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

SUPPLIER AUDIT REPORT

OF

ACTIVATION LABORATORIES LTD.

ANCASTER, ONTARIO, CANADA

REPORT NUMBER OQA-SA-96-021
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Approved by: [signature] **Date:** 9/3/96
Donald G. Horton
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Enclosure

1.0 EXECUTIVE SUMMARY

The results of the supplier audit of Activation Laboratories Ltd. (ACTLABS) revealed unsatisfactory implementation of the Quality Assurance (QA) requirements for the Office of Civilian Radioactive Waste Management (OCRWM) activities. Numerous deficiencies were identified in the implementation of the QA program and procedure requirements. The technical work performed was determined to be satisfactory; however, without full implementation of the QA program, the results of the data are considered to be indeterminate and implementation of the QA program ineffective.

The unsatisfactory conditions identified during the audit were discussed with the management representatives at ACTLABS who agreed to correct the unsatisfactory conditions. Corrective actions associated with Corrective Action Request (CAR) YM-96-C-009 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 ACTLABS QA program. This was accomplished by determining if the ACTLABS QA program meets the quality and technical requirements specified in the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) procurement document number BA0000000-01717-0500-00001-Rev. 00, the ACTLABS' QA Manual, Revision 1, dated August 17, 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; Test Control; Control of Measuring and Test Equipment; Nonconformances; Corrective Action; QA Records; Audits; 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

Eric Hoffman, President, Activation Laboratories Ltd.
Adrienne Rittas, Laboratory Manager, Activation Laboratories Ltd.
Dario D'Anna, Laboratory Supervisor, Activation Laboratories Ltd.

5.0 SUMMARY OF AUDIT RESULTS

The ACTLABS' QA Manual, Revision 1, dated August 17, 1995, addresses the applicable elements of the CRWMS M&O purchase order BA0000000-01717-0500-00001-Rev. 00 and the applicable elements of the OCRWM QARD for the intended scope of work. Technical procedures were in place; however, implementation of the QA program was determined to be ineffective. Training documentation was incomplete; procurement documents did not contain sufficient detail or were not available; procedures and the QA Manual did not receive independent review; implementation of procedures and the QA Manual was not as prescribed; distribution and control of documents is inadequate; there were no supplier evaluations; inadequate control of calibrated instruments and related documentation; inadequate control of QA records; and internal audits were not formalized. Details of the unsatisfactory conditions and recommendations are described in Section 6.0

6.0 DEFICIENCIES/RECOMMENDATIONS

The unsatisfactory conditions have been documented on CAR YM-96-C-009 and have been submitted to the CRWMS M&O for resolution. Recommendations, as applicable, have been provided for ACTLABS consideration and action as deemed appropriate. The recommendations are offered as suggestions to improve specific processes and are not required to be acknowledged unless otherwise stated.

DEFICIENCIES

1. Some training records were incomplete and did not show evidence of what specific training was administered.

2. Procurement documents for calibration services were unavailable as the services were procured verbally and payment was made by invoice.

3. Procedures and the QA Manual did not receive independent review and approval as required by the QA Manual.

4. Distribution of procedures and the QA Manual are not controlled in accordance with the QA Manual requirements.

5. No supplier evaluation information was available for calibration services performed by VACS LTD.

6. The calibration of balance weight set, serial number AL01, is past due.

7. QA records are not maintained as required by the QA Manual.

8. Internal audits are not being conducted as required by the QA Manual.

9. The QA Manual and Quality Operating Procedures (QOP) SaNoncon A do not address the issues of the CRWMS M&O procurement document, Section F2.

10. Client name is not included in the chemical laboratory technical worksheets, as required.

11. Mistakes are sometimes obliterated on worksheets and not initialed (dates also need to be added).

12. The QOP SaNoncon forms are in the procedure, but are not being used by the sample receiving personnel.

13. The following sections of the QA Manual contain statements that are not performed in all cases:

    - 13.4, "Test data and calculations are checked against the technician's worksheets."
    - 13.6, "National Bureau of Standards traceable standards as well as in house proprietary standards are run with the clientele samples."
    - 10.4, "QA Manager is responsible for the safekeeping of test documents and keeps them in the mechanical test lab and the chemical analysis lab."

    The QA Manual must be written to address all circumstances for compliance verification.

14. Calibrations are performed and monitored by the Laboratory Manager, not QA Manager. The QA Manual should be changed to reflect who actually performs these activities.

15. The list of equipment does not include model and serial number in several cases.

16. The sticker on the balance weights is past due. Calibration stickers do not indicate due date of next calibration.

17. The calibration equipment sheets do not indicate the instrument being calibrated by model number (i.e., ICPMs Perkin Elmer 6000).

RECOMMENDATIONS

1. The ACTLABS nonconformance documentation and reporting system is at an indeterminate stage of implementation due to the changes recently made and incorrect forms used in the past. The criteria used and described in the QA Manual need to be carefully evaluated as to what is considered a nonconformance. Once established, training of personnel to the process and forms to be used needs to be performed.

2. ACTLABS needs to review the actual processes of the laboratory against the described processes in the QA Manual and procedures to make certain they address actual practices. Determine that the data trail from receipt of sample through data obtained from the analysis identifies and captures all required documentation to support the results of the analysis.

3. Make sure Certificate of Conformances are signed and dated by a designated and technically qualified individual.

4. Purge the documents located throughout the laboratory to ensure the latest document is the one that is identified as the latest approved version being used and obsolete documents are removed from the system.

5. Consideration should be given to filling the position of QA Manager to comply with the requirements in the QA Manual for the responsibilities and duties described for the QA Manager as far as implementation of the QA program.