



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

OCT 11 1996

L. D. 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

**VERIFICATION OF CORRECTIVE ACTIONS AND CLOSURE OF DR YM-96-D-056
AND YM-96-D-057 RESULTING FROM YMQA AUDIT YM-ARC-96-11 OF
LAWRENCE LIVERMORE NATIONAL LABORATORY**

The Yucca Mountain Quality Assurance staff has verified the corrective actions to Deficiency Reports (DR) YM-96-D-056 and YM-96-D-057 and determined the results to be satisfactory. As a result, the DRs are considered closed.

If you have any questions, please contact either Mario R. Diaz at (702) 794-1489 or Richard L. Weeks at (702) 794-1431.

Richard E. Spence
Yucca Mountain Quality Assurance

YMQA:MRD-0086

Enclosure:
DRs YM-96-D-056 and
YM-96-D-057

cc w/encl:
T. A. Wood, DOE/HQ (RW-14) FORS
J. G. Spraul, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
R. L. Strickler, M&O, Vienna, VA
B. R. Justice, M&O, Las Vegas, NV
R. E. Monks, M&O/LLNL, Livermore, CA
Records Processing Center

cc w/o encl:
W. L. Belke, NRC, Las Vegas, NV
R. L. Weeks, YMQA/QATSS, Las Vegas, NV
D. G. Sult, YMQA/QATSS, Las Vegas, NV
D. G. Horton, DOE/OQA, Las Vegas, NV

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
033-YMP-QP 12.0, Revision 6

2 Related Report No.
YM-ARC-96-11

3 Responsible Organization:
Lawrence Livermore National Laboratory (LLNL)

4 Discussed With:
D. McCright / R. Monks

5 Requirement/Measurement Criteria:

Section 12.0.4, states in part: "The M&TE Master Status List identifies the M&TE authorized for use on the YMP. ...Principal Investigators and Task Leaders will request and place the appropriate stickers or reasonable facsimiles on YMP instruments used for quality affecting activities...."

6 Description of Condition:

Contrary to the above requirements, the current Measuring and Test Equipment (M&TE) Master Status List of Calibrated Instruments, dated 4/18/96, states that there are no calibrated instruments. However, four M&TEs are currently in use and collecting quality affecting data in support of the Metal Barrier Study (Work Breakdown Structure 1.2.2.5.1). Two Potentiostat/Galvanostats, Model 283 (LLNL/DOE Property No. 8032230) and Model No. 273 (LLNL/DOE Property No. 4053581). Orion pH Meter, Model 520A (no unique ID identified), and Sartorius Analytical Balance (ID#4273774) are utilized to collect quality affecting data for the aforementioned studies.

Additionally, instruments identified above were not labeled with appropriate stickers or reasonable facsimiles, as required.

7 Initiator *Richard L. Weeks*
Richard L. Weeks Date 5/1/96

9 QA Review
QAR *Richard L. Weeks* Date 5/1/96

10 Response Due Date

11 QA Issuance Approval
QAR (PR)/AOQAM (DRI) *Richard L. Weeks* Date 5/8/96

20 Working Days From Issuance

12 Remedial Actions:

Evaluate the calibration status of each instrument utilized to collect quality affecting data. Upon assurance that M&TE identified in Block 6 is calibrated as required, add to the M&TE Master Status List of Calibrated Instruments. Label M&TE as required.

All TALs will be interviewed and Activity Plans used during the preceding 12 months will be discussed. All M&TE used to collect "Q data" will be listed and status verified.

YMP-QP 12.0 is being revised. A Master List no longer will be required. M&TE will be tracked via Activity Plans and Scientific Notebooks.

13 Remedial Action Response By:
Richard L. Weeks Date 6-9-96

14 Remedial Action Due Date
N/A Date

15 Remedial Action Response Acceptance
QAR N/A Date

16 PR Verification/Closure
QAR N/A Date

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17 Recommended Actions:

Investigate the impact of the use of M&TE for which the calibration is indeterminate on the collection of quality affecting data. Provide actions to preclude recurrence of the identified deficient conditions.

Any impact will be evaluated when M&TE status is determined.

18 Investigative Actions:

A review of all Activity Plans and M&TE supporting the activity during the past 12 months will be performed and documented. Data collected will be analyzed for impact on activities. Appropriate action will be taken if any adverse impact is found.

19 Root Cause Determination:

Technical staff was performing work which they thought to be experimental set-up and check out of laboratory equipment and process as was allowed for in the draft Activity Plan for this work. They were not aware of this activity having been graded as "Q" or "subject to the QARD" in its entirety.

20 Action to Preclude Recurrence:

Retrain Technical Staff in technical areas identified as non-compliant. Cancel LLNL grading procedure and use "Q" determination in Participant Planning Sheet (PPS). Activity Plans will further describe appropriate quality controls for work to be accomplished.

21 Response by: <i>[Signature]</i> Date 6-1-96	22 Corrective Action Completion Due Date: August 30, 1996
23 Response Accepted N/A Date	24 Response Accepted N/A Date
25 Amended Response Accepted <i>[Signature]</i> Date 8/9/96	26 Amended Response Accepted <i>[Signature]</i> Date 8-20-96
27 Corrective Actions Verified <i>[Signature]</i> Date 10/4/96	28 Closure Approved by <i>[Signature]</i> Date 10/11/96

EVALUATION OF RESPONSE TO DR YM-96-D-056

This response is not satisfactory for the following reasons:

Remedial Actions

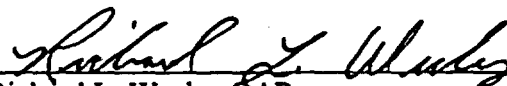
- Remedial Action Due Date is not indicated as required in Block 14.
- This response does not address unlabeled Measuring and Test Equipment. Provide remedial actions to be taken to address this deficiency.

Corrective Actions

- Corrective Action Completion Due Date is not indicated in Block 22 as required.

Root Cause Determination

- Response does not adequately describe the root cause. Additional determination as to why QP requirements were not followed, is necessary.


Richard L. Weeks, QAR

7/8/96
Date

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Block 12. Remedial Actions

Initial Response:

All TALs will be interviewed and Activity Plans used during the preceding 12 months will be discussed. All M&TE used to collect "Q data" will be listed and status verified.

YMP-QP 12.0 is being revised. A Master List no longer will be required. M&TE will be tracked via Activity Plans and Scientific Notebooks.

Amended Response:

All TALs will be interviewed and Activity Plans used during the preceding 12 months will be discussed. All M&TE used to collect "Q data" will be listed and status verified.

YMP-QP 12.0 is being revised. A Master List no longer will be required. M&TE will be tracked via Activity Plans and Scientific Notebooks. All M&TE equipment has been labeled.

Block 18. Investigative Actions

Initial Response:

A review of all Activity Plans and M&TE supporting the activity during the past 12 months will be performed and documented. Appropriate action will be taken if any adverse impact is found.

Amended Response:

A review of all Activity Plans and M&TE supporting the activity during the past 12 months will be performed and documented. Data collected will be analyzed for impact on activities. Appropriate action will be taken if any adverse impact is found.

Block 19. Root Cause Determination

Initial Response:

Technical staff did not follow QP requirements.

Amended Response:

Technical staff was performing work which they thought to be experimental set-up and check out of laboratory equipment and process as was allowed for in the draft Activity Plan for this work. They were not aware of this activity having been graded as "Q" or "subject to the QARD" in its entirety.

Block 20. Action to Preclude Recurrence

Initial Response:

Retrain Technical Staff in technical areas identified as non-compliant.

Amended Response:

Retrain Technical Staff in technical areas identified as non-compliant. Cancel LLNL grading procedure and use "Q" determination in Participant Planning Sheet (PPS). Activity Plans will further describe appropriate quality controls for work to be accomplished.

8/8/96 LLXMP9608034

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Verification of Corrective Action to DR YMQAD-96-D056

Verification of actions taken to correct deficient conditions was completed by examination of documentation provided by LLNL personnel. A visit was not made to LLNL.

Remedial Action:

LLNL Surveillance Report S96-03 was examined. This surveillance verified that the status of M&TE utilized for work conducted under Activity Plan E-20-43/44 was in compliance with program requirements.

LLNL Surveillance Report S96-03 indicated that data collected was not Q-data.

The requirement to maintain a master list of M&TE was removed from 033-YMP-QP 12.0 as revised by Revision 7.

LLNL Surveillance Report S96-03 stated that all M&TE was properly labeled.

Investigative Action:

Surveillance Report S96-04 was conducted by LLNL QA staff to evaluate the use of M&TE used to record "Q" data from 7/95 to 7/96. The surveillance report indicated that data was collected with properly calibrated M&TE.

Action to Preclude Recurrence:

A memo, McCleary to Monks, dated 8/27/96 with designation LLYMP9608080, was sent to LLNL QA listing the names of individuals receiving training to the following procedures:

- 033-YMP-QP 12.0, Measuring and Test Equipment
- 033-YMP-QP 1.0, Organization
- 033-YMP-QP 2.1, Preparation, Approval, and Revision of Procedures, Requirements, and Plans
- 033-YMP-QP 3.0, Scientific Investigation Control

LLNL procedure 033-YMP-QP 2.8, Revision 4, Quality Assurance Grading was canceled effective 9/10/96.

Verified By: Richard L. Weeks Date: 10/4/96
Richard L. Weeks

ORIGINAL
THIS IS A RED STAMP

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
033-YMP-QP 2.1, Revision 6

2 Related Report No.
YM-ARC-96-11

3 Responsible Organization:
Lawrence Livermore National Laboratory

4 Discussed With:
D. McCright / R. Monks

5 Requirement/Measurement Criteria:

Section 2.1.1, states in part: "All quality affecting work performed in support of YMP is accomplished according to controlled procedures and documents..."

6 Description of Condition:

Contrary to the above requirement, quality-affecting work for Metal Barrier Studies identified in Activity Plan E-20-43 and 44, "Critical Pitting Potential Measurements and Critical Crevice Potential Measurements," is being conducted; however, the Activity Plan has not yet been approved and issued. Additionally, TIP-YM-6, Revision 0, "Measurement of the pH of Aqueous Solutions with Glass Electrode," which is utilized for the collection of quality-affecting data from the Orion pH meter was not a controlled copy.

7 Initiator

Richard L. Weeks

Date 5/1/96

9 QA Review

QAR

Date 5/1/96

10 Response Due Date

20 Working Days From Issuance

11 QA Issuance Approval

QAR IPRI/RODAM (DR)

Date 5/8/96

12 Remedial Actions:

Approve and issue Activity Plan E-20-43 and 44.

Obtain a controlled copy of TIP-YM-6.

Work was stopped in this area until an approved Activity Plan and appropriate procedures are available.

13 Remedial Action Response By:

Date 6-11-96

14 Remedial Action Due Date

N/A

Date

15 Remedial Action Response Acceptance

QAR

Date

16 PR Verification/Closure

QAR

Date

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17 Recommended Actions:

Investigate the impact of conducting quality affecting work to an unapproved Activity Plan. Attention should be given to specific activities that may be impacted by resolution of unresolved review comments.

Investigate the impact of conducting quality affecting work to a TIP that has not been controlled per program requirements.

Provide an action plan to ensure that documents required to conduct quality affecting work are approved, issued, and controlled prior to the start of work.

18 Investigative Actions:

Work that was completed and/or started on this activity was not done in accordance with LLNL QA procedures (i.e. Activity Plan was not approved).

Data obtained was used for technique development only. Data collected using the draft Activity Plan will be Non-Q data. Data collected using draft TIP or otherwise inappropriate techniques will not be Q data.

An Nonconformance Report will be generated if it is determined that quality affecting data had been collected using inappropriate M&TE or other quality requirements.

19 Root Cause Determination:

Technical staff was trying to accomplish work within expected time frame. The experiment set-up was accomplished prior to finishing the planning documentation and some of the staff continued work without recognizing a mandatory hold point (i.e. no work, even technique development, is allowed without approved planning documents).

20 Action to Preclude Recurrence:

Retraining of all staff assigned to this area of work will be accomplished. The new Surveillance Schedule (FY96) shows areas to be looked at by Program Elements. The old (pre-FY96) schedules were for activities only. The FY96 schedule provides for looking at a broader range of activities, but in less detail than before. TIP-YM-6, Rev. 0, is not appropriate for work done in this activity and is not referenced in the approved Activity Plan.

21 Response by:

Ray C. Mafe Date *7/30/96*

22 Corrective Action Completion Due Date:

August 15, 1996

23 Response Accepted

OAR *N/A* Date

24 Response Accepted

AOQAM *N/A* Date

25 Amended Response Accepted

OAR *Richard L. White* Date *8/9/96*

26 Amended Response Accepted

AOQAM *Richard L. White* Date *8.20.96*

27 Corrective Actions Verified

OAR *Richard L. White* Date *10/4/96*

28 Closure Approved by:

AOQAM *R. C. Spruce* Date *10/11/96*

EVALUATION OF RESPONSE TO DR YM-96-D-057

This response is not satisfactory for the following reasons:

Remedial Actions

- Remedial Action Due Date is not indicated as required in Block 14.

Corrective Actions

- Corrective Action Completion Due Date is not indicated in Block 22 as required.

Investigative Action

- Additional information that specifically identifies the data collected including the type of data, and date that data was collected should be provided as part of the the response to this DR. Consideration should be given to generation of a Nonconformance Report to address data collected with a draft TIP.


Richard L. Weeks, QAR

7/8/96
Date

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Block 18. Investigative Actions

Initial Response:

Work that was completed and/or started on this activity was not done in accordance with LLNL QA procedures.

Data collected using the draft Activity Plan will be Non-Q data. Data collected using draft TIP or otherwise inappropriate techniques will not be Q data.

Amended Response:

Work that was completed and/or started on this activity was not done in accordance with LLNL QA procedures (i.e. Activity Plan was not approved).

Data obtained was used for technique development only. Data collected using the draft Activity Plan will be Non-Q data. Data collected using draft TIP or otherwise inappropriate techniques will not be Q data.

A Nonconformance Report will be generated if it is determined that quality affecting data had been collected using inappropriate M&TE or other quality requirements.

Block 19. Root Cause Determination

Initial Response:

Technical staff was trying to accomplish work within expected time frame. The experiment set-up was accomplished prior to finishing the planning documentation and some of the staff continued work without recognizing a mandatory hold point.

TIP-YM-6, Rev. 0, is not appropriate for work done in this activity.

Amended Response:

Technical staff was trying to accomplish work within expected time frame. The experiment set-up was accomplished prior to finishing the planning documentation and some of the staff continued work without recognizing a mandatory hold point (i.e. no work, even technique development, is allowed without approved planning documents).

Block 20. Action to Preclude Recurrence

Initial Response:

Retraining of all staff assigned to this area of work will be accomplished. The new Surveillance Schedule (FY96) shows areas to be looked at by Program Elements. The old (pre-FY96) schedules were for activities only. The FY96 schedule provides for looking at a broader range of activities, but in less detail than before.

Amended Response:

Retraining of all staff assigned to this area of work will be accomplished. The new Surveillance Schedule (FY96) shows areas to be looked at by Program Elements. The old (pre-FY96) schedules were for activities only. The FY96 schedule provides for looking at a broader range of activities, but in less detail than before. TIP-YM-6, Rev. 0, is not appropriate for work done in this activity and is not referenced in the approved Activity Plan.

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Verification of Corrective Action to DR YMQAD-96-D057

Verification of actions taken to correct deficient conditions was completed by examination of documentation provided by LLNL personnel. A visit was not made to LLNL.

Remedial Action:

A memo from McCright to Roy, dated 4/24/96 was issued indicating that all experimental work related to activities described in E-20-43/44 stop until an approved activity plan has been issued. Activity Plan E-20-43/44 was approved on 6/7/96 and became effective on 6/12/96.

Investigative Action:

A nonconformance report was not issued since all work completed prior to the issuance of an approved activity plan was classified non-Q.

Action to Preclude Recurrence:

A memo, McCleary to Monks, dated 8/27/96 listed individuals that completed training to required documents for work activities described in Activity Plan E-20-50, Long-Term Corrosion Test.

A revised surveillance schedule was issued on 8/7/96 and included oversight of scientific investigations described in Activity Plan E-20-43/44.

It was verified that TIP-YM-6, Revision 0 was not referenced in the approved and issued Activity Plan E-20-43/44, Revision 0.

Verified by:


Richard L. Weeks

Date:

10/4/96