



# Department of Energy

Washington, DC 20585

FEB 29 1996

L. Dale 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) YMQAD-96-D043 RESULTING FROM  
OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT OQA-SA-96-011 OF  
SANDIA NATIONAL LABORATORIES (SCPb: N/A)

Enclosed is DR YMQAD-96-D043 generated as a result of OQA  
Supplier Audit OQA-SA-96-011.

Please identify the corrective action to be taken and  
implemented to correct the deficiency. A DR Continuation Page  
has been provided. Send the original of your response to  
Deborah Sult, YMQAD/QATSS, 101 Convention Center Drive,  
Suite 640, Las Vegas, Nevada 89109. Response to the DR is due  
20 working days from the date of issuance. Any extension to due  
date must be requested in writing, with appropriate  
justification, prior to the due date.

If you have any questions, please contact either Robert B.  
Constable at 794-7945 or Richard L. Maudlin at 794-7290.

*Robert B. Constable*

YMQAD:RBC-1268

Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

## Enclosures:

1. DR YMQAD-96-D043
2. PR/DR Continuation Page

050067



Printed with soy ink on recycled paper

9603050399 960229  
PDR WASTE  
WM-11 PDR

102.7  
WM-11  
N403

L. Dale Foust

-2-

FEB 29 1996

cc w/encls:

T. A. Wood, HQ (RW-14) FORS  
J. G. Spraul, NRC, Washington, DC  
S. W. Zimmerman, NWPO, Carson City, NV  
R. R. Richards, M&O/SNL, Albuquerque, NM, M/S 1333  
R. L. Strickler, M&O, Vienna, VA  
R. P. Ruth, M&O, Las Vegas, NV

cc w/o encls:

W. L. Belke, NRC, Las Vegas, NV  
R. L. Maudlin, YMQAD/QATSS, Las Vegas, NV  
D. G. Sult, YMQAD/QATSS, Las Vegas, NV

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

8 ☐ Performance Report  
☒ Deficiency Report  
NO. YMQAD-96-D043  
PAGE 1 OF 3  
QA: L

**PERFORMANCE/DEFICIENCY REPORT**

1 Controlling Document:  
OCRWM Quality Assurance Requirements and Description (QARD), Rev. 5

2 Related Report No.  
OQA-SA-96-011

3 Responsible Organization:  
SNL Primary Stds. Lab/Sandia Stds. Lab/LLNL/SNL

4 Discussed With:  
R. Pettit / D. Braudaway / R. Richards

5 Requirement/Measurement Criteria:


- A. QARD, Section 5.0, Subsection 5.2.2, states in part: "Implementing documents shall include the following information .... to the work to be performed .... (C) A sequential description of the work to be performed .... (D) Quantitative and qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished."
- B. QARD, Section 5.0, Subsection 5.2.3, states: "Implementing documents shall be reviewed, approved, and controlled in accordance with Section 6.0, Document Control."
- C. QARD, Section 12.0, Subsection 12.2.7, states, in part: "M&TE calibration documentation shall include the following information: .... (B) Traceability to the calibration standard used for calibration ...."


6 Description of Condition:  
Contrary to the above:

A. Operating and Procedures' (O&P) implementing documents in some instances are vague, ambiguous, or nonexistent. Examples include:

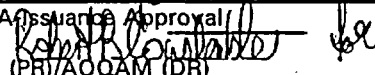
1. Calibration guideline 5.1 indicates end user will establish standard calibration interval; however, the interval for the Digital Temperature Indicator, serial #4559, owned by the Temperature Lab (Sandia Standards Lab) was established by the Primary Standards Lab. Note: There was confusion over who the end user is.
2. There was no procedure for the generation of records which described how records are corrected.

(Continued on Page 3)

7 Initiator   
Richard L. Maudlin Date 02/27/96

9 QA Review  
QAR  Date 2/27/96

10 Response Due Date  
20 Working Days from Issuance

11 QA Assurance Approval  
QAR (PR)/AOQAM (DR)  Date 2-28-96

12 Remedial Actions:

13 Remedial Action Response By:  
Date

14 Remedial Action Due Date  
Date

15 Remedial Action Response Acceptance  
QAR Date

16 PR Verification/Closure  
QAR Date

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

8  
DR NO. YMQAD-96-D043  
PAGE 2 OF 3  
QA: L

**DEFICIENCY REPORT**

**17 Recommended Actions:**

- A. Review MSP Quality/Business Plan and assure that all applicable elements of the QARD are included. Evaluate all references to the O&P Manual to assure implementing procedures exist.
- B. Clarify O&P implementing documents and generate implementing procedures as appropriate to address requirements of MSP Quality/Business Plan and QARD.
- C. Resolve discrepancies with all examples noted in Block 6 of this deficiency report.

(Continued on Page 3)

**18 Investigative Actions:**

**19 Root Cause Determination:**

**20 Action to Preclude Recurrence:**

**21 Response by:**

Date

**22 Corrective Action Completion Due Date:**

**23 Response Accepted**

QAR

Date

**24 Response Accepted**

AOQAM

Date

**25 Amended Response Accepted**

QAR

Date

**26 Amended Response Accepted**

AOQAM

Date

**27 Corrective Actions Verified**

QAR

Date

**28 Closure Approved by:**

AOQAM

Date

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

8 ☐ Performance Report  
☒ Deficiency Report

NO. YMQAD-96-D043

PAGE 3 OF 3

QA: L

PR/DR CONTINUATION PAGE

BLOCK 6 - Description of Condition: (Continued)

3. There are no implementing procedures which define a formal internal audit program.
  4. The MSP Quality/Business Plan, Section 5.3.3, references that out-of-tolerance situations are contained in O&P Manual 5.1; however, procedural requirements for out-of-tolerance situations have been deleted from the O&P Manual.
  5. There were no implementing procedures which describe the process for documenting and processing nonconformances.
- B. Objective evidence is not available in all cases to demonstrate that calibration procedures have been reviewed and approved by authorized personnel (example: calibration procedure titled "Resistive Temperature Device Certification," dated 3/30/89).
- C. O&P procedures do not require M&TE calibration documentation to include reference to the standard(s) used to perform the calibration. Also, M&TE calibration documentation was found not to reference standard(s) used to perform the calibration.

BLOCK 17 - Recommended Actions: (Continued)

- D. Develop procedural requirement to reference standards in calibration documentation used in calibration of YMP equipment/standards. Implement requirements.