

U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE

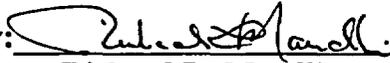
SUPPLIER AUDIT REPORT OQA-SA-97-024

OF

CAMPBELL SCIENTIFIC, INC.

LOGAN, UTAH

AUGUST 25-26, 1997

Prepared by: 
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Office of Quality Assurance

Date: 09-15-97

Approved by: 
for: Donald G. Horton
Director
Office of Quality Assurance

Date: 9/18/97

1.0 EXECUTIVE SUMMARY

The results of the supplier audit of Campbell Scientific, Inc. (CSI) revealed unsatisfactory conditions resulting in the issuance of one Deficiency Report (DR) to the United States Geological Survey (USGS) for action which relates to the Quality Assurance (QA) program for the Office of Civilian Radioactive Waste Management (OCRWM) activities. The DR relates to: (1) CSI's Operating Procedures do not address requirements that procurement documents include quality and technical requirements. As a result, procurement documents issued to sub-tier suppliers do not include these requirements; (2) No evidence could be provided to reflect supplier evaluation of Data Precision; (3) No documented evidence of traceability of Data Precision standards to NIST; (4) No evidence could be provided to reflect that CSI notified the USGS when standards used by CSI were found to be out-of-tolerance; (5) CSI Certificates of Calibration did not include an accuracy statement and did not in all cases reference the procedure and revision level used in performing the calibration; and (6) CSI has not issued an Operating Procedure for the control of QA records. It should be noted that since the last audit in January 1996, CSI has issued all of the Operating Procedures (implementing procedures) and is satisfactorily implementing them except where noted in this report.

The unsatisfactory conditions identified during the audit were discussed with the QA Manager and President of CSI who agreed to work with USGS in resolving the unsatisfactory conditions.

2.0 SCOPE

The supplier audit was conducted to evaluate the implementation and effectiveness of CSI's quality program. This was accomplished by evaluating implementation of CSI's Quality Assurance Manual, Revision 2, and determining if CSI is satisfactorily implementing the QA requirements specified in the USGS procurement document 1434-CR-97-SA-00067 for the scope of work. The QA program elements determined to be applicable are: Organization; QA Program; Procurement Document Control; Implementing Documents; Document Control; Control of Purchased Items and Services; Measuring and Test Equipment; Corrective Action; QA Records; and Audits. Also, a follow-up was performed to verify implementation of corrective action to DR YM-96-D035.

3.0 AUDIT TEAM AND OBSERVERS

Richard L. Maudlin, Audit Team Leader, OQA
Thomas Chaney, Observer, USGS

4.0 PERSONNEL CONTACTED DURING FACILITY AUDIT

P. Campbell, President , CSI
C. Howell, QA Manager, CSI
T. Steer, Calibration/Customer Service Manager, CSI
B. Lamborn, Design Engineer, CSI

5.0 SUMMARY OF AUDIT RESULTS

CSI's Quality Assurance Manual, Revision 2, does not address all of the applicable elements of the USGS Purchase Order (PO) Number 1434-CR-95-SA-00067 for the intended scope of work. Implementation of the CSI's Quality Assurance Manual was considered satisfactory except for one instance; however, implementation of the USGS PO was determined to be less than satisfactory. Subsequently, effectiveness in producing the desired results could not be determined. Specifics of the unsatisfactory conditions are described in Section 6.0 of this report, "Deficiencies/Recommendations." The results of the follow-up verification to DR YM-96-D-035 revealed that implementation was acceptable with the exception of procurement control. This issue has been addressed by the DR referenced in Section 6.0 of this report; subsequently, DR YM-96-D-035 has been closed.

The details of the audit, along with the objective evidence reviewed, are contained within the audit checklist, which is available from the OQA's supplier evaluation files.

6.0 DEFICIENCIES/RECOMMENDATIONS

The unsatisfactory conditions have been documented on the respective corrective action document and submitted to USGS for resolution. Recommendations have been provided for USGS management consideration and action as deemed appropriate.

DEFICIENCY

DR YM-97-D-087 - USGS PO 1434-CR-97-SA-97-00067, Attachment "YMP-USGS-Quality Assurance Requirements for Suppliers of Quality Services," Parts II and III, provide specific quality program requirements which CSI was required to implement. In part, they are as follows: (1) Part II, Section 4, addresses requirements that CSI describe the approach used to assure that the scope of work, and technical/quality requirements are incorporated into procurement documents and procurement document changes. These are to include requirements to document the evaluation and selection of suppliers prior to the award of a contract/purchase order.... The procurement documents for services directly supporting this procurement work shall incorporate appropriate YMP USGS QA program requirements; (2) Part III, Section 3, requires CSI to notify the YMP-

USGS technical contact when a calibration instrument used to calibrate and certify YMP-USGS equipment is found to be defective or out-of-calibration; (3) Part II, Section 6, requires CSI's calibration documentation (e.g. Certificate of Calibration) to include the following:....D. A statement of a accuracy of the Principle Reference Standard(s) used in the calibration is greater than (or equal to with justification) the required accuracy of the equipment being calibrated...G...and calibration procedure or method used; (4) Part II, Section 8, requires CSI to describe methods for specifying, preparing, and maintaining QA records that provide evidence of quality.... The requirements and responsibilities for records transmittal, distribution, retention, maintenance, and disposition shall be established and documented; and (5) Part II, Section 6, requires methods to be used to assure that Measuring and Test Equipment is adjusted and maintained against reference standards traceable to nationally recognized standards.

In addition, CSI's QA Manual, Section 4.11, requires all measurement standards used for calibration and final testing of their products show traceability to the National Institute of Standards and Technology (NIST) or other nationally recognized standards.

Contrary to the above, CSI is not implementing USGS procurement document requirements. Examples are as follows:

1. CSI's Operating Procedures for purchasing do not address requirements that procurement documents include technical and quality requirements. In addition, no evidence could be provided to reflect that procurement documents for the purchase of calibration services of Stabro Laboratory and Data Precision included technical and quality requirements.
2. No documented evidence could be provided to reflect a supplier evaluation and qualification of Data Precision who provided calibration services in relation to the purchase and calibration of a Data Precision Model 8200 voltage source, Serial No. A031746.
3. No evidence of traceability to NIST could be provided for the calibration of CSI Standard (Data Precision Model 8200, Serial No. A031746) used to calibrate USGS Model 21X Data Logger, Serial No. 10494.
4. No objective evidence could be provided to reflect that USGS was notified, as required by the USGS PO 1434-CR-97-SA-00067, when CSI standard Data Precision Model 8200, Serial No. A014824, was found to be out of calibration upon receipt by the calibration supplier and when the CSI standard Oscillatek frequency oscillator, Serial No. 315550, was found to have failed operation and removed form service not to be reused.

5. CSI Certificates of Calibration for the calibration of USGS 21X Data Loggers, Serial Nos. 10494, 4941, and 2833, did not include a statement of accuracy of the reference standards used in performing the calibrations as required by the USGS PO reference above. Also, the Certificate of Calibrations for USGS 21X Data Loggers, Serial Nos. 4941 and 2833, did not include a reference to the procedure used to perform the calibration.
6. CSI has not developed and issued an Operating Procedure for the control of QA Records as committed to in DR YM-96-D-035.

RECOMMENDATION

The USGS PO 1434-CR-97-SA-97-00067, Attachment "YMP-USGS-Quality Assurance Requirements for Suppliers of Quality Services," Part 2, Section 3, describes requirements for control of Software. Since CSI only uses software to extract data from sensors during the automated calibration process and there is no data manipulation, it is suggested that this requirement be removed from the PO or indicated as not applicable for this procurement. Also, it was pointed out by the CSI calibration representative that bench checks are performed on every piece of equipment calibrated to assure accurate results of the computer automated calibration.