



Department of Energy

Washington, DC 20585

QA: L

AUG 13 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

**ISSUANCE OF DEFICIENCY REPORTS (DR) YM-97-D-074 THROUGH
YM-97-D-077 AND PERFORMANCE REPORT (PR) YM-97-P-016 RESULTING
FROM OFFICE OF QUALITY ASSURANCE (OQA) AUDIT LANL-ARC-97-19 OF
LOS ALAMOS NATIONAL LABORATORY**

Enclosed are DRs YM-97-D-074 through YM-97-D-077 and PR YM-97-P-016 generated
as a result of OQA Audit LANL-ARC-97-19.

Please provide responses to these deficiencies that meet the applicable requirements of
Administrative Procedure 16.1Q, Performance/Deficiency Reporting. Send the originals of
your responses to Deborah Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455,
North Las Vegas, Nevada 89036-0307. Responses to the DRs are due 20 working days
after the date of this letter. Extensions to due dates must be requested in writing, with
appropriate justification, prior to the due dates.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or
Kristi A. Hodges at (702) 734-0871.

Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-2060

Enclosures:

1. DR YM-97-D-074
2. DR YM-97-D-075
3. DR YM-97-D-076
4. DR YM-97-D-077
5. PR YM-97-P-016

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cc w/encls:

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cc w/o encls:

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

8 Performance Report
 Deficiency Report
NO. YM-97-D-074
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: RW/DOE 0333P, R-7 QARD; LANL-YMP-QP 4.6 R-5
2 Related Report No. LANL-ARC-97-19


3 Responsible Organization: LANL
4 Discussed With: Mike Clevenger, Karen West


5 Requirement/Measurement Criteria:
QARD R-7 4.2.1 requires procurement documents to include technical requirements and Quality Assurance Program requirements.
QARD R-7 4.2.2 requires both an independent technical review and QA review of procurement documents.
QARD R-7 12.7 identifies required documentation for calibration of M&TE.
LANL-YMP-QP 4.6 R-5, paragraph 1.0 depicts this procedure as the applicable document for describing the procurement process for LANL's Yucca Mountain Project. QP-4.6, paragraph 2.0 scopes the procurement of calibration standards and services specifically for YMP work.

6 Description of Condition:
It was found during a review of procurement and calibration documentation that LANL procurements for YMP work are not accomplished in accordance with QARD and LANL YMP program requirements:
1) PR8832U failed to require that the implementing procedure revision level (for a calibration) be included in required documents from SIMCO Electronics. A review of the calibration certificates furnished by SIMCO with this PR disclosed that the revision levels were not indicated as required. Additionally, one certificate did not identify by name or number the specific calibration protocol used; 2) It was found that consumable standards used for calibrations are not procured per QP 4.6. (NOTE: QP 12.3 defines calibration standards as "consumable" and "non-consumable" standards). Consumable standards are procured as "Just in Time" procurements through a non-YMP/OCRWM procurement process that does not require the technical and QA review described in QP 4.6; 3) A procurement to NIST for calibrations of Mass Weight Standards (re:file number 0128) on PO#B9245tel68H was not processed in accordance with QP-4.6 but rather a LANL "lab" procedure which did not require the independent technical and QA review per QP 4.6 or QARD requirements; 4) There is still no documented methodology in place for passing on technical and quality requirements to Primary Standards Laboratory at SNL (re:DR YM-96D-073). This was a commitment to referenced DR that

7 Initiator: K. O. Gilkerson  Date 07/28/97
8 Is condition an isolated occurrence? Yes No Unknown; Must be Yes if PR

10 Recommended Actions: (Not required for PR)
Investigate the extent of the deficiencies and identify any additional remedial and corrective actions. Identify actions to preclude recurrence. Identify cause(s) (not root cause) of violations. Assure that no impact on data or other products has resulted from these deficiencies.

11 QA Review:  Date 7/28/97
12 Response Due Date: 20 working days from issuance

13 Director, OQA Issuance Approval: (QAR for PR)
Printed Name DONALD G. HORDON Signature  Date 8/8/97

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

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PR/DR CONTINUATION PAGE

Block 6 Description of Condition cont'd:

required LANL to address a methodology for passing on requirements to PSL since no real procurement document between labs exists. This deficiency is addressed here to allow closure of DR YM-96-D-073 since it is the only remaining issue that was addressed in DR YM-96-D-073 that corrective action is not completed.

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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:

Date

Phone

20 Response Accepted

21 Response Accepted (N/A for PR)

QAR

Date

DOQA

Date

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: AP-17.1Q, "Record Source Responsibilities for Inclusionary Records," Rev. 0
2 Related Report No. LANL-ARC-97-19

3 Responsible Organization: LANL
4 Discussed With: M. Clevenger, S. Martinez

5 Requirement/Measurement Criteria:
AP-17.1Q, "Record Source Responsibilities for Inclusionary Records," Rev. 0, Para. 5.7.4, states in part: "Create a list of cited references by correspondence for study plans, progress reports, or any published technical or scientific reports submitted to the RPC that contain cited references . . . Send the list to an OCRWM TIC (i.e., Vienna TIC or Las Vegas TIC) . . . Submit the list as a record . . ."

6 Description of Condition:
LANL has not submitted a list of cited references to the Technical Information Center (TIC) since January of 1996, although there are cited references in technical publications and plans generated since that time.

7 Initiator *Kristi A. Hodges*
Kristi A. Hodges Date 07/29/97
9 Is condition an isolated occurrence?
 Yes No Unknown; Must be Yes if PR

10 Recommended Actions: (Not required for PR)
1. Compile and submit a list of cited references to the TIC and RPC in accordance with Para. 5.7.4.
2. Establish a time interval; e.g., quarterly, to generate and submit cited reference updates.

11 QA Review: *Kristi A. Hodges*
QAR Kristi A. Hodges Date 07/29/97
12 Response Due Date
20 working days from issuance

13 Director, OQA Issuance Approval: (QAR for PR)
Printed Name DONALD SHORRAN Signature *Donald Shorran* Date 8/8/97

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

Date

Phone

20 Response Accepted

21 Response Accepted (N/A for PR)

QAR

Date

DOQA

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: DOE/RW-0333P, "OCRWM Quality Assurance Requirements and Description," Rev. 7
2 Related Report No. LANL-ARC-97-19

3 Responsible Organization: LANL
4 Discussed With: M. Clevenger, S. Martinez

5 Requirement/Measurement Criteria:
QARD, Rev. 7, Section 17.0, Para. 17.2.2B, states in part: "Individuals creating QA records shall ensure that the QA records are legible, accurate, complete appropriate to the work accomplished and identifiable to the item(s) or activity(s) to which they apply."
AP-17.1Q, Rev. 0, Para 5.2.1 C & D, state in part: "Ensure that records have all blank lines and spaces accounted for in accordance with governing procedures, or provide a statement indicating that blank lines and spaces are intentional and identify the affected pages . . . Ensure that records are complete and contain all attachments and enclosures." Para. 5.5.a, states in part: ". . . Initial or sign and date the changes or corrections."

6 Description of Condition:
Measuring and Test Equipment (M&TE) Reports submitted by LANL to the Records Processing Center (RPC) in January and May of 1997 contained multiple record violations, including: unaccounted for blank lines and spaces, references to attachments that were not part of the submitted records packages, incomplete information (i.e., reference to a scientific notebook with no identifier to determine which notebook), and failure to initial and/or date corrections. Thirteen of sixteen M&TE Report records packages reviewed were found to be deficient. These records had been received but not processed by the RPC, and were considered as part of the RPC records backlog.
Indicated record identifiers of subject records: SN011964, PN441939, PN487281, PN486921, PN400508, SN20322906, 016532, SN2410090, PN608866, PN295584, PN817330, PN405742, & SN1288G

7 Initiator: *Kristi A. Hodges*
Kristi A. Hodges Date 07/29/97
9 Is condition an isolated occurrence?
 Yes No Unknown; Must be Yes if PR

10 Recommended Actions: (Not required for PR)
Describe remedial actions required to correct the specific conditions noted.
Describe investigative actions performed to determine the extent of the condition and the result of the determination.
Describe actions to preclude recurrence.

11 QA Review: *Kristi A. Hodges*
QAR Kristi A. Hodges Date 07/29/97
12 Response Due Date
20 working days from issuance

13 Director, OQA Issuance Approval: (QAR for PR)
Printed Name DONALD G. HODGES Signature: *Donald G. Hodges* Date 8/8/97

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

Date

Phone

20 Response Accepted

21 Response Accepted (N/A for PR)

QAR

Date

DOQA

Date

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: DOE/RW-0333P, Rev. 7, Quality Assurance Program Description
2 Related Report No. LANL-ARC-97-19

3 Responsible Organization: Los Alamos National Laboratory
4 Discussed With: Mike Cleveringer, Cloeves Martinez
Cleveringer

5 Requirement/Measurement Criteria:
Section 5.2.2 states, "Implementing documents shall include the following information as appropriate to the work to be performed:....H. Identification of the lifetime and nonpermanent quality assurance records generated by the implementing document...."

Section 17.2.2 A. states, "Implementing documents shall:
1. Identify those documents that will become QA records.
2. Identify the organization responsible for submitting the QA records to the records management system."

6 Description of Condition:
Contrary to the above, no evidence could be found of these requirements within the following reviewed procedures:
LANL-YMP-QP-02.5, R4
LANL-YMP-QP-02.7, R4
LANL-YMP-QP-02.11, R6
LANL-YMP-QP-06.1, R8
LANL-YMP-QP-06.2, R6
LANL-YMP-QP-06.3, R5
LANL-YMP-QP-18.2, R6

7 Initiator: *Cynthia A. Humphries-Alder*
Cynthia A. Humphries-Alder Date 7/31/97
9 Is condition an isolated occurrence?
 Yes No Unknown; Must be Yes if PR

10 Recommended Actions: (Not required for PR)
1. Investigate the extent of the deficiency.
2. Determine actions needed to preclude recurrence.
3. Revise procedures to include the above mentioned QARD requirements.

11 QA Review: *Cynthia A. Humphries-Alder*
Cynthia A. Humphries-Alder Date 7/31/97
12 Response Due Date
20 working days from issuance

13 Director, QQA Issuance Approval: (QAR for PR)
Printed Name DONALD G. HOOPER
Signature *Donald G. Hooper* Date 8/1/97

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

Date

Phone

20 Response Accepted

21 Response Accepted (N/A for PR)

QAR

Date

DOQA

Date

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
LANL-YMP-QP-12.3, R3

2 Related Report No.
Audit LANL-ARC-97-19

3 Responsible Organization:
LANL

4 Discussed With:
Jim Young, Steve Chipera

5 Requirement/Measurement Criteria:
Paragraph 6.2.3 of subject procedure requires the M&TE Custodian to verify that the calibration standard have a greater accuracy than the M&TE being calibrated. If standards with an accuracy equal to the M&TE being calibrated must be used, and can be shown to be adequate for the requirements, the Custodian documents the basis for calibration acceptance on line 10 of the M&TE Report and obtains authorization for the calibration acceptance by having the principal Investigator sign and date line 11.

6 Description of Condition:
Contrary to the above, for the Thermolyne Automatic Furnaces that were calibrated (e.g s/n 645327, 645328), the standard used (YMP Long Thermocouple)(identifier #67132) had a accuracy requirement of 5 degrees celsius, while the accuracy requirement for the furnace was also 5 degrees celsius. The M&TE Reports reviewed did not document a basis for calibration acceptance relative to using a standard of equal accuracy. In addition the custodian maintained that all calibrations were being performed with standards of greater accuracy . A review of documentation for other LANL M&TE on the project did not disclose similar problems.

7 Initiator *K. O. Gilkerson*
K. O. Gilkerson Date 07/31/97

8 Is condition an isolated occurrence?
 Yes No Unknown; Must be Yes if PR

10 Recommended Actions: (Not required for PR)
Either provide a rationale for use of equal standards in accordance with procedure ; or, evaluate the acceptable tolerance requirements for the furnaces and the standards and modify the procedures as necessary.

11 QA Review:
QAR *K. O. Gilkerson* Date 7/31/97

12 Response Due Date
20 working days from issuance

13 Director, QQA Issuance Approval: (QAR for PR)
Printed Name KENNETH O Gilkerson

Signature *Kenneth O Gilkerson* Date 7/31/97

22 Corrective Actions Verified
QAR Date

23 Closure Approved by: (N/A for PR)
DOQA 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:

Date

Phone

20 Response Accepted

21 Response Accepted (N/A for PR)

QAR

Date

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Date