

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 92-07
FOR THE OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
AUDIT NO. YMP-92-09 OF
SANDIA NATIONAL LABORATORIES

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1.0 INTRODUCTION

From February 11-13, 1992, U.S. Nuclear Regulatory Commission (NRC) staff members participated as observers on the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Yucca Mountain Quality Assurance Division (YMQAD) Quality Assurance (QA) Audit YMP-92-09 of the Sandia National Laboratories (SNL) Nuclear Waste Repository Technology Department (NWRT) QA program at the SNL offices in Albuquerque, New Mexico. The audit scope was limited to eight programmatic elements. No technical reviews or evaluations were included in the scope of the audit, and the audit team did not include any technical specialists.

2.0 OBJECTIVES

The objectives of this YMQAD audit were to evaluate the implementation and effectiveness of the SNL NWRT QA program in meeting the requirements of the SNL NWRT Quality Assurance Program Description (QAPD). The NRC staff's objective was to gain confidence that YMQAD and SNL are properly implementing the requirements of their QA programs in accordance with the OCRWM Quality Assurance Requirements Document (QARD), DOE/RW-0214, Revision 4 and Title 10 Code of Federal Regulations (10 CFR), Part 50, Appendix B.

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the YMQAD audit process and the SNL QA program on direct observations of the auditors, discussions with the audit team and SNL personnel, and reviews of pertinent audit information (e.g., audit plan, checklists and SNL documents). The audit was well organized and conducted in a thorough and professional manner with minimal logistic delays. The audit team was well qualified in the QA discipline, and its assignments and checklist items were, for the most part, acceptably described in the audit plan.

The NRC staff agrees with the preliminary YMQAD audit team findings that the SNL QA program has adequate procedural controls in place, and program implementation is adequate, in six of the programmatic areas audited. Two of the programmatic areas audited were found to be indeterminate, due to a lack of quality-affecting work in these areas. One preliminary Corrective Action Request (CAR) was issued by the YMQAD audit team, concerning the lack of objective evidence of planning for readiness/preparedness reviews as required by the OCRWM QARD. This deficiency is not significant in terms of the overall QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

Pauline P. Brooks	Observer
Kenneth R. Hooks	Observer

4.2 YMQAD

Neil D. Cox	Audit Team Leader	Science Applications International Corporation (SAIC)
Kenneth T. McFall	Auditor	SAIC
Cynthia H. Prater	Auditor	SAIC
James Blaylock	Auditor	DOE/Yucca Mountain Site Characterization Project Office (YMPO)

5.0 REVIEW OF THE AUDITED ORGANIZATION

This audit was conducted in accordance with OCRWM QA Administrative Procedure (QAAP) 18.2, "Audit Program," Revision 5, effective January 3, 1992 and OCRWM QAAP 16.1, "Corrective Action," Revision 4, effective November 12, 1991.

The NRC staff observation audit of this YMQAD audit of SNL was based on the NRC procedure, "Conduct of Audits," issued October 6, 1989.

5.1 Purpose/Scope of Audit

The purpose of the YMQAD audit was to evaluate the implementation and effectiveness of the SNL's QA program relative to the eight programmatic elements.

(a) Programmatic Elements

The audit was based on the requirements in the SNL NWRT QAPD Revision 00, effective July 29, 1991, Sections 1.0, 2.0, 7.0, 12.0, 13.0, 15.0, 16.0, and 18.0 (10 CFR 50 Appendix B Criteria I, II, VII, XII, XIII, XV, XVI, and XVIII), and other applicable documents pertaining to QA controls.

(b) Technical Areas

This audit did not involve technical review or evaluation of technical work or work products.

5.2 Timing of the Audit

The NRC staff believes the timing of the QA audit of SNL was acceptable, considering the OCRWM "limited" audit program began in fiscal year 1992. Although there was limited quality affecting work done in some of the programmatic elements, the last audit of all these elements was in August 1991.

5.3 Examination of Programmatic Elements

The audit checklists covered the QA program controls for the five programmatic elements listed below:

- 1.0 Organization
- 2.0 Quality Assurance Program
- 15.0 Control of Nonconformance
- 16.0 Corrective Action
- 18.0 Audits

Three programmatic elements were added to the audit scope too late for checklists to be prepared; marked-up procedures were used instead of checklists for the following:

- 7.0 Control of Purchased Items and Services
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Shipping, and Storage

The NRC staff observed the YMQAD audit team's evaluation of programmatic elements/criteria 1.0, 2.0, 12.0, and 18.0. Only these criteria will be discussed in detail.

(a) Organization (Criterion 1) and Quality Assurance Program (Criterion 2)

In the initial session, it was stated that a restructuring of the SNL's NWRT will become effective April 2, 1992. Repository Engineering, which includes design functions, is not in the new organization. In examining Criterion 1, Organization, the auditor sought assurance that all of the quality-affecting responsibilities previously assigned to Repository Engineering could be accounted for in going from the present organizational units to the new units. Most of the present SNL NWRT design functions are expected to be transferred to the DOE Management and Operating Contractor.

For Criterion 2, Quality Assurance Program, the auditor verified that applicable QA controls had been determined by checking for approved Quality Assurance Grading Reports for five Work Breakdown Structure (WBS) elements. Approved reports were available for each WBS element. Training and qualification files for a sample of employees were found to be up-to-date.

The auditor noted a preliminary deficiency related to SNL NWRT Department Operating Procedure (DOP) 02.09, "Preparedness Reviews." There is no objective evidence of planning preparedness reviews. An Interim Change Notice (ICN) to DOP 02.09 takes out the paragraph that requires a list of planned preparedness reviews. Thus the planning phase is removed from the DOP but it is still required by the QARD.

A new SNL NWRT procedure, "Study Plan Requirements" (Quality Assurance Implementing Procedure 2-2, Rev. 00) became effective December 10, 1991. No study plans have been prepared according to this procedure. However, it appears to the NRC observers that use of this procedure could eliminate many of the questions being raised in NRC staff reviews.

The audit of Criteria 1 and 2 was well-organized and conducted in a thorough and professional manner with minimal logistic delays. The auditor was well qualified in the QA discipline, his questions were searching and persistent, and his checklist items were adequate. The audit of these criteria was effective and SNL implementation under these criteria is adequate.

(b) Control of Measuring and Test Equipment (Criterion 12)

Three items of Measuring and Test Equipment (M&TE) were due for calibration between the time of the last DOE audit of this criteria and this present audit. The certification document for one of these items was missing, but a copy was obtained prior to the close of this audit.

Although this portion of the audit was not supported by a checklist, the auditor did a thorough job, and was careful to check for details and objective evidence. The audit of this criterion was effective, and SNL implementation under this criterion is adequate.

(c) Audits (Criterion 18)

The auditors used the checklists as the basis for reviewing documents and discussions with SNL personnel. SNL NWRT auditors have performed only one audit since the last DOE audit of this criteria; the audit was of the National Center for Atmospheric Research (NCAR) in Boulder, Colorado. NCAR is working under the SNL NWRT QA program, rather than developing an NCAR QA program. During the audit of Criterion 7, the auditor reviewed the NCAR letter stating that NCAR would work under the SNL NWRT QA program.

The report for Audit No. NCAR-A91-1 was adequate, and identified a number of deficiencies which NCAR is resolving. The report was issued within 30 days of completion of the audit. Audit report NCAR-A91-1 appropriately captured the pertinent facts from the audit checklists, which were reviewed by the auditors and the NRC observer.

Review of surveillances was also covered under this criterion. Five surveillances were conducted by the SNL NWRT QA Division since the last YMQAD audit. No deficiencies were identified related to surveillances.

The auditors were thorough in their review of documents and questioning of SNL and contractor personnel; and probed as required to follow up checklist items. The audit of this criterion was effective, and SNL implementation under this criterion is adequate.

5.4 Conduct of Audits

This audit was performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the SNL's QA program. The audit checklists generally included the important controls addressed in SNL's QAPD. The auditors used the checklists effectively during the interviews with personnel and review of documents. The observers were kept well informed during the entire audit.

5.5 Qualification of Auditors

The qualifications of the QA auditors on this audit team had been previously reviewed by the NRC staff and found to be acceptable, meeting the requirements of Yucca Mountain Site Characterization Project Office Quality Management Procedure (QMP)-02-02, "Qualification of Quality Assurance Program Audit Personnel."

5.6 Audit Team Preparation

The auditors were prepared in the areas they were assigned to audit and knowledgeable in the SNL QA procedures. Overall, Audit Plan YMP-92-09 was complete and included: (1) the audit scope; (2) a list of audit team personnel; (3) a list of the audit activities; (4) the audit notification letter; (5) the appropriate SNL QA procedures; and (6) the QA checklists except as previously noted. (See Section 5.3)

5.7 Audit Team Independence

The audit team members did not have prior responsibility for performing the activities they investigated. The audit team members had sufficient independence to carry out their assigned functions in a correct manner without adverse pressure or influence.

5.8 Review of Previous Audit Findings

There were no previous unresolved audit findings to review.

5.9 Summary of NRC Staff Findings

(a) Observations

The NRC staff did not identify any observations relating to deficiencies in either the audit process or of SNL QA program implementation.

(b) Weaknesses

The SNL NWRT QAPD, Revision 00, effective date July 29, 1991, was in effect for this audit. The NRC staff had not received this document by the time of the audit in mid-February 1992. The NRC staff is concerned that quality assurance documents are not being forwarded to the NRC in a timely fashion.

(c) Good Practices

The auditors were well prepared, thorough, and displayed acceptable knowledge of the appropriate SNL procedures.

5.10 Summary - YMQAD Audit Team Findings

The audit team wrote one potential CAR against SNL's QA program, concerning the lack of objective evidence of planning for readiness reviews. (See Section 5.3 (a)).