



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

JUL 12 1996

L. Dale Foust
Technical Project Officer
for Yucca Mountain
Site Characterization Project
TRW Environmental Safety Systems, Inc.
Bank of America Center, Suite P-110
101 Convention Center Drive
Las Vegas, NV 89109

ISSUANCE OF DEFICIENCY REPORTS (DR) YM-96-D-063, YM-96-D-064 AND
YM-96-D-066 THROUGH YM-96-D-069 RESULTING FROM YUCCA MOUNTAIN
QUALITY ASSURANCE DIVISION'S (YMQAD) AUDIT YM-ARC-96-16 OF LOS
ALAMOS NATIONAL LABORATORY (SCPb: N/A)

Enclosed are DRs YM-96-D-063, YM-96-D-064, and YM-96-D-066 through YM-96-D-069
generated as a result of YMQAD Audit YM-ARC-96-16.

Please identify the corrective actions to be taken and implemented to correct the deficiencies. A
DR Continuation Page has been provided. Send the originals of your responses to Deborah Sult,
YMQAD/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608. Responses
to the DRs are due 20 working days from the date of this letter. Extensions to the due dates must
be requested in writing, with appropriate justification, prior to the due dates.

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-2153

Enclosures:

1. DRs YM-96-D-063,
YM-96-D-064 and
YM-96-D-066 thru
YM-96-D-069
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

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R. L. Strickler, M&O, Vienna, VA

R. B. Justice, M&O, Las Vegas, NV

R. P. Ruth, M&O, Las Vegas, NV

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M. J. Clevenger, M&O/LANL, Los Alamos, NM

J. B. Tillman, LAAO, Los Alamos, NM

Records Processing Center

cc w/o encls:

W. L. Belke, NRC, Las Vegas, NV

D. G. Horton, OQA, NV

R. L. Maudlin, YMQAD/QATSS, Las Vegas, NV

D. G. Sult, YMQAD/QATSS, Las Vegas, NV

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8 ☐ Performance Report
☒ Deficiency Report
NO. YM-96-D-063
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QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: LANL-YMP-QP-04.6, Revision 4	2 Related Report No. YM-ARC-96-16
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3 Responsible Organization: Los Alamos National Laboratory (LANL)	4 Discussed With: P. Gillespie
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5 Requirement/Measurement Criteria:

LANL-YMP-QP-04.6, Subparagraph 6.3.7, states in part: "A Los Alamos YMP Quality Assurance Representative conducts an annual performance evaluation of suppliers used by Los Alamos YMP according to AP-7.4Q."

6 Description of Condition:

Contrary to the above, there is no documented evidence that LANL has conducted an annual performance evaluation of SIMCO. The last performance evaluation of SIMCO was performed January 1995.

7 Initiator Richard L. Maudlin <i>R. Maudlin</i> Date 07/02/96	9 QA Review QAR <i>R. Maudlin</i> Date 07/02/96
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10 Response Due Date: 20 Working Days From Issuance	11 QA Issuance Approval QAR (PR)/AOCAM (DR) <i>[Signature]</i> Date 7/11/96
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12 Remedial Actions:

13 Remedial Actions Response By: Date	14 Remedial Action Due Date Date
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15 Remedial Action Response Acceptance QAR Date	16 PR Verification /Closure QAR Date
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DEFICIENCY REPORT

17 Recommended Actions:

Investigate and determine if there are any other instances of lapsed performance evaluations. Take the necessary action to do the performance evaluation on SIMCO.

18 Investigative Actions:

19 Root Cause Determination:

20 Action to Preclude Recurrence:

<p>21 Response By:</p> <p style="text-align: right;">Date</p>	<p>22 Corrective Action Completion Due Date</p>
<p>23 Response Accepted</p> <p>QAR Date</p>	<p>24 Response Accepted</p> <p>AOQAM Date</p>
<p>25 Amended Response Accepted</p> <p>QAR Date</p>	<p>26 Amended Response Accepted</p> <p>AOQAM Date</p>
<p>27 Corrective Action Verified</p> <p>QAR Date</p>	<p>28 Closure Approved by:</p> <p>AOQAM Date</p>

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8 ☐ Performance Report
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NO. YM-ARC-96-D064
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: QARD, Revision 5 / LANL-YMP-QP-03.20, Revision 4	2 Related Report No. YM-ARC-96-16
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3 Responsible Organization: Los Alamos National Laboratory (LANL)	4 Discussed With: B. J. Fabryka-Martin / A. Wolfsberg
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5 Requirement/Measurement Criteria:
QARD, Section 1.2.2(A), states: "Software verification and software validation shall be performed prior to release. In those cases where this requirement cannot be met prior to the release of the software, the portions of the software that have not been verified and validated shall be identified and controlled and written justification of the reason documented."

LANL-YMP-QP-03.20, Subparagraph 6.2.1, states in part: "It is the responsibility of the SCM to ensure that software verification and validations of developed or modified software is performed prior to release."

6 Description of Condition:
Contrary to the above:

A. LANL procedure YM-QP-03.20, Revision 4, does not require: (1) that written justification be documented when software that has not been verified and validated is released for use and (2) the mechanism for controlling its use prior to validation and verification.

B. Software FEHM was used in the Chlorine-36 (quality affecting) activity in the Milestone Report: "Systematic Sampling for Chlorine-36 in Exploratory Studies Facility;" however there is no documented evidence to establish (1) documented justification for use and (2) released for use under the configuration management program. NOTE: Software FEHM is not verified and validated and has not been placed under configuration management.

7 Initiator Richard L. Maudlin <i>RM</i> Date <u>7/2/96</u>	9 QA Review QAR <i>RM</i> Date <u>7/2/96</u>
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10 Response Due Date: 20 Working Days From Issuance	11 QA Issuance Approval QAR (PR)/AOGAM (DR) <i>[Signature]</i> Date <u>7/11/96</u>
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12 Remedial Actions:

13 Remedial Actions Response By: Date	14 Remedial Action Due Date Date
15 Remedial Action Response Acceptance QAR Date	16 PR Verification /Closure QAR Date

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DR NO. DS 7/2/96
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DEFICIENCY REPORT

17 Recommended Actions:

- A. Investigate the impact on quality in using software which has not been released for use. Also, determine if there are other instances of software being used for quality affecting work which has not been formally accepted.
- B. Identify what actions will or have been taken to bring the FEHM software under configuration management.
- C. Revise LANL-YMP-QP-03.20 to be consistent with the requirements of the QARD.

18 Investigative Actions:

19 Root Cause Determination:

20 Action to Preclude Recurrence:

21 Response By: Date		22 Corrective Action Completion Due Date	
23 Response Accepted QAR	Date	24 Response Accepted AOQAM	Date
25 Amended Response Accepted QAR	Date	26 Amended Response Accepted AOQAM	Date
27 Corrective Action Verified QAR	Date	28 Closure Approved by: AOQAM	Date

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: QARD, DOE/RW-0333P, Revision 5	2 Related Report No. YM-ARC-96-16
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3 Responsible Organization: Los Alamos National Laboratory (LANL)	4 Discussed With: M. Clevenger
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5 Requirement/Measurement Criteria:

QARD, Section 6.0, Paragraph 6.2.5C, states: "The disposition of obsolete or superseded documents shall be controlled to ensure that they are not used to perform work."

6 Description of Condition:

Contrary to the above, five of eleven controlled document manuals (both Quality Procedure and Detail Procedure Manuals) had superseded/deleted procedures in the manual.

7 Initiator James Blaylock <i>James Blaylock</i> Date <u>7/2/96</u>	9 QA Review QAR <i>James Blaylock</i> Date <u>7/2/96</u>
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10 Response Due Date: 20 Working Days From Issuance	11 QA Issuance Approval <i>[Signature]</i> QAR (PR)/AOQAM (DR) Date <u>7/11/96</u>
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12 Remedial Actions:

13 Remedial Actions Response By: Date	14 Remedial Action Due Date Date
15 Remedial Action Response Acceptance QAR Date	16 PR Verification /Closure QAR Date

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DEFICIENCY REPORT

17 Recommended Actions:

18 Investigative Actions:

19 Root Cause Determination:

20 Action to Preclude Recurrence:

21 Response By

Date

22 Corrective Action Completion Due Date

23 Response Accepted

QAR

Date

24 Response Accepted

AOQAM

Date

25 Amended Response Accepted

QAR

Date

26 Amended Response Accepted

AOQAM

Date

27 Corrective Action Verified

QAR

Date

28 Closure Approved by

AOQAM

Date

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8 ☐ Performance Report
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: QARD, DOE/RW-0333P, Revision 5	2 Related Report No. YM-ARC-96-16
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3 Responsible Organization: Los Alamos National Laboratory (LANL)	4 Discussed With:
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5 Requirement/Measurement Criteria:

QARD, Paragraph 12.2.1A, states in part: Measuring and Test Equipment...shall be calibrated...against reference standards having traceability to nationally recognized standards."

QARD, Paragraph 12.2.1C, states in part: "The method and interval of calibration for each device shall be defined, based on the type of equipment stability characteristics, required accuracy, intended use...etc."

6 Description of Condition:

Contrary to the above, LANL weight set standard identifier 0347 used to calibrate Measuring and Test Equipment by ESH-9 does not have certification to a specific National Institute of Standards and Technology (NIST) Calibration Report. The calibration traceability stops at Sandia National Laboratories - Primary Standards Laboratory (PSL). In addition, this standard had its calibration expiration date extended by one and a half years to March 26, 1997, with no apparent approval under the LANL YMP QA program. The original calibration due date was September 26, 1995, and was extended by PSL to March 26, 1997. During this extended time ESH-9 used this standard in calibrating LANL-YMP equipment, i.e., Weight Set 0347 calibrated March 26, 1996.

7 Initiator Hank T. Greene Date <u>7/3/96</u>	9 QA Review QAR <u>[Signature]</u> Date <u>7/3/96</u>
10 Response Due Date: 20 Working Days From Issuance	11 QA Issuance Approval QAR (PR)/AOQAM (DR) <u>[Signature]</u> Date <u>7/11/96</u>

12 Remedial Actions:

13 Remedial Actions Response By: Date	14 Remedial Action Due Date Date
15 Remedial Action Response Acceptance QAR Date	16 PR Verification /Closure QAR Date

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DEFICIENCY REPORT

17 Recommended Actions:

1. Provide traceability to NIST Calibration Reports for all standards used in support of the LANL YMP QA program.
2. Evaluate impact of extending the interval of calibration by one and a half years for LANL weight sets. Provide acceptance of this extension (if required) under the LANL YMP QA program.

18 Investigative Actions:

19 Root Cause Determination:

20 Action to Preclude Recurrence:

21 Response By:

Date

22 Corrective Action Completion Due Date

23 Response Accepted

QAR

Date

24 Response Accepted

AOQAM

Date

25 Amended Response Accepted

QAR

Date

26 Amended Response Accepted

AOQAM

Date

27 Corrective Action Verified

QAR

Date

28 Closure Approved by:

AOQAM

Date

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:

QARD, DOE/RW-0333P, Revision 5 / AP-16.1Q, Revision 0

2 Related Report No.

YM-ARC-96-16

3 Responsible Organization:

Los Alamos National Laboratory (LANL)

4 Discussed With:

M. Clevenger

5 Requirement/Measurement Criteria:

QARD, Paragraph 16.1, states in part: "...conditions adverse to quality are promptly identified and corrected as soon as practical."

AP-16.1Q, Paragraph 5.1.1(a), states: "Upon discovering a potential performance condition or deficiency, the Affected Organization completes the Initiator actions on the PR/DR Form."

6 Description of Condition:

Potential conditions adverse to quality have not been promptly documented on the Performance Report (PR) or Deficiency Report (DR) Form.

Examples:

- On May 3, 1996, a Measuring and Test Equipment item was found out of calibration and was not (to date) documented on a PR/DR form by the responsible Principal Investigator or equipment custodian.
- Between the dates April 4 through May 17, 1996, a Quality Assurance Survey (LA-SR-CST-13-96-02) was performed which identified two potential conditions adverse to quality. Neither of these have been documented (to date) on a PR/DR form and processed in accordance with AP-16.1Q, Revision 0.

7 Initiator

Hank T. Greene

Date

7/3/96

9 QA Review

QAR

Date

7/3/96

10 Response Due Date:

20 Working Days From Issuance

11 QA Issuance Approval

QAR (PR)/AOQAM (DR)

Date

7/11/96

12 Remedial Actions:

13 Remedial Actions Response By:

Date

14 Remedial Action Due Date

Date

15 Remedial Action Response Acceptance

QAR

Date

16 PR Verification /Closure

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Date

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DEFICIENCY REPORT

17 Recommended Actions:

Prepare appropriate deficiency documents for those items identified as conditions adverse to quality.

18 Investigative Actions:

19 Root Cause Determination:

20 Action to Preclude Recurrence

21 Response By:

Date

22 Corrective Action Completion Due Date

23 Response Accepted

QAR

Date

24 Response Accepted

AOQAM

Date

25 Amended Response Accepted

QAR

Date

26 Amended Response Accepted

AOQAM

Date

27 Corrective Action Verified

QAR

Date

28 Closure Approved by:

AOQAM

Date

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⁸ ☐ Performance Report
☒ Deficiency Report
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: LANL-YMP-96-12.3, Revision 2	2 Related Report No. YM-ARC-96-16
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3 Responsible Organization: Los Alamos National Laboratory (LANL)	4 Discussed With: M. Clevenger / J. Canepa / *Inez Triay
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5 Requirement/Measurement Criteria:
LANL-YMP-QP-12.3, Paragraph 6.6.2.6.

The Principal Investigator (PI) or custodian performs the following:

"If the Measuring and Test Equipment (M&TE) accuracy was out of tolerance before calibration and was used to collect data that is governed by LANL YMP QPs or DPs since its last calibrations, the PI or custodian initiates a Performance Report (PR) or Deficiency Report (DR) in accordance with AP-16.1Q to determine the validity of results obtained."

6 Description of Condition:

On May 3, 1996, M&TE Report for M&TE identifier PN817330 for microbalance C-31 indicated that the instrument was not within tolerance before calibration. Contrary to the requirement, the PI approved the M&TE Report without issuing a PR/DR form. One contributory cause for this deficiency could be the fact that this PI has not received any training on procedure AP-16.1Q.

* Inez Triay is the PI responsible for this M&TE. Numerous attempt were made to discuss this condition adverse to quality with Ms. Triay; however, all were unsuccessful, hence this deficiency was discussed with Ms. Julie Canepa, Laboratory Lead.

7 Initiator Hank T. Greene <i>H. T. Greene</i> Date 7/3/96	9 QA Review QAR <i>H. T. Greene</i> Date 7/3/96
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10 Response Due Date: 20 Working Days From Issuance	11 QA Issuance Approval QAR (PR)/AOQAM (DR) Date
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12 Remedial Actions

13 Remedial Actions Response By: Date	14 Remedial Action Due Date Date
15 Remedial Action Response Acceptance QAR Date	16 PR Verification /Closure QAR Date

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DR NO. YM-96-D-069.

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DEFICIENCY REPORT

17 Recommended Actions:

1. Issue PR/DR in accordance with AP-16.1Q to determine the validity of results obtained. Evaluate extent of deficiency as it pertains to other M&TE.
2. Provide training to appropriate staff members in applicable procedures associated with their responsibilities; i.e., PIs and other employees working to the QA program should have training in AP-16.1Q.

18 Investigative Actions:

19 Root Cause Determination:

20 Action to Preclude Recurrence:

<p>21 Response By:</p> <p style="text-align: right;">Date</p>	<p>22 Corrective Action Completion Due Date</p>
<p>23 Response Accepted</p> <p>QAR Date</p>	<p>24 Response Accepted</p> <p>AOQAM Date</p>
<p>25 Amended Response Accepted</p> <p>QAR Date</p>	<p>26 Amended Response Accepted</p> <p>AOQAM Date</p>
<p>27 Corrective Action Verified</p> <p>QAR Date</p>	<p>28 Closure Approved by:</p> <p>AOQAM Date</p>

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PR/DR CONTINUATION PAGE