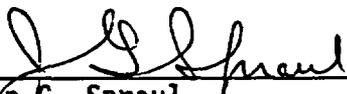
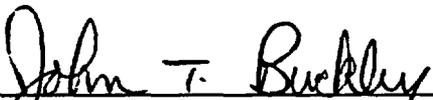


U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 93-09
FOR THE CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
AUDIT NO. CNWRA 93-1

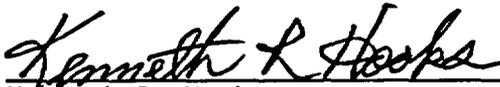


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1.0 INTRODUCTION

From May 4-7, 1993, members of the U.S. Nuclear Regulatory Commission quality assurance (QA) staff participated as observers in the Center for Nuclear Waste Regulatory Analyses (CNWRA) QA Audit No. 93-1 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 six 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 [who 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 93-1 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 NRC 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 QA program includes activities being performed by CNWRA QA staff, the audit was performed by SwRI personnel to avoid any potential conflict of interest. The audit team included the Audit Team Leader (ATL), Tom Trbovich, auditors Robert Mielke and Rod Weber, and technical specialists David Stevens, Richard Page, Robert Mason, and Tom Owen. The NRC observers were Jack Spraul and John Buckley.

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. NRC staff findings are classified in accordance with the guidelines in that procedure.

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, CQAM, Research Project Plans, Operations Plans, Technical Operating Procedures (TOPs) and QA Procedures (QAPs).

5.1.1 QA Programmatic Elements

The checklists covered the QA program requirements for the 14 elements listed in Table 1 (page 9). Table 1 lists the applicable sections of the CQAM, the title of each 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 10) 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:

- Technical qualifications of investigators and analysts
- Understanding of procedural requirements (by CNWRA's technical staff) as they pertain to scientific investigations and analysis activities
- Adequacy of TOPs and scientific notebooks
- 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 93-1 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 was observed by an NRC observer. For each task that was audited, the auditor (or audit sub-team) began by examining the qualifications of the Principal Investigator (PI) and other key technical personnel. The audit team concluded that each of the individuals interviewed was well qualified to perform the assigned tasks. The NRC staff did not disagree.

The following paragraphs discuss additional results of the audit and the NRC staff observations.

5.4.1 Repository Design, Construction, and Operations - Tasks 2 and 3

The audit sub-team did not identify any weaknesses or deficiencies with regard to the control of work done on Task 2, "Regulatory and Technical Guidance Development." However, the sub-team did identify a deficiency in the area of Task 3, "Analysis Codes and Methods." Corrective Action Request (CAR) 93-3 was written because CNWRA document 93-002 reported the results of a test case using the code "UDEC" without the software being baselined or a request for variance being generated or acted on as required by TOP-018, "Configuration Management of Scientific and Engineering Computer Codes," Revision 2, Change 2. Some responses to auditor sub-team' questions indicated that the CNWRA

technical staff may benefit from additional training to TOP-018. In addition, the audit sub-team made numerous recommendations regarding software control/configuration management.

The audit of Repository Design, Construction, and Operations was thorough and effective in determining CNWRA compliance with procedural controls. The NRC staff agrees with the sub-team's assessment that the CNWRA is acceptably implementing its QA program in this area.

5.4.2 Seismic Rock Mechanics Research - Tasks 2, 3, 4, 5, and 9

The results of the technical work to date and the future plans for seismic rock mechanics research were assessed by reviewing the available documentation and by interviews of the involved personnel. The audit of Task 2, "Laboratory Characterization of Jointed Rock," included a laboratory review of the equipment used for shear testing of the rock samples and a review of the sample handling and control process as well as the interviews and documentation reviews.

Under Task 3, "Assessment of Analytical Models/Computer Codes," computer code "UDEC" was chosen for qualification. The verification/assessment of this code is underway.

The audit sub-team determined through interviews with the CNWRA staff that there has been little activity to date associated with the experimental work to be done as part of Task 4, "Rock Dynamics Laboratory and Field Studies and Code Validation." The experiments were being designed, and there was basically nothing to audit in this area. The field studies of Task 4 and Task 5, "Groundwater Hydrology Field Studies and Code Validation," (two years of monitoring field data) have been completed, and a final report is being prepared. There have been no computer simulations to date under these tasks.

The design of the experiments of Task 9, "DECOVALEX Modeling," has been completed, delivered to the NRC, and discussed at a technical conference in May, 1992. DECOVALEX stands for "Development of Coupled models and their VALidation against Experiments in nuclear waste isolation," and the experimental tests were being set-up at the time of the audit.

The audit sub-team concluded that procedures and protocols are being followed, and no noncompliance with procedural controls was identified. The audit of Seismic Rock Mechanic Research Tasks was thorough and effective in determining CNWRA compliance with procedural controls. The NRC staff agrees with the sub-team's assessment that the CNWRA is acceptably implementing its QA program in this research area.

5.4.3 Stochastic Flow and Transport Research - Tasks 3 and 5

After examining the qualifications of key technical personnel, the audit sub-team continued its evaluation of Stochastic Flow and Transport Research Tasks 3 & 5 by determining what work had been done to date. The sub-team found the CNWRA technical staff to be knowledgeable of the QA requirements stated in TOP-018. However, the sub-team identified one weakness regarding the control

of the computer code "BIGFLOW," which is being modified under Task 5. The CNWRA currently has two versions of "BIGFLOW" in use. One version contains documentation and the other version does not. The auditors recommended that the PI perform a detailed comparison of the two versions to ensure uniformity and then archive the undocumented version under the configuration management procedures of TOP-018.

To date there have been no computer codes, developed or modified under Tasks 3 or 5, which have been baselined. Thus, a complete evaluation of TOP-018, compliance with it, and its effectiveness was not possible during the audit.

The audit sub-team used the checklist effectively to determine what activities are currently underway, how well the CNWRA staff understands the QA requirements imposed on its activities, and (within the limits described above) the effectiveness and implementation of these requirements. The audit of Stochastic Flow and Transport Research activities was thorough and effective in determining CNWRA compliance with procedural controls. The NRC staff agrees with the sub-team's assessment that the CNWRA is acceptably implementing its QA program in this research area.

5.4.4 Performance Assessment Research - Tasks 1, 2, and 3

During the audit of the Performance Assessment Research Task 1, 2, and 3 activities, the audit sub-team did not identify any deficiencies in the program. However, several weaknesses were discovered in the overall program.

First, it did not appear that there was a clear methodology or plan of action established for work conducted under Task 1, "Conceptual Model Development." Second, work on Task 3, "Model Evaluation," is being conducted by one PI, and there does not appear to be sufficient documentation to track the work under this task should the PI suddenly become unavailable. For instance, there is currently no control on the data pre-processors and no scientific notebook (or equivalent) describing the pre-processor functions and activities. In addition, given the relatively long time required to complete the work under this task, it would be beneficial to control or document the software development and model evaluation efforts prior to baselining. (There is no requirement for these controls in TOP-018.) The audit sub-team made numerous recommendations to improve the Performance Assessment Research program.

The audit of Performance Assessment Research was thorough and effective in determining CNWRA compliance with procedural controls. In spite of the weaknesses noted above, the NRC staff agrees with the sub-team's assessment that the CNWRA is acceptably implementing its QA program in this research area.

5.4.5 Volcanism Research - Tasks 1 and 2

The audit sub-team evaluated CNWRA technical activities in Volcanism Research Tasks 1 and 2 by interviewing the CNWRA technical staff and reviewing selected technical products. The audit was guided by the QA programmatic and technical checklists. The CNWRA staff working directly in this technical area include the PI and a Co-PI. Task 1, a review of applicable literature, had been

completed by others prior to this audit and reported to the NRC on September 29, 1992. Task 2, a compilation of available data, is ongoing. Task 3, a critical review of the available data, is in its infancy. Future tasks in this technical area involve modeling the probability of volcanic disruption and then making probability studies to bound the uncertainties. The PIs believe that there is currently a lack of adequate data for model creation.

The audit sub-team assessed the technical qualifications of the involved personnel by interviewing those currently working on the project and by reviewing their background and the background of those no longer on the project. The audit sub-team systematically reviewed the control of samples to evaluate compliance with the CNWRA's QA programmatic controls. Calibration records for laboratory equipment were also examined.

The results of the technical work to date and the future plans for volcanism research were assessed by reviewing the available documentation and by interviews of the involved personnel. The audit sub-team indicated that the project is going well (although some schedule slippage is expected) and that procedures and protocols are being followed. Several recommendations to improve the Volcanism Research program were made by the audit sub-team, but no noncompliance with procedural controls was identified.

The audit of Volcanism Research was thorough and effective in determining CNWRA compliance with procedural controls. The NRC staff agrees with the sub-team's assessment that the CNWRA is acceptably implementing its QA program in this research area.

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 three 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." An 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 observers 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) 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 three deficiencies in the CNWRA QA program which were documented on CARs and will be resolved in accordance with Section 16 of the CQAM. The CARs are summarized below:

6.0.1 CAR 93-1: Several chemicals in a laboratory were found to have shelf-life dates which had passed.

6.0.2 CAR 93-2: A nonconformance report had not been issued when a torque wrench was found to be out of tolerance.

6.0.3 CAR 93-3: Results of a test code case were issued in a draft document without the code being baselined or a variance sought.

7.0 SUMMARY - NRC STAFF FINDINGS

7.1 Weakness

It appears that the QA program could benefit substantially by improving the configuration management system. An example problem is described in Section 6.0.3 above. The NRC staff believes that TOP-018 could be improved to more effectively control the development and maintenance of computer software.

7.2 Good Practices

Integration of the QA programmatic and technical portions of the audit was very good. The NRC staff believes that some of the integration problems reported earlier have been overcome since the first "performance-based" audit for the ATL. The "performance-based" audit process has also become more effective with the increased number of work products. Evaluating the QA

programmatic controls becomes more effective with more technical products to examine.

The audit team was well prepared and conducted a thorough audit in a professional manner.

The ATL did an excellent job of organizing and executing the audit. The practice of reviewing the checklist items at the daily caucus to ensure completion of the checklist by the end of the audit was very effective and useful.

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	TASK DESCRIPTION
Repository Design, Construction, and Operations	2*	Regulatory and Technical Guidance Development
	3*	Analysis Codes and Methods
Seismic Rock Mechanics Research	2*	Laboratory Characterization of Jointed Rock
	3*	Assessment of Analytical Models/ Computer Codes
	4*	Rock Dynamics Laboratory and Field Studies and Code Validation
	5*	Groundwater Hydrology Field Studies and Code Validation
	9*	DECOVALEX Modeling
Integrated Waste Package Experiments Research	2	Stress Corrosion Cracking
	3	Materials Stability
Stochastic Flow and Transport Research	3*	Large-Scale Flow/Transport Simulation and Data Analysis
	5*	Documentation of "BIGFLOW" Computer Code Analysis
Performance Assessment Research	1*	Conceptual Model Development
	2*	Computational Model Development
	3*	Model Evaluation
Volcanism Research	1*	Review of Data on Volcanism and Tectonics of the Basin and Range
	2*	Compilation of Data into a Computerized Database

* The audit of all or a portion of the tasks that are shown with an asterisk was observed by an NRC observer.