

U. S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 90-4
FOR THE CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
AUDIT NO. CNWRA 90-1

James T. Conway 08/2/90
James T. Conway
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management

Mark S. Delligatti 08/02/90
Mark S. Delligatti
Special Projects
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste
Management

Shirley L. Fortuna 08/2/90
Shirly L. Fortuna
Program Management, Policy Development
and Analysis Staff
Office of Nuclear Material Safety
and Safeguards

Reviewed and Approved by: Kenneth R. Hooks 08/102/90
Kenneth R. Hooks
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management

1.0 INTRODUCTION

From June 26 through 28, 1990, members of the U.S. Nuclear Regulatory Commission (NRC) staff participated as observers in the Center for Nuclear Waste Regulatory Analyses (CNWRA) QA Audit No. CNWRA 90-1 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, to a lesser extent, the adequacy of the CNWRA QA Program.

2.0 OBJECTIVES

The CNWRA objective for this audit was to evaluate the adequacy and implementation of the CNWRA QA programmatic controls 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 auditor, who was 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 programmatic controls which were reviewed indicated that Revision 2 of the CQAM reflects the lessons learned from two years of operational experience and contains the applicable requirements of Appendix B to 10 CFR Part 50. However, due to the limited amount of work conducted by the CNWRA under Revision 2 to the CQAM, the NRC staff has determined that, overall, Audit No. CNWRA 90-1 was marginal in achieving its purpose of determining the effectiveness of the CNWRA QA program. The audit was conducted in a professional manner. The auditor was well qualified in the QA disciplines, and the checklist items were adequately described.

The NRC staff recommended, and the CNWRA agreed, that a scheduled audit (late in 1990) involving technical aspects of the CNWRA program should be expanded to consider programmatic implementation under Revision 2 to the CQAM and to focus, particularly, on outstanding Corrective Action Requests (CARs) from previous audits.

4.0 AUDIT PARTICIPANTS

Due to the high level of QA program development currently being accomplished by CNWRA QA staff, the audit was performed by Michael R. Gonzalez, an SwRI Lead Auditor, to avoid any potential conflict of interest. The NRC

observers were James T. Conway, Senior Quality Assurance Engineer, Mark S. Delligatti, CNWRA Internal QA Project Officer and Shirley L. Fortuna, Deputy CNWRA Program Manager.

5.0 NRC OBSERVATIONS

The NRC staff conducted the observation of the CNWRA audit in accordance with the applicable portions of the HLW Division Procedure for Conducting Observation Audits of DOE High-Level Waste Repository QA Audits, Revision 1, dated May 25, 1988. The NRC staff observed and evaluated the following areas to determine whether the audit and auditor 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, as noted in the CNWRA Audit Plan, was limited to evaluating the adequacy and implementation of the QA programmatic controls.

The requirement's basis of the audit included Appendix B to 10 CFR Part 50, NQA-1, NRC Review Plan for High-Level Waste Repository QA Program Descriptions dated March 1989, and CQAM, Revision 2. The programmatic checklist covered the QA program controls for the 10 elements listed below:

- 1.0 Organization
- 2.0 QA Program
- 4.0 and 7.0 Procurement Control
- 5.0 Instructions, Procedures, and Drawings
- 6.0 Document Control
- 15.0 Nonconformance Control
- 16.0 Corrective Action
- 17.0 Records Control
- 18.0 Audits

Implementation of the remaining five elements (3.0, 8.0, 9.0, 12.0 and 13.0 of the CQAM) and the QA operational controls applicable to research and technical assistance activities will be evaluated in an audit scheduled later in 1990.

The NRC staff reviewed the Audit Plan dated April 25, 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 auditor were appropriate to support the evaluation of the 10 QA programmatic elements.

5.2 Timing of the Audit

Initially, the NRC staff felt that the benefit of auditing to the recently completed CQAM, Revision 2 outweighed concerns of limited implementation or the limited utility of auditing to the outdated CQAM, Revision 1. However, the NRC staff now believes that the timing of the audit was not appropriate in that only a minimal amount of work had been performed under Revision 2 to the CQAM which was used as a basis for the audit.

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. The NRC staff expects future CNWRA QA audits to evaluate technical work activities and work products and stated this position at both the entrance and exit meetings.

5.4 Conduct of the Audit

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

5.5 Qualifications of the Auditor

Mr. Gonzalez is 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 NQA-1-1986 "Quality Assurance Program Requirements for Nuclear Facilities". Mr. Gonzalez has also participated as an observer in the NRC Observation Audits of Los Alamos National Laboratory in November 1989 and March 1990 and Fenix & Scisson of Nevada in November 1988 and April 1989.

5.6 Auditor Preparation

The auditor appeared adequately prepared to perform the audit. He personally prepared the audit checklist which required review and evaluation of the CQAM.

5.7. Conduct of Meetings

The auditor conducted professional and appropriate entrance and exit meetings with CNWRA personnel, as listed on Enclosures 1 and 2. His statements of the audit purpose and findings were clear and concise. No meetings other than the entrance and exit meetings were held during the audit.

5.8 Auditor Independence

The auditor had no involvement with or responsibility for performing any of the activities he audited. He is one of a group of Lead Auditors from SwRI and was 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 auditor identified four deficiencies in the CNWRA QA program which will be documented as CARs and resolved in accordance with Section 16 of the CQAM. In addition, six observations were noted by the auditor. A summary statement of each of the findings follows:

CARS

- (a) Personnel performing activities affecting quality have not been evaluated by the cognizant director for position requirements, education, experience, and training requirements.
- (b) Verification of completion of correction action was not accomplished for all open items identified in Audit No. 89-C-1.
- (c) Several CNWRA records processed are not being indexed for documentation of required information.
- (d) Each section of the CQAM was not audited during calendar year 1989.

OBSERVATIONS

- (a) Contract was let out to the University of Arizona (UA) for services, but UA was not on the Qualified Supplier's List.
- (b) Current log for tracking nonconformance reports does not address the required content requirements.
- (c) Adequate guidance for performing trending analysis of CARs, nonconformance reports, and NRC audit findings does not exist in the CQAM.

The NRC staff reviewed the Audit Plan dated April 25, 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 auditor were appropriate to support the evaluation of the 10 QA programmatic elements.

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- (d) There is a lack of general consensus on the classification of records which in turn impacts retention periods.
- (e) Current practice of maintaining QA records does not meet the record storage requirements of NQA-1.
- (f) QA indoctrination and training requirements for consultants and individuals were not met for some work accomplished under Rev. 1 to the CQAM.

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

It was noted that four detailed procedures pertaining to control of Measuring and Test Equipment, Nonconformance Control, Corrective Action, and Audits are incorporated in the CQAM, Revision 2. The NRC staff believes that implementing procedures should not be a part of the CQAM which documents the CNWRA's policies relating to QA. Furthermore, the CNWRA has also developed Technical Operating Procedures which are similar to these implementing procedures, but are not a part of the CQAM. This inconsistency is confusing and is a further reason to remove the implementing procedures from the CQAM.

To date, only six QA procedures (QAP) have been written and approved. The QAPs implement and supplement the CQAM requirements, and they should be developed as soon as possible.

The overall audit was marginally effective due to limited implementation of the QA program. Few programmatic records and no technical products generated under Revision 2 to the CQAM were available upon which audit conclusions could be based. It is anticipated that these areas will be covered in an audit to be held in the December 1990 time-frame.

(c) Good Practices

The CNWRA QA staff showed a real interest in finding and correcting problems with the CQAM Revision 2, and they were honest, open and willing to admit shortcomings.

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

