



Department of Energy
Office of Civilian Radioactive Waste Management
Yucca Mountain Site Characterization Office
P.O. Box 98608
Las Vegas, NV 89193-8608

JUL 25 1996

L. Dale Foust
Technical Project Officer
For Yucca Mountain
Site Characterization Project
TRW Environmental Safety Systems, Inc.
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101 Convention Center Drive
Las Vegas, NV 89109

ISSUANCE OF DEFICIENCY REPORT (DR) YM-96-D-073 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION'S (YMQAD) AUDIT YM-ARC-96-16 OF LOS ALAMOS NATIONAL LABORATORY (SCPB: N/A)

Enclosed is DR YM-96-D-073 generated as a result of YMQAD Audit YM-ARC-96-16.

Please identify the corrective action to be taken and implemented to correct the deficiency. A DR Continuation Page has been provided. Send the original of your response to Deborah Sult, YMQAD/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608. Response to the DR is due 20 working days from issuance. Any extension to the due date must be requested in writing, with appropriate justification, prior to that date.

If you have any questions, please contact either Robert B. Constable at (702) 794-5580 or Richard L. Maudlin at (702) 794-1302.

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2269

Enclosures:

1. DR YM-96-D-073
2. PR/DR Continuation Page

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L. Dale Foust

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cc w/encls:

T. A. Wood, DOE/HQ (RW-14) FORS
J. G. Spraul, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
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R. L. Strickler, M&O, Vienna, VA
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R. P. Ruth, M&O, Las Vegas, NV
Records Processing Center

cc w/o encls:

W. L. Belke, NRC, Las Vegas, NV
R. L. Maudlin, YMQAD/QATSS, Las Vegas, NV
D. G. Sult, YMQAD/QATSS, Las Vegas, NV
D. G. Horton, OQA, NV

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

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 Deficiency Report
 NO. YM-96-D-073
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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 *RES PENCE* Signature *R. Pence* 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:

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

18 Corrective Action Completion Due Date:

19 Response by:

Initial

Amended

Date

Phone

20 Response Accepted

21 Response Accepted (N/A for PR):

QAR

Date

AOQAM

Date

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PR/DR CONTINUATION PAGE

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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