

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 92-13
FOR THE CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
AUDIT NO. CNWRA 92-1

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1.0 INTRODUCTION

From June 2-5, 1992, members of the U.S. Nuclear Regulatory Commission (NRC) quality assurance (QA) staff participated as observers in the Center for Nuclear Waste Regulatory Analyses (CNWRA) QA Audit No. 92-1 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. This report addresses the effectiveness of the audit and the procedural adequacy and effectiveness of implementation of QA program controls in both programmatic and technical areas.

2.0 OBJECTIVES

The CNWRA objective for this audit was to evaluate the implementation of QA controls associated with CNWRA 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 objective was 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 Revision 2 to the Center 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 discussions with, and direct observations of, the auditors and technical specialists who were on loan from the CNWRA's parent organization, Southwest Research Institute (SwRI), CNWRA staff and reviews of pertinent audit information (e.g., audit plan, checklist, and CNWRA documents). The NRC staff has determined that, overall, Audit No. CNWRA 92-1 achieved its purpose of evaluating the implementation of QA control for 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. Their 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 program controls are being adequately implemented in the areas that were evaluated. The audit team also determined that the technical procedures reviewed were technically adequate, the technical staff was appropriately qualified, and the technical work was adequate. The presence of an NRC technical staff observer at the audit permitted verification of these conclusions with regard to engineered barrier system (EBS). Further, the technical qualifications of CNWRA technical staff and the technical adequacy of the procedures and work products are subject to continuing evaluation by NRC technical staff.

The CNWRA QA personnel should closely 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 QA program development is currently being accomplished by CNWRA QA staff, the audit was performed by Lead Auditor Tom Trbovich, auditors Randolph Folck and Don Dunavant, and technical specialists Mark Sarlo, Mike MacNaughton, Karen Kohl, K. Chan, and A. C. Rogers, from SwRI, to avoid any potential conflict of interest. The NRC observers were John Buckley, Pauline Brooks, and David Dancer.

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 programmatic and technical activities. The bases of the audit included Appendix B to 10 CFR Part 50, NQA-1, CQAM, Research Project Plans, Operations Plans, Technical Operating Procedures (TOPs) and QAPs.

(a) Programmatic Elements

The checklists covered the QA program requirements for the 14 elements (related to the 18 criteria of Appendix B to 10 CFR Part 50) listed below:

- 1.0 Organization
- 2.0 QA Program
- 3.0 Scientific Investigation and Analysis Control
- 5.0 Instructions, Procedures, and Drawings
- 6.0 Document Control
- 7.0 Procurement Control
- 8.0 Identification and Control of Items, Software, and Samples
- 9.0 Control of Processes
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Storage, and Shipping
- 15.0 Nonconformance Control
- 16.0 Corrective Action
- 17.0 Records Control
- 18.0 Audits

Elements 4, 10, 11 and 14 are not presently applicable to CNWRA work.

(b) 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, as follows:

Geologic Setting Task 2 - Regulatory and Technical Guidance Development 20-3702-121 through 127

Geologic Setting Task 3 - Analysis Codes Methods 20-3702-131 through 133

Performance Assessment Task 5 - Iterative Performance Assessment 20-3702-065

Engineered Barrier System Task 2 - Regulatory and Technical Guidance Development 20-3702-012

Engineered Barrier System Task 3 - Analysis Codes and Methods 20-3702-231 through 232

Thermohydrology Research Tasks 1, 2, & 3 20-3704-021 through 023

Geochemistry Research Task 2 - Geochemical Modeling of Fluid/Rock Interactions 20-3704-012

Geochemical Analog Research Tasks 1-4 20-3704-061 through 064
Sorption Modeling Research Tasks 1-3 20-3704-071 through 073

Audit technical specialists were instructed to evaluate the technical activities to determine the following:

- a. Technical qualifications of investigators and analysts.
- b. Understanding of procedural requirements (by technical staff) as they pertain to scientific investigations and analysis activities.
- c. Adequacy of TOPs and scientific notebooks.
- d. 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 Examination of Programmatic Activities

Audit 92-1 was conducted as a "performance-based" audit. Instead of conducting evaluations focusing on compliance with the QA programmatic criteria, the auditors focused on the technical activities and evaluated the programmatic controls applicable to those activities. Therefore, discussions about the observed programmatic controls are incorporated into Section 5.4, "Examination of Technical Activities."

5.4 Examination of Technical Activities

The NRC staff observed the audit team's evaluation of the following technical activities.

(a) Geologic Setting (GS) Task 2/3, Probability of Fault/Seismic Hazards

The auditors evaluated the activities of GS Tasks 2/3 by examining the work associated with the SEISM 1 computer code. The auditors determined that Task 3 is essentially complete but the reports have not been released yet. Based on reviews of CNWRA staff technical qualification and QA indoctrination records, the auditors developed one Corrective Action Request (CAR).

The CAR identified a CNWRA staff member working on GS Tasks 2/3 who performed work under the CNWRA Quality Assurance Manual without receiving indoctrination training in the CNWRA QA System.

The auditors also identified a concern associated with the CNWRA's implementation of TOP-018. There appears to be some confusion over when a computer code becomes "baselined." The CNWRA acquired the SEISM 1 computer code from Lawrence Livermore National Laboratory (LLNL). The CNWRA considered the as-acquired version of SEISM as baselined and placed a copy in the fire-rated safe for storage even though this version required modifications to run on CNWRA computers. TOP-018 is not clear if SEISM 1 should be "baselined" as acquired or following modifications making it compatible with CNWRA computers. The programmatic and technical audit of this activity was thorough and effective.

(b) GS Tasks 2/3 Natural Resources/Flooding

The auditors determined through interviews with the CNWRA staff that there has been no activity to date associated with Task 3. The major activity associated with Task 2 is Systems Regulatory Analyses (SRA). There were no final SRA products for the auditors to review. Therefore, the auditors examined the technical qualifications and QA training requirements for CNWRA staff members working on SRA. CNWRA training records indicate that one CNWRA staff member was working to a TOP without the proper training as required by TOP-001-011 and QAP-005.

(c) Geochemical Analog Research Tasks 1-4

The auditors used their checklist effectively to determine what activities are currently underway, how well the CNWRA staff understands the QA requirements imposed on their activities, and effectiveness of implementation of these requirements. The auditors systematically traced the control of samples to evaluate compliance with the CNWRA's QA programmatic controls. Samples were traced from the laboratory and field notebooks through the sample log books to the sample storage areas. Calibration records for laboratory equipment were also examined.

The audit of Geochemical Analog Research Activities was thorough and effective in determining CNWRA compliance with procedural controls.

(d) EBS Task 3

The auditors determined through interviews with the CNWRA staff that EBS Task 3 work is currently being done to EBS Program Element Intermediate Milestone 20-3702-013-210, EBSPAC Plan Status 1, even though the work plan is in draft form. Under EBS Task 3, the CNWRA staff is developing the following computer codes;

- (1) MARIANNA - a mass transfer equilibrium solver,
- (2) TWITCH - Transient Diffusion Electromigration and Chemical Reaction Code.

As a result of the audit in this area, the auditors identified several deficiencies. First, the CNWRA Information Processing Standard Summary Form used was not the same form specified in TOP-018. Second, software has been developed without initially developing Requirements Document as specified in TOP-018. Finally, a CNWRA staff member was working to TOP-018 without the required training to that TOP. Based on the responses provided by several CNWRA technical staff to auditors' questions, it appears that the CNWRA staff may benefit from additional training to the requirements of TOP-018. The auditors conducted a thorough and effective audit of this activity.

(e) Performance Assessment (PA) Task 5, Iterative Performance Assessment

The auditors evaluated CNWRA technical activities in PA Task 5 by interviewing the technical staff and reviewing selected technical products. The audit was guided by prepared technical and programmatic checklists.

Technical products reviewed include CNWRA 91-010, Sensitivity and Uncertainty Analysis Applied to One-Dimensional Transport in a Layered Fractured Rock--Part I: Analytic Solutions and Local Sensitivities; CNWRA 92-002, Sensitivity Analysis, Part II: Evaluation of Limit State Approach; CNWRA 91-003, PreFOR: A

Preprocessor for Fortran Files User's Manual; and CNWRA 91-009, Total System Performance Assessment Computer Codes: Description of Executive Module.

Fifteen programmatic areas were covered with respect to PA Task 5. Deficiencies, corrected during the audit, were noted in the CNWRA personnel records of two persons. A concern was raised as to whether TOP-018 was being properly implemented in PA Task 5 as well as in other technical areas. No computer codes have yet been "baselined" in PA Task 5.

The technical and programmatic audits of PA Task 5 were thorough and effective.

(f) Sorption Modeling Research Tasks 1-3

To evaluate the CNWRA's work in sorption modeling research, the auditors interviewed the researchers, examined the control of laboratory procedures and reviewed selected technical products. Technical and programmatic checklists provided the framework for the evaluation.

The technical auditor had reviewed the CNWRA's Annual Research Report, and the reports: CNWRA 91-011, Sorption Modeling for High Level Waste Performance Assessment - A Literature Review and CNWRA 91-016, Sorption Modeling for High Level Waste Performance Assessment: A Literature Review. At the request of the technical auditor, these reports were tracked through the QA records system, with special attention to the review folder.

To evaluate compliance with the CNWRA's QA programmatic controls, the auditors traced the control of laboratory samples through a succession of laboratory notebooks and examined the calibration records of the equipment.

The auditors examined the QA control of the computer program, MINTEC, Version 2 and identified a concern that each group is implementing TOP-018 differently.

The audit of Sorption Modeling Research Tasks was thorough and effective in determining CNWRA compliance with procedural controls.

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 and technical specialists used their checklists effectively during discussions with CNWRA personnel and review of documents. They asked detailed questions and requested evidence as required to support conclusions.

5.6 Qualifications of the 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." The five technical specialists were given specific training in conducting audits by the lead auditor.

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. Other than audit interviews, no meetings were held during the audit.

5.9 Auditor Independence

The audit team had no involvement with or responsibility for performing any of the activities they audited. They are from SwRI and were assigned the 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 auditors 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.

CAR 92-01 - TOP-018, Revision 1, "Configuration Management and Control of Scientific and Engineering Computer Codes," is not being fully implemented.

CAR 92-02 - In some instances training of Center personnel had not been conducted as required by the CQAM, QAP or TOPs.

CAR 92-03 - QAP-013, paragraph 3.1 and QAP-008, paragraph 3.2.1 establish a requirement that the applicable portions of the CQAM be identified in the Operations (OPs) Plans to the extent possible. Several OPS plans were found not to contain any reference to the CQAM.

7.0 SUMMARY - NRC STAFF FINDINGS

(a) Observations

As noted by the audit team in CAR 92-01, there are problems associated with the implementation of TOP-018. The NRC staff also believes that TOP-018 could be improved to more effectively control the development and maintenance of computer software. As noted in Section 5.4 (d) of this report, some responses to auditors' questions indicate that the CNWRA technical staff may benefit from additional training to TOP-018. The NRC staff would like to be notified in advance when the auditors verify correction action to close CAR 92-01. The NRC staff plans to closely monitor this portion of the CNWRA QA program to ensure that future implementation is carried out in an adequate manner.

(b) Weaknesses

Integration of the programmatic and technical portions of the audit could have been improved. The NRC staff understands that some of the integration problems were due to the fact that this was the first "performance-based" audit for the audit team. The "performance-based" audit may be more effective when the number of work products increases. In some cases, namely GS Tasks 2/3, evaluating the programmatic controls would have been more effective if there were more technical products to examine.

(c) Good Practices

The audit team was well prepared and conducted a thorough audit in a professional manner even though it was the first CNWRA "performance-based" audit.

The Audit Team Leader did an excellent job of organizing and executing the audit. The practice of reviewing the checklist items at the daily caucus to assure completeness of the checklist items was very effective and useful.