



Department of Energy

Washington, DC 20585

DEC 26 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**

**ISSUANCE OF DEFICIENCY REPORT (DR) YM-97-D-020 RESULTING FROM OFFICE
OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT OQA-SA-97-006 OF MET ONE
INSTRUMENTS**

Enclosed is DR YM-97-D-020 generated as a result of OQA Supplier Audit OQA-SA-97-006.

Please provide a response to this deficiency that meets the applicable requirements of Administrative Procedure 16.1Q, Performance/Deficiency Reporting. Send the original of your response to Deborah Sult, OQA/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608. Response to the DR is due 20 working days from the date of this letter. Any extension to the due date must be requested in writing, with appropriate justification, prior to the due date.

If you have any questions, please contact either Mario R. Diaz at (702) 794-1489 or Daniel A. Klimas at (702) 794-1495.

James Blaylock
Donald G. Horton, Director
Office of Quality Assurance

OQA:MRD-0605

Enclosure:
DR YM-97-D-020

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PDR WASTE
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DEC 26 1996

L. D. Foust

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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
Records Processing Center = "8"

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV
D. A. Klimas, 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-020

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QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:

Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 5/Met One Instruments (MOI) Quality Control Manual, Revision 0, March 1, 1995

2 Related Report No.

OQA-SA-97-006

3 Responsible Organization:

Civilian Radioactive Waste Management System
Management and Operating Contractor/MOI

4 Discussed With:

Robert Justice/ Dennis Recla

5 Requirement/Measurement Criteria:

See Page 3

6 Description of Condition:

See Page 3

7 Initiator

Daniel Thomas

Date 12/18/96

9 Is condition an isolated occurrence?

☐ Yes

☒ No

☐ Unknown; Must be Yes if PR

10 Recommended Action: (Not required for PR)

Correct the noted deficiencies; develop the required implementing documents; train individuals to requirements and determine the impact of calibration services provided due to the lack of implementation of the Quality Program.

11 QA Review

QAR Daniel Klimas

Date 12/16/96

12 Response Due Date

20 working days from issuance

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

Printed Name Donald G. Horton

Signature *James Blaylock Jr*

Date 12/24/96

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.

PR/DR/NO. YM-97-D-020

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QA: L

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:

☐ Initial

☐ Amended

Date

Phone

20 Response Accepted

QAR

Date

21 Response Accepted (N/A for PR):

AOQAM

Date

**OFFICE OF CIVILIAN
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PR/DR CONTINUATION PAGE

5. Requirements: (continued from Page 1)

QARD, Section 4.0, Paragraph 4.2.1C.1:

A requirement for the supplier to have a documented Quality Assurance (QA) program that implements applicable QARD requirements prior to the initiation of work. The extent of the QA program shall depend on the scope, nature, or complexity of the item or service being procured.

6. Description of Condition: (continued from Page 1)

Contrary to the above requirements, the following conditions were identified during supplier Audit OQA SA-97-006 of MOI:

- 1) There are no implementing procedures that adequately describe the requirements for Implementing Documents, Document Control, Control of Purchased Items and Services, Corrective Action, QA Records, and Audits.
- 2) There is no objective evidence (i.e., documentation) that personnel performing quality related activities have been indoctrinated and trained to the technical and quality assurance elements that they implement.
- 3) The purchase orders for suppliers of calibration services (i.e., SIMCO; Caltronics), do not contain quality and technical requirements.
- 4) There is no documented evidence of evaluations for all MOI suppliers.
- 5) There is no procedure requirements for the review, approval, and control of implementing documents.
- 6) There are no methods to describe the identification, distribution, and control of procedures.
- 7) There is no evidence that the MOI QC Manual is reviewed annually, as required by their manual.
- 8) The temperature and humidity recorder, Serial Number 6529, is past due for calibration.
- 9) Measuring and Test Equipment utilized is not entered into the calibration system using the calibration sheets, as required by MOI procedure.
- 10) There are no controls for identifying or segregating out-of-calibration equipment.
- 11) There is no evidence of internal audits being performed, as required.