

June 20, 2003

Mr. Bruce Mabrito, Director
Quality Assurance
Center for Nuclear Waste Regulatory Analyses
6220 Culebra Road, Building 189
San Antonio, TX 78238-5166

SUBJECT: OBSERVATION OF THE ANNUAL INTERNAL AUDIT OF CENTER FOR
NUCLEAR WASTE REGULATORY ANALYSES

Dear Mr. Mabrito:

From May 20 through May 23, 2003, members of the U.S. Nuclear Regulatory Commission (NRC) Office of Nuclear Material Safety and Safeguards staff participated as NRC observers in the Center for Nuclear Waste Regulatory Analyses (CNWRA) Internal Quality Assurance (QA) Audit 2003-1, conducted in San Antonio, Texas. The NRC staff evaluated this audit to determine whether the CNWRA is effectively implementing the requirements of its QA program. This letter transmits NRC Observation Audit Report Number OAR-03-03-CNWRA.

The audit evaluated the adequacy and effectiveness of the CNWRA QA program and its implementation. Eighteen applicable QA programmatic areas and seven technical areas were audited. The technical areas included: 1) Structural Deformation and Seismicity Key Technical Issue (KTI); 2) Evolution of the Near-Field Environment KTI; 3) Thermal Effects on Flow KTI; 4) TSPA and Technical Integration KTI; 5) Radionuclide Transport KTI; 6) Repository Design and Thermal-Mechanical Effects KTI; and 7) Baltimore Tunnel Fire Report. This report addresses the effectiveness of the audit and the procedural adequacy and effectiveness of implementation of QA programs controls in the audited areas.

During the audit, the audit team identified deficiencies in the program, which resulted in the following potential non-conformances: Non-Conformance Report (NCR) 2003-10: Sample control was not consistently exercised and NCR 2003-11: Quality Assurance Procedure-11-1 forms did not indicate training was needed for several staff performing, or expected to perform, procedures.

The observers determined that, overall, CNWRA Audit 2003-1 achieved its purpose, and was thorough, effective, and performed in a professional manner. The observers based their evaluation of the audit process and the CNWRA QA program on: 1) discussions with, and direct observations of: a) the audit team; and b) CNWRA staff being audited; and 2) reviews of pertinent audit documentation, such as the audit plan, the audit checklist, CNWRA deliverables, and other CNWRA documents. The observers agree with the audit team's findings and that, overall, the CNWRA QA program controls are being adequately implemented in the areas that were evaluated, except for the identified non-conformances.

The observers discussed their observations with the CNWRA audit team and CNWRA management during the conduct of the audit and at the post-audit meeting: these observations are enclosed in the attached NRC Observation Audit Report No. OAR-03-03-CNWRA, "Observation Audit of the Center for Nuclear Waste Regulatory Analyses Audit 2003-1."

We will continue to monitor the CNWRA progress in correcting its QA-related problems. Although a written response to this letter or the enclosed report is not required, we request that the CNWRA provide us with copies of its response to the audit team's findings. If you have any questions, please call Ted Carter at (301) 415-6684.

Sincerely,

/RA/

Deborah A. DeMarco
NRC CNWRA Deputy Program Manager
Program Management, Policy Development
and Analysis Staff
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report No. OAR-03-03-CNWRA, "Observation Audit of Center for Nuclear Waste Regulatory Analyses"

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Office of Nuclear Material Safety
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Enclosure: NRC Observation Audit Report No. OAR-03-03-CNWRA, "Observation Audit of Center for Nuclear Waste Regulatory Analyses Audit 2003-1"

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U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. OAR-03-03-CNWRA,
"OBSERVATION AUDIT OF THE
CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
AUDIT 2003-1"

 /RA/ Date:6/19/03

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1.0 INTRODUCTION

From May 20-23, U. S. Nuclear Regulatory Commission (NRC) staff participated as NRC observers (observers) in the Center for Nuclear Waste Regulatory Analyses (CNWRA) internal Quality Assurance (QA) Audit 2003-1, conducted in San Antonio, Texas. The NRC staff evaluated this performance-based audit to determine whether the CNWRA is continuing to effectively implement the requirements of its QA program.

The audit evaluated the adequacy and effectiveness of the CNWRA QA program and its implementation. Eighteen applicable QA programmatic areas and seven technical areas were audited. The technical areas included: 1) Structural Deformation and Seismicity Key Technical Issue; 2) Evolution of the Near-Field Environment (ENFE) KTI; 3) Thermal Effects on Flow KTI; 4) TSPA and Technical Integration KTI; 5) Radionuclide Transport KTI; 6) Repository Design and Thermal-Mechanical Effects KTI; and 7) Baltimore Tunnel Fire Report. This report addresses the effectiveness of the audit and the procedural adequacy and effectiveness of implementation of QA program controls in the audited areas.

2.0 OBJECTIVES

The CNWRA objective for this audit was to evaluate whether the implementation of QA controls, associated with CNWRA QA programmatic and technical activities, met the applicable requirements of Appendix B to Title 10, U. S. Code of Federal Regulations (10 CFR), Part 50, as required by NRC contract NRC-02-02-012. The NRC staff's objectives were to determine: 1) if the audit was performed in such a manner as to provide confidence in the CNWRA audit process; and 2) whether CNWRA staff was adequately implementing QA program requirements specified in the CNWRA Quality Assurance Manual (CQAM), thus meeting contractual QA requirements.

3.0 SUMMARY AND CONCLUSIONS

The observers' evaluations of the audit process and the CNWRA QA program were based on: 1) discussions with and direct observations of: a) the auditors and technical specialists of the audit team, and b) CNWRA staff being audited; and 2) reviews of pertinent audit documentation such as the audit plan, the audit checklist, and other CNWRA documents.

The NRC observers determined that CNWRA Audit 2003-1 achieved its purpose of evaluating the implementation of the QA controls of programmatic and technical activities. The audit team was qualified and familiar with the QA requirements of the CNWRA program. The audit was conducted in a professional manner. The audit schedule and individual assignments were adequately described in the audit plan, and the audit checklist was detailed and complete.

During the audit, the audit team identified two non-conformances in the areas of sample control and personnel performing functions for which they had not been trained. All the findings were discussed with CNWRA management during daily debriefs and at the post-audit meeting.

The observers agreed with the audit team findings that the CNWRA QA program is being effectively implemented and appears to provide effective controls for technical product development. The audit team also indicated that the non-conformances identified during the audit are unlikely to have adverse impacts on the technical products.

4.0 PARTICIPANTS

The audit team was staffed with NQA-1 qualified lead auditors and auditors from the Southwest Research Institute (SwRI) QA Department and by technical specialists from SwRI and local universities. The lead auditor, auditors, and technical specialists were independent of the audited activities and technical areas, and were technically qualified and trained in auditing techniques. In each case, a sub-team of a Technical Specialist and a QA Auditor performed the audit of each technical activity.

4.1 DOE Audit Team Members

Don Dunavant	Audit Team Leader	SwRI
Bob Brient	QA Auditor	SwRI
Thomas Trbovich	QA Auditor	SwRI
Rodney Weber	QA Auditor	SwRI
Alex Bernardo	Technical Specialist	SwRI
Mary Ann Clarke	Technical Specialist	SwRI
Jimell Erwin	Technical Specialist	SwRI
Jim Griffith	Technical Specialist	SwRI
Diane Smith	Technical Specialist	Trinity University
William Thomann	Technical Specialist	University of the Incarnate Word
Charles Zinsmeyer	Technical Specialist	SwRI

4.2 NRC Observation Team Members

Ted Carter	Observer (Team Leader)
James Pearson	Observer (QA Specialist)
Wilkins Smith	Observer (QA and Technical Specialist)
Charles Greene	Observer (Technical Specialist)
Robert K. Johnson	Observer (Technical Specialist)
Deborah DeMarco	Observer (NRC CNWRA Deputy Program Manager)

5.0 CONDUCT OF THE AUDIT AND OBSERVATION

The CNWRA audit was conducted in accordance with CNWRA Quality Assurance Procedure (QAP)-011, "Audits." The NRC staff's observation of the CNWRA audit was based on the NRC procedure, "Conduct of Observation Audits," issued July 12, 2000.

5.1 Scope of the Audit

The audit evaluated the CNWRA QA program to determine whether it met the applicable requirements of 10 CFR Part 50, Appendix B. Such evaluation was accomplished by verifying the QA program implementation and effectiveness. The audit was performance-based and evaluated programmatic requirements in light of their applications to technical activities.

5.2 Conduct and Timing of the Audit

The audit was performed in a professional manner and the audit team was adequately prepared and demonstrated a sound knowledge of the CNWRA QA program. The auditors and technical specialists used the checklist effectively during discussions with CNWRA personnel and review of documents. The audit plan was thorough in describing the scope of the audit. The audit

team and the observers caucused at the end of each day. Also, a meeting of the audit team, observers, and CNWRA management was held each morning to discuss the current audit status and preliminary findings. In general the NRC staff believes the timing of the audit was appropriate.

5.3 Audit Team Qualification and Independence

The QA audit team was staffed with auditors and a lead auditor who were qualified to the CNWRA QA manual. The qualifications of the Audit Team Leader and the audit team members were found to be acceptable in that each met the requirements of SwRI procedure No. NQAP 2.0-1, "Qualification and Certification of QA Auditors," dated November 1989. The team members had no involvement with, or responsibility for, performing any of the activities they audited.

5.4 QA Programmatic Elements

The audit addressed the programmatic elements that were applicable to the technical areas selected for detailed audit.

<u>10 CFR Part 50, Appendix B, Criteria</u>		<u>CQAM Chapter</u>
I	Organization	1
II	QA Program	2
III	Design Control	N/A
	Scientific Investigation and Analysis Control	3
IV	Procurement Document Control	4
V	Instructions, Drawings, and Procedures	5
VI	Document Control	6
VII	Control of Purchased Material	7
VIII	Identification and Control of Items	8
IX	Control of Special Processes	9
X	Inspection	10
XI	Test Control	11
XII	Control of Measuring and Test Equipment	12
XIII	Handling, Storage, and Shipping	13
XIV	Inspection Test and Operating Status	14
XV	Nonconformance Control	15
XVI	Corrective Action	16
XVII	Records Control	17
XVIII	Audits	18

5.5 Technical Areas

The Technical Director and QA Director determined the technical and programmatic areas selected for audit and the CNWRA President approved them. The determination was made based on the level of activity, technical risks involved, programmatic risks involved, and the time since each area had last been audited. Since CNWRA does not perform design-related activities, criterion III of Part 50, Appendix B, is not applicable to this audit.

The audit team used a performance-based approach, during the audit, to evaluate the effectiveness of the QA program in ensuring product quality. They used direct evaluation of selected activities, assessment of products, and evaluations of product development processes. The performance-based approach was implemented by using teams of programmatic auditors and technical specialists who evaluated activities from their individual perspectives, and evaluated

implementation of procedures and plans associated with product development. The following areas were selected for this audit:

- 1) Structural Deformation and Seismicity KTI
- 2) Evolution of the Near-Field Environment KTI
- 3) Thermal Effects on Flow KTI
- 4) Total System Performance Assessment Integration KTI
- 5) Radionuclide Transport KTI
- 6) Repository Design and Thermal-Mechanical Effects KTI
- 7) Baltimore Tunnel Fire Report.

5.6 Examination of QA Programmatic and Technical Activities

CNWRA Audit 2003-1 was conducted as a performance-based audit. The audit team focused on the technical activities and evaluated the QA programmatic controls applicable to those activities. The NRC staff observed that each of the auditors reviewed related documentation and interviewed a representative sample of CNWRA personnel to determine their understanding of implementing procedures and processes. Checklists were used effectively, and issues were addressed, beyond the checklists, when appropriate. The observers were provided ample opportunities to provide comments and ask questions.

The audit of all or a portion of the above seven technical areas listed in section 5.5 was performed. Out of the seven technical areas audited by the audit team, the observation team observed all but the Structural Deformation and Seismicity KTI.

Training, education, and experience records were reviewed for personnel conducting scientific studies, to ensure such personnel were in compliance with their individual position descriptions. Objective evidence was provided to, and reviewed by, the audit team, and it was determined that all personnel were in compliance, except as noted in the audit team's non-conformance .

During the audit, the audit team identified deficiencies in the program, which resulted in the following non-conformances: Non-Comformance Report (NCR) 2003-10: Sample control was not consistently exercised and NCR 2003-11: QAP-11-1 forms did not indicate training was needed for several staff performing, or expected to perform to procedures. These findings were discussed with CNWRA management at the post-audit meeting.

The audit was effective in determining CNWRA compliance with procedural controls in the areas examined. The audit was thorough and effective in determining CNWRA personnel knowledge of, and compliance with, procedural controls. The NRC staff agrees with the audit team's assessment that, overall, the CNWRA is acceptably implementing its QA program.

6.0 NRC STAFF FINDINGS AND RECOMMENDATIONS

In general the QA programmatic and technical portions of the audit were conducted in a professional manner and the audit team evaluated activities and objective evidence adequately. The Audit Team Leader was effective in his daily presentation to the CNWRA management and staff and provided guidance to the audit team. Both the auditors and CNWRA staff were knowledgeable in their respective disciplines. The checklist was an excellent tool for providing a sound basis from which to conduct the performance-based audit. The auditors and specialists were particularly effective in identifying good technical and management practices in the technical and programmatic areas reviewed. The observers believed that the CNWRA audit was thorough and effective; however, several specific comments for a more effective audit are presented in the

following sections. The observers also determined that the audit was effective in determining CNWRA compliance with procedural controls in the areas examined and that the CNWRA QA program controls are being adequately implemented. The technical qualifications of CNWRA staff were satisfactory. The technical adequacy of the work products and procedures was found satisfactory and is subject to continuing in-depth evaluation by NRC technical staff. The observers agree with the audit team's assessment that the CNWRA is implementing its QA program satisfactorily. The auditors and specialists were particularly effective in seeking and noting good technical and management practices observed in the technical and programmatic areas reviewed.

6.1 NRC Findings

CNWRA Audit 2003-1 was conducted as a performance-based audit. The audit team focused on the technical activities and evaluated the QA programmatic controls applicable to those activities. Out of the seven technical areas audited by the audit team, all were observed by the observation team, with the exception of Structural Deformation and Seismicity.

Structural Deformation and Seismicity KTI

Observers did not participate in or observe this element of the audit.

Evolution of the Near-Field Environment KTI

The audit team reviewed several related CNWRA reports in the Evolution of the Near-Field Environment (ENFE) area, including: "Effects of Salt Formations on the Chemical Environment of Drip Shields and Waste Packages at the Proposed Nuclear Waste Repository at Yucca Mountain, Nevada." The audit team reviewed CNWRA scientific notebook numbers 430, 464, and 533.

The audit team found that the reports and scientific notebooks adequately met the QA requirements. The audit team technical specialist recommended that the scientific notebooks include more explanation of the assumptions and why the work was done (i.e., relate the activities and results to the goals and objectives). The audit team also noted that the key report in the ENFE area had not been provided to the technical specialist before the audit and recommended that planning be improved. The document was listed in the audit plan distributed on May 1, 2003. The technical specialist's flexibility in working around this omission during the audit was commendable.

Reviews of scientific notebooks and QA procedures were conducted in an objective and in-depth manner. The NRC observers agree with the technical specialist's recommendations made during his review of the scientific notebooks. The technical specialist was objective, knowledgeable, and familiar with the CNWRA QA procedures.

The technical work reviewed by the technical specialist appeared to be well-documented in the appropriate scientific notebooks. The technical work was of a high quality, of value to evaluating evolution of the near-field, and clearly reported.

The observers agreed with the audit team's findings and recommendations.

Thermal Effects on Flow KTI

The technical work described by the CNWRA technical staff, including experimental investigations and theoretical analyses of existing data, appeared to have been conducted in a careful and

organized manner. A scientific notebook used during the experiments was observed and found to be well-organized, up to date, and of sufficient detail to allow a scientist with appropriate background knowledge in the field and unfamiliar with the work to reproduce the data, using reasonable effort.

The observers agreed with the audit team's findings and recommendations.

Total System Performance and Integration KTI

The audit team's review focused on the processing and technical quality of the "TPA Code Version 5.0 Validation Test Plan and Validation Test Process," (Milestone 20.06002.01.111) and associated supporting documentation.

The audit team found that the deliverable adequately met the QA requirements. Several good practices were identified, including: the use of software change records (SCRs) to assign and track development tasks identified in the software requirements description (SRD); the use of testing in SCRs appearing to be comprehensive and well documented; and the use of independent staff for testing each of the TPA modules. Software documentation was complete and readily available.

The audit team noted that the TPA development process used SCRs to document changes outlined in the SRD between releases and changes identified during testing and routine use. The audit team recommended that the software development plan be revised to take credit for the fact that the testing done as part of the TPA development process constitutes an informal acceptance test, although not specifically required procedurally.

The audit team identified one general recommendation. The team indicated that the software development and acceptance testing processes would benefit from the use of peer reviews in the absence of a formal "walk-through."

The observers agreed with the audit team's findings and recommendations.

Radionuclide Transport KTI

The audit team discussed the prior year's task activities with the lead CNWRA personnel in the radionuclide transport area. Scientific notebooks were examined for compliance with QA procedural requirements. The audit team reviewed the documentation associated with the receipt and analysis of well cuttings from Forty Mile Wash and water samples from Pina Blanca. Samples of the well cuttings and water were sent to outside laboratories that were not on the CNWRA approved supplier list. Well-cutting samples were sent to Washington State University for x-ray fluorescence and inductively coupled mass spectroscopy analysis and Core Laboratory for x-ray diffraction analysis of the mineral and chemical constituents. To provide for QA of the analyses, known content samples were also sent with the samples from CNWRA internal standards. The laboratory's results from these standards were compared to the CNWRA standard values, to accept the results.

The water samples were sent to Coastal Sciences Laboratory for the stable isotopes ratio of Ozone, Hydrogen, and Carbon content. Coastal Sciences uses recognized and established analytical techniques and nationally accepted standards. The CNWRA review and acceptance of the Coastal Sciences results were documented in Scientific Notebook number 556. Documentations of the review and acceptance of the Core Laboratory and Washington State

University analyses were not readily available. This documentation was found and provided during the audit.

The documentations of the receipt and sub-sampling of the water and well-cutting samples were reviewed. Procedure TOP-012, Revision 2, "Sample Custody," and form TOP-004/TOP-2, "Sample Custody Entry Form," are used for receipt and tracking of samples. The completed form was used for the water samples, but not for the well cuttings. TOP-012 referred to a sample log; however, only the sample form was used, and the procedure does not specifically address the sub-sampling control and documentation requirements. The audit team stated that these issues would be included in a non-conformance for control of samples in various areas.

The observers agreed with the audit team's findings and recommendations.

Repository Design and Thermal-Mechanical Effects KTI

The audit team reviewed the technical quality of the "MECHFAIL: A Total-System Performance Assessment Code Module for Evaluating Engineered Barrier Performance Under Mechanical Loading Conditions" (Milestone 20.06002.01.101.320) and associated supporting documentation.

In this area the technical specialist did not appear to be familiar with CNWRA QA procedures. Having an additional technical specialist or training the technical specialist auditor, may improve the adequacy and effectiveness of an audit. The technical specialist did not appear to challenge the investigators sufficiently. The audited report, "MECHFAIL: A Total-System Performance Assessment Code Module for Evaluating Engineered Barrier Performance Under Mechanical Loading Conditions," contains well-documented sources of data and clearly states the objectives, purpose, and conclusions. The analyses contained in the report are comprehensive and well-organized. The scientific notebooks were well-organized, detailed, and clearly documented the in-process development of the report.

The audit team also reviewed the technical quality of the "PCSA Code Version 3.0 - Validation Test Plan Preparation." The audit team found that the developmental activities associated with the PCSA Code Version 3.0 validation test plan, to date, adequately met the QA requirements. Several "good practices" were identified, including: using scientific notebooks to document detailed information on code development, software design, data flow, and acceptance testing; using a consultant in development process as facilitator of sound software engineering practices and CNWRA Top 18 software QA requirements; using spreadsheets to organize and document acceptance testing; and using SCR forms to identify and correct problems or make other minor changes in software configuration or software documentation. Software documentation was complete and readily available. The audit team suggested that the software development and acceptance testing process would benefit from the use of peer reviews in the absence of a formal walk-through.

The observers agreed with the audit team's findings and recommendations in both of the observed technical areas.

Baltimore Tunnel Fire Report

The technical specialist was familiar with the CNWRA QA practices and he exhibited sufficient experience in the technical area and knowledge of the subject to perform an adequate audit. The observers noted the following points for improving the quality of future CNWRA analyses of this type: 1) clarify data that need to be qualified as CNWRA-generated original data; 2) institute sample and sub-sample tracking such as initial documentation and logging of metallographic mounts; 3) identify sources of data, such as type of paint and temperature of blistering; 4) include

simple schematics showing sample locations; and 5) clarify significance of unexpected results such as unexpected phases identified in the specimens. The quality of this CNWRA product would be improved by clearly stating the objective, purpose, and conclusions. Given the extent and quality of the experimental work, which was very good, more time and effort were needed for analysis of these results, to produce a high-quality finished product.

The observers agreed with the audit team's findings and recommendations.

6.2 NRC Recommendations

The observers made the following recommendations.

- The observers recommend that the CNWRA review its approach to audit planning and preparation to ensure that the appropriate documents are provided to the team members. Lead auditor and all team members should verify that their audit material packages are complete.
- The observers noted a wide range of technical specialist audit skill levels and recommend that the CNWRA reevaluate its QA training to assure that the technical specialists are appropriately trained in QA auditing techniques.