# QUALITY ASSURANCE AUDIT REPORT

of

## THE CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CNWRA AUDIT 2005-1

San Antonio, Texas

May 9–13, 2005

# CONTENTS

# EXECUTIVE SUMMARY

The annual internal Quality Assurance (QA) audit of the Center for Nuclear Waste Regulatory Analyses (CNWRA) was conducted May 9–13, 2005. The audit team, comprised of technical and quality assurance specialists, 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 pre-audit meeting, audit activities, and the post-audit meeting.

The CNWRA staff was operating in accordance with the CNWRA QA Manual, Operations Plans, Technical Operating Procedures, QA Procedures, and applicable Administrative Procedures. The technical staff was judged to be appropriately qualified through education, experience, and training. The technical work was being conducted in a satisfactory manner. The audit team identified a number of corrective actions, nonconformances, and other opportunities for improvement that may facilitate CNWRA maintaining and improving its quality program and technical products.

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 May 13, 2005. Four corrective actions (addressed in Corrective Actions) and five minor nonconformances (addressed in Nonconformance Reports) were identified. The corrective action reports documented conditions that indicated potential trends and/or may require additional review to address. Related nonconformances were considered in determining the need for corrective action, with two of the corrective actions involving previous audit findings. The nature of the nonconformances was judged to pose little risk to the quality of CNWRA products.

# 1 AUDIT SCOPE

This audit evaluated the Center for Nuclear Waste Regulatory Analyses (CNWRA) Quality Assurance (QA) program to verify that it met the applicable requirements of 10 CFR Part 63, Subpart G and 10 CFR Part 50, Appendix B 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 its effectiveness.

# 2 PROGRAMMATIC ELEMENTS AUDITED

| | Corresponding CNWRA QA Manual (CQAM) Chapter |
|---|---|
| Organization | 1 |
| QA Program | 2 |
| Scientific/Engineering Investigation & 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, Test, and Operating Status | 14 |
| Nonconformance Control | 15 |
| Corrective Action | 16 |
| Records Control | 17 |
| Audits | 18 |

Design-related activities were not performed by CNWRA, so 10 CFR 63.142(d), Design Control, was not applicable. All CQAM sections were addressed in this audit.

# 3 AUDIT APPROACH

A performance-based approach to auditing was applied to evaluate the effectiveness of the QA program in ensuring and improving product quality. This was accomplished by direct evaluation of selected technical activities, assessment of products, evaluations of technical product development processes, 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 operations plans, quality planning documents, operating procedures, 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 audits were conducted through discussions with project managers, principal investigators, 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 observers and daily meetings between the audit team leader and CNWRA management were held.

## 4 TECHNICAL ACTIVITIES AUDITED

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

- Evolution of Near Field Environment
- Repository Design and Thermo-Mechanical Effects
- Igneous Activity
- Container Life and Source Term
- Thermal Effects on Flow
- Radionuclide Transport
- Preclosure—Seismic Analysis
- Total System Performance Assessment and Integration (Software)
- Total System Performance Assessment and Integration (Risk Analysis)
- Decommissioning (Task Order 4)
- External Quality Assurance
- Inspection Program

## 5 AUDIT TEAM

| Name | Role/Expertise | Affiliation |
|---|---|---|
| Rod Weber | Audit Team Leader (ATL) | Institute Quality Systems (IQS) |
| Tom Trbovich | Quality Assurance (QA) Auditor | IQS |
| Chris Hobson | QA Auditor | IQS |
| Don Dunavant | QA Auditor | IQS |
| Ashley Smith | QA Auditor/Technical Specialist, Software | IQS |
| Jim Dante | Technical Specialist, Material Science | Southwest Research Institute® (SwRI®) |
| Larry Goland | Technical Specialist, Structural Engineering | SwRI |
| Tom Morrow | Technical Specialist, Modeling and Risk Management | SwRI |
| William Thomann | Technical Specialist, Geosciences | University of the Incarnate Word (UIW) |
| Dibyendu Sarkar | Technical Specialist, Geochemistry | University of Texas at San Antonio (UTSA) |

## 6 APPLICABLE DOCUMENTS

The following documents formed the basis of the audit and for the checklists.

- 10 CFR Part 63, Subpart G
- 10 CFR Part 50, Appendix B
- American National Standards Institute (ANSI)/ASME NQA–1–1986
- CQAM
- CNWRA QA Procedures (QAPs)
- CNWRA Technical Operating Procedures (TOPs)
- CNWRA Administrative Procedures (APs)

# 7 U.S. NUCLEAR REGULATORY COMMISSION OBSERVERS

| | |
|---|---|
| Thomas Matula | Senior QA Engineer (Observer Team Lead), High-Level Waste Repository Safety (HLWRS), Office of Nuclear Material Safety and Safeguards (NMSS) |
| Deborah DeMarco | U.S. Nuclear Regulatory Commission (NRC) Center Deputy Program Manager, HLWRS, NMSS |
| Bret Leslie | Senior Project Manager, HLWRS, NMSS |
| Aladar Csontos | Materials Engineer, HLWRS, NMSS |
| Frank Jacobs | Safety Inspector, Spent Fuel Project Office (SFPO), NMSS |
| Jack Parrott | Senior Onsite Licensing Representative |
| Tina Ghosh | Systems Performance Analyst |

# 8 AUDITED ACTIVITIES

Technical activities were audited by teams of technical specialists and QA auditors. Products delivered since the last audit (June 2004) were reviewed against procedural requirements and compared to the objectives listed in the appropriate operations plans.

## 8.1 Integrated Issue Resolution Status Report and Agreement Items

Task Description

Four of the technical activities audited included evaluations of the Integrated Issue Resolution Status Report (IIRSR) and Key Technical Issue Agreement Item Letters. These products of the CNWRA are extremely important to developing a license application review capability and considerable resources were expended in their development. These products document NRC–U.S. Department of Energy (DOE) regulatory interactions and NRC and CNWRA reviews of DOE technical documents and, compared to the CNWRA technical activities audited in the past, fewer QA program controls apply. These factors contributed to the difficulty in developing performance-based audit criteria (i.e., checklists) and in conducting the audits. The performance-based approach could not be applied to the level originally planned for the IIRSR and Agreement Items, however the compliance-oriented portion of the audit comprehensively assessed implementation of the QA program controls applicable to these products and activities. In the future, technical activities will be audited using the performance-based approach whenever possible, but audit planning will more carefully consider the extent to which the performance-based approach is appropriate for specific technical activities.

### 8.1.1 Evolution of Near-Field Environment (ENFE)

Audit Team

Dr. D. Sarkar and T. Trbovich

Products Reviewed

- Agreement Item Letters for Evolution of Near Field Environment Key Technical Issue: ENFE 1.06, 4.03, 4.04, 4.06, 3.04, 2.05, 2.06, 2.10, 2.13, 2.17, 2.07, 2.03, 1.03, 1.04, 1.05, 1.07, 4.02, 3.05, and 4.05

- IIRSR, NUREG–1762, Revision 1, Section 5.1.3.3, Quantity and Chemistry of Water Contacting Engineered Barriers and Waste Forms

### 8.1.2 Repository Design and Thermal Mechanical Effects (RDTME)

Audit Team

L. Goland and R. Weber

Products Reviewed

- Agreement Item Letters for Repository Design and Thermal-Mechanical Effects Key Technical Issue: RDTME 3.14 and 3.18
- IIRSR, NUREG–1762, Revision 1, Section 5.1.3.2, Mechanical Disruption of Engineered Barriers

### 8.1.3 Igneous Activity (IA)

Audit Team

W. Thomann and R. Weber

Products Reviewed

- Agreement Item Letters for Igneous Activity Key Technical Issue: IA 2.03, 2.19, 2.20, 2.17, 2.18
- IIRSR, NUREG–1762, Revision 1, Section 5.1.3.10, Volcanic Disruption of Waste Packages; Section 5.1.3.11, Airborne Transport of Radionuclides; Section 5.1.3.12, Concentration of Radionuclides in Ground Water; and Section 5.1.3.13, Redistribution of Radionuclides in Soil

### 8.1.4 Container Life and Source Term (CLST)

Audit Team

J. Dante and C. Hobson

Products Reviewed

- Agreement Item Letters for Container Life and Source Term Key Technical Issue: CLST 2.03, 1.15; and GEN.1.01 Comment 119, 1.14, 2.08, 2.09, 2.01, and 2.02
- Agreement Item Letters for Container Life and Source Term and Total System Performance and Integrations Key Technical Issues: CLST 1.06, TSPAI 3.01, TSPAI 3.03, TSPAI 3.04, TSPAI 3.05, TSPAI 3.12, and GEN 1.01 (Comment 11), CLST 3.03, CLST 3.04, CLST 3.06, CLST 3.07, CLST 3.08, CLST 3.09, ENFE 3.03, TSPAI 3.08, TSPAI 3.14, GEN 1.01 Comment 116, GEN 1.01 Comment 124, and GEN 1.01 Comment 126
- Agreement Item Letters for Container Life and Source Term and Evolution of Near Field Environment Key Technical Issues: CLST 3.02, ENFE 3.04, and CLST 3.05
- Agreement Item Letters for Container Life and Source Term Key Technical Issues: 1.08, 1.09, 2.04, 2.05 and PRE 7.03, 7.05; 6.01, 1.02, 1.03, 1.04, 1.10, and 1.11; 1.12, 1.13, 6.02, and 6.03
- IIRSR, NUREG–1762, Revision 1, Section 5.1.3.1, Degradation of Engineered Barrier System

## 8.2 Technical Activities

### 8.2.1 Thermal Effects on Flow (TEF)

Audit Team

T. Morrow and C. Hobson

Task Description

An objective of the TEF Key Technical Issue is to estimate postclosure in-drift temperature and relative humidity conditions that may be favorable to the onset and duration of localized corrosion. Attention focused on the effects of drift degradation, axial convection along the drift, and the cold-trap process. Two laboratory experiments, a water vapor condensation cell and a 20-percent scale drift model, are providing data for comparison with computer code simulations. The estimates obtained in this task are used as input to chemical corrosion and radionuclide transport models for the potential high-level waste repository at Yucca Mountain.

Products Reviewed

- Temperature and Relative Humidity Along Heated Drifts with and Without Drift Degradation. R. Fedors, S. Green, D. Walter, G. Adams, D. Farrell, and S. Svedeman)—Report CNWRA 2004-4, June 28, 2004.

- Numerical Simulation of Thermal-Hydrological and Thermal-Mechanical Processes Observed at the Drift-Scale Heater Test at Yucca Mountain, Nevada. R. Green, S. Hsiung, S. Painter, A. Chowdhury, and M. Nataraja)—journal paper submitted to International Journal of Rock Mechanics and Mining Sciences

- Three-Dimensional Model of Heat and Mass Transfer in Fractured Rocks to Estimate Environmental Conditions Along Heated Drifts. R. Fedors and S. Painter)—abstract for 2004 AGU Fall Meeting

- Heat Transfer Through Rockfall Collapse Materials. R. Green, J. Pohle, and J. Prikryl)—abstract for 2004 AGU Fall Meeting

- Effects of Natural Drift Degradation on In-Drift Thermohydrological Conditions (C. Manepally, A. Sun, and R. Fedors)—abstract for 2004 AGU Fall Meeting

### 8.2.2 Radionuclide Transport (RT)

Audit Team

D. Sarkar and T. Trbovich

Task Description

The overall objective of the task was to identify the key geochemical processes that may control radionuclide transport at Yucca Mountain. To accomplish this broad objective, the CNWRA staff reviewed DOE documents to address agreement items, evaluated the use of TPA Version 5.0 code for radionuclide transport parameters and performed experimental and modeling analysis to develop risk information besides addressing uncertainties in model abstractions. Experimental analysis were performed on environmental samples (e.g., rock, sediment, water) that were collected from the Forty Mile Wash Area and stored in the CNWRA facility following standard protocols. The staff followed the guidelines in the CNWRA QAP in performing the experimental and data analysis.

Products Reviewed

- Development of Updated Total-System Performance Assessment (TPA) Parameter Distributions for Radionuclide Transport in the Saturated Zone—September 23, 2004
- Scientific Notebooks Nos. 653, 696, 631, and 710

### 8.2.3 Preclosure: Seismic Analysis

Audit Team

W. Thomann and C. Hobson

Task Description

This task involved conducting activities to resolve issues related to repository design and operations and thermal-mechanical effects on pre-closure and postclosure performance. The task included an evaluation of a letter report on geotechnical data at the Yucca Mountain for potential seismic hazards at a waste handling building site at the proposed repository. Additional work included review of the Scientific Notebook 644 on Geotechnical Data for a Potential Waste Handling Building and for Ground Motion Analyses for the Yucca Mountain Site Characterization Project, by A. Ghosh, J. Stamatakos, K. Murphy, L. McKague, and S. Gonzalez. This notebook includes data and calculations referenced in Intermediate Milestone (IM) 20.06002.01.102.422, Evaluation of Geotechnical Data at Yucca Mountain Site—Letter Report. The Report Review and Comment Resolution Record for the letter report also was examined for information related to technical reviews of the letter report. The CNWRA Operations Plan for the Repository Program, Revision 18, Change 1, June 2004, Repository Design, Thermal-Mechanical Effects (RDTME) 2.10 and Quality Requirements Application Matrix—CNWRA Ops for the Repository (RDTME), Revision 18, Change 0 also were reviewed for background on this task.

Products Reviewed

- Evaluation of Geotechnical Data at Yucca Mountain Site—Letter Report, and the attached CNWRA Instructions to Technical Reviewers and Report Review/ Comment Resolution Record for this report
- CNWRA Scientific Notebook 644, Review of Scientific Analysis Document, Geotechnical Data for a Potential Waste Handling Building and for Ground Motion Analyses for the Yucca Mountain Site Characterization Project by A. Ghosh, J. Stamatakos, K. Murphy, L. McKague, and S. Gonzalez; entries from March 16, 2004–June 22, 2004

### 8.2.4 Total System Performance Assessment and Integration: TPA Software Development

Audit Team

A. Smith and D. Dunavant

Task Description

The primary objective of this subtask was to maintain and enhance the TPA Version 5.0 code. The audit activities focused on the development activities and control of the TPA code.

Products Reviewed

- Software Development Plan for changes to TSPA Code, V5.0, April 22, 2005
- Software Requirements Description TSPA Code, V5.0, December 7, 2001

### 8.2.5 Total System Performance Assessment and Integration for Risk Analysis

Audit Team

T. Morrow and T. Trbovich

Task Description

The general objective of this subtask was to perform and document 12 separate analyses conducted by CNWRA and NRC personnel to enhance the understanding of specific features, events, processes, and uncertainties identified in the Risk Insights Baseline Report. The areas addressed were (i) repository near-field environment, (ii) extrusive volcanism, (iii) radionuclide transport in the saturated zone, and (iv) radionuclide inventory. Most of the alternative models have been incorporated in the latest version of the TPA code.

Products Reviewed

- Risk Analysis for Risk Insights Progress Report (S. Mohanty, et al.)— December 2004

### 8.2.6 Decommissioning (Task Order 4)

Audit Team

A. Smith and T. Trbovich

Task Description

The scope of work for the Decommissioning Task Order 4: Evaluation and Testing of Multi-Media Models and Codes for Complex Dose Analysis of Decommissioning Sites included review, evaluation, and testing of the GoldSim, FRAMES-MEPAS, FRAMES-GENII, and RESRAD-OFFSITE computer codes for potential application in dose analysis of complex decommissioning and low-level radioactive waste disposal sites. This activity also required participation in the Multi-Agency Memorandum of Understanding Working Group meetings on multi-media environmental models. Technology transfer and training of NRC staff on modeling complex decommissioning and low-level waste disposal sites was also included in the scope.

The audit activities focused on any development activities and control of any software used for this task.

Products Reviewed

- Proposal for Technical Assistance for Reviewing Licensee Submittals Concerning Decommissioning, Center for Nuclear Waste Regulatory Analyses, San Antonio, Texas, changed February 2004
- Software Requirements Description for a Generic Decommissioning Transport and Exposure Model being Developed in the GoldSim Probabilistic Simulation Environment, November 3, 2004

### 8.2.7 External QA

Auditor

D. Dunavant

Task Description

The External QA tasks for the prior year have been the performance of observation audits for NRC. The CNWRA staff participated in three observation audits. The review of these activities included verification of compliance to TOP–025 for report preparation, document review and participant qualifications. The audit was conducted through review of the three reports generated and interview with the CNWRA Director of QA.

Product Reviewed

- Inputs to Observation Audit Reports: OAR–04–02, (NSNFP), OAR–05–01, (OQA), and OAR–05–02, (Joseph Oat Corporation)

### 8.2.8 Inspection Program

Auditor

C. Hobson

Task Description

The objectives for the Inspection Program task were to provide assistance to NRC in the development and documentation of this program; development of QA-related inspection procedures; development of performance confirmation-related inspection procedures; and ultimately to assist NRC in inspection activities. Considering the current level of activity in this task, the scope of the program audited primarily included development of the fiscal year 2004 draft inspection procedures (IPs) and discussion concerning continued work with the objective of progression towards licensing and construction. The interview was conducted with the CNWRA QA Director who is the Project Manager for this task. Six of 17 fiscal year 2004 draft IPs were provided to the auditor prior to the audit and these served as the foundation of the discussion.

Products Reviewed

- IP 78400, Routine Activities of Site Representatives and Resident Inspectors (License Application Review)
- IP 78010, Reporting of Defects and Noncompliance (Pre-Licensing and Construction)
- IP 78130, Nondestructive Examination (Pre-Licensing and Construction)
- IP 78270, Control of the Electronic Management of Data (Pre-Licensing and Construction)
- IP 78120, Control of Special Processes—Welding (Pre-Licensing and Construction)
- IP 78040, Training and Qualifications (Pre-Licensing and Construction

# 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 QA auditor. Based on review of deliverables produced in the period since the last audit in June 2004, 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, rigorousness of the science or engineering involved, and thoroughness of supporting documentation, the QA auditor would confirm the presence of required documentation supporting the processes involved and their compliance to procedural requirements.

## 9.1 Good Practices

The audit team noted a number of examples of laudatory practices. Some of the practices commented on included

- An excellent, diverse, and cooperative staff
- Some outstanding examples of Scientific Notebook detail, 410 and others (nonelectronic notebooks)
- Establishment of a working group to analyze NRC's observation of inattention to detail
- Agreement Item Letters were detailed and overall well documented
- IIRSR documents were well organized and highly detailed, with consideration to risk significance
- Preclosure Seismic Analysis notebook with easy reference to allow data verification
- Well run demonstration of EarthVision software
- ENFE: good protocols, scientific practices, qualification, and document reviews
- Total System Performance Assessment and Integration configuration management was implemented for the code under development prior to release and QA verification
- Building 57, Laboratory 113: excellent sample control, control log, documentation trail from sample collection through testing (water and soil).

## 9.2 Corrective Actions

Four corrective action reports were issued related to multiple and similar findings. Two of these reports document related findings from previous audit activities.

- [Corrective Action Report (CAR) 2005-2] Contrary to the requirements of TOP–012, Rev. 3, Chg. 0, a number of metal samples were not identified with required identifications, the identifications were not properly maintained, or the location log was not properly maintained:

    1. One sample identification was partially removed and not reestablished after machining (paragraph 4.1)

    2. Multiple bagged C22 test pieces, identification not carried over to bags (paragraph 4.2.2)

3. C22 plate in the machine shop missing required sample identification (paragraph 4.1)

4. Location log did not reflect correct location of C22 samples: one log entry missing and one entry showed the location in two different locations (paragraph 4.3.2)

5. Sample control findings noted in the last two audits, reference Nonconformance Report (NCR) 2004-13 and NCR 2003-10

- (CAR 2005-3) Contrary to the requirements of the CQAM, Section 12, Rev.4, Chg. 3, inadequate labeling or other non-compliance(s) to calibration requirements were noted:

  Fourteen thermocouples were calibrated, but found without labels [Section 12.4 (4)]

  The following apply to the slow-rate strain testing performed in Division 18, Building 90 Annex:

  1. Load cell and linear displacement transducers calibrated by Division 18 but not labeled as to status [Section 12.4 (4)]

  2. Thermocouple calibration by Division 18 not documented [Section 12.4 (6)]

  3. Identification of the digital voltmeter used to take voltage potential across specimen not noted in the test documentation. Traceability not available to evaluate subsequent out of tolerance conditions

- (CAR 2005-4) Contrary to the requirements of TOP-018, Rev. 9, Chg. 0, the following discrepancies were found:

  Version control and software documentation package discrepancies:

  1. No objective evidence available to verify ProShake Version 1.11 used for Preclosure—Seismic Analysis was controlled in accordance with Section 4

     a. ProShake Version 1.1 was listed as controlled on CNWRA Controlled Software Directory

     b. Disks included with package indicated Version 1.10

     c. User's manual included with package indicated Version 1.1

     d. Screenshot of "About" indicated Version 1.11

  2. No objective evidence was available for EarthVision to verify that:

     a. Version 7.0 was listed on the CNWRA Controlled Software Directory prior to retirement as required by Section 4.1.4

     b. Version 7.0 was retired with the issuance of a Software Release Notice (SRN) as required by Section 4.3

     c. Version 7.0.1 used for Preclosure—Seismic Analysis was controlled in accordance with Section 4

3. Of 19 software documentation packages reviewed, all having had a QA verification:

   a. Seven packages contained media that did not include all of the required media label information per Section 4.1.3

   b. Two packages did not include any media as required by Section 4.1.2

   c. Four packages did not include documentation or reference to documentation of installation testing as required by Section 4.1.1

TPA Code Discrepancies

1. No objective evidence was available to verify code reviews were being conducted of the TPA Code Version 5.0.1 in accordance with Section 5.4.7

2. No objective evidence was available to verify a user's manual was developed for the TPA Code Version 5.0 as required by Section 5.5

Findings on TOP–018

1. Section 4.2.9 references Section 3.4.4 that does not exist in the procedure

2. Section 5.3.1 and 5.4.1 reference Section 5.1 for guidance; no guidance is available in Section 5.1

3. Section 5.1 references criteria for determination of development of a Software Requirements Description and/or Software Development Plan; no criteria are listed

4. Section 6 does not list CNWRA Controlled Software Directory or acceptance test results as records

- (CAR 2005-5) Contrary to the requirements of QAP-005, Rev. 3, Chg. 0, the following discrepancies were identified:

  1. Training requirements review for one consultant exceeded the due date of March 18, 2005; reference Form QAP–11–1

  2. Training in TOP–018 for two IMS personnel performing software installations has not been completed (paragraph 3.2.1)

  3. CQAM program training was not documented for one SwRI auditor (Paragraph 3.1.1 and related QAP–012, Paragraph 3.2)

  4. Audit Observer Training for one staff member who has been involved in observation audits was not documented or could not be located; reference TOP–025, Rev. 0, Chg. 0, paragraph 4.2.1

  5. Previous findings related to training issues: See NCR 2004-09 and NCR 2004-14

## 9.3 Nonconformances

Five nonconformances were noted in the course of the audit and are documented on CNWRA NCRs. These NCRs are

- (NCR 2005-21) Contrary to the requirements of QAP–007, Rev. 3, Chg. 1,the position descriptions for two staff members do not reflect responsibilities as noted next [paragraph 3.2 (iii)]

    1. The position description for a person identified as a participant in the ENFE IIRSR resolution reviews does not identify report reviews as part of the description. Also, QAP–002 training has not been provided. (Note: position description identifies duties as laboratory analyst.)

    2. The position description for Director of QA does not reference software control or verification responsibilities. (Note: the Director of QA is identified as Software Custodian in TOP–018, Section 8, Definitions)

- (NCR 2005-22) Contrary to the requirements of QAP–009, Rev. 2, Chg. 2, two of three stored and red-tagged metal samples did not reference the applicable NCR [Paragraph 3.1 (3)]

- (NRC 2005-23) Contrary to the requirements of QAP–001, Rev. 6, Chg. 2, several electronically maintained scientific notebooks were noted as having incomplete header/footer information (paragraph 3.2.4)

- (NCR 2005-24) Contrary to the requirements of QAP–016, Rev. 8, Chg. 1, Q-codes had not been applied to on a purchase order for chemicals (paragraphs 4.1 and 4.2)

- (NCR 2005-25) Contrary to the requirements of QAP–002, Rev. 9, Chg. 1, the Risk Analysis for Risk Insights Report, December 2004, was missing the Y-axis on Figure 2-2, and the AP–6 form did not have sign-off initialed by all technical reviewers (paragraphs 3.1 and 4.3.6)

## 9.4 Recommendations

During the course of the audit activities, a number of recommendations were made which might prevent a future nonconformance or will support continuous improvement of the CNWRA program. These recommendations are

- Enhance surveillance activities. Surveillance has been effective in the past in addressing programmatic areas of weakness, should be used to address the appropriate areas as identified in this audit.

- The atomic absorption instrument manufacturers manual should be consulted for direction on periodic calibration as opposed to the current practice of calibrate before use.

- QAP–008, 3.1.3, requires that the control log of scientific notebooks contain the notebook subject. Instead, the project number is recorded. Recommend the procedure be revised to agree with practice.

- QAP–013, requires QRAM updates as appropriate. External QA QRAM should be updated to reflect that TOP–025 applies.

- TOP–025 requires observers be trained in NRC MC–2410. Documentation now indicates Audit Observation Training. A memo to file would clarify that this training is to MC–2410.
- SRN for acquired software should be revised to include who performed installation testing.
- Controlled Software Directory contains a column for Validation Category that is not described in TOP–018. Procedure should be revised to include a definition or description.
- TEF Lab—establish the frequency of calibration verification for thermocouple last calibrated April 2004.
- Preclosure—Seismic Analysis—revise the QRAM to show software now being used.
- RDTME, a summary section in Agreement Item Letters identifying areas of concern, disagreement, etc, would be helpful.
- Revise QAP–007 to clearly identify the quality documents and training required for a person who leaves CNWRA and subsequently returns as a consultant.

## 10 QUALITY ASSURANCE PROGRAM EFFECTIVENESS

The QA program applied by CNWRA was being effectively implemented. The nature of the nonconformances identified in the audit did not appear to have a significant potential to adversely affect products or the overall effectiveness of the program. Attention to recurring nonconformances, however, will provide for improvements and reduce the potential to adversely affect products.

## 11 PERSONS CONTACTED

| | Attended Pre-Audit Meeting | Contacted During Audit | Attended Post-Audit Meeting |
|---|---|---|---|
| **CNWRA Staff** | | | |
| Bertetti, P. | | X | X |
| Brient, R. | X | X | X |
| Chowdhury, A. | X | X | X |
| Dunn, D. | | X | X |
| Farrell, D. | | X | |
| Fedors, R. | | X | |
| Folck, R. | | X | |
| Folk, O. | | X | |
| Garcia, S. | | X | X |
| Gonzalez, S. | | X | |
| Green, R. | | X | |
| Gute, D. | | X | |
| Guzman, W. | | X | |
| He, X. | | | X |
| Hill, B. | | X | X |
| Hooper , D. | | X | X |
| Hsiung, S. | | | X |
| Jain, V. | X | X | X |
| Janetzke, R. | X | X | X |

| | Attended Pre-Audit Meeting | Contacted During Audit | Attended Post-Audit Meeting |
|---|---|---|---|
| LaPlante, P. | | X | |
| Mackin, P. | X | | |
| Maldonado, P. | | | X |
| Manepally, C. | | X | X |
| McMurry, J. | | X | X |
| Mohanty, S. | X | X | X |
| Naukum, N. | | | X |
| Nes, R. | | X | |
| Ofoegbu, G. | X | X | X |
| Pabalan, R. | X | X | X |
| Padilla, M. | | X | |
| Painter, S. | | X | |
| Pan, Y.-M. | | | X |
| Patrick, W. | X | | X |
| Pearcy, E. | X | X | X |
| Pensado, O. | | X | |
| Pickett, D. | | X | |
| Povetko, O. | | | X |
| Russell, J. | | X | |
| Sagar, B. | | | X |
| Shukla, P. | | | X |
| Stamatakos, J. | | X | X |
| Turner, D. | | | X |
| Werling, B. | | X | |
| Winterle, J. | X | X | |
| Wittmeyer, G. | X | X | X |
| **NRC** | | | |
| Collins, E. | | | X |
| Csontos, A. | X | | X |
| DeMarco, D. | X | | X |
| Ghosh, T. | X | | X |
| Jacobs, F. | X | | X |
| Leslie, B. | X | | X |
| Matula, T. | X | | X |
| Parrott, J. | X | | X |
| **Others** | | | |
| Clair, P. | X | | X |
| Clay, S. | | X | |
| Dante, J. | X | | |
| Domine, S. | | | X |
| Dunavant, D. | X | | X |
| Ehnstrom, M. | X | | X |
| Goland, L. | X | | X |
| Hill, W. | | | X |
| Hobson, C. | X | | X |
| Holt, A. | X | | |
| Mabrito, B. | | | X |
| Machowski, W. | | X | |
| Morrow, T. | X | | X |
| Sarkar, D. | X | | |
| Smith, A. | X | | X |
| Thomann, W. | X | | X |
| Trbovich, T. | X | | X |

**APPROVALS**

Rodney M. Weber, Audit Team Leader — Date 6/6/05

Thomas C. Trbovich, Auditor — Date 6/2/05

Christopher D. Hobson, Auditor — Date 6/8/2005

Donald W. Dunavant, Auditor — Date 6/13/05

Ashley H. Smith, Auditor/Technical Specialist — Date 6/8/05

Dibyendu Sarkar, Technical Specialist — Date 6/13/05

William Thomann, Technical Specialist — Date 6/13/05

James F. Dante, Technical Specialist — Date 6/3/05

Larry J. Goland, Technical Specialist — Date June 3, 2005

Thomas B. Morrow, Technical Specialist — Date June 2, 2005

Robert D. Brient, Geosciences and Engineering, Director of Quality Assurance — Date June 1, 2005