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U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE

AUDIT REPORT

OF

LOS ALAMOS NATIONAL LABORATORY
LOS ALAMOS, NEW MEXICO

AUDIT YMP-93-11
MAY 24 - 28, 1993

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Date:

6-28-93

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102.7

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit YMP-93-11, the audit team determined that the Los Alamos National Laboratory (Los Alamos or LANL as sometimes used in document identification numbers) is satisfactorily implementing an effective QA program in accordance with the Los Alamos Quality Assurance Program Plan (QAPP), LANL-YMP-QAPP, Revision 5, for the Yucca Mountain Site Characterization Project (YMP), and its implementing procedures for QA Program Elements 1.0, 2.0, 5.0, 6.0, 12.0, 16.0, 17.0, and 18.0. QA Program Element 13.0 was examined but was found to have had no implementation.

The audit team identified three deficiencies during the audit that resulted in the issuance of three Corrective Action Requests (CAR). CAR YM-93-049 concerns the failure to identify, document and control interfaces in accordance with procedure TWS-QAS-QP-01.1, Revision 2; CAR YM-93-050 concerns a form that is a quality record which does not provide for unique identification and traceability; and CAR YM-93-051 addresses the failure to train all Los Alamos YMP personnel to procedure LANL-YMP-QP-17.4 as required by the procedure. There were three deficient conditions identified and subsequently corrected during the audit. These conditions are described in Section 5.5.2 of this report. Additionally, there were four recommendations resulting from the audit which are detailed in Section 6.0 of this report.

2.0 SCOPE

The audit was conducted to evaluate compliance to, and the effectiveness of, the Los Alamos QA Program as described in the Los Alamos QAPP and implementing quality procedures.

The QA program elements/requirements evaluated during the audit are in accordance with the published audit plan and are as follows:

QA PROGRAM ELEMENTS

- 1.0 Organization
- 2.0 Quality Assurance Program
- 5.0 Instructions, Procedures, Plans, and Drawings
- 6.0 Document Control
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Shipping, and Storage
- 16.0 Corrective Action
- 17.0 Records
- 18.0 Audits

The following QA program elements/requirements were not reviewed during the audit because Los Alamos has no activity for which these elements apply.

- 9.0 Control of Processes
- 14.0 Inspection, Test, and Operating Status of Engineered Items

TECHNICAL AREAS

The scope of this audit did not include any technical areas.

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members and assigned areas of responsibility.

<u>Individual</u>	<u>QA Program Element/Requirement</u>
Thomas J. Higgins, Audit Team Leader (ATL), Yucca Mountain Quality Assurance Division (YMQAD)	12.0, 13.0
Sandra D. Bates, Auditor, YMQAD	12.0, 13.0, 17.0
James Blaylock, Auditor, YMQAD	1.0, 2.0
Frank J. Kratzinger, Auditor, YMQAD	5.0, 6.0, 16.0, 18.0

No Observers were present at this audit.

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The preaudit meeting was held at Los Alamos Technical Associates' (LATA) offices on the branch campus of the University of New Mexico in Los Alamos, New Mexico, on May 24, 1993. Briefing and coordination meetings were held with Los Alamos/LATA management and staff on a twice daily basis. Audit team meetings were also held daily to discuss issues and potential deficiencies. The audit was concluded with a postaudit meeting held at the LATA offices at 1650 Trinity Drive in Los Alamos, New Mexico on May 28, 1993. A list of personnel contacted during the audit is found in Attachment 1 of this report. The list includes those who attended the preaudit and postaudit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall, the Los Alamos QA Program is adequate and is being satisfactorily implemented for the scope of this audit. Individually, QA Program Elements 1.0, 2.0, 5.0, 6.0, 12.0, 16.0, 17.0, and 18.0 are satisfactory in implementation. QA Program Element 13.0 had no implementation so an evaluation was not possible.

5.2 Stop Work or Immediate Corrective Actions or Additional Actions

There were no Stop Work Orders (SWOs), immediate corrective actions or related additional items resulting from this audit.

5.3 QA Program Audit Activities

Details of the QA program audit activities are provided in Attachment 2. A list of objective evidence reviewed during the audit is provided in Attachment 3.

5.4 Technical Activities

No technical activities were included in the scope of this audit.

5.5 Summary of Deficiencies

The audit team identified three deficiencies during the audit for which CARs have been issued. Three additional deficiencies were corrected prior to the postaudit meeting.

A synopsis of the deficiencies documented as CARs and those corrected during the audit, is detailed below. Information copies of the CARs are included in Attachment 4.

5.5.1 Corrective Action Requests

As a result of the audit, the following CARs were issued:

CAR YM-93-049

Contrary to the requirements of TWS-QAS-QP-01.1, Revision 2, the identification and control of interfaces is not being properly documented on Interface Description Forms (IDFs).

CAR YM-93-050

Attachment 1 of Los Alamos procedure LANL-EES 13-DP-609, Revision 0, is a quality record resulting from the execution of this procedure. Contrary to the above requirements that records be identifiable, Page 2 of Attachment 1 lacks any provision of information linking it unambiguously to any specific Page 1 or the attachment.

CAR YM-93-051

Contrary to the requirements of LANL-YMP-QP-17.4, Revision 0, not all Los Alamos YMP personnel are being trained to this procedure, as required.

5.5.2 Deficiencies Corrected During the Audit

Deficiencies that are considered isolated in nature and require only remedial action can be corrected during the audit. The following three deficient conditions were identified and corrected during the course of the audit:

1. LANL-YMP-QP-17.4, Revision 0, Section 6.6.3 contains the statement that, "The originator reviews the record package to ensure that the table of contents is accurate and complete, that all documents and YMP records in the package meet the requirements of this procedure and its Attachment 2, and that the records in the package are accurate and complete." In addition, LANL-YMP-QP-17.5, Revision 0, states that the Record Processing Center (RPC) staff rejects records not meeting the requirements of Quality Procedure (QP) 17.4.

Contrary to the requirements of QP-17.4, a single record package, TWS-EES-13-03-93-073 was submitted to the RPC with misplaced pages, incorrect order of pages, and misnumbered pages. Contrary to the requirements of QP-17.5, the RPC accepted this package as meeting requirements and transmitted it to the YMP Central Records Facility (CRF) in Las Vegas, Nevada. This record package was the only one examined to exhibit these conditions. Investigation revealed that the cause was related to an attempt to conserve paper by double-sided copying from a 178 page single-sided original. Copy machine misfeeds scrambled the product and either the record source and/or an RPC staff member failed to check the results.

This was an isolated condition that required only remedial corrective action. During the course of the audit, Los Alamos issued a letter (EES-13-05-93-1812), Bolivar to Rixford, dated May 27, 1993, recalling the record package. At the same time, an amended record package was prepared and submitted to the RPC.

2. LANL-YMP-QP-02.4, Revision 1, "Management Assessment," requires that the initial notification letter for a management assessment be included in the records package. Contrary to this requirement, the initial letter announcing the 1992 assessment, dated January 10, 1992, was not included in this records' package. This was an isolated condition that required only remedial corrective action. During the course of the audit, this omission was corrected.
3. QP-16.3, Paragraph 6.5.2, contains the statement that, "If a request for extension is received, the Deficiency Report (DR) coordinator completes Section II of the form, updates the DR database, includes the form in the DR package, and returns a copy of the form to the individual."

The record packages for 29 DRs were examined at the RPC. Two of these (LANL-0195 and LANL- 0197), were found to have DR Deadline Extension forms that were incompletely filled out. The blocks indicating approval or disapproval of the request were not marked.

This condition required only remedial corrective action and was corrected during the audit by the completion of the forms and their resubmittal to RPC.

5.5.3 Follow-up of Previously Identified CARs

1. CAR YM-91-041 was issued on April 3, 1991, and addressed multiple instances of failure to incorporate QAPP requirements into implementing procedures. This CAR remains open and completion of corrective actions by Los Alamos was scheduled for May 30, 1993, two days after the audit's close. Los Alamos management indicated that bringing their procedures into line with the Quality Assurance Requirements and Description document (QARD) was scheduled for the end of July 1993. Completion of this latter task

would bring Los Alamos into overall compliance and the CAR would be closed.

2. CAR YM-92-058 was issued on July 14, 1992, and was closed on January 29, 1993. It addressed the failure to conduct the required independent technical review of completed Scientific Notebooks (SNs), field books, and log books in a timely manner.

During the course of the audit, many record packages were examined in the process of evaluating QA Program Element 17.0. Among these were packages transmitting completed field and log books and SNs. It seems clear that the corrective actions instituted to satisfy this CAR have been adopted and applied more widely than was addressed in that CAR. This is a good example of effective corrective action.

6.0 RECOMMENDATIONS

The following recommendations resulted from the audit and are presented for consideration by Los Alamos management.

1. Los Alamos should evaluate its broad practice of specifying that "Proper completion and filing of the QA records listed in Section 7.0 constitute the acceptance criteria for this procedure," in many of its procedures. This choice of criterion is not always appropriate.
2. Los Alamos management should re-evaluate its implementation of requirements for the submittal of records and record packages. The lack of emphasis on timely, frequent, required submittal of records has had a number of negative results. Among these are the following:
 - The unsubmitted record packages from the preparation, review and approval of four Detailed Technical Procedures that had been issued for use eight to 14 months prior to the audit. See Attachment 2, Section 5.0/6.0, "Results" for a full discussion of this situation.
 - The deficient condition of the yearly Measuring and Test Equipment (M&TE) quality records for 39 instruments, assembled into a single 178-page record package (Record Traveler No. TWS-EES-13-03-93-073), that had to be recalled from the YMP CRF and replaced with a fresh submittal. See Section 5.5.2, Item 1, of this report.

3. Los Alamos should revise QP-01.2 to include clarification of:
 - The responsibilities of all personnel with regard to reporting conditions that may warrant evaluation for a SWO.
 - The mechanism for the resolution of disagreements arising from implementation of this procedure.
4. Los Alamos should revise QP-02.4 to address the handling of open items resulting from management assessments and to provide a tracking mechanism to assure their timely closure.

7.0 LIST OF ATTACHMENTS

- Attachment 1: Personnel Contacted During the Audit
- Attachment 2: Audit Details
- Attachment 3: List of Objective Evidence Reviewed During the Audit
- Attachment 4: Information Copies of CARs

ATTACHMENT 1

PERSONNEL CONTACTED DURING THE AUDIT

<u>Name</u>	<u>Organization/Title</u>	<u>Preaudit Meeting</u>	<u>Contacted During Audit</u>	<u>Postaudit Meeting</u>
Bates, S.	YMQAD, Auditor	X		X
Blaylock, J.	YMQAD, Auditor	X		X
Bolivar, S.	Los Alamos QA Project Leader	X	X	X
Broxton, D.	Los Alamos PI, Mineralogy-Petrology		X	
Canepa, J.	Los Alamos, TPO	X	X	X
Carlos, B.	Los Alamos, PI		X	
Chavez, C.	LATA, Training Coordinator	X	X	X
Chipera, S.	Los Alamos, Associate PI		X	
Clark, D.	Los Alamos, Associate PI		X	
Clevenger, M.	Los Alamos, Deputy QA Project Leader	X	X	X
Day, J.	LATA, QA Verification Coordinator	X	X	X
Eckhardt, R.	Los Alamos, Database Coordinator	X		X
Gillespie, P.	Los Alamos, QA Engineer	X		X
Higgins, T.	YMQAD, ATL	X		X
Hyer, D.	Los Alamos, Study Plan Coordinator	X		
Kratzinger, F.	YMQAD, Auditor	X		X
Lopez, R.	Los Alamos, Research Technician		X	
Martinez, C.	Los Alamos, QA Engineer	X		
Martinez, S.	LATA, RPC Operations Coordinator	X	X	X
Mitchell, A.	Los Alamos, Research Technician		X	X
Palmer, P.	Los Alamos, Chemical Technician		X	
Raymond, R.	Los Alamos, Staff			X
Robinson, M.	LATA, Database Admin. Specialist	X		
Romero, B.	LATA, Document Control Coordinator	X	X	X
Sanders, L.	LATA, Records Coordinator	X	X	X
Shay R.	LATA, QA Engineer/M&TE Coordinator	X	X	X
Snow, M.	Los Alamos, Research Technician		X	X
Triay, I.	Los Alamos, Technical Coordinator, Geochemistry	X	X	X
White, C.	Los Alamos, Records File Custodian		X	
Williams, D.	LATA, QA Liaison	X	X	X

Legend

PI = Principal Investigator
 TPO = Technical Project Officer

ATTACHMENT 2

AUDIT DETAILS

The following is a summary of the Los Alamos QA Program activities covered during the audit. The list of objective evidence reviewed and specific procedures audited is provided in Attachment 3.

1.0 ORGANIZATION

The evaluation of this QA program element was based on interviews with Los Alamos QA organization management and examination of objective evidence to determine the degree of compliance with selected requirements from QP-01.1, QP-01.2, and QP-01.3. The specific requirements selected for evaluation of compliance and effectiveness are listed below.

Interface Control Procedure (QP-01.1)

Requirements:

- Interfaces for technical or QA information shall be identified and controlled
- Interfaces are documented on an IDF and will have appropriate, required signatures
- Changes to an interfaces are appropriately documented and approved
- Interfaces between YMP Participants are handled in accordance with YMP Administrative Procedure (AP)-5.19Q

Results:

QP-01.1 requires the identification and control of interfaces for the exchange of technical or QA information across organizational boundaries. However, the Los Alamos organization is not clearly delineated in the Los Alamos QAPP and this contributes to the inconsistencies found in implementation of the procedure. The procedure requires all interfaces be described on an IDF. For those interfaces between YMP at Los Alamos and other YMP participating organizations, the procedure further instructs that YMP AP-5.19Q be followed.

The audit investigation determined that Los Alamos has identified only four such interfaces. Two IDFs with other YMP organizations were initiated by the Test Coordination Office in accordance with AP-5.19Q and resulted in two Interface Memorandums of Understanding (IMOU): 660025 and 330018. An un-numbered IMOU was executed directly between the Los Alamos and U.S. Geological Survey (USGS) TPOs for "LANL/USGS for Sample and Data Transfers Involving the Hydrogenic Deposits Study" during 1990. An IDF was initiated for Work Breakdown Structure (WBS) No. 1.2.3.3.1.2.2, "Water Movement Tracer Tests," with USGS; however, there is no indication that USGS signed the IMOU. This process was not completed following AP-5.19Q. In reviewing the WBS, the area of Volcanism, WBS No. 1.2.3.2.5 shows USGS and Technical and Management Support Services (T&MSS) as participating organizations, yet no IDF has been initiated. This condition associated with interfaces was documented on CAR YM-93-049. See Section 5.5.1 of this report.

Los Alamos is in the process of preparing QP-01.4, "Organization," in partial response to CAR YM-91-041 that addresses the failure to adequately implement all requirements in implementing procedures. However, it was still a draft at the time of the audit. The lack of this document as an approved procedure is considered contributory to the deficiency above.

Stop Work Control (QP-01.2)

Requirements:

- Personnel are responsible for informing the Quality Assurance Project Leader (QAPL) of conditions that are potentially serious enough for a SWO.
- The QAPL has the responsibility to investigate the condition and initiate the stop work process, if needed.
- The QAPL has the responsibility to monitor the SWO and oversee the proper resolution and lifting.

Results:

QP-01.2 describes the process of identifying stop work conditions, imposition of an SWO, and the resolution and lifting of such an order. A review of this procedure produced two comments:

- Paragraph 6.1 does not explicitly require the reporting of a potential stop work condition to the QAPL.

- The procedure is not clear whether QP-01.3, "Conflict Resolution," must be invoked if there is a disagreement between the QAPL and initiator on the potential SWO condition.

There is a recommendation addressing both of the above comments in Section 6.0 of this report.

The descriptions of the deficient conditions in SWO-06 and SWO-07 were not clear on the SWO. However, SWO-08 which is still in progress, does give a clear description of the identified condition. It appears that this potential problem has been corrected.

Conflict Resolution (QP-01.3)

There has been no implementation of this procedure.

Summary for the Program Element:

Based on the interviews conducted and review of the objective evidence, except for the deficiency related to identification of interfaces, Los Alamos is implementing QA Program Element 1.0 satisfactorily.

2.0 QUALITY ASSURANCE PROGRAM

The evaluation of this QA program element was based on interviews with Los Alamos QA organization management and examination of objective evidence to determine the degree of compliance with selected requirements from QP-02.3, QP-02.4, QP-02.5, QP-02.7, QP-02.9, and QP-02.11. The specific requirements selected for evaluation of compliance and effectiveness are listed below.

Procedure For Readiness Review (QP-02.3)

QP-02.3, "Procedure for Readiness Review," has not been implemented. Los Alamos management does not intend to perform readiness reviews except at the direction of YMP and to the YMP procedure. A potential problem exists since AP-5.13Q, "Readiness Reviews," was cancelled and redesignated as a U.S. Department of Energy Quality Assurance Procedure (QAP) which is not implemented by YMP participants. Los Alamos management needs definitive direction from YMP management to determine their responsibilities for performing Readiness Reviews.

Management Assessment (QP-02.4)

Requirements:

- A Management Assessment is conducted annually.
- The TPO initiates the assessment by means of a memorandum.
- The assessment team leader prepares an assessment plan that includes evaluation of the following:
 - Adequacy of Los Alamos' organizational structure and staff to implement the QA program.
 - Effectiveness of the QA Program.
 - Adequacy of training programs.
 - Effectiveness of deficiency reporting systems.
 - Adequacy of QA management administrative activities, planning, and procedural controls.
 - Status of open deficiencies resulting from the previous management assessment.
- The Management Assessment Report meets the format content requirements set forth in the procedure and has the required signatures
- The QAPL initiates deficiency reports for conditions adverse to quality identified in the assessment report
- The TPO reports by memorandum on the disposition of assessment report recommendations
- A complete records package is prepared and submitted as required

Results:

The annual Management Assessment was conducted in accordance with QP-02.4. The Assessment Team identified no deficiencies but made recommendations in their final letter report to the TPO. Several recommendations have not yet been fully resolved and the QAPL continues to track these items. A recommendation has been made in

Section 6.0 of this report which addresses timely resolution of, and the need for a procedural tracking mechanism for, open items resulting from management assessments. In addition, the initial announcement of the assessment was not included in the management assessment record package (TWS-EES-13-04-93-002) but was added when its omission was noted. This condition is discussed in Section 5.5.2 of this report.

Selection of Personnel (QP-02.5)

Requirements:

- Personnel have written Position Descriptions (PDs) that contain position title, duties and responsibilities, and appropriate education and experience.
- The employee's statement of education and experience is verified and recorded on the Personnel Qualification Evaluation (PQE) form and signed by the authorized verifier.
- The PD and the PQE compared to verify the employee meets the PD requirements.

Results:

Files were selected for 11 employees. The PDs were verified to contain a title, duties and responsibilities, and the minimum education and experience to fulfill the job. The qualifications of the incumbent were then compared to the PD, based on the information provided on the PQE. All PQEs met or exceeded the minimum qualifications on the PD.

Personnel Training (QP-02.7)

Requirements:

- The type of training (i.e. read, class, etc.) is determined for QP by the QAPL and for each technical procedure by the PI.
- Supervisors are notified when new or revised procedures are issued.
- Read-only training is documented on Reading Acknowledgement Forms.
- Classroom training is documented on the Classroom Training Attendance Form.
- Formal nonclassroom training is documented on the Formal Training Form.

Results:

Determination of training requirements is established by the QAPL for the QPs and by the PI for detailed procedures. The current Table of Contents for both QPs and Detailed Procedures (DPs) depicts such a determination. For selected QP and DPs, it was verified that the Records Coordinator notified all YMP supervisors whenever a new or revised QP or DP was issued. For the read-only training or classroom training documentation had been completed and resided in the training file of the individual. The training files of 14 individuals were examined.

Personnel Proficiency Evaluations (QP-02.9)

Requirements:

- The required proficiency evaluation for employees includes review of the training file to verify necessary training and job performance to verify satisfactory execution of duties.
- Both supervisor and employee contribute to the proficiency evaluation.
- Remedial action is taken for incomplete and unsatisfactory completion of duties.

Results:

The Proficiency Evaluations of 11 personnel were examined and found to be complete and signed by the supervisor and employee. Other than creating a piece of paper and complying with a procedural requirement, the auditor did not feel that this procedure contributed to the evaluation process. Los Alamos has gone to a just-in-time training mode; this showed up consistently in training for QA Program Element 17.0, "Records." With the designation of the Document File Custodians (DFC) as the records originators, the DFCs and records authenticators are typically among the few trained to records procedures.

Personnel Orientation (QP-02.11)

Requirements:

- Employees receive orientation prior to participating in Los Alamos YMP activities

Results:

Personnel orientation consists of two elements, the initial orientation of personnel, and the annual review of the orientation presentation by the QAPL. The training files reflected that those training records for individuals selected as part of the audit of QP-02.7, had all received orientation. No examples were found of the QAPL exempting a new hire from attending the earliest scheduled class after being employed. Classroom Attendee Lists for Personnel Orientation presented on six dates were examined.

The QAPL completed the first quarter evaluation of the YMP Orientation Plan. This was documented by a memorandum dated February 8, 1993. The follow-up to those comments is being tracked, but completion of the revisions is not scheduled to be complete until June 30, 1993.

Summary for the QA Program Element:

Based on the interviews conducted and review of the objective evidence, Los Alamos is implementing QA Program Element 2.0 satisfactorily.

5.0 INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS
6.0 DOCUMENT CONTROL

These QA program elements were evaluated based on objective evidence to determine compliance with the requirements of implementing procedures QP-06.1, QP-06.2, and QP-06.3 as listed below:

Preparation, Review, and Approval of Quality Administrative Procedures (QP-06.2)

Requirements:

- Action Request (AR) Forms are completed for each new, revised, or deleted QP.
- The QAPL completes and signs off in Section II of the AR.
- After a draft procedure is written, the draft QAPL determines the organizations affected by the QP and forwards it to the responsible individuals in those organizations for review.
- The quality reviewer completes the QA Review Checklist.
- The preparer signs and dates the cover page and forwards copies of the following documents to the QAPL: QP AR, draft QP, Review Sheets, QA Review Checklist, final QP, and correspondence related to these documents.

- The QAPL signs and dates the cover page, selects the type of training required in Section III of the QP AR, and forwards the QP to the TPO.
- The TPO signs and dates the cover page and returns the QP to the QAPL.
- The Document Control Center (DCC) updates the QA Manual and issues the QP.
- The QAPL prepares a record package consisting of the following documents:
 - QP AR
 - Draft QP
 - Review Sheets
 - QA Review Checklist
 - Final Approved QP
 - Correspondence related to these documents

Preparation, Review and Approval of Detailed Technical Procedures (QP-06.3)

Requirements:

- An AR is completed for each new, revised, or deleted DP.
- The PI completes and signs off in Section II of the AR.
- After a draft procedure is written, the preparer completes the first block of the Los Alamos YMP Review Sheet and forwards it and the draft DP to the reviewers.
- The QA reviewer completes both a Los Alamos YMP Review Sheet and the QA Review Checklist.
- The technical reviewers complete the Los Alamos YMP Review Sheet.
- The preparer signs and dates the cover page, obtains dated signatures from the QA and technical reviewers, and forwards the DP and DP AR to the PI.
- The PI determines training needs and completes Section III of the AR, signs and dates the cover page, and forwards the package to the QAPL.
- The QAPL signs and dates the cover page and forwards the package to the TPO.

- The TPO signs and dates the cover page and forwards the package to the Records Coordinator.
- The preparer files a copy of the DP AR, the original draft DP, all Los Alamos YMP Review Sheets, the QA Review Checklist, and any related correspondence in the group resident file.
- The preparer sends two copies of the record package to the Records Coordinator.
- The Records Coordinator files a copy of the DP AR and related correspondence as a records package in the Quality Assurance Services (QAS) Resident File and forwards two copies to the RPC.

Document Control (QP-06.1)

Requirements:

- The DCC updates the master list of controlled documents and the master file of controlled documents.
- The DCC initiates a Controlled Document Acknowledgement Form that includes the appropriate instructions for implementation of the controlled document.
- The DCC notifies YMP supervisors in writing that a controlled document was issued.
- The recipient signs and dates the Controlled Document Acknowledgement Form and returns it to the DCC.
- Some of the controlled document holder's manuals were reviewed to verify that they contained the latest revision of selected QPs and DPs.

Results:

Twenty-eight procedures were selected for evaluation and their record packages were examined to determine compliance with procedural requirements. These were found to be complete and satisfactory with the exception of four procedures for which the record packages had not yet been transmitted to the RPC, nor had their Record Package Travellers been authenticated. No requirements of the Los Alamos QAPP for QA Program Elements 5.0, 6.0, or 17.0 or their implementing procedures, has any specific time limit for submitting record packages. The identified procedures are:

<u>Procedure</u>	<u>Date Issued</u>	<u>Period</u>
LANL-EES-DP-101, Revision 2	3/16/93	14 months
LANL-EES-DP-129, Revision 0	3/16/93	14 months
LANL-EES-DP-130, Revision 0	5/27/93	12 months
LANL-EES-DP-131, Revision 0	9/11/93	8 months

The list above demonstrates that the processing of these records has been unduly delayed and represents the lack of a full commitment to the protection of data and records. However, there is no basis in the Los Alamos QA Program on which to initiate a CAR. This condition represents a weakness in the current Los Alamos QA Program. A recommendation dealing with this situation has been made in Section 6.0 of this report.

Based on interviews and the objective evidence, the implementation of QA Program Elements 5.0 and 6.0 is satisfactory and effective.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

The evaluation of this QA program element was based on compliance with procedure QP-12.1, and on interviews with the M&TE Coordinator, PIs, and other technical personnel. The specific requirements selected for this evaluation of compliance and effectiveness are listed below.

Requirements:

- Instruments exempted from the controls of this procedure have this exemption documented.
- Exempt instruments are so tagged with a label that references the exemption documentation.
- Instruments controlled by this procedure appear on the M&TE Inventory List.
- Controlled instruments are selected via the Selection Form which is stored in the Resident and M&TE Coordinators file until transmitted to the RPC.
- The Selection Form identifies the appropriate technical requirements for the calibration and control of the instrument.
- Calibration standards are listed on the M&TE Inventory List.

- Controlled instrumentation is tagged with a label that uniquely identifies the instrument and indicates the date of next calibration, the procedure used in calibration, and the individual responsible.
- Calibration of an instrument is conducted according to the specified, appropriate procedure.
- The calibration process is recorded in accordance with the specified procedure.
- Calibration performed by the User on an approved as-needed schedule is recorded in SNs or logbooks.
- The results of the calibration process is reported on the Calibration Form that is stored in the Resident File with a copy to the M&TE Coordinator's file.
- The M&TE Coordinator reviews the Calibration Form and initiates a DR if the instrument was found to be out of calibration and had been used in measurement.
- Suspect or out-of-calibration instruments are so tagged.
- The M&TE Coordinator submits the M&TE quality records in one or more record packages to the RPC on a yearly basis.

Results:

The evaluation of this QA program element was based upon the examination of M&TE records for 34 instruments for overall compliance. The quality records of 16 instruments were selected for verification of internal consistency and compliance with technical requirements. In both of the preceding cases, all were found to be satisfactory and in compliance. The records were found in the RPC, the M&TE Coordinator's file, and several Resident Files (EES-1, INC-7, and INC-11). Thirty instruments were examined in the laboratory to verify current calibration status and proper tagging; all were satisfactory. Interviews were also conducted with the M&TE Coordinator, PIs, laboratory technicians, and QA liaison personnel.

There were no CARs initiated against this QA program element during the audit.

Based on interviews and the objective evidence, the implementation of QA Program Element 12.0 is satisfactory and effective.

13.0 HANDLING, SHIPPING AND STORAGE

The requirements of this QA program element are implemented through QP-13.1. There has been no implementation.

The evaluation of this QA program element was based on interviews with the management of the Los Alamos QA organization, PIs and technical personnel in the various laboratories visited by the auditor. There was uniform agreement among the individuals interviewed that there was no activity related to this QA program element. This testimony was corroborated by the absence of any objective evidence to the contrary. Consequently, there could be no evaluation of the effectiveness of QA Program Element 13.0 by virtue of no implementation.

16.0 CORRECTIVE ACTION

This QA program element was evaluated based on objective evidence to determine compliance with implementing procedures QP-15.2, QP-16.2, and QP-16.3. The selected requirements are as listed below:

Deficiency Reporting (QP-15.2)

Requirements:

- The QAPL assigns the next available number to the DR from the DR Log and enters the information from Part I of the DR into the DR Log.
- The QAPL evaluates the severity of the deficiency and checks either the "Condition Adverse to Quality" or the "Significant Condition Adverse to Quality" box in Part III of the DR.
- The QAPL assigns an organization to resolve the deficiency, completes Part III of the DR, and forwards the original to the YMP supervisor of the assigned organization and a copy to the Quality Assurance Liaison (QAL).
- The deficiency is resolved and the DR returned to the QAPL within thirty calendar days of the date of the QAPL's signature on Part II of the DR.
- The responsible individual proposes the disposition of the deficiency by entering the applicable information in Part IV of the DR and signs and dates Part IV.
- The YMP supervisor reviews the information in Part IV of the DR for completeness and correctness, signs and dates Part IV, and forwards it to the QAPL.

- The approval or disapproval of the proposed disposition is made within fifteen calendar days of the YMP supervisor's signature on Part IV of the DR.
- Upon approval of the proposed disposition, the QAPL signs and dates Part V of the DR.
- The YMP supervisor notifies the QAPL in writing when the corrective actions are complete.
- The QAPL verifies that the deficiency was corrected adequately, the completion date was met, quality requirements were met, and documents the method of verification in Part VI of the DR.
- The QAPL closes the DR by signing and dating Part VI of the DR.
- The QAPL prepares a record package that includes the DR, its attachments, and related correspondence and forwards one copy to the originator, one copy to the groups QAL, and two copies to the RPC.

Trending (QP-16.2)

Requirements:

- On a quarterly basis, the QAPL examines all internal deficiency reports for the preceding 12 month period.
- The QAPL sends a copy of the trend report to the TPO, Project Leaders, and any other YMP Staff as appropriate.

Deficiency Reports (QP-16.3)

Requirements:

- The DR coordinator checks the form for completeness, issues the DR number, creates a DR package, enters the DR into the DR database, and sends the DR package to the QAPL.
- The QAPL evaluates all deficiencies to determine if work should be stopped and completes the appropriate line in Section II.
- The QAPL assigns responsibility for the DR to a LANL YMP Project Leader (or TPO) and includes that information in Section II.

- The QAPL signs Section II and forwards the DR package to the Project Leader identified in Section II.
- The Project Leader assigned responsibility for DR action completes and signs Part A, Section III and returns the DR package to the DR coordinator within 20 working days of the date of the QAPL's signature in Section II.
- If the proposed action is satisfactory, the DR coordinator indicates approval; signs and dates Part B, Section III; and sends the DR package to the individual responsible for resolving the DR.
- The individual responsible for resolving the deficiency completes the corrective action; signs and dates Part B, Section III; and sends the DR package to the DR coordinator on or before the effective date listed in Section III.
- If the DR package is complete, the DR coordinator updates the database and sends the DR package to the Verification Coordinator.
- If the deficiency was adequately resolved, the Verification Coordinator documents the objective evidence in Part A, Section IV; signs and dates the form; and returns the DR package to the DR coordinator within 20 working days of the date of the DR coordinator signature in Part B, Section III.
- If the QAPL concludes that the verification is adequate, the QAPL signs Part B, Section IV, and returns the DR package to the DR coordinator for closure.
- The DR coordinator updates the DR database, files a copy of the DR package in the EES-13 Resident File, and submits the DR package as a record package to the RPC.
- If a request for extension of time is received, the DR coordinator completes Section II of the request, updates the DR database, includes the request form in the DR package, and returns a copy of the request form to the individual.

Results:

The documentation supporting seven reported deficiencies was reviewed to the requirements of QP-15.2 and the results were acceptable. The documentation of 21 DRs was also reviewed to the requirements of QP-16.3 and the results were also acceptable. In two cases, LANL-0195 and LANL-0197, the DR Deadline Extension form was incompletely filled out. This omission was completed during the audit and is discussed in Section 5.5.2 of this report.

Based on the interviews and review of objective evidence, the implementation of QA Program Element 16.0 is satisfactory and effective.

17.0 QUALITY ASSURANCE RECORDS

This QA program element was evaluated based on the review of objective evidence to determine compliance with selected requirements taken from implementing procedures QP-17.4 and QP-17.5. The specific requirements selected for evaluation of compliance and effectiveness are listed below.

Records Preparation (QP-17.4)

Requirements:

- Individual records and record packages are identified by TWS number, WBS number to the fourth level, and designation of QA or non-QA in the upper-right corner of the first page of individual record packages.
- YMP records or documents contain record date, originator's name and/or organization, recipient's name and/or organization, descriptive title or subject, and unique descriptor for records with similar titles.
- Individual records and record packages meet Attachment 2 requirements for records protection, legibility, error correction, completeness, and records requirements.
- Completed individual QA records and QA record packages are authenticated by the originator according to requirements of Section 6.8 of the procedure.
- Each completed record package contains a completed Record Package Traveler.
- Completed YMP records are submitted to the RPC within ten working days after the date of authentication.
- One copy of YMP records is retained for the Resident File and two copies are submitted to the RPC.
- Corrected records are submitted to the RPC no later than thirty days from the due date on the Record Correction Request.
- All Los Alamos YMP employees are trained to procedure QP-17.4, Revision 0.

Results:

The evaluation of compliance to this procedure was based on the examination of two Los Alamos group TWS Logs (non-record, administrative lists for record tracking), four record packages containing individual quality records, four individually submitted records, the storage container for an in-use one-of-a-kind record, and the provisions for dual storage of two additional records. Two deficient conditions were identified.

- A CAR was submitted due to use of a form determined to be unidentifiable when separated from other records in a completed quality records packages (see CAR YM-93-050, Section 5.5.1).
- A CAR was initiated for failure to train all employees to LANL-YMP-QP-17.4, Revision 0, as required by the procedure (see CAR YM-93-051, Section 5.5.1).

In addition, a single one-of-a-kind record is recorded at the Records Processing Center. Follow-up verification disclosed that the record is being kept in a one-hour UL listed fire-rated filing device which meets requirements for a record in process or use.

In the process of records verification, it was noted that controls were in place regarding privileged records and that records processing areas were manned at all times by authorized personnel.

Records Processing (QP-17.5)

Requirements:

- The date of receipt is indicated on each YMP record when received by the RPC.
- An explanation is submitted by originator when records cannot be regenerated or corrected, as required.
- Completed Record Transmittal Forms and completed, accepted YMP records are submitted to the Central Records Facility within 30 working days of RPC acceptance of the YMP records.
- One copy of the processed YMP record is retained until the CRF returns a signed receipt acknowledging the records were received and microfilm.

Results:

One deficient condition concerning compilation and submittal of an inaccurate quality records package (TWS-EES-13-03-93-073) was identified during the audit. A subsequent follow-up disclosed that the package had been received by the CRF, but that due to the above discrepancies was in the process of being rejected. The package was corrected during the audit and will be resubmitted as required by records processing procedures. A review of several records and records packages revealed that the incident was isolated. The one deficiency was corrected prior to the audit exit meeting (see Section 5.5.2).

Summary for the QA Program Element:

Based on the evaluation of the objective evidence, the implementation of QA Program Element 17.0, is satisfactory and effective.

18.0 AUDITS

This QA program element was evaluated based on objective evidence to determine compliance with implementing procedures QP-18.1, QP-18.2, and QP-18.3. The selected requirements are as listed below:

Audits (QP-18.1)

Requirements:

- The QAPL signs and dates the annual audit schedule and returns a copy to the Quality Assurance Verification Coordinator (QAVC) and copies to supervisors of the audited organizations.
- The QAVC forwards a copy of the audit plan to the QAPL.
- The QAVC retains a copy of the audit checklists and audit results for reference until the next audit is performed on the same organization.
- The QAPL reviews the audit report, signs and dates it, and returns a copy to the QAVC.
- The QAVC forwards the audit plan and audit report, along with any correspondence, as a record package to the EES-13 Resident File, and submits two copies of the record package to the RPC.

Auditor Qualification and Certification (QP-18.3)

Requirements:

- Los Alamos YMP employees and Los Alamos YMP contractor employees are certified as auditors and lead auditors by the QAPL prior to performing audits of Los Alamos YMP activities.
- The Los Alamos contractor documents the method(s) used to qualify each auditor on the Record of Auditor Qualification/Certification form and certifies the qualification by signing and dating the form.
- The QAPL documents on a blank Record of Auditor Qualification/Certification form the methods used to qualify each Los Alamos YMP employee and Los Alamos YMP contractor employee as an auditor for Los Alamos YMP activities and certifies the qualification by signing and dating the form.
- The QAPL forwards a copy of the Indoctrination Classroom Attendance List, Training Classroom Attendance List, and Record of Auditor Qualification/Certification form to the EES-13 group Resident File Custodian and a copy to the training coordinator.
- The QAPL documents on a blank Record of Lead Auditor Qualification/Certification form the qualifications of the individual, including those listed on the documentation provided by his previous or current employer, and the indoctrination and training provided and certifies the qualification by signing and dating the form.
- The QAPL forwards a copy of the Indoctrination Classroom Attendance List, Training Classroom Attendance List, and Record of Lead Auditor Qualification/Certification form to the EES-13 Resident File Custodian and a copy to the Training Coordinator.
- The QAPL maintains copies of the objective evidence regarding the type(s) and content of the examination administered.
- The QAPL documents the requalification of lead auditors on an annual basis.

Surveys (QP-18.2)

Requirements:

- During the first month of each calendar year, the QAS Verification Coordinator prepares an annual survey schedule and forwards it to the QAPL for approval.
- The QAS Verification Coordinator forwards a copy of the annual survey schedule to the QAS Resident File Custodian and two copies to the RPC.
- The survey team leader prepares a survey report that documents the following:
 - organization surveyed,
 - organization's location,
 - date of survey,
 - survey report number,
 - individuals contacted,
 - survey team members,
 - activities or items surveyed,
 - survey criteria,
 - equipment used during the survey (if applicable),
 - observations noted,
 - findings noted and DR number for each,
 - results (i.e. acceptance statement),
 - signature and date.
- The QAPL signs and dates the survey report and forwards a copy to the supervisor of the surveyed organization.
- The survey team leader prepares a survey records package that contains the survey report, survey checklists, and any correspondence related to the survey and forwards a copy of the package to the QAS Resident File Custodian and two copies to the RPC.

Results:

The record packages for seven audits were examined including the checklists of four of these audits. The audit schedule for the last two years and the current survey schedule was also reviewed. In the area of personnel qualification, five auditor/Lead Auditor certifications were examined as were the written Lead Auditor examinations completed by four individuals. Two survey reports were also reviewed.

Based on the examination of the objective evidence, the implementation of QA Program Element 18.0 is satisfactory and effective.

ATTACHMENT 3

OBJECTIVE EVIDENCE

QA PROGRAM ELEMENT 1.0, "ORGANIZATION"

Procedures:

Compliance with the following procedures was reviewed:

TWS-QAS-QP-01.1, Revision 2, Interface Control Procedure
LANL-YMP-QP-01.2, Revision 1, Stop Work Control
LANL-YMP-QP-01.3, Revision 1, Conflict Resolution

Objective Evidence Examined:

Record Packages:

TWS-EES-13-12-92-039, Record Package for SWO-LA-06
TWS-EES-13-03-92-055, Record Package for SWO-LA-07

Letters:

IMOU 660025, Revision 0, Draft D, "Title I Design Summary Report, Revision 1," from Science Applications International Corporation (SAIC) to Los Alamos, dated April 25, 1991

IMOU 330018, Revision 0, Draft A, "Development of Test Planning Package (TPP) 91-5...", from SAIC to Los Alamos, dated September 9, 1991

IMOU LANL/USGS (unnumbered), "Sample and Data Transfers Involving the Hydrogenic Deposits Study," Los Alamos to USGS, dated July 19, 1990 and USGS to Los Alamos, dated September 7, 1990

QA PROGRAM ELEMENT 2.0, "QUALITY ASSURANCE PROGRAM"

Procedures:

Compliance with the following procedures was reviewed:

TWS-QAS-QP-02.3, Revision 1, Procedure For Readiness Review
LANL-YMP-QP-02.4, Revision 1, Management Assessment
LANL-YMP-QP-02.5, Revision 1, Selection of Personnel

TWS-QAS-QP-02.7, Revision 1, Personnel Training
LANL-YMP-QP-02.9, Revision 1, Personnel Proficiency Evaluations
LANL-YMP-QP-2.11, Revision 1, Personnel Orientation

Objective Evidence Examined:

Letter:

EES-13-04-92-1288, dated 4/8/92
Los Alamos YMP QA Management Assessment

Record Packages:

TWS-EES-13-04-93-002, dated 4/07/93
QA Management Assessment Yucca Mountain Site Characterization Plan

Current Position Description and Personnel Qualification Evaluation Forms (LANL-YMP-QP-02.5, Revision 1, Attachments 1 and 2 respectively) and Proficiency Evaluation forms (LANL-YMP-QP-02.9, Revision 1, Attachment 1) for the following personnel:

J. Leckie	S. Forman	S. Carpenter
S. Martinez	L. Sandas	R. Shay
J. Poths	H. Bentley	W. Poler
M. Hawley	D. Boak	

The content of the current Training Files (TWS-QAS-QP-02.7, Revision 1, Attachments 1, 2, and 3 as found) for the following personnel:

G. Casedy	L. Bader	J. Fabryka-Martin
N. Elkins	L. McFadden	H. Nitsche
I. Triay	S. Wells	C. White
D. Williams	R. Shay	M. Robinson
A. Thompson	D. Broxton	

Classroom Attendee Lists for Personnel Orientation presented on the following dates:

2/7/92 3/13/92 4/17/92 5/15/92 11/19/92 2/25/93

QA PROGRAM ELEMENT 5.0, 'INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS' AND QA PROGRAM ELEMENT 6.0, 'DOCUMENT CONTROL'

Procedures:

Compliance with the following procedures was reviewed:

LANL-YMP-QP-06.1, Revision 5, "Document Control"
LANL-YMP-QP-06.2, Revision 1, "Preparation, Review, and Approval of Quality Administrative Procedures"
LANL-YMP-QP-06.3, Revision 0, "Preparation, Review and Approval of Detailed Technical Procedures"

Objective Evidence Examined:

Quality Procedures:

QP-02.4, R1	QP-02.9, R1	QP-02.11, R1
QP-03.5, R1	QP-03.24, R0	QP-03.25, R0
QP-06.1, R5	QP-08.3, R0	QP-12.1, R6
QP-16.2, R2		

Detailed Technical Procedures:

INC-DP-15, R3	INC-DP-60, R3	INC-DP-61, R3
INC-DP-63, R3	INC-DP-90, R1	INC-DP-87, R2
INC-DP-94, R0	INC-DP-92, R1	INC-DP-95, R1
EES-13-DP-6-5, R1	EES-13-DP-606, R2	EES-13-DP-608, R1
EES-13-DP-610, R0	EES-13-DP-101, R2	EES-DP-125, R1
EES-DP-129, R0	EES-DP-130, R0	EES-DP-131, R0

Forms:

Action Request for Quality Procedures
Action Request for Detailed Procedures
Receipt Acknowledgement Forms for Procedures
Comment/Resolution Review Sheets
Quality Assurance Review Checklists
Master List of Controlled Documents (QPs) dated 12/7/92
Master List of Controlled Documents (DPs) dated 4/28/93

Letters from the Document Control Coordinator informing supervisors of required training dated:

5/27/92	2/5/93	4/9/92
12/1/92	8/13/92	9/4/921
7/10/92	6/15/92	8/20/92

Books Reviewed by Manual Holders:

Donna Williams No. 4	Paul Gillespie No. 13
John Day No. 19	Sandy Martinez No. 45

QA PROGRAM ELEMENT 12.0, CONTROL OF MEASURING AND TEST EQUIPMENT

Procedure:

Compliance with procedure LANL-YMP-QP-12.1, Revision 6, "Control of Measuring And Test Equipment" was reviewed.

Objective Evidence Examined:

M&TE List:

Los Alamos M&TE List dated 5/22/93

RPC record packages and transmittals to verify compliance with procedural requirements on frequency and handling:

TWS-EES-13-03-93-073, dated 3/29/93, INC-7/11 Measuring and Test Equipment (M&TE) 1992
TWS-EES-13-03-93-074, dated 3/29/93, INC-7/11 Measuring and Test Equipment (M&TE) 1992
TWS-EES-13-03-93-075, dated 3/29/93, INC-7/11 Measuring and Test Equipment (M&TE) 1992
TWS-EES-13-03-93-083, dated 3/29/93, INC-7/11 Measuring and Test Equipment (M&TE) 1992

Individual yearly records for selected instruments in order to verify completeness of documentation:

PN 076073, Balance, Ohaus B-5000
PN 295584, Balance, Sartorius 2462
PN 318476, Balance, Ainsworth 50

PN 405661, Balance, Mettler AE-240
PN 348308, Balance, Ainsworth XS-250
PN 348309, Balance, Ainsworth A-250
PN 365386, Balance, Ainsworth MX-200
PN 405656, Balance, Mettler AE-240
PN 405662, Balance, Mettler AE-240
PN 405742, Balance, Mettler PM-460
PN 405771, Balance, Mettler PM-400
PN 441222, Spectrophotometer, Cary 17D UV-VIS-NIR
PN 441939, Balance, Sartorius PT-120
PN 608838, Balance, Mettler AE-160
PN 608866, Balance, Mettler PC-440
PN 625021, Balance, Sartorius 1419
PN 625058, Balance, Mettler AE-163
PN 645140, Balance, Mettler PM-200
PN 645262, Balance, Ohaus
PN 645263, Balance, Mettler AT-261
PN 652589, Spectrophotometer, Perkin Elmer 9
PN 671323, Balance, Mettler L-420-P
PN 753721, Balance, Mettler PK-4800
PN 757322, Balance, Mettler PE-1600
PN 757327, Balance, Sartorius
PN 757328, Balance, Sartorius 1712-MP-8
PN 817100, Balance, Ohaus GA 200
PN 761277, Balance, Sartorius L-420-P
PN 817248, Balance, Mettler AE-200
PN 817261, Balance, Mettler AT 261 Delta Range
PN 817330, Balance, Cahn C-31
PN 871847, Balance, Ohaus D-124
PN 857352, pH Meter, Orion Expandable Ion Analyzer
RC-45-001, Weight Set, Troemner

Selected M&TE records to verify compliance with control and technical requirements:

SN 98019, Hygrometer, Vaisala HMI-32
PN 671239, Balance, Sartorius LS-2
SN 038630, Balance, Mettler AE-160
PN 754430, Mettler P-1210
SN DO9548, Balance, AE-200
H 47337, Balance, Mettler AE-200
PN 671239, Balance, Sartorius L-220-S
PN 757321, Balance, Mettler PK-4800

PN 305016, Balance, Ainsworth A-200
PN 156106, Balance, Sartorius Projecta
PN 291874, Balance, Mettler
PN 608838, Balance, Mettler
PN 076073, Balance, Ohaus B-5000
PN 318476, Balance, Ainsworth 50
PN 295584, Balance, Sartorius 2462
PN 441939, Balance, Sartorius PT-120

Instrument tags/labels to verify compliance with control and technical requirements:

SN 671322, Thermogravimetric Analyzer, Omega AHT-450
SN 76169, Thermogravimetric Analyzer, Omnitherm TGA-1000
Long, Thermocouple probe, Omega type-K
PN 844983, Energy Dispersive X-Ray Analyzer, Princeton Gamma Tech PGT-EDS
PN 818979, Electron Microprobe, SX-50
PN 458694, Thermogravimetric Analyzer, DuPont de Nemours 951
SN 98019, Hygrometer Humidity Probe, Vaisala HMI-32
PN 817065, Furnace, Thermolyne
PN 487066, 2-Theta X-Ray Diffractometer, Siemens
PN 473467, 2-Theta X-Ray Diffractometer, Siemens
PN 487078, Stage Attachment, Anton Parr TTK Med T
PN 348308, Balance, Ainsworth XS-250
PN 400132, Fisher, Selion Analyzer Accumet-750
PN 400684, pH Monitor, Fisher Accumet-750
PN 400955, pH Monitor, Corning 130
PN 441277, Spectrophotometer, Varian 17-015
PN 608838, Balance, Mettler AE-160
PN 625058, Balance, Mettler AE-163
PN 645255, Ionanalyzer, Orion EA-940
PN 645262, Balance, Ohaus E-120
PN 645399, Ion Specific Analyzer, Orion EA-940
PN 652589, Spectrophotometer, Perkin-Elmer Lambda-9
PN 761277, Balance, Sartorius L-420P
PN 817248, Balance, Mettler AE-200
PN 841221, Liquid Scintillation Counter, Packard Tricarb
PN 817090, pH Meter, Orion EA-940
PN 817100, Balance, Ohaus GA-2000
PN 901133, Liquid Scintillation Counter, Packard Tri Carb 2550 TR/AB
SN 004620, pH Meter, Orion 290A
PN 441222 Spectrophotometer, Varian 17-015 (Carey)

SNs and logbooks to verify compliance with instrument-specific M&TE requirements in Detailed Technical Procedures:

PN 743467	TWS-EES-1-1-90-1
PN 817065	TWS-EES-1-11-92-3
SN 41200331	TWS-EES-1-11-92-3
PN 707058	TWS-EES-1-11-92-3
PN 671322	TWS-EES-1-2/87-14
SN 98019	TWS-EES-1-2/87-14
PN 707058	TWS-EES-1-2/87-14
PN 487066	TWS-EES-1-2/87-25
PN 652589	TWS-INC-11-11/89-9

DRs to verify compliance with procedural requirements for internal oversight and checking of the M&TE control process:

PN 447337, DR-176 and PN 400152, DR-208

QA PROGRAM ELEMENT 16.0, CORRECTIVE ACTION

Procedures:

Compliance with the following procedures was reviewed:

LANL-YMP-QP-16.2, Revision 2, "Trending"
LANL-YMP-QP-16.3, Revision 1, "Deficiency Reports"
TWS-QAS-QP-15.2, Revision 1, "Deficiency Reporting"

Objective Evidence Examined:

DRs to Requirements of QP-15.2:

LANL-0163	LANL-0167	LANL-0169	LANL-0170
LANL-0172	LANL-0180	LANL-0190	

DRs to Requirements of QP-16.3:

LANL-0195	LANL-0196	LANL-0197	LANL-0198
LANL-0199	LANL-0200	LANL-0201	LANL-0202
LANL-0203	LANL-0206	LANL-0207	LANL-0208
LANL-0209	LANL-0210	LANL-0211	LANL-0212
LANL-0213	LANL-0214	LANL-0215	LANL-0216
LANL-0217			

DR Logbook

Trend Evaluation Reports:

Trend Report, dated 10/14/92 (Period 7/1/92 - 9/30/92)

Trend Report, dated 1/8/93 (Period 10/1/92 - 12/31/92)

Trend Report, dated 4/9/93 (Period 1/1/93 - 3/31/93)

QA PROGRAM ELEMENT 17.0, "QUALITY ASSURANCE RECORDS"

Procedures:

The following procedures were reviewed for compliance with requirements.

LANL-YMP-QP-17.4, Revision 0, "Records Preparation"

LANL-YMP-QP-17.5, Revision 0, "Records Processing"

Objective evidence examined to verify compliance with Procedure QP-17.4:

TWS Logs:

Log for Group EES-1, dated April 1993

Log for Group INC, dated May 1993

Individual Records:

TWS-EES-1-4-93-10, dated 4/21/93, authentication 4/19/93, to RPC 4/22/93, received 5/5/92, rejected 5/5/93.

TWS-EES-1-4-93-11, dated 4/21/93, authentication 4/21/93, to RPC 4/22/93, received 5/5/92, rejected 5/5/92.

TWS-EES-1-4-93-12, dated 4/21/93, authentication 4/21/93, to RPC 4/22/93, lost in transit (Note: Originator has 90 days to replace a lost or damaged record).

TWS-EES-1-4-93-13, dated 4/21/93, authentication 4/19/93, to RPC 4/22/93, RPC accepted 5/25/93.

Records Packages:

TWS-EES-13-03-93-073, dated 3/26/93, authenticated 3/29/93, to RPC 3/30/93, RPC accepted 5/17/93.

TWS-EES-13-03-93-074, dated 3/30/93, authenticated 3/30/93, to RPC 4/6/93, RPC accepted 4/11/93.

TWS-EES-13-03-93-075, dated 3/30/93, authenticated 3/30/93, to RPC 4/6/93, RPC accepted 5/17/93.

TWS-EES-13-03-93-083, dated 3/30/93, authenticated 3/31/93, to RPC 4/6/93, RPC accepted 5/17/93.

One-of-a-kind Records:

TWS-EES-1-4-93-18, dated 4/21/93, David Broxton, Originator, EES-1.

Fire Protection:

UL Listed Filing Device, No. B632410, Class 350, 1 hour fire-rated.

Objective Evidence Examined to verify compliance with procedure QP-17.5:

TWS Logs:

TWS Log for Group EES-1, dated April 1993

TWS Log for Group INC, dated May 1993

Individual Records:

TWS-EES-1-4-93-10, dated 4/21/93, authenticated 4/19/93, to RPC 4/22/93, RPC received 5/5/93, rejected 5/5/93.

TWS-EES-1-4-93-11, dated 4/21/93, authenticated 4/21/93, to RPC 4/22/93, RPC accepted 5/5/92, rejected 5/5/93.

TWS-EES-1-4-93-12, dated 4/21/93, authenticated 4/21/93, to RPC 4/22/93, lost in transit. (Note: Originator has 90 days to replace a lost or damaged record.)

TWS-EES-1-4-93-13, dated 4/21/93, authenticated 4/19/93, to RPC 4/22/93, RPC accepted 5/25/93.

Records Packages:

TWS-EES-13-03-93-073, dated 3/26/93, authenticated 3/29/93, to RPC 3/30/93, RPC accepted 5/17/93.

TWS-EES-13-03-93-074, dated 3/30/93, authenticated 3/30/93, to RPC 4/6/93, RPC accepted 4/11/93.

TWS-EES-13-03-93-075, dated 3/30/93, authenticated 3/30/93, to RPC 4/6/93, RPC accepted 5/17/93.

TWS-EES-13-03-093-083, dated 3/30/93, authenticated 3/31/93, to RPC 4/6/93, RPC accepted 5/17/93.

Other Records checked to verify compliance with dual storage requirements:

TWS-INC-05-93-03, dated 5/6/93, authentication 5/6/93, to RPC 5/14/93, received 5/17/93.

TWS-INC-05-93-04, dated 5/6/93, authentication 5/6/93, to RPC 5/14/93, received 5/17/93.

QA PROGRAM ELEMENT 18.0, "AUDITS"

Procedures:

Compliance with the following procedures was reviewed:

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"

Objective Evidence Examined:

Audit Schedules:

Calendar Year 1992, Revision 4 and Calendar Year 1993, Revision 2

Audit Reports:

LANL-AR-92-08 LANL-AR-92-10 LANL-AR-92-11
LANL-AR-92-13 LANL-AR-92-17 LANL-AR-93-01
LANL-AR-93-02 LANL-AR-93-03

Audit Checklists:

LANL-AR-92-08 LANL-AR-92-13 LANL-AR-93-01 LANL-AR-93-03

Auditor/Lead Auditor Certifications:

Cleoves B. Martinez (LATA)
Paul Gillespie (LATA)
P. Chavez (LATA)

Gabriela Gainer (LATA)
John Day (LATA)

Results of written examinations for Lead Auditor:

Cleoves B. Martinez
Gabriela Gainer

Paul Gillespie
John Day

Survey Schedule:

Schedule dated 1/8/93

Survey Reports:

LANL-SR-93-001
LANL-SR-93-004

ATTACHMENT 4

INFORMATION COPIES

OF

CORRECTIVE ACTION REQUESTS

ORIGINAL
THIS IS A RED STAMP

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		8 CAR NO.: <u>YM-93-049</u> DATE: <u>June 02, 1993</u> SHEET: <u>1</u> OF <u>1</u> <div style="text-align: center;">QA</div>
CORRECTIVE ACTION REQUEST		
1 Controlling Document TWS-QAS-QP-01.1, R2		2 Related Report No. Audit Report YMP-93-11
3 Responsible Organization Los Alamos Nat. Lab		4 Discussed With S. Bolivar, M. Clevenger
5 Requirement: Procedure TWS-QAS-QP-01.1, R2, "Interface Control Procedure", requires in sections 6.1 and 6.2 that interfaces be identified and controlled and that an Interface Description Form be completed. Section 6.3 requires that interfaces between Los Alamos and other Project Participants be described and documented in accordance with YMP AP-5.19Q.		
6 Adverse Condition: The following interfaces have not been controlled and documented in accordance with the procedural requirements of TWS-QAS-QP-01.1, R2: <ul style="list-style-type: none"> * IMOU Los Alamos/USGS (no number) consummated by letters rather than through the mechanisms described in AP-5.19Q. The letters referenced are: <div style="margin-left: 40px;"> Los Alamos to USGS, dtd. 7/09/90 USGS to Los Alamos, dtd. 9/07/90 </div> * Interface Description Form (IDF) initiated between USGS/Los Alamos for WBS 1.2.3.3.1.2.2 but never completed * WBS Element 1.2.3.2.5 is an activity involving USGS, Los Alamos, and TEMS for which no IDF could be produced. 		
9 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C		10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D
11 Response Due Date: June 30, 1993		
12 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
13 Recommended Actions: <ol style="list-style-type: none"> 1. Conduct investigative action to determine all interfaces subject to this procedure. 2. Complete the identification and documentation for the Los Alamos/USGS interface associated with WBS 1.2.3.3.1.2.2. 3. Document all interfaces identified in item 1. in accordance with the procedure. 4. Take action to preclude recurrence. 		
7 Initiator: <i>James Blaylock</i> James Blaylock Date: <u>6/3/93</u>		14 Issuance Approved by: <i>AC [Signature]</i> OADD <i>AC [Signature]</i> Date: <u>6/8/93</u>
15 Response Accepted QAR _____ Date _____		16 Response Accepted OADD _____ Date _____
17 Amended Response Accepted QAR _____ Date _____		18 Amended Response Accepted OADD _____ Date _____
19 Corrective Actions Verified QAR _____ Date _____		20 Closure Approved by: OADD _____ Date _____

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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		CAR NO.: <u>YM-93-050</u> DATE: <u>May 28, 1993</u> SHEET: <u>1</u> OF <u>1</u> QA
CORRECTIVE ACTION REQUEST		
1 Controlling Document LANL-YMP-QAPP, R5		2 Related Report No. YMP-93-11
3 Responsible Organization LANL	4 Discussed With Stephen L. Bolivar	
5 Requirement: LANL-YMP-QAPP, Revision 5, dated March 1, 1991, Section 17.0, Paragraph 17.4, states in part: ". . . . Records shall be legible, identifiable, accurate, complete, reproducible on microfilm and other media, and appropriate to the work accomplished"		
6 Adverse Condition: Attachment 1 of Los Alamos procedure LANL-EES 13-DP-609, R0, is a quality record resulting from the execution of this procedure. Contrary to the above requirement that records be identifiable, page 2 of Attachment 1 lacks any provision for information linking it unambiguously to any specific page 1 of the attachment.		
8 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	11 Response Due Date: 06/30/93
12 Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
13 Recommended Actions: 1. Amend page 2 of the attachment to provide for traceability to page 1.		
7 Initiator S.D. Bates <i>J.D. Bates</i> Date <i>6/3/93</i>	14 Issuance Approved by: QADD <i>RC James</i> Date <i>6/8/93</i>	
15 Response Accepted QAR Date	16 Response Accepted QADD Date	
17 Amended Response Accepted QAR Date	18 Amended Response Accepted QADD Date	
19 Corrective Actions Verified QAR Date	20 Closure Approved by: QADD Date	

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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		8 CAR NO.: <u>YK-93-051</u> DATE: <u>May 28, 1993</u> SHEET: <u>1</u> OF <u>1</u> QA
CORRECTIVE ACTION REQUEST		
1 Controlling Document LAL- YMP -QP-17.4, RO		2 Related Report No. YMP-93-11
3 Responsible Organization LAL	4 Discussed With Stephen L. Bolivar	
5 Requirement: LAL- YMP -QP-17.4, RO, Section 9.0, states in part: "All Los Alamos YMP employees are required to be trained to this procedure."		
6 Adverse Condition: Contrary to this requirement, Los Alamos management has elected to train only selected individuals to this procedure. Training records indicate that the following individuals have not been given the required training to implement QP-17.4, RO: <ul style="list-style-type: none"> 1. M. Elkins 2. G. Casedy 3. R. Lopez 		
9 Does a significant condition adverse to quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C D	11 Response Due Date: June 30, 1993
12 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
13 Recommended Actions: <ul style="list-style-type: none"> 1. Perform investigative action to include all Los Alamos procedures in order to determine all employees for whom procedurally required action has not been performed. 2. Perform remedial training for all identified individuals. 		
7 Initiator S.D. Bates <i>S.D. Bates</i> Date <u>6/4/92</u>	14 Issuance Approved by: QADD <i>[Signature]</i> Date <u>6/8/92</u>	
15 Response Accepted QAR Date	16 Response Accepted QADD Date	
17 Amended Response Accepted QAR Date	18 Amended Response Accepted QADD Date	
19 Corrective Actions Verified QAR Date	20 Closure Approved by: QADD Date	