U.S. NUCLEAR REGULATORY COMMISSION STAFF OBSERVATION OF THE FISCAL YEAR 2007 CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE AUDIT 2007-1

OBSERVATION AUDIT REPORT NO. OAR-07-05

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Enclosure

1.0 INTRODUCTION

The Center for Nuclear Waste Regulatory Analyses (CNWRA) provides technical support to U.S. Nuclear Regulatory Commission (NRC) staff under NRC Contract NRC-02-02-012. Under this contract, CNWRA is required to meet the Quality Assurance (QA) requirements of 10 CFR Part 63. On June 5-8, 2007, QA and technical staff from Southwest Research Institute (SwRI), Trinity University, and the University of Texas San Antonio (auditors) conducted the Fiscal Year 2007 CNWRA, Geosciences and Engineering Division, QA Audit 2007-1 at CNWRA facilities in San Antonio, Texas. NRC staff from the Office of Nuclear Material Safety and Safeguards (observers) observed the CNWRA audit.

The objective of this audit was to evaluate the CNWRA QA program to verify that it met applicable requirements and was being effectively implemented. The objective of the observers was to evaluate the effectiveness of the audit process and the implementation of the QA program.

Details of the scope, conduct, findings, and conclusion of the audit are available in the July 25, 2007, CNWRA report, Quality Assurance Audit Report for Geosciences and Engineering Division Audit 2007-1 of NRC-Funded Programs Conducted by the Center for Nuclear Waste Regulatory Analyses.

2.0 MANAGEMENT SUMMARY

The auditors identified four nonconformances with QA program requirements, two of which were corrected during the course of the audit, eight recommendations to improve implementation of the QA Program, and two good practices (see Section 8.3). The auditors determined that the four identified nonconformances are unlikely to have an adverse impact on the quality of CNWRA technical products. The audit team comprised qualified auditors and technical specialists trained by CNWRA in auditing techniques. The auditors concluded that the CNWRA QA Program was being effectively implemented and provided adequate controls over technical product development. The observers found the auditors to be independent of the activities and technical areas being audited.

The observers noted that the implementation of the CNWRA QA Program has improved over the past four years. The observers have seen improvements in areas such as attention to detail, completion and control of scientific notebooks, utilization of the QA trend program, and conduct of surveillances. The observers recommended that CNWRA management and staff maintain their focus on continuing improvement. The observers also made a recommendation regarding the use and control of electronic media for technical information. Specifically, increased training and process controls may be appropriate because of the greatly increased use of electronic media to document and store technical information.

The observers determined that the auditors achieved their objectives, the audit was effective in verifying compliance with procedural controls in the areas examined, and the CNWRA QA program procedures were being implemented adequately. The observers also determined that the technical adequacy of the work products and procedures used to govern and control work was satisfactory. The observers agreed with the auditors' conclusions that the CNWRA has effectively implemented its QA Program.

3.0 PARTICIPANTS

3.1 Auditors

Thomas Trbovich	Audit Team Leader, Institute Quality Systems (IQS)
Christopher Hobson	QA Auditor, IQS
Donald Dunavant	QA Auditor, IQS
Ashley Smith	QA Auditor, IQS
Joseph Brewer	Technical Specialist, Analysis and Monitoring, SwRI
James Dante	Technical Specialist, Material Sciences, SwRI
Ewan Grantham	Technical Specialist, Software, SwRI
Edgar Oelkers	Technical Specialist, Safety Analysis, SwRI
Kurt Schrader	Technical Specialist, Structural Engineering, SwRI
Dr. Alan Dutton	Technical Specialist, Aqueous Geochemistry, Hydrogeology, University of Texas San Antonio
Dr. Diane Smith	Technical Specialist, Geosciences, Trinity University

3.2 NRC Observers

Thomas Matula	Observation Team Leader
Frank Jacobs	QA Specialist
Jack Gwo	Technical Specialist
Rosemary Reeves	Technical Specialist
Deborah DeMarco	Program Management Specialist

4.0 REVIEW OF AUDIT AND AUDITED ORGANIZATION

The CNWRA provides technical support to NRC staff under NRC Contract NRC-02-02-012. In performing work under this contract, CNWRA must meet the 10 CFR Part 63 QA requirements. The CNWRA conducted the annual audit to determine whether its QA program is effectively implemented. NRC staff observed the conduct of the QA audit to determine the adequacy of the audit process and the effectiveness of the QA program implementation. The auditors performed the audit following CNWRA Quality Assurance Procedure (QAP)-011, Audits, and NRC staff observed the audit following NRC Manual Chapter 2410, Conduct of Observation Audits.

5.0 SCOPE OF AUDIT

The scope of this performance-based audit was to determine whether the CNWRA QA Program meets 10 CFR Part 63 QA requirements and is being effectively implemented for NRC-sponsored technical activities. The audit evaluated programmatic requirements and the corrective action process to determine effectiveness.

6.0 CONDUCT AND TIMING OF THE AUDIT

The observers determined that the audit scope was achieved. The observers determined that the auditors were thorough, effective, and performed in a professional manner. The observers determined that the timing, length, and application of resources to complete this annual CNWRA QA audit were appropriate for the current level and type of activities.

7.0 AUDIT TEAM QUALIFICATION AND INDEPENDENCE

The audit team comprised an Audit Team Leader, three QA auditors, and seven technical specialists. The observers found the qualifications of the Audit Team Leader and QA auditors to be acceptable and in compliance with the CNWRA QA Program. The observers also found the audit team technical specialists to be qualified through training and experience. The QA auditors and technical specialists were independent of the activities they reviewed.

8.0 AREAS OF EXAMINATION AND RESULTS

8.1 QA Elements

The auditors evaluated the following QA programmatic elements:

QA Programmatic Elements	CNWRA QA Manual Chapter
Organization	1
QA Program	2
Design Control	*
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
Corrective Action	16
Records Control	17
Audits	18

* CNWRA does not perform design-related activities.

The auditors reviewed and evaluated material and documentation related to the QA programmatic procedures and interviewed responsible CNWRA personnel to determine the effectiveness of implementing procedures and technical processes. Details of the scope, conduct, findings, and conclusion of the audit are available in the July 25, 2007, CNWRA Audit Report. (ML072070157)

8.2 Technical Activities

CNWRA management selected technical activities to be evaluated during the CNWRA QA Program audit based on CNWRA risk-informed programmatic and technical insights gained since the previous QA audit in June 2006. The auditors evaluated the following technical

activities:

Technical Activities
Flow Paths in the Unsaturated Zone
Volcanic Disruption of Waste Packages
Airborne Transport of Radionuclides
Degradation of Engineered Barriers
Performance Confirmation
Total-System Performance Assessment (TPA) Code Development
Preclosure Safety Evaluation
Mechanical Disruption of Engineered Barriers
Fuel Cycle Projects
Methodology and Overall System Performance
Redistribution of Radionuclides in Soil
Waste Incidental to Reprocessing

The auditors used a performance-based approach to evaluate the effectiveness of the QA Program by interviewing technical personnel responsible for the development of technical products, evaluating selected scientific activities, assessing products, and analyzing documentation supporting the underlying engineering and scientific processes for compliance with associated procedural requirements. Details of the scope, conduct, findings, and conclusion of the audit are available in the July 25, 2007, CNWRA Audit Report.

The auditors evaluated the qualifications of personnel performing technical work in the areas reviewed by reviewing training, education, and experience records of personnel who conducted scientific studies. The auditors concluded that the technical personnel reviewed were qualified for the work they performed and their qualification records supported their individual position descriptions.

8.3 Results

The auditors identified the following nonconformances with QA program requirements and determined that they are minor in significance and unlikely to have an adverse impact on the quality of CNWRA technical products:

A Scientific Notebook was found to contain data on post-it-notes to be recorded in the notebook at a later time, and approximately 20 pages were left blank before a separate task was started.

Quality Indoctrination and Training Forms QAP-11-1 for one consultant and one CNWRA staff member could not be located.

A required Software Development Plan was not readily available but was eventually recovered during the audit. (Nonconformance corrected during the audit.)

A Scientific Notebook was only partially paginated and another Scientific Notebook contained an incorrect statement on Scientific Notebook management review. (Nonconformance corrected during the audit.)

The auditors identified the following QA Program implementation improvement recommendations:

Mechanical Disruption of Engineered Barriers: Technical reports should be reviewed for errors identified during discussions to determine importance of missing data, incorrect figures, and footnote issues. Any references to previous models or analysis should be explicitly identified in reports.

Waste Incidental to Reprocessing: Formal documentation of NRC requests and actions taken should be considered to provide objective evidence of task understanding and completion.

Airborne Transport of Radionuclides: Identification on outside of sample storage boxes should be considered to ensure ease of retrieval.

TPA Code Development: Procedure for Development and Control of Scientific and Engineering Software should provide better guidance regarding software change request accountability and management.

Redistribution of Radionuclides in Soil: Techniques utilized could have been improved or industry reference methods used to measure airborne particulate in both total and size-fractioned samples.

Flow Paths in the Unsaturated Zone: Requirements should be added for metadata files, readme files and <dir.lis> list files on data Compact Disks included in Scientific Notebooks. Also, Texas Water Development Board has exemplary contract specification that could be adapted as specifications for metadata and QA requirements.

The auditors also identified the following good practices:

Technical authors working with software coders during development ensures efficient knowledge transfer and desired software performance.

Detailed trend program is established to provide information in programmatic and technical areas to ensure adverse trends are captured.

9.0 NRC STAFF FINDINGS/CONCLUSIONS

The NRC observers concluded the audit process was well planned, thorough, effective, and performed in a professional manner. Audit checklists developed and used by the auditors were comprehensive and effective in providing guidance to the auditors. The Audit Team Leader provided ample opportunities for the observers to provide comments and ask questions throughout the audit process. The auditors and observers discussed potential findings with CNWRA management during daily caucuses, audit debriefs, and at the post-audit conference.

The observers determined that CNWRA Audit 2007-1 achieved its objectives of evaluating the CNWRA QA program to verify that it met applicable requirements and was being effectively implemented. NRC observers determined that the CNWRA audit was effective in reviewing, evaluating, and determining risks and the associated compliance with procedural requirements in the areas controlled by QA program requirements. NRC observers agreed with the auditors' conclusions that the CNWRA QA Program was being effectively implemented and provided adequate controls over technical product development.

Specific comments and recommendations for more effective future audits or QA Program implementation are presented as follows:

The observers agreed with CNWRA management's comment that some of the audit topics contain limited technical work subject to QA requirements and internal review process.

The observers noted that CNWRA staff is extensively utilizing electronic media, such as Compact Disks, for storing technical information associated with scientific activities and notebook entries. It is recommended that the CNWRA consider reviewing and evaluating processes and controls for the safe storage, protection, backup, and recovery of technical information stored on electronic media.

The observers noted that the implementation of the CNWRA QA Program has improved over the past four years. The observers have seen improvements in areas such as attention to detail, completion and control of scientific notebooks, utilization of the QA trend program, and conduct of surveillances. The observers recommended that CNWRA management and staff maintain their focus on continuing improvement.