

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. 91-6
FOR THE YUCCA MOUNTAIN PROJECT OFFICE
AUDIT NO. 91-03
OF LOS ALAMOS NATIONAL LABORATORY

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1.0 INTRODUCTION

From March 25-29, 1991, members of the U.S. Nuclear Regulatory Commission (NRC) staff participated as observers on the U.S. Department of Energy (DOE)/Yucca Mountain Site Characterization Project Office (YMPO) Quality Assurance (QA) Audit No. 91-03 of Los Alamos National Laboratory (LANL), which was conducted in Los Alamos, New Mexico. LANL, a participant in the Yucca Mountain Site Characterization Project (YMP), is responsible for radionuclide migration, geochemistry, mineralogy, and petrology studies, and is the lead organization for the coordination and scheduling of the site characterization activities in the Exploratory Studies Facility. This report addresses the effectiveness of the DOE/YMPO audit and the adequacy and effectiveness of implementation of the LANL QA program for YMP work.

2.0 OBJECTIVES

The objectives of the DOE/YMPO audit were to determine the adequacy and effectiveness of implementation of the LANL QA program in meeting the applicable requirements of the DOE Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements Document (QARD) for the YMP work. The NRC staff's objective was to gain confidence that DOE and LANL are properly implementing the requirements of their QA programs by evaluating the effectiveness of the DOE/YMPO audit and determining whether the LANL QA program is in accordance with the requirements of the OCRWM QARD and Title 10 of the Code of Federal Regulations, Part 50 (10 CFR Part 50), Appendix B.

3.0 SUMMARY AND CONCLUSIONS

The NRC staff based its evaluation of the DOE/YMPO audit process and the LANL QA program on direct observations of the auditors, discussions with the audit team, and reviews of the pertinent audit information (e.g., audit plan, checklists, and LANL documents).

The NRC staff found that, overall, DOE/YMPO Audit No. 91-03 of LANL was effective. The programmatic and technical portions of the audit, including their subsequent integration, were effective. The NRC staff concluded that the DOE/YMPO audit team, in general, was well qualified and prepared and conducted the audit in a professional manner. The audit team was familiar with the requirements of the OCRWM QARD and the LANL Quality Assurance Program Plan (QAPP) and their checklists were well prepared and used effectively.

The NRC staff agrees with the preliminary DOE/YMPO audit team findings that: 1) the LANL QA program, in general, is adequate to control QA-related activities, and 2) LANL, overall, is satisfactorily implementing an effective quality assurance program in accordance with the LANL QAPP and procedures. The NRC staff also agrees with the audit team's conclusion that one specific element of the LANL QAPP (Section 13, Handling, Storage and Shipping) was considered indeterminate due to lack of activity.

The audit team identified 10 deficiencies during the audit, and all but one were resolved prior to the post-audit conference. The one unresolved deficiency was related to inconsistencies between the LANL QAPP and implementing procedures. This deficiency was documented by the audit team in a Corrective Action Request (CAR) No. YM-91-041.

DOE/YMPO should monitor the LANL QA program to ensure that the deficiency identified during this audit is corrected, and future implementation is carried out in an adequate manner. The NRC staff expects to participate in this monitoring as observers and may perform its own independent audit at a later date to assess the adequacy and effectiveness of the LANL QA program.

4.0 AUDIT PARTICIPANTS

4.1 NRC

| | | |
|------------------|----------|---|
| Tilak R. Verma | Observer | |
| John W. Bradbury | Observer | |
| Robert D. Brient | Observer | Center for Nuclear Waste Regulatory Analyses |

4.2 DOE

| | | |
|--------------------|----------------------|---|
| James Blaylock | Audit Manager | DOE/YMPO |
| Richard E. Powe | Audit Team Leader | Science Applications International Corporation (SAIC) |
| Neil D. Cox | Auditor | SAIC |
| Donald J. Harris | Auditor | Harza Engineering Company |
| John S. Martin | Auditor | SAIC |
| Richard L. Maudlin | Auditor | MAC Technical Services Co. |
| Kenneth T. McFall | Auditor | SAIC |
| Richard L. Weeks | Auditor | SAIC |
| Paul L. Cloke | Lead Technical Spec. | SAIC |
| Ardyth M. Simmons | Technical Spec. | DOE/YMPO |

4.3 State of Nevada

| | |
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| Susan Zimmerman | Observer |
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4.4 Clark County, Nevada

Engelbrecht von Tiesenhausen Observer

5.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The DOE/YMPO audit was conducted in accordance with OCRWM Quality Assurance Administrative Procedure (QAAP) 18.2, Revision 3, "Audit Program," and OCRWM QAAP 16.1, Revision 3, "Corrective Action Request".

The NRC staff observation of the DOE/YMPO audit was based on the NRC procedure "Conduct of Observation Audits" issued October 6, 1989. NRC observer findings are classified in accordance with this procedure. Levels 1, 2, and 3 of NRC Observations require a written response from DOE to be resolved. The NRC findings may also include weaknesses (actions or items which are not deficiencies but could be improved), good practices (actions or items which enhance the QA program), and requests for information required to determine if an action or item is deficient. Written responses to weaknesses identified by the NRC staff will be requested when appropriate. In general, weaknesses and items related to requests for information will be examined by the NRC staff in future audits or surveillances.

5.1 Scope of Audit

The Audit Plan for Audit No. 91-03 stated that the scope of the audit was to evaluate whether the LANL QA program meets the requirements and commitments imposed by OCRWM by verifying implementation and effectiveness of the system in place, as well as verifying compliance with requirements.

A representative sample of discrepancies identified during previous DOE/YMPO audits and surveillances of the LANL QA program were also included in the scope of this audit to determine the effectiveness of the LANL corrective actions.

(a) Programmatic Elements

The programmatic portion of the audit utilized checklists based on the requirements in the OCRWM QARD, LANL YMP QAPP, YMPO Administrative Procedures - Quality (APQ), and LANL Quality Assurance Procedures (QPs). The checklists covered QA program controls for fourteen of the eighteen 10 CFR Part 50, Appendix B criteria.

Criteria IX, X, XI and XIV of 10 CFR Part 50, Appendix B (Sections 9.0, 10.0, 11.0 and 14.0 of the OCRWM QARD and LANL YMP QAPP, Revision 5) were not included in the scope of the audit since LANL currently has no activities (i.e., engineered items) to which these criteria apply. The NRC staff has accepted this position and found the other 14 programmatic elements addressing Appendix B criteria acceptable in its review of the LANL QAPP (ref. Linehan/Stein letter dated November 1, 1989).

(b) Technical Areas

Five technical areas were selected by DOE/YMPO to be reviewed during the audit. The technical checklists were developed from information contained in LANL monthly Project Status Reports, Detailed (technical) Procedures (DPs), and Study Plans (SPs).

The audit team technical specialists were instructed to review the following personnel and procedural-type elements common to all the technical (subject) areas:

- ° Technical qualifications of LANL scientific investigation personnel (technical staff);
- ° LANL technical staff understanding of technical and QA procedural requirements as they pertain to scientific investigation activities;
- ° Adequacy of technical procedures; and
- ° Development of SPs, work supporting the Site Characterization Plan (SCP), and any related work products.

The audit plan specifically included the requirement to determine whether LANL had taken effective corrective actions to resolve discrepancies identified during previous DOE/YMPO audits and surveillances. The audit team was required to review the corrective actions for the Standard Deficiency Reports (SDRs) resulting from the March 1990 audit to determine if the corrective actions were acceptable and the CARs could be closed. As required by QAAP-18.2, Revision 3 the nature and frequency of previously identified deficiencies were considered in establishing the audit scope. The DOE/YMPO Audit Team Leader stated during the pre-audit briefing for the observers that NRC and State of Nevada findings from the previous DOE/YMPO audit of LANL were reviewed as input to the scope of this audit.

The programmatic scope of the audit was acceptable in that it appeared to cover all the 10 CFR Part 50, Appendix B criteria for which LANL had responsibility. The scope of the technical portion of the audit was also acceptable as it included two technical areas in which there was significant activity. The remaining three areas only had activities that were preliminary in nature.

5.2 Timing of the Audit

The NRC staff believes the timing of the QA audit was appropriate, since LANL had instituted many significant changes to its QA program since the last DOE/YMPO audit in March, 1990 and made significant progress in implementing its program.

5.3 Examination of Programmatic Elements

The DOE/YMPO programmatic checklists covered the QA program controls for the 14 elements listed below:

- 1.0 Organization
- 2.0 Quality Assurance Program
- 3.0 Scientific Investigation Control and Design Control
- 4.0 Procurement Document Control
- 5.0 Instructions, Procedures, Plans, and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Items, Samples and Data
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Shipping, and Storage
- 15.0 Control of Nonconformances
- 16.0 Corrective Action
- 17.0 Records
- 18.0 Audits

The NRC staff observed the audit team's evaluation of selected programmatic elements of the LANL QAPP. Only portions of some elements were observed. The details of program deficiencies identified by the DOE/YMPO audit team members which were not part of the portion observed will not be discussed in this report.

(a) Organization (Criterion 1)

Interviews were conducted by the DOE/YMPO auditors with the LANL Technical Project Officer (TPO), the LANL QA Project Leader, and Los Alamos Technical Associates QA support staff to obtain their description of the LANL project and QA organizations. The interviews were based on the checklist questions. The auditors also reviewed the LANL project and QA organization charts, and several QPs such as "Procedure for Interface Control," "Procedure for Stop Work Control," and "Procedure for Conflict Resolution."

Based on the depth of questioning and satisfactory completion of the audit checklist, the auditors adequately reviewed and evaluated the LANL organizational structure for compliance to the QARD and the QAPP. LANL has adequately implemented the requirements of its QAPP under Criterion 1.

(b) Quality Assurance Program (Criterion 2)

The auditors reviewed selected LANL personnel records files for compliance to QPs 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, and 2.9 requirements relating to readiness review, management assessment, qualification, education, experience, training, indoctrination and training development and review, and personnel proficiency evaluation. Record packages were reviewed for randomly selected personnel or individuals having performed technical activities. The auditors developed a matrix correlating individuals with their position description, training, and required records for documentation and verifications. The NRC observers reviewed some of the personnel records directly, and found the sample they reviewed to be adequate.

Based on the extent of the records reviewed and interviews conducted with the TPO and personnel records clerk, Criterion 2 was effectively audited, and the implementation by LANL appeared to be adequate.

(c) Scientific Investigation Control and Design Control (including Software Control) (Criterion 3)

Scientific Investigation Control and Design Control

The observed portion of the audit of Criterion 3 consisted of the evaluation of technical review documentation for Technical Information Products, which are essentially LANL technical reports, papers, and presentation abstracts. The auditor sampled 10 records packages (six for papers and four for abstracts) from several of the LANL YMP divisions, and evaluated document reviews and comment resolution and other associated documentation required by LANL procedure TWS-QAS-QP-03.2. No peer reviews had been performed in the past year. The audit was sufficient to determine that LANL is adequately implementing applicable requirements.

Software Quality Assurance

The LANL Software Quality Assurance (SQA) Plan and implementing procedures became effective on January 25, 1991, so implementation is just beginning. Approximately 40 software items, ranging from commercially available (common) software to in-house developed software for complex predictive models, have been placed under configuration control. The SQA Plan was about one year in development, and provides a graded approach based on the origin of the software and its application. This approach appears to provide documentation appropriate to the circumstances; relatively light documentation for commercial software in wide use and more extensive documentation for the more complex, unique, modeling software.

The auditors followed their checklists and reviewed most of the 40 or so Software Change Requests, which are completed to enter items into configuration control. In addition, associated Engineering Change Directives, Life Cycle Specifications and the few Software Requirements, Specifications and Verification and Validation Reports completed were reviewed. The Configuration Accounting Database, which provides automated configuration and software documentation capabilities, was demonstrated by LANL staff.

The SQA Plan was in the early stages of implementation at the time of the audit. The portions of the plan and its procedures that had been completed were effectively implemented.

(d) Procurement Document Control, and Control of Purchased Items and Services (Criteria 4 and 7)

Both procurement related criteria are implemented through LANL procedures QP-04.4, for commercial grade procurement, and QP-04.5, for non-commercial grade. Both procedures had been issued during December, 1990. Procurements prior to December, 1990, were evaluated in previous surveillances. During the portion of the audit observed, the auditor reviewed 10 of the 18 commercial grade procured items. No non-commercial grade procurement had been completed since issuing QA-04.5. QA Liaison personnel representing various LANL YMP divisions were interviewed, and records from the various divisions were reviewed to obtain a cross section of procurement activities. Commercial grade procurement appears adequately controlled and implemented; however, the effectiveness of non-commercial grade implementation could not be determined because of the lack of activity.

(e) Instructions, Procedures, Plans, and Drawings; and Document Control (Criteria 5 and 6)

As with Criteria 4 and 7, Criteria 5 and 6 are implemented through procedures of the QP-06 series, i.e., QP-06.1, QP-06.2, QP-06.3. The portion of the audit observed involved evaluation of compliance to QP-06.1, "Document Control." The auditor verified that the documents identified on distribution lists for four individuals were in their possession by looking through their respective QA manuals and procedures manuals. The same records and procedure had been evaluated during a February, 1991 Yucca Mountain Quality Assurance Division surveillance, so a more extensive review was unnecessary. The auditor discussed how document distribution is determined with several LANL QA liaison personnel. Essentially the work supervisor is responsible to assure that his/her personnel have procedures available when needed, and the worker or supervisor requests distribution as necessary. Based on the records reviewed, this method appears to provide sufficient control. The audit of these two criteria was thorough and effective, and the LANL QA program appeared to be effectively implemented in these areas.

(f) Identification and Control of Samples and Data (Criterion 8)

LANL procedures implementing Criterion 8 focus on sample control and data control. The sample control procedure, QP-08.1, also provides controls for handling, shipping, and storage thus implementing Criterion 13.

During the observed portion of this audit, the auditor followed the checklist and reviewed processing of a set of rock field samples through field notebooks, LANL sample logs, and DOE Sample Management Facility documents. The sample storage room was visited, identification of several samples was verified, and the computer sample tracking system was demonstrated. Sample custody appeared well documented and controls appeared effective. The audit of this area was thorough and effective, and implementation by LANL appeared to be effective.

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

Calibration reports, calibration labels on laboratory equipment, and laboratory notebooks (for documentation of calibration standards) were reviewed and examined in the LANL YMP technical divisions during the audit of this criterion. The auditor reviewed the master inventory list of measuring and test equipment to select a sample of approximately 15 instruments for evaluation. The checklist was sufficiently detailed and the sample size was sufficient to determine that controls are adequate and implementation is effective. LANL technical personnel seemed knowledgeable of measuring and test equipment requirements and documented calibration activities thoroughly.

(h) Handling, Shipping, and Storage (Criterion 13)

As indicated in the discussion of Criterion 8, handling, shipping and storage of samples is covered by the implementing procedure for that criterion. QP-13.1 addresses measuring equipment whose handling, shipping and storage requirements are covered by their respective (Criterion 12) calibration procedure. The auditor interviewed technical division QA liaison personnel and the EES-1 Division Technical Coordinator to determine that no equipment has had this procedure applied. The calibration procedures had specified special requirements when necessary. In most cases, no special handling, shipping, or storage has been necessary. The entire checklist was classified as "N/A", and implementation of Criterion 13 as applied to equipment was indeterminate.

(i) Records (Criterion 17)

QP-17.3, the LANL records control procedure, was revised in January, 1991, and the auditor reviewed virtually all of the records processed since that time, a total of 135. (Previous surveillances evaluated records processed to earlier procedure revisions.) The records originated in five of the LANL YMP divisions plus contractor Lawrence Berkeley National Laboratory. The records were reviewed for proper processing, validation, retrieval, and for completion of the Records Package Traveler when necessary. The auditor also verified dual storage of records through the division resident files and the Records Processing Center, until records are accepted at the DOE Control Records Facility in Las Vegas. LANL Records Processing personnel and QA liaison personnel appeared to be familiar with their system. The audit of this area was adequate, and the QP appeared to be effectively implemented.

(j) Conclusions

The programmatic audit of the LANL QA program effectively evaluated the degree of compliance to the OCRWM QARD, the LANL QAPP and associated procedures. The auditors utilized appropriate checklist questions and in-depth interviews to obtain the required information in evaluating the LANL QA program. The daily caucuses held by the audit team provided good interaction between the technical and programmatic auditors.

5.4 Examination of Technical Products

The audit team technical specialists reviewed, to varying degrees, the technical areas listed below by Work Breakdown Structure (WBS) Number, Site Characterization Plan (SCP) section reference, and title:

| <u>WBS Number</u> | <u>SCP Reference</u> | <u>Title</u> |
|-------------------|----------------------|---|
| 1.2.3.2.1.1.1 | 8.3.1.3.2.1 | Mineralogy, Petrology, and Rock Chemistry of Transport Pathways |
| 1.2.3.2.1.1.2 | 8.3.1.3.2.2 | Mineralogic and Geochemical Alteration |
| 1.2.3.2.1.2 | 8.3.1.3.3 | Stability of Minerals and Glasses |
| 1.2.3.3.1.2.2 | 8.3.1.2.2.2 | Water Movement Tracer Test |
| 1.2.3.4.1.1 | 8.3.1.3.1 | Ground-Water Chemistry Model |

The NRC staff reviewed copies of five SPs prior to the start of the audit, with the understanding that these SPs were used by the audit team technical specialists in their preparation for the audit. The technical specialists used SPs, in various states of revision, and monthly progress reports as bases for developing checklist questions. The monthly progress reports were not included in the audit notebooks sent to the observers. This put the observers at a disadvantage, and they were not as well prepared for the audit as they could have been. During the audit these reports were made available to the observers, but it was too late for the NRC observers to use the material effectively.

The audit team members included a Lead Technical Specialist and a Technical Specialist. These two technical people worked together at times and separately at other times. The interviews were conducted with the Principle Investigators (PI) and laboratory technicians involved in the technical activities listed above. The NRC staff observed interviews on all the technical activities except "Stability of Minerals and Glasses." Apparently, this technical area has had no activity for several years.

The technical specialists used the vertical slice approach whenever they could to track published interpretations and results back to the raw data and samples. This approach is useful in evaluating the effectiveness of the QA program in controlling technical information.

Both technical specialists were qualified to audit the technical activities chosen for this audit. The interviews were conducted in a professional but collegial manner. As a result, the audit ran smoothly and efficiently.

The technical portion of the audit was thorough and effective, and integration of the technical portion with the programmatic portion was good. The LANL technical personnel appeared well qualified and generally understood the QA requirements in their areas.

5.5 Conduct of Audit

The audit team members were generally well prepared and demonstrated a sound knowledge of the QA and technical aspects of the LANL program. The audit checklists included the important QA controls addressed in the OCRWM QARD that are applicable to LANL. In general, the audit team used the checklists effectively in their interviews with LANL personnel and review of documents. The technical and programmatic portions of the audit were generally effective, and integration of the technical and programmatic portions of the audit was effective.

5.6 Qualification of Auditors

The qualifications of the QA auditors on the team were previously accepted by the NRC staff (ref. NRC Observation Audit Report for USGS dated August 22, 1988) or were acceptable based on QMP-02-02, the DOE procedure for qualifying auditors. In general, the technical specialists appeared knowledgeable in the technical areas which they reviewed and knowledgeable of the LANL QA program requirements.

5.7 Audit Team Preparation

The QA auditors were generally well prepared in the areas they were assigned to audit and knowledgeable in the LANL QAPP and implementing procedures. The technical specialists were familiar with the technical activities of the LANL personnel as described in the SPs and monthly progress reports. Audit Plan 91-03 overall was complete and included: (1) the audit scope; (2) a list of audit team personnel and observers; (3) a list of all the audit activities; (4) the audit notification letter; (5) the LANL QAPP, and past audit report; and (6) the programmatic and technical checklists.

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) SDRs 511, 512, 513, and 514 resulting from the March 1990 QA audit were closed prior to this audit. Corrective actions were reviewed and found effective.
- (b) The NRC had no observations resulting from the March 1990 QA audit, and all NRC observations from previous audits were effectively resolved during the March 1990 audit.
- (c) Based on discussions between the State of Nevada and NRC observers, the State of Nevada observations from previous audits 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 DOE/YMPO audit process or the LANL QA program.

(b) Weaknesses

- o The DOE/YMPO technical specialists used SPs and monthly progress reports as bases for developing technical checklists. These monthly progress reports were not included in the audit notebooks sent to the observers. This put the observers at a disadvantage for preparing for this audit. During the audit these reports were made available to the observers but this was too late for the NRC observers to use the material effectively. It is recommended that, in the future, materials such as monthly progress reports used to prepare the technical checklists be included in the audit notebooks.

(c) Good Practices

- o The software QA program is being implemented in an effective manner.
- o There is a strong commitment and support for an effective QA program at the management level. The TPO at LANL has a good knowledge of the QA requirements and demonstrated a positive attitude toward an effective QA program.

5.11 Summary - DOE/YMPO Audit Team Findings

During the course of the audit, the audit team identified approximately 10 deficiencies in the LANL QA program and prepared draft documentation describing these deficiencies. One of these deficiencies remained unresolved at the time of the exit briefing on March 29, 1991. Preliminary CAR YM-91-041 was identified, and this CAR relates to inconsistencies between the LANL QAPP and implementing procedures. This deficiency was documented as Severity Level 2 and, if corrected in a timely manner, it should not have any significant impact on the quality of data generated through the activities under the LANL QA program.