Department of Energy
Washington, DC 20585

QA: L

MAY 20 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 AMENDED RESPONSE TO DEFICIENCY REPORT (DR) YM-97-D-020 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT OQA-SA-97-006 OF MET ONE INSTRUMENTS

The OQA staff has evaluated the amended response to DR YM-97-D-020. 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 that date. Please send a copy of extension requests to Deborah G. 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 Daniel A. Klimas at (702) 794-1495.

Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-1565

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

NH33
1021
wm-11

270092

recip: DWM/HLW

THIS IS A RED STAMP

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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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 Kilmas Date 12/13/96

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~~ Kilmas 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 B. Blaylock for 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.

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 Daniel Kunjas Date 2/20/97

21 Response Accepted (N/A for PR):
AOQAM R.W. Date 3/4/97

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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.

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; Caltroinics), 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.

Audits
QC Records
CA
CP 13.5

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WASHINGTON, D.C.

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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.

CERTIFICATION

This certifies that JACKIE BARNES has been properly trained on the assembly of 2484 Cup Assy. using the proper procedure and fully understands the performance and quality requirements involved.

Certified by [signature] Date : 8-9-96

R.D. Ralston Date : 8-9-96

Employee Jackie Barnes Date : 8-9-96

FAX FORM

MET ONE INSTRUMENTS
1600 WASHINGTON BLVD
GRANTS PASS OR 97526

TEL NO. (541) 471-7111
FAX NO. (541) 471-7116

From: Dennis Recla

To: David VanBibber

Company: CRWMS

Fax No: (702) 295-5223

Per Your Request __

Please Reply __

No. of Pages _7_

January 24, 1997

MSG:

Dear David

Here is the audit report on SIMCO that was done on November 18th, 1996. The calibration vendor has gone through a number of changes of ownership in the past year or so. They started as Caltronics, were bought out by AEL and recently purchased again by another company called SIMCO.

Received your FAX message, OK.

If you have any other questions regarding this , please contact me.

Regards

DENNIS RECLA
Quality Manager

Met One Instruments

November 19, 1996

TO: Joe Gran, Tom Pottberg, David Frith, Rod Ralston

FROM: Dennis Recla Manager Quality Control

SUBJECT: Audit of SIMCO, Instrument Calibration and Repair

On November 18th, David Frith and I went to the SIMCO Instrument Calibration and Repair Facility in Richardson, Texas. At the location we met with Eric Webb the operations supervisor. We have been using a company named AEL, but they were purchased by SIMCO. The structure of AEL, remains in place, and calibration documentation of AEL is being converted to SIMCO. There are no major changes that would effect the calibration and certification of the equipment that we send to them. AEL proceedures remain in place, and are being revised with SIMCO title blocks as required. The new QC Manual was given to us, and it is currently out to ISO for approval.

The combining of the two companies, has provided a much larger space to work in, and has added the addition of nearly all calibration data entry directly to the computer system. Test forms were examined, and several of the Standard Operating Proceedures were examined from the QC Manual.

Overall, it was a well kept facility, and documentation was controlled by the software provided by SIMCO. It also kept track of standards calibration, so that they could be recalled for certifications. I talked with them about certification of RTD probes and other temperature measurment devices, but they are still unable to provide the nccessary calibration. We will remain with Rosemount on these items.

Attached: Copy of Vendor Evaluation Questionaire

Met One Instruments

Southwest Office
3206 Main Street
Suite 106
Rowlett, Texas 75088
(214) 412-4716
(214) 412-4747
FAX (214) 412-4716

Oregon Office
(503) 471-7
FAX (503) 471-7116

Vendor Quality Rating Evaluation Questionnaire

GENERAL INFORMATION DATE: 11/18/96

Vendors Name: SIMCO

Address or Box No: 783 N. GROVE RD SUITE 106

City & State: RICHARDSON, TX 75081

Type of Work: -TEST EQ CALIBRATION-

Specific Product Line:

Survey for Approval of:

President or Owner SIMCO

Sales Contact John Kowalski Title GM

Quality Contact Eric Webb Title Ops Supervisor

Production Contact " " Title " "

Engineering Contact Carl Quinn Title VP. tech

Title

Quality Control Contact Eric Webb Answers To

Carl Quinn Title

Production Area, Clean X Lighted X Air Conditioned X

Inspection Area, Clean X Lighted X Air Conditioned X

General Comment: Formerly AEL

MET ONE INSTRUMENTS

VENDOR QUALITY RATING - Evaluation Questionnaire

Vendors Name _____

1.	Number of Production Personnel	14
2.	Number of Quality Control Personnel (Insp. & Test Operators not included)	3
3.	Number of Inspectors and Test Personnel	3
4.	Quality Control Manual Issued	Yes X No ___
5.	Does QC Program Comply with MIL-Q ~~9858~~ 45662A 2-540B	Yes X No ___
6.	Inspection, Quantities: Sample ___ 100% ___	N/A
7.	Sampling: MIL-STD-105 _____ 100% ___	
8.	Government Inspection Service Resident_____ Itinerant _____ AAF _____ Navy _____ Army _____ Ord. _____ Sig. Corp. _____	Yes ___ No ___ N/A
9.	Does Vendor Have Government Approval Type _____	Yes ___ No /
10.	Does Vendor Have Government Approved Process Type _____	Yes ___ No ___ N/A
11.	Does Vendor use Sub-contractors Foundry_____ Welding_____ Heat Treat_____ Assembly_____ Finishing_____ Testing_____	Yes ___ No ___
12.	Does Vendor have Process Specifications	Yes X No ___
13.	Does Vendor Have Laboratory Facility	Yes X No ___
14.	Is Laboratory Facility Certified	Yes ___ No ___
15.	Does Vendor Maintain Certification	Yes ___ No ___ N/A

MET ONE INSTRUMENTS

VENDOR QUALITY RATING - Evaluation Questionnaire

Vendors Name _____

16. MEASURING EQUIPMENT

N/A Master Gage Blocks		Microscopes	
Working Gage Blocks		Gear Wires	
Supermike		Gear Checker	
Surface Plates		Master Gears	
Angle Plates		Thread Plugs	
Pla-Check		Thread Rings	
Height Gages		Set Plugs	
Indicators		Air Gaging	
Profilometer		Magna-flux or Zyglo	
Optical Projector		Hardness Checker	

17. TESTING EQUIPMENT

Analyzers	✓	Volt Standards	✓
Attenuators	✓	Res. Standards	✓
Bridges	✓	Oscilloscopes	✓
Counters	✓	Strobotac	✓
Gaussmeters		Timers	✓
Signal Generator	✓	Tube Tester	✓
Amp Meters	✓	Multi-meters	✓
Amp Standards	✓	Watt-meters	✓
Temperature Standard	✓	Frequency Standard	✓

18. SPECIAL EQUIPMENT _____

19. Does Vendor Calibrate Measuring and Testing Equipment — Yes X No

20. Is there a Calibration Schedule — Yes X No

21. Are wear allowances set-up — Yes X No

22. Are Gages Seal - Peal dipped — Yes ___ No ___

23. Is Gage Room Temperature Controlled — Yes ___ No ___

24. Does Vendor Issue & Control Meesuring and Test Equipment — Yes X No ___

25. Is Measuring Testing Equipment for Quality Control use only — Yes X No ___

26. Is Measuring and Testing Equipment for all Engineering and Production Use — Yes X No ___

N/A

MET ONE INSTRUMENTS

VENDOR QUALITY RATING - Evaluation Questionnaire

Vendors Name _____

27.	Does Vendor Issue Production Procedures	Yes X No ___
28.	Does Vendor Have own Print System	Yes X No ___
29.	Does Vendor Issue Inspection Procedures	Yes X No ___
30.	Does Vendor Issue Test Procedures	Yes X No ___
31.	Does Vendor Control Production Tooling	Yes X No ___
32.	Does Vendor Have Material Review	Yes X No ___
33.	Is Material Review documented	Yes X No ___
34.	Are deviations cleared with customer SOP 10-01-01	Yes X No ___
35.	Does Material Review initiate Corrective Action	Yes X No ___
36.	Does Vendor have Salvage Control	Yes ~~No~~ N/A
37.	Does Vendor have Plating Facilities Type _____	Yes ~~No~~
38.	Does Vendor have Painting Facilities Type _____	Yes ~~No~~ N/A
39.	Are Comparison Standards used for Inspection of Plating/Painting	Yes ~~No~~
40.	Does Vendor Have Receiving Inspection	Yes X No ___
41.	Does Vendor Have First Part Inspection	Yes X No ___

MET ONE INSTRUMENTS

VENDOR QUALITY RATING - Evaluation Questionnaire

Vendors Name _____

42.	Does Vendor have In-Process Inspection	Yes X No ___
43.	Does Vendor have Finish Inpsection	Yes X No ___
44.	Does Vendor have Final Inpsection	Yes X No ___
45.	Does Vendor Have Functional Test	Yes X No ___
46.	Does Vendor use Inpsection and/or Process Stamp Identification	Yes ___ No ___
	(Samples if Convient) Company controlled AT THE time	
47.	Does Vendor Comply with Government Shipping Specs	Yes X No ___
48.	Are Packaging Methods Satisfactory	Yes X No ___
49.	Are Packing Procedures Written	Yes X No ___
50.	Does Vendor have Shipping Inspection	Yes X No ___

EVALUATION TEAM

#1 [signature] Dept. QC Div. LP

#2 Davis Frith Dept. TEST Div. Packett

#3 _____ Dept. _____ Div. _____

#4 _____ Dept. _____ Div. _____

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

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

See Continuation Page from 4/17/97 response.

18 Corrective Action Completion Due Date: 05/15/97

19 Response by: See 4/17/97 response.
☐ Initial
☑ Amended Date 04/17/97 Phone

20 Response Accepted
QAR Date 5/14/97

21 Response Accepted (N/A for PR):
AOCAM Date 5/19/97

Exhibit AP-16.1Q.2 Rev. 07/15/96

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PR/DR CONTINUATION PAGE

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

Page 5 of 5, *AMENDED RESPONSE*, 4/17/97

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 of audits will be described in the MOI program. An internal audit is being scheduled to be completed by May 15, 1997.

Response to Block, 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.

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