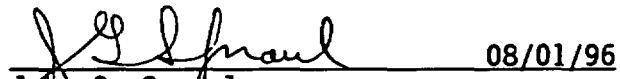
U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. 96-07

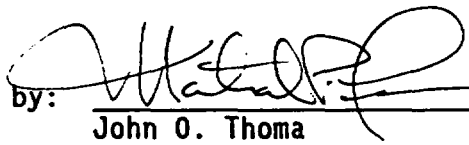
FOR THE CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

AUDIT NO. 96-01



08/01/96

John G. Spraul
Performance Assessment and
High-Level Waste Integration Branch
Division of Waste Management

Reviewed and Approved by:  08/2/96

John O. Thoma
Performance Assessment and
High-Level Waste Integration Branch
Division of Waste Management

Enclosure

1.0 INTRODUCTION

From June 23-26, 1996, a member of the U.S. Nuclear Regulatory Commission quality assurance (QA) staff participated as an observer in the Center for Nuclear Waste Regulatory Analyses (CNWRA) QA Audit No. 96-01 conducted in San Antonio, Texas. The CNWRA is the NRC's Federally Funded Research and Development Center and is the NRC's primary source of research and technical assistance in the high-level nuclear waste program. The audit evaluated the adequacy and effectiveness of the CNWRA QA program and its implementation. Fourteen QA programmatic areas and five key technical areas were audited. The key technical areas audited included 1) Radionuclide Transport, 2) Near-Field Environment, 3) EPA Standard, 4) Structural deformation, and 5) Total System Performance and Technical Integration. 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 the implementation of QA controls associated with CNWRA QA programmatic and technical activities in meeting the applicable requirements of Appendix B to Title 10, Code of Federal Regulations (10 CFR), Part 50. 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 were properly implementing QA program requirements specified in the CNWRA Quality Assurance Manual (CQAM).

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the audit process and the CNWRA QA program on 1) discussions with and direct observations of a) the auditors and technical specialists of the audit team [most of whom were on loan from the CNWRA's parent organization, Southwest Research Institute (SwRI)], 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 staff has determined that CNWRA Audit No. 96-01 achieved its purpose of evaluating the implementation of controls of QA programmatic and technical activities. The audit was conducted in a professional manner. The audit team was well qualified and familiar with the QA requirements of the CNWRA program. The individual assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the audit team's preliminary findings that, overall, the CNWRA QA program controls are being adequately implemented in the areas that were evaluated. In addition, the staff believes that the CNWRA audit was thorough and effective. The qualifications of CNWRA technical staff and the technical adequacy of the procedures and work products are subject to continuing evaluation by NRC technical staff.

CNWRA QA personnel should continue to monitor the QA program to ensure that future implementation is carried out in an adequate manner. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audit at a later date to determine the adequacy and effectiveness of the CNWRA QA program.

4.0 AUDIT PARTICIPANTS

Because implementation of the CNWRA QA program includes activities being performed by CNWRA QA staff, the audit was performed by SwRI personnel and two technical specialists from a nearby college/university to avoid any potential conflict of interest.

4.1 NRC

John G. Spraul	Observer

4.2 SwRI

Don Dunavant	Audit Team Leader (ATL)
Rod Weber	QA Auditor
Randy Folch	QA Auditor
Tom Mayces	QA Auditor
Dr. Mike MacNuaghton	Technical Specialist
Dr. Scott Runnels	Technical Specialist
Dr. Jimell Erwin	Technical Specialist
Dr. Richard A. Page	Technical Specialist

4.3 Incarnate Word College

Dr. William Thomann	Technical Specialist

4.4 Trinity University

Dr. Diane Smith	Technical Specialist

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The CNWRA audit was conducted in accordance with CNWRA Quality Assurance Procedure (QAP)-011, "Audits." The NRC staff observation of the CNWRA audit was based on NRC procedure "Conduct of Observation Audits" issued October 6, 1989.

5.1 Scope of Audit

The audit was conducted to evaluate the implementation of QA requirements associated with CNWRA QA programmatic and technical activities. The bases of the audit included Appendix B to 10 CFR Part 50, the CQAM, Research Project Plans, Operations Plans, Technical Operating Procedures, and QAPs.

5.1.1 QA Programmatic Elements

The checklists covered the QA program requirements for the applicable fourteen elements listed in Table 1 (page 7). Table 1 lists the applicable sections of the CQAM, the title of the section, and the related criteria of Appendix B to 10 CFR Part 50.

CNWRA does not currently design structures, systems, or components that are important to safety or waste isolation. However, pertinent requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50 are applied to CNWRA activities such as software design and the design of experiments.

Criterion X, "Inspection," and the inspection-related requirements of Criterion XIV, "Inspection, Test, and Operating Status," of 10 CFR Part 50 Appendix B are satisfied by the procurement controls of CQAM Section 7 or by treating inspections as "delegated work" in accordance with CQAM Section 1. Criterion XI, "Test Control," and the test-related requirements of Criterion XIV, "Inspection, Test, and Operating Status," of 10 CFR Part 50 Appendix B are satisfied by CQAM Sections 2 and 3.

5.1.2 Key Technical Areas

Specific key technical areas to be audited were selected based on their levels of activity and the time since the activity was last audited. Five (of ten) key technical areas were audited. The key technical areas audited were 1) Radionuclide Transport, 2) Near-Field Environment, 3) EPA Standards, 4) Structural Deformation, and 5) Total System Performance and Technical Integration.

Technical specialists on the audit team were instructed to evaluate and determine the acceptability/adequacy of items such as:

- Qualifications of personnel performing technical activities
- "Quality Requirements Application Matrix" applicable to the specific key technical area being audited
- Scientific notebooks
- Technical work and the review of technical products
- Appropriateness of conclusions
- Routine calculations
- Samples
- Software.

5.2 Timing of the Audit

The NRC staff believes the timing of the QA audit was appropriate in that a little over one year had elapsed since the previous audit.

5.3 Conduct of Audit

The technical portion of the audit was conducted by sub-teams. Each sub-team included an auditor and a technical specialist. Each sub-team member addressed the checklist items in the member's area of expertise.

5.4 Examination of QA Programmatic and Technical Activities

Audit 96-01 was conducted as a performance-based audit. Instead of conducting evaluations focusing on compliance with the QA programmatic criteria, each auditor and audit sub-team focused on the technical activities and evaluated the QA programmatic controls applicable to those activities. Therefore, discussions about the observed QA programmatic controls and the technical activities are combined in this section.

The auditors and technical specialists were guided by the QA programmatic and technical checklist that was developed before the audit. The checklist questions were identified so as to be asked by an auditor and/or a technical specialist. The ATL had prepared a matrix of the checklist questions and verified from the matrix that each of the questions had been asked and responded to at least once during the audit. The matrix showed that questions specified for use by the audit sub-teams were generally asked during the audit of each key technical issue.

The audit of all or a portion of the key technical areas of 1) Radionuclide Transport, 2) EPA Standards, and 3) Total System Performance and Technical Integration were observed by the NRC observer. For each key technical area observed, the audit sub-team reviewed the pertinent scientific notebooks and discussed these documents with the involved CNWRA staff. When laboratory work was included in an audited area, the auditing personnel reviewed the laboratory and its equipment and discussed the facilities with the responsible CNWRA personnel. The auditors also reviewed calibration records for the laboratory equipment.

During the audit, the audit team identified deficiencies in the program that resulted in four draft Corrective Action Requests (CARs). These are summarized in Section 6.0 of this report. In addition, the audit team made two recommendations to improve the program. The first had to do with technical monitoring of scientific notebooks and training of personnel in scientific notebook philosophy and intent. The second recommendation was that affected technical staff be included in quality planning activities such as the determination of procedural requirements and the generation of the pertinent Quality Requirements Application Matrix.

The audit was effective in determining CNWRA compliance with procedural controls in the areas examined. The audit team concluded that procedures and protocols are generally being followed and the deficiencies noted in the CARs have had no significant affect on the CNWRA QA program. The portion of the audit that was observed was thorough and effective in determining CNWRA compliance with procedural controls. The staff agrees with the audit team's assessment that, overall, the CNWRA is acceptably implementing its QA program.

5.5 Conduct of the Audit

The conduct of the audit was productive and the audit was performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the QA aspects of the CNWRA program. The auditors, the technical specialists, and the audit sub-teams used the checklist effectively

during discussions with CNWRA personnel and review of documents. They asked detailed questions and requested objective evidence as required to support conclusions.

5.6 Qualifications of Audit Team Members

The ATL and auditors were certified to SwRI procedure No. NQAP 2.0-1, "Qualification and Certification of QA Auditors, dated November 1989. Procedure No. NQAP 2.0-1 is used by SwRI to implement Supplement 2S-3, "Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel," of NQA-1-1986, "Quality Assurance Program Requirements for Nuclear Facilities." Prior to the audit, the technical specialists on the audit team were given specific training in conducting audits by the ATL.

5.7 Auditor Preparation

The ATL, auditors, and technical specialists were adequately prepared to perform the audit. They were familiar with the questions assigned to them in the audit checklist.

5.8 Conduct of Meetings

The audit team conducted professional and appropriate audit entrance and exit meetings with CNWRA personnel. The ATL's statements of the audit purpose and findings at these meetings were clear and concise. In addition, the audit team and observer caucused after each day's audit activities, and the ATL (along with the observer and selected team members) met each morning with CNWRA management personnel to inform them of the audit status. These meetings were of an appropriate length and depth.

5.9 Auditor Independence

The audit team had no involvement with or responsibility for performing any of the activities they audited. Each audit team member was from SwRI (but not CNWRA) or from a nearby college/university and was assigned specific auditing tasks for the sole purpose of performing this CNWRA internal audit.

6.0 AUDIT TEAM FINDINGS

Although the audit team identified four deficiencies in the CNWRA QA program which were documented on draft CARs and will be resolved in accordance with Section 16 of the CQAM, the audit team concluded that procedures and protocols are generally being followed and the deficiencies noted in the CARs (and summarized below) have had no significant affect on the CNWRA QA program. The audit team also concluded that, overall, the CNWRA is acceptably implementing its QA program.

6.1 CAR 96-01: TOP-018, "Development and Control of Scientific and Engineering Software," was not complied with in several instances for code related to Total System Performance Assessment.

6.2 CAR 96-02: There was no evidence in several cases that checks of calculations had been performed and documented as required by QAP-002, "Review of CNWRA Documents, Reports, and Papers."

6.3 CAR 96-03: A number of audited scientific notebooks were deficient in describing the planning, objectives, methods, or results as required by QAP-001, "Scientific Notebook Control."

6.4 CAR 96-04: Several procedural requirements of QAP-008, "Document Control," had not been complied with.

7.0 NRC STAFF FINDINGS

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

Integration of the QA programmatic and technical portions of the audit was very good. The audit team was well prepared and conducted a thorough audit in a professional manner.

TABLE 1. QA PROGRAM REQUIREMENTS AUDITED

CQAM SECTION	QA PROGRAM REQUIREMENTS	APPENDIX B CRITERION
1	Organization	I
2	Quality Assurance Program	II
3	Scientific Investigation and Analysis Control	III
5	Instructions, Procedures, and Drawings	V
6	Document Control	VI
7	Procurement Control	IV & VII
8	Identification and Control of Items, Software, and Samples	VIII
9	Control of Processes	IX
12	Control of Measuring and Test Equipment	XII
13	Handling, Storage, and Shipping	XIII
15	Nonconformance Control	XV
16	Corrective Action	XVI
17	Records Control	XVII
18	Audits	XVIII