



Department of Energy

Washington, DC 20585

QA: L

JUL 21 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

EVALUATION OF RESPONSE TO DEFICIENCY REPORT (DR) YM-97-D-052
RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER
AUDIT OQA-SA-97-023 OF KEITHLEY INSTRUMENTS, INC.

The OQA staff has evaluated the response to DR YM-97-D-052. The response has been determined to be satisfactory. Verification of completion of the corrective action will be performed after the effective date provided. Any extension to this date must be requested in writing, with appropriate justification, prior to the date. Please send a copy of extension requests to Deborah Sult, OQA/QATSS, P.O. Box 30307, Mail Stop 455, North Las Vegas, Nevada 89036-0307.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or Richard L. Maudlin at (702) 794-1302.


Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-1949

Enclosure:
DR YM-97-D-052

cc w/encl:
T. A. Wood, DOE/HQ (RW-55) FORS
J. O. Thoma, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
R. W. Henderson, M&O, Las Vegas, NV
B. R. Justice, M&O, Las Vegas, NV
R. A. Morgan, M&O, Las Vegas, NV

cc w/o encl:
W. L. Belke, NRC, Las Vegas, NV
R. L. Maudlin, 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
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

8 Performance Report
 Deficiency Report

NO. YM-97-D-052

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:

Keithley Quality Manual, QSIP 100, Revision A

2 Related Report No.

OQA-97-SA-023

3 Responsible Organization:

Civilian Radioactive Waste Management System
Maintenance and Operations (CRWMS M&O)/
Keithley Instruments, Inc.

4 Discussed With:

William Pelster

5 Requirement/Measurement Criteria:

A. Keithley Quality Manual, Section 8.3, states in part: "The supervisor and the employee identify and plan training needs The supervisor records the plans on the review form. They then schedule the training and record it in the persons' training log."

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6 Description of Condition:

Contrary to the above:

A. There is no objective evidence to establish that personnel performing calibration have been trained to the task specific procedures required to perform their functions.

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7 Initiator

D. Manelli

Date 05/28/97

9 Is condition an isolated occurrence?

Yes No Unknown; Must be Yes if PR

10 Recommended Action: (Not required for PR)

A. If personnel have been trained to the applicable procedures, then document this training. If they have not been trained to the applicable procedures, then identify the impact on quality and provide the necessary training.

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11 QA Review:

QAR *D. Manelli*

Date 05/28/97

12 Response Due Date

20 working days from issuance

13 Affected Organization QA Manager Issuance Approval: (QAR for PR)

Printed Name D. G. Horton

Signature *D. G. Horton*

Date 6/3/97

22 Corrective Action Verified

QAR

Date

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

AOQAM

Date

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

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PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:
A. Personnel will document training to manufactures procedures/manuals for the instances indicated.
B. The survey form will be generated for the subject PRs issued to Fluke Service Center.
C. Procedures for the Metrology Department will be brought under the company controls system or be placed under a department specific controls system.
D. The status of open deficiencies will be determined. Deficiencies will then be closed or updated and impact to Yucca Mountain specific activities will be documented.

All corrective action identified in blocks 14 and 15 will be completed by William Pelster by the date indicated in block 18.

15 Extent of Condition: (Not required for PR)
A. Keithley personnel have historically only documented training to company procedures and no to manufactures documentation. For future YMP specific tasks, personnel will document all applicable training related to the work.
B. Investigative action identifies PRs P139793 and P147420 as the only procurements without a survey form on file. No additional action required.
C. This condition applies to all department procedures. Remedial action identified in block 14 above will prevent recurrence.
D. Investigative action identified a total of 9 deficiencies issued between 1/1/95 and 1/1/97 have not been close out due to lack of management focus. Issuance of this DR has resulted in obtaining managements attention to the degree necessary to prevent

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: 10/01/97
19 Response by: William Pelster
William Pelster
Date 07/01/97 Phone (216) 498-2713

20 Response Accepted QAR *[Signature]* Date 07/16/97
21 Response Accepted (N/A for PR) *[Signature]* Date 7/2/97

7/1/97 LV. SPO. TEST. A6B. 07/97-114

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PR/DR CONTINUATION PAGE

5. Requirement/Measurement Criteria: (Continued)

- B. QS-101, Revision F, Section 14.0(A-2 & 3) state in part: "All potential subcontractors shall be requested to complete a survey form listing their response to specific requirements. When returned, the survey shall be evaluated to determine if the response is satisfactory."
- C. Keithley Quality Manual, Section 1.3 states in part: "Our procedures and work instructions used to support our quality system and product quality are also under full documentation change and revision control."
- D. Keithley Quality Manual, Section 7.1 states in part: "We developed a corrective action system that will quickly handle a specific customer problem in addition to investigating underlying causes of potential process or product problems."

6. Description of Condition: (Continued)

- B. Keithley purchase requisitions PR P139793 and P147420 were issued to Fluke Service Center in Carrollton, Texas, however there was no documented evidence that a survey form had been sent to this facility and returned for review.
- C. Calibration procedures prepared and issued by the Metrology Department are not under the documentation change and revision control system. Examples of procedures found not to be under the documentation and revision control system are: QA-1000C, QA-1004B, QA-1006B, and QA-1012B.
- D. Audit deficiency documents issued in January 1995 have not been resolved and closed to date. No documented justification exists to support why these deficiencies have not been processed in a timely manner. Examples include: NCM 401, NCM 402, NCM 403, and NCM 404.

10. Recommended Action: (Continued)

- B. Investigate the depth of this problem and assure that survey forms have been issued to all calibration suppliers and that the survey forms are returned and evaluated for acceptability. Determine if there is any impact on work performed for the CRWMS M&O by suppliers who may have calibrated standards used in the calibration of CRWMS M&O equipment. Identify the cause of why these survey forms were not sent to the respective suppliers.
- C. Take action to inventory all Metrology Department procedures and bring them under the documentation change and revision control system. If the Metrology Department intends to maintain their procedures separate from the document control system in place, then develop procedures which describe the methods to be implemented by the Metrology Department for preparation, review and approval, distribution and change control.
- D. Review all open deficiencies to determine status. Then prioritize them based on significance and impact and require responses, where necessary, and perform follow-up verification as appropriate. Evaluate any impact on work performed for the CRWMS M&O. Identify the cause for untimely corrective action and identify action needed to prevent recurrence.