

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

**SUPPLIER AUDIT REPORT
OF
QUALITY CONTROL SERVICES
PORTLAND, OREGON**

**REPORT NUMBER OQA-SA-97-008
JANUARY 8-9, 1997**

Prepared by:  Date: 1/15/97
Richard L. Maudlin
Audit Team Leader
Office of Quality Assurance

Approved by:  Date: 1/21/97
Donald G. Horton
Director
Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

The results of the supplier audit of Quality Control Services (QCS) revealed unsatisfactory conditions resulting in the issuance of one Deficiency Report (DR) to the U.S. 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 addresses deficiencies as follows: (1) Lack of documentation to support the performance of the annual management review; (2) Purchase orders did not reference quality requirements; and (3) No documented evidence to support the performance of annual internal audits.

The unsatisfactory conditions identified during the audit were discussed with the Quality Assurance Manager, QCS, who agreed to work with the US Geological Survey (USGS) in the resolution of the unsatisfactory conditions. All of the deficiencies noted during the audit were indicators of a lack of attentiveness to detail. QCS has only performed three calibrations for the USGS. None of the conditions identified during this audit had an adverse impact on the work performed for the USGS, but did reflect a lack of compliance with the commitments in the QCS QA Manual.

The results of the audit do not warrant any recommendation for limitations or other conditions that should be invoked relative to the items or services being provided by QCS; however, responsibility for determination of continued use of this supplier rests with the USGS.

2.0 SCOPE

The supplier audit was conducted to evaluate the adequacy, implementation, and effectiveness of QCS's quality program. This was accomplished by determining if QCS's program implements the applicable portions of the OCRWM QARD; satisfies the applicable QA requirements specified in the USGS procurement document 1434-CR-96-SA-00951, and satisfactorily implements the QCS's Quality Assurance Manual, dated March 8, 1994, as accepted by the USGS, 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.

3.0 AUDIT TEAM AND OBSERVERS

Richard L. Maudlin, Audit Team Leader, Office of Quality Assurance (OQA)

4.0 PERSONNEL CONTACTED DURING FACILITY AUDIT

George A. Cahill, President and QA Manager, Quality Control Services

5.0 SUMMARY OF AUDIT RESULTS

QCS's QA Manual, dated March 8, 1994, addresses the applicable elements of the OCRWM QARD for the intended scope of work. Effective implementation of the applicable elements of the QARD by QCS is considered satisfactory, with the exception of those unsatisfactory conditions described in Section 6.0 of this report, "Deficiencies/ Conditions Corrected During the Audit/Recommendations." Also there were three conditions adverse to quality which were corrected during the audit. Details of these conditions corrected during the audit are discussed in Section 6.0 of this report.

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/CONDITIONS CORRECTED DURING THE AUDIT/RECOMMENDATIONS

The unsatisfactory conditions identified below have been documented on the respective corrective action document which was submitted to the USGS for action and resolution.

DEFICIENCIES

DR No. YMQAD-97-D024 - QCS QA Manual, Section 5.2.4, reflects that the chief quality officer will appoint an independent person to review the quality program periodically (annually at a minimum). Section 6.2.4.3 requires that all purchase orders accurately describe the product or service required and all quality requirements. Section 5.4.4 requires that internal quality audits be performed annually to verify implementation and effectiveness of the quality system.

Contrary to the above, (A) No objective evidence could be provided to support the performance of annual management reviews, (B) Purchase orders issued by Quality Control Services do not include reference to quality requirements which are to be implemented in the performance of the service or manufacture of the item. An example was QCS purchase order 2709. It should be noted that none of the purchase orders issued by QCS impacted work performed for USGS, and (C) From March 1994 to September 1996, there was no evidence that an internal audit of QCS had been performed. It should be noted that the audit performed in 1996 was performed by a QCS customer and did address all elements of the QCS program.

CONDITIONS CORRECTED DURING THE AUDIT

1. QCS QA Manual, Section 5.3.2.2, requires that personnel be trained. Contrary to this requirement, there was no evidence that the person who performed the calibrations for USGS was trained to the required calibration procedures. Prior to the completion of the audit, the Training Record was updated to reflect that the training had been completed. It should be noted that the person who performed the calibrations was trained prior to performing the work. This information had not been transferred to the training record.
2. QCS QA Manual, Section 5.4.3.2, requires that a master document index be maintained. There was no objective evidence in the form of a master document list for the Standard Operating Procedures (SOP). Prior to completion of the audit, a Table of Contents (master index) was prepared for the SOP and placed in the manual to show the SOP number, document title, and issue/revision date.
3. The USGS purchase order 1434-CR-96-SA-00951 requires that certain information be contained on calibration records such as: reference to the USGS purchase order; a statement of accuracy; the identification of the calibration standard or procedure used to perform the calibration; and records of calibration data. Contrary to the requirements of the USGS purchase order, the information noted above was not included in the calibration documentation for the USGS calibrations. Prior to the completion of the audit, the calibration records had been updated to include all of the necessary information required by the USGS purchase order. Copies of this updated calibration data will be forwarded to the USGS.

RECOMMENDATIONS

None