# **INSTITUTE QUALITY SYSTEMS**

# **QUALITY ASSURANCE AUDIT REPORT**

OF

# GEOSCIENCES AND ENGINEERING DIVISION (20) CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

**CNWRA AUDIT 2006-1** 

SAN ANTONIO, TEXAS JUNE 26–30, 2006

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#### **EXECUTIVE SUMMARY**

The annual internal Quality Assurance (QA) audit of the Center for Nuclear Waste Regulatory Analyses (CNWRA) within the Geosciences and Engineering Division (GED) was conducted June 26–30, 2006. The audit team, comprised of technical specialists and quality assurance auditors, determined that the CNWRA QA program was being effectively implemented and provided adequate controls over technical product development. U.S. Nuclear Regulatory Commission (NRC) observers (QA, technical, and program management) observed the audit conduct.

The CNWRA 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.

Areas of concern from the previous annual audit were addressed by the CNWRA management and staff in such a way as to correct the concern and significantly improve the process. Improvements were noted throughout the system, including sample identification and traceability, procurement documentation, surveillances, training and qualification, and the nonconformance and corrective action process. The CNWRA management and staff should be commended for the corrective actions taken during the last year to address the findings from the previous annual audit, as these corrective measures improved several processes within the program.

The results of the audit were discussed with the CNWRA management and staff during daily management briefings and in a post-audit meeting held on June 30, 2006. Two minor nonconformance reports (NCR) were initiated and two minor nonconformances were corrected during the audit (CDA), which were also documented in NCRs for trending purposes. The nature of the nonconformances identified was judged by the audit team to pose little risk to the quality of CNWRA products. In addition, several opportunities for improvement were identified that may facilitate the CNWRA maintaining and improving its quality program and technical products.

# 1 AUDIT SCOPE

This audit evaluated the CNWRA QA program to verify that it met the applicable requirements of 10 CFR Part 50, Appendix B and 10 CFR Part 63, Subpart G, and was being effectively implemented. The audit was performance-based and evaluated programmatic requirements in light of their application to technical activities. In addition, the corrective action process was reviewed to determine the appropriateness of actions taken and implementation effectiveness.

# 2 PROGRAMMATIC ELEMENTS AUDITED

GED 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, Drawings, and Procedures	5		
Document Control	6		
Control of Purchased Material	7		
Identification and Control of Items	8		
Control of Special Processes	9		
Inspection	10		
Test Control	11		
Control of Measuring and Test Equipment	12		
Handling, Storage, and Shipping	13		
Inspection, Test, and Operating Status	14		
Nonconformance Control	15		
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Design-related activities are not performed by CNWRA; therefore, Design Control requirements are not applicable. All QAM sections were addressed in this audit. 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 applied and was accomplished by direct evaluation of selected technical activities, assessment of products, discussions with key project staff, and the contributions of these processes to product quality. Teams composed of a programmatic auditor and a technical specialist performed the technical audits.

In preparation for the audit, technical specialists and auditors reviewed applicable operation plans, procedures, quality planning documents, and technical products. Technical checklists were prepared based on these reviews appropriate to the scopes of work. QA programmatic checklists were prepared for application during the technical audits and for QA systems (i.e., document control, records control, nonconformance and corrective actions, etc.) assessments.

The audit sessions were conducted through discussions with project management and technical staff, review of objective evidence (including review packages and scientific notebooks), and when appropriate, observation of laboratory activities. Technical and programmatic findings were compiled by the audit teams for discussions and reporting.

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:

## High-Level Waste Repository Safety Program:

- TPA Code Development
- General Information: Evaluation of Site Characterization
- Climate and Infiltration
- Radionuclide Release Rates and Solubility Limits
- Preclosure Safety Evaluation
- Degradation of Engineered Barriers
- Methodology and Overall System Performance

## Non-Repository Program:

- Waste Incidental to Reprocessing
- Standard Review Plan Development

# 1 AUDIT TEAM

Thomas Trbovich	Audit Team Leader (ATL)	Southwest Research Institute <sup>®</sup> (SwRI <sup>®</sup> ) Institute Quality Systems (IQS)
Rodney Weber	QA Auditor	IQS
Christopher Hobson	QA Auditor/ATL-In-Training	IQS
Joerg Gerhardus	QA Auditor	IQS
Robert Morgan	Technical Specialist, Software	IQS
Alexander Bernardo	Technical Specialist, Engineering Analysis	SwRI Division 18
Dr. Robert Mason	Technical Specialist, Statistical Analysis	SwRI Division 08
Dr. William Thomann	Technical Specialist, Geosciences	University of the Incarnate Word (UIW)
James Dante	Technical Specialist, Material Science	SwRI Division 18
Dr. Alan Dutton	Technical Specialist, Aqueous Geochemistry; Hydrogeology	University of Texas San Antonio (UTSA)

# 2 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 72.22(f)]
- Title 10 CFR Part 63, Subpart G
- Title 10 CFR Part 72, Subpart G
- ANSI/ASME NQA-1-1996
- GED QAM
- GED QA Procedures (QAPs)

# 1 U.S. NUCLEAR REGULATORY COMMISSION (NRC) OBSERVERS

Wilkins Smith	Observer Team Lead	
Deborah DeMarco	Program Management Observer	
Paul Bell	QA Observer	
James Pearson	QA Observer	
Eugene Peters	Technical Observer	
Mahendra Shah	Technical Observer	
Bret Leslie	Technical Observer	

# 2 AUDITED ACTIVITIES

Teams comprised of a technical specialist and QA programmatic auditors audited the following activities. When available, products delivered since the last audit were reviewed against procedural requirements and compared to the objectives listed in the appropriate operations plans.

# 2.1 High-Level Waste Repository Safety Program

# 2.1.1 TPA Code Development

# Audit Team

Robert Morgan and Joerg Gerhardus

## Task Description

The TPA code is being modified to create version 5.1. The task includes code development and validation testing. The activities are conducted in accordance with Technical Operating Procedure, TOP-018, *Development and Control of Scientific and Engineering Software*.

## Products and Associated Documents Reviewed

- TPA version 5.1, the application code, which is TPA Version 5.0 software as extended by Software Change Reports (SCRs) and Software Release Notices (SRNs)
- Software Development Plan (SDP) for TPA Version 5.0, dated 5/10/2005
- Draft Software Requirements Description (SRD), dated 11/01/2005
- SRD Review Document, dated 10/14/2005
- GED Controlled Software Directory List and the Master Directory of Software
- *CNWRA Operations Plan* for FY06, High Priority Tasks, Methodology and Overall System Performance, Milestones
- TOP-018, *Development and Control of Scientific and Engineering Software*, Rev 10, Chg 0, dated 8/08/2005
- Scientific Notebook 612-6E, with QAP-001, *Scientific Notebook Control* and QAP-014, *Documentation and Verification of Calculations*
- GED Quality Assurance Surveillance Reports, dated 12/02/2005, and 02/17/2006
- CNWRA 2005-1 Audit follow-up of findings (CAR-2005-4)

## 1.1.1 General Information: Evaluation of Site Characterization

#### Audit Team

Dr. William Thomann and Rodney Weber

#### Task Description

This task involved a comprehensive review of intermediate milestone (IM) 20.06002.01.292.510; Summary and Analysis of Subsurface Fracture Data from the Topopah Spring Tuff Upper Lithophysal, Middle Nonlithophysal, Lower Lithophysal, and Lower Nonlithophysal Zones at Yucca Mountain, Nevada, March 7, 2006 authored by Smart, Kevin J., Wyrick, Danielle Y., Landis, Paul S., and Waiting, Deborah J. This report provides information on subsurface fracture data collected at Yucca Mountain. Nevada for use by the NRC and CNWRA in the evaluation of the potential license application for a high-level nuclear waste repository. The audit included an evaluation of a nonconforming condition report (NCR) 2006-5 of the technical review and calculation verifications for report IM20.06002.01.292.510, September 16, 2005. Included as a hard copy attachment to the NCR, an email by John Stamatakos to Robert Brient and Mark Ehnstrom on disposition of corrective action for the NCR regarding revisions to the report was also reviewed. Additional work included review of the Scientific Notebook 606E, which included Yucca Mountain fracture data and data organization compiled by Kevin Smart, and Scientific Notebook 685E, Synthesis of Subsurface Fracture Data collected at Yucca Mountain, Nevada, by Smart, Lands, Waiting, Wyrick, Sims, Ferrill, Franklin, and Morris. The auditors posed questions from their respective checklists related to the deliverables of this task. Examination of Scientific Notebooks 606E and 685E included evidence of documentation and verification of scientific and engineering calculations as well as all other QAP requirements. The auditors discussed the programmatic elements related to future field and laboratory work with the researchers.

## Products and Associated Documents Reviewed

- CNWRA Operations Plans for the Repository Program, Revision 20, Change 0, 2006, General Information (Evaluation of Site Characterization) 2.16; Appendix B-12 GI: General Information (Evaluation of Site Characterization)
- *Quality Requirements Application Matrix (QRAM) General Information*, Revision 20, Change 0, Project Numbers 20.06002.02.292, 20.06002.02.293, and 20.06002.02.294
- IM20.06002.01.292.510 Summary and Analysis of Subsurface Fracture Data from the Topopah Spring Tuff Upper Lithophysal, Middle Nonlithophysal, Lower Lithophysal, and Lower Nonlithophysal Zones at Yucca Mountain, Nevada, March 7, 2006 authored by Smart, Kevin J., Wyrick, Danielle Y., Landis, Paul S., and Waiting, Deborah J.
- NCR 2006-05 initiated on the technical review and calculation verifications for report, Summary and Analysis of Subsurface Fracture Data from the Topopah Spring Tuff Upper Lithophysal, Middle Nonlithophysal, Lower Lithophysal, and Lower Nonlithophysal Zones at Yucca Mountain, Nevada performed on September 16, 2005
- Electronic Scientific Notebook 606E was reviewed. A paper copy of the Yucca Mountain fracture data was provided with an entry start date of 8/12/2003 and end date on 5/5/2004. Notebook includes Yucca Mountain fracture data and data organization

compiled by Kevin Smart. Electronic initials were present in all cases.

• Electronic Scientific Notebook 685E on *Synthesis of Subsurface Fracture Data collected at Yucca Mountain, Nevada*, by Smart, Lands, Waiting, Wyrick, Sims, Ferrill, Franklin, and Morris. A paper copy of the fracture data analysis by several authors was provided with an entry start date of 11/8/2004 and end date on 9/1/2005. Electronic initials were present in all cases.

# 1.1.1 Climate and Infiltration

## <u>Audit Team</u>

Dr. Alan Dutton and Rodney Weber

## Task Description

The purpose of this task is to perform scientific analysis of data and models for climate and infiltration modeling. CNWRA staff is to implement an internal performance assessment model that requires input on future climate and infiltration. One reviewed report asks for comparison of how the US Department of Energy (DOE) performance assessment model handles climate and infiltration. The other two reviewed reports focus on providing basic information from which a later task can draw to establish bounded climate and infiltration input values for the performance assessment model.

## Products and Associated Documents Reviewed

- Stothoff, S. and Musgrove, M., April 2006, *Literature Review and Analysis: Climate and Infiltration*, prepared for U.S. NRC under contract NRC 02-02-012, variously paginated
- Stothoff, S. and Walter G. R., August 2005, *Implementation of the Climate and Infiltration Abstractions in the GOLDSIM TSPA-SR Code*, prepared for U.S. NRC under contract NRC 02-02-012, 11 p.
- Woolhiser, D. A., Combined Effects of the Southern Oscillation Index and the Pacific Decadal Oscillation on a Stochastic Daily Precipitation Model
- Document Review/Comment Resolution Record (QAP-3) for Literature Review and Analysis: Climate and Infiltration. Project No. 20.06002.01.252, April 18, 2006
- Document Review/Comment Resolution Record (TOP-3) for Implementation of the Climate and Infiltration Abstractions in the GOLDSIM TSPA-SR Code. Project No. 20.06002.01.252, June 23, 2005
- Document Review/Comment Resolution Record (TOP-3) for Combined Effects of the Southern Oscillation Index & the Pacific Decadal Oscillation on a Stochastic Daily Precipitation Model. Project No. 20.06002.01.252, March 9, 2006

## **Scientific Notebooks Reviewed**

Three Scientific Notebooks (362, 444 and 597) contributed by D. Woolhiser were reviewed for technical and QAP-001, *Scientific Notebook Control*, conformance.

# 1.1.1 Radionuclide Release Rates and Solubility Limits

#### Audit Team

Dr. Alan Dutton and Thomas Trbovich

#### Task Description

The purpose of this task is to improve the conceptual basis for how radionuclide transport might be modeled in a performance assessment code. The question relates to the relative importance of equilibrium and kinetic processes and the degree to which each process might be modeled for performance assessment. The analysis was conducted by (a) developing and solving the mathematical equations or functions that describe equilibrium and kinetic transfer processes; (b) running multiple simulations to account for uncertainty in parameter values that are included in the transfer functions; (c) graphing and interpreting results; and (d) writing a technical report that documents the analysis and findings.

#### Products and Associated Documents Reviewed

- Painter, S. L., and Cvetkovic, V., 2006, Effect of kinetic Limitations on Colloid-Facilitated Radionuclide Transport at the Field Scale. Presented at High-Level Radioactive Waste Management Conference, Las Vegas, April 30-May 4, 2006, 7 p.
- Document Review/Comment Resolution Record (QAP-3) for Effect of Kinetic Limitations on Colloid-Facilitated Radionuclide Transport at the Field Scale. Project No. 06002.01.242, Dec. 21, 2005
- Milestone Log from the CNWRA Operations Plan (Rev. 20 Chg 0). Section 2.10, *Radionuclide Release Rates and Solubility Limits*, p. 2-15 through 2-18
- Scientific notebook 318E was reviewed and determined to incorporate the notebook output from *Mathematica* software

#### 1.1.1 Preclosure Safety Evaluation

#### Audit Team

Alexander Bernardo and Joerg Gerhardus

#### **Task Description**

The primary line of inquiry focused on the content of document, *Assessment of Structural Robustness Against Aircraft Impact at the Potential Repository at Yucca Mountain* – Progress Report (Predecisional). Particular attention was given to the clarity of the document, notably how the work described related to work referenced. Questions were also asked regarding the control and validation of the software that was implemented in the effort (TOP-18), and the technical review process (QAP-002).

#### Products and Associated Documents Reviewed

• Predecisional: Assessment of Structural Robustness Against Aircraft Impact at the Potential Repository at Yucca Mountain--Progress Report.

- Excerpts from the CNWRA Operations Plan: Section 2.20, *Preclosure Safety Evaluation* & Section 2.21, *Mechanical Disruption of Engineered Barriers*.
- Malvar, Et. al. *A Plasticity Concrete Material Model for DYN3D*, International Journal of Impact Engineering Vol. 19, Nos. 9-10, pp. 847-873, 1997

## **1.1.1 Degradation of Engineered Barriers**

## Audit Team

James Dante and Christopher Hobson

# Task Description

This task involves conducting activities to resolve issues associated with the degradation of engineered barrier systems. This is critical to understanding the possible risk associated with the release of nuclear waste into the environment. Two technical documents were reviewed regarding the corrosion of Alloy 22 in concentrated nitrate and chloride salt environments, at elevated temperature, and the stress corrosion cracking susceptibility of Alloy 22. Additionally, several scientific notebooks were examined for completeness of data, verification of data analysis from commercial software, and documentation of equipment verification. Finally, a laboratory tour was conducted to determine that appropriate laboratory procedures were followed in performing testing.

# Products and Associated Documents Reviewed

- Corrosion of Alloy 22 in Concentrated Nitrate and Chloride Salt Environments at Elevated Temperatures – Progress Report
- Stress Corrosion Cracking of Waste Package Material Modeling and Experiments

# 1.1.1 Methodology and Overall System Performance

## Audit Team

Dr. Robert Mason and Joerg Gerhardus

## Task Description

The primary objective of this task is to prepare for the review of a potential DOE license application. The audit was conducted through review of the three documents listed below, through interviews with the project manager for this task, and with two staff scientists conducting the work. The review included document review and verification of participant and consultant qualifications. Discussion was also held on the question why these were only draft strategies rather than preliminary strategies. There were no scientific notebooks to review.

## Products and Associated Documents Reviewed

- Methodology and Overall System Performance Operations Plan
- Document No. 06002.01.352.550 (Preliminary) A Potential Strategy for Conducting a Review of Scenario Analysis and Identification of Events with Probabilities Greater Than 10<sup>-8</sup> Per Year

• Document No. 06002.01.352.550 (Preliminary) - A Draft Strategy for Conducting a Review of System Description and Demonstration of Multiple Barriers

#### 1.1 Non-Repository Program

#### 1.1.1 Waste Incidental to Reprocessing

#### Audit Team

Dr. Robert Mason and Christopher Hobson

#### Task Description

The main objective of this task is for the CNWRA staff to provide technical assistance to support the NRC in consulting with the DOE on non-high-level waste determinations and disposal strategies at Savannah River and the Idaho National Laboratory. In particular, current attention is given to preparing input to requests for additional information if the information provided by DOE is incomplete. The audit was conducted through review of the three documents listed below and through interviews with an Assistant Department Director, who is the Project Manager for this task, and with a Senior Research Engineer conducting the work. The review included document review and verification of participant and consultant qualifications. One recommendation was provided concerning the use of references to document comments in one of the reports.

## Products and Associated Documents Reviewed

- Operations Plan for Technical Assistance in Evaluating Non-High-Level Waste Determinations for the U.S. Department of Energy Facilities in South Carolina and Idaho
- IM 06004.01.001.110 and 120 Input to a Request for Additional Information for Technical Assistance in Evaluating Section 3116 of the National Defense Authorization Act Determination for Closure of Tanks 18 and 19 at the Savannah River Site
- IM 06004.01.001.300 Input to a Request for Additional Information for Technical Assistance in Evaluating a Waste Determination Methodology for Closure of High-Level Waste Tanks at Idaho National Laboratory

## 1.1.1 Standard Review Plan Development

## Audit Team

Thomas Trbovich and Christopher Hobson

## Task Description

The main objective of this task was for the CNWRA staff to provide technical assistance to support the NRC development of a standard review plan (SRP) that will provide a standard approach and format for reviewing non-high level waste determinations. Standard review plans are used by the NRC as guidance to establish and ensure consistency in reviews undertaken as part of the regulatory process.

Through the interview with the project manager it was determined that numerous meetings were held with the NRC counterparts to determine the format and content of the various sections of

the plan. The Yucca Mountain Review Plan was used as a guide for the Standard Review Plan (SRP) development. CNWRA staff selected to write various sections were assigned based on knowledge and ability in writing skills. Draft versions of the CNWRA prepared sections were sent to the NRC for review and comment; however, no tracking system was maintained to assure all NRC comments had been incorporated or resolved. The draft version of the SRP went through the required QAP-002 review where over thirty pages of comments were noted and resolved. After the submittal of the draft to the NRC, a meeting was held to review the document that was noted as being unacceptable to the NRC. Required changes were made and resubmitted. A Lessons Learned Review is being performed both at the CNWRA and NRC to determine the root cause of the problem.

#### Products and Associated Documents Reviewed

- Operation Plan for Technical Assistance in Evaluating High Level Waste Determinations for the US Department of Energy Facilities in South Carolina and Idaho. Change 2, August 2005. Section 3.5, Support the Development of a Standard Review Plan
- Draft Standard Review Plan, Comment/ Resolution Records
- Final revised Standard Review Plan with mark-ups

#### 1.1 Programmatic QA

#### **Auditors**

R. Weber, C. Hobson, J. Gerhardus, T. Trbovich

#### **Quality Procedures Reviewed**

- QAP-005, *Quality Indoctrination and Training* Records of training, training notification, training notification and database were reviewed. With the exception as noted below, the indoctrination and training processes are in accordance with QAP-005. One recommendation was made.
- QAP-007, Professional Personnel Qualification
   Qualification records are being effectively managed; files are complete and are readily
   available. The position descriptions, qualifications, and other information, as required by
   this procedure, are complete and appropriate in the records reviewed. Reviews are
   performed to ensure personnel meet the requirements of the position and annual
   reviews are being conducted and documented accordingly.
- QAP-002, *Review of Documents, Reports, and Papers* The entire team was involved in reviewing documents associated with their assigned technical areas. Each technical document was verified as having the proper form completion and comment/resolution sheets with appropriate signatures and acceptance.
- QAP-008, Document Control
  - Documents are 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 in accordance with AP-020, *Managing Sensitive Unclassified and Export-Controlled Information*. Uncontrolled copies generated by the document control clerk are being stamped as *Uncontrolled*.

The master document list, previously maintained manually, has been replaced by the controlled directories in the ELF. Reports are generated by this software that list current documents and the applicable identifying information. These reports effectively replace the master document list. A recommendation was made to update the procedure.

 TOP-012, Identification and Control of Samples and Chemical Reagents and Standards The laboratory controls implemented in Buildings 51 and 57 were reviewed. Control of Alloy 22 samples was demonstrated in the Corrosion Laboratory. Traceability of these samples was much improved from previous years. Reagents and standards were appropriately labeled and stored. Recently received core samples from the DOE Sample Management Facility were processed by appropriate logging, marking, and handling. A spreadsheet log was created to capture the information required by the procedure.

#### • QAP-016, Procurement

Thirteen purchase requisitions were reviewed and found to be in conformance with procedural requirements. QA reviews are performed and proper quality codes are identified. The procurement package, complete with requisition, purchase order and signed receipt inspection, is maintained in the ELF system which facilitates surveillance and audit reviews.

• QAP-009, Nonconformance Control

Since the 2005 internal audit, 24 Nonconforming Condition Reports (NCRs) have been issued. A sample of six NCRs was reviewed during this audit. NCR 2005-20 exceeded the required timeframe for closure to be within 10 working days of the target completion date. The target date shown is 05/20/2005 and the report was closed on 06/17/2005. The organization should review this requirement to evaluate the value of such a strict requirement for closure.

Section 5 of QAP-009 requires an annual trend analysis of the nonconformances. Evidence of the analysis was provided by and discussed with the Director of QA. The change of assigning calibrated equipment to only one custodian has greatly improved the documentation of out-of-tolerance conditions. This was identified in the management review of the trend analysis. The Director of QA is using the summary of the trend analysis as a baseline for the 2006 analysis.

• QAP-010, Corrective Action

Five Corrective Action Requests (CARs) written since the last audit were reviewed. The actions taken to address the documented findings were appropriate and thorough. Follow-up action included verification by quality assurance personnel that actions taken had addressed all proposed corrective actions. It was noted the corrective action process had been improved over previous years.

#### • QAP-004, Surveillance Control

The surveillance schedule for calendar year 2006, Revision 2, was reviewed and noted that the planned surveillances had been performed within the month indicated or within 30 days of the month scheduled. Ten surveillance reports were reviewed and found to contain detailed summaries with some discrepancies noted and documented in NCRs. The surveillance program was noted as being much improved over previous years.

# 1 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 auditor. Based on review of deliverables produced in the period since the last audit in May 2005, 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. The following is a detailed description of the audit results including the technical task from which the results were noted. Two minor nonconformances, two minor nonconformances corrected during the audit and documented as NCRs for trending purposes, and thirteen recommendations are described below.

# 1.1 Good Practices

## Radionuclide Release Rates and Solubility Limits

Use of *Mathematica* software enables proficient capture of traceable calculations, data, graphics and report in combination with a scientific notebook. This approach minimizes or even avoids the use of stand-alone or one-time scripts for data analysis, which can be difficult and expensive to document. The *Mathematica* tool supports enhanced work productivity and improved capability of meeting quality requirements for document control.

## Programmatic QA

CARs and NCRs issued during the last year and their verification of implementation was detailed, thorough, and resulted in significant improvements throughout the quality program, including sample identification and traceability, procurement documentation, training and qualification, surveillance and the nonconformance and corrective action process. Actions were taken to improve the entire quality program rather than to only address the immediate concern.

## 1.2 Minor Nonconformances

## Programmatic QA

- Contrary to the requirements of QAP-001, *Scientific Notebook Control*, Section 3.4.1, which requires that each initial and in-process entry be signed, initialed, and dated by the authorized individual; three electronic notebooks (606E, 612E, 685E) were identified that did not fully meet this requirement.
- Contrary to the requirements of QAP-005, *Quality Indoctrination and Training*, Section 3.2.2, form QAP-11-1, *Procedure Identification and Training Record*, does not always identify a training completion date. The *Indoctrination and Training Tracker (ITT)* system automatically identifies a 10-day completion requirement.

# 1.1 Corrected During Audit (CDA)

#### Programmatic QA

- Contrary to the requirements of QAP-001, *Scientific Notebook Control*, the notebook number was not identified on each page of scientific notebook 612-6E.
- One Form QAP-12-1, *Geosciences Engineering Division Instructions to Technical Reviewers*, was not initialed by the reviewer for one of several review criteria.

#### 1.1 Recommendations

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

#### **TPA Code Development**

- Code reviews and any other reviews are not handled as traditional peer reviews and are all considered informal, with no records kept as objective evidence. The auditors recommend that even *buddy checks* should have a minimum of documentation to record that they were conducted and any action items or issues found should be documented. Informal code reviews should be documented. Note that this item is a repeat from CNWRA Audit 2005-1.
- The process should be clarified regarding the use of acceptance tests for minor *Software Change Report* (SCR) testing versus tests conducted just prior to a major release. TOP-018, Sections 5.6.2 and 5.7.1, are not clear in the directions for minor SCR testing or major release acceptance testing.
- TOP-018, *Development and Control of Engineering and Scientific Software*, should be revised to include provisions for maintenance and modification oriented work.
- Quarterly software QA surveillances should include more detail on the results. Regular surveillances performed by an outside consultant are very brief and mainly indicate that a review was conducted and certain sections of TOP-018, *Development and Control of Engineering and Scientific Software*, were addressed. These surveillances would be more helpful if the surveyor would elaborate on the results.
- TOP-018 should be reviewed and revised to remove references to the former paperbased process and the electronic processes currently being used, e.g., controlled software listing versus a software directory file.
- TOP-018, Section 5.7.6, and associated Software Release Notice form should be revised to indicate that the QA custodian performs *QA reviews* or *QA checks*, rather than *QA verification*, which implies the implementation of more rigorous requirements.

## **Climate and Infiltration**

The *EXCEL* worksheets, used to compile and archive the results of data mining from literature, were the core of the *Literature Review* report. At least three personnel checked the entries, but there is no objective evidence available documenting that review. This process of proofreading

or fact-checking entries of raw data entered into a database, whether from literature searches or other sources, should be documented.

## Preclosure Safety Evaluation

QAP-002, *Review of Documents, Reports, and Papers*, Section 3.1, requires the technical reviewer to have technical expertise at least equivalent to that required to perform the original work available. Although the technical reviewer was qualified to perform the review, a more experienced reviewer may have provided additional value to the review process. This process for determining the qualifications of a technical reviewer should be more rigorous to ensure more technical equivalency in the review for deliverable products, thus reducing the risk of NRC rejection.

## Degradation of Engineered Barriers

As identified through discussions of *Corrosion of Alloy 22 in Concentrated Nitrate and Chloride Salt Environments at Elevated Temperatures* – Progress Report, in order to ensure that consistent concentrations in the liquid phase are achieved and to minimize variation in vapor phase chemistry during the tests, a procedure should be defined specifically outlining the required steps for adding water to both the liquid phase test cell and the condenser. Currently the method has a large degree of subjectivity and can be addressed by simply applying a fill line to each of the cells to ensure a constant volume of water.

#### Waste Incidental to Reprocessing

References should be provided in *Request for Additional Information (RAI)* letters to DOE to substantiate and justify comments. One report included these references in all comments, though the other report lacked references in some cases, which would have provided valuable information to the reader.

#### **Standard Review Plan Development**

A mechanism or process should be developed for tracking the incorporation and closure of NRC comments when informal submittal of documents is made on multiple occasions for regulatory tasks.

## Programmatic QA

- QAP-008, *Document Control*, should be revised to reflect the replacement of *Master Document List* with the ELF menus.
- The QAP 009, *Nonconformance Control*, requirement for a stringent 10-day time frame for closure should be revaluated for necessity.

## 1 QUALITY ASSURANCE PROGRAM EFFECTIVENESS

As determined by this annual audit, the QA program applied by the CNWRA was being effectively implemented. The nature of the nonconformances identified in the audit did 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.

# 2 PERSONS CONTACTED

	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
GED Staff and Consultants			
Adams, N.			Х
Basu, D.			Х
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Dasgupta, B.			Х
Derby, B.		Х	
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Flock, R.			Х
Galloway, A.	Х		Х
Ghosh, A.	Х	Х	
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Hooper, D.			Х
Howard, L	Х	Х	Х
Hsiung, S.			Х
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McKaque, L.	Х	Х	
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Padilla. M.		Х	Х
Painter, S.	Х	Х	
Pan, Y.	Х	Х	Х
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Peters, E.	Х		Х
Shah, M.	Х		Х
Smith, W.	Х		Х
Audit Team and Others			
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Dante, J.	Х		Х
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Gerhardus, J.	Х		Х
Hobson, C.	Х		Х
Holt, A.	Х		
Mabrito, B.			Х
Mason, R.	Х		Х
Morgan, R.	Х		Х
Smith, A.	Х		Х
Thomann, W.	Х		X
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Weber, R.	X		X

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7/27/04 Date

06 Date

Date

66 Date

06

6 Date

7/27/04 Date

7/06

1/27/04 Date

7/27/04 Date

7/27/06

Date

1/27/2006 Date

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