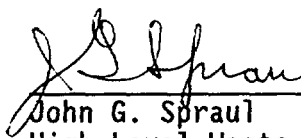
U.S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. 94-03

FOR THE CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

AUDIT NO. CNWRA 94-1



05/25/94

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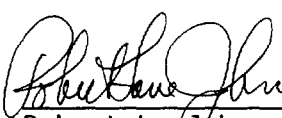

6/13/94

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Enclosure

1.0 INTRODUCTION

From April 26-29, 1994, 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. 94-1 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 seven technical areas were audited. 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, overall, Audit No. CNWRA 94-1 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.

In general, the NRC staff agrees with the audit team's preliminary findings that 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

Thomas C. Trbovich	Audit Team Leader (ATL)	Quality Assurance (IQA)
Donald W. Dunavant	Auditor	Quality Systems Technology
Rodney M. Weber	Auditor	IQA
Randall W. Folck	Technical Specialist	IQA
Dr. Robert L. Mason	Technical Specialist	Statistical Analysis Section
Dr. Chris J. Freitas	Technical Specialist	Structural Systems & Technology
Dr. Richard A. Page	Technical Specialist	Materials Engineering & Technology

4.3 Trinity University

Dr. Diane R. Smith	Technical Specialist	Department of Geology

4.4 Incarnate Word College

William F. Thomann	Technical Specialist	Division of Sciences

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 (TOPs), and QAPs.

5.1.1 QA Programmatic Elements

The checklists covered the QA program requirements for the 14 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 Technical Areas

Specific technical areas to be audited were selected based on their levels of activity and the time since the activity was last audited. Table 2 (page 8) shows the specific technical areas and tasks that were audited.

Technical specialists on the audit team were instructed to evaluate the technical activities to determine the following:

5.1.2.1 Technical qualifications of investigators and analysts

5.1.2.2 Understanding of procedural requirements (by CNWRA's technical staff) as they pertain to scientific investigations and analysis activities

5.1.2.3 Adequacy of TOPs and scientific notebooks

5.1.2.4 Adequacy of technical work and appropriateness of conclusions.

5.2 Timing of the Audit

The NRC staff believes the timing of the QA audit was appropriate.

5.3 Conduct of Audit

Most 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 94-1 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 audit of all or a portion of the tasks that are shown with an asterisk in Table 2 were observed by the NRC observer. The auditors and technical

specialists were guided by the their QA programmatic and technical checklists that they developed before the audit. For the audit of each task/subtask that was observed, the audit sub-team interviewed and examined the qualification/ certification records of the Principal Investigator and other involved key technical personnel. These interviews also were used to establish the understanding of procedural requirements for scientific investigations and analyses activities by the CNWRA staff. The audit team concluded that each of the individuals interviewed was well qualified to perform the assigned tasks and knowledgeable of the procedural requirements. The staff did not disagree.

After examining the qualifications of key technical personnel, each audit sub-team continued its evaluation by determining what work had been done on each task/subtask to date, what activities are currently underway, and plans for future work. For each task/subtask audited, the audit sub-team reviewed the TOPs and 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 systematically reviewed calibration records for the laboratory equipment.

During the audit, the audit team identified deficiencies in the program that resulted in five draft Corrective Action Requests (CARs). These are summarized in Section 6.0 of this report. In addition, the audit team made several recommendations to improve the program.

The audit was thorough and effective in determining CNWRA compliance with procedural controls. The audit team concluded that procedures and protocols are generally being followed, and the deficiencies noted in the CARs were minor with 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 the CNWRA is acceptably implementing its QA program.

5.5 Conduct of the Audit

The overall conduct of the audit was productive and 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 their checklists 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 two 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 endorses Supplement 2S-3 of NQA-1-1986, "Quality Assurance Program Requirements for Nuclear Facilities." The NRC observer reviewed the qualification records of the auditors and agreed with the certification that each was qualified. 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 auditors and technical specialists appeared adequately prepared to perform the audit. They personally prepared the audit checklist which required review and evaluation of the CQAM, applicable TOPs and QAPs, Research Project Plans, and Operations Plans.

5.8 Conduct of Meetings

The audit team conducted professional and appropriate entrance and exit meetings with CNWRA personnel. Its statements of the audit purpose and findings were clear and concise. In addition, the audit team and observer caucused after each day's audit activities, and the ATL (along with the observers and selected team members) met each morning with CNWRA upper management 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 SUMMARY - PRELIMINARY AUDIT FINDINGS

During the course of the audit, the audit team identified five 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 CARs are summarized below:

6.1 CAR 94-01: "Qualified" data in CNWRA data files are not differentiated from data that are not "qualified."

6.2 CAR 94-02: Deficiencies - such as corrections not dated, blank pages not lined out, lack of initial entries, etc. - were noted in a number of scientific notebooks.

6.3 CAR 94-03: Deficiencies - lack of a vacuum gauge, a data logger outside the CNWRA calibration system, and SwRI Calibration Laboratory personnel that calibrate CNWRA measuring and test equipment (M&TE) have not been qualified in accordance with CQAM Section 2 - were found in the audit of M&TE.

6.4 CAR 94-04: Two procurements of analytical services were not being controlled in a manner that verifies the accuracy of the results.

6.5 CAR 94-05: Work orders issued to by CNWRA to other SwRI divisions do not impose the quality requirements specified in Section 7 of the CQAM.

7.0 SUMMARY - NRC STAFF FINDINGS

7.1 Weakness

An October 1993 surveillance, including the review of computer/software-related scientific notebooks, identified problems like those identified in draft CAR 94-02. Corrective action taken was generally limited to the personnel involved in computer/software activities. Since auditors sample only a portion of items and activities, the extent of all deficiencies found during an audit should be determined in order for the corrective action to be most effective.

7.2 Good Practices

Integration of the QA programmatic and technical portions of the audit was again 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

TABLE 2. TECHNICAL AREAS AND TASKS AUDITED

TECHNICAL AREA	TASK/ SUBTASK	TASK/SUBTASK DESCRIPTION
Waste Systems Engineering and Integration	2.1	Compliance Determination Strategy Development
	5.2*	Regulatory Program Database (RPD) and Open Item Tracking System (OITS) Development
	5.3*	RPD and OITS Maintenance and Operation
External Quality Assurance	All	
Iterative Performance Assessment	2.3	Performance Assessment Research
Thermohydrology	5*	Matrix and Fracture Properties
Integrated Waste Package Experiments	1*	Corrosion
Field Volcanism	2*	Mafic Eruption Dynamics
	3	Release of Volatiles and Hydrothermic Alteration
Geology/Geophysics and Tectonics	2.5*	Investigation of Issues Related to Geology/Geophysics
	1	Review of Literature ...
	2	Compilation of Tectonic Data ...
	3	Review of Tectonic Data ...
	4	Field Investigations ...
	5	Assessment of Geochronological ...
	6	Analysis of Database ...
	7	Report Preparation