> Quality Reporting System (QRS)*. The nature of the nonconformances identified was judged by the audit team to pose little risk to the quality of GED products. In addition, nine (9) recommendations were identified that may facilitate the GED maintaining and improving its 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 and was accomplished by direct evaluation of selected technical activities, assessment of products, and discussions with key project staff. 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.

In addition to the technical topics identified below, sixteen (16) additional projects were chosen for programmatic compliance evaluation based on the time since the previous audit of the activity.

### 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, i.e., *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. Technical and programmatic results were compiled for discussion and reporting. Programmatic activities were also conducted through review of objective evidence, evaluation of reports and scientific notebooks through the *Electronic Library Facility (ELF)* database, 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:

- *Climate and Infiltration (14002.01.110)*
- *Coating Debris Source Term for PWR LOCA (13335.01.001)*
- *BDOSE Software Development (14003.01.006)*

### 5 AUDIT TEAM

Christopher Hobson	Audit Team Leader (ATL)	Institute Quality Systems (IQS)
Thomas Trbovich	QA Auditor	IQS
Donald Dunavant	QA Auditor	IQS
Julie Garcia	QA Auditor	IQS

Robert Morgan	Technical Specialist Software	IQS
Dr. Alan Dutton	Technical Specialist Aqueous Geochemistry; Hydrogeology	University of Texas San Antonio
Dr. Richard Page	Technical Specialist Institute Scientist; Materials Science	SwRI 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 60, Subpart G and 10 CFR 70.22(f)]
- Title 10 CFR Part 63, Subpart G
- Title 10 CFR 71, Subpart H
- Title 10 CFR 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
Christopher Markley	Technical Observer
Hipolito Gonzalez	Technical Observer

## 8 AUDITED ACTIVITIES

### 8.1 Climate and Infiltration

#### Audit Team

Dr. Alan Dutton (technical specialist)  
Thomas Trbovich, Julie Garcia (QA auditors)

#### Task Description

A series of studies document previous research and develops models and input parameters that were used in the *Infiltration Tabulator for Yucca Mountain (ITYM)* code to provide estimates of net infiltration as input to the TPA Version 5.1 code. The first report (included in 2006 audit) reviewed literature from outside of the Yucca Mountain program related to infiltration under climates analogous to climates that may occur at Yucca Mountain. This audit focused on work related to estimates of million-year-average net infiltration sequences using the ITYM mathematical model. ITYM is part of the TPA code. Data on infiltration presently being used in TPA dates back to circa 2000. This set of studies has verified that those infiltration estimates are reasonable and has provided an updated set of infiltration estimates for an upgrade to the TPA runs.

### **Products and Associated Documents Reviewed**

- Ops Plan 2.11 *Climate and Infiltration (UZI) Rev 22 Chg 1*
- CNWRA 2007-003 *Stothoff, S. and Walter, G., August 2007, Long-term average infiltration at Yucca Mountain, Nevada: Million-year estimates*, Intermediate Milestone IM No. 06002.01.252.730
- *Million-Year Estimates of Net Infiltration at Yucca Mountain, Nevada*, poster presented by S. Stothoff, AGU Fall 2007 Meeting
- *Infiltration tabulators for Yucca Mountain: Bases and confirmation*, Report prepared by S. Stothoff for U.S. Nuclear Regulatory Commission under Contract NRC-02-07-006, variously paginated
- *Infiltration tabulators for Yucca Mountain: Bases and confirmation* (QAP-12 technical review comments)

### **8.2 Coating Debris Source Term for Pressurized Water Reactor (PWR) Loss-Of-Coolant Accident (LOCA)**

#### **Audit Team**

Dr. Richard Page (technical specialist)  
Donald Dunavant, Julie Garcia (QA auditors)

#### **Task Description**

This task focused on providing critical evaluations of two licensee reports and two reports prepared by the Electric Power Research Institute (EPRI). The primary objective of the evaluation of the two licensee reports was to determine the technical adequacy of the coating test results and the proposed approach for calculating destruction pressure and the corresponding zone of influence. The primary objective of the evaluation of the two EPRI reports was to determine the technical adequacy of the coating test results and the proposed approach for evaluating coating performance presented in the two reports.

### **Products and Associated Documents Reviewed**

- *Review of Coating Destruction Reports Related to Debris Source Term for Coatings Subjected to an Adverse Environment from a Pressurized Water Reactor Loss-of-Coolant Accident—Draft Report*
- *Ops Plan—Review of Coating Destruction Reports Related to Debris Source Term for Coatings Subjected to an Adverse Environment from a Pressurized Water Reactor Loss-of-Coolant Accident Project 13335.01.001*
- *QRAM—Review of Coating Destruction Reports Related to Debris Source Term for Coatings Subjected to an Adverse Environment from a PWR LOCA, Rev 0 Chg 0, May 2007*

### **8.3 BDOSE Software Development**

#### **Audit Team**

Robert Morgan (technical specialist)  
Christopher Hobson (QA auditor)

#### **Task Description**

The *Biosphere Dose Assessment Model (BDOSE)* software product was developed by GED personnel as a tool to accept a host of parameters related to environmental conditions that can

affect people and then provide a rating as to the impact they have on the health of the individuals. BDOSE was designed as a customized version of the *GoldSim* utility, much like a MicroSoft EXCEL spreadsheet. The developers were requested to make modifications and usability improvements, which in no way changed the purpose or basic capabilities of the product. Some of the changes involved the following:

- Input parameters were scattered throughout the graphical interface in BDOSE; input modified to be localized into a single input container to enhance transparency and improve QA capabilities;
- NRC staff requested implementation of a stochastic model for soil KDs; and
- Fluid element *BDOSE\_soil* moved to the physical soil submodel to ease BDOSE installation into existing models.

BDOSE was identified as developed software with validated Versions 1 and 1.1, according to the GED Controlled Software Directory. The involved developers were working on upgrades to Version 1.1 with a planned delivery of 06/30/2008. Software Change Request (SCR) 714 describes the requirements and scope of the work being executed, as per TOP-018, *Development and Control of Scientific and Engineering Software*. The changes were such that the Software Development Plan (SDP) and the Software Requirements Specification (SRS) did not require updating. The SCR was reviewed and the product was demonstrated for the auditor and the product updates were explained.

#### **Products and Associated Documents Reviewed**

- Ops Plan— *Biosphere Dose Assessment Model (BDOSE) Software Development* Project 14003.01.006
- Software Change Request (SCR) 714

#### **8.4 Programmatic QA**

##### **QA Auditors**

Donald Dunavant, Julie Garcia, Christopher Hobson, Thomas Trbovich

##### **Audit Approach**

Considering the limited technical topics chosen for the audit, a more comprehensive approach to the programmatic elements was taken. Each QA auditor was assigned four (4) projects each to verify programmatic requirements had been implemented using the QA checklist as the criteria. For 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. Below 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 scientific notebooks in each technical session and in the evaluation of laboratory activities. In addition, ten (10) archived notebooks were reviewed in the *Electronic Library Facility (ELF)* database during scheduled programmatic activities. One (1) good practice and one (1) minor nonconformance CDA were identified under this programmatic element. Each notebook was evaluated to determine conformance with the requirements of this procedure. Included in the notebooks



reviewed was an external notebook generated by Ankem Technologies, Inc. that did not meet the requirements of QAP-001. This SN had been identified by CNWRA QA and documented on NCR 2007-0021 and Corrective Action Request (CAR) 2008-0001. In addition to the issues identified above, questions were presented during the *Debris Source Term PWR LOCA* regarding the detail required to be included in scientific notebooks during tasks focusing on reviews of documents by others. A recommendation was provided to address this concern.

- **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 completion and comment/resolution sheets with appropriate signatures and approval. Project reviews performed by all audit team members included verifying conformance with this QAP. Two (2) minor nonconformances CDA 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. One (1) planned surveillance scheduled for January 2008 was identified that had not been performed within the month indicated. A memo was prepared during the audit stating that the surveillance was not necessary as a result of limited activity. This minor nonconformance was CDA. All other scheduled surveillances 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.
- **QAP-005, *Quality Indoctrination and Training***  
Records of training, training notification, and the database were reviewed during the technical sessions for the personnel involved in the activities. The indoctrination and training processes were found to be in accordance with QAP requirements.
- **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 *Electronic Library Facility* (ELF). Files are being maintained in a storage vault, environmentally protected, and 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*. All areas of document control conformed to the requirements of the QAP.
- **QAP-009, *Nonconformance Control***  
All 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.

There was evidence to verify that nonconforming conditions were being identified and documented during surveillance activities. The *SwRI® Quality Reporting System (QRS)* is now being utilized to capture nonconforming conditions. NCRs reviewed were found to be in accordance with QAP requirements.

- **QAP-010, Corrective Action**  
All CARs generated since the last audit were reviewed. The actions taken to address the documented findings were appropriate and thorough. Follow-up action included verification by QA personnel that actions taken had addressed all proposed corrective actions. QRS is now being utilized to capture corrective action requests. CARs reviewed were found to be in accordance with QAP requirements.
- **QAP-011, Audits**  
The results of GED 2007-1 annual audit were reviewed and the corrective actions were adequately addressed and closed as determined by the follow-up surveillance, 2007-SR-0261, conducted in December 2007. 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*, retention period marked, verified by manager, and stored in 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.
- **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, although more emphasis should be placed on the generation, review, and approval of the QRAM.
- **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 scientific notebook 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 and found to be in conformance with procedural requirements. QA reviews are performed and proper quality codes are identified for purchases with quality requirements.
- **QAP-017, Drawing Control**  
Drawings and drawing logs were reviewed in QA records. These drawings were controlled and approved in accordance with the QAP requirements.

- **QAP-018, Procedure for Confirmatory Analysis**  
Evidence of conformance was observed during the project review. Only one example of confirmatory analysis was identified in the reviews.
- **QAP-019, Control of Measuring and Test Equipment**  
Measuring and test equipment was evaluated in the laboratories of Bldg 51 and 57. Calibration of equipment in use was verified to be current or evidence of calibration verification was documented in the scientific notebooks. Three (3) out-of-tolerance notices had been received from the Institute Calibration Laboratory and all had been documented on an NCR and the impact evaluated. All equipment was found to be in conformance with the requirements. One (1) good practice was identified under this programmatic element regarding the meticulous documentation of the verification process in SN for equipment required to be *verified before use*.
- **AP-001, Source Selection and Evaluation**  
The entire audit team was involved in verifying whether subcontractors were used on the projects reviewed in the technical sessions. Appropriate training documentation was available for review in those instances where subcontract services were employed.
- **TOP-012, Identification and Control of Samples and Chemical Reagents and Standards**  
Laboratory controls implemented in Buildings 51 and 57 were reviewed. One (1) minor nonconformance was identified regarding the control of natural geological samples in Bldg 51, including identification and *Sample Custody/Control Log* discrepancies. The control of samples has improved greatly over the past years; however, more focus should be placed on the geological samples to ensure conformance to QAP requirements. In addition, one (1) minor nonconformance CDA was issued regarding several expired chemical reagents and standards found within the laboratories.

#### **Technical Specialist**

Robert Morgan (software)

- **TOP-018, Development and Control of Scientific and Engineering Software**  
In addition to *BDOSE Software Development*, the QRAM for several additional software products was reviewed and the products were evaluated based on TOP-018 programmatic requirements. These project reviews included *Airborne Transport of Radionuclides and Redistribution (ATR)* in which controlled software ArcGIS Version 9, ENVI Version 4.1, and ERDAS Imagine Version 8.7 were involved but all are acquired software (not to be modified), and consequently, there was no development or modification that significantly involves TOP-018 procedures; *Flow Paths in the Unsaturated Zone (FPUZ)* for which the software involved is FLUENT Version 6.3, which is acquired software. Also, xFLO/ 1.0 Beta was indicated to be developed/modified, and validated, with no current work having been done. A recent Software Validation Report (SVR) for FLUENT Version 6.3 was also reviewed and a good practice was identified; *Volcanic Disruption of Waste Packages (VDWP)* for which involved software included MFIX Version 2005-4, which is acquired software to be validated; *3DStress® Development*, in which 3DS® is developed software, but there was no work being done at this time.

## **9 SUMMARY OF RESULTS**

Each 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 June 2007, checklists were created specific to each technical task in addition to a general programmatic checklist addressing the QA requirements. One exception was the checklist generated for the *BDOSE Software Development* activity; this checklist was generated based on the requirements defined in TOP-018, *Development and Control of Scientific and Engineering Software*. 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, scientific notebook controls, 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. Five (5) good practices; one (1) minor nonconformance, five (5) minor nonconformances CDA; and nine (9) recommendations are described below.

## 9.1 Good Practices

### Climate and Infiltration

1. Climate & Infiltration team working on the *Infiltration Tabulator for Yucca Mountain (ITYM)* code were well-integrated into the TPA effort; as a result, the transfer of study results from ITYM to the next upgrade of TPA input expected to be well-coordinated.

### Programmatic QA—Scientific Notebook Control

2. The scientific notebook process, which is important as a log or daily scientific diary of activities and thoughts, was very thorough, detailed and complete in two SNs reviewed during the audit:
  - SN 563E (S. Stothoff)
  - SN 783 (X. He)

### BDOSE Software Development

3. BDOSE product was very user friendly with text and graphical representation indicating how the application should be used; changes incorporated to the product resulted in much greater functionality, including enhanced transparency; more security for core features; localized input parameters; locked calculations; improved configuration control; improved QA capabilities; color-coded icons and data areas; and built-in help and instructions.

### Programmatic Topics—Control of M&TE

4. All required equipment was calibrated, current and properly labeled. Equipment required to be *verified before use* was meticulously documented in scientific notebooks to ensure the equipment is adequate for use. (X. He)

### Various Project Programmatic Review

5. *FLUENT 6.3 Software Validation Report*, dated 1/8/2008 was very thorough, detailed and complete. (K. Das and D. Basu)

## 9.2 Minor Nonconformance

### Programmatic Topics—Sample Control

1. TOP-012, *Identification and Control of Samples, Chemical Reagents and Standards*, defines specific requirements for controlling samples; the following discrepancies were identified in the control of natural geological samples in Bldg 51:

- No unique sample ID code identified for one (1) sample and four (4) subsamples;
  - Sample—unidentified rock in Bldg 51, last stand, second shelf from top
  - Subsamples from samples—CFP-7; CFP-11; CFP-16; CFP-17
- *Sample Custody/Control Log* was not available for twenty-nine (29) samples;
  - GB-3-5; TB-4; FSRR6; FSN1-4; THSI.1; THS-CW; DS1 thru DS10; US1 thru US9; US9-P1; US9-P2; USA-P2; USII-P1
- *Sample Custody/Control Log* created for fourteen (14) samples was missing required fields, including *Date of receipt*; *Date of entry into log*; *Person making entry*; and *Storage location*; and
  - A1 thru A5; Q1 thru Q3; JFS1 thru JFS3; G1 thru G3
- *Sample Custody/Control Log* was not updated after subsample BB3-16 was taken from sample BB3.

See attached QRS report 2008-NCR-0163.

### 9.3 Corrected During the Audit

#### Debris Source Term PWR LOCA

1. QAP-001, *Scientific Notebook Control*, defines specific requirements for documentation in each SN; the following discrepancies were identified for SN 891E that did not conform to these requirements:
  - No record of person making entries;
  - Information was not marked *proprietary*, when required;
  - Pages were not numbered; and
  - Confirmatory calculations included in SN were not complete.

See attached QRS report 2008-NCR-0154.

2. Documentation errors were identified that did not conform to QAP requirements included the following:
  - Form QAP-6, *Document Review Request and Transmittal Control*—correction made, but not initialed and dated, as required by QAP-012, *Quality Assurance Records Control*.
  - Form QAP-3, *Report Review/Comment Resolution Record*—reviewer did not sign and date *Response Accepted By* on pages 1-2, as required by QAP-002, *Review of Documents, Reports, and Papers*.

See attached QRS report 2008-NCR-0157.

#### Programmatic Topics—Surveillance Control

3. Surveillance schedule shall be revised as necessary, as required by QAP-004, *Surveillance Control*.
  - Software development surveillance scheduled for January 2008 was not conducted, rescheduled or justified; memo was prepared and dated 4/16/2008 stating the surveillance was not necessary as a result of limited activity and other surveillances planned for FY08.

See attached QRS report 2008-NCR-0155.

#### Programmatic Topics—Chemical Reagents and Standards

4. Expired chemical reagents and standards were not disposed of, as required by TOP-012, *Identification and Control of Samples, Chemical Reagents and Standards*.
  - Several bottles of expired reagents and undated reference material
  - Two bottles of iron sulfate and ferric sulfate could not be traced to purchase and verified as being from ASL supplier

See attached QRS report 2008-NCR-0156.

### **Various Project Programmatic Reviews**

5. Documentation errors identified in the review of *Technical Assistance to the Division of Spent Fuel Storage and Transportation for Transportation Aging and Disposal Canister Designs (TAD Design)* included the following:
  - Form QAP-12, *Instructions to Technical Reviewers*—two boxes for *Software Control* and *Calculation Verification* were not initialed as completed, as required by QAP-012, *Quality Assurance Records Control*.
  - Form QAP-6, *Document Review Request and Transmittal Control*—QA review of QAP-002 requirements noted as NA by mistake. Review required by QAP-002, *Review of Documents, Reports, and Papers*.See attached QRS report 2008-NCR-0157.

### **9.4 Recommendations**

During the course of the audit activities, nine (9) 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:

#### **Climate and Infiltration**

1. GED should implement an *electronic “smart form”* for QAP-3, *Report Review/Comment Resolution Record*, to increase efficiency and clarity of record.
2. *First Draft Report: Infiltration Tabulator for Yucca Mountain: Bases and Confirmation Section on Analysis and Codes*, identifies a non-validated code *KINEROSZ* as being used to generate results; other codes identified have been validated. Recommend separating codes and identifying other wording to indicate results are *preliminary* or *intermediate*.
3. An *Incorporation or Completion Check Box* should be added to QAP-3, *Report Review/Comment Resolution Record*, as a method for verifying each comment has been incorporated in the revised document.

#### **BDOSE Software Development**

4. TOP-018, *Development and Control of Scientific and Engineering Software* should be revised in the following areas to provide guidance for applications similar to BDOSE; these areas are limited and do not cover all situations:
  - description of code documentation;
  - individual runs of software;
  - test case run procedure;
  - configuration control; and
  - remove quarterly surveillance requirement, as the practice has changed.

#### **Debris Source Term PWR LOCA**

5. In recognition of the transition from classical scientific experiments and engineering testing toward the review of documents by others, the CNWRA should review the process for documenting activities to decide if further guidance is warranted.

#### **Programmatic Topics—Chemical Reagents and Standards**

6. An inventory should be conducted of all chemicals in storage cabinets located in Bldg 57 in order to dispose of unnecessary and expired chemicals, reagents and reference material.

### Programmatic Topics—Management Interviews

7. A discussion was held with division senior management concerning the descriptions contained within the QAM and NUREG/BR-0240, *Reporting Safety Concerns to the NRC* (identified as AP-0240), regarding how allegations against quality are to be investigated and reported. The QAM states that allegations will be investigated by the Division Vice President and a determination then made by him to report to the NRC. NUREG/BR-0240 states that allegations should be directly reported to the NRC with as much information as possible requested from the person presenting the allegation. This guidance implies that no internal investigation is to be conducted. Both documents should be reviewed and a determination made which process will be followed; the QAM and NUREG/BR-0240 should identify the same process.

### Various Project Programmatic Reviews

8. Several changes or corrections to comments and responses were noted on Form QAP-3, *Report Review/Comment Resolution Record*, that were not initialed and dated; the process for initialing and dating corrections should be implemented in all cases.
9. More emphasis should be placed on the generation, review and approval of the *Quality Requirements Application Matrix (QRAM)* and to accurately indicate only those QA elements that are appropriate for the project.
  - In a number of cases, several QA procedures were identified that were not applicable to the project
  - QRAM reviewed for 3DStress® indicates software modification; though no modification was ever intended to take place, even though signed off and approved in October 2007

## 10 QUALITY ASSURANCE PROGRAM EFFECTIVENESS

As determined by this annual audit, the QA program applied by the GED continues to be effectively implemented. The nature of the nonconformances identified in the audit do 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
<b>GED Staff and Consultants</b>			
Adams, N.		X	
Axler, K.		X	
Bannon, D.		X	X
Basu, D.		X	
Brient, R.	X	X	X
Chiang, K.			X
Chowdhury, A.			X
Das, K.		X	
Dubreuilh, P.		X	X
Ferrill, D.		X	
Galloway, A.			X
He, X.		X	
Hinojosa, D.			X
Hooper, D.		X	

	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Imtiaz, H.		X	
Janetzke, R.		X	
Lenhard, R.	X		X
Mackin, P.	X	X	X
Mancillas, J.		X	
Manepally, C.		X	
Mintz, T.	X	X	X
Myers, J.			X
Pabalan, R.			X
Padilla, M.		X	X
Pan, Y.		X	X
Patrick, W.	X	X	X
Pearcy, E.	X	X	X
Pensado, O.		X	
Sagar, B.	X	X	
Simpkins, A.	X	X	X
Simpson, M.	X	X	X
Stothoff, S.	X	X	X
Turner, D.	X	X	
Winterle, J.	X		
Wittmeyer, G.	X	X	X
<b>NRC Observers</b>			
DeMarco, D.	X		X
Gonzalez, H.	X		X
Jacobs, F.	X		X
Markley, C.	X		X
<b>Audit Team and Others</b>			
Dunavant, D.	X		X
Dutton, A.	X		
Garcia, J.	X		X
Hill, W.		X	
Hobson, C.	X		X
Holt, A.			X
Morgan, R.	X		X
Page, R.	X		X
Trbovich, T.	X		X



**APPROVAL SIGNATURES**

*Christopher Hobson*

Christopher Hobson  
Audit Team Leader (ATL)

5/14/2008  
Date

*Thomas Trbovich*

Thomas Trbovich  
QA Auditor

5/14/08  
Date

*Christopher Hobson*  
for

Donald Dunavant  
QA Auditor

5/14/2008  
Date

*Julie Garcia*

Julie Garcia  
QA Auditor

5/14/2008  
Date

*Robert Morgan*

Robert Morgan  
Technical Specialist, Software

5/14/2008  
Date

*Christopher Hobson*  
for

Dr. Alan Dutton  
Technical Specialist, Aqueous Geochemistry, Hydrogeology

5/14/2008  
Date

*Richard Page*

Dr. Richard Page  
Technical Specialist, Material Sciences

5/14/2008  
Date

*Robert Brient*

Robert Brient  
Director of Quality Assurance, GED

5/14/2008  
Date