



Department of Energy

Washington, DC 20585

JUL 25 1997

QA: L

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

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY
REPORT (DR) YM-97-D-020 RESULTING FROM OFFICE OF QUALITY
ASSURANCE (OQA) SUPPLIER AUDIT OQA-SA-97-007 OF MET ONE
INSTRUMENTS

The OQA staff has verified the corrective action to DR YM-97-D-020 and determined the
results to be satisfactory. As a result, the DR is considered closed.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or
Daniel A. Klimas at (702) 734-0853.

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

OQA:JB-1980

Enclosure:
DR YM-97-D-020

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
R. A. Morgan, M&O, Las Vegas, NV

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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Recip: WMS/HLWR

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

8 Performance Report
 Deficiency Report

NO. YM-97-D-020

PAGE 1 OF 25
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 Klimas 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*

Date 12/24/96

22 Corrective Action Verified

QAR *Daniel Klimas*

Date 7/17/97

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

AOQAM *James Blaylock* Date 7/25/97

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U.S. DEPARTMENT OF ENERGY
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PR/DR NO. YM-97-D020
PAGE 2 OF 5
QA: L

PERFORMANCE/DEFICIENCY REPORT RESPONSE

14 Remedial Actions:

The Met One Instrument (MOI) Quality Control (QC) program and implementing Quality Operating Procedures (QOPs) will be reviewed and revised to comply with the direction and recommendations prescribed in the audit deficiency report. These activities are scheduled to be completed by March 3, 1997.

15 Extent of Condition: (Not required for PR)

There are several concerns listed in the deficiency report, which are directed at A program improvement. The extent of these conditions have been determined to be limited as programmatic in nature; having little or no adverse impact on the services provided by MOI.

16 Root Cause Determination: (Not required for PR) Required Yes No

Based upon discussion with Dennis Recla (MOI QA Manager) and M&O QA staff, it has been determined that the root cause determination is Code 1Bd, as prescribed in AP-16.4Q.

17 Action to Preclude Recurrence: (Not required for PR) Required Yes No

See continuation pages 4 of 5 and 5 of 5. Response is directed at resolution of concerns identified in Block 6, Description of Condition and Block 10, Recommended Actions.

18 Corrective Action Completion Due Date:

01/27/97
03/03/97

19 Response by: David Van Bibber

Initial
 Amended

Date 01/27/97

Phone (702)295-5072

20 Response Accepted

QAR

David Klimis Date *2/20/97*

21 Response Accepted (N/A for PR):

AOQAM

R.W. Cep Date *3/4/97*

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

Performance Report
 Deficiency Report

NO. YM-97-D-020

PAGE 3 OF 25
QA: L

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.

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

8 Performance Report
 Deficiency Report

NO. YM-97-D020
PAGE 4 OF 5
QA: L

PR/DR CONTINUATION PAGE

Block 17 (continuation)

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.

Response: Procedures (QOPs) and related processes, which govern these criteria will be revised to reflect the controls established and implemented by MOI. This activity is scheduled to be completed by March 3, 1997.

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.

Response: Subsequent to the audit, training documentation has been submitted for auditor review and acceptance.

3. The purchase orders for suppliers of calibration services (i.e., SIMCO; Caltronics), do not contain quality and technical requirements.

Response: QOP-1-1 will be revised to reflect this requirement. This activity is expected to be completed by March 3, 1997.

4. There is no documented evidence of evaluations for all MOI suppliers.

Response: Parts suppliers are not audited, however, calibration service suppliers are audited. Audit documentation of SIMCO has been completed. See attached..

5. There is no procedure requirements for the review, approval, and control of implementing documents.

Response: A QOP will be developed to prescribe the processes and controls for development, review, approval and control of QOPs. This activity is scheduled to be completed by March 3, 1997.

6. There are no methods to describe the identification, distribution, and control of procedures.

Response: Methods, which describe the identification, distribution, and control of QOPs, will be described in a QOP. This activity is scheduled to be completed by March 3, 1997.

7. There is no evidence that the MOI QC Manual is reviewed annually, as required by their manual.

Response: Requirements for annual review are to be modified to reflect an "as required or deemed necessary" frequency for review of the QC Manual.

8. The temperature and humidity recorder, Serial Number 6529, is past due for calibration.

Response: The temperature and humidity recorder, Serial Number 6529, has been recalibrated.

Continued on Page 5 of 5.

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

8 Performance Report
 Deficiency Report

NO. YM-97-D020
PAGE 5 OF 5
QA: L

PR/DR CONTINUATION PAGE

Block 17 (Continued from Page 4 of 5), Response to Block 6, Description of Conditions

9. Measuring and test Equipment utilized is not entered into the calibration system using the calibration sheets, as required by MOI procedure.

Response: QOP-2-2, will be revised to reflect current procedural practices. This revision will be accomplished by March 3, 1997.

10. There are no controls for identifying or segregating out-of-calibration equipment.

Response: QOP-2-2, will be revised to include segregation of equipment identified as being out-of-calibration.

11. There is no evidence of internal audits being performed, as required.

Response: Documentation and frequency of audits will be described in the MOI program. This activity is scheduled to be completed by March 3, 1997.

Response to Block 10, Recommended Action.

The noted deficiencies, as described in Block 6, will be corrected as described in the responses to the eleven concerns identified. Impacts to the calibration services provided have been evaluated and determined to have very little or no adverse impacts. The deficiencies identified are of a programmatic nature and do not impact the technical calibration services provided.

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

NO. YM-97-D-020

PAGE _____ OF _____

QA: L

PR/DR CONTINUATION PAGE

VERIFICATION OF CORRECTIVE ACTION FOR DEFICIENCY REPORT (DR) YM-97-D-020

Implementing procedures (QOPs) and the QA Manual have been developed and revised describing current practices and the requirements for implementing documents, document control, control of purchased items and services, corrective action, QA records and audits.

Indoctrination and training records have been provided for the technicians performing calibrations.

The QOP on purchasing has been revised to require appropriate requirements in purchase orders.

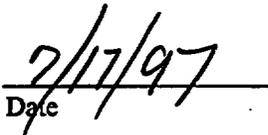
The evaluation for Simco (vendor) has been documented and provided to the QAR.

The temperature and humidity recorder has been calibrated.

The internal audit of Met One Instruments has been completed on 6/27/97.



Daniel A. Klimas, QAR



Date