U.S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

OFFICE OF QUALITY ASSURANCE

AUDIT REPORT

OF

LOS ALAMOS NATIONAL LABORATORY

AUDIT NO. YMP-91-03

MARCH 25 THROUGH MARCH 29, 1991

Prepared by: Richard E. Powe Date: 4/29/91

Richard E. Powe
Audit Team Leader
Yucca Mountain Quality Assurance Division

Approved By: James Blaylock for Date: 4/30/91

Donald G. Horton
Acting Director
Office of Quality Assurance

9105280131 910513
PDR WASTE
WM-11 PDR

ENCLOSURE

Audit Report
No. YMP-91-03

EXECUTIVE SUMMARY

Overall, the Los Alamos National Laboratory (Los Alamos) is satisfactorily implementing an effective Quality Assurance (QA) program in accordance with the Los Alamos Yucca Mountain Site Characterization Project (YMP) Quality Assurance Program Plan (QAPP) and implementing procedures. No Los Alamos QA Program elements or procedures were considered inadequate; however, some areas were considered indeterminate due to lack of activity.

The Yucca Mountain Quality Assurance Division (YMQAD) Audit Team identified 10 deficiencies during the audit and all but one were resolved prior to the post-audit conference. The one unresolved deficiency dealt with inconsistencies between the Los Alamos QAPP and implementing procedures and is documented as Corrective Action Request No. YM-91-041 (see Enclosure 5).

Several areas within the Los Alamos QA Program that were considered strengths worthy of note are:

1. The Los Alamos Software QA Program is well developed and, although implementation has just begun the audit team, as well as the observers, concluded that the program is being implemented in an effective manner.

2. Scientific Investigation Control procedures are being effectively implemented.

3. Management support, especially at the Technical Project Officer level, was positive and contributed to the overall effectiveness of the QA program.

4. Los Alamos and Los Alamos Technical Associates, Inc. personnel are working well as a team to assure the quality of their work.

Some areas identified within the Los Alamos QA Program where opportunities for improvements exist are:

1. Paying particular attention to detail when determining root causes of conditions adverse to quality.

2. Processing QA records, especially audit checklists, in a timely manner.

3. Expedient processing of commercial-grade procurement.

Details regarding these and other opportunities for improvements can be found Section 7.0 of the audit report.

The YMQAD audit team appreciated the cooperativeness and professional attitude of the Los Alamos YMP organization during the conduct of this audit.

1.0 INTRODUCTION

This report contains the results of the Office of Civilian Radioactive Waste Management (OCRWM) Audit YMP-91-03 of Los Alamos National Laboratory (Los Alamos), conducted at Los Alamos, New Mexico on March 25 through 29, 1991. This audit was conducted by an Audit Team from the Yucca Mountain Quality Assurance Division (YMQAD) of the Office of Quality Assurance (OQA) in accordance with the approved Audit Plan (reference: correspondence OQA:JB-2199, dated 2/15/91). Los Alamos Technical Associates, Inc., (LATA), the Los Alamos quality services contractor hosted the audit.

2.0 AUDIT SCOPE

This audit evaluated the Los Alamos Yucca Mountain Site Characterization Project (YMP) Quality Assurance (QA) Program to determine whether it met the requirements and commitments imposed by the OCRWM as reflected in the Los Alamos YMP Quality Assurance Program Plan (QAPP). This was done by verifying implementation and effectiveness of the system in place, as well as verifying adequate compliance with requirements.

A representative sample of discrepancies/observations identified during the previous QA Audit No. 90-01 and surveillances of the Los Alamos YMP organization were included in the scope of this audit to determine the effectiveness of Los Alamos YMP corrective actions.

The programmatic elements and technical areas audited, as well as those programmatic elements that were not included in this audit, are identified below:

Programmatic Elements

1.0 Organization
2.0 Quality Assurance Program
3.0 Scientific Investigation Control and Design Control (including Software 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, Storage and Shipping
15.0 Control of Nonconforming Items
16.0 Corrective Action
17.0 Quality Assurance Records
18.0 Audits

The following programmatic elements were not included in the scope of the audit because Los Alamos currently has no activities to which these elements apply:

9.0 Control of Processes
10.0 Inspection
11.0 Test Control
14.0 Inspection, Test and Operating Status

Technical Areas

Technical Specialists reviewed and evaluated the following technical activities (keyed to Work Breakdown Structure (WBS) and Site Characterization Plan (SCP) numbers):

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

In addition, the above technical activities were evaluated to determine adequacy in the following areas:

1. Technical qualifications of scientific investigation personnel.

2. Understanding of procedural requirements as they pertain to scientific investigation activities.

3. Adequacy of technical procedures.

4. Development of scientific investigation planning documents, study plans, work supporting the Site Characterization Plan (SCP), and any related work products.

3.0 AUDIT TEAM AND OBSERVERS

The list of audit team members and observers can be found in Enclosure 1.

4.0 SUMMARY OF AUDIT RESULTS

4.1 Program Effectiveness

Overall, Los Alamos is satisfactorily implementing an effective QA program in accordance with the Los Alamos YMP QAPP and implementing procedures. No Los Alamos QA Program elements or

procedures were considered inadequate; however, one specific element of the Los Alamos QA Program (Program Element 13: Handling, Storage, and Shipping), fourteen implementing procedures, and 3 study plans were considered indeterminate due to lack of activity. The procedures and plans considered indeterminate are identified by an asterisk within Enclosure 4. Several areas within the Los Alamos QA program that were considered strengths worthy of note are:

1. The Los Alamos Software QA Program is well developed and although implementation has just begun the audit team, as well as the observers, concluded that the program is being implemented in an effective manner.

2. Scientific Investigation Control procedures are being effectively implemented.

3. Management support, especially at the Technical Project Officer (TPO) level, was positive and contributed to the overall effective implementation of the QA program.

4. Los Alamos and LATA personnel are working well as a team to assure the quality of their work.

4.2 Programmatic Activities

Details of programmatic audit activities can be found in Enclosure 2.

4.3 Technical Activities

Work performed under five study plans (SPs) was examined during the audit. Work on three of the SPs had not progressed beyond preliminary and scoping activities. The SPs that had progressed beyond preliminary and scoping activity were SP 8.3.1.3.2.1, "Mineralogy, Petrology, and Rock Chemistry of Transport Pathways" and SP 8.3.1.3.2.2, "Mineralogic and Geochemical Alteration."

The notebooks, logbooks, and other documents generated to date for all five SPs were examined for appropriate technical detail and no discrepancies were identified. The technical qualifications of the scientific investigation personnel involved with the SPs were reviewed and found to be adequate. During interviews, Los Alamos personnel demonstrated their understanding of procedural requirements as they pertain to scientific investigation activities. Eight Detailed Procedures (DPs) were reviewed and found to be technically adequate. Overall, the results of the technical activities audited were found to be adequate and implementation was found to be

effective; however, a number of areas were identified where there are opportunities for improvement (see Section 7.0, Items 5 through 12 of this report for details). See Enclosure 4 for a list of objective evidence reviewed.

4.4 Summary of Deficiencies

The YMQAD Audit Team identified 10 deficiencies during the audit and all but one were resolved prior to the post-audit conference. The one unresolved deficiency dealt with inconsistencies between the Los Alamos QAPP and implementing procedures and is documented in a Corrective Action Request (CAR). A synopsis of the CAR and the nine deficiencies corrected during the audit are presented in Section 6.0 of this report. An information copy of CAR No. YM-91-041, a Severity Level 2 CAR, can be found in Enclosure 5.

5.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The pre-audit conference was held at LATA facilities on March 25, 1991. Daily coordination meetings were held with Los Alamos management and staff. The audit was concluded with a post-audit conference held at LATA facilities on March 29, 1991. A list of auditors, observers and personnel contacted during the audit is included in Enclosure 3. The list includes an indication of those who attended the pre- and post-audit conferences.

6.0 SYNOPSIS OF CORRECTIVE ACTION REQUEST AND DEFICIENCIES CORRECTED DURING THE AUDIT

6.1 Corrective Action Request (CAR)

YM-91-041 QAPP requirements are not being consistently reflected in the Quality Procedures (QPs). See Enclosure 5 for details.

6.2 Deficiencies Corrected During The Audit

Deficiencies corrected during the audit which were considered isolated in nature and only required remedial corrective action were:

1. QP TWS-QAS-QP-02.5, Revision 0, requires that verification of education and experience be documented on a personnel qualification evaluation form. The documentation of verification of education and experience had not been completed for a number of Los Alamos personnel who were performing quality affecting activities. Los Alamos personnel were aware of the problem prior to the start of the audit and during the audit issued Deficiency Report (DR) No. LANL-136 to track the problem to closure.

2. QP TWS-QAS-QP-03.5, Revision 0, requires experimenters to sign and date lab notebook entries. The signatures of a Principal Investigator (PI) was missing in three places in one lab notebook. The notebook was corrected during the audit.

3. QP TWS-QAS-QP-3.21, Revision 0, requires completion of a software Life-Cycle Specification form. A necessary checkmark on a Life-Cycle Specification form was omitted. The form was corrected during the audit.

4. TWS-QAS-QP-12.1, Revision 4, requires that a DR be issued when equipment is found out of calibration. A Mettler balance instrument, PN 625058, was found to be out of allowed tolerances; however, no DR had been written. Los Alamos QA personnel initially indicated they had not issued a DR because the instrument had not been used in any quality affecting work. Subsequent investigation revealed quality-affecting work had occurred and Los Alamos QA personnel issued DR No. LANL-0137 during the audit.

5. Contrary to the requirements of QP TWS-QAS-QP-15.2, Revision 1, the Technical Project Officer (TPO) did not document his rational for nonconcurrence on DR No. LANL-0052. The TPO documented a satisfactory rational on the DR during the audit.

6. Contrary to the requirements of QP TWS-QAS-QP-15.2, Revision 1, a record copy of DR Numbers LANL-0098 and LANL-0115 was not being maintained. Subsequent investigation revealed that DR No. LANL-0098 was associated with Audit Report LANL-AR-90-010, which noted that the DR was never issued. A record copy of DR No. LANL-0115 was subsequently found and it was determined that it had never been issued and had been replaced by DR No. LANL-132. The DR Log was updated to reflect the status of these DRs during the audit.

7. QP TWS-QAS-QP-18.3, Revision 2, requires that a record copy of auditor's certifications be maintained. Los Alamos had used a qualified auditor from an outside organization in the performance of an audit but had failed to file a record copy of his certification from his employer. The certification records were obtained and filed during the audit.

8. QP TWS-QAS-18.2, Revision 2, requires that surveillances be performed in accordance with a pre-planned surveillance schedule. LANL had failed to provide an explanation to the Surveillance file for not performing scheduled surveillances. The surveillances were not performed as originally scheduled because an extensive audit of the same scope as the scheduled surveillances was performed during the same time frame. An explanation was placed in the surveillance file during the audit.

9. QP TWS-QAS-QP-18.2, Revision 2, requires that a surveillance report with surveillance checklist be submitted to the local Records Processing Center (RPC). Los Alamos failed to submit a checklist with the surveillance report to the RPC for Surveillance No. LANL-SR-90-004. The subject checklist was submitted to the RPC during the audit.

7.0 REQUIRED ACTIONS AND RECOMMENDATIONS

A response to the CAR (delineated in Section 6.0) is due within the time frame stated in block 10 of the CAR, as detailed in the CAR transmittal letter. Upon receipt of an acceptable response and satisfactory verification of all corrective actions, the CAR will be closed and LANL will be notified (by letter) of the closure.

During the audit, several areas were identified within the Los Alamos QA Program where there were opportunities for improvement. The following recommendations are offered for Los Alamos management consideration:

1. QP TWS-QAS-QP-02.5, Revision 0, Personnel Selection, describes the methods to be used for preparation of Position Descriptions (PDs) and the evaluation of personnel to meet those PDs. This procedure requires that the evaluation be documented on a Personnel Qualification Evaluation (PQE) form. In some instances the PQE form could have contained more detail regarding the education and experience of the individual, so that supervisors could readily assure that the requirements of the PD were met. Los Alamos should evaluate the need for more detailed information on the PQE forms.

2. Currently there is no procedural requirement for PIs to document the training required for individuals assigned to them prior to the start of quality affecting activities. However, each PI interviewed did have some form of documented system for keeping track of training requirements. Los Alamos should consider establishing guidelines for tracking required training.

3. QP LANL-YMP-QP-04.4, Revision 0, describes the methods used to control the purchase of commercial-grade items and services. The scope of this QP provides some guidelines regarding procurements that are exempt from Los Alamos YMP QA requirements; however, in actual practice Los Alamos is being extremely conservative in application of those exemptions. Los Alamos should consider establishing amplified guidelines concerning application of QP-04.4 requirements. For example, a list of procurements considered exempt (QA "N/A") could be maintained. This list could contain such items/services as:

   Administrative office equipment (furniture, material supplies, graphic art supplies and services)
   Audio-visual equipment and services
   Facility maintenance and repair services

Books, reference material, and subscriptions
Personnel protective equipment and items
General laboratory supplies (except for chemicals used in quality affecting analysis)
Tooling and equipment not subject to calibration
Sample processing supplies, handling and support equipment
Commercially available computer software hardware, equipment, and spare parts
Non-quality related training and seminars
Computer program software (not subject to the Software QA Program)

This list could be revised and expanded with the concurrence of the QA organization.

4. QP LANL-YMP-QP-18.1, Revision 4, became effective on March 7, 1991 and no longer requires audit checklists to be a QA record. However, the previous revision to the QP did require that audit checklists be retained as a QA record. None of the checklists associated with the ten 1990 Los Alamos audits have been authenticated and processed to the RPC. Although there is no procedural time frame established for authentication, and therefore no CAR is being issued, it is strongly recommended that Los Alamos take timely action to complete the audit checklists and file them as quality records.

5. QP TWS-QAS-QP-03.5, Revision 0, provides guidelines regarding indexes to notebooks and suggests leaving space at the front of the notebook to add an index. Whereas putting the index at the back of the notebook is acceptable, a reference at the front of the notebook as to the location of the index should be made. (Refer to notebook TWS-ESS-1-7/87-39).

6. When notebooks and lcgbooks use abbreviations and acronyms, a reference list that indicates their meanings should be included either within the document or within the record package. (Refer to notebooks TWS-ESS-1-7/87-39 and TWS-EES-1-11-90-16).

7. Notebook TWS-ESS-1-7/87-39, Page 12, has a September 15, 1987 entry that identifies the need to correct nickel analytical data because of an erroneous calculation factor for the $NiFe_2O_4$ standard. Examination of later entries in this and other notebooks indicated that these corrections were made; however, there was no indication that all corrections had been accomplished or that there was a corrective action document such as a DR to assure tracking to close-out. Los Alamos should investigate to assure that all necessary corrections have been made.

8. QP TWS-QAS-QP-03.5, Revision 0, establishes methods to be used in initiating and maintaining notebooks, including documenting objectives of activities, descriptions of proposed approaches or cross reference to applicable study plans, and potential sources of

error or uncertainty. Greater care should be given, in some instances, to document this information to a sufficient level of detail such that it is clear for example, what the purposes are, etc., of subactivities, (e.g. the purposes of collection and intended use of samples). Greater care should also be given to assuring legibility of handwritten notebook entries. It is recommended that responsible Los Alamos management consider performing a review of laboratory notebooks to assure the above areas of concern are adequately addressed.

9. A reference to the number of notebooks, logbooks, or binders and their identification numbers was found in record packages for specific reports; however, in anticipation of the need to retrieve records rapidly during a licensing hearing, it is recommended that cross-reference information of page numbers within a notebook, logbook, etc. that apply to that specific report also be included in the record package. Having this cross-reference information or actual copies of relevant parts of logbooks, etc. in the file would enhance retrievability times.

10. Criteria used for selection of Standards should be included in notebooks, and Lists of Standards should be included in DPs such as the microprobe procedure, TWS-ESS-DP-07.

11. QP TWS-QAS-QP-03.5, Revision 0, Paragraph 6.3, requires laboratory notebook and logbook entries to be made in a color of ink that can be photocopied. Los Alamos notebooks and logbooks outside the YMP do not necessarily adhere to this requirement (e.g. pencil is used). If Los Alamos uses data from notebooks and logbooks of Los Alamos employees not assigned to YMP, care should be taken to make certain these data meet QP requirements.

12. Notebook TWS-INC7-8/88-07 did not include any entries describing the library research or theoretical developments for the paper, "Illitization of Smectite," (submitted to the YMP Office on 6/11/90). No other notebook for this task apparently exists. Los Alamos should consider establishing a guideline that all scientific and technical research be included in suitable notebooks, using appropriate procedures. This includes not only experimental, petrographic, and mineralogic investigations, but also literature research and theoretical developments. For example, for literature research the title and abstract, or a brief summary by the investigator, could appropriately be entered into a laboratory notebook, together with a brief evaluation on the validity, usefulness, or relevance, if any, of the publication to the investigation being conducted. Similarly, theoretical ideas and the sequence of stages in the development of mathematical or conceptual models could appropriately be entered into a laboratory notebook; perhaps one maintained especially for that purpose.

8.0 LIST OF ENCLOSURES

Enclosure 1. Audit Team Members and Observers
Enclosure 2. Audit Details
Enclosure 3. Personnel Contacted During Audit
Enclosure 4. List of Objective Evidence Reviewed During the Audit
Enclosure 5. Information Copy of CAR's

AUDIT TEAM MEMBERS AND OBSERVERS

Responsibility	Individual
Audit Team Leader	Richard E. Powe
Audit Manager	James Blaylock
Auditors	Neil D. Cox
	Donald J. Harris
	John S. Martin
	Kenneth T. McFall
	Richard L. Maudlin
	Richard L. Weeks
Lead Technical Specialist	Paul L. Cloke
Technical Specialist	Ardyth M. Simmons
Observers	Tilak R. Verma (Lead) U.S. Nuclear Regulatory Commission (NRC)
	John Bradbury NRC
	Robert D. Brient Southwest Research Institute/NRC
	Englebrecht von Tiesenhausen Clark County, Nevada
	Susan W. Zimmerman * Nevada Waste Project Office

* Participated in audit on March 28 and 29, 1991 only.

AUDIT DETAILS

The following is a summary of programmatic activity covered during the audit. A list of objective evidence reviewed during this audit is shown in Enclosure 4. The full document identification number, revision status, and title for Quality Procedures (QPs) referenced below can be found in Enclosure 4.

1. 1.0 "Organization"

There is no specific implementing procedure covering organization. This situation was identified in last years audit and documented in Standard Deficiency Report (SDR) 511. In response to SDR 511, Los Alamos addressed organizational requirements within the Los Alamos National Laboratory Yucca Mountain Project Quality Assurance Program Plan (QAPP), Revision 5. The QAPP assigns responsibility for managing the Los Alamos Yucca Mountain Site Characterization Project (YMP) to the Earth and Environmental Sciences (EES) Division, Group 13, and the EES-13 Group Leader is designated the Technical Project Officer (TPO). To verify implementation of QAPP organizational requirements, the following personnel were interviewed to determine their knowledge and understanding of their duties and responsibilities as described in the QAPP:

Los Alamos TPO
Los Alamos Quality Assurance (QA) Project Leader (QAPL)
Three Los Alamos QA Liaison personnel
Los Alamos Verification Coordinator

Los Alamos personnel had a clear understanding of their duties and responsibilities. The Los Alamos Quality Assurance (QA) organization is independent of the technical organization and reports through the QAPL to the TPO. The Los Alamos Verification Coordinator (who reports directly to the QAPL) and his staff work for a subcontractor, Los Alamos Technical Associates, Inc. (LATA).

A concern developed during the audit when it was discovered that the Los Alamos Quality Assurance Officer (QAO) position was determined to be vacant. The QAO position is described in the QAPP as one of the possible routes the QAPL might take for resolution of disputes. Further discussion revealed that the position was not part of the YMP and therefore did not belong in the Los Alamos YMP QAPP. Los Alamos documented this situation in Los Alamos Deficiency Report (DR) No. 0135.

2. 2.0 "Quality Assurance Program"

Aspects of the Los Alamos QA Program element evaluated during this audit were:

Changes to the QAPP
Dissemination of information regarding the QA program
Readiness Reviews
Management Assessments
Quality Grading
Personnel Qualification
Indoctrination and Training

The method used to control changes to the QAPP is described in Section 2.1 of the Los Alamos QAPP, Revision 5. Any changes to the QAPP require Yucca Mountain Quality Assurance Division (YMQAD) approval prior to implementation. A review of objective evidence concerning the processing of Revision 5 to the QAPP revealed no discrepancies.

Management above and outside the QA organization is regularly informed as to the scope, status, adequacy, compliance, etc., of the QA program via quarterly QA meetings, receipt of audit and surveillance reports, changes to procedures, and receipt of internal memos and newsletters.

The Los Alamos QAPP requires Readiness Reviews to be performed prior to major scheduled and/or planned activities. Quality Procedure QP-02.3 establishes that a readiness review will be performed when requested by the TPO. No Readiness Reviews have been performed to date, therefore this activity is considered indeterminate.

The Los Alamos QAPP requires Management Assessments to be performed at least annually. No Management Assessment had been performed for 1990. Los Alamos QA was aware of this discrepancy and had documented this fact in Los Alamos DR No. LANL-0132. Due to the lack of activity in this area, it is considered indeterminate.

Five completed grading packages were reviewed for compliance to YMP Administrative Procedure-Quality AP-5.28Q and all activities performed by Los Alamos were found to be in compliance.

Four personnel qualification record packages were audited for compliance to QP-02.5 requirements. Except for two concerns, implementation was considered adequate. The first concern dealt with the amount of detail provided on the Personnel Qualification Evaluation form and resulted in a recommendation for improving the system (see Section 7.0, Item 1 of this report). The second concern dealt with the documentation of the verification of education and experience of employees prior to the start of quality-affecting activities and was resolved during the audit (see Section 6.2, Item 1 for details of the resolution).

The training records for four Los Alamos personnel were reviewed for compliance to the requirements of QP-2.6 and no deficiencies were identified; however, there was one area identified that could be improved (see Section 7.0, Item 2 for details).

3. 3.0 "Scientific Investigation Control and Design Control" (including Software Control)

Scientific Investigation Control

Procedural compliance was verified for three QPs, QP-03.2, -03.3, and -03.5. Five study plans, 10 Technical Information Products (four abstracts and six papers), and four laboratory notebooks were reviewed. These procedures were being implemented adequately and effectively. One minor deficiency was identified, which was corrected during the audit (see Section 6.2, Item 2).

Design Control

No design control procedures, QP's -03.14, -03.15, and -03.16, were being implemented at Los Alamos in Los Alamos, New Mexico. Los Alamos design control activities being performed in Las Vegas, Nevada, were not included in this audit for logistics reasons. A YMQAD surveillance of the Los Alamos Las Vegas activity is scheduled to be performed the week of April 15, 1991.

Software Quality Assurance

The Los Alamos Software QA Plan and six implementing QPs, QP-03.17, -03.18, -03.19, -03.20, -03.21, and -03.22 became effective on January 25, 1991. Since that time, 49 Software Change Requests had been placed under Configuration Management, as well as 45 Engineering Change Directives and 45 Lifecycle Specifications. Also, although not yet approved by the Configuration Control Board, a Software Requirements Specification for the software TRACRN had been entered into the configuration control system. This activity was audited for procedural compliance and resulted in only one minor deficiency which was corrected during the audit (see Section 6.2, item 3).

4. 4.0 "Procurement Document Control"

Los Alamos uses two QP's to control this activity; QP-04.4 and -04.5. At the time of the audit Los Alamos had processed 18 Commercial-Grade Purchase Requisitions (PRs) and had 8 more PRs in process. A representative sample of 10 completed and 2 in-process PRs were selected for audit for compliance to selected portions of the applicable procedure,

QP-04.4 (see Enclosure 4 for a list of PRs selected). None of the PRs selected included any procurement of commercial-grade services. The following activities/attributes were verified:

PRs had appropriate scope of work (catalog number), and technical requirements and appropriate quality representative approval.

Appropriate receipt inspection had been performed and documented.

Completed procurement record packages included PRs, procurement information form, receiving inspection form, and other supporting documentation required by the PR, and the packages were stored in both the group resident file and the Records Processing Center (RPC).

Personnel involved as PR requesters, PR reviewers, and receipt inspectors were properly trained to the requirements of QP-04.4 prior to performing the activity.

No deficiencies were identified and, overall, the procurement program for commercial-grade items and services is functioning properly within the QA program requirements. In fact, based on the PRs examined, Los Alamos is being extremely conservative in application of the requirements and could improve their system by clarifying the scope of the QP (see Section 7.0, Item 3 of this report).

Only one PR (N3991) had been initiated for non-commercial-grade work, and it had not been completed. The partial processing of the PR was verified to be in accordance with QP-04.5; however, due to the lack of non-commercial-grade procurement activity, it was concluded that implementation of QP-04.5 was indeterminate.

5. 5.0 "Instructions, Procedures, Plans, and Drawings"

Los Alamos implementation of this program element is accomplished using the same QPs as program element 6.0 Document Control.

6. 6.0 "Document Control"

The record packages concerning the document review and approval process for four QPs were audited. The record packages for these procedures (QPs -06.1, Revision 2; -04.4, Revision 0; -04.5, Revision 0; and -17.3, Revision 1) met the requirements of implementing procedure QP-6.2.

No Detailed Procedures (DPs) had been processed since the issuance of the new implementing procedure (QP-06.3, Revision 0).

The Los Alamos document control system was audited for compliance to selected portions of implementing procedure QP-06.1. The QA Support Resident File Custodian maintains Master Controlled Document Lists for each type of document used at Los Alamos. Four sets of controlled documents were audited for compliance and all were found to be up-to-date and maintained adequately.

7. 7.0 "Control of Purchased Items and Services"

Los Alamos implementation of this program element is accomplished using the same QPs as Program Element 4.0, Procurement Document Control.

8. 8.0 "Identification and Control of Items" (Samples and Data)

A total of 68 of 100 samples collected since March 1989 and corresponding documentation, were audited. Documentation for 53 samples were examined and found to meet the requirements of AP-6.3, Revision 0, Paragraph 5.7.1, for sample information. Five of the 53 samples were observed and found to be in the correct location and properly marked. Thirteen additional samples were examined to verify that they were physically located as depicted in the master logbook. The remaining 34 samples were found to be correctly entered into the master logbook. All samples examined were processed in accordance with procedural requirements.

9. 12.0 "Control of Measuring and Test Equipment"

Based on the February 28, 1991 Los Alamos Master Inventory List of Measuring and Test Equipment (M&TE), 18 items and associated documentation were selected for audit. Except for one instance of failure to initiate a DR when required, procedural compliance was satisfactory. The failure to initiate a DR was resolved during the audit (see Section 6.2 for details of the resolution). Additionally, the results of actions taken by Los Alamos to resolve Observations 90-1-10 and 90-1-11, which were issued as a result of the 1990 YMP audit of Los Alamos, were reviewed and found to be satisfactory.

10. 13.0 "Handling, Storage and Shipping"

Due to lack of activity this element and the implementing procedure QP-13.1, Revision 2 were considered indeterminate.

11. 15.0" Control of Nonconforming Items"

Los Alamos YMP has combined Control of Nonconforming Items and Corrective Action program elements into one implementing procedure, QP-15.2. Los Alamos documents all conditions adverse to quality on one form, the DR. To verify compliance, the DR Log and 21 DRs were reviewed for procedural compliance. Except for one CAR (YM-91-041) and two deficiencies corrected during the audit these program elements were satisfactory (see Section 6.0 for details regarding the corrected deficiencies).

12. 16.0 "Corrective Action"

Except for trending, Los Alamos implementation of this program element is accomplished using the same QPs as Program Element 15.0, Control of Nonconforming Items. The QP for trending (QP-16.2) was not audited since there was a hold placed on implementation of the procedure awaiting Yucca Mountain Site Characterization Project Office direction (see SDR 597 for details).

13. 17.0 "Quality Assurance Records"

Approximately 130 records and record packages that had been submitted to the RPC by Los Alamos Groups EES-1, EES-13, EES-5, EES-15, LS-1, and LBL since the effective date of the QP-17.3, Revision 1 procedure (1/11/91) were audited. The records were examined at both the RPC and the Resident Files of each Los Alamos Group. All records examined were clear and easy to read or marked "Best Available Copy" if of substandard quality. Corrections were done in accordance to requirements and no information had been obliterated. Errors were corrected with a single line through the appropriate material, initialed, and dated. No write-overs, or use of correction fluid or tape were encountered.

The access lists in the RPC and the Group Resident Files were posted, signed, and dated by appropriate supervisory and QA personnel.

14. 18.0 "Audits"

To verify compliance six revisions of the audit schedule, the latest revision of the surveillance schedule, four audit plans, three audit checklists, four audit reports, the audit status log, six surveillance checklists/reports, and six auditor certification files were audited. Three deficiencies were identified that were corrected during the audit and one recommendation was generated (see Section 6.2, items 7, 8, and 9 for details of the corrected deficiencies and see Section 7.0, Item 4 for the recommendation).

LOS ALAMOS NATIONAL LABORATORY
YMP-91-03 AUDIT ROSTER

NAME	ORGANIZATION	TITLE	PRE-AUDIT	CONTACTED DURING AUDIT	POST-AUDIT
D. L. Bish	Los Alamos	Principal Investigator		X*	
J. Blaylock	DOE/YMQAD	Audit Manager	X	X	X
S. L. Bolivar	Los Alamos	QAPL	X	X	X
J. Bradbury	NRC	Observer	X	X	X
R. D. Brient	NRC	Observer	X	X	X
D. E. Broxton	Los Alamos	Tech. Coord.	X	X	X
P. Butler	Los Alamos	RFC, INC-7	X		
B. A. Carlos	Los Alamos	PI, EES-1	X	X	
J. A. Canepa	Los Alamos	PL, Site & Reg. Invest		X	X
P. L. Chavez	LATA	Train. Records Clerk	X	X	X
S. J. Chipera	Los Alamos	Assoc. Invest.		X	
M. J. Clevenger	Los Alamos	QAL	X	X	X
P. L. Cloke	SAIC	Lead Tech. Spec.	X	X	X
N. D. Cox	SAIC/YMQAD	Auditor	X	X	X
E. M. Cole	LATA	QA Engineer	X		X
G. P. Cort	Los Alamos	S/W Mgmt. Coord.		X	X
D. C. Cruze	Los Alamos	S/W Spec. Librarian		X	
J. L. Day	LATA	QA Verif. Coord.	X	X	X
M. H. Ebinger	Los Alamos	PI Grd. Water Chem	X	X	X
J. T. Fabryka-Martin	Los Alamos	PI, INC-7	X	X	X
G. M. Gainer	LATA	QA Engineer	X	X	X
M. E. Gutierrez	LATA	Records Assistant	X	X	X
D. J. Harris	Harza/YMQAD	Auditor	X	X	X
R. J. Herbst	Los Alamos	TPO	X	X	
H. N. Kalia	Los Alamos	PL, ESF Test		X	
C. M. LaDelfe	Los Alamos	QAL	X	X	X
S. S. Levey	Los Alamos	PI, EES-1	X	X	X
J. S. Martin	SAIC/YMQAD	Auditor	X	X	X
R. L. Maudlin	MACTEC/YMQAD	Auditor	X	X	X
K. T. McFall	SAIC/YMQAD	Auditor	X	X	X
A. J. Mitchell	Los Alamos	Research Tech.	X		
D. A. Mann	Los Alamos	EES-1, Research Tech.		X	
T. L. Morgan	Los Alamos	QAL, INC-7	X	X	X
W. A. Morris	Los Alamos	Group Leader	X		X
H. P. Nunes	Los Alamos	EES-13		X	
M. A. Ott	Los Alamos	Research Tech.	X		

* Actually contacted the week following the audit to make certain there was no misunderstanding concerning the CAR, he was unavailable during the audit

LOS ALAMOS NATIONAL LABORATORY
YMP-91-03 AUDIT ROSTER

NAME	ORGANIZATION	TITLE	PRE-AUDIT	CONTACTED DURING AUDIT	POST AUDIT
E. S. Patera	Los Alamos	Tech. Coord.	X	X	
R. E. Powe	SAIC/YMQAD	Audit Team Leader	X	X	X
G. P. Rand	LATA	QA Engineer	X	X	X
R. Raymond, Jr.	Los Alamos	Assoc. Investigator		X	X
L. A. Sanders	LATA	Records Coord.	X	X	X
A. M. Simmons	DOE/YMPO	Technical Specialist	X	X	X
I. R. Triay	Los Alamos	PI, Diffusion Testing	X		
P. Trujillo	Los Alamos	Lab Tech. (Not YMP)		X	
D. T. Vaniman	Los Alamos	PI, EES-1	X	X	X
T. R. Verma	NRC	Observer	X	X	X
E. von Tiesenhausen	Clark Co, NV	Observer	X	X	X
R. L. Weeks	SAIC/YMQAD	Auditor	X	X	X
K. A. West	Los Alamos	PL, Admin. Control	X	X	X
D. L. Williams	Los Alamos	QAL, EES-13	X	X	X
S. W. Zimmerman	State of NV	Observer		X	X

OBJECTIVE EVIDENCE REVIEWED DURING AUDIT
(Examples of)

Plans

LANL-YMP-QAPP, Revision 5	Los Alamos Quality Assurance Program Plan
LANL-YMP-SQAP, Revision 0	Los Alamos Software Quality Assurance Plan

Quality Procedures

TWS-QAS-QP-01.1, Revision 2*	Interface Control
TWS-QAS-QP-01.2, Revision 0* Change Request (CR) 063	Stop Work Control
TWS-QAS-QP-01.3, Revision 0*	Conflict Resolution
TWS-QAS-QP-02.3, Revision 1*	Readiness Review
TWS-QAS-QP-02.4, Revision 0* CR 101	Management Assessment
TWS-QAS-QP-02.5, Revision 0	Selection of Personnel
TWS-QAS-QP-02.6, Revision 1	Personnel Orientation and Indoctrination
TWS-QAS-QP-02.7, Revision 1	Personnel Training
TWS-QAS-QP-02.8, Revision 0*	Indoctrination and Training Development and Review
TWS-QAS-QP-02.9, Revision 0	Personnel Proficiency Evaluation
TWS-QAS-QP-03.2, Revision 0 CR No. 071 CR No. 130 CR No. 160	Preparation and Technical and Policy Review of Technical Information Products
TWS-QAS-QP-03.3, Revision 0 CR No. 068 CR No. 108	Preparation and Review of an SCP Study Plan
TWS-QAS-QP-03.5, Revision 0 CR No. 074 CR No. 131	Documenting Scientific Investigation

TWS-QAS-QP-03.7, Revision 0* CR No. 106	Peer Review
TWS-QAS-QP-03.14, Revision 1*	Submittal of Design Input for the Exploratory Shaft Facility
TWS-QAS-QP-03.15, Revision 1*	Los Alamos Test Manager's Office Design and Interface Control
TWS-QAS-QP-03.16, Revision 0* CR No. 125	TMO Review of Design Information
TWS-QAS-QP-03.17, Revision 0	Review of Software and Computational Data
TWS-QAS-QP-03.18, Revision 0	Creation, Management, and Use of Computational Data
TWS-QAS-QP-03.19, Revision 0	Documentation of Software and Computational Data
TWS-QAS-QP-03.20, Revision 0	Software Configuration Management
TWS-QAS-QP-03.21, Revision 0	Software Life-Cycle
TWS-QAS-QP-03.22, Revision 0	Verification and Validation of Software and Computational Data
LANL-YMP-QP-04.4, Revision 0	Commercial-Grade Items and Service
LANL-YMP-QP-04.5, Revision 0*	Non-Commercial-Grade Items and Service
LANL-YMP-QP-06.1, Revision 2	Document Control
LANL-YMP-QP-06.2, Revision 0	Preparation, Revisioneview and Approval of Quality Administrative Procedures
LANL-YMP-QP-06.3, Revision 0*	Preparation, Review and Approval of Detailed Technical Procedures
TWS-QAS-QP-08.1, Revision 1	Identification and Control of Samples
TWS-QAS-QP-08.2, Revision 0	Control of Data
TWS-QAS-QP-12.1, Revision 4 CR No. 140	Control of Measuring and Test Equipment
TWS-QAS-QP-13.1, Revision 2*	Handling, Storage, and Shipping Equipment
TWS-QAS-QP-15.2, Revision 1	Deficiency Reporting

TWS-QAS-QP-16.2, Revision 0* CR No. 120 CR No. 123	Trending
LANL-YMP-QP-17.3, Revision 1	Records Management
LANL-YMP-QP-18.1, Revision 4	Audits
TWS-QAS-QP-18.2, Revision 2	Surveys
TWS-QAS-QP-18.3, Revision 2	Auditor Qualification and Certification

Detailed Procedures

TWS-ESS-DP-07, Revision 3 CR No. 079 CR No. 127 CR No. 138	Microprobe Operating Procedure
TWS-ESS-DP-16, Revision 4	Siemens X-Revisionay Diffraction Procedure
TWS-ESS-DP-25, Revision 3	Clay Mineral Separation and Preparation for X-Revisionay Diffraction Analysis
TWS-ESS-DP-51, Revision 1 CR No. 80	Mettler AE100 Operating Procedure (X-Ray Fluorescence Analysis Sample Weighing Procedure)
TWS-ESS-DP-52, Revision 3	Sample Preparation for X-Ray Fluorescence Analysis: Fusing and Lapping
TWS-ESS-DP-53, Revision1	Pulverizing Using the Revisionocklabs 3E Shatterbox
TWS-ESS-DP-55, Revision 1	Rock-Splitting: Operation of 50 Ton Hydralic Press
TWS-ESS-DP-111, Revision 1 CR No. 78	Procedure for X-Ray Fluorescence Analysis

Study Plans

8.3.1.3.2.1, Revision 0 (6/89)	Mineralogy, Petrology, and Rock Chemistry of Transport Pathways
8.3.1.3.2.2, Draft (10/90)	Mineralogic and Geochemical Alteration

8.3.1.3.3.2, Draft (2/89)* & 8.3.1.3.3.3	Kinetics and Thermodynamics of Mineral Evolution and Conceptual Model of Mineral Evolution
8.3.1.2.2.2, Revision 0 (1/89)*	Water Movement Tests
8.3.1.3.1, Draft (3/91)*	Ground-Water Chemistry Model

Publications

European Journal of Mineralology, 1990, Volume 2, Pages 771-777, Long-term Thermal Stability of Clinoplilolite: The Development of a "B" Phase, by David L. Bish

Purchase Requisitions (PRs)

PR No.	Orig.	Type
N3991 In process	INC-7	Non Commercial-Grade
U5548	EES-13	Commercial-Grade
U5552	EES-13	Commercial-Grade
H6231	EES-13	Commercial-Grade
V7734	EES-15	Commercial-Grade
M8449	EES-15	Commercial-Grade
V7761 In process	EES-15	Commercial-Grade
V7745 In process	EES-15	Commercial-Grade
V3137	INC-11	Commercial-Grade
V3147	INC-11	Commercial-Grade
V3148	INC-11	Commercial-Grade
U9796	LS-2	Commercial-Grade
U9800	LS-2	Commercial-Grade

Notebooks

TWS-ESS-1-2/88-20	SP 8.3.1.3.2.1
TWS-EES-11-90-16	SP 8.3.1.3.2.1
TWS-ESS-1-7/87-39	SP 8.3.1.3.2.1
TWS-EES-1-10-90-6	SP 8.3.1.3.2.1
TWS-INC7-8/88-07	SP 8.3.1.3.3.2/.3
TWS-EES-13-02-91-049	Software
TWS-EES-13-03-91-023	Software
TWS-EES-13-03-91-025	Software
TWS-EES-13-03-91-026	Software
TWS-EES-15-01-90-005	Groundwater Chemistry Model

Logbooks

TWS-ESS 1/7/86-36
ESS-1-5/86-18

Deficieny Reports (DRs)

LANL-0014, -0017, -0052, -0055, -0058, -0089, -0098, -0110, -0111, -0112, -0119, -0121, -0122, -0126, -0127, -0128, -0129, -0130, -0131, -0132, -0133, -0135, -136, and -0137

Samples

CDH031990-01 thru CDH031990-17

CDH032090-201 thru CDH032090-215

DV-FCW-1-SSL (356), DV-NV-1-SSL (357), and DV-GS-1-SSL (358)

HD-441 (342), HD-443-3 (343), HD-444 (344), HD-446-1 (345), HD-446-2 (346), HD-450 (347), HD-450-1 (348), HD-465 (349), HD-466 (350), HD-467 (351), HD-468 (352), HD-469 (353), and HD-470 (354)

DEB 3/90-1 (157) thru DEB 3/90-50 (206)

Measuring and Test Equipment and associated documents

Identifier	Description
PN 329903	Mettler balance, PL-3000
PN 486983	Scanning Electron Microscope
PN 487066	Siemens diffractometer
PN 487078	Anton Parr TTK Med T stage attachment
PN 487147	Mettler balance, AE-30
PN 624829	Mettler balance, AE-50
PN 707058	Thermolyne oven
PN 715661	Tracor Northern EDS (old SEM)
PN 722765	Tracor Northern EDS (probe)
PN 652706	Tracor/electron beam instrument (ADEM), SN 1289054
SN 98019	Vaisala HMI 32 humidity probe
PN 649497	Ion chromatograph
PN 695197	Sorvall centrifuge
SN 040187017	AMETEK
20322906	NIST traceable weight set (1mg-100g)
4526	500g weight
4527	1000g weight
4528	2000g weight
BC 695207	Sartorius analytical balance

Measuring and Test Equipment (M&TE) Record Packages

TWS-EES-13-01-91-015
TWS-EES-13-01-91-016
TWS-EES-13-01-91-019
Los Alamos M&TE Master Inventory List, 2/28/91

Miscellaneous

Los Alamos YMP Organizational Chart, 3/7/91 (Information copy)
Position Descriptions and Personnel Qualification Evaluation forms for four individuals
Indoctrination and training forms
Audit schedule, 6 revisions
Audit plans for 4 audits, LANL-AR-90-05, -08, -09, -10
Audit Checklists for 3 audits, LANL-AR-90-08, -09, -10
Audit Revisioneports for 4 audits LANL-AR-90-05, -08, -09, -10
Audit status log
Survey Checklists and Survey Reports for six Surveillances, LANL-SR-90-001 thru -90-006
Auditor certification files for 6 auditors

* Insufficient activity, therefore implementation effectiveness is considered "Indeterminate."

Audit Report
YMP-91-03
Enclosure 5

INFORMATION COPY OF
CORRECTIVE ACTION REQUEST

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.

14CAR NO.: YM-91-041
DATE: 04/01/91
SHEET: 1 OF 2
QA
WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document	2 Related Report No.
LANL-YMP-QAPP, Rev. 5	Audit No. 91-03

3 Responsible Organization	4 Discussed With
Los Alamos National Laboratory	R. Herbst, S. Bolivar

10 Response Due	11 Responsibility for Corrective Action	12 Stop Work Order Y or N
30 Days From Issue	R. Herbst	No

5 Requirement:

LANL-YMP-QAPP, Rev. 5, Sect. 1.2 states in part:

"... Implemmentation of the requirements of the QAPP shall be accomplished through quality implementing procedures (QPs)..."

LANL-YMP-QP-6.2, Rev. 0 "Preparation , Review and Approval of Quality Administrative Procedures, Para. 4.4 states:

"QPs are documents that describe the methods used to conduct LANL YMP activities that affect quality. QPs implement the QA program requirements of the LANL QAPP."

6 Adverse Condition:

QAPP requirements are not being consistently reflected in QPs.

DISCUSSION: The following representative examples illustrate the adverse condition.

1. LANL-YMP-QAPP, Rev. 5, Section 15.5.3 states in part, "Persons responsible for dispositioning the NCR shall ensure that the following requirements are met....The disposition shall document action needed to preclude recurrence of the nonconforming condition."

   Los Alamos QP TWS-QAS-QP-15.2, Rev. 1, "Deficiency Reporting" only requires documentation of actions to preclude recurrence of significant conditions adverse to quality (i.e., the QP does not require documentation of action needed to preclude recurrence of all nonconforming conditions).

7 Recommended Action(s):

1. Take necessary action to resolve the representative examples identified in the CAR.
2. Investigate to determine the extent of inconsistencies and resolve all inconsistencies found.
3. Evaluate results of investigation to determine if preventative action is necessary.

8 Initiator	Date:	9 Severity Level -	13 Approved By:	Date:
J.S. Martin and R.E. Lowe	04/01/91	1☐ 2☒ 3☐	QQA James Blaylock for	4/3/91

15 Verification of Corrective Action:

16 Corrective Action Completed and Accepted:	17 Closure Approved By:
QAR _____ Date _____	QQA _____

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.

CAR NO.: YM-91-041
DATE: 04/01/91
SHEET: 2 OF 2

CORRECTIVE ACTION REQUEST (continuation sheet)

6 Adverse Condition (continued)

2. LANL-YMP-QAPP, Rev. 5, Section 7.1.3 "Bid Evaluation" states in part, "Bid evaluation shall determine the extent of conformance to the procurement documents. The evaluation, by the designated organizations, shall consider the following, as applicable to the type of procurement:

   - o technical considerations
   - o QA requirements
   - o personnel
   - o production capabilities
   - o past performance
   - o alternatives
   - o exceptions

   Los Alamos QP LANL-YMP-QP-04.5, Rev. 0, "Procurement of Noncommercial-Grade Items and Services," Para. 6.2.1 limits the evaluation of supplier's capability to provide an item or service in accordance with the technical and QA requirements of the procurement documents. (i.e., Personnel, production capabilities, past performance, alternatives, and exceptions are not addressed in the QP.)

3. LANL-YMP-QAPP, Rev, 5, Section 7.1.6, "Control of Documents Generated by Suppliers," states, "Documents generated by suppliers shall be submitted in accordance with requirements of the procurement documents and shall be handled, approved, and controlled according to LANL QPs for document control. The documents shall be evaluated against the criteria for procurement acceptance."

   Los Alamos QP LANL-YMP-QP-04.5, Rev. 0, "Procurement of Noncommercial-Grade Items and Services" does not address this section of the QAPP.

4. LANL-YMP-QAPP, Rev. 5, Section 2.2.2, "Use of Data Not Generated Under Quality Assurance Controls," states in part, "For use in licensing activities, the QA Program for the LANL YMP provides some data or data integrations that were not generated under a program that meets the requirements of 10 CFR 60, Subpart G...A LANL QP shall be prepared to implement these requirements..."

   No Los Alamos QP could be found that addresses this subject.

5. LANL-YMP-QAPP, Rev. 5, Section 2.5.2, "Indoctrination" states in part, "Personnel assigned to perform activities affecting quality shall first be indoctrinated to the purpose, scope, methods of implementation, and applicability of the following documents (including revisions and changes) as they relate to the work to be accomplished:

   - o QAPPs
   - o implementing procedures and work instructions (applicable to the individual's responsibilities)
   - o regulations, and
   - o Project-level documents..."

   LANL-YMP-QAPP, Rev. 5, Section 3.1.1, "Preparation of Scientific Investigation Planning Documents," states in part, "Scientific investigations affecting quality shall be planned and documented to ensure a systematic approach..."

   No QP or group of QPs could be found that clearly addresses control of activities performed by personnel who are not assigned to the YMP.

   e.g. In support of a publication, (Eus. J. Mineral, 1990, 2, 771-777, Long-term Thermal Stability of Clinoplilolite: The Development of a "B" Phase, by David L. Bish), a Los Alamos employee not assigned to the YMP performed an analysis. No objective evidence could be found within the LANL YMP organization that this Los Alamos employee had received appropriate orientation and training or that the analysis was performed using appropriately calibrated instruments and approved procedures.