U. S. NUCLEAR REGULATORY COMMISSION

OBSERVATION AUDIT REPORT NO. 93-02

FOR THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION

AUDIT NO. YMP-93-02 OF LOS ALAMOS NATIONAL LABORATORY

11/17/92
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1.0 INTRODUCTION

During November 2-5, 1992, U.S. Nuclear Regulatory Commission staff members participated as observers of the U.S. Department of Energy, Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance, Yucca Mountain Quality Assurance Division (YMQAD) Quality Assurance (QA) Audit No. YMP-93-02 of the Los Alamos National Laboratory (LANL)-Yucca Mountain Project (YMP) QA program at the LANL-YMP offices in Los Alamos, New Mexico. The audit scope included six QA programmatic areas and four technical areas.

This report addresses the effectiveness of the YMQAD audit and the adequacy of implementation of QA controls in the audited programmatic areas of the LANL-YMP QA program.

2.0 OBJECTIVES

The objective of the YMQAD audit was to evaluate the implementation and effectiveness of the LANL-YMP QA program in meeting the applicable requirements of the OCRWM Quality Assurance Requirements Document (QARD), the LANL-YMP Quality Assurance Program Description (QAPD), the LANL-YMP Software Quality Assurance Plan (SQAP), and associated LANL-YMP implementing procedures.

The NRC staff's objective was to gain confidence that YMQAD and LANL-YMP are properly implementing the requirements of their QA programs in accordance with the QARD and Title 10 Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the YMQAD audit process and the LANL-YMP QA program on direct observations of the auditors; discussions with audit team, LANL-YMP, and contractor personnel; and reviews of the audit plan, the audit checklists, and pertinent LANL-YMP documents. The NRC staff has determined that YMQAD QA Audit No. YMP-93-02 was useful and effective. 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 adequately described in the audit plan.

The NRC staff agrees with the preliminary YMQAD audit team findings that the LANL-YMP QA program has adequate procedural controls in place and that QA program implementation in the areas audited is generally adequate. Three preliminary Corrective Action Requests (CARs) were identified by the YMQAD audit team. However, one of them was acceptably addressed by the LANL-YMP organization during the audit, leaving only two preliminary CARs outstanding. None of the three

CARs identified by the YMQAD audit team are significant in terms of the overall LANL-YMP QA program.

OCRWM should closely monitor the LANL-YMP QA program to ensure that the deficiencies identified during this audit and earlier audits and surveillances are corrected in a timely manner and future implementation is carried out effectively. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audits later to assess the LANL-YMP QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

John G. Spraul	Observation Audit Team Leader	
Pauline P. Brooks	Observer	
Robert D. Brient	Observer	Center for Nuclear Waste Regulatory Analyses

4.2 DOE

Frank J. Kratzinger	Audit Team Leader (ATL)	Science Applications International Corp. (SAIC)
Amelia I. Arceo	Auditor	SAIC
John R. Matras	Auditor	SAIC
John E. Thereien	Auditor	SAIC
Thomas E. Vandel	Auditor	MAC Technical Services Co.
Richard L. Weeks	Lead Technical Specialist	SAIC
Neil D. Cox	Technical Specialist	SAIC
Nile O. Jones	Technical Specialist	Management and Operating Contractor
Donald Horton	Observer	OCRWM Headquarters

4.3 State of Nevada

Susan Zimmerman	Observer

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This audit was conducted in accordance with OCRWM QA Administrative Procedures 18.2, "Audit Program," Revision 5, and 16.1, "Corrective Action," Revision 4. The NRC staff observation audit of this YMQAD audit of LANL-YMP 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 determine whether the LANL-YMP QA program meets the requirements imposed by the QARD and to assess the extent and effectiveness of implementation of the program. Technical areas were audited for compliance with procedural controls. The technical specialists reviewed the adequacy of the technical procedures, the LANL-YMP staff's understanding of the procedural requirements, and the technical qualifications of the LANL-YMP design staff. The audit scope included six QA programmatic elements and four technical areas.

(a) QA Programmatic Elements

The programmatic portion of the audit utilized checklists based on the requirements in the LANL-YMP QAPD, the LANL-YMP SQAP, and associated LANL-YMP implementing procedures. The checklists covered QA program controls for the six QA programmatic elements listed in Section 5.3 below. LANL, at present, has no design function. Therefore, auditing of QA Programmatic Element 3.0, "Design Control," was conducted simultaneously with auditing of QA Programmatic Elements 19.0, "Software QA," and 20.0, "Scientific Investigations."

(b) Technical Areas

Checklists based on LANL-YMP procedures and applicable scientific investigation study plans were developed by the auditors and the technical specialists to examine scientific notebooks, computer codes, and other documents for four technical areas:

Work Breakdown Structure Number (WBS) 1.2.3.2.1.1.1 - Mineralogy, Petrology, and Rock Chemistry of Transport Pathways

WBS 1.2.3.2.1.1.2 - Mineralogical and Geochemical Alteration

WBS 1.2.3.3.1.2.2 - Water Movement Tracer Tests

WBS 1.2.3.3.1.3.1 - Site Saturated Zone Ground Water Flow System.

Two audit sub-teams of a QA programmatic auditor and a technical specialist audited the four technical areas. The technical specialists on the YMQAD Audit Team evaluated LANL-YMP personnel technical qualifications, their procedural understanding, and the adequacy of applicable technical procedures.

Because no technical specialists were included on the NRC observation audit team, technical products were not evaluated by the NRC staff. Discussion of technical areas is incorporated in the discussion of QA programmatic elements. The NRC did not observe the audit of WBS 1.2.3.3.1.2.2 - Water Movement Tracer Tests.

5.2 Timing of the Audit

The NRC staff believes the timing of this audit, November 2-5, 1992, was appropriate to verify corrective actions from previous YMQAD audits and for the staff to evaluate the YMQAD audit process and the LANL-YMP QA program. Although only a little more than 6 months had passed since the last audit of the areas covered by this audit, this audit was timely because 1) the developers of the software QA program had left LANL-YMP shortly after software QA was last audited, 2) the technical programs audited during this audit were different from the technical programs of the prior audit, and 3) LANL-YMP may be providing design input for the current Exploratory Studies Facility design activities.

5.3 Examination of Programmatic Elements

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

3.0 Design Control
4.0 Procurement Document Control
7.0 Control of Purchased Material, Equipment, and Services
8.0 Identification and Control of Items
19.0 Software QA
20.0 Scientific Investigations

QA Program Elements 10.0, "Inspection;" 11.0, "Test Control;" and 15.0, "Control of Nonconforming Items" were determined by YMQAD to be not applicable at LANL because LANL has no current activities to which these elements apply.

The NRC staff observed the YMQAD audit team's evaluation of each of the QA programmatic elements audited. The NRC staff's observations regarding each of these QA programmatic elements are discussed below. The discussion of technical areas is also included.

(a) Design Control/Software QA (Programmatic Elements 3.0/19.0)

The audit checklist for this programmatic element was based on LANL-YMP's SQAP and Quality Administrative Procedures (QPs) TWS-QAS-QP-03-17 and TWS-QAS-QP-03-19 through 03-22 which provide requirements for software QA. The audit checklist contained 31 items to be examined, evaluated, or verified. Each of these items was addressed during the audit. The auditor reviewed the LANL codes discussed below as they relate to the LANL-YMP.

LANL's Software Management Status Report, dated October 13, 1992, includes a list of some 141 qualified (that is, verified and validated) software packages released by

LANL for quality-affecting use. Documentation associated with one of these packages, CDFTOOLS, was examined in detail and discussed with involved LANL personnel by the auditor. Other conceptual code packages that are approaching the release stage, such as FEHMN, SORBEQ, and FRACNET, were similarly reviewed. The development effort for each of these codes is graded as quality-affecting, and the current development activities are in accordance with the SQAP.

Although two CARs resulted from this portion of the audit, both were minor with one that reflected acceptable practices that were not in strict conformance with the applicable procedure such that the procedure will probably be changed rather than the practices. The auditor and the observer concluded that Programmatic Elements 3.0/19.0 have been adequately implemented.

The auditor was competent, thorough, used the checklists appropriately, and performed a useful and effective audit. The auditor determined that implementation of the LANL-YMP program for software QA was acceptable. The NRC observer agrees with the auditor's findings.

(b) Design Control/Scientific Investigations (Programmatic Elements 3.0/20.0)

Additional auditing for Programmatic Element 3.0 was conducted simultaneously with evaluations of the four identified technical areas (Programmatic Element 20.0): Mineralogy, Petrology, and Rock Chemistry of Transport Pathways; Mineralogical and Geochemical Alteration; Water Movement Tracer Tests; and Site Saturated Zone Ground Water Flow System. The auditor and technical specialist of each sub-team worked well together. The technical specialist usually led the initial discussion with members of the LANL-YMP technical staff with the QA programmatic auditor interjecting to discuss programmatic issues.

The programmatic checklist for scientific investigations was used by both sub-teams and was applied, in total, to each technical activity. Requirements for the checklist were developed solely from LANL-YMP QPs covering the documentation of scientific investigations, peer reviews, preparation and review of technical products and study plans, and submittal and review of design and test-related information. However, there are some technical activities (qualification of existing data, for example) that LANL-YMP plans to perform in accordance with YMP procedures. Since the checklist did not include requirements from YMP procedures, some key elements of the OCRWM QA program could have been insufficiently evaluated. In this audit, no adverse impact was apparent, due primarily to the lack of implementation of affected activities. This condition is reported as a weakness in Section 5.9.

Existing data qualification and peer reviews had not been performed for the technical activities audited, so implementation could not be verified. Implementation of QPs TWS-QAS-QP-03.5, "Documenting Scientific Investigations," and LANL-YMP-QP-

03.23, "Preparation and Review of Technical information Products and Study Plans," was verified during the technical audit. Scientific notebooks (both laboratory and field) and log books provided an ample sample to evaluate TWS-QAS-QA-03.5. Few technical information products had been completed, and only 1 (draft) study plan that had been developed to the current procedure was available for review.

Activities governed by LANL-YMP-03.24, "Submittal of Design and Test-Related Information," and LANL-YMP-03.25, "Review of Design and Test-Related Information," were determined to be performed only at the LANL office in Las Vegas, NV, so these procedures were audited on November 6, 1992, in Las Vegas. The NRC did not observe this portion of the audit. LANL-YMP has not performed design activities, *per se*, but will provide information to the Regulatory Information Base that may become design input.

One preliminary CAR concerning missing entries on the first page of one Scientific Notebook was initiated in this program area and corrected during the audit. Overall, these programmatic elements appeared to be audited sufficiently by YMQAD and implemented adequately by LANL-YMP. The effectiveness of controls for peer reviews and existing data qualification was indeterminate due to the lack of implementation. LANL-YMP staff, both technical and QA, demonstrated a good understanding and interest in implementing the QA program.

The NRC observer determined that the auditors did a thorough and effective audit on these programmatic elements and agrees with the audit team finding that Programmatic Elements 3.0/20.0, where implemented, have been adequately implemented.

(c) Procurement Document Control/Control of Purchased Items and Services (Programmatic Elements 4.0/7.0)

The YMQAD auditor used a prepared checklist consisting of nine multiple-part questions based on LANL-YMP-QP-04.4, "Procurement of Commercial-Grade Items and Services," (effective 11/91) and eight multiple-part questions based on LANL-YMP-QP-04.5, "Procurement of Noncommercial-Grade Items and Services" (effective 12/91). The auditor examined all of the LLNL-YMP procurement packages, concentrating on those that had been closed since these procedures became effective. The auditor was persistent and thorough, probing beyond the checklist when necessary and undertaking a review of associated objective evidence as needed. Only one of the procurement packages examined was non-commercial, and it had not been closed at the time of the audit. The auditor concluded that implementation of LANL-YMP-QP-04.4 was adequate. The auditor concluded that implementation of LANL-YMP-QP-04.5 was indeterminate because of its limited use.

The audit of this area was effective. The NRC observer agrees with the auditor's conclusion that implementation of Programmatic Elements 4.0 and 7.0 has been

adequate for commercial grade items and indeterminate for noncommercial-grade items.

(d) Identification and Control of Items (Programmatic Element 8.0)

The auditor of this programmatic element visited the various laboratories to verify appropriate identification and control of samples. Each of the divisions of LANL performing YMP activities has individual sample management needs, and each was controlling its samples in accordance with its specific division procedures. The auditor's checklist was developed from LANL-YMP-QP-08.1, "Identification and Control of Samples," on which the division procedures are based. A sufficient number of samples - stored in dedicated storage rooms, in the offices of Principal Investigators, and in laboratory storage cabinets - were examined and their traceability to scientific notebooks verified.

The audit of this programmatic element was effective and the NRC observer agrees with the auditor's conclusion that its implementation by LANL-YMP has been adequate.

5.4 Examination Of Technical Areas

As noted above, NRC staff review of technical areas is reported in Section 5.3 in conjunction with the results of the examination of QA programmatic elements. Because no technical specialists were included on the NRC observation audit team, technical products were not evaluated by the NRC staff.

5.5 Conduct Of Audit

The audit was productive and performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the LANL-YMP QA program. A weakness regarding the audit checklists is discussed in Section 5.9(b). In general the YMQAD audit team was persistent in its interviews and challenged responses when necessary. Daily caucuses were held between auditors and observers, and daily audit status meetings were held between LANL-YMP management and the ATL to discuss the preliminary findings. The auditors who identified concerns were included in these meetings to more clearly explain their concerns.

5.6 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 YMPO Quality Management Procedure 02-02, "Qualification of Quality Assurance Program Audit Personnel."

5.7 Audit Team Preparation

The auditors were prepared in the areas they were assigned to audit and were knowledgeable of the LANL-YMP procedures. The audit plan for this audit included (1) the audit scope, (2) the audit schedule, (3) a list of audit team personnel, (4) a list of the activities to be audited, and (5) audit checklist references. However, a weakness reported in Section 5.10(b)1 of Observation Audit Report 93-01 was present in the audit plan for this audit. That is, the audit plan neither prescribed nor referenced criteria for conducting the technical evaluation portion of the audit.

5.8 Audit Team Independence

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

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 the LANL-YMP QA program implementation.

(b) Weakness

The NRC staff noted that the technical checklists did not address the area of existing data qualification. Further investigation showed that LANL-YMP intends to use the YMPO procedure if it gets involved in this area. Since the audit checklists are based on LANL-YMP procedures and there was no LANL-YMP procedure to cover this area, the checklists did not cover this area. We recommend that future checklist preparation use the auditee's matrix of procedures versus requirements to ensure that all applicable procedures are addressed in the checklists.

(c) Summary

The NRC staff agrees with the preliminary audit team findings that the LANL-YMP QA program has adequate procedural controls in place and implementation in the areas audited is satisfactory.

5.10 Summary - YMQAD Audit Findings

As a result of this audit, the audit team developed three preliminary CARs against the LANL-YMP program, one of which was resolved during the audit [See Section 5.3(b)]. In addition, the audit team produced several recommendations to improve the

LANL-YMP QA program. A summary of the two preliminary CARs which were not closed during the audit is presented below.

Programmatic Element	CAR
19.0	Three individuals signed SQA documents as "Change Control Authority" with no evidence that they had been authorized to do so by the Change Control Board as required by TWS-QAS-QP-03.20.
19.0	Issues identified during early review of software baseline submittals were not handled in accordance with the requirements specified in TWS-QAS-QP-03.17. That is, the "Disposition" block of the Baseline Submission Summary was not checked "Not Accepted," and the proposed baseline was not removed from the LANL-YMP certification environment.