

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

SUPPLIER AUDIT REPORT

OF

UNIVERSITY OF SASKATCHEWAN
SASKATOON, SASKATCHEWAN, CANADA

REPORT NUMBER OQA-SA-96-022
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1.0 EXECUTIVE SUMMARY

The results of the supplier audit of the University of Saskatchewan revealed unsatisfactory implementation of the Quality Assurance (QA) requirements for the Office of Civilian Radioactive Waste Management (OCRWM) activities. Quality implementing procedures and processes were not in place for the scope of work which made implementation indeterminate. There were minimal technical procedures in place for performing the analyses requested. The technical work performed appeared to be done in a satisfactory manner; however, without the QA Program in place, the data obtained lacked the necessary related documentation. Implementation of the University of Saskatchewan QA Program was determined to be ineffective. The University of Saskatchewan performs chemical laboratory analyses for the U.S. Geological Survey (USGS.)

The unsatisfactory conditions identified during the audit were discussed with the representatives audited at the University of Saskatchewan. Corrective actions associated with Corrective Action Request (CAR) YM-96-C-006 will be evaluated by the Office of Quality Assurance (OQA) and closed as appropriate. The unsatisfactory conditions are detailed in Section 5.0.

2.0 SCOPE

The supplier audit was conducted to evaluate the adequacy, implementation, and effectiveness of the University of Saskatchewan quality program within the University. This was accomplished by determining if the University of Saskatchewan's program meets the quality and technical requirements specified in the USGS procurement document number 1434-CR-95-SA-01689, the University of Saskatchewan QA Manual, Revision 0, dated June 9, 1995, SILAB.DOC2, technical procedures, dated June 19, 1995, and the OCRWM Quality Assurance Requirements and Description (QARD) for the specific 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; Control of Measuring and Test Equipment; Nonconformances; Corrective Action; QA Records; Audits; Software; and Sample Control.

3.0 AUDIT TEAM AND OBSERVERS

Daniel A. Klimas, Audit Team Leader, OQA, Yucca Mountain Quality Assurance Division (YMQAD)

Stephen D. Harris, Audit Team Member, OQA, YMQAD

4.0 PERSONNEL CONTACTED DURING THE AUDIT

David C. Pezderic, Technician, University of Saskatchewan
Robert Kerrich, Professor, University of Saskatchewan

5.0 SUMMARY OF AUDIT RESULTS

The University of Saskatchewan QA Manual, Revision 0, dated June 9, 1995, did not address all the applicable elements of the USGS purchase agreement number 1434-CR-95-SA-01689. It did address the applicable elements of the OCRWM QARD for the intended scope of work. Procedures or processes described within the QA manual were not in place and consequently no implementation was observed. Technical procedures, SILAB.DOC2, were in place but the processes were minimally described.

The details of the audit, along with the objective evidence reviewed and items corrected during the audit, are contained within the audit checklist which is available from the OQA's quality records files.

6.0 DEFICIENCIES/RECOMMENDATIONS

The deficiencies have been documented on CAR YM-96-C-006 and will be submitted to the USGS for resolution.

DEFICIENCIES

1. The responsibilities for implementing a QA Program are defined in the QA Manual. As implementation has not been executed, it appears there may be misunderstanding as to responsibilities.
2. The documentation required to show evidence of the training to the QA Manual and procedures was not available for review although the requirements are described in the QA Manual. Attached forms described in the QA Manual are not being used.
3. Procurement document packages as described in Section 4.0 of the QA Manual are incomplete.
4. Calibration of balances, used for Yucca Mountain work, did not show evidence of traceability to National Institute of Standards and Technology (NIST) standards. In addition, no documentation was available for traceability of the AGS standard to NIST 28.

5. Procurement documents do not exist for the requirements listed in the QA Manual, Section 4.2.1, "information for calibration or services."
6. Procurement planning, although possibly accomplished informally, does not show evidence of required activities listed in the QA Manual, Section 4.2.2.
7. There is no evaluation of capabilities for Pulse Instrumentation LTD/SET Instrument Service: subcontracted service for calibration, as required in the QA Manual, Section 4.2.3.
8. Receipt inspection is not being performed as required by the QA Manual, Section 4.2.5.
9. There is no evidence that technical procedures SILAB.DOC2 are reviewed, approved, and controlled in accordance with QA Manual, Section 6.0 (reference Section 5.2).
10. The QA Manual and technical procedures lack evidence of proper review, approval, and distribution as required by Section 6.0 of the QA Manual.
11. Two sets of the QA Manual, numbered and maintained, and a master set with current table of contents were not available for review as required in the QA Manual, Section 6.2.
12. There is no evidence of data review by a qualified individual prior to submittal to the client as required by the QA Manual, Section 3.2.2.
13. The Individual Tracking Form, attachment 7.1, is not used to track samples as required by the QA Manual, Section 7.2.2.
14. There is no evidence of a calibration schedule or prescribed intervals identified for calibration as required by the QA Manual, Section 8.0.
15. Calibration stickers are missing required information: calibration due date, individual performing calibration, serial number (identification) of instrument.
16. Reference standards are missing NIST standard certification.
17. Equipment calibration schedule, QA Manual, Section 8.0, Attachment 8.1, is not being used.

18. Calibration records are not maintained.
19. The deficiency reporting system is not being implemented as required by the QA Manual, Section 9.0. Deficiency system logbooks are not being used as required.
20. A system to assure QA records are prevented from loss or deterioration has not been established and implemented as required by the QA Manual, Section 10.
21. Those records identified in Section 10.2.2 of the QA Manual, that include audit assessment reports done internally, are not available as QA records.
22. The QA Manual, Section 11, does not reflect the correct organization to perform internal audits. This is a requirement of the University.
23. There is no objective evidence of supervisory faculty determination of accuracy of data prior to release as required by SILAB.DOC2, organizational structure, bullet 2.
24. There is no calibration of balances prior to each weighing procedure. Zeroing of the balance is performed. (See SILAB.DOC2, "Extraction Procedures," bullet 3).
25. There is no evidence the first aliquot of BrF₃ is discarded as stated in SILAB.DOC2, "Extraction Procedures," bullet 7. There is also no evidence of monitoring and recording conversion of O₂ to CO₂ and residual gas pressures as required by bullet 9.
26. Optimization peaks are not always printed out as evidence of activity performed, (See SILAB.DOC2, "Mass Spectroscopy," iii, sentence 3).
27. The discrepancy in the use of a spreadsheet file in SILAB.DOC2, "Sample Handling Protocol," viii, is in conflict with the QA Manual, Section 7.2.2.

RECOMMENDATION

It appears additional implementing procedures (QA and administrative) need to be prepared to describe what needs to be accomplished in order to assure compliance with requirements.