

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 92-09
FOR THE YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION
AUDIT NO. YMP-92-12 OF LOS ALAMOS NATIONAL LABORATORY


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1.0 INTRODUCTION

From March 17-20, 1992, members of the U.S. Nuclear Regulatory Commission (NRC) quality assurance (QA) and technical staff participated as observers on the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Yucca Mountain Quality Assurance Division (YMQAD), QA Audit No. YMP-92-12 of the Los Alamos National Laboratory (LANL) in Los Alamos, New Mexico. The audit scope was limited to four QA program elements and five technical areas.

This report addresses the effectiveness of the DOE/YMQAD audit and the adequacy of the LANL QA program.

2.0 OBJECTIVES

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

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the DOE/YMQAD audit process and the LANL QA program on direct observations of the auditors, discussions with audit team and LANL personnel, and reviews of pertinent audit information (e.g., audit plan, checklists, and LANL documents). The audit was well organized and conducted in a professional manner with minimal logistic delays. The audit team was well qualified in the QA and technical disciplines, and the assignments and checklist items were adequately described in the audit plan.

The NRC staff determined that the audit was effective, and implementation of the LANL QA program was adequate for the four programmatic elements and five technical areas that were audited. One deficiency for the LANL QA program was noted and added to an existing deficiency report because it was similar in nature. A second deficiency will be issued to the Yucca Mountain Site Characterization Project Office. These deficiencies are not significant in terms of the overall QA program and did not affect the quality of any LANL site characterization activities.

DOE should continue to monitor the LANL QA program to ensure that it is implemented adequately. The NRC staff expects to participate in this monitoring as observers and may perform its own audits at a later date to assess the adequacy and effectiveness of the LANL QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

William L. Belke	Observation Team Leader
Neil M. Coleman	Observer
Pauline P. Brooks	Observer
Bruce E. Mabrito	Observer (Center for Nuclear Waste Regulatory Analyses)

4.2 DOE

Stephen R. Dana	Science Applications International Corp. (SAIC)	Audit Team Leader (ATL)
Sandra D. Bates	SAIC	Auditor
Neil D. Cox	SAIC	Auditor
Gerald Heaney	SAIC	Auditor
John S. Martin	SAIC	Auditor
Paul L. Cloke	SAIC	Technical Specialist
Ardyth M. Simmons	DOE/Yucca Mountain Site Characterization Project (YMP)	Technical Specialist

4.3 STATE OF NEVADA

Susan Zimmerman	Observer
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5.0 REVIEW OF THE AUDITED ORGANIZATION

The DOE/YMQAD audit was conducted in accordance with OCRWM QA Administrative Procedure (QAAP) 18.2, "Audit Program," Revision 5, and OCRWM QAAP 16.1, "Corrective Action," Revision 4.

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

5.1 PURPOSE/SCOPE OF AUDIT

The purpose of the audit was to evaluate the implementation and effectiveness of the LANL QA program relative to the control of scientific investigations; instructions, procedures, plans, and drawings; document control; and QA records.

(a) Programmatic Elements

The auditors used checklists based on the requirements in the LANL QA Program Plan (QAPP) Sections 3.0, 5.0, 6.0, 17.0, and 19.0 (10 CFR 50 Appendix B Criteria III, V, VI, and XVII), and other applicable documents pertaining to QA controls.

(b) Technical Areas

The technical activities selected by DOE/YMQAD to be reviewed during this audit were:

- (1) Work Breakdown Structures (WBS) 1.2.3.4.1.2.1 and 1.2.3.4.1.2.3, Batch Sorption Studies and Sorption Models;
- (2) WBS 1.2.3.4.1.2.2, Biological Sorption and Transport;
- (3) WBS 1.2.3.4.1.3, Radionuclide Retardation by Precipitation Processes;
- (4) WBS 1.2.3.4.1.4, Radionuclide Retardation by Dispersive, Diffusive, and Advective Processes; and
- (5) WBS 1.2.3.4.1.5.1, Retardation Sensitivity Analysis

5.2 TIMING OF THE AUDIT

The NRC staff believes the timing of the LANL QA audit was acceptable, even though there was limited quality-affecting work being performed in the areas being audited, i.e., most of the work appeared to be of a "development" or "scoping" nature conducted under the approved LANL QA program that could eventually be applied towards quality-affecting activities.

5.3 EXAMINATION OF PROGRAMMATIC ELEMENTS

The programmatic checklists covered the QA program controls for the four criteria or programmatic elements listed below:

- 3.0 Scientific Investigation Control (including Software Control)
- 5.0 Instructions, Procedures, Plans, and Drawings
- 6.0 Document Control
- 17.0 Quality Assurance Records

The NRC staff observed the audit team's evaluation of selected programmatic and technical elements of the LANL QA program. Only portions of some elements were observed. Therefore, some deficiencies identified by the audit team were not observed by the NRC staff. Such deficiencies will not be discussed in detail in this report.

(a) Scientific Investigation Control (including Software Control)
(Criterion 3)

The checklist was prepared based on LANL implementing procedures TWS-QAS-QP-03.2, "Preparation and Technical and Policy Review of Technical Information Products," TWS-QAS-QP-03.3, "Preparation and Review of SCP Study Plan," and TWS-QAS-QP-3.5, "Documenting

Scientific Investigations." The QA auditor combined this effort in concert with the technical specialist's evaluation of biological sorption and transport, radionuclide retardation by precipitation processes, and radionuclide retardation by dispersive, diffusive, and advective processes.

During this portion of the audit, the audit team visited several of the laboratory areas that were involved in scientific studies pertaining to microbiological techniques, radiological transport, spectroscopic analysis, laser technology, and core samples. In all of the laboratory areas that were visited, instrumentation was found to be clearly identified, calibrated, and accurately documented in laboratory notebooks. Laboratory notebooks were found to be neatly kept, consecutively numbered, clearly written in ink, and could be readily understood by any user. All corrections were lightly made with a single line stroke, initialed, and dated. Completed laboratory notebooks were verified as being independently reviewed by a technically qualified reviewer, signed and dated with any appropriate remarks (if necessary). Core samples and associated testing materials were properly identified and stored.

The auditor and technical specialist were well prepared and knowledgeable in the requirements that they were auditing and persistent in their interviews and document reviews. There were some questions on the technical checklist that could have been asked during the Study Plan technical review or could have possibly been answered during the audit preparation. However, this did not interfere with the technical portion of the audit or the technical specialist's conclusion. The NRC staff commented that, for the next audit, checklist questions should be reviewed more carefully to determine those areas that can possibly be answered prior to the audit. Overall, the auditor and technical specialist used the published checklists effectively during the audit process and the audit was observed to be effective. The NRC staff agrees with the audit team's conclusion that the implementation of the QA program for Scientific Investigation Control was adequately implemented.

LANL has developed and implemented a state-of-the-art program for software quality assurance. The system is designed to minimize paperwork by maximizing the use of computer tracking systems to document the entire software QA process. Elements of this program include software planning, review and approval, code and data maintenance and verification, software modifications, and model validation. This QA program provides a framework within which software can be developed and approved by formal reviews and configuration audits.

A Technical Software Management Group is responsible for managing all LANL YMP software and computational data used to support licensing. Their responsibilities include administering and enforcing the software QA plan and maintaining an archive of certified software and data for use within the LANL YMP. They also distribute certified software to external participants. The groups that develop and use technical software are organizationally independent from the Technical Software Management Group.

A Configuration Control Board (CCB) is responsible for authorizing development of new software and evaluating the technical merit of all proposed changes to software. The CCB also provides a forum for formal reviews of software and computational data.

Specific procedures that support the Software Quality Assurance Plan include the following:

TWS-QAS-QP-03.17, RO	Reviews of Software and Computational Data
TWS-QAS-QP-03.18, RO	Creation, Management, and Use of Computational Data
TWS-QAS-QP-03.19, RO	Documentation of Software and Computational Data
TWS-QAS-QP-03.20, RO	Software Configuration Management
TWS-QAS-QP-03.21, RO	Software Life Cycle
TWS-QAS-QP-03.22, RO	Verification and Validation of Software and Computational Data

Before new software can be developed, the CCB specifies a "life-cycle" that is appropriate for the software. This is based on the designated "class" of the software. Examples include Administrative Data Base Application (ADB), Scientific and Engineering Software (SES), and Technical Data Base Application (TDB). There are four "life-cycle" phases that software can undergo, including (1) requirements, (2) design, (3) implementation, and (4) operation. Not all software must pass through all four phases. For example, the minimum life-cycle requirement for ADB software does not include the requirements and design phases, whereas the SES class does require these phases.

The audit of this area was effective, and the staff agrees with the audit team evaluation that implementation of LANL Software QA program under this criterion was adequate.

(b) Instructions, Procedures, Plans, and Drawings and Document Control
(Criteria 5/6)

The auditor covered 41 separate checklist items for these criteria and went beyond the audit checklist when necessary. Sufficient sampling of the document control process was performed which provided confidence that the LANL Quality Assurance Program Plan (QAPP) and implementing procedures were being complied with acceptably. The auditor performed a review of 53 LANL technical procedures to verify that preparation, review, and approval of these technical procedures were in compliance with the LANL QAPP and implementing procedures and none were found deficient.

Overall, the auditor conducted a sufficiently detailed review of Criteria 5 and 6 to determine that these criteria were being satisfactorily implemented. The audit for these areas was effective and the NRC staff agrees with the auditor's conclusion that implementation was adequate.

(c) Records (Criterion 17)

The auditor used a prepared checklist consisting of 15 requirements and probed beyond the checklist when necessary. Fourteen requirements were taken from the implementing procedure, LANL-YMP-QP-17.3, "Records Management," and one from Section 17 of the LANL QAPP on records.

During the course of auditing Criterion 17, the auditor identified three deficiencies in the QA records program. None of the deficiencies were written as new Corrective Action Requests (CARs). Two of the deficiencies were minor and were corrected during the course of the audit. The third deficiency was added to an existing CAR from the previous March 1991 audit. This deficiency cites an inconsistency between the LANL QAPP, which requires LANL to maintain a list of signatures and initials for personnel authorized to authenticate records, and the implementing procedure. LANL had not incorporated this requirement into the implementing procedure.

The auditor was persistent in interviewing responsible personnel and thorough in using the prepared checklist questions and in reviewing the associated objective evidence. The audit of this area was effective. The NRC staff agrees with the auditor's conclusion that the implementation of Criterion 17 was satisfactory.

5.4 EXAMINATION OF TECHNICAL PRODUCTS

NRC staff observed the audit of the following technical activities, all related to QA Criterion 3:

SITE CHARACTERIZATION PLAN STUDIES	TOPICS
8.3.1.3.4.1	Batch sorption studies
8.2.1.3.4.3	Development of sorption models
8.3.1.3.7.1.	Retardation sensitivity analysis

The auditor and technical specialist appeared well prepared and capable. Excellent coordination was observed between the technical specialist and the QA auditor. The technical portion of the audit was very detailed, including extensive review of scientific notebooks and procedures. The review process for study plans, including resolution of technical comments, was not examined because none of the audited study plans have been approved by the DOE.

Scientific notebooks that were reviewed had been well maintained and provided adequate documentation for the ongoing work. This work is being documented using LANL Procedure No. TWS-QAS-QP-3.5, RO, "Procedure for Documenting Scientific Investigations." This procedure outlines QA requirements for field and laboratory notebooks and logbooks.

5.5 CONDUCT OF AUDIT

The QA programmatic and technical portions of the audit were productive and performed in a professional manner. The audit team was well prepared and demonstrated a sound knowledge of the QA and technical aspects of the LANL program. The audit checklists included the important controls addressed in LANL's QAPP. The audit team used the comprehensive checklists effectively during the interviews and review of documents. When appropriate, the auditors extended their investigations beyond the checklists. Daily caucuses were held between the observers and auditors in addition to the daily audit meetings between LANL management and the ATL. In general, the audit team was persistent in its interviews, challenging responses when necessary. Observers were kept well informed during the entire audit.

5.6 QUALIFICATION OF AUDITORS

The qualification of the QA auditors on the audit team were acceptable to the NRC staff in view of the requirements of QAAP 18.1, the Yucca Mountain Site Characterization Project Office procedure for qualifying auditors.

5.7 AUDIT TEAM PREPARATION

The auditors were prepared in the areas they were assigned to audit and knowledgeable in the LANL QAPP, technical requirements, and implementing procedures. The Audit Plan/Book for YMP-92-12 only included the QA programmatic checklists, the technical checklists, the list of the daily audit activities, and the November 1991 LANL Monthly Activity Report. Not included, as in past Audit Plans/Books, were: (1) the audit notification letter (sent/received prior to this audit); (2) the LANL QAPP; and (3) the previous audit report of LANL, including CARs and their resolution.

5.8 AUDIT TEAM INDEPENDENCE

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

5.9 REVIEW OF PREVIOUS AUDIT FINDINGS

- (a) There were two open CAR from previous audit findings. As a result of verifying acceptable corrective action implementation on this audit, one of the CARs was closed. An audit finding similar in nature was added to the existing open CAR.
- (b) The NRC staff did not have any Observations from previous audits relating to this audit that required resolution.
- (c) Based on discussions between the State of Nevada and NRC observers, the State of Nevada observations appeared to have been resolved during this audit.

5.10 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 other elements of LANL QA program implementation.

(b) Weaknesses

Three Audit Observer Inquiry forms were initiated by the NRC staff during the audit process. Responses to these inquiries were informally discussed but never formally documented and closed out. The Audit Observer Inquiry forms were never returned to the NRC staff and consequently, the NRC staff did not document and acknowledge receipt of the auditee response in order to close out the inquiry response. The policy for the use of these forms was established and documented in Quality Management Procedure QMP-18-01. However, the NRC is unable to locate any documentation or procedural guidance related to the use of the Audit Observer Inquiry form. DOE should consider developing guidance to control the use of this form for future audits.

(c) Good Practices

(1) The entire LANL staff demonstrated an impressive positive attitude of embracing the concept of QA as a valuable tool for improvement rather than objecting to its presence. LANL staff was constantly receptive to any suggestions or audit findings that would better their operation. Several LANL people commented on the recent DOE Tiger team assessment and how it made LANL a safer and improved facility. This positive attitude and dedicated commitment to quality may be attributed, in part, to the comprehensive six hour QA orientation training program developed as result of a collective effort by involved LANL staff.

(2) There was evidence of improved technical communication between various DOE contractors. Along with the previously existing Hydrology Integration Task Force (HITF), there now exists a Geochemistry Integration Task Force (GITF) which has held two meetings. A joint meeting of these two groups is now being planned, providing a mechanism for principal investigators in the hydrology and geochemistry disciplines to meet and coordinate on related technical projects. The NRC observer was informed that the GIT includes representatives from the following organizations: YMPO, USGS, LANL, Lawrence Livermore, Sandia, and SAIC.

5.11 SUMMARY - DOE/YMQAD AUDIT TEAM FINDINGS

The audit team identified one potential CAR written against the LANL QA program. The audit finding pertained to a procedural requirement that was not being implemented and was similar in nature to the findings documented on a previously written CAR. Consequently, this finding was added to the existing open CAR (See Section 5.3).

Another potential CAR was identified against the Yucca Mountain Site Characterization Project Office for a grading activity which was funded under the international program and inappropriately included under a WBS.