

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 91-3
FOR THE CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
AUDIT NO. CNWRA 90-3

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1.0 INTRODUCTION

From December 4 through 6, 1990, a member of the U.S. Nuclear Regulatory Commission (NRC) staff participated as an observer in the Center for Nuclear Waste Regulatory Analyses (CNWRA) QA Audit No. CNWRA 90-3 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, to a lesser extent, the adequacy of the CNWRA QA program.

2.0 OBJECTIVES

The CNWRA objective for this audit was to evaluate the implementation of QA programmatic controls associated with CNWRA technical activities in meeting the applicable requirements of Appendix B to 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, who were on loan from the CNWRA's parent organization, Southwest Research Institute (SwRI), and reviews of the pertinent audit information (e.g., audit plan, checklist, and CNWRA documents). The NRC staff has determined that, overall, Audit No. CNWRA 90-3 achieved its purpose of evaluating the implementation of QA controls for technical activities. The audit was conducted in a professional manner. The audit team was well qualified in the QA disciplines, and their assignments and checklist items were adequately described in the audit plan.

The NRC staff agrees with the audit team's preliminary findings that the CNWRA generally has an adequate QA program for the areas that were evaluated, with the exception that certain activities are being performed without approved and controlled instructions or procedures. This deficiency should receive immediate management attention for appropriate corrective action.

In addition 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 Randolph Folck and Rodney Weber, Lead Auditor and Auditor, respectively, from SwRI, to avoid any potential conflict of interest. The NRC observer was James T. Conway, Senior Quality Assurance Engineer and CNWRA Internal QA Project Officer.

5.0 NRC OBSERVATIONS

The NRC staff conducted the observation of the CNWRA audit in accordance with the applicable portions of the NRC procedure "Conduct of Observation Audits" issued October 6, 1989. The NRC staff observed and evaluated the following areas to determine whether the audit and auditors were effective:

- (1) scope of the audit
- (2) timing of the audit;
- (3) examination of technical products;
- (4) conduct of the audit;
- (5) qualifications of the auditor;
- (6) auditor preparation;
- (7) conduct of meetings; and
- (8) auditor independence

The acceptability of each aforementioned area is based on direct NRC staff observations of the audit and review of documentation.

5.1 Scope of Audit

The audit was conducted to evaluate the implementation of QA requirements associated with CNWRA technical activities. The bases of the audit included Appendix B to 10 CFR Part 50, NQA-1, NRC Review Plan for High-Level Waste Repository QA Program Descriptions, Revision 2, dated March 1989, and the CQAM, Revision 2, dated April 1990.

In addition, the personnel qualification records of sixteen individuals who performed technical or peer reviews were evaluated and found satisfactory. Discrepancies identified during QA Audit No. CNWRA 90-1 were also evaluated to determine whether CNWRA had taken effective corrective actions.

(a) Programmatic Elements

The programmatic checklist covered the QA program requirements for the nine elements listed below:

- 2.0 QA Program
- 3.0 Scientific Investigation and Analysis Control
- 4.0 and 7.0 Procurement Control
- 5.0 Instructions, Procedures, and Drawings
- 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

The NRC staff reviewed the Audit Plan dated October 31, 1990, audit checklist, and the applicable sections of CQAM, Revision 2. (The NRC staff is awaiting resolution by the CNWRA of a number of comments that were raised during the staff's review of Revision 2 to the CQAM). The checklist items selected from the CQAM by the auditors were appropriate to support the evaluation of the nine QA programmatic elements.

(b) Technical Areas

Technical activities that were evaluated included eight Research Projects and seven tasks associated with Operation Plans.

5.2 Timing of the Audit

The NRC staff believes the timing of the QA audit was appropriate. The CNWRA had made a number of improvements in their QA program since the last audit in June 1990, and even though implementation was limited, it was beneficial to assess the adequacy of the improvements to date.

5.3 Examination of Technical Products

Technical evaluations of work activities or work products were not performed, and technical specialists were not included as auditors or observers. However, a review of QA requirements relating to activities, records, plans, and procedures was undertaken for the following Research Projects:

- Thermohydrology
- Seismic Rock Mechanics
- Integrated Waste Package Experiments
- Stochastic Modeling
- Geochemical Analogs
- Sorption Modeling
- Performance Assessment
- Geochemistry

A QA review was also conducted of technical activities associated with the following tasks related to Operation Plans:

- Systematic Regulatory Analysis
- Substantially Complete Containment Engineered Barrier System
- Engineered Barrier System Package
- Ground Water Travel Time
- Geological Setting
- Repository Design Construction and Operation
- Performance Assessment

5.4 Conduct of the Audit

The overall conduct of the audit was productive and performed in a professional manner. The auditors were well prepared and demonstrated a sound knowledge of the QA aspects of the CNWRA program. The auditors used the checklist effectively during discussions with CNWRA personnel and review of documents. They asked detailed questions and requested evidence as required to support conclusions.

5.5 Qualifications of the Auditors

The two auditors were both 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."

5.6 Auditor Preparation

The auditors appeared adequately prepared to perform the audit. They personally prepared the audit checklist which required review and evaluation of the CQAM and applicable Technical Operating Procedures (TOP) and QA Procedures (QAP).

5.7. Conduct of Meetings

The auditors conducted professional and appropriate entrance and exit meetings with CNWRA personnel (See Enclosure 1). Their statements of the audit purpose and findings were clear and concise. Other than audit interviews, no other meetings were held during the audit.

5.8 Auditor Independence

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

6.0 SUMMARY - PRELIMINARY AUDIT FINDINGS

During the course of the audit, the auditors identified one deficiency in the CNWRA QA program which will be documented as a Corrective Action Report (CAR) and resolved in accordance with Section 16 of the CQAM. In addition, two observations were noted by the auditors. A summary statement of each of the findings follows:

CAR

Quality affecting activities in the areas of: (a) sample receipt and control; (b) receipt, control and verification of software used for data reduction and analysis; and (c) qualification of existing data were being performed without approved and controlled instructions or procedures.

OBSERVATIONS

Three volumes of controlled CNWRA procedures were found in the Geochemistry laboratory area without the latest revision of procedure No. QAP-001 "Scientific Notebook Control."

Untimely and incomplete corrective action (CA) in responding to CARs as noted by:

- (a) CA for an audit finding in February 1989 to revise TOPs of the 001 series had not been accomplished by November 1990 when a new CAR was issued extending the completion date to June 1991.
- (b) Three out of four CARs identified in the June 1990 audit remain open five months after management was officially notified of the deficiencies.

7.0 SUMMARY - NRC STAFF FINDINGS

(a) Observations

The NRC staff did not identify any observations in either the audit process or the CNWRA QA program.

(b) Weaknesses

Documented implementing procedures were not available for the qualification of existing data, control of software, and control of samples.

Maintenance of all QA records was not in accordance with the requirements of Section 17 "Records Control" of the CQAM, Revision 2.

Lack of objective evidence that cognizant Directors evaluated the personnel qualifications of approximately 72 individuals to determine if they are qualified to perform CNWRA activities.

Existing data which may or may not have to be qualified to meet licensing requirements is being referenced, without any qualifications, and used to support conclusions in technical reports from the CNWRA.

(c) Good Practices

Non-QA CNWRA staff involved in the audit were aware of QA requirements and appeared to be supportive of the CNWRA QA program.

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

The peer review of Substantially Complete Containment (CNWRA 90-001/-002) was conducted prior to issuance of Procedure No. QAP-002, Revision 0, (endorses NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories"), but the records indicate that the review was done in a planned and controlled manner. An evaluation of six technical reviews performed since the issuance of QAP-002 indicate the reviews were done in a manner that met the applicable requirements of QAP-002.

Nine internal surveillances performed by QA personnel during 1990 addressed a cross section of technical activities and were conducted and documented in a satisfactory manner.

Enclosure 1

Audit Meeting

- * Bruce Mabrito
- * Robert Brient
- * Rawley Johnson
- * Allen Whiting
- * Michael Miklas
- * Asadul Chowdhury
- * Jim Conway (NRC)
- * Randy Folck
- * Rodney Weber
- ** Roberto Pabalan
- ** Herbert Pennick
- ** Bill Murphy
- ** Rachid Ababou
- ** Stephen Young
- ** David Turner
- ** Ted Romine
- ** Gustavo Cragolino
- ** Henry Garcia
- ** English Percy

- * Attended entrance and exit meetings
- ** Attended exit meeting