



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

SEP 12 1996

R. W. Craig  
Technical Project Officer  
for Yucca Mountain  
Site Characterization Project  
U.S. Geological Survey  
1261 Town Center Drive  
Building 4, Room 423, M/S 423  
Las Vegas, NV 89134

**EVALUATION OF AMENDED RESPONSE TO DEFICIENCY REPORT (DR) YM-96-D-046  
RESULTING FROM OFFICE OF QUALITY ASSURANCE SUPPLIER AUDIT  
OQA-SA-96-012 OF COLORADO DEPARTMENT OF AGRICULTURE**

The Yucca Mountain Quality Assurance Division staff has evaluated the amended response to DR YM-96-D-046. The amended 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 Sult, YMQAD/QATSS, P.O. Box 98608, Mail Stop 455, Las Vegas, Nevada 89193-8608.

If you have any questions, please contact either Robert B. Constable at (702) 794-5580 or Richard L. Maudlin at (702) 794-1302.

Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2630

Enclosure:  
DR YM-96-D-046

cc w/encl:  
J. G. Spraul, NRC, Washington, DC  
S. W. Zimmerman, NWPO, Carson City, NV  
T. H. Chaney, USGS, Denver, CO  
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  
D. G. Horton, 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. YMOAD-96-D046

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:

OCRWM QARD, DOE/RW-0333P, Revision 5

2 Related Report No.

OQA-SA-96-012

3 Responsible Organization:

Colorado Dept. of Agriculture/U.S. Geological Survey  
(USGS)

4 Discussed With:

W. Young / W. Rodman / A. Lykins

5 Requirement/Measurement Criteria:

- A. QARD, Section 12.0, Subsection 12.2.1A, states in part: "Measuring and Test Equipment....shall be calibrated...against reference calibration standards having traceability to nationally recognized standards."
- B. QARD, Section 12.0, Subsection 12.2.7, states in part: "Measuring and Test Equipment calibration documentation shall include the following information....identification of the implementing document (including revision level) used in performing the calibration."
- C. QARD Section 17.0, Subsection 17.2.11, states in part: "....QA Records shall be temporarily stored in a container or facility with a fire rating of 1hr, or dual storage shall be provided."
- D. QARD, Section 12.0, Subsection 12.2.1, states in part: "Software developed or modified by the user shall be controlled in accordance with Supplement I, Software." QARD, Supplement I, Subsection I.2.3, states: "The software verification shall be performed and documented to insure that baseline elements meet the established requirements."

6 Description of Condition:

Contrary to the above:

- A. No documentation could be provided to demonstrate the calibration of the devices used to monitor temperature, humidity, and barometric pressure in the laboratory.
- B. Calibration documentation for the calibration of USGS standards Troemner 211.11g x 1mg weight set, Troemner 1kg weight, and Ainsworth 222.221g x 1mg weight set does not reference the procedure(s) used to perform the calibration.
- C. Calibration records (worksheets) maintained by the Colorado Dept. of Agriculture are not being stored in a 1hr fire rated cabinet or in duplicate storage.
- D. Computer software has been developed by the Colorado Dept. of Agriculture in performing the calculations described in SOPs 2 and 4; however, there is no documentation to indicate that the software was tested for validity prior to use.

7 Initiator

Richard L. Maudlin

Date 3/13/96

9 QA Review

QAR

Date

3/14/96

10 Response Due Date:

20 Working Days From Issuance

11 QA Issuance Approval

QAR (PR)/AOQAM (DR)

Date 3-19-96

12 Remedial Actions:

13 Remedial Actions Response By:

Date

14 Remedial Action Due Date

Date

15 Remedial Action Response Acceptance

QAR

Date

16 PR Verification /Closure

QAR

Date

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8

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DEFICIENCY REPORT

17 Recommended Actions:

- A. Take the necessary action to document last calibration of devices used to monitor laboratory environment. Document all future calibrations.
- B. Update all USGS calibration records to include the procedure and revision of the procedure used to perform USGS calibrations. Establish controls to assure this occurs in future calibrations.
- C. Either require Colorado Dept. of Agriculture to maintain calibration and other records in a 1hr fire rated facility or duplicate storage, or request all pertinent records to be submitted to USGS for storage.
- D. Document the testing (verification) of software program Doublesb.bas. Provide documented requirements for version control and software verification (testing for validity).

18 Investigative Actions:

SEE ATTACHED SHEET

19 Root Cause Determination:

20 Action to Preclude Recurrence:

With each purchase order the USGS will request that work be done according to SOPs 2 and 4, and that calibration worksheets be included with calibration documentation.

21 Response By:

*T. M. L. [Signature]*

Date *5/32/98*

22 Corrective Action Completion Due Date

23 Response Accepted

QAR

Date

24 Response Accepted

AOQAM

Date

25 Amended Response Accepted

QAR *[Signature]*

Date *09/04/96*

26 Amended Response Accepted

AOQAM *[Signature]*

Date *9/12/96*

27 Corrective Action Verified

QAR

Date

28 Closure Approved by:

AOQAM

Date

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**DEFICIENCY REPORT - YMQAD-96-D046**

**Remedial Actions: Block 12**

None.

**Investigative Actions: Block 18**

A. The Colorado Department of Agriculture is not required by YMP/USGS, the State of Colorado or by NIST to calibrate laboratory environmental monitoring equipment. The computation of uncertainty used during a calibration is broad enough to account for changes in environmental conditions that may occur in the laboratory.

B. NIST Handbook 145, SOP 2 and 4 are the only methods used since 1986. Adherence to and changes to these methods can be verified during annual evaluations and triennial audits. USGS procurements will specify that all calibrations be performed according to these SOPs.

C. The Colorado Department of Agriculture does not plan to purchase 1-hour fire rated facilities. The USGS will request that calibration worksheets be provided with calibration documentation.

D. William Young, Chief Metrologist, Department of Agriculture, has hand-verified the Doublesp.bas software. No documentation is needed or required by the Department of Agriculture program. Documentation of software and version control will be addressed upon implementation of ISO 9000 which is expected to occur approximately March 1997.

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**PR/DR CONTINUATION PAGE**

**EVALUATION OF RESPONSE TO DR YMQAD-96-D046**

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

- A. **RESPONSE:** The Colorado Department of Agriculture is not required by YMP/USGS, the State of Colorado or by NIST to calibrate laboratory environmental monitoring equipment. The computation of uncertainty used during a calibration is broad enough to account for changes in environmental conditions that may occur in the laboratory.

**EVALUATION:** The response does not provide sufficient detail for evaluation. Please provide the appropriate computational criteria and the allowable uncertainty values and how they relate to temperature and humidity. Also please provide the manufactures specifications regarding environmental criteria for the calibration of such weights.

- B. **RESPONSE:** NIST Handbook 145, SOP 2 and 4 are the only methods used since 1986. Adherence to and changes to these methods can be verified during annual evaluations and triennial audits. USGS procurements will specify that all calibrations be performed in accordance with SOPs.

**EVALUATION:** As was stated in the DR, QARD, Section 12.0, Subsection 12.2.7 requires that measuring and test equipment calibration documentation include the identification of the implementing document, including revision level, used in performing the calibration. There are no provisions in the QARD to allow for verification of the procedures used to perform the calibration by audits, surveillances or annual evaluation. The requirements are explicit in that the procedure and revision level be documented on the calibration documentation. Please re-evaluate your response in light of the requirements and identify how USGS intends to assure that the calibration documentation identifies the procedures and revision level used to perform the calibration. No alternative methods to those stated in the QARD will be accepted unless the QARD is modified to allow for these exceptions.

- C. **RESPONSE:** The Colorado Department of Agriculture does not plan to purchase 1-hour fire rated facilities. The USGS will request that calibration work sheets be provided with calibration documentation.

**EVALUATION:** The response is satisfactory except that it does not address past calibration documentation. Please amend this response to include the disposition of previous calibration documentation.

- D. **RESPONSE:** D. William Young, Chief Metrologist, Department of Agriculture, has hand verified the Doublesp.bas software. No documentation is needed or required by the Department of Agriculture program. Documentation of software and version control will be addressed upon implementation of ISO 9000 which is expected to occur approximately March 1997.

**EVALUATION:** As was stated in the DR, QARD, Section 12.0, Subsection 12.2.1 requires that software developed or modified by the user shall be controlled in accordance with Supplement I, Software. QARD, Supplement I, Subsection 1.2.3 requires software verification to be performed and documented to insure that baseline elements meet the established requirements. The Colorado Department of Agriculture, as an approved supplier of calibration services, is required to have a program which satisfies the requirements of the QARD. Please re-evaluate you response and identify the measures that will be taken to assure that the Colorado Department of Agriculture documents the verification and version control of all software used in the calibration of USGS equipment.

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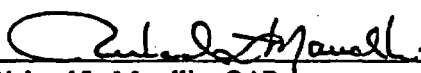
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The quality program for all of OCRWM, which includes the Affected Organizations and their suppliers is the Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description Document. It should be noted that the QARD does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

  
Richard L. Maudlin, QAR

5/27/96  
Date

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DEFICIENCY REPORT

17 Recommended Actions:

- A. Take the necessary action to document last calibration of devices used to monitor laboratory environment. Document all future calibrations.
- B. Update all USGS calibration records to include the procedure and revision of the procedure used to perform USGS calibrations. Establish controls to assure this occurs in future calibrations.
- C. Either require Colorado Dept. of Agriculture to maintain calibration and other records in a 1hr fire rated facility or duplicate storage, or request all pertinent records to be submitted to USGS for storage.
- D. Document the testing (verification) of software program Doublesb.bas. Provide documented requirements for version control and software verification (testing for validity).

18 Investigative Actions:

SEE ATTACHED SHEET

19 Root Cause Determination:

20 Action to Preclude Recurrence:

With each purchase order the USGS will request that work be done according to SOPs 2 and 4, and that calibration worksheets be included with calibration documentation.

21 Response By:

Date

22 Corrective Action Completion Due Date

August 15, 1996

23 Response Accepted

QAR

Date

24 Response Accepted

AOQAM

Date

25 Amended Response Accepted

QAR

Date

26 Amended Response Accepted

AOQAM

Date

27 Corrective Action Verified

QAR

Date

28 Closure Approved By:

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**DEFICIENCY REPORT - YMQAD-D046**

**Remedial Actions: Block 12**

Response A: Although many calibration labs choose to calibrate environmental monitoring equipment, based on the professional judgement of the Chief Metrologist and in concurrence with NIST, the Deptment of Agriculture does not.

Response B: The intent of the QARD relative to calibration procedures is to be able to identify which procedures were used. The original response identifies the only two procedures in use. The USGS will specify in future purchase orders that these procedures shall be followed and request that the calibration documentation identify which procedure was used.

Response C: The USGS will request copies of worksheets for FY96 calibrations and the Deptment of Agriculture is willing to supply them in the future.

Response D: The software employed by Deptment of Agriculture is simplistic in nature and has been verified by the Chief Metrologist. There is no documentation available and since the verification of software changes was verified during this audit, none will be requested. The referenced QARD requirements have not been fully transitioned into the USGS program. Software documentation requirements will be revised appropriately in FY97 procurements.



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**DEFICIENCY REPORT - YMQAD-D046**

**Remedial Actions: Block 12**

**Response A:** Although many calibration labs choose to calibrate environmental monitoring equipment, based on the professional judgement of the Chief Metrologist and in concurrence with NIST, the Department of Agriculture does not. The computation of uncertainty used during a calibration is broad enough to account for changes in environmental conditions that may occur in the laboratory.

**Response B:** The intent of the QARD relative to calibration procedures is to be able to identify which procedures were used. The original response identifies the only two procedures in use. The USGS will specify in future purchase orders that the calibration documentation identify which procedure was used.

**Response C:** The USGS will request copies of worksheets for FY96 calibrations and the Department of Agriculture is willing to supply them in the future.

**Response D:** The software employed by Department of Agriculture is simplistic in nature and has been verified by the Chief Metrologist. The USGS will work with Colorado Department of Agriculture to ensure that their software is verified and the verification documented.

**Completion Date:** December 15, 1996

Submitted by: \_\_\_\_\_

*T. H. Chaney*  
T. H. Chaney, Quality Assurance Manager-YMP

Date: \_\_\_\_\_

*4/4/96*

*9/4/96 Chaney to Spence*