



Department of Energy

Washington, DC 20585

OCT 17 1997

QA: L

R. W. Craig, Technical Project Officer
for Yucca Mountain Site
Characterization Project
U.S. Geological Survey
1261 Town Center Drive
Building 12, Room 1249, M/S 423
Las Vegas, NV 89134

VERIFICATION OF CORRECTIVE ACTION OF DEFICIENCY REPORT (DR)
YM-96-D-035 RESULTING FROM OFFICE OF QUALITY ASSURANCE (OQA)
SUPPLIER AUDIT OQA-SA-96-009 OF CAMPBELL SCIENTIFIC, INC.

The OQA staff has verified the corrective action to DR YM-96-D-035 and determined the results to be unsatisfactory because of reasons stated in the enclosed DR.

Your response, indicating the appropriate corrective action completion date, 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, 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 Richard L. Maudlin at (702) 794-1302.

Donald G. Horton, Director
Office of Quality Assurance

OQA:JB-0106

Enclosure:
DR YM-96-D-035

cc w/encl:

- ~~J. O. Thoma, NRC, Washington, DC~~
- S. W. Zimmerman, NWPO, Carson City, NV
- T. H. Chaney, USGS, Denver, CO
- D. J. Sinks, OQA/USGS, Denver, CO
- A. M. Whiteside, OQA/USGS, Denver, CO

cc w/o encl:

- W. L. Belke, NRC, Las Vegas, NV
- R. L. Maudlin, OQA/QATSS, Las Vegas, NV
- D. G. Sult, OQA/QATSS, Las Vegas, NV
- R. W. Clark, DOE/OQA, 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 QARD, Rev. 5 / USGS PO 1434-CR-SA-00200 / Campbell Scientific, Inc. QA Manual, Rev. 01	2 Related Report No. OQA-SA-96-009
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3 Responsible Organization: Campbell Scientific, Inc. / USGS	4 Discussed With: P. Campbell / C. Howell / T. Chaney
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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 <u>Richard L. Mauclin</u> Richard L. Mauclin Date <u>2/1/96</u>	9 QA Review QAR <u>Richard L. Mauclin</u> Date <u>2/5/96</u>
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10 Response Due Date: 20 Working Days From Issuance	11 QA Issuance Approval: QAR (PRV/ACQAM) DR. <u>P. Campbell</u> Date <u>2-6-96</u>
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12 Remedial Actions

SEE ATTACHED SHEET

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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

Henry Thibeau

Date 4/17/96

22 Corrective Action Completion Due Date

NOT APPLICABLE

23 Response Accepted

QAR *McDonald*

Date 4/22/96

24 Response Accepted

AOQAM *RBC Available*

Date 5.2.96

25 Amended Response Accepted

QAR *N/A*

Date

26 Amended Response Accepted

AOQAM *N/A*

Date

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DEFICIENCY REPORT

17 Recommended Actions:

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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:

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 Action Verified

QAR

[Signature]

Date

09/26/97

28 Closure Approved by:

AOQAM

Date

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PERFORMANCE/DEFICIENCY REPORT

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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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.



IN REPLY REFER TO.

United States Department of the Interior

U. S. GEOLOGICAL SURVEY
Box 25046 M.S. 425
Denver Federal Center
Denver, Colorado 80225

February 3, 1997

Mr. Paul Campbell, President, and
Mr. Clint Howell, Quality Assurance Manager
Campbell Scientific, Inc.
815 West 1800 North
Logan, UT 84321-1784

SUBJECT: Surveillance Report USGS 97002-SS

Gentlemen:

Enclosed is the surveillance report resulting from the surveillance conducted at your facility on November 14, 1996. There were no findings and no further action relative to the surveillance is needed. Completion of actions for closure of deficiency 96-D035 is still scheduled for March 1, 1997. If for some reason you are not able to meet this date, please let me know. Thank you for your participation during the surveillance and your continued cooperation with the USGS Yucca Mountain Project.

Sincerely,

T. H. Chaney, Quality Assurance Manager
Yucca Mountain Project

WR/THC/aa
Enclosure

Copies to: ~~A.~~ Anderson, USGS, Denver, Co
E. S. Reiter, PWT, Denver, CO.
R. L. Maudlin, YMQATSS, Las Vegas, NV
Record Processing Center

**SURVEILLANCE REPORT
SUPPLIER SURVEILLANCE NO. USGS - 97002-SS**

CAMPBELL SCIENTIFIC, INC. (CSI)

November 14, 1996

**YUCCA MOUNTAIN PROJECT
U.S. GEOLOGICAL SURVEY
QUALITY ASSURANCE OFFICE**

Prepared by: Wayne R. ...
Surveillance Team Leader

Date: 1/31/97

Approved by: Tom Cheney
YMP-USGS QA Manager

Date: 1/31/97

SURVEILLANCE REPORT
SUPPLIER SURVEILLANCE NO. USGS 97002-SS
Campbell Scientific, Inc. (CSI)

SUMMARY:

This surveillance was conducted to determine progress and plans for resolving DR YMQAD-96-D035. The surveillance opened and closed with discussions with Mr. Paul Campbell, CSI President and Mr. Clint Howell, QA Manager. These discussions centered around the opinions that CSI has concerning the appropriateness, applicability and urgency of meeting YMP QA requirements and responding to deficiency findings. These were recurring concerns throughout the surveillance and have a definite impact on the timeliness of response to the subject deficiency report.

CSI is working towards a QA program which meets ISO requirements, although they may not seek ISO certification. Quality improvement is promoted through quality circles and monthly reports with an emphasis on actions that materially improve the end products, a method which CSI felt was much more effective than the YMP-mandated annual internal audit. They also expressed frustration that YMP did not look at their total operation and end products as a way of determining acceptable quality. Mr. Campbell suggested that perhaps YMP could quit trying to force QARD requirements on them and instead randomly submit their products to an independent lab for comparison. The company is committed to quality but must at the same time preserve their economic viability in the competitive marketplace.

Mr. Campbell has a growing concern with the increasing amount of time his personnel are spending not only with audits, findings, and resolution of findings, but also with the time spent interpreting the constantly changing language and requirements of purchase orders. If this recent trend is allowed to persist, CSI is considering charging YMP for audit and resolution time, increasing charges for calibration (approx \$1500 per P.O.) to cover the additional requirements, and setting up a special in-house group to address YMP complications. There are currently over 20 YMP dataloggers from 2 PIs being held at CSI while they attempt to decipher the P.O. requirements. It was noted that YMP constitutes a very minute portion of CSIs total business.

With the above concerns and well-being of the company in mind, CSI is willing to work with YMP as much as possible and progress has been made towards resolution of YMP-identified deficiencies. New operating procedures (OPR) have been issued for audits and M&TE. Of the 8 conditions identified in the DR, 5 responses are complete and 3 have actions that will be completed by March 1, 1997. These actions include 1) an annual internal QA audit by CSI, 2) a management review of the internal audit, 3) documentation of vendor audits for the Stabro calibration facility.

SURVEILLANCE ACTIVITY:

1. Discussions with Mr. Paul Campbell, CSI President, and Mr. Clint Howell, QA Manager.
2. The current QA manual (5/31/96) and the recently completed "Tier II Operating Procedures" were examined.

3. A USGS Supplier Checklist was completed.

SURVEILLANCE DATE:

November 14, 1996

SURVEILLANCE LOCATION:

Campbell Scientific Inc
Logan, Utah

SURVEILLANCE PERSONNEL:

Wayne Rodman, USGS QA

PERSONNEL CONTACTED:

Clint Howell, Campbell Scientific QA Manager
Paul Campbell, President

REFERENCE DOCUMENTS:

DR YMQAD-96-D035
Campbell Scientific Quality Manual R2 05/31/96
CSI Tier II Operating Procedures (OPRs)
USGS-QMP-7.04, R3 Supplier Checklist

SURVEILLANCE DETAILS:

The following information is in reference to YMQAD-96-D035 and relates directly to section 6 (Description of Condition) numbering.

1. A management review of annual audits will be performed (see #8 below).
2. Operating procedures (OPR) are completed for audits and M&TE.
3. Qualification and training records for CSI employees do exist. These are considered confidential by management. Section 4.18.2 of the CSI QA Manual states "To verify adequate training, an auditor may make a random selection of employees to observe at work and to interview to determine competence for assigned work or obtain a curriculum vitae from the employee. The scope of such auditing activity shall be pre-approved by the General Manager in each instance." Mr. Campbell emphasized that information must be requested in advance.
4. Stabro, the calibration vendor to CSI, is well known to CSI and they have visited the Stabro facility several times to evaluate their technical and quality program. These visits will be

documented as a vendor evaluation according to the CSI QA Program.

5. Condition corrected in original response.

6. There was a mis-communication in this finding. At some time in the past, Mr. Howell instructed an employee in the use of deficiency reporting. A deficiency report was filled out as an exercise to familiarize the employee with the process. There was no intent or need to process the report and it was discarded.

7. Calibration data provided to CSI by Stabro is stored in a Victor Fire Master 1-hour exposure rated safe. The files that were examined during the audit were one CSI sections working files, not official files. All other data are either stored in two locations or provided to USGS.

8. With the completion and issuance of CSI Operating Procedures, they now have procedures to audit to. The CSI President and QA Manager have committed to completion of an internal program audit by March 1, 1997.

DEFICIENCY REPORTING:

No new deficiencies reported.

RECOMMENDATIONS:

None related to closure of the deficiency.

Since most of the surveillance discussion centered around CSIs concern about the applicability and appropriateness of the YMP QA program to their operation the following recommendations are made:

- 1) YMP should allow some flexibility in the methods companies use to address quality requirements. There should be some recognition that quality may be addressed in ways that are not traditional QARD practices and that not all QARD requirements are appropriate for every company.
- 2) YMP should have an appreciation of top quality companies such as CSI and strive to retain their services rather than driving them into higher prices, less cooperation, and perhaps ultimately, their refusal to accept work from YMP.

ORIGINAL

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- Deficiency Report

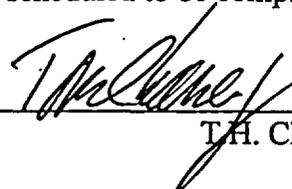
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AMENDED RESPONSE (page 1 of 1)

Campbell Scientific has not completed the internal audit and management review of the audit as committed to by March 1, 1997, in the response to this deficiency and documented in supplier surveillance report USGS-97002-SS. The audit has been delayed pending sufficient implementation of its QA program. All actions are now scheduled to be completed prior to August 15, 1997.

Submitted by: _____



T.H. Chaney, USGS QA Manager

Date: _____

5/21/97

5/21/97 Craig & Clark

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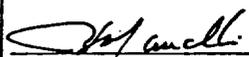
FOLLOW-UP VERIFICATION OF DR YM-96-D-035

Based on the re-audit of Campbell Scientific, Inc. (CSI) performed on August 25-26, 1997, and the verification of approval and issuance of the CSI Operating Procedures which address the quality requirements for the USGS scope of work, primary action related to this DR is considered complete. As to the specific items of noncompliance, the following was verified during the audit.

- A. CSI has completed an internal audit of its QA Program; however, the audit report has not been completed and issued and the identified nonconformance reports have not been issued. As a result, this action is incomplete.
- B. Reviewed training records of training to CSI's QA Program for personnel performing USGS activities.
- C. Qualification of suppliers and procurement documents including technical and quality requirements continues to be a problem and is being addressed in DR YM-97-D-87 being issued as a result of supplier audit OQA-SA-97-024.
- D. Since CSI management is involved in the review of internal audit reports, the need for implementation of management reviews for the intended scope of work does not add any value to the service being provided. Subsequently, actions required for assessment of the QA program by CSI management is performed during the review of internal audit reports.
- E. The calibration certificates found in error have been provided to USGS and will be evaluated during future audits of the USGS.
- F. The deficiency report that was not found related to an audit of a subtier calibration supplier, Stabro. The deficiency report was never located. Since then, a reevaluation of Stabro has been performed with no identified deficiencies.
- G. In accordance with the USGS procurement document for calibration suppliers, the documentation not being requested and maintained by CSI is being adequately protected in metal file cabinets and the building is secured at night.

Based on the above and the issuance of DR YM-97-D-087, implementation of corrective action for this DR is considered complete except for Item A.

As a result, this DR cannot be closed until issuance of the CSI internal audit report and associated nonconformance reports.


R.L. Maudlin
Date 10/08/97