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PROJECT OFFICE QUALITY ASSURANCE AUDIT REPORT FOR

THE YUCCA MOUNTAIN PROJECT OFFICE AUDIT OF

LOS ALAMOS NATIONAL LABORATORY

AUDIT NO. 90-01

CONDUCTED MARCH 26-30, 1990

AND

APRIL 2, 1990

Prepared By:

Audit Team Leader

Approved By:

Donald G. Horton Director

Quality Assurance Division

Yucca Mountain Project Office

Date: 5/15/90

EXECUTIVE SUMMARY

In the opinion of the Yucca Mountain Project Office (Project Office) audit team, the Los Alamos National Laboratory (Los Alamos) Quality Assurance (QA) program is adequate for the initiation of quality affecting activities. Therefore, Los Alamos should be allowed to proceed with these activities, as adequate QA controls appear to be in place (i.e., the Quality Assurance Program Plan and implementing procedures) to control their quality-affecting activities, with the following noted exception:

Software QA Program--The Software QA Program Plan has not been approved by the Project Office and Los Alamos has imposed a stop work (Stop Work Order No. SWO-LA01) on all activities involving the use or development of software for the Yucca Mountain Project.

The audit team reviewed actions taken by Los Alamos, as detailed in a Project Office letter, dated December 11, 1989, with the following noted results:

Item No. 1 identified some Los Alamos procedures as inadequate. The audit team determined that reviewed procedures appeared to contain adequate program guidance and controls. This would also indicate that the overall review process is capable of identifying procedural weaknesses and inconsistencies.

Item No. 2 identified that training and qualification procedures were not consistently followed, and some personnel were not aware of their training responsibilities. During the audit, no deficiencies were identified in the area of training and qualification. In addition, the audit team determined that Los Alamos is effectively implementing this area of their QA program.

Item No. 3 identified that Los Alamos did not seem to have a consistent approach as to how a technical review is defined or how the review should be documented. Since Audit No. 89-07, Los Alamos has not completely addressed this issue. In addition, there seems to be uncertainty in the minds of some Los Alamos technical staff concerning the reason for and use of procedures. This impacts the level of detail in the procedures, including points where decisions are made and documented, the continuing issue of acceptance and rejection criteria, accuracy and precision, and verification and hold points. Therefore, Standard Deficiency Report (SDR) No. 465 will remain open until appropriate actions have been taken.

Item No. 4 identified the corrective action program as inadequate. No deficiencies were identified during the audit in the area of corrective action. However, SDR No. 468 (which identified corrective action deficiencies during Project Office Audit No. 89-07) cannot be closed and will remain open until training of Los Alamos personnel has been completed and verified by the Project Office. In addition, the effectiveness of the Los Alamos QA program in the area of corrective action cannot be determined due to lack of implementation.

Item No. 5 identified the Los Alamos audit and surveillance implementation program as inadequate. The control elements appear to be in place and adequate to control this area of their QA program. However, the effectiveness of the Los Alamos QA program in the area of audits and surveillances cannot be determined due to lack of implementation.

The Project Office will revisit all areas of the Los Alamos QA program in which the audit team was unable to determine effectiveness due to lack of implementation during the next scheduled surveillance or audit of Los Alamos.

As a result of this audit, four SDRs were issued to Los Alamos. A total of 14 observations were issued: 13 to Los Alamos and 1 to the Project Office. It should be noted that during the course of the audit, Los Alamos was able to correct 12 concerns identified by the auditors. These 12 concerns and the actions taken to correct them are described in this report.

It is apparent to the audit team that a great deal of effort and time has been expended by Los Alamos to correct the previously identified QA program deficiencies and to bring the current QA program into compliance with Project Office requirements. Los Alamos personnel should be commended for the cooperation and effort necessary to bring their QA program to this level.

1.0 INTRODUCTION

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This report contains the results of a Quality Assurance (QA) audit of the activities conducted by Los Alamos National Laboratory (Los Alamos) in support of the Yucca Mountain Project Office (Project Office). The audit was conducted at the Los Alamos facilities in Los Alamos, New Mexico (March 26-30, 1990) and Las Vegas, Nevada (April 2, 1990). The audit was conducted in accordance with the requirements of Quality Management Procedure QMP-18-01, Revision 3, "Audit System for the Waste Management Project Office." The QA program requirements to be verified were taken from the Project Office Quality Assurance Plan (NNWSI/88-9), Revision 4.

2.0 AUDIT SCOPE

The scope of the audit was to evaluate the Los Alamos QA program to determine whether it meets the requirements and commitments imposed by the Project Office. This was done by verifying implementation and effectiveness of the systems in place, as well as verifying compliance with requirements.

The following program elements were audited to assess compliance with NNWSI/88-9, Revision 4, and the Los Alamos Quality Assurance Program Plan (QAPP), Revision 4.4:

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

The following program elements, described in the Los Alamos QAPP, Revision 4.4, were reviewed prior to the audit and were deemed to be not applicable to activities currently assigned to Los Alamos:

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

The audit scope included a review and evaluation of the following technical activities:

WBS Number	SCP Reference	<u>Title</u>
1.2.3.2.5	8.3.1.8	Postclosure Tectonics
1.2.3.2.1.1.1	8.3.1.3.2.1	Mineralogy, Petrology, and Rock Chemistry of Transport Pathways
1.2.3.4.1.3	8.3.1.3.5	Radionuclide Retardation by Precipitation Processes
1.2.3.4.1.5.2	8.3.1.3.7.2	Demonstration of Applicability of Laboratory Data

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

- 1. Technical qualification of scientific investigation personnel.
- 2. Understanding of procedural requirements as they pertain to scientific investigation activities.
- 3. Adequacy of technical procedures.
- 4. Development of Study Plans, work supporting the Site Characterization Plan, and any related work products.

3.0 AUDIT TEAM PERSONNEL AND OBSERVERS

<u>Individual</u>	Responsibility		
Stephen R. Dana	Audit Team Leader		
James Blaylock	Audit Manager		
Sidney L. Crawford	Auditor		
Amelia I. Arceo	Auditor		
Anthony E. Cocoros	Auditor		
Richard L. Maudlin	Auditor		

<u>Individual</u> <u>Responsibility</u>

Mario R. Diaz Auditor

Terry W. Noland Auditor-In-Training

Martha J. Mitchell Lead Technical Specialist

Forrest D. Peters Technical Specialist

Christopher J. Fridrich Technical Specialist

John Marchand Observer, DOE/HQ

William Haslebacher Observer, DOE/HQ

Kenneth Hooks Lead Observer, NRC

John Bradbury Observer, NRC

John Trapp Observer, NRC

Michael Gonzalez Observer, NRC

Susan Zimmerman Observer, State of Nevada

Joe Caldwell Observer, MACTEC

4.0 SUMMARY OF AUDIT RESULTS

4.1 Statement of Program Effectiveness

In the opinion of the Project Office audit team, the effectiveness of the overall Los Alamos QA program cannot be currently determined. Until such time as sufficient objective evidence is available to demonstrate program implementation in the areas of (1) corrective action, (2) surveillances, and (3) audits, the effectiveness of the program will remain indeterminate.

However, based on the results of the audit, the Los Alamos QA program appears to be adequate for the initiation of quality-affecting activities, with the following noted exception:

Software QA Program--the Software Quality Assurance Program Plan has not been approved by the Project Office.

4.2 Summary of Technical Activities

In the opinion of the Technical Specialists assigned to the audit, Los Alamos technical staff are competent, capable, and appropriately dedicated to plan and carry out activities for this project. Technical training appears to be sufficient to initiate new work or to work under a qualified QA program.

In the areas relating to good scientific practice, the following were observed by the technical audit team:

- The quality of the technical laboratory notebooks demonstrates significant improvement over the time periods covered by recent audits. The amount of referencing is increasing and in general, the notebooks are more easily interpreted and of more technical value to the Project.
- 2. Samples that were evaluated during the audit are managed in an appropriate manner. Numerous sample management systems are in use, all of which meet the necessary requirements. However, none of the systems has a large number of samples to date. In the future, when there are large numbers of samples in some of the systems, tracking problems may arise. The samples derived from the United States Geological Survey (USGS) core are internally controlled at Los Alamos. The fact remains that traceability of the core samples outside Los Alamos is in question and that this open issue impacts the use of data collected on these samples.
- 3. Some Los Alamos technical staff still have questions concerning the reason for and use of procedures. This uncertainty impacts the level of detail in the procedures, including points where decisions are made and documented; the continuing issue over acceptance and rejection criteria, accuracy, and precision; and verification and hold points. Verification and hold points are also discussed in Item 4, below, and Observation No. 90-1-13 (regarding scientific practice).
- 4. More attention needs to be given to internal verification by laboratory staff and hold points identified in procedures. In many cases, staff are checking data and calculations. These checks are often not identified as such in laboratory notebooks and are not required by the procedures. The scientific practice is better and more complete than described in the controlling work documents. Credit should be taken for good practices and these good practices should be included in the procedures and passed on to other Project staff. In many cases, the procedures appear to be written with the intent of meeting minimum QA requirements. Many of the reviews of the implementing procedures appear to be very brief; this type of review may not be sufficient to identify procedural weakness.

For the individual project areas sampled during the audit, the Technical audit team has the following comments:

WBS 1.2.3.4.1.5.2—Although the preliminary work has been conducted by subcontractors as non-quality affecting, the activity is sufficiently mature for the staff to recognize the potential problems associated with the expected interfaces with other activities and with schedule and data availability.

WBS 1.2.3.1.1.1--Much of the petrographic analysis is subjective and attempts to delineate features of internal stratigraphy that are subtle and difficult to defend. Currently, the sample control system in this area is adequate to control this activity.

WBS 1.2.3.4.1.3--Laboratory work is proceeding in the areas of solubility determinations and colloidal studies. The quality achievement/quality control system for this work appears to be adequate, but documentation of quality control (quality verification) activities appears to be somewhat weak.

WBS 1.2.3.2.5--Field and laboratory work is proceeding in the area of volcanics. The quality achievement/quality control system for this work appears to be adequate, but documentation of quality control (quality verification) activities appears to be somewhat weak.

4.3 Summary of Findings

A total of four Standard Deficiency Reports (SDRs) were generated during the course of this audit. Information copies of the SDRs are attached as Enclosure 3. Thirteen Observations were issued to Los Alamos and one (No. 90-1-02) to the Project Office; these are attached as Enclosure 2. A synopsis of SDRs and observations is presented in Section 6 of this report. Additionally, this synopsis includes 12 concerns that were corrected during the course of the audit.

5.0 AUDIT MEETINGS

5.1 Pre-audit Conference

A pre-audit conference was held with the Los Alamos Technical Project Officer (TPO) and his staff at 10:30 a.m. on March 26, 1990. The purpose, scope, and proposed agenda for the audit were presented and the audit team was introduced. A list of those attending is attached as Enclosure 1.

5.2 Persons Contacted During the Audit

See Enclosure 1.

5.3 Post-audit Conference

The post-audit conference was held at 2:00 p.m. on March 30, 1990, at the Los Alamos office in Los Alamos, New Mexico. A synopsis of the preliminary SDRs and observations identified during the course of the audit was presented to the TPO and his staff. The audit for technical activity WBS No. 1.2.3.2.5, "Postclosure Tectonics," was not completed prior to the post-audit conference. This audit element was completed in Las Vegas, Nevada, on April 2, 1990. A close-out meeting was held with the Los Alamos Principal Investigator (PI) in Las Vegas to discuss results of this element. A list of those attending the post-audit conference is attached as Enclosure 1.

5.4 Audit Status Meetings

Audit status meetings were held with the Los Alamos TPO and his key staff at 8:45 a.m. on each day of the audit. A status of how the audit was progressing and identification of discrepancies were discussed.

6.0 SYNOPSIS OF STANDARD DEFICIENCY REPORTS, OBSERVATIONS, AND CONCERNS CORRECTED DURING THE AUDIT

6.1 Standard Deficiency Reports

- SDR No. 511 An implementing procedure that clearly describes the authority and responsibility of each position in the QA organization does not exist.
- SDR No. 512 Non-Los Alamos or subcontractor YMP personnel have performed technical reviews of documents in accordance with Los Alamos procedures without documentation or certification of qualification or indoctrination to applicable Los Alamos procedures for the reviews and for the activities being reviewed.
- SDR No. 513 Internal and external audits of all phases of the application of Los Alamos QAPP for all activities affecting quality during 1989 were not conducted.
- SDR No. 515 No modification has been made to the existing Lawrence Berkeley Laboratory (LBL) contract to describe rights of access by DOE, pass-through of QA requirements to sub-tier contractors, and control of supplier-issued nonconformances.

6.2 Observations

- 1. The new QA organization has recognized the need to revise several procedures to reflect new Los Alamos organizational changes. However, a plan is needed to determine: (1) how many of these procedures should be revised, and (2) the period of time or schedule by which this task should be finished.
- 2. The Project Office requested that a Readiness Review of Study Plan 8.3.1.3.2.1 be conducted per Administrative Procedure AP-5.13Q. Los Alamos responded by suggesting a Los Alamos person as the Readiness Review board chairman. The Readiness Review has not been performed to-date, pending resolution and verification of Audit 89-7, Observation Nos. 89-7-01 and 89-7-02, and revision of Los Alamos procedure QP-02.4. Based on the correspondence, it is not clear who is responsible for the Readiness Review (the Project Office or Los Alamos) or which procedure governs. In addition, the chairman suggested by Los Alamos is the author from the subject study plan and does not appear to have sufficient independence from the activity to be reviewed.
- 3. Los Alamos Detailed Technical Procedures (DPs) and Quality Assurance Procedures (QPs) referenced or identified in a study plan are incorrect or have not been prepared.
- 4. A QA review of a study plan was conducted following the issuance of AP-1.10Q. The QA review identified conflicting QA program criteria between two tables in the study plan, but did not identify numerous unissued and superseded QPs in one of the Tables.
- 5. Los Alamos DPs reference obsolete QPs. Although action is being taken to cross reference on procedure tables-of-content obsolete and superseded QPs to the equivalent current procedures, Los Alamos should establish measures to review DPs on a periodic basis for changes, updates, and corrections.
- 6. LBL procedures for Project activities are prepared, reviewed, and approved under the Los Alamos QAPP and QP-05.2. The TWS-LBL-DP-XX procedures, although issued in their own controlled binder set, were not issued to various "reference" set QA binder assignees who have a need for the LBL procedures for reference purposes.
- 7. The purchase requisition and associated "Statement of Work" for the University of Colorado does not define which Los Alamos implementing procedures are required to perform the scope of work described by the statement.

- 8. Los Alamos procedure QP-05.2 states that the purpose of the QP is to "describe the writing, reviewing, approving...of technical procedures (DPs) used by Los Alamos and any of its contractors." Throughout the rest of the procedure, there is no further reference to the subcontractor's effort.
- 9. The Los Alamos QAPP for the Project provides instructions to apply the QA requirements to the technical activities conducted by Los Alamos in support of the Project. Los Alamos does not have a mechanism (procedure) for making changes to their QAPP.
- 10. AP-6.3Q identifies the Project Sample Management Facility (SMF) provisions for control of samples. Los Alamos procedure QP-08.1 identified AP-6.3Q provisions and requirements to certify field sample collection personnel per AP-6.3Q. Detailed technical procedures for sample collection and identification didn't fully address or reference AP-6.3Q and/or QP-8.1.
- 11. Laboratory analytical Measuring and Test Equipment (M&TE), to be used by Isotope and Nuclear Chemistry (INC), and LBL for Project activities, and identified in study plans and detailed technical procedures (DPs), have not been added to the "List of Calibrated Measuring and Test Equipment (M&TE)" by initiation of an M&TE calibration record per QP-12.1.
- 12. Los Alamos procedure QP-17.3 does not address all of the record review criteria specified in AP-1.7Q.
- 13. During the audit, it was noted by the technical auditors that, as part of good scientific practice, calculations or other actions were internally verified by Los Alamos technical staff. These actions were not identified as having been checked in laboratory notebooks and these checks were not identified as mandatory verification points in the controlling procedures.
- 14. Letter reports were found attached to monthly activity reports for the Project. These letter reports were identified as Level III milestones and contain a considerable amount of data in some cases. These reports are viewed as internal, informal, and preliminary by the authoring staff. Some of these letter reports originate at subcontract organizations. It appears that these reports are intended for administrative purposes only and for that reason do not receive technical review. Data included in activity reports that have not been technically reviewed should be identified as preliminary and a mechanism needs to be established that can exclude such reports from the technical review cycle.

6.3 Concerns Corrected During the Audit

- 1. No documented evidence existed to substantiate that a reviewer's comments had either been incorporated into or resolved for Study Plan 8.3.1.8.5.1, "Charactization of Volcanic Features." Los Alamos corrected this deficiency per memorandum TWS-EES-1-3-90-27, dated March 29, 1990, addressing the reviewers comments and reviewers acceptance of the present version of the study plan.
- 2. During review of the publication entitled "Basaltic Volcanic Episodes of the Yucca Mountain Region," a completed Attachment 3, "Technical Review Criteria," (per Los Alamos procedure QP-03.2) was not included in the review package. All reviews had been signed off by the responsible PI. Los Alamos corrected this deficiency by having the reviewer complete Attachment 3 for the previously referenced publication. The attachment was included as part of the review package per memorandum, TWS-EES-13-03-90-113, dated March 30, 1990.
- 3. The University of New Mexico was identified as a qualified supplier of QA Level I services; however, they are not listed on the Approved Vendors List (AVL). Los Alamos corrected this deficiency per memorandum, TWS-EES-13-LV-03-90-09, dated March 29, 1990, by adding the University of New Mexico to the AVL for Volcanism Studies. [Reference the Los Alamos/Project AVL, Page 1, dated March 30, 1990.]
- 4. The approved purchase requisition (8482Y) for the University of Colorado did not include provisions for the application of appropriate QA requirements to be passed on to its subcontractors. Los Alamos corrected this deficiency by revising Appendix B, "Statement of Work, University of Colorado purchase requisition (8482Y)," to include flow-down of any appropriate QA requirements to subcontractors.
- 5. The USGS is writing a report for Los Alamos relative to potassium -argon age determination for samples taken from Lathrop Wells, which is a QA Level I activity. No documented evidence was available to substantiate that the Quality Assurance Project Leader (QAPL) advised the Project Office regarding the activity so that an audit and/or surveillance could be performed. Los Alamos corrected this deficiency per letter, TWS-EES--13-03-90-109, dated March 29, 1990, requesting that the Project Office take the necessary steps to perform an audit or survey of the USGS relative to QA Level I work in the "Characterization of Volcanic Features" task.

- 6. Purchase requisition H-7123, dated March 15, 1990, was approved for the purchase of QA Level I calibration services from Troemner, Inc. The purchase requisition was marked "QA Level I, Commercial Grade Acceptable." Los Alamos corrected this deficiency per the following:
 - a. Memorandum, TWS-EES-15-03-90-024, dated March 30, 1990, clarified that the purchase requisition for No. H-7123 should have originated as a procurement for a QA Level I service, which requires vendor qualification. Attached to the letter is the purchase requisition, which has been revised to reflect the new QA level assignment.
 - b. Memorandum, TWS-EES-15-03-90-025, dated March 30, 1990, details that the method "evidence of prior acceptance" was used to qualify Troemner, Inc. for weight set calibration. Attached to the letter is a survey performed of Troemner, Inc. by General Instrument Corporation.
 - c. Troemner, Inc. was added to the Los Alamos/Project AVL, Page 1, dated March 30, 1990.
- 7. With regard to activities for which a stop work order had been issued, Los Alamos did not identify the method used to monitor the "stop work" to ensure that work related to the affected activity did not continue. Los Alamos corrected this deficiency per memorandum, TWS-EES-13-03-90-106, dated March 29, 1990, which identifies the method of verification for Stop Work Order SWO-LA01.
- 8. Los Alamos procedure QP-15.2, Revision 0, did not address the requirements stated in NNWSI/88-9, Revision 4, Section XV, Paragraph 1.4.5. Los Alamos corrected this deficiency by adding the above Project requirement to procedure QP-15.2, Revision 1, Paragraph 6.5.2.1.
- 9. Changes were made to Los Alamos procedure QP-18.2, Revision 1 after the effective date of March 12, 1990. Los Alamos corrected this deficiency by issuing Change Request (CR) No. 136 to procedure QP-18.2, to formally document the changes.
- 10. Los Alamos procedure QP-12.1, Revision 4, Paragraph 4.6, contradicted the requirement stated in NNWSI/88-9, Revision 4, Section XII, Paragraph 2.2, which states in part, "Calibrating standards shall have equal or greater accuracy than the equipment being calibrated." Los Alamos corrected this deficiency by issuing Change Request (CR) No. 140 to procedure QP 12.1, to revise the procedure to meet the above stated Project requirement.

- 11. An auditor certification was missing. Los Alamos corrected this deficiency by producing a new certification for the auditor in question.
- 12. Los Alamos procedure DP-07, Revision 3, "Electron Microprobe," omitted establishment or selection of the electron gun operating voltage. Los Alamos corrected this deficiency by issuing CR No. 138 to procedure DP-07.

7.0 RECOMMENDED ACTION

Responses to each SDR (delineated in Section 6.0) are due within 20 working days from the date of the SDR transmittal letter. Upon response, and satisfactory verification of all remedial and corrective actions, the SDRs will be closed and Los Alamos will be notified (by letter) of the closure.

A written response is required for the observations contained in Enclosure 2 of this report., Responses are due within 20 working days from the date of the transmittal letter of this report.

ENCLOSURE 1

LOS ALAMOS NATIONAL LABORATORY 90-01 AUDIT ROSTER

NAME	ORGANIZATION	TITLE	PRE- AUDIT	CONTACTED DURING AUDIT	POST AUDIT
Arceo, Amelia I.	SAIC	Auditor	X		X
Bish, David	Los Alamos			X	
Blaylock, James	DOE/YMP	Audit Manager	X		X
Bolivar, Stephen L.	Los Alamos	QA Liaison	X	X	
Bradbury, John	NRC	Observer	X		
Broxton, Dave	Los Alamos	Technical Coordinator	X	X	X
Caldwell, J. R.	MACTEC	Observer			X
Campbell, Katherine	Los Alamos			X	
Canepa, Julie A.	Los Alamos	Project Leader	X	X	
Carpenter, Scott A.	LBL	Designated QA Liaison		X	X
Chavez, C.	Los Alamos	-			X
Clevenger, Michael S.	Los Alamos	QA Liaison	X	X	X
Cole, Eric M.	LATA	QA Specialist	X	X	X
Collins, Ron	DOE	Observer	X		X
Cocoros, A. Edward	MACTEC	Auditor	X		X
Crawford, Sidney L.	SAIC	Auditor	X		X
Crowe, Bruce	Los Alamos	Principal Investigator		X	
Curtis, David	Los Alamos	Group Leader	X		X
Dana, Stephen R.	SAIC	Audit Team Leader	X		X
Daniels, William R.	Los Alamos	Group Leader	X		X
Day, John L.	LATA	QAS Verif. Coordinator	X	X	X
Diaz, Mario R.	DOE/YMP	Auditor	X		χ.
Essington, Edward H.	Los Alamos	Staff			X
Foster, Karen L.	LATA	QAS - Records	X	X	X
Friedrich, Chris	DOE/YMP	Technical Specialist	X		
Gainer, Gabriela M.	LATA	QA Engineer	X	X	X
Gancarz, Alex	Los Alamos	Dep. Div. Leader	X		X
Gonzalez, Michael R.	NRC	Observer	X		
Goulding, Patricia F.	LATA	QA Specialist	X	X	
Guthals, P.	AOD	QAO	X		
Harrington, Charles	Los Alamos	Staff	X		X
Haslebacher, W.	Weston/DOE	Observer	X		
Herbst, Richard J.	Los Alamos	Tech. Proj. Officer	X	X	X
Hersman, Larry	Los Alamos	Principal Investigator	X	X	
Hessman, Larry E.	Los Alamos	Principal Investigator			X
Hooks, Kenneth R.	NRC	Observer	X		X
Horton, Donald G.	DOE/YMP	Director, QA			X
Humes, H.	Los Alamos			X	
Hutton, Richard D.	SAIC	Resident Integrator	Χ .		
Jones, Marcia	Los Alamos	REC	X		

LOS ALAMOS NATIONAL LABORATORY 90-01 AUDIT ROSTER

<u>NAME</u>	ORGANIZATION	TITLE	PRE- AUDIT	CONTACTED DURING AUDIT	POST AUDIT
Kalia, Hemendra N.	Los Alamos	Leader - ESP Testing	X		
Maasser, Larry	Los Alamos	QA Project Leader			X
Marchand, W. R.	Weston/DOE	Observer	X		X
Maudlin, Richard L.	MACTEC	Auditor	X		
Mitchell, Alan	Los Alamos	INC			X
Mitchell, Martha J.	SAIC	Lead Technical Spec.	X		
Morgan, Terry	Los Alamos	QA Liaison	X	X	
Morley, Richard	Los Alamos	QA Liaison	X	X	X
Morris, Wayne A.	Los Alamos	Group Leader			X
Myers, C. W.	Los Alamos	EES-DC	X		_
Nettles, Ed	Los Alamos	Spec. Project Officer	X		
Newman, Brent D.	Los Alamos	Resident Technician	X		X
Noland, Terry W.	Westinghouse	Auditor-In-Training	X		X
Nunes, Henry P.	Los Alamos	QA Project Leader	X	X	X
Patera, Edward S.	Los Alamos	Technical Coordinator	X		X
Peters, Forrest D.	SAIC	Technical Specialist	X		X
Polzer, Wilfred L.	Los Alamos	EES-15	X		X
Robinson, Bruce	Los Alamos	Principal Investigator	X		
Sebring, Sue R.	Los Alamos	QA Liaison	X	X	X
Schempp, Lloyd W.	Los Alamos	Proj. Dev. Coordinator	X	X	X
Simundson, Dan	LATA	Training Coordinator			X
Springer, Everett P.	Los Alamos	Principal Investigator		X	X
Sprouse, Bill	Los Alamos	Security Specialist	X		
Trap, John S.	NRC	Observer	X		
Triay, Ines	Los Alamos	INC			X
Vaniman, Dave	Los Alamos	EES-1	X	X	X
West, Karen A.	Los Alamos	Project Leader	X	X	X
Whetten, John	Los Alamos	Associate Director			X
Williams, Donna	Los Alamos			X	
Zimmerman, Susan	St. of NV	Observer	x		x

ENCLOSURE 2

	YUCCA MOUNTAIN PROJECT OFFICE N-QA-01 YMPO OBSERVATION NO. 90-01-01 4/89						
on	2Noted During: Audit 90-1	90-1 3Identified By: M. Diaz					
ganizati	5Organization: Los Alamos	6Person(s) Contacted: H. Nunes		7 Response Due Date is 20 Days from Date of Transmittal			
Completed by Originating Organization	The new QA organization has recognized the need to revise several procedures to reflect new Los Alamos organizational changes. However, a plan is needed to determine: a) How many of these procedures should be revised; and b) The period of time or schedule by which this task should be finished. PQAE/Lead Auditor Date 10 Branch Manager Date 5 (0/00)						
		8/90	Catheir Han	sto for			
Completed by Respondee	11 Response:						
	¹² Signature:		Date:	:			
	13 Response Receipt Acceptable ☐ Initiator 14 Remarks:	Date	QA/Lead Auditor	Date			
Completed by QA Org.				Page _1of_1			

	YUCCA MOUNT YMPO OBSERVA	N-QA-012 4/89				
uo	2Noted During: Audit 90-1	³ Identifie	ed By: S. L. Crawford	4 Date: 3-30-90		
ganizati	5Organization: YMPO	⁶ Person	(s) Contacted: D. Broxton	7 Response Due Date is 20 Days from Date of Transmittal		
Completed by Originating Organization	YMPO (M. Blanchard) requested on 10/25/89 that a Readiness Review of SP 8.3.1.3.2.1 be conducted per AP-5.13Q. Los Alamos responded 11/21/89 suggesting a Los Alamos person as the Readiness Review board chairman. The Readiness Review has not been performed to-date pending resolution and verification of Audit 89-7 Observations 89-7-01 and 89-7-02, and revision of Los Alamos procedure QP-02.4. Based on the correspondence, it is not clear who is responsible for the Readiness Review (YMPO or Los Alamos) or which procedure governs (AP-5.13Q or QP-02.4). In addition, the Los Alamos					
	9QAE/Dead Auditor	Date /1//90	10 Branch Manager	Date 4/الداج ט		
Completed by Respondee	11 Response:					
	12Signature:		Date:			
Completed by QA Org.	13 Response Receipt Acceptable ☐ Initiator 14 Remarks:	Date	QA/Lead Auditor	Date		
Complei				Page _1 _ of _2		

YMPO OBSERVATION NO. 90-1-02 CONTINUATION PAGE

N-QA-012 1/89

8 Discussion: (continued)

suggested chairman is the author of the subject study plan and does not appear to have sufficient independence of the activity to be reviewed.

Page

	YUCCA MOUNTAIN PROJECT OFFICE N-QA-012 1YMPO OBSERVATION NO. 90-1-03 4/89						
on	2Noted During: Audit 90-1	³ Identifie	ed By: S. L. Crawford	4Date: 3/30/90			
rganizati	5Organization: Los Alamos	⁶ Person	(s) Contacted: D. Broxton	7 Response Due Date is 20 Days from Date of Transmittal			
Completed by Originating Organization	BDiscussion: Los Alamos Detailed Technical Procedures (DPs) and Quality Assurance Procedures (QPs) referenced or identified in Study Plan 8.3.1.3.2.1, Rev. 0, 6/89 are incorrect or have not been prepared. The Study Plan has been issued by YMPO as a controlled document. Los Alamos should issue a Study Plan Change Request to YMPO per the requirements of AP-1.10Q, Rev. 1, Paragraph 5.7. Examples to follow:						
O	9QAE/Lead Auditor	Date ////90	10Branch Manager	Date 4//6/90			
Completed by Respondee	11 Response:						
	12Signature:		Date:				
	13 Response Receipt Acceptable ☐ Initiator	Date	QA/Lead Auditor	Date			
Completed by QA Org.	14Remarks:			Page _1of_2_			

YMPO OBSERVATION NO. 90-1-03 CONTINUATION PAGE

N-QA-012 1/89

8 Discussion: (continued)

SP PARA.#	PROCEDURE #	EXAMPLE
2.5.6	TWS-MSTQA-QP-18	Obsolete procedure
3.1.1	TWS-ESS-DP-28	Rescinded 2/7/89 (P 3.3.1, 3.4.1 also)
3.1.4	TWS-QAS-QP-3.11	Not prepared (P 3.3.4 also)
	QP-3.12	Not prepared " "
	QP-3.13	Not prepared " "
3.3.1	TWS-ESS-DP-117	Rescinded 6/29/89 (P 3.4.1 also)
Table A-1		Numerous unissued and superseded QPs

Page

	YUCCA MOUNT YMPO OBSERVA			N-QA-012 4/89		
ion	2Noted During: Audit 90-1	³ Identifie	ed By: S. L. Crawford	4 Date: 3-30-90		
rganizat	⁵ Organization: Los Alamos	6Person K. West	(s) Contacted: D. Hobart,	7 Response Due Date is 20 Days from Date of Transmittal		
Completed by Originating Organization	A QA Review of Study Plan SP-8.3.1.3.5.1/3.5.2 was conducted 1/2/90 following the issue of AP-1.10Q, Rev. 1 (signed 12/21/89, effective 1/22/90). The QA review identified conflicting QA program criteria between Table A-1 and Table A-2, but did not identify numerous unissued and superseded Quality Procedures in Table A-1. The study plan was still in internal Los Alamos review and had not been submitted to YMPO. See examples to follow.					
	9QAE/Lead Auditor	Date	10 Branch Manager	Date 5 4/16/90		
Completed by Respondee	11 Response:					
	¹² Signature:		Date:			
Completed by QA Org.	13 Response Receipt Acceptable ☐ Initiator 14 Remarks:	Date	QA/Lead Auditor	Date		
Comple				Page _1of_2		

YMPO OBSERVATION NO. 90-1-04 CONTINUATION PAGE

N-QA-012 1/89

8 Discussion: (continued)

Examples: QP-3.6 - superseded by QP-3.15, QP-3.16

QP-3.8 - superseded by QP-3.15, QP-3.16

QP-3.11 - not issued QP-3.12 - not issued QP-3.13 - not issued

QP-17.1 - superseded by QP-17.3 QP-17.2 - superseded by QP-17.3

Additional Los Alamos QPs were issued or superseded 3/2/90 subsequent to the QA review of the Study Plan.

Page

	YUCCA MOUN YMPO OBSERVA	DJECT OFFICE 90-01-05	N-QA-012 4/89			
· uo	2Noted During: Audit 90-1	90-1 3Identified By: S. L. Crawford				
rganizati	5Organization: Los Alamos	6Person(s) Contacted: D. Broxton, D. Hobart, Vaniman		7 Response Due Date is 20 Days from Date of Transmittal		
Completed by Originating Organization	**BDiscussion: Los Alamos Detailed Technical Procedures (DPs) referenced obsolete Quality Assurance procedures. Although action to cross reference obsolete and superseded QPs to the equivalent current procedures on procedure tables of contents is being taken, Los Alamos should establish measures to review DPs on a periodic basis (for example 1 year) for changes, updates, and corrections.					
	9QAE/Lead Auditor	Date 5/8/90	10 Branch Manager	Date 5/8/9 5		
Completed by Respondee	11 Response:					
	12Signature:		Date:			
	13 Response Receipt Acceptable Initiator	Date	QA/Lead Auditor	Date		
Completed by QA Org.	14 Remarks:			- Para		
				Page of _2		

YMPO OBSERVATION NO. 90-01-05 CONTINUATION PAGE

N-QA-012 1/89

8 Discussion: (continued)

The following procedures are identified as examples only, and not for specific corrective action:

TWS-ESS-DP-03 Reference obsolete MSTQA-QP-14, MSTQA-QP-16
TWS-INC-DP-35 Reference obsolete MSTQA-QP-14, QAS-QP-07
TWS-INC-DP-78 Reference obsolete QAS-QP-0.5, QAS-QP-14
TWS-INC-DP-79 Reference obsolete MSTQA-QP-14, QAS-QP-07
TWS-INC-DP-80 Reference obsolete MSTQA-QP-14, QAS-QP-07, QAS-QP-14

Page

	YUCCA MOUNTAIN PROJECT OFFICE N-QA-012 1YMPO OBSERVATION NO. 90-1-06 4/89						
uo	2Noted During: Audit 90-1	3 identified By: S. L. Crawford					
rganizati	5Organization: Los Alamos	6Person T. Morg	(s) Contacted: D. Hobart,	7 Response Due Date is 20 Days from Date of Transmittal			
Completed by Originating Organization	**BDiscussion: Lawrence Berkeley Laboratory (LBL) procedures for YMP activities are prepared, reviewed, and approved under the Los Alamos QAPP and QP-05.2. The TWS-LBL-DP-XX procedures, although issued in their own controlled binder set, were not issued to various "reference" set Quality Assurance Binder (QAPP/QP/DP) assignees who have a need for the LBL procedures for reference purposes. These assignees include, for example: D. E. Shelor, D. G. Horton, J. E. Clark, K. L. Foster, J. L. Day, G. Gainer, R. R. Loux, and D. Porter.						
	Some how or	Date 4/11/90	10 Branch Manager	Date 4/16/20			
Completed by Respondee	11 Response:						
	¹² Signature:		Date:				
Completed by QA Org.	13 Response Receipt Acceptable Initiator 14 Remarks:	Date	QA/Lead Auditor	Date			
Complete				Page _1 _ of _1			

YUCCA MOUNTAIN PROJECT OFFICE N-QA-012 YMPO OBSERVATION NO. 90-01-07 4/89						
2Noted During: Audit 90-1	³ Identifie	ed By: R. L. Maudlin	4Date: 3-29-90			
5Organization: Los Alamos	6Person	(s) Contacted: R. Morley	7Response Due Date is 20 Days from Date of Transmittal			
**SDiscussion: The purchase requisition and associated "Statement of Work" for the University of Colorado (Req. No. 8482Y) does not define which Los Alamos implementing procedures are required to perform the scope of work described by the "Statement of Work".						
		10 Branch Manager	Date 58-90			
11 Response:						
12Signature:		Date:				
13 Response Receipt Acceptable ☐ Initiator	Date	QA/Lead Auditor	Date			
14 Remarks:			Page _1 of_1			
	2 Noted During: Audit 90-1 5 Organization: Los Alamos 8 Discussion: The purchase requisition and a University of Colorado (Req. Nimplementing procedures are redescribed by the "Statement of Durang Planck: 05, 11 Response: 12 Signature: 13 Response Receipt Acceptable Initiator	12 Signature: 1 YMPO OBSERVATION NO 2 Noted During: Audit 90-1 3 Identified 3 Identified 3 Identified 3 Identified 3 Identified 3 Identified 4 Personal 6 Personal 7 Identified 7 Identified 8 Discussion: The purchase requisition and associate University of Colorado (Req. No. 8482Y implementing procedures are required to described by the "Statement of Work". 9 QAE/Lead Auditor 9 QAE/Lead Auditor Date 12 Signature: 13 Response Receipt Acceptable Initiator Date	Noted During: Audit 90-1 Noted During: Audit 90-1 Sorganization: Los Alamos Sorganization: Sorganization: Northery Sorganization: Los Alamos Sorganization: Sorganization: Northery Sorganization: Northe			

YUCCA MOUNTAIN PROJECT OFFICE 1 YMPO OBSERVATION NO. 90-1-08					
uo	2Noted During: Audit 90-1	3 Identified By: A. E. Cocoros		4Date: 3-26-90	
rganizati	5Organization: Los Alamos	⁶ Person	(s) Contacted: H. Hunes	7 Response Due Date is 20 Days from Date of Transmittal	
Completed by Originating Organization	**BDiscussion: TW-QAS-QP-05.2, Rev. 2, Para. 1.0 states that the purpose of the QP is to describe the writing, reviewing, approvingof technical procedures (DP) used by Los Alamos and any of its' contractors. Throughout the rest of the procedure, there is no further reference to the subcontractor's effort. There is no indication that the subcontractor may write his own procedures. Also, Para. 6.2 does not refer to any technical or QA review by Los Alamos personnel of procedures developed by a contractor nor is there a procedural (con't)				
	9QAE/Lead Auditor	Date 4/10/90	10 Branch Manager	Date	
Completed by Respondee	11 Response:	·			
	¹² Signature:		Date:		
:	13 Response Receipt Acceptable Initiator 14 Remarks:	Date	QA/Lead Auditor	Date	
Completed by QA Org.	- From Marino			Page 1 of 2	

YMPO OBSERVATION NO. 90-1-08 CONTINUATION PAGE

N-QA-012 1/89

8 Discussion: (continued)

requirement for Los Alamos personnel to sign the title page.

Page

	YUCCA MOUNTAIN PROJECT OFFICE N-QA-012 YMPO OBSERVATION NO. 90-01-09 4/89					
no	2Noted During: Audit 90-1	3 Identified By: A. E. Cocoros		4Date: 3-26-90		
ganizati	5Organization: Los Alamos	6Person(s) Contacted: R. Herbst		7 Response Due Date is 20 Days from Date of Transmittal		
Completed by Originating Organization	**BDiscussion: The Los Alamos QA Program Plan for the Yucca Mountain Project (Los Alamos-YMP-QAPP-R4.4) provides instructions to apply the QA requirements to the technical activities conducted by Los Alamos in support of the Project. Los Alamos does not have a mechanism (procedure) for making changes to this QAPP.					
	9QAE/Lead Auditor 5/	Date 8/9 0	10 Branch Manager	Date		
Completed by Respondee	11 Response:					
	¹² Signature:		Date:	:		
Completed by QA Org.		Date	QA/Lead Auditor	Date		
	14 Remarks:					
)				Page _1 _ of _1		

Y	YUCCA MOUN YMPO OBSERVA	OJECT OFFICE). 90-1-10	N-QA-012 4/89		
on	2Noted During: Audit 90-1	3 Identifie	ed By: S. L. Crawford	4Date: 3-30-90	
rganizati	5Organization: Los Alamos		(s) Contacted: D.Broxton, ington, B.Crowe	7 Response Due Date is 20 Days from Date of Transmittal	
Completed by Originating Organization	BDiscussion: AP-6.3Q identifies the YMP Sample Management Facility (SMF) provisions for the control of samples. Los Alamos procedure QP-08.1 identified AP-6.3Q provisions and requirements to certify field sample collection personnel in accordance with AP-6.3Q. Detailed technical procedures for sample collection and identification did not fully address or reference AP-6.3Q and/or QP-08.1. For example: (con't)				
	9 QAE/Lead Auditor	Date 4/11/90	10 Branch Manager	Date 4/16/40	
Completed by Respondee	11 Response:				
	¹² Signature:		Date:		
	13 Response Receipt Acceptable ☐ Initiator	Date	QA/Lead Auditor	Date	
Completed by QA Org.	14Remarks:				
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YMPO OBSERVATION NO. 90-1-10 **CONTINUATION PAGE**

N-QA-012 1/89

8 Discussion: (continued)

TWS-ESS-DP-101, R1

(Change Request 139 initiated during audit)

TWS-ESS-DP-114, R1

TWS-EES-13-DP-606, R1

References AP-6.3Q, but does not reference QP-08.1 or provide for AP-6.3Q certified field sample

collection personnel.

Page

YUCCA MOUNTAIN PROJECT OFFICE 1YMPO OBSERVATION NO. 90-1-11 4/89					
ganization	2Noted During: Audit 90-1	3 Identified By: S. L. Crawford		4Date: 3-30-90	
	5Organization: Los Alamos	6Person(s) Contacted: D. Hobart, T. Morgan		7 Response Due Date is 20 Days from Date of Transmittal	
Completed by Originating Organization	**Bolistussion: Laboratory analytical M&TE to be used by INC and LBL for YMP activities, and identified in Study Plans and detailed technical procedures (DP) have not been added to the "List of Calibrated Measuring and Test Equipment (M&TE)" by initiation of an M&TE Calibration Record per QP-12.1 (and previously by QP-12.2). The equipment has not been used under current QA program requirements yet. (con't)				
	9QAE/Cead Auditor	Date	10 Branch Manager	Date 5 4/16/90	
Completed by Respondee	11 Response:				
	¹² Signature: Date:				
Completed by QA Org.	13 Response Receipt Acceptable Initiator 14 Remarks:	Date	QA/Lead Auditor	Date	
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YMPO OBSERVATION NO. 90-1-11 CONTINUATION PAGE

N-QA-012 1/89

8 Discussion: (continued)

Examples:

Beckman NaI Gamma Counter (SP 8.3.1.3.5.1/2)
Baird Eagle Mount Atomic Emission Spectrometer (SP 8.3.1.3.5.1/2)
Alpha/Beta Liquid Scintillation Counter (SP 8.3.1.3.5.1/2)
Phillips Norelco X-Ray Powder Diffraction Analyzer (SP 8.3.1.3.5.1/2)
Varian Cary Spectrophotometer (TWS-INC-DP-78)
Perkin Elmer Ge/Li Gamma Counter (TWS-INC-DP-64)
Brookhaven/EG&G Autocorrelation Photon Spectroscope (TWS-INC-DP-75)

Page

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	YUCCA MOUNTAIN PROJECT OFFICE N-QA-012 1YMPO OBSERVATION NO. 90-1-12 4/89						
Completed by Originating Organization	2Noted During: Audit 90-1	³ Identified By: R. L. Maudlin		4 Date: 3-29-90			
	5Organization: Los Alamos	⁶ Person(s) Contacted: M. Williams		7 Response Due Date is 20 Days from Date of Transmittal			
	**BDiscussion: TWS-QAS-QP-17.3, R0, Section 6.1 does not address all of the record review criteria that is specified in AP-1.7Q, Section 5.7.1. Items not addressed by QP-17.3 include a verification that records are authenticated, record contains WBS number, records in record packages are checked against table of contents received with packages, and QA designation noted on record. It was found that in practice all items are verified, however, the procedure lacks definition.						
	l	Date -10 - 90	10 Branch Manager	Date > 4/16/90			
Completed by Respondee	11 Response:						
	¹² Signature:	_	Date:				
Completed by QA Org.	13 Response Receipt Acceptable ☐ Initiator 14 Remarks:	Date	QA/Lead Auditor	Date			
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YUCCA MOUNTAIN PROJECT OFFICE N-Q. 1YMPO OBSERVATION NO. 90-01-13						
ganization	2Noted During: Audit 90-01	³ Identifie	ed By: M.J. Mitchell	4Date: 03/28/90		
	5Organization: Los Alamos	⁶ Person(s) Contacted: R. Herbst		7 Response Due Date is 20 Days from Date of Transmittal		
Completed by Originating Organization	*Discussion: The purpose of a technical procedure is to control the potential sources of uncertainty and error in activities. In order to achieve this end, specific requirements have been established for information to be included in procedures. This required information includes accept and reject criteria, calibration requirements, and accuracy and precision for recording data. Mandatory verification points should be included in the procedures, as applicable.					
	9QAE/Lead Auditor	Date	10 Branch Manager	Date		
	11 Response:	18/90	(ather for	sh 5-8-90		
Completed by Respondee						
	¹² Signature:		Date:			
Completed by QA Org.	13 Response Receipt Acceptable ☐ Initiator 14 Remarks:	Date	QA/Lead Auditor	Date		
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YMPO OBSERVATION NO. 90-01-13 CONTINUATION PAGE

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8 Discussion: (continued)

In several instances during Los Alamos Audit 90-01, it was noted by technical auditors that as part of good scientific practice, calculations, or other actions, were internally verified by Los Alamos technical staff. These actions were not identified as having been checked in laboratory notebooks and these checks were not identified as mandatory verification points in the controlling procedures. This indicates that there needs to be a better understanding of the purpose of technical procedures developed and used by Los Alamos on this project.

Credit should be taken for good scientific practice. Activities such as verification and new or expanded methods for research, or support activities including calibration, should be included in the technical procedures.

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YUCCA MOUNTAIN PROJECT OFFICE N-QA-012 1YMPO OBSERVATION NO. 90-01-14 4/89							
uo	2Noted During: Audit 90-01	³ Identifie	ed By: M.J. Mitchell	4Date: 03/28/90			
Completed by Originating Organization	5Organization: Los Alamos	⁶ Person	(s) Contacted: R. Herbst	7 Response Due Date is 20 Days from Date of Transmittal			
	During Los Alamos Audit 90-01, letter reports were found attached to monthly activity reports for the project. These letter reports were identified as Level III milestones and contain a considerable amount of data in some cases. These reports are viewed as internal, informal, and preliminary by the authoring staff members. Some of these letter reports orginate at subcontract organizations. It appears that these reports are intended for administrative purposes only and for that reason do not receive technical review. Data included in activity reports that has not been technically						
	9QAE/Lead Auditor 5-	8-90	10 Branch Manager	Date			
Completed by Respondee	11 Response:						
	¹² Signature:		Date:				
Completed by QA Org.	13 Response Receipt Acceptable ☐ Initiator 14 Remarks:	Date	QA/Lead Auditor	Date			
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YMPO OBSERVATION NO. 90-01-14 CONTINUATION PAGE

N-QA-012 1/89

8 Discussion: (continued)

reviewed should be identified as preliminary and a mechanism needs to be established that can exclude such reports from the technical review cycle.

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2 of 2

ENCLOSURE 3

UKIGINAL N-QA-038 YMPO STANDARD DEFICIENCY REPORT 4/89 Date 03/30/90 **X** 2 2 2 Severity Level Page 1 of Organization 3 Discovered During YMP Audit 90-1 32 Identified By M. R. Diaz, 4 SDR No. 511 0 Rev. T. W. Noland 7 Response Due Date is 5 Organization 6 Person(s) Contacted 20 Working Days from Los Alamos H. Nunes Date of Transmittal 80 8 Requirement (Audit Checklist Reference, if Applicable) QAP/88-9, Rev. 4, Sect. 1, Para. 1.0 states in part, "The organizational Originating structure, lines of communication, authority and duties of persons and organizations performing activities affecting quality shall be clearly 9 Deficiency An implementing procedure that clearly describes the authority and **会** responsibility of each position in the Quality Assurance organization, in effect as of March 27, 1990, does not exist. Completed 10 Recommended Action(s):

Remedial
Investigative Identify the remedial action(s) to be taken to correct the deficiencies noted in Block 9. Identify the cause of the condition and the planned 12 Division Manager/Date QAE/Lead Auditor/Date Project Quality/Mor./Date 40-90 1)/00014 10:90 14 Remedial/Investigative Action(s) 15 Effective Date Block ⊑ Organization 16 Cause of the Condition & Corrective Action to Prevent Recurrence 17 Effective Date 么 Sompleted 18 Signature/Date 19 Response QAE/Lead Auditor/Date Division Manager/Date Project Quality Mgr./Date Accepted QAE/Lead Auditor/Date Division Manager/Date 20 Corrective Action Project Quality Mgr./Date Verif. Satisfactory à 21 Remarks Orig. \$ Comp.

Division Manager/Date

PQM/Date

QAE/Lead Auditor/Date

QA CLOSURE

N-QA-038 2/89

SDR No. 511

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of 2

8 Requirement (continued)

established and delineated in writing. Para. 2.3 states in part, The QA responsibilities of all organizational elements depicted on organization charts shall be described.

10 Recommended Actions (continued) action to prevent recurrence.

ORIGINAL

	YMPO STANDARD DEFICIENCY REPORT					N-QA-038 4/89
	1 Date 03/30/90	2 Severity Le	evel 🗆 1 🔯	2 🗆 3	Page 1	of 2
Organization	3 Discovered During YMP Audit 90-1	3a Identified By F.D. Peters			4 SDR No. 512	Rev. <u>0</u>
	5 Organization Los Alamos	6 Person(s) Contact D. Hobart, B.M. C				Due Date is g Days from ransmittal
Originating QA	8 Requirement (Audit Checklist Reference, if Applicable) (T-67, T-112, T-116) Los Alamos procedure TWS-QAS-QP-03.2, Rev. 0, Para. 6.2.1, requires reviewers to be technically qualified and certified per QP-02.1 (for Los Alamos YMP and Los Alamos YMP subcontractor personnel) or					
þ	9 Deficiency Non-Los Alamos or subcontractor YMP personnel have performed technical reviews of documents in accordance with QP-03.2 and QP-03.5 without documentation or certification of qualification or indoctrination to					
Completed	10 Recommended Ac	tion(s): 🛛 Remedial 🖾 In	vestigative	Correc	tive	
Con	Identify the remedial actions to be taken to correct the deficiencies noted in Block 9. Investigate the program, process, activities, or documentation to					
Aprvi.	11 QAE/Lead Auditor/E	Date 4/29, 12 Division Man	ager/Date	13.5	Project Quality	Mgr./Date
5	14 Remedial/Investigative Action(s) 15 Effective Date					
Block			15	Enecu	ve Date	
in						
tion						
Organization	16 Cause of the Cond	lition & Corrective Action	to Prevent Recu	ırrence		
Orga			17	Effectiv	ve Date	
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eted						
Completed	18 Signature/Date					
A Org.	19 Response Accepted	QAE/Lead Auditor/Date	Division Manag	er/Date	e Project Qua	ality Mgr./Date
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manag	ger/Date	e Project Qua	ality Mgr./Date
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N-QA-038 2/89

SDR No. 512

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of 2

8 Requirement (continued)

authorized by a Los Alamos Group Leader on a Reviewer Qualification form (for persons "not associated with the Project").

Los Alamos procedure TWS-QAS-QP-03.5, Rev. 0, Para. 4.8, provides for technical reviewers of laboratory notebooks, field notebooks, and logbooks to have the training and experience to understand and repeat the work being reviewed, but does not specifically require documentation or certification of the reviewer's qualification basis.

9 Deficiency (continued)

applicable Los Alamos procedures for the reviews and for the activities being reviewed.

- 1. Report LBL-27173A, "Solubility Studies of Transuranic Elements for Nuclear Waste Disposal: Principles and Overview" was technically reviewed by a Lawrence Livermore National Laboratory (LLNL) employee.
- Paper, "Basaltic Volcanic Episode of the Yucca Mountain Region" for the 1990 International High Level Waste Management conference was technically reviewed by a DOE/YMP employee.
- 3. Field notebooks for volcanism studies (WBS 1.2.3.2.5; SP 8.3.1.8.1.1, 8.3.1.8.5.1) were technically reviewed by a DOE/YMO employee.

COMMENTS:

QP-02.1, referenced by QP-03.2, has been superseded by TWS-QAS-QP-02.5, Rev. 0, TWS-QAS-QP-02.6, Rev. 0, and TWS-QAS-QP-02.9, Rev. 0. QP-02.5, QP-02.6, and QP-02.9 apply only to Los Alamos YMP Personnel (Los Alamos employees) and Los Alamos subcontractors working under the Los Alamos YMP QA program. The procedures do not apply to DOE/YMP personnel or employees of other project participants.

A similar condition was previously identified during YMP Audit 89-07 by Cbservation No. 89-07-04. The Los Alamos response clarification to that observation stated "Training files for non-employees who have performed quality related work will be updated in accordance with approved changes to the program."

10 Recommended Actions (continued)

determine the extent and depth of similar deficient conditions to those listed on the SDR. Identify these deficiencies and provide the measures required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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	YMPO STANDARD DEFICIENCY REPORT N-QA-038 4/89					
	1 Date 03/30/90	2 Severity Le	evel 🛛 1 🗆 2 🖂 3	Page 1 of 3		
Organization	3 Discovered During YMP Audit 90-1	3a Identified By M.R. Diaz		4 SDR No. 513 Rev. 0		
	5 Organization Los Alamos	6 Person(s) Contac H. Nunes	ted	7 Response Due Date is 20 Working Days from Date of Transmittal		
Originating QA	8 Requirement (Audit Checklist Reference, if Applicable) Los Alamos YMP QAPP, Rev. 4.3, Sect. 2, para. 2.1.1 states in part, "The QAPL or his appointee shall conduct internal audits of all phases of the application of this QAPP for all Los Alamos YMP activities affecting					
by	9 Deficiency Contrary to the above requirements:					
Completed		and external audits of				
ngle Be		tion(s): 🖾 Remedial 🖾 Ir				
Ço	Identify the remedial actions to be taken to correct the deficiencies noted in Block 9. Investigate the program, process, activities, or documentation to					
Aprvl.	Malio Las 4	Date 12 Division Man	ager/Date 13 Pr	pject Orgality Mgr./Date		
5	14 Remedial/Investigative Action(s)					
Block			15 Effective	Date		
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zati	16 Cauco of the Cond	lition & Corrective Action	to Provest Popursones			
Organization	To Cause of the Cond	illion & Conective Action	to Prevent Recurrence	Date		
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A Org.	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
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N-QA-038 2/89

SDR No. 513

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of 3

- 6 Persons contacted (continued)
- 8 Requirement (continued)
 quality.**

Section 18, para. 18.2.1, 18.2.2, and 18.2.3 state in part, "Internal and external QA audits shall be scheduled annually to provide complete coverage of QA program activities. The audit schedule shall be prepared annually and evaluated periodically and revised as necessary to ensure that coverage is maintained current. Los Alamos shall perform or arrange for annual evaluations of suppliers. The audit schedule, including dates and any revisions thereof, shall be sent to the PQM.

All applicable elements of Los Alamos' internal QA program shall be audited at least annually or at least once during the life of the activity, whichever is shorter.

Applicable elements of an external organization's QA program shall be audited at least annually or once during the activity, whichever is the shorter period.

The justification for not performing audits of vendors whose activities are less than four months in duration shall be documented, approved by the QAPL and sent to the PQM.*

9 Deficiency (continued)

Alamos QAPP for all YMP activities affecting quality during 1989 were not conducted. Consequently, it was not possible to verify the adequacy of the following evaluations performed by Los Alamos during internal/external audits:

- a) Compliance of the QA program.
- b) Adequacy of the QA program.
- c) Effectiveness of the QA program.
- d) Continuing implementation of the QA program.
- 2. The following specific notation to the audit program requirements were found:
 - a) The audit schedule was rescinded during May 1989. It was never formally reissued. Documented evidence of the event was not sent to the POM.
 - b) Audit commitments were reinstated to start on June 1989. However, only two of the audits were conducted and portions of the QA documentation of those audits was found inadequate as previously identified on SDR 470.
 - c) With the disruption of the audit schedule, there was no evaluation of the remainder of the schedule to assure complete coverage of QA program activities. The emphasis of the two audits focused on

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9 Deficiency (continued)

implementation of activities without consideration that the development and approval process of procedures fall within QA program purview.

- d) Two subcontractors, EG&G and University of Texas, El Paso were not audited in accordance with program requirements; furthermore, neither is a subcontractor at the present time to Los Alamos. No documentation exists to justify cancellation of these audits.
- e) Applicable elements of all external organization's QA program were not audited.
- f) The conditions described above are indicative that the audit schedule needed to be revised; however, this action never took place.

10 Recommended Actions (continued)

determine the extent and depth of similar deficient conditions to those listed on the SDR. Identify these deficiencies and provide the measures required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

ORIGINAL

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Organization	3 Discovered During Audit 90-1	3a Identified By R.L. Maudlin			4 SDR No. 515 R	ev. <u>0</u>
	5 Organization Los Alamos	6 Person(s) Contac T. Moran, S. Sebr			7 Response I 20 Working Date of Tra	Days from
Originating QA	8 Requirement (Audit Checklist Reference, if Applicable) TWS-QAS-QP-04.1, R2, Para. 6.4 states in part: "The requestor supplements the PR with additional documentationthe requestor particularly considers the following points and requires only those that are appropriate					
þ	describe rights of access by DOE, pass-through of QA requirements to sub-tier					
Completed	10 Recommended Action(s): A Remedial A Investigative A Corrective Identify the remedial actions to be taken to correct the deficiencies noted in Block 9. Investigate the program, process, activities, or documentation to					
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8 Requirement (continued)

right-of-access provision which allows designated Los Alamos and Department of Energy (DOE) personnel entry to suppliers facilities...Subcontracting Requirements...Any subcontracts must include a pass-through of appropriate QA requirements...Control of supplier-issued nonconformances...".

10 Recommended Actions (continued)

determine the extent and depth of similar deficient conditions to those listed on the SDR. Identify these deficiencies and provide the measures required to correct them. Identify the cause of the condition and the planned action to prevent recurrence.