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Audit Report
YMP-92-01
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U.S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

OFFICE OF QUALITY ASSURANCE

AUDIT REPORT

FOR AUDIT OF

LOS ALAMOS NATIONAL LABORATORY

LOS ALAMOS, NEW MEXICO

AUDIT No. YMP-92-01

OCTOBER 1 THROUGH OCTOBER 4, 1991

PRIMARY ACTIVITIES EVALUATED:

- 4.0 Procurement Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Items (Samples and Data)
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Storage and Shipping

Prepared by:

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Audit Team Leader
Yucca Mountain Quality Assurance Division

Date:

10/28/91

Approved by:

Donald G. Horton
Donald G. Horton
Director
Office of Quality Assurance

Date:

10/30/91

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Accession No. 9111130140

Enclosure 2

100.7

1.0 INTRODUCTION

This report contains the results of the Office of Civilian Radioactive Waste Management (OCRWM) Audit YMP-92-01 of Los Alamos National Laboratory (Los Alamos), conducted at Los Alamos, New Mexico on October 1 through 4, 1991. This audit was conducted by an Audit team from the Yucca Mountain Quality Assurance Division (YMQAD) of the Office of Quality Assurance (OQA), in accordance with the approved Audit Plan. (Reference: letter dated August 28, 1991, Horton to Herbst). Los Alamos Technical Associates, Inc. (LATA), Los Alamos' quality services contractor hosted the audit.

2.0 AUDIT SCOPE

This audit evaluated selected portions of the Los Alamos Yucca Mountain Site Characterization Project (YMP) Quality Assurance (QA) Program to determine whether it met the requirements and commitments imposed by the OCRWM as reflected in the Los Alamos Yucca Mountain Project Quality Assurance Program Plan (QAPP), Revision 5. This was done by verifying implementation and effectiveness of the system in place, as well as verifying adequate compliance with requirements.

A representative sample of deficiencies and recommendations identified during the previous QA audit of the Los Alamos YMP organization (Audit No. YMP-91-03) were included in the scope of this audit to determine the effectiveness of Los Alamos YMP resolutions.

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

Programmatic Elements:

- 4.0 Procurement Document Control
- 7.0 Control of Purchased Items and Services
- 8.0 Identification and Control of Items (Samples and Data)
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Storage and Shipping

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

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

Technical Areas

No technical areas were specifically audited.

Other programmatic elements as well as technical areas will be covered in subsequent audits during the fiscal year.

3.0 AUDIT TEAM AND OBSERVERS

The Audit Team consisted of the following personnel:

<u>Name</u>	<u>Organization and Location</u>	<u>Title</u>	<u>Programmatic Element</u>
Richard E. Powe	SAIC*, Las Vegas, Nevada	ATL**	13
John S. Martin	SAIC, Las Vegas, Nevada	Auditor	8, 12
Kenneth T. McFall	SAIC, Las Vegas, Nevada	Auditor	4, 7

* SAIC = Science Applications International Corporation

** ATL = Audit Team Leader

Observers

There were no Observers participating in this audit.

4.0 SUMMARY OF AUDIT RESULTS

4.1 Program Effectiveness

Overall, Los Alamos is satisfactorily implementing an effective QA Program in accordance with the LANL-YMP-QAPP, Revision 5 and procedures. No Los Alamos QA program elements or procedures were considered inadequate; however, one specific element of the Los Alamos QA program (Section 13, "Handling, Storage and Shipping"), two implementing procedures were considered indeterminate due to lack of activity, and two implementing procedures which deal with procurement control were considered marginally acceptable for procurement of calibration services. The procedures and plans considered indeterminate are identified by an asterisk within Enclosure 3.

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

- a. The excellent maintenance of the Los Alamos Sample Storage Room.
- b. The overall cooperativeness of Los Alamos and LATA personnel.

4.1.1 Effectiveness of Program Elements

The adequacy/effectiveness of the Los Alamos QA Program Elements audited are:

- a. 4.0 Procurement Document Control and
7.0 Control of Purchased Items and Services

Quality Procedures QP-4.4, Revision 0, and QP-4.5, Revision 0 are being effectively implemented overall; however, the adequacy of the procedures in the areas concerning the procurement of calibration services is not sufficient.

- b. 8.0 Identification and Control of Items (Samples and Data)

Implementation of Los Alamos QP-8.1, Revision 1 and QP-8.2, Revision 0 was found to be effective.

- c. 12.0 Control of Measuring and Test Equipment (M&TE)

Overall, implementation of the Los Alamos procedure for control of M&TE, QP-12.1, Revision 4, was found to be effective. However, since examples were found where memos/draft procedures were being used in lieu of approved procedures, the adequacy of ensuring that activities that affect quality are being properly documented and controlled (i.e., reviewed and approved procedures) was found to be marginal.

- d. 13.0 Handling, Storage and Shipping

The effectiveness of implementation of this program element is indeterminate at this time due to a lack of activity. However, since inconsistencies between the QAPP and the implementing procedures were found, the adequacy of implementing procedures generated to meet the QAPP was found to be marginal.

4.2 Programmatic Activities

Details of programmatic audit activities can be found in Enclosure 1.

4.3 Technical Activities

NONE

4.4 Summary of Deficiencies

The audit team identified five deficiencies during the audit and one was resolved prior to the post-audit conference. Three of the four unresolved deficiencies were documented in new Corrective Action Requests (CARs). The final unresolved deficiency dealt with inconsistencies between the Los Alamos QAPP and their implementing procedures. This deficiency had been previously identified in CAR No. YM-91-041. A synopsis of the CARs and the one deficiency corrected during the audit are presented in Section 6.0 of this report. An information copy of the updated CAR No. YM-91-041 can be found in Enclosure 4. An information copy of CAR Nos. YM-92-001, -002, and -003 can be found in Enclosure 5.

5.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The pre-audit conference was held at LATA facilities on October 1, 1991. Daily coordination meetings were held with Los Alamos management and staff. The audit was concluded with a post-audit conference held at LATA facilities on October 4, 1991. A list of auditors, observers and personnel contacted during the audit is included in Enclosure 2. The List includes an indication of those who attended the pre- and post-audit conferences.

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

6.1 Corrective Action Request (CAR)

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

YM-91-041 QAPP requirements are not being consistently reflected in QPs.

NOTE: CAR YM-91-041 was issued as a result of audit YMP-91-03 in April 1991 and corrective action was still being implemented at the time of this audit. During this audit additional examples of inconsistencies between the QAPP and QPs were identified. (See Enclosure 4 for details.)

YM-92-001 Los Alamos has purchased calibration services as commercial grade services and not qualified the vendor. (See Enclosure 5 for details.)

- YM-92-002 No objective evidence could be produced to demonstrate implementation of the requirement to document that the manner utilized to ship samples from the Sample Management Facility (SMF) will not degrade the samples. (See Enclosure 5 for details.)
- YM-92-003 Los Alamos has performed calibrations using memos/draft procedures. (See Enclosure 5 for details.)

6.2 Deficiencies Corrected During The Audit

Deficiencies which are considered isolated in nature and only require remedial corrective action can be corrected during the audit. Only one such deficiency was identified and corrected as follows:

- a. Purchase requisition PR No. Q8489 requested by G. WoldGabriel was found to contain several errors in procedural compliance. The requester performed the service and also performed the receipt inspection. When the receipt inspection was performed both the accept and reject boxes were checked and no indication of follow-up on the rejection could be determined. This PR was indicated as QA Level 1. After management examination of the actual content of the PR (rental of laboratory space and supplies to analyze a number of samples for K/Ar dates), it was decided that the QA designation should be QA/NA which would remove the QA requirements from the procurement. The Principal Investigator was contacted and was agreeable to the change of QA status as was the Quality Assurance Project Leader. (Refer to correspondence TWS-ESS-1-10-91-1 dated October 3, 1991 and TWS-EES-13-10-91-003 October 3, 1991). With the change of QA status to QA/NA the requirements were lifted and the purchase requisition was no longer in violation of QP-04.4, Revision 0. The approval of the change of QA status was documented appropriately.

7.0 REQUIRED ACTIONS AND RECOMMENDATIONS

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

During this audit additional examples of deficiencies associated with CAR No. YM-91-041 were identified (See Enclosure 4 for details). Los Alamos is hereby requested to take appropriate action to resolve these additional

deficiencies and be prepared to discuss these actions during YMQAD follow-up verification.

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

1. As a result of Audit YMP 91-03 in March 1991, YMQAD issued the following recommendation:

"Los Alamos Quality Procedure LANL-YMP-QP-18.1, Revision 4 became effective on March 3, 1991, and no longer requires audit checklists to be a QA record. However the previous revision to the QP did require that audit checklists be retained as a QA record. None of the checklists associated with the ten 1990 Los Alamos audits have been authenticated and processed to the Records Center. Although there is no procedural time frame established for authentication and therefore no CAR is being issued, it is strongly recommended that Los Alamos take timely action to complete the audit checklists and file them as quality records."

Follow-up on this audit revealed that these checklists still had not been fully processed. There had been significant progress since the March 1991 audit and the Los Alamos QA Verification Coordinator indicated that these records should be fully processed by the end of 1991. It is recommended that Los Alamos management take action to allocate the manpower necessary to assure these checklists are processed as soon as possible.

2. As a result of Audit YMP 91-03 in March 1991, YMQAD issued the following recommendation:

"Presently there is no procedural requirement for PI's to document the training required for individuals assigned to them prior to the start of quality affecting activities. Each PI interviewed did have some form of documented system for keeping track of training requirements. Los Alamos should consider establishing guidelines for tracking required training."

Subsequent to that audit a revision to the QARD has been issued, ICN No. 4.1, effective September 3, 1991, that imposes a the new U.S. Department of Energy "DOE System 80" for QA Training and Qualification Records that imposes the use of a Training Matrix among its requirements. Los Alamos management should consider establishing a matrix of required training for employees that meets the requirements of the DOE System 80.

8.0 LIST OF ENCLOSURES

- Enclosure 1 Audit Details
- Enclosure 2 Personnel Contacted During Audit
- Enclosure 3 List of Objective Evidence Reviewed During the Audit
- Enclosure 4 Information Copy of Updated CAR No. YM-91-041
- Enclosure 5 Information Copy of CARs

ENCLOSURE 1
AUDIT DETAILS

AUDIT DETAILS

The following is a summary of programmatic activity covered during the audit. A list of objective evidence reviewed during this audit is shown in Enclosure 3. The full document identification number, revision status, and title for Quality Procedures (QPs) referenced below can be found in Enclosure 3.

1. 4.0 "Procurement Document Control"

Los Alamos uses two QPs to control this activity, QP-04.4, Revision 0, and QP-04.5, Revision 0. At the time of the audit Los Alamos had processed 35 Purchase Requisitions (PRs) since the last audit in March 1991: 35 Commercial Grade PRs and no Non-Commercial Grade PRs. A representative sample of 11 PRs were reviewed to determine compliance to selected portions of the applicable procedure. Of the 11 PRs selected, 9 PRs were processed for procurement of items and 2 were processed for procurement of services. (Refer to Enclosure 3 for list of PRs selected). The following activities/attributes were verified:

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

Appropriate receipt inspection had been performed and documented.

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

Personnel involved as PR requesters, PR reviewers, and receipt inspectors were properly trained to the requirements of QP-04.4, Revision 0, prior to performing the activity.

There were no instances identified of changes made as a result of bid evaluations. Receipt inspections were properly performed on incoming items and service deliverables as required. There was no evidence of incomplete or damaged items among the examined PRs.

Not all resident files could be examined during the audit because some of the files were located in sensitive areas of Los Alamos. Area EES-5 resident files contained one PR file that was not examined. Additionally, the resident file for Area LS-2 had been purged of the purchase requisition files as is allowed by Los Alamos QP-17.3, Revision 1, after submittal of the records to Central Records Facility (CRF). Resident files for areas EES-1 and EES-15 were examined and all appropriate documentation was on hand as required.

Training records for all individuals requesting PRs and providing receipt inspections and QA input were found to be properly trained to the latest revision of the procedure.

Overall the procurement program for commercial grade items and services is functioning properly within the QA program requirements. However, one deficiency was identified which indicates the possibility of misinterpretation of requirements concerning procurement of calibration services. (Refer to Enclosure 5, CAR No. YM-92-001, for details).

Except for the receipt inspection concerning PR No. 1281Q there was no implementation of non-commercial grade procurement, QP 4.5, Revision 0; therefore, implementation of non-commercial grade procurement activity is considered indeterminate.

2. 7.0 "Control of Purchased Items and Services"

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

3. 8.0 "Identification and Control of Items (Samples and Data)"

Compliance with the Los Alamos procedure for sample control, QP-08.1, Revision 1, was verified by checking various aspects of procedural implementation, i.e., sample collection records, application of bar codes, traceability and documentation of the samples processed derivatives, analytical history and chain of custody and storage conditions. In addition, verification was performed to ensure that personnel involved in the collection of samples were trained to appropriate Yucca Mountain Site Characterization Project Office (YMPO) Administrative Procedures--Quality (AP-Qs) as required by Los Alamos procedure QP-08.1, Revision 1.

A total of nine samples collected since March 1991 and corresponding documentation were audited. Except for one deficiency regarding implementation of the procedure when receiving samples from the Sample Management Facility (SMF), all samples examined were processed in accordance with procedural requirements. (Refer to Enclosure 5, CAR No. YM-92-002, for details).

A detailed description of the attributes checked are included the following QP-08.1, Revision 1, Paragraphs: 6.2.1, 6.2.3, 6.3, 6.4, 6.5

Compliance with the Los Alamos procedure for control of data, QP-08.2, Revision 0, was verified by checking various aspects of procedural implementation, (i.e., appropriate accomplishment of reviews and approvals and that required documentation for the submittal of data to the Reference Information Base (RIB) was properly completed).

A detailed description of the attributes checked are included the following QP-08.2, Revision 0, Paragraphs: 6.0 step 3, 6.0 Step 4, 6.0 Step 5, 6.0 Step 6, 6.0 Step 7, 6.0 Step 9, and 7.0.

4. 12.0 "Control of Measuring and Test Equipment (M&TE)"

Evaluation of Los Alamos control of M&TE was performed to verify compliance to Los Alamos procedure QP-12.1, Revision 4. A sample of 23 separate pieces of M&TE, as selected from the August 6, 1991 Los Alamos M&TE Inventory List, were visually examined and the calibration records for each piece was carefully reviewed. The M&TE was examined for appropriate identification and having a current calibration sticker applied and to ensure that proper maintenance and storage was accomplished. Documentation was reviewed to ensure that procedural prerequisites were completed relative to recording: location, M&TE description, capacity, tolerance, unique ID, calibration interval and that the calibration standards were traceable to the National Institute of Standards and Technology (NIST) or other nationally recognized standard or physical constant.

A detailed description of the attributes checked are included the following QP-12.1, Revision 4, Paragraphs: 4.6, 5.3, 6.1.1, 6.3, 6.4, 6.6, and 6.7.

Except for one discrepancy concerning the use of memos/draft procedures to calibrate equipment, Section 12.0, "Control of M&TE," is being satisfactorily implemented. (Refer to Enclosure 5, CAR No. YM-92-003, for details).

5. 13.0 "Handling, Storage and Shipping"

Due to lack of activity this element and the implementing procedure QP-13.1, Revision 2 were considered indeterminate. Los Alamos implementing procedures were reviewed to determine if they adequately addressed the requirements established in the Los Alamos QAPP, Revision 5. This review resulted in identification of inconsistencies similar to the ones already identified in CAR No. YM-91-041. (See Enclosure 4 for details).

6. Follow-up on Previous CARs

Part of the commitment to resolve CAR No. YM-91-041 was to correct QP-04.5, Revision 0, by adding a section on "Bid Evaluation." This procedural correction was made. (See Enclosure 4 for details).

ENCLOSURE 2
PERSONNEL CONTACTED DURING THE AUDIT

PERSONNEL CONTACTED DURING THE AUDIT

<u>Name</u>	<u>Organization/Title</u>	<u>Pre-Audit Conf.</u>	<u>Contacted During Audit</u>	<u>Post-Audit Conf.</u>
D. L. Bish	Los Alamos Princ. Investigator (PI)		X	
S. L. Bolivar	Los Alamos QA Proj. Leader (PL)	X	X	X
D. E. Broxton	Los Alamos Tech. Coord.		X	X
J. A. Canepa	Los Alamos PL, Site & Reg. Invest		X	X
P. L. Chavez	LATA Training Coord.	X	X	X
S. J. Chipera	Los Alamos Assoc. Invest.		X	
M. J. Clevenger	Los Alamos QAL	X	X	X
R. L. Cover	Los Alamos RFC INC-7		X	
J. L. Day	LATA QA Verif. Coord.	X		X
G. M. Gainer	LATA QA Engr.	X	X	
P. F. Gillespie	LATA QA Engr.	X		
M. E. Gutierrez	LATA Records Assistant		X	
R. J. Herbst	Los Alamos TPO	X	X	
L. E. Hersman	Los Alamos LS-2		X	
J. L. Kingsley	LATA Tech. Editor	X		
C. M. LaDelfe	Los Alamos QAL, EES-1	X	X	X
S. S. Levey	Los Alamos PI, EES-1	X	X	
L. L. Lopez	Los Alamos Tech Cord. EES-13	X	X	X
A. J. Mitchell	Los Alamos Research Tech.		X	X
S. Martinez	LATA Records Assistant	X		X
L. P. McDonald	Los Alamos Resch. Tech		X	
A. J. Mitchell	Los Alamos Resch. Tech		X	
T. L. Morgan	Los Alamos QAL, INC-7	X	X	X
W. A. Morris	Los Alamos Group Leader EES-1			X
B. D. Newman	Los Alamos Resch. Tech		X	
E. S. Patera	Los Alamos Tech. Coord.- INC	X		X
G. P. Rand	LATA QA Engr.	X		X
R. Raymond, Jr.	Los Alamos Assoc. Investigator		X	
B. Romero	LATA Document Control Coord.	X		X
L. A. Sanders	LATA Records Coord.	X	X	X
R. S. Shay	LATA QAS	X		
M. G. Snow	Los Alamos Resch. Tech.		X	
E. P. Springer	Los Alamos Tech Cord.			X
I. R. Triay	Los Alamos PI, Diffusion Testing		X	X
D. T. Vaniman	Los Alamos PI, EES-1	X		
K. A. West-	Los Alamos PL, Admin. & Control	X	X	X
D. L. Williams	Los Alamos QAL, EES-15	X	X	X
G. WoldeGabriel	Los Alamos EES-1		X	

ENCLOSURE 3
OBJECTIVE EVIDENCE

OBJECTIVE EVIDENCE REVIEWED DURING AUDIT
(Examples of)

Element 4 Procurement Document Control and
Element 7 Control of Purchased Items and Services
Plans

LANL-YMP-QAPP, R5 Los Alamos Quality Assurance Program Plan

Quality Procedures

LANL-YMP-QP-04.4, R0 Procedure for Commercial-Grade Items and Service

LANL-YMP-QP-04.5, R0* Procedure for Non Commercial-Grade Items and
Services

Purchase Requisitions (PRs)

<u>PR No.</u>	<u>Type</u>
V9767	Commercial-Grade Item
V9804	Commercial-Grade Item
N2988	Commercial-Grade Item
Q8521	Commercial-Grade Item
Q8530	Commercial-Grade Item
Q8663	Commercial-Grade Item
Q8489	Commercial-Grade Item
Q8520	Commercial-Grade Item
V7768	Commercial-Grade Item
M9658	Commercial-Grade Service
M9657	Commercial-Grade Service
1281Q	Non-Commercial-Grade Service

Training records for the following personnel:

B. Newman	D. Broxton
S. Chipera	L. McDonald
L. Hersman	M. Clevenger
C. LaDelf	G. WoldGabriel

Element 8.0 Identification and Control of Items (Samples and Data)

Plans

LANL-YMP-QAPP, R5 Los Alamos Quality Assurance Program Plan

Quality Procedures

TWS-QAS-QP-08.1, R1	Procedure for Identification and Control of Samples
TWS-QAS-QP-08.2, R0	Procedure for Control of Data
TWS-QAS-QP-03.5, R0	Procedure for Documenting Scientific CR No. 074 Investigation CR No. 131

Samples

SPC-5371
SPC-5370
SPC-5365
SPC-5364
SPC-5369
USW-G4-0016408
USW-G4-0016409
USW-G4-0016410
USW-G4-0016412

Data Travelers

Report on Manganese-oxide Minerals in Fractures of the Crater Flat Tuff in Drill Core USW-G4

Submission on Groundwater Chemistry

Element 12.0 "Control of Measuring and Test Equipment (M&TE)"

Plans

LANL-YMP-QAPP, R5	Los Alamos Quality Assurance Program Plan
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Quality Procedures

TWS-QAS-QP-12.1, R4 CR No. 140	Procedure for Control of Measuring and Test Equipment
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M&TE and associated documents

<u>Identifier</u>	<u>Description</u>
PN 458693	DuPont de Nemours-910 differential scanning calorimeter
PN 486983	Scanning Electron Microscope
PN 487156	Rigaku 3064 X-Ray spectrometer
PN 707058	Thermolyne furnace

PN 715661	Tracor Northern EDS (old SEM)
PN 840982	Automated digital electron microscope (ADEM)
LONG	Omega thermocouple probe "LONG"
PN 405676	Mettler balance, PM-4600
PN 649497	Ion chromatograph
PN 748585	Voltametric analyzer
20322906	NIST traceable weight set (1mg-100g)
4526	500g weight
4527	1000g weight
4528	2000g weight
BC 695205	Mettler top load balance
BC 636915	Fluorometer
BC 649092	Malvern Zetasizer 3
PN 318476	Ainsworth balance 50
PN 625021	Sartorius balance 1419
PN 645262	Ohaus balance
PN 757321	Mettler balance PK-4800
PN 757328	Sartorius balance 1712-MP-8
PN 076073	Ohaus balance B-5000

LANL M&TE Master Inventory List, 8/6/91

Element 13.0 Handling, Storage and Shipping

Plans

LANL-YMP-QAPP, R5	Los Alamos Quality Assurance Program Plan
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Quality Procedures

LANL-YMP-QP-06.3, R0	Preparation, Review and Approval of Detailed Technical Procedures
TWS-QAS-QP-13.1, R2*	Procedure for Handling, Storage, and Shipping Equipment

Detailed Procedures

TWS-INC-DP-05, R2	Sorption, Desorption Ratio Determination of Geologic Materials by a Batch Method
TWS-INC-DP-26, R1 CR No. 110	Preparation of Aqueous Solutions for Analysis, Use in Experiments, or as Standards for Water Sample Analysis
TWS-INC-DP-27, R1 CR No. 111	Elemental Concentration Determination by Direct-Current-Plasma Atomic-Emission-Spectroscopy

TWS-INC-DP-35, R1	pH Measurement
TWS-INC-DP-60, R2	Preparation of NTS Samples for LANL YMP Solid Core Experiments
TWS-INC-DP-66, R0	Saturated Diffusion Cell Experiment
TWS-INC-DP-74, R0 CR No. 112	Flexible Cell Hydrothermal Experiments
TWS-INC-DP-79, R0	Liquid Scintillation Counting of Samples
TWS-INC-DP-83, R1	Storage and Handling of Solid Samples
TWS-LS2-DP-401, R0 CR No. 100	Maintenance of Culture Collection
TWS-ESS-DP-52, R3	Sample Preparation for X-Ray Fluorescence Analysis: Fusing and Lapping
LANL-EES-DP-110, R2	Zeolite Purification/Separation Procedure
TWS-HSE12-DP-316, R1	Preparation of Standard and Reagent Solutions
TWS-HSE12-DP-318, R1	pH Measurement, Acid-Base Solution Standardization, and Total Alkalinity Determination

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

ENCLOSURE 4
INFORMATION COPY OF UPDATED CAR NO. YM-91-041

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

1 Controlling Document LANL-YMF-QAPP, Rev. 5		2 Related Report No. Audit No. 91-03	
3 Responsible Organization Los Alamos National Laboratory		4 Discussed With R. Herbst, S. Bolivar	
10 Response Due 30 Days From Issue	11 Responsibility for Corrective Action R. Herbst		12 Stop Work Order Y or N No
5 Requirement: <p>LANL-YMF-QAPP, Rev. 5, Sect. 1.2 states in part:</p> <p>"... Implementation of the requirements of the QAPP shall be accomplished through quality implementing procedures (QPs)..."</p> <p>LANL-YMF-QP-6.2, Rev. 0 "Preparation , Review and Approval of Quality Administrative Procedures, Para. 4.4 states:</p> <p>"QPs are documents that describe the methods used to conduct LANL YMF activities that affect quality. QPs implement the QA program requirements of the LANL QAPP."</p>			
6 Adverse Condition: <p>QAPP requirements are not being consistently reflected in QPs.</p> <p>DISCUSSION: The following representative examples illustrate the adverse condition.</p> <p>1. LANL-YMF-QAPP, Rev. 5, Section 15.5.3 states in part, "Persons responsible for dispositioning the NCR shall ensure that the following requirements are met....The disposition shall document action needed to preclude recurrence of the nonconforming condition."</p> <p>Los Alamos QP TWS-QAS-QP-15.2, Rev. 1, "Deficiency Reporting" only requires documentation of actions to preclude recurrence of significant conditions adverse to quality (i.e., the QP does not require documentation of action needed to preclude recurrence of all nonconforming conditions).</p>			
7 Recommended Action(s): <p>1. Take necessary action to resolve the representative examples identified in the CAR.</p> <p>2. Investigate to determine the extent of inconsistencies and resolve all inconsistencies found.</p> <p>3. Evaluate results of investigation to determine if preventative action is necessary.</p>			
8 Initiator J. S. Martin and Date: 04/01/91		9 Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	
13 Approved By: OQA James B. Taylor for		Date: 4/13/91	
15 Verification of Corrective Action:			
16 Corrective Action Completed and Accepted: QAR _____ Date _____		17 Closure Approved By: OQA _____	

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

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

**CORRECTIVE ACTION REQUEST
(continuation sheet)**

6 Adverse Condition (continued)

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

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

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

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

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

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

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

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

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

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

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

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

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WASHINGTON, D.C.

CAR NO. _____
DATE: _____
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CORRECTIVE ACTION REQUEST
(continuation sheet)

CAR YM-91-041

A. EXTENT - NA

B. ROOT CAUSE

We will matrix existing Quality Procedures (QPs) with the revised Quality Assurance Program Plan (QAPP) to bound the problem identified in CAR-041. We will then make a root cause determination. This will be completed 30 days after YMQAD acceptance of the revised QAPP.

C. REMEDIAL ACTION

The QAPP will be revised for compliance with the latest revision of the Quality Assurance Requirements Document (QARD) and paragraphs, or sections, needing revision will be identified. This effort will take 3 months; estimated date of completion will be July 30, 1991.

The QAPP will be revised and submitted to YMQAD for approval by September 30, 1991.

Existing QPs will be matrixed against the new QAPP. Any QPs that need to be revised to meet QAPP requirements will be identified and scheduled for revision. This task will be completed by October 15, 1991.

An evaluation will be made on a case by case basis regarding the need to stop work until affected QPs are revised.

Training to the new QAPP will commence after YMQAD acceptance. Training to revised QPs will be on a case by case basis, as needed.

The responsible individual for rewriting and obtaining approval for the new QAPP will be S. Bolivar, the QAPL. The individual responsible for training to the new QAPP will be Karen West (acting Training Coordinator).

The specific problems identified in the five representative examples (listed in the CAR) will be resolved by the above actions. Specifically:

1. Example 1 in CAR-041 is a QAPP over commitment. The QP 15.2 (Deficiency Reporting) meets QARD/NQA-1 requirements and the QAPP went beyond these requirements. The QAPP will be revised as per the time schedule described above.

After the QAPP revision is accepted by the YMQAD, it will be matrixed against QP 15.2. A revision to QP 15.2, if necessary, will be completed after the QAPP has been accepted by YMQAD.

File dtd 5/5/91 - TWS - EES - 13 - 05 - 91 - 029

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(continuation sheet)

2. QP 4.5 will be revised to create a section titled Bid Evaluations. The evaluation of bid evaluations will include technical considerations, QA requirements, personnel, production capabilities, past performance, alternatives and exceptions. A QP Action Request to withdraw QP 4.5 will be submitted by May 15. The QP will be revised by July 30, 1991.

Since there have been no procurements requiring bid evaluations, there has been no impact on the quality program.

3. To resolve example 3, the QAPP will be revised. In section 7.1.6 of the QAPP, 'documents' will be changed to 'quality-affecting documents'. The revised QAPP will be submitted to the YMQAD by September 30, 1991.

QP 4.5 will be revised to address this section of the QAPP. A QP Action Request to withdraw QP 4.5 will be submitted by May 15. The QP will be revised by July 30, 1991.

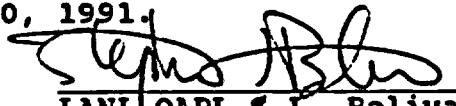
4. The QAPP requires a QP be written to handle the use of data not generated under QA controls. Since no LANL personnel have attempted to qualify this type of data, the lack of a procedure has had no impact on the LANL QA program. The QAPP will be revised to identify that LANL personnel will follow the appropriate AP or APQ. The revised QAPP will be submitted to the YMQAD by September 30, 1991.

5. Example 5 states that no QP exists that addresses control of activities performed by personnel who are not assigned to the YMP. QP 2.5 (Selection of Personnel) will be revised by July 30, 1991 to address this issue. Until this procedure is rewritten, personnel not assigned to the YMP will not be allowed to conduct quality-affecting work on YMP.

D. CORRECTIVE ACTION TO PREVENT RECURRENCE

The requirement to matrix is in the QARD, R4, paragraph 2.7. This will be addressed in the revised QAPP, which will be submitted to the YMQAD by September 30, 1991.

CAR 041 Response Approved


LANL QAPL S.L. Bolivar

5/6/91
Date

CAR 041 Response Approved


LANL TPO R.J. Herbst

5/7/91
Date

CAR 041 Response Approved


YMQAD

5-17-91
Date

Response Approved


YMQAD

5-17-91
Date

REV. 10/90

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DATE: _____
SHEET: _____ OF _____

CORRECTIVE ACTION REQUEST
(continuation sheet)

AMENDED RESPONSE NO. 1
CAR NO. YM-91-041
Page 1 of 2

A. EXTENT - NA

B. ROOT CAUSE

Existing LANL YMP Quality Administrative Procedures (QPs) will be matrixed with the new quality assurance requirements document using the matrix provided by the Project Office, to bound the adverse condition identified in Section 6 of this CAR. A root cause determination will then be made. This will be completed within 180 days of receipt of the new quality assurance requirements document requirements matrix from the Project Office.

C. REMEDIAL ACTION

Implementation of the remedial actions will be the responsibility of the LANL YMP Quality Assurance Project Leader.

- > Upon receipt of YMQAD approval of this revised response, the LANL YMP Quality Assurance Program Plan (QAPP) will be deleted.

Existing QPs will be matrixed with the new quality assurance document. Any LANL YMP exceptions to the requirements matrix will be noted thereon. Any QPs that need to be revised to implement the new quality assurance requirements document will be identified and revised as necessary. This task will be completed within six months of receipt of the new quality assurance requirements document from the Project Office except as noted in the representative examples below. Any LANL YMP QPs that are issued prior to the receipt of the new quality assurance requirements document will be matrixed to the existing QARD, Revision, 4.

An evaluation will be made on a case by case basis regarding the need to stop work until affected QPs are revised.

Training to revised QPs will be on a case by case basis, as needed.

The five representative examples listed in Section 6 of this CAR will be resolved by the above actions. Specifically:

1. This is a QAPP over commitment to QARD requirements. To ensure that QP TWS-QAS-QP-15.2, Revision 1, "Deficiency Reporting" meets QARD/NQA-1 requirements it will be matrixed with the new quality assurance document, and revised as necessary.

Str dtd 8/20/91 - TWS-EES-13-08-91-016

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DATE: _____
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CORRECTIVE ACTION REQUEST
(continuation sheet)

AMENDED RESPONSE NO. 1

CAR NO. YM-91-041

Page 2 of 2

2. LANL-YMP-QP-04.5, Revision 0, "Procurement of Non-commercial Grade Items and Services" will be revised to create a section titled Bid Evaluations. The evaluation of bid evaluations will include technical considerations, QA requirements, personnel, production capabilities, past performance, alternatives, and exceptions. A QP Action Request to withdraw this QP was submitted on May 15, 1991. A draft of this procedure was completed on July 30, 1991 and it will be issued as soon as possible, but no later than October 30, 1991.
3. LANL-YMP-QP-04.5, Revision 0, "Procurement of Non-commercial Grade Items and Services" will be matrixed with the new quality assurance requirements document and revised as necessary.
4. Since no LANL YMP personnel have attempted to qualify data not generated under QA controls, the lack of a QP has had no impact on the LANL YMP QA program. LANL YMP personnel will follow the appropriate AP or APQ for use of data not generated under QA controls. This will be identified in the new quality assurance requirements document requirements matrix.
5. TWS-QAS-QP-02.5, Revision 0, "Selection of Personnel" has been revised to address this issue. A draft of this procedure was completed on July 30, 1991 and it will be issued as soon as possible, but no later than October 30, 1991. Until this revised procedure is issued, personnel not assigned to the LANL YMP will not be allowed to conduct quality-affecting work on the LANL YMP.

D. CORRECTIVE ACTION TO PREVENT RECURRENCE

The implementation of the corrective action to prevent recurrence will be the responsibility of the LANL YMP Quality Assurance Project Leader.

The existing QPs will be matrixed with the new quality assurance requirements document and revised as necessary. The root cause(s), if any, of the adverse condition will be determined and corrected.

Response Approved

Stephen L. Bolivar
LANL OAPL S. L. Bolivar

8/21/91
Date

Response Approved

R. J. Herbst
LANL TPO R. J. Herbst

9/21/91
Date

Response Approved

John M. Smith
QA

9-5-91
Date

Response Approved

Catharine L. Hanger
YMOAD

9-5-91
Date

see attachment to
amended
Response by YMOAD
exception no response

9-5-91

CAR YM-91-041

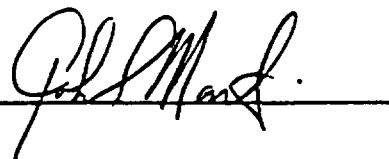
YMQAD

ATTACHMENT TO AMENDED RESPONSE DATED AUG. 20, 1991, (TWS-EES-13-08-91-016)

An evaluation of LANL amended response was performed by YMQAD on August 30, 1991. This evaluation found the amended response to be acceptable with the exception of "REMEDIAL ACTION" second sentence which reads as follows: " Upon receipt of YMQAD approval of this revised response, LANL YMP Quality Assurance Program Plan (QAPP) will be deleted.". Deletion of the LANL QAPP is unacceptable at this time. As such, LANL Quality Assurance has been notified that the rest of the response is acceptable, however; approval is not granted to delete the LANL QAPP. A new amended response is not required of at this time. In addition, in review of the LANL amended response it was noted that an extension has been requested to previously committed corrective action that was to be completed by July 30, 1991, for procedure revisions. LANL YMP Quality Assurance has been notified via telecommunication that no further extensions will be granted.

In follow-up to the amended response YMQAD requested and received from LANL draft procedures for TWS-QAS-QP-02.5 and LANL-YMP-QP-04.5 and the STOP WORK order issued by LANL against procurement.

QAR

A handwritten signature in black ink, appearing to read "John S. Mandel", is written over a horizontal line.

MEMORANDUM TO FILE

TO: CAR YM-91-041 File

10/11/91
Page 1 of 3

FROM: R. E. Powe

ATI for Audits YMF-91-03 and YMF-92-01

SUBJECT: Follow-up Status

BACKGROUND

This memorandum is being issued to the subject file to assure the results of Audit YMF 92-01 are reflected in CAR YM-91-041. A copy of this memorandum is being enclosed in Audit Report YMF 92-01.

BRIEF CHRONOLOGY OF CAR YM-91-041

4/9/91 CAR issued to document an adverse quality condition identified during Audit YMF-91-03.

The CAR indicated that the Los Alamos QAPP requirements were not being consistently reflected in QPs and cited 5 examples.

5/8/91 Response received.

5/17/91 Response accepted.

8/20/91 Amended response received.

9/5/91 Amended response accepted. Expected completion date: 6 months after issuance of the revision of the Quality Assurance Requirements Document that consolidates the OCRWM QARD, QAPD, and ASME NQA-1.

RESULTS OF AUDIT YMF-92-01

During Audit YMF-92-01, which was conducted at the Los Alamos National Laboratory October 1 through October 4, 1991, a number of additional examples of the same adverse quality condition were found. These additional examples are:

(NOTE: The following examples start numbering at 6 to preclude confusion with the 5 examples already cited in the CAR).

6. Example 3. in CAR YM-91-041 indicated that the LANL QAPP required that vendor documents be controlled according to LANL QPs for document control and that LANL QP 4.5 did not reflect this method of control.

During this audit (YMF-92-01) it was determined that vendor manuals were being used to calibrate M&TE and the method of control of those vendor manuals was not in accordance with LANL QPs for document control. In one instance (refer to the vendor manual for the Automated Digital Electron Microscope, PN 840982) two different revisions of the same vendor manual was found to be in use. (Note: The method of calibration reflected in both revisions of the manual was the same, i.e. the method of calibration had not changed)

7. LANL-YMP-QAPP, Rev. 5, Section 13.0 HANDLING, SHIPPING, AND STORAGE, paragraph 13.1 "General" states in part "Work and inspection instructions, drawings, specifications, shipment instructions, or other procedures, shall be established as necessary to control the packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss, or deterioration."

TWS-QAS-QP-13.1, Rev. 2, PROCEDURE FOR HANDLING, STORING, AND SHIPPING EQUIPMENT does not address packaging, cleaning or preservation.

The terms "packaging" and "preserve" are used in paragraph 6.3 "Marking and Labeling" and the term "packing" is used in paragraph 6.4 "Procuring Services or Equipment", however overall the QP does not reflect how to package, clean, and preserve materials and equipment.

A review of 14 Detailed Technical Procedures (DPs) during the audit revealed that, although the QP for developing DPs, LANL-YMP-QP-06.3, Revision C, does not address cleaning, Los Alamos is addressing cleaning as necessary within DPs.

8. LANL-YMP-QAPP, Revision 5, Section 13.0 HANDLING, SHIPPING, AND STORAGE, paragraph 13.3 "Specific Procedures" states "When required for critical, sensitive, perishable, or exceptionally expensive articles, DPs shall be written for handling, storage, packaging, shipping, and preservation. DPs shall be subject to LANL QAPL approval."

TWS-QAS-QP-13.1, Rev. 2, PROCEDURE FOR HANDLING, STORING, AND SHIPPING EQUIPMENT, paragraph 6.1 "Special Equipment and Protective Environments" states in part "To maintain accuracy, measuring and test equipment is handled and stored using good scientific and engineering judgment, following manufacturer's recommendations of following a specific procedure if the PI so directs. Any special requirements not covered in a specific procedure are documented by the PI or experimenter in the laboratory notebook, in a DP, or in a memo to the group Resident File and are explained by the PI to the users."

In other words the QAPP requires the use of QAPL approved DPs while the QP allows the use of a laboratory notebook, DP, or memo with no QAPL approval required.

Also the QP does not define critical, sensitive, perishable or exceptionally expensive articles.

9. LANL-YMP-QAPP, Revision 5, Section 13.0 HANDLING, SHIPPING, AND STORAGE, paragraph 13.6 "Marking and Labeling" states "Marking and labeling instructions for packaging, shipment, handling, and storage of items shall be specified in LANL DPs to adequately identify, maintain, and preserve the item. Marking requirements for special environments or special controls shall also be specified in LANL DPs."

TWS-QAS-QP-13.1, Rev. 2, PROCEDURE FOR HANDLING, STORING, AND SHIPPING EQUIPMENT, paragraph 6.3 "Marking and Labeling" states "Marking and labeling instructions for packaging, shipment, handling, and storage of items are specified in LANL DPs or in memos to the group Resident File prepared by the PI and containing specific instructions to adequately identify, maintain, and preserve the item. Marking requirements for special environments or special controls are also specified in LANL DPs or memos containing specific instructions. The PI explains any such instructions to users and other appropriate personnel."

Again, the QP allows the use of a memo and the QAPP makes no provision for the use of memos in lieu of DPs.

When follow-up is performed verify that the above examples have been resolved.

FOLLOW-UP VERIFICATION

Part of the commitment to resolve CAR YM-91-041 included correcting Example 2 by revising LANL QP-04.5 to add a section on Bid Evaluation. During Audit YMP-92-01 it was verified that Procedure LANL-YMP-QP-04.5, Revision 1 became effective 9//30/91 and included the required section on Bid Evaluation.

ENCLOSURE 5
INFORMATION COPY OF CARS

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14CAR NO.: YM-92-001
DATE: 10/09/91
SHEET 1 OF 1
QA
WBS No.: 1.2.9.2

CORRECTIVE ACTION REQUEST

1 Controlling Document LANL-YMF-QP-04.4, Rev. C, & LANL-YMF-QP-04.5, Rev. C		2 Related Report No. Audit: YMF-92-C1	
3 Responsible Organization Los Alamos Nat'l. Lab.		4 Discussed With M. Cleavenger & S. Bolivar	
10 Response Due 20 days from issue	11 Responsibility for Corrective Action R. Herbst	12 Stop Work Order: Y or N Nc	
5 Requirement: 1. LANL-YMF-QP-04.4, Rev. C, Para. 2.C, states in part, "...However, maintenance/repair services that involve calibration as part of that service will be procured pursuant to LANL-YMF-QP-04.5." 2. LANL-YMF-QP-04.5, Rev. C, Para. 4.2, Definitions states, "A noncommercial grade service is the performance of activities that include, but are not limited to site characterization, design, fabrication, investigation, inspection, nondestructive examination, calibration, or installation and for which controls for acceptance are set prior to procurement." 3. LANL-YMF-QP-04.5, Rev. C, Para. 6.2.1 states in part, "...The requester, QAL, or QAS evaluates a supplier for qualification..."			
6 Adverse Condition: Contrary to the above, Los Alamos has purchased calibration services as commercial grade services and has not qualified the vendor. DISCUSSION 1. Purchase Requisition (PR) No. Q8608 concerning the procurement of calibration services from Simco was processed according to LANL-YMF-QP-04.4, Rev. C instead of LANL-YMF-QP-04.5, Rev. C as required. 2. The Simco calibration services were identified as a commercial-grade service instead of a noncommercial-grade service. 3. Simco has not been qualified as a provider of calibration services. 4. ASME NQA-1-1989 does not define commercial-grade services, (see attached ASME NQA-1 Interpretation QA89-003).			
7 Recommended Action(s): 1. Correct deficiency identified by obtaining calibration from a qualified source. 2. Investigate to determine if similar procurements have been made. 3. Take action to prevent recurrence.			
8 Initiator K.T. McFall <i>Kenneth McFall</i>	Date: 10/4/91	9 Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	13 Approved By: OQA <i>R.C. Sprince</i> Date: <i>10/5/91</i>
15 Verification of Corrective Action:			
16 Corrective Action Completed and Accepted:		17 Closure Approved By:	
OAR _____ Date _____		OQA _____	

File: QA89-003

Subject: ANSI/ASME NQA-1-1986 Edition, and later Addenda through 1c-1988, S-1; 4S-1, Para. 2; 7S-1, Paras. 3.1 and 10; Commercial Grade Services — Subtier Suppliers

Date Issued: November 21, 1989

Question (1): Does ANSI/ASME NQA-1, 7S-1 require that suppliers of commercial grade calibration services for safety-related measuring and testing equipment be evaluated in accordance with para. 3.1?

Reply (1): ANSI/ASME NQA-1 defines commercial grade items in Supplement S-1 and addresses purchasing commercial grade items in Supplement 7S-1, para. 10 but commercial grade services are not defined.

However, ANSI/ASME NQA-1 does include requirements for the control of purchased services as defined by ANSI/ASME NQA-1, Supplement S-1, including supplier selection, bid evaluation, supplier performance evaluation, acceptance of services, and verification of conformance. See Supplement 7S-1 for specific requirements.

Question (2): Do the requirements of ANSI/ASME NQA-1, 7S-1, para. 3.1 for evaluation of suppliers of services apply through succeeding levels of subtier suppliers?

Reply (2): Yes, procurement documents issued at all tiers of procurement shall include provisions deemed necessary by the purchaser at each tier. See ANSI/ASME NQA-1, 4S-1, para. 2.

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14CAR NO.: YM-92-002
DATE: 10/09/92
SHEET 1 OF 2
QA
WBS No.: 1.2.5.3

CORRECTIVE ACTION REQUEST

1 Controlling Document
TWS-QAS-QP-08.1, Rev. 1

2 Related Report No.
Audit: YM-92-01

3 Responsible Organization
Los Alamos Nat'l. Lab.

4 Discussed With
S. Bolivar

10 Response Due
20 days from issue

11 Responsibility for Corrective Action
R. Berbst

12 Stop Work Order Y or N
No

5 Requirement:

TWS-QAS-QP-08.1, Rev. 1, Para. 6.4, states in part, "...If samples are shipped by the SMF, the PI determines that the manner utilized will not degrade the samples and will record such in a notebook."

6 Adverse Condition:

No objective evidence could be produced to demonstrate implementation of the requirement to document that the manner utilized to ship samples from the SMF will not degrade the samples.

DISCUSSION

Examples of samples received from the SMF for which this requirement has not been documented are core samples Nos. 0016408, 0016409, 0016410, and 0016412.

7 Recommended Action(s):

1. Take action to correct the deficiencies identified.
2. Investigate to determine if there are other similar deficiencies.
3. Take action to preclude recurrence.

8 Initiator *RP*
J.S. Martin

Date:
10/4/91

9 Severity Level -
1 ☐ 2 ☒ 3 ☐

13 Approved By:

Date:

OQA *R.C. Holmes* 10/15/91

15 Verification of Corrective Action:

16 Corrective Action Completed and Accepted:

OAR _____ Date _____

17 Closure Approved By:

OQA _____

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14 CAR NO.: YM-92-003
DATE: 10/09/91
SHEET: 1 OF 1
QA
WBS No.: 2.2.9.2

CORRECTIVE ACTION REQUEST

1 Controlling Document TWS-QAS-QP-12.1, Rev. 4		2 Related Report No. Audit: YMP-92-01	
3 Responsible Organization Los Alamos Nat'l. Lab.		4 Discussed With S. Bolivar	
10 Response Due 20 days from issue	11 Responsibility for Corrective Action R. Berbst	12 Stop Work Order Y or N No	
5 Requirement: TWS-QS-QP-12.1, Rev. 4, Para. 6.3, states in part, "...Instruments are calibrated by LANL's Standards and Calibration Group, by a service organization or by the operator. Individuals who perform calibrations...use written procedures."			
6 Adverse Condition: Contrary to the above, the Laboratory has performed calibrations to memos/draft procedures. DISCUSSION Examples include use of Memo No. TWS-EES-13-11-90-002 to perform calibrations for standards nos. 4526, 4527, and 4528. In addition, the automated digital electron microscope (ADEM) No. PN 840982 was calibrated utilizing a draft procedure. (Reference draft: TWS-EES-DP-129).			
7 Recommended Action(s): 1. Correct the deficiencies identified. 2. Investigate to determine if there are other similar deficiencies. 3. Take action to preclude recurrence.			
8 Initiator <u>J.S. Martin</u> <u>J.S. Martin</u>	Date: <u>10/4/91</u>	9 Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	13 Approved By: <u>[Signature]</u> OQA <u>[Signature]</u> Date: <u>10/15/91</u>
15 Verification of Corrective Action:			
16 Corrective Action Completed and Accepted: OAR _____ Date _____		17 Closure Approved By: OQA _____	