



Department of Energy

Yucca Mountain Project Office
P. O. Box 98608
Las Vegas, NV 89193-8608

WBS 1.2.9.3
QA

JUN 05 1990

Richard J. Herbst
Technical Project Officer
for Yucca Mountain Project
Los Alamos National Laboratory
University of California
N-5, Mail Stop J521
P.O. Box 1663
Los Alamos, NM 87545

ACCEPTANCE OF RESPONSES TO STANDARD DEFICIENCY REPORTS (SDRs) 511, 512, 513, AND 515, REVISIONS 0, RESULTING FROM YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA) AUDIT 90-01 OF LOS ALAMOS NATIONAL LABORATORY (LOS ALAMOS)

The Project Office QA staff has evaluated and accepted your responses to SDRs 511, 512, 513, and 515, Revisions 0, generated as a result of Project Office QA Audit 90-01 of Los Alamos. The SDRs will be closed after verification of satisfactory completion of the specified corrective actions. Copies of the SDRs are enclosed for your information.

Verification of completion of your corrective action will be performed after the effective dates that were provided. Any extension to these due dates must be requested in writing with appropriate justification prior to the due date. Please send copies of the extension request to Nita J. Brogan, Science Applications International Corporation, 101 Convention Center Drive, Las Vegas, Nevada 89109, and Ralph W. Gray, U.S. Department of Energy, P.O. Box 98518, Las Vegas, Nevada 89193.

If you have any questions, please contact either Catherine E. Hampton at (702) 794-7973 or FTS 544-7973 or Stephen R. Dana at (702) 794-7176 or FTS 544-7176 of the Yucca Mountain Project QA staff.

YMP:CEH-3552

Enclosures:
SDRs 511, 512, 513 and 515

James Blaylock
Donald G. Horton, Director
Quality Assurance
Yucca Mountain Project Office

9006180121 900605
PDR WASTE
WM-11 PDC

ADD: K Hooks

102.7
WM-11
NH03

ORIGINAL

THIS IS A RED STAMP

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 03/30/90		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 3
	3 Discovered During YMP Audit 90-1		3a Identified By M. R. Diaz, T. W. Noland		4 SDR No. 511 Rev. 0
	5 Organization Los Alamos		6 Person(s) Contacted H. Nunes		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) QAP/88-9, Rev. 4, Sect. 1, Para. 1.0 states in part, "The organizational structure, lines of communication, authority and duties of persons and organizations performing activities affecting quality shall be clearly				
Completed by Organization in Block 5	9 Deficiency An implementing procedure that clearly describes the authority and responsibility of each position in the Quality Assurance organization, in effect as of March 27, 1990, does not exist.				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 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				
	11 QAE/Lead Auditor/Date Mario San 4/9/90		12 Division Manager/Date N/A 4-10-90		13 Project Quality Mgr./Date C. H. H. 4-10-90
	14 Remedial/Investigative Action(s) Refer to Page 3 of 3				
Completed by Organization in Block 5	15 Effective Date July 1, 1990				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence Refer to Page 3 of 3				
	17 Effective Date July 1, 1990				
Comp. by Orig. QA Org.	18 Signature/Date H. Nunes 5/18/90				
	19 Response Accepted	QAE/Lead Auditor/Date Mario San 5/25/90	Division Manager/Date N/A	Project Quality Mgr./Date C. H. H. 5-25-90	
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	21 Remarks RESPONSE 5/17/90 TWS-EES-13-05-90-066				
Comp. by Orig. QA Org.	22 QA CLOSURE				
	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

ENCLOSURE

**YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET**

N-QA-038
2/89

SDR No. 511

Page 2 of 23

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.

14. Remedial/Investigative Action(s)

Remedial Actions: LANL management will revise the Quality Assurance Program Plan to describe the organizational structure with reporting authorities, lines of responsibility, and duties properly described in the revision.

Investigative Actions: None required.

16. Cause of the Condition and Corrective Action to Prevent Recurrence

Cause of the Condition: LANL organization was changed before the audit, and no steps were taken to formally record this change in either the LANL Quality Assurance Program Plan or a new implementing procedure.

Corrective Action to Prevent Recurrence: A revision to the LANL Quality Assurance Program Plan will be prepared describing the LANL Yucca Mountain organizational structure and submitted to the Yucca Mountain Project Office for approval.

ORIGINAL

THIS IS A RED STAMP

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 03/30/90		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 23
	3 Discovered During YMP Audit 90-1		3a Identified By F.D. Peters		4 SDR No. 512 Rev. 0
	5 Organization Los Alamos		6 Person(s) Contacted D. Hobart, B.M. Crowe		7 Response Due Date is 20 Working Days from Date of Transmittal
	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				
Completed by Organization in Block 5	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				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial actions to be taken to correct the deficiencies noted in Block 9. Investigate the program, process, activities, or documentation to				
	11 QAE/Lead Auditor/Date <i>S. J. Jones</i> 4/9/90	12 Division Manager/Date N/A 4-12-90		13 Project Quality Mgr./Date <i>Chad N. Jones</i> 4-12-90	
	14 Remedial/Investigative Action(s) Refer to Page 3 of 3				
Completed by Organization in Block 5	15 Effective Date June 29, 1990				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence Refer to Page 3 of 3				
	17 Effective Date July 31, 1990				
Comp. by Orig. QA Org.	18 Signature/Date <i>H. P. Nunes</i> 5/18/90				
	19 Response Accepted	QAE/Lead Auditor/Date <i>S. J. Jones</i> 5/3/90	Division Manager/Date N/A	Project Quality Mgr./Date <i>Chad N. Jones</i> 5/3/90	
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	21 Remarks Response 5/17/90 - TWS-EES-13-05-90-066				
22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date	

ENCLOSURE

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
2/89

SDR No. 512

Page 2 of 13

CHPL

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.
2. 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 Observation 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.

14. Remedial/Investigative Actions

Remedial Actions: R. Morley will review the documentation files for Report LBL-27173A, "Basaltic Volcanic Episode of the Yucca Mountain Region," and Volcanism field notebooks for compliance with the appropriate implementing procedural requirements. The reviewer documentation files will be updated to include qualification and training information on the reviewers involved with the above listed items.

Investigative Actions: LANL QALs will review the documentation for internal technical reviews for fiscal years 1989 and 1990 to ascertain if any non-LANL YMP personnel performed technical reviews. Those personnel will be cross checked against the qualification files to ensure that they are qualified and trained for this function. The appropriate files will be updated based on the results of this review, and each QAL will send a written report of actions, if any, to the QAPL.

16. Cause of the Condition and Corrective Action to Prevent Recurrence

Cause of the Condition: The LANL QA procedural requirements were unclear for non-LANL reviewers conducting technical reviews.

Corrective Action to Prevent Recurrence: The appropriate procedures will be revised to clearly define reviewer qualifications and training for both LANL and non-LANL personnel.

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 03/30/90		2 Severity Level <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 24
	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) Contacted H. Nunes		7 Response Due Date is 20 Working Days from Date of Transmittal
	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				
Completed by Organization in Block 5	9 Deficiency Contrary to the above requirements: 1. Internal and external audits of all phases of the application of Los				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial actions to be taken to correct the deficiencies noted in Block 9. Investigate the program, process, activities, or documentation to				
	11 QAE/Lead Auditor/Date Mario San 4/9/90		12 Division Manager/Date N/A 4-10-90		13 Project Quality Mgr./Date Catherine Lopez 4-10-90
Completed by Organization in Block 5	14 Remedial/Investigative Action(s) Refer to Page 4 of 4				
	15 Effective Date MAY 31, 1990				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence Refer to Page 4 of 4				
Comp. by Orig. QA Org.	17 Effective Date June 29, 1990				
	18 Signature/Date H. Nunes 5/18/90				
	19 Response Accepted	QAE/Lead Auditor/Date Mario San 5/25/90	Division Manager/Date N/A	Project Quality Mgr./Date Catherine Lopez 5-30-90	
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
Comp. by Orig. QA Org.	21 Remarks RESPONSE 5/17/90 TWS-EES-13-05-90-066				
	22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date	

**YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET**

N-QA-038
2/89

SDR No. 513

Page 2 of 3/4

CHP/1

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 PQM.
- 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

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
2/89

SDR No. 513

Page 3 of 24

HPM

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.

14. Remedial/Investigative Actions

Remedial Actions: Issue a new audit and survey schedule.

Investigative Actions: The Verification Manager will review the revised audit and survey schedules to ensure that the appropriate criteria and activities are covered-- complete audit coverage of the LANL program (full criteria coverage), complete coverage of the LANL subcontractors (applicable criteria), and ongoing surveys for program implementation. The Verification Manager will issue a written report to the QAPL for review and action. These immediate actions are documented in LANL Deficiency Report No. LANL - 0017, which has been judged to be a significant condition adverse to quality. The first audit in the new schedule is set for June 4-8, 1990, at the LANL Test Manager's Office in Las Vegas and will include TMO functions and Volcanism studies.

16. Cause of the Condition and Corrective Action to Prevent Recurrence

Cause of the Condition: LANL activities to achieve a fully qualified program conflicted with the execution of the audit and survey program. The LANL QAPL directed QA staff efforts towards achieving program qualification not executing the internal audit and survey program. The LANL TPO notified the PQM, letter TWS-EES-13-90-088, Herbst to Horton, that the LANL audit and survey program was not implemented:

"The Los Alamos audit and survey program has not been fully implemented because our resources were fully committed to finishing the QA program and obtaining the Project Office approval of the program. We will now start the annual cycle of audit and survey March 1990. A new schedule will be transmitted to you. Project Office personnel are welcome to observe any audit or survey. Completion of the proposed procedural revisions and subsequent internal audits of the completed program will allow Los Alamos audit staff to assess the effectiveness of the quality program."

This action was prompted by the YMP No. 89-7, SDR No. 469 and SDR No. 470. Because these two SDRs defaulted the LANL internal audit program, the QAPL decided to redirect efforts towards correcting the audit procedure, including additional staff training to the revised procedure, instead of continuing with an unacceptable audit program. This action was extended to the survey program at the verbal direction of the QAPL.

Corrective Action to Prevent Recurrence: Establish a separate verification organization to maintain the required implementing procedures (QP-18.1, QP-18.2, and QP-18.3) and to execute the audit and survey schedules. This organization will not be charged with any program development or training responsibilities except those directly related to audits or surveys. This group will commence audits as required by LANL Deficiency Report No. LANL - 0017.

ORIGINAL

THIS IS A RED STAMP
N-QA-038
4/89

YMPO STANDARD DEFICIENCY REPORT

Completed by Originating QA Organization	1 Date 3-29-90		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 23	
	3 Discovered During Audit 90-1		3a Identified By R.L. Maudlin		4 SDR No. 515 Rev. 0	
	5 Organization Los Alamos		6 Person(s) Contacted T. Moran, S. Sebring		7 Response Due Date is 20 Working Days from Date of Transmittal	
	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 documentation...the requestor particularly considers the following points and requires only those that are appropriate..."					
Completed by Organization in Block 5	9 Deficiency No modification has been made to the existing Lawrence Berkeley contract to describe rights of access by DOE, pass-through of QA requirements to sub-tier contractors, and control of supplier-issued nonconformances.					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial actions to be taken to correct the deficiencies noted in Block 9. Investigate the program, process, activities, or documentation to					
	11 QAE/Lead Auditor/Date <i>Richard Maudlin 04-11-90</i>		12 Division Manager/Date <i>N/A 4-12-90</i>		13 Project Quality Mgr./Date <i>John A. [unclear] 4-12-90</i>	
	14 Remedial/Investigative Action(s) <i>Refer to Page 3 of 3</i>					
Completed by Org. QA Org.	15 Effective Date <i>June 29, 1990</i>					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence <i>Refer to Page 3 of 3</i>					
	17 Effective Date <i>July 31, 1990</i>					
	18 Signature/Date <i>HPMunes 5/18/90</i>					
Comp. by Orig. QA Org.	19 Response Accepted	QAE/Lead Auditor/Date <i>Maudlin 5-29-90</i>	Division Manager/Date <i>N/A</i>	Project Quality Mgr./Date <i>John A. [unclear] 5-30-90</i>		
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
	21 Remarks <i>Response 7/17/90 - TWS-EES-13-05-90-066</i>					
22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

**YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET**

N-QA-038
2/89

SDR No. 515

Page 2 of 2 ~~2~~

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.

14. Remedial/Investigative Actions

Remedial Actions: The Lawrence Berkeley Laboratory procurement will be modified to include provisions for DOE right of access, subcontractor pass through requirements, and nonconformance reporting.

Investigative Actions: All service procurements will be reviewed by the appropriate QAL to ensure that the appropriate contractual commitments have been made. Each QAL will issue a written report of the review, including copies of the revised scope of work where appropriate.

16. Cause of the Condition and Corrective Action to Prevent Recurrence

Cause of the Condition: The LANL staff has failed to modify the existing contracts to include the new Yucca Mountain Project contractual commitments.

Corrective Action to Prevent Recurrence: The LANL implementing procedure for preparation of procurements for services will be revised. The revision will require the use of standard language to cover these specific Yucca Mountain requirements and a method for QAL verification that this standard language is included in all procurements for special services.

JUN 05 1990

cc w/encls:

Ralph Stein, HQ (RW-30) FORS
D. E. Shelor, HQ (RW-3) FORS
K. R. Hooks, NRC, Washington, DC
H. P. Nunes, LANL, Los Alamos, NM
S. W. Zimmerman, NWPO, Carson City, NV

cc w/o encls:

J. W. Hines, NWQA, AL
A. R. Chernoff, MSD, AL
H. E. Valencia, LAAO
J. W. Gilray, NRC, Las Vegas, NV
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08
J. E. Clark, SAIC, Las Vegas, NV, 517/T-12
S. R. Dana, SAIC, Las Vegas, NV, 517/T-06
S. R. Dippner, SAIC, Las Vegas, NV, 517/T-08