



Department of Energy
Washington, DC 20585

QA: L

FEB 11 1997

L. D. Foust, Technical Project Officer
for Yucca Mountain Site
Characterization Project
TRW Environmental Safety Systems, Inc.
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Las Vegas, NV 89134

EVALUATION OF AMENDED RESPONSE TO DEFICIENCY REPORT (DR) YM-96-D-073
RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) AUDIT YM-ARC-96-16
OF LOS ALAMOS NATIONAL LABORATORY (LANL)

The OQA staff has evaluated the amended response to DR YM-96-D-073. The amended response has been determined to be satisfactory based on the following:

In a telecon on January 27, 1997, between LANL Quality Assurance (QA) representatives and a representative of OQA, LANL QA representatives agreed on a date of July 31, 1997 for a completion of corrective action. This timeframe will hopefully allow for the proposed Quality Assurance Requirements and Description (QARD) document change to be incorporated in the QARD and issued. In addition, this will allow sufficient time for LANL to revise the affected LANL internal procedures which would be impacted by the QARD change.

Verification of completion of the corrective action will be performed after this date. If you have any questions, please contact either James Blaylock at (702) 794-1420 or Richard L. Maudlin at (702) 794-1302.

R.W. Clark
for Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-0858

Enclosure:
DR YM-96-D-073

cc w/encl:
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RADIOACTIVE WASTE MANAGEMENT
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: QARD, Rev. 5 / LANL-YMP-QP-04.6, Rev. 3 / LANL-YMP-QP-12.3, Rev. 2
 2 Related Report No. YM-ARC-96-16

3 Responsible Organization: Los Alamos National Laboratory
 4 Discussed With: P. Gillespie

5 Requirement/Measurement Criteria:

A. QARD, Section 4.0, Subsection 4.2.1, states in part: "Procurement documents issued by each affected organization shall include the following provisions...Quality Assurance program requirements including: 1. A requirement for the supplier to have a documented QA Program that implements applicable QARD requirements prior to the initiation of work."

B. LANL-YMP-QP-04.6, Revision 3, Paragraph 6.5.2, Subparagraph 6.5.2.2, states: "The technical reviewer evaluates the analytical service requirements to determine if the technical requirements have been adequately addressed as required by Attachment 2, if the technical requirements are adequate, signs and dates the analytical service requirements."

6 Description of Condition:
 Contrary to the above:

A. LANL-YMP-QP-04.6, Revision 4, does not require procurement documents to include requirements that the supplier have a documented Quality Assurance (QA) program that implements applicable QARD requirements prior to the initiation of work for analytical services and Purchase Requisitions (PR) # 289BA and 021BA (Purchase Orders # 021BA0015-8V and 289BASML6-8V) for accelerator mass spectrometry (AMS) services and sample preparation do not reference QA requirements.

NOTE: Prime Laboratory (Purdue University) is performing Chlorine-36 Sample Preparation and AMS Analytical Services without having an approved documented QA program.

B. There is no objective evidence that the technical reviewer signed and dated the analytical service requirements for PRs 021BA and 289BA.

7 Initiator *R. Maudlin*
 Richard L. Maudlin Date 7/19/96
 9 Is condition an isolated occurrence?
 Yes No Unknown; Must be Yes if PR

10 Recommended Actions: (Not required for PR)

A. Take immediate action to address and require any analytical labs performing work for LANL to implement a quality program which meets the applicable portions of the QARD.

B. Evaluate present and previous work performed by all analytical labs in the absence of an approved QA program and determine the impact on previous work.

C. Revise LANL-YMP-QP-04.6, to require a documented QA program to be implemented by all suppliers of quality affecting items and services.

D. Investigate and document the results of all augmented staff procuring items or services which impact OCRWM quality affecting activities.

11 QA Review QAR *R. Maudlin* Date 7/19/96
 12 Response Due Date 20 working days from issuance

13 Affected Organization QA Manager Issuance Approval: (QAR for PR)
 Printed Name P. GILLESPIE Signature *P. Gillespie* Date 7-24-96

22 Corrective Actions Verified QAR Date
 23 Closure Approved by: (N/A for PR) AOQAM Date

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

- a. Los Alamos National Laboratory (LANL) Yucca Mountain Project (YMP) has initiated an investigation to determine if there is any impact on the work and the extent of the condition.
- b. Purchase requisitions #021BA ^{and 289BA JRF 2/1/96} were technically reviewed but not documented. A memorandum will be generated to document the review (isolated occurrence).
- c. LANL YMP will determine how services are provided and requirements passed on to the Primary Standards Laboratory (PSL), and document these activities.

15 Extent of Condition: (Not required for PR)

- a. All LANL YMP analytical services are potentially affected.
- b. Isolated occurrence.
- c. Isolated occurrence.

16 Root Cause Determination: (Not required for PR)

Required Yes No

At this point there is no other cause for this condition other than a difference of opinion on how the QARD requirements are to be implemented. Additional determination will be made with Yucca Mountain Quality Assurance Division (YMQAD) assistance.

17 Action to Preclude Recurrence: (Not required for PR)

Required Yes No

In conjunction with YMQAD, actions to prevent recurrence will be determined and this section supplemented by December 31, 1996.

18 Corrective Action Completion Due Date:

19 Response by: *Michael J. Cavanaugh*

- Initial
- Amended

Date *8/9/96*

Phone *665-1454*

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

AOQAM

Date

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Block 5, Requirements, cont'd:

- C. LANL-YMP-QP-12.3, Subparagraph 6.31, states: "If the calibration is to be performed by an agency outside Los Alamos, initiates a Purchase Request in accordance with QP-04.6."

Block 6, Description of Condition, cont'd:

- C. The Sandia National Laboratories' (SNL) "Primary Standards Laboratory," is being used by LANL augmented staff to perform calibrations of primary standards. However, there is no objective evidence that a PR has been generated to procure these services and no documented evidence that the appropriate QA program requirements have been passed onto SNL Primary Standards Laboratory.

Block 14, Recommended Actions, cont'd:

- E. Require augmented staff to implement LANL procurement requirements for the purchase of items or services.
F. Evaluate the impact on augmented staff procurements in the absence of an approved QA program on suppliers of items and services.
G. Determine the cause of the conditions documented in Block 6 and provide the measures which will be instituted to prevent recurrence.

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#14 continued

The requirement stated in block 5 does not accurately address the Quality Assurance Requirement Document (QARD) requirement. Section 4.0, subsection 4.2.1 of the QARD, specifically states:

"Procurement documents issued by each affected organization shall include the following provisions as appropriate to the item or service being procured."

- Los Alamos does not consider all of the requirements of subsection 4.2.1 to be appropriate to the procurement of analytical services. Los Alamos National Laboratory (LANL) Yucca Mountain Project (YMP) provided alternate requirements in the implementing procedure, and included these requirements in the cited procurement documents (see attachments Purchase Requests #289BA and #021BA).

Although we are in agreement that the statement in block 6, the results of our investigation indicates that we are in compliance with both the QARD and LANL-YMP-QP-04.6, Revision 4 "Procurement."

- QP-04.6, Revision 4 does require procurement documents to include requirements that the supplier have a documented Quality Assurance (QA) program that implements the applicable QARD requirements prior to the initiation of work for analytical services.
- Los Alamos YMP did follow the provisions of the QARD subsection 4.2.1 during the preparation of QP-04.6, and based on the technical evaluation determined that it was not appropriate to require a documented QA program be required for analytical services.
- LANL YMP acceptance of analyses through the use of blind, duplicate, and blank samples assures that technical and QA requirements are met. This is in accordance with QP-04.6, Revision 4. These analyses are therefore accepted under LANL's YMP approved QA program.
- QP-04.6, Revision 4 was reviewed by the Office of Quality Assurance (OQA) and determined to meet the requirements of the QARD.

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

15 Extent of Condition: (Not required for PR)

16 Root Cause Determination: (Not required for PR) Required Yes No

17 Action to Preclude Recurrence: (Not required for PR) Required Yes No
See December 16, 1996 amended response.

18 Corrective Action Completion Due Date: 19 Response by: See December 16, 1996 amended response.

Initial
 Amended Date Phone

20 Response Accepted QAR *[Signature]* Date 01/29/97
21 Response Accepted (N/A for PR) AOQAM *R.W. [Signature]* Date 2/10/97

Revised Response to Deficiency Report YM-96-073

As directed in R.E. Spence's memo of September 27, 1996, we are forwarding a revised response for Block 17 of the subject DR.

As a result of discussions between LANL YMP, the M&O, and YMQAD, a Document Action Request (DAR) No. 1976, 12/3/96, has been issued to request that the QARD be revised to include an alternative for requiring a documented QA program for suppliers of analytical services. The alternative would include the use of QC Sample Plans to verify acceptability of analytical services. The DAR has requested a need date of 4/1/97.

Since closure of this DR hinges on the approval of the DAR and the subsequent QARD revision, LANL requests an extension for corrective action completion until the QARD is revised and LANL-YMP-QP-04.6, "Procurement", has been revised to address the new requirements. The actual date cannot be determined at this time.

In addition to the above, two items were found in the initial response which need to be corrected. They are as follows:

- Page 4 of 4, third para., 1st bullet, should read in part, "QP-04.6, Revision 4 does not require....."
- Page 4 of 4, third para., last bullet, DELETE.