

U. S NUCLEAR REGULATORY COMMISSION
AUDIT OBSERVATION REPORT
FOR THE
CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
INTERNAL QUALITY ASSURANCE AUDIT
NUMBER 89-C-1

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1. INTRODUCTION

The Center for Nuclear Waste Regulatory Analyses (CNWRA) conducted the first internal audit of CNWRA work activities from February 27 through March 1, 1989 at the CNWRA offices in San Antonio, Texas. The audit was conducted in accordance with CNWRA Quality Assurance Manual (CQAM) Section 18 "Audits" and the Audit Plan (including Audit Checklist) transmitted to the NRC on February 16, 1989 (Enclosure 1). The purpose of the audit was to evaluate program architecture (PA) activities for compliance with applicable QA program requirements.

2. PURPOSE OF STAFF PARTICIPATION

The purpose of the NRC staff observation of the CNWRA audit 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 the CQAM and CNWRA Technical Operating Procedures (TOPs).

3. AUDITOR AND OBSERVERS

The CNWRA audit was performed by Robert E. Engelhardt, an SwRI Lead Auditor on loan to CNWRA for this audit.

The NRC observers were Kenneth R. Hooks, Senior Quality Assurance Engineer and Mark S. Delligatti, NRC QA Sub-Element Manager.

4. 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.

4.1 Scope of the Audit

The audit, as indicated in the CNWRA Audit Plan, was limited to evaluating PA activities for compliance with the CQAM and selected TOPs. As the only significant work activities and work products of the CNWRA to date have been development of portions of the PA, this selection was appropriate.

The audit covered nine of the eighteen criteria in 10 CFR Part 50, Appendix B, consistent with the criteria applicable to PA as shown in Table II-1 of the CQAM. The CQAM was accepted by the NRC as stated in Mr. Joseph O. Bunting's letter to Mr. John Latz dated December 19, 1988.

The NRC staff reviewed the Audit Plan (including the Audit Checklist), the CQAM and CNWRA TOPs -001, -001-01, -001-02 and -001-03 and their applicable TOP Change Notices prior to the beginning of the audit. The checklist items selected from the CQAM and TOPs by the CNWRA/SwRI auditor were appropriate and sufficient in number to support evaluation of PA activities for compliance with applicable procedures.

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

4.2 Timing of the Audit

The audit was performed early enough in the PA development process to provide useful guidance to improve or correct work activities.

4.3 Examination of Technical Products

The audit was for compliance with applicable procedures. No technical specialists were included as auditors or observers, and no technical evaluations of work activities or work products were performed.

4.4 Conduct of the Audit

The audit was accomplished by review of selected electronic and hard copy work products and discussions with CNWRA personnel who participated in the development of the work products. The auditor performed in a professional manner. He asked detailed questions and requested supporting evidence as required to support conclusions.

4.5 Qualifications of the Auditor

Mr. Engelhardt is certified to SwRI-NQAP-15.2 which invokes ANSI N45.2.23. The CQAM requires lead auditors to be certified to ANSI N45.2.23. Mr. Engelhardt participated as an observer in the NRC Observation Audit of Lawrence Livermore National Laboratory in October 1988. He has a BS degree in Mechanical Engineering and twenty years experience as an auditor, including eighteen years as an SwRI Lead Auditor.

4.6 Auditor Preparation

The auditor appeared adequately prepared to perform the audit. He personally prepared the Audit Plan and Audit Checklist, which required review and evaluation of the CQAM and TOP requirements.

4.7 Conduct of Meetings

The auditor conducted professional and appropriate entrance and exit meetings with CNWRA personnel, as listed on Enclosures 2 and 3. 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.

4.8 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 employed by SWRI. He was temporarily assigned to the CNWRA for the purpose of performing this internal audit. He was not requested by name by the CNWRA.

5. PRELIMINARY AUDIT FINDINGS

The auditor identified eleven of the seventy-nine Audit Checklist items as "unsatisfactory." These are:

- Item 12 - Not all CNWRA employees involved in PA activities have received QA indoctrination and training.
- Item 24 - Uncontrolled copies of Operations Plans and Project Plans are not correctly marked.
- Item 31 - The NRC Program Element Manager was not properly notified of the one Deviation and Nonconformance Report (DNR).
- Item 36 - Hardcopy backups of electronic records are not certified as bonafide copies.
- Item 38 - The CNWRA has not prepared a vendor audit schedule.
- Item 39 - The CNWRA Lead Auditor (Mr. Engelhardt in this instance) was not certified to ANSI N45.2.23 except through SWRI-NWAP-15-2 and was not specified (by name) in writing by the CNWRA QA Director.
- Item 46 - No Database Administrator has been designated, although Mr. Robert Marshall of the CNWRA is acting in this capacity.
- Item 49 - Program Architecture Review Committee (PARC) members have not been identified as voting or only participating.

- Item 68 - There is insufficient objective evidence that PARC members have reviewed submitted information.
- Item 70 - The review and marking of PARC comments has not been in accordance with the procedural requirements.
- Item 71 - The reviewer has not signed and dated a hard copy of the revised review packages.

6. NRC STAFF OBSERVATIONS

The NRC observers agree with the auditor's preliminary findings as stated in Paragraph 5 above; it is possible that the CNWRA may provide additional documentation to the auditor to demonstrate compliance with one or more of the items preliminarily identified as unsatisfactory.

The NRC observers were present while the CNWRA/SWRI auditor reviewed Items 1 through 61 and Items 70, 71 and 72 of the Audit Checklist. The results of the remainder of the audit were discussed by telephone between CNWRA and the NRC staff on March 2, 1989.

The NRC observers identified one concern not explicitly stated by the auditor, which was technically not part of the stated scope of the audit, regarding classification and storage of documents. The NRC observers believe that the CNWRA should define those documents which should be treated as QA records in accordance with the intent of 10 CFR Part 50, Appendix B. Such documents should be protected by a system equivalent to that specified in ANSI N45.2.9. The NRC staff acknowledges that the CNWRA is now controlling documents in accordance with contract requirements.

The audit identified a number of failures of CNWRA personnel to comply with applicable requirements of the CQAM and TOPs. Although no single failure in itself had a significant effect on the overall quality of the work activities and work products, the CNWRA should review the CQAM and TOPs for compatibility with the actual PA work activities. Failure to bring practice and procedures into conformance with each other and the CNWRA QA program requirements could result in significant effects on future work.

In summary, the NRC staff determined that, considering the scope of the audit as stated in Paragraph 4.1, the audit was performed in an acceptable manner and resulted in meaningful findings. The NRC staff also determined that, in spite of a number of unsatisfactory audit findings, the CNWRA staff's implementation of the CNWRA QA program is adequate for their early stage of development of the program architecture.