



Department of Energy

Washington, DC 20585

QA: L

AUG 12 1997

L. D. Foust, Technical Project Officer
for Yucca Mountain Site
Characterization Project
TRW Environmental Safety Systems, Inc.
1180 Town Center Drive, M/S 423
Las Vegas, NV 89134

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY
REPORT (DR) YM-96-D-073 RESULTING FROM OFFICE OF QUALITY
ASSURANCE (OQA) AUDIT YM-ARC-96-16 OF LOS ALAMOS NATIONAL
LABORATORY

The OQA staff has verified the corrective action to DR YM-96-D-073 and determined the results to be satisfactory. As a result, the DR is considered closed.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Kenneth O. Gilkerson at (702) 794-1486.


Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-2069

Enclosure:
DR YM-96-D-073

- cc w/encl:
- T. A. Wood, DOE/HQ (RW-55) FORS
 - J. O. Thoma, NRC, Washington, DC
 - S. W. Zimmerman, NWPO, Carson City, NV
 - B. R. Justice, M&O, Las Vegas, NV
 - R. A. Morgan, M&O, Las Vegas, NV
 - Thomas Hirons, M&O/LANL, Los Alamos, NM
 - M. J. Clevenger, M&O/LANL, Los Alamos, NM
 - L. E. Souza, OQA/LANL, Los Alamos, NM

- cc w/o encl:
- W. L. Belke, NRC, Las Vegas, NV
 - K. O. Gilkerson, OQA/QATSS, Las Vegas, NV
 - D. G. Sult, OQA/QATSS, Las Vegas, NV
 - R. W. Clark, DOE/OQA, Las Vegas, NV

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OFFICE OF CIVILIAN
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WASHINGTON, D.C.

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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
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3 Responsible Organization: Los Alamos National Laboratory	4 Discussed With: P. Gillespie
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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 Richard L. Maudlin Date 7/19/96	9 Is condition an isolated occurrence? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown; Must be Yes if PR
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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 [Signature] Date 7/19/96	12 Response Due Date 20 working days from issuance
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13 Affected Organization QA Manager Issuance Approval: (QAR for PR)

Printed Name RESPERNCE Signature [Signature] Date 7-24-96

22 Corrective Actions Verified QAR [Signature] Date 7/31/97	23 Closure Approved by: (N/A for PR) [Signature] Date 8/8/97
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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 ^{QMS 289BA JWB 8/9/96} 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 D. Cemerger*

Initial

Amended

Date *8/9/96*

Phone *665-1454*

20 Response Accepted

21 Response Accepted (N/A for PR):

QAR *n/a*

See amended response
Date *12/16/96*

AOQAM *n/a*

see amended response
Date *12/16/96*

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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 *[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.

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CLOSURE VERIFICATION FOR DEFICIENCY REPORT (DR) YM-96-D-073

During the compliance audit of LANL in Los Alamos, New Mexico (LANL-ARC-97-19), a follow-up to subject DR was performed to determine if it could be closed. The DR addresses three basic issues:

1. The first issue relative to analytical services being procured from sources not meeting QARD program requirements was addressed by changes to the QARD in Rev. 7 which now allows alternate methodologies for analytical services. The use of a Quality Sampling Plan for evaluating analytical results was used by LANL initially. The QARD requirements now legitimizes this. A review for impact on products was performed by LANL PIs relative to this first deficiency (See Block 5, Item A). See attached memorandum. Additionally, the current PR to Purdue University for analytical services (PR 464BA) was reviewed to assure that it meets the new QARD requirements for analytical services and found acceptable.
2. The second deficient condition (Item B) identified that a technical review was not performed for PRs, 021BA and 289BA. Documentation was reviewed in the record packages for these PRs during the audit that documented that an independent technical reviewer (Paul Dixon, an Isotope Geologist) performed the prerequisite reviews as required.
3. The third issue (Item C) addressed a deficiency relative to the passing on of technical and QA requirements to Sandia's Primary Standards Laboratory for calibrations that are performed to LANL. Since no real procurement document is generated due to inter lab agreements, LANL was supposed to document a methodology for how the passing on of these requirements is actually accomplished. PSL is a qualified vendor for YMP and in the past, performed calibrations of mass weight sets for LANL to NIST requirements. However, during this audit it was determined that LANL has not used PSL for YMP equipment in two years and, has opted to go direct to NIST instead. Since there is still the possibility that LANL may use PSL in the future, this issue is being captured in DR ~~YM-96-D-074~~ issued for other procurement problems.

Based on this verification and the issuance of another DR to trace Item C, DR YM-96-D-073 is closed.


Kenneth O. Gilkerson, OQA/QATSS

7/31/97
Date

Attachment to DR YMP-98 0073
Closure verification

Los Alamos

NATIONAL LABORATORY

memorandum

Earth and Environmental Sciences Division

EES-19-Nuclear Waste Management R&D
Mail Stop J521, Los Alamos, NM 87545
Phone (505) 667-9768, Fax (505) 667-1934

To/MS: Mike Clevenger, EES-13
From/MS: June Fabryka-Martin CST-7
Frank Perry, EES-13
Phone/FAX: 7-0149 - 7-1934
Symbol: N/A
Date: July 30, 1997

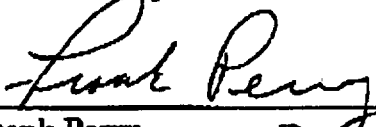
Evaluation of the Procurement of Analytical Services for Volcanism and Chlorine-36

LANL YMP has evaluated the procurement of analytical services for Volcanism and Chlorine-36 activities. The undersigned Principal Investigators reviewed the work products relative to the analytical services provided and determined that there were no adverse impacts to any of the completed products as a result of the differences between the technical and QA requirements imposed by prior QA requirements and current QARD QA program requirements. The procurement documents of concern include:

Purchase Requisition Number 216AW (Volcanism)

Purchase Requisition Number 021BA (Chlorine-36)

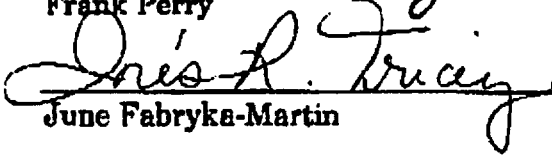
Purchase Requisition Number 289BA (Chlorine-36)



Frank Perry

7/30/97

Date



June Fabryka-Martin

7/30/97

Date