



**Department of Energy**  
Office of Civilian Radioactive Waste Management  
Yucca Mountain Site Characterization Office  
P.O. Box 98608  
Las Vegas, NV 89193-8608

MAY 31 1996

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Technical Project Officer  
for Yucca Mountain  
Site Characterization Project  
TRW Environmental Safety Systems, Inc.  
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101 Convention Center Drive  
Las Vegas, NV 89109

EVALUATION OF RESPONSE TO DEFICIENCY REPORT (DR) YMQAD-96-D043  
RESULTING FROM OFFICE OF QUALITY ASSURANCE SUPPLIER AUDIT  
OQA-SA-96-011 OF SANDIA NATIONAL LABORATORIES (SCPB: N/A)

The Yucca Mountain Quality Assurance Division staff has evaluated the response to DR YMQAD-96-D043. The response has been determined to be unsatisfactory because of reasons stated in the enclosed DR.

An amended response is required to be submitted to this office within ten working days of the date of this letter. Send the original of your response to Deborah Sult, YMQAD/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608. If an extension to the due date is necessary, it must be requested in writing, with appropriate justification, prior to that date.

If you have any questions, please contact either Robert B. Constable at (702) 794-7945 or Richard L. Maudlin at (702) 794-1302.

Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

YMQAD:RBC-1848

Enclosure:  
DR YMQAD-96-D043

cc w/encl:

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

cc w/o encl:

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

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

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**PERFORMANCE/DEFICIENCY REPORT**

1 Controlling Document: OCRWM Quality Assurance Requirements and Description (QARD), Rev. 5	2 Related Report No. OQA-SA-96-011
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3 Responsible Organization: SNL Primary Stds. Lab/Sandia Stds. Lab/LLNL/SNL	4 Discussed With: R. Pettit / D. Braudaway / R. Richards
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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 <i>R. Maudlin</i> Richard L. Maudlin Date 02/27/96	9 QA Review QAR <i>R. Maudlin</i> Date 2/27/96
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10 Response Due Date 20 Working Days from Issuance	11 QA Issuance Approval <i>R. Maudlin</i> QAR (PR)/AQQAM (DR) Date 2-28-96
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12 Remedial Actions:

13 Remedial Action Response By: Date	14 Remedial Action Due Date Date
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15 Remedial Action Response Acceptance QAR Date	16 PR Verification/Closure QAR Date
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**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

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**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.

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EVALUATION OF RESPONSE TO DR YMQAD-96-D043

The response to the subject DR has been reviewed and found unacceptable, except where noted otherwise, in responding to the condition adverse to quality for the following reasons.

- A(1). **RESPONSE:** No action required. O&P 5.1.7, Intervals, requires that project leaders are responsible for establishing and adjusting certification intervals; the requirement portions of the document are developed around satisfying the "customers" needs. The term "end user" is used only in the background discussion section of the document in describing some existing calibration/interval philosophies.

**EVALUATION:** The QARD, Section 12, Subsection 12.2.1 requires that the method and interval of calibration for each device be defined, based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting measurement control. Identifying in a procedure that the project leader will determine the interval is not a defined requirement that can be measured against the QARD. Intervals must be defined within the quality program for each standard used in the calibration of equipment for the OCRWM program. Please re-evaluate your response and identify how and where the interval for each standard will be addressed and the basis for establishing the interval.

- A(2) **RESPONSE:** The Quality/Business Plan will be revised to provide instructions on how to make corrections to records in a manner that does not compromise records.

**EVALUATION:** Corrections to records must be accomplished as required by the QARD. The QARD requires that corrections to QA records including documents which will become QA records shall include the initials or signature of the person authorized to make the correction and the date the correction was made. Please re-evaluate your response to assure that the change to the Quality/Business Plan address the requirements of the QARD.

- A(3) **RESPONSE:** A more formalized and documented internal audit procedure has been developed to meet the requirements of NVLAP. This documented procedure has been submitted to NVLAP for review. It will be issued and implemented upon NVLAP acceptance.

**EVALUATION:** NVLAP requirements for an audit program tend to be more focused on the technical requirements, but less focused on documentation. The QARD, Section 18, subsection 18.2.1 requires that internal audits are to be performed of the work to verify QA program compliance at least annually. It is important that the internal audit program adequately meet the requirements of the QARD along with that of NVLAP. An evaluation of the QARD requirements with those of NVLAP should be performed to determine similarity in requirements. Where the QARD identifies requirements different than that of NVLAP, determinations need to be made as to how the PSL is going satisfy those requirements. Please re-evaluate your response and identify where and how PSL intends to meet the audit requirements of the OCRWM QARD.

- A(4) **RESPONSE:** This finding is in error. The documentation in 5.1 has not been deleted. O&P 5.1.2 DOE/SNL requirements which references SLI 2855 and OI 2855-A and 2855-B, OI 2855-A, Standards and Calibration Program, gives the specific procedures to be followed for out-of-tolerance reporting within Sandia. The reference to out-of-tolerance as listed in the MSP Quality/Business Plan, section 5.3.3 has been corrected to identify the correct reference.

**EVALUATION:** Response acceptable. Will be verified during a scheduled follow-up verification of PSL.

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A(5) RESPONSE: The issue of dealing with nonconformances will be addressed by the Quality Council. If any cases of nonconformances other than out-of-tolerance conditions and defective material received via procurement, situations which are covered by existing SNL procedures or will be addressed by the action above, are identified for MSP operations, procedural guidance for dealing with such nonconformances will be developed and issued.

EVALUATION: Your response is not clear as to what the final action is regarding the development of a procedure to address the control of nonconforming items. Please re-evaluate your response and identify what action you are taking in the development of a nonconforming procedure which addresses the appropriate requirements of the QARD.

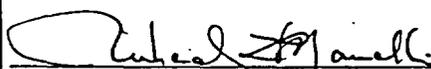
B RESPONSE: O&P 5.2.3, Project Summary contains a listing of the approved calibration procedures for each project. The summary also lists the status of each calibration procedure as determined by internal self-survey. Because of the complexity of moving into the new facility, adding some new measuring capability and consolidating other calibration capability into the MSP, these are not currently up-to-date. To update this summary, Project Leaders will be asked to review their project's calibration procedures and complete the summary update by August 1996. The documentation provided by the Project Summary indicates formal approval of existing procedures by the project leader. This summary will continue to be updated periodically.

EVALUATION: Response acceptable. Will be verified during a scheduled follow-up verification of PSL.

C RESPONSE: This finding is in error. O&P 5.2.2, Item 2, Requirements for Data Sheets in the PSL (MSP), gives the requirements for listing of all reference standard(s) or instrument(s) and their expiration dates used in the calibration. Rather than on the certificate or report, the information is in the data file which is part of the documentation for each calibration. Also, MSP Quality/Business Plan, Section 5.3.5, states the requirement that the data file for all calibrations shall contain the "identification of the appropriate standards, calibrated M&TE and auxiliary equipment used to perform the calibration."

EVALUATION: During the course of the audit, documentation which referenced the standards used in the calibration of equipment was requested. At that time no one provided either a procedure or the documentation. Subsequently, compliance to the requirements of the QARD could not be established. Response is acceptable. The procedures you reference and evidence of compliance will be verified during a scheduled follow-up verification of PSL.

The quality program for all of OCRWM, which includes the Affected Organizations and their suppliers is the Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description Document. It should be noted that the QARD does allow the grading of quality requirements, however, there are no provisions to deviate from the requirements. PSL is encouraged to work with the SNL YMP QA Manager and the OCRWM Office of Quality Assurance in resolving the noted conditions.

  
Richard L. Maudlin, QAR

5/23/96  
Date