



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

MAY 03 1996

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Acting Technical Project Officer
for Yucca Mountain
Site Characterization Project
U.S. Geological Survey
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EVALUATION OF RESPONSE TO DEFICIENCY REPORT (DR) YMQAD-96-D035
RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA) SUPPLIER AUDIT
OQA-SA-96-009 OF CAMPBELL SCIENTIFIC, INC. (SCPB: N/A)

The Yucca Mountain Quality Assurance Division staff has evaluated the response to DR YMQAD-96-D035. 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 the date. Please send a copy of extension requests to Deborah Sult, YMQAD/QATSS, 101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109.

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

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-1651

Enclosure:
DR YMQAD-96-D035

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

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.

8 ☐ Performance Report
☒ Deficiency Report
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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document

OCRWM QARD, Rev. 5 / USGS PO 1434-CR-SA-00200 / Campbell Scientific, Inc.
QA Manual, Rev. 01

2 Related Report No.

OQA-SA-96-009

3 Responsible Organization

Campbell Scientific, Inc. / USGS

4 Discussed With

P. Campbell / C. Howell / T. Chaney

5 Requirement/Measurement Criteria

QARD, Section 5.0, Subsection 5.2, states: "Work shall be performed in accordance with controlled implementing documents."

USGS PO, Quality Assurance Requirements for Supplier of Calibration Services, states in part: "...Procedures...and include methods used for ensuring only the latest revision of the procedure is used."

Campbell Scientific, Inc. QA Manual, Subsection 4.2.1, states in part: "...The QA Manager shall be responsible for preparation of a documented quality system, procedures, and instructions..."

6 Description of Condition

Contrary to the above, implementing procedures which implement the Campbell Scientific, Inc. QA Manual are not complete and have not been issued for implementation by Campbell Scientific, Inc. personnel. Subsequently, requirements as stated in the Campbell Scientific, Inc. QA Manual have not been implemented. Examples are as follows:

1. No evidence of management reviews of internal quality audits at least annually.
2. The implementing procedure for audits is only in draft. No implementing procedure for Measuring and Test Equipment.
3. No documented evidence of qualification indoctrination and training of personnel.
4. No records exist to demonstrate supplier qualification, vendor performance, and reliability for Stabro, who was used to calibrate standards used in USGS calibrations

7 Initiator

Richard L. Maudlin

Date 2/1/96

9 QA Review

QAR

Date 2-5-96

10 Response Due Date

20 Working Days From Issuance

11 QA Issuance Approval

QAR (PRIVACQAM) FOR

Date 2-6-96

12 Remedial Actions

SEE ATTACHED SHEET

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DEFICIENCY REPORT

17 Recommended Actions:

1. Take immediate action to issue and implement procedures which support the Campbell Scientific, Inc., QA Manual.
2. Evaluate each example identified against all work performed for USGS and determine impact on quality.
3. Implement corrective action to resolve each of the examples noted.
4. Investigate and document the cause of the condition and all associated examples.
5. Identify what measures have been taken to prevent the condition and noted examples from recurring.

18 Investigative Actions:

SEE ATTACHED SHEET

19 Root Cause Determination:

NOT APPLICABLE

20 Action to Prevent Recurrence:

SEE ATTACHED SHEET

21 Response by

Ernest Huber

Date 4/17/96

22 Corrective Action Completion Due Date

NOT APPLICABLE

23 Response Accepted

QAR *OK*

Date 4/22/96

24 Response Accepted

AOQAM *RBC*

Date 5-2-96

25 Amended Response Accepted

QAR

Date

26 Amended Response Accepted

AOQAM

Date

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Block 6 : DESCRIPTION OF CONDITION (continued)

5. Wayne 723T PRT was listed on USGS Certificates of Calibration as a Standard used to calibrate two dataloggers. First, the serial number of standard was erroneous and second, no documented evidence exists to indicate 723T PRT was calibrated to standards traceable to NIST.
6. A deficiency report was generated to document a deficiency in procurement, but unable to find deficiency report.
7. Handwritten calibration data filed to support USGS calibrations is not being stored in a 1-hour fire rated facility or container to prevent destruction by fire.
8. Audits of all levels of the quality system within each year have not been performed.

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PR/DR CONTINUATION PAGE

Remedial Actions: Block 12

Campbell Scientific, Inc is in the process of developing a new documented quality assurance system. The new system will include implementing procedures for annual internal audits as well as implementing procedures for M&TE. Campbell estimates that preparation, training, and implementation will be completed in August 1996.

Corrective actions will be evaluated upon implementation of the new Campbell quality system.

Investigative Actions: Block 18

Condition 1: Annual evaluations and triennial audits performed by USGS have consistently found the work performed by Campbell to be technical adequate.

Condition 2: The lack of procedures for internal audits is a programmatic issue which has not adversely affected USGS calibrations.

Condition 3: Direct surveillance of personnel performing calibrations has shown that Campbell employs a qualified, well trained staff, therefore, the lack of qualification and training records has no effect on USGS products.

Condition 4: USGS has never imposed requirements for vendor qualification on Campbell Scientific. Campbell's consistent record of equipment reliability throughout the years and widespread acceptance of their equipment within the scientific community provides a high degree of confidence in equipment accuracy.

Condition 5: The PRT listed on calibration documentation was an error. The documentation has been corrected.

Condition 6, 7, 8: These programmatic conditions have no effect on USGS products.

Campbell had anticipated the implementation of an ISO 9000 program. After approximately 18 months, they determined that the ISO program was not appropriate for them. They are now preparing a new system but in the interim, procedures and implementation of procedures lapsed.

Action to Preclude Recurrence: Block 20

USGS will provide better communications with vendors establishing new QA Programs.