Summary of ISO/IEC 17025

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Any comments, questions, or suggestions regarding the content of this document may be directed to:

Environmental Monitoring and Science Division
Alberta Environment and Parks
10th Floor, 9888 Jasper Avenue NW
Edmonton, Alberta T5J 5C6

Tel: 780-229-7200
Toll Free: 1-844-323-6372
Fax: 780-702-0169
Email: EMSD-Info@gov.ab.ca
Media Inquiries: AEP.Mediainquiries@gov.ab.ca
Website: http://environmentalmonitoring.alberta.ca/

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1.0 Introduction

The mandate of the Environmental Monitoring and Science Division is to monitor, evaluate and report on the state of Alberta's environment. This includes the requirement to develop standards and quality measures to ensure scientifically-sound environmental policy development; that key environmental issues identified by multiple users are addressed using the best available science; and credible legislated and non-legislated public reporting.

This document provides an overview of the International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) 17025 document entitled "General requirements for the competence of testing and calibration laboratories," which is the international standard for quality assurance that all Canadian accredited laboratories must meet (either under the Canadian Association for Laboratory Accreditation (CALA) or the Standards Council of Canada (SCC)).

The summary below is a plain-language synopsis that identifies the best practices the analytical laboratories should follow and is by no means comprehensive. The full ISO/IEC 17025 standard is available for purchase through the ISO website.

This document is part of the Alberta Environment and Park's (Environmental Monitoring and Science Division) quality assurance principles and procedures program for contract commercial laboratories. EMSD will update the data quality requirements from time to time for laboratories that provide analytical services on air, water and biodiversity sample analysis.

2.0 Summary of ISO/IEC 17025

2.1 Scope

The ISO/IEC 17025 international standard provides a description of the requirements for laboratories performing tests or calibrations (including sampling) and includes standard, non-standard and laboratory-developed methods.

The standard provides the general requirements for laboratories to develop an ISO 9001-compliant management system to carry out quality, administrative and technical operations.

2.2 Management requirements

- Organization

The laboratory is required to have the following:

There must be assigned personnel with the authority to implement, maintain and improve the management system. Their duties include identifying deviations from the management system and also implementing corrective actions. The quality management staff must be able to perform their duties without pressure (ie. commercial or financial) that could negatively affect their work.

There must be policies and procedures in place to protect the confidential information of customers, including protecting the electronic storage and transmission of data.

Any activity that would compromise the integrity of the laboratory must be avoided.

The laboratory must have an organizational and management structure in place, with a clear definition of the relationship between quality management, operations and support services. There must be defined responsibilities, authority and interrelationships of the staff involved in determining the quality of tests or calibrations. Adequate supervision for laboratory staff involved in testing or calibrations must be provided.

Designated staff must be tasked with the role of technical operations and maintenance of the resources needed to operate at the required quality. An employee must be designated as the quality manager and given the responsibility and authority to ensure the quality management system is implemented and followed at all times. The laboratory must ensure their staff are aware of their activities and how each person contributes to meeting the objectives of the quality management system.

- Management system

A management system corresponding to the scope of the laboratory activities must be established, implemented and maintained. The policies, programs, procedures and instructions needed to assure the quality of the tests or calibration results must be documented and communicated to personnel.

A quality policy statement must be defined in the quality manual. This statement includes the laboratory's commitment to good professional practice and service to customers; the laboratory's standard of service; the purpose of the management system related to quality; the requirement that staff involved with testing and calibration be familiar with the quality documentation and to implement the quality system in their work; and the laboratory's commitment to comply with ISO 17025 and to continually improve their system.

- Document control

There must be an established, documented policy and procedure in place for the management system controlling and identifying documents (regulations, standards, methods, etc. A master list with the status of the current revision must be maintained, with authorized copies are available where needed; these documents must be reviewed periodically to ensure suitability, and obsolete documents must be removed and stored in an appropriate place for archival purposes.

- Review of requests, tenders and contracts

Procedures for reviewing requests, tenders and contracts must be established.

- Subcontracting of tests and calibrations

When subcontract work is needed for tests normally conducted by the lab, a competent contractor that complies with ISO 17025 should be selected. The laboratory must report the subcontracting to the customer in writing and, where appropriate, gain approval from the customer. The laboratory is responsible for the subcontractor's work except when the customer specifies a particular subcontractor. The laboratory must maintain a record of the subcontractors used, and their compliance with ISO 17025.

- Purchasing services and supplies

There must be a policy and procedure for selecting and purchasing services and supplies, particularly if the services and supplies affect the quality of the test or calibration. There must be a procedure in place for the reception and storage of consumable materials. These materials

should not be used until they have been inspected and verified to comply with standard specifications. Suppliers for these materials should be evaluated and a list of approved vendors be maintained.

- Service to the customer

The laboratory must work with customers to clarify customer requests and also to monitor the laboratory performance for the customer. The laboratory will ask the customer for feedback in order to improve the management system.

- Complaints

The laboratory must have a policy and procedure for the resolution of complaints received from customers. Records of these complaints and the resulting corrective action must be maintained.

- Control of nonconforming test or calibration work

There must be a policy and procedure for addressing work that does not conform to set procedures or requirements from customers. The policy must ensure that management of the nonconforming work be assigned to authorized staff and defined actions are taken when nonconforming work is identified. Furthermore, an evaluation of the significance of the nonconformity must be completed, with corrective action, customer notification, and the responsibility for authorizing the resumption of work clearly defined.

- Improvement

The quality management system must be continuously improved by using quality policy, quality objectives, audits, data analysis, corrective and preventative actions and management review.

- Corrective action

There will be a policy and procedure established to designate appropriate staff to implement corrective action when there are departures from established policies and procedures, beginning with an investigation to determine root cause. When a problem is identified, corrective action is required to eliminate the problem and prevent reoccurrence.

- Preventative action

Improvements and sources of nonconformity need to be identified. If preventative action is required, action plans must be developed, implemented and monitored to prevent re-occurrence.

- Control of records

There must be procedures for the identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. All records must be legible and stored with easy access but protected from damage or deterioration. Document retention times must be established. These records will be securely and confidentially held. These records must be protected, backed up or stored electronically.

Records of original observations and derived data will be retained to establish an audit trail. The technical records for each test or calibration must have enough information to identify factors that affect uncertainty and to allow for the calibration to be repeated. The records will include the identity of all the personnel responsible for the results. Mistakes will be crossed out, not erased or deleted.

- Internal audits

The laboratory must regularly conduct internal audits to verify that operations comply with the management system and ISO 17025. These audits must be carried out by trained and qualified personnel. If the audit findings reveal nonconformity then corrective actions should take place in a timely fashion and customers notified of affected laboratory results. There must be a procedure in place.

- Management reviews

The laboratory's management staff must regularly review the management system and test or calibration activities to evaluate suitability and to initiate changes if needed. Changes should be implemented in a timely manner.

2.3 Technical requirements

Factors contributing to total uncertainty must be considered when the laboratory develops test or calibration methods and procedures.

- Personnel

The personnel operating the equipment or performing tests or calibrations, evaluating results and signing test reports and calibration certificates must be competent for the position, with appropriate education, training, experience and/or demonstrated skills. The laboratory must have a procedure in place for identifying training needs and providing appropriate training. Current

job descriptions for managerial, technical and support staff involved in tests or calibrations must be maintained. A record of the relevant authorizations, competence, educational and professional qualifications must be maintained.

- Accommodation and environmental conditions

The working environmental conditions cannot negatively affect the quality of work performed at the laboratory. If conditions affect the quality of results, the laboratory will monitor, control and record the environmental conditions.

- Test and calibration methods and method validation

Appropriate methods for tests or calibrations must be used, including sampling, handling, transport, storage and preparation of samples to be tested or calibrated. There must be instructions on how to use and operate all equipment and on the handling and preparation of samples for testing or calibration. These procedures will be kept up to date and made available to staff. Deviations from the methods must be documented and authorized and accepted by the customer.

Methods published by international, regional, or national organizations are preferred, and the lab must use the latest edition of the standard where appropriate and possible. The laboratory will let the customer know if a requested method is inappropriate or out-of-date. The laboratory must confirm that it can properly operate standard methods before using the tests on samples. The confirmation will be repeated when the standard method changes.

Method development for a laboratory's own use must be planned and assigned to qualified personnel. If a method is requested that is not from standard methods, the method must be properly validated. The laboratory will keep a record of the results obtained, the methods used, and a statement regarding whether the method is fit for intended use. For the validation, the range and accuracy (including precision, uncertainty, detection limit, selectivity, linearity, repeatability and/or reproducibility, robustness and cross-sensitivity against interferences from the matrix) must be assessed where applicable, to meet customer requirements.

The laboratory must have a procedure in place to determine the uncertainty of measurement for calibrations/tests. The laboratory will attempt to identify all components of uncertainty to make a reasonable estimation based on knowledge of the performance of the method.

If computers or automated equipment are used for acquisition, processing, recording, reporting, storage, or retrieval of test or calibration data, the laboratory will ensure the developed software

is documented and validated as appropriate for use and there are procedures in place for protecting the data. The equipment must be maintained to ensure it functions properly.

- Equipment

The correct equipment for sampling, measurement, and test equipment will be purchased for tests/calibrations and must meet international standards. Equipment and software used for testing, calibrations and sampling should comply with relevant specifications. Before equipment is ordered, the equipment information should be checked to meet compliance with relevant specifications. The equipment will be operated by authorized personnel and up-to-date instructions on how to use and maintain the equipment provided. Records of the equipment maintenance will be kept updated. Equipment that has been mishandled or defective will be taken out of service. The laboratory will examine the effect of the defect and will implement a "control of nonconforming work" procedure. The testing and calibration equipment must be protected from adjustments that would invalidate the data.

- Measurement traceability

The equipment used for test or calibrations will be calibrated before use based on an established procedure. The method for calibration must be traceable to the International System of Units (SI). If the calibration cannot be made in SI units, confidence in the measurement must be proven by the use of certified reference materials or the use of specific and/or consensus standards.

The laboratory will have a procedure in place for calibration of the reference standards. The reference standards will be purchased from a source that can provide traceability of their materials. Where possible, the materials will be traceable to SI units of measurement or to certified reference materials. There will be a procedure in place for the safe handling, transport, storage and use of reference standards/materials to prevent contamination or deterioration.

There will be procedures in place for sampling substances, materials or products for testing or calibration. The sampling plan will be readily available at the location where sampling occurs. The sampling plans will be based on appropriate statistical methods. If a customer requires deviations, additions or exclusions from the sampling plan, these deviations will be recorded.

There must be a procedure for transporting, receipt, handling, protection, storage, retention and disposal of test or calibration items. This system will ensure that items cannot be confused physically when referred to in documents. Any abnormalities from normal or specified conditions will be recorded. There must be appropriate facilities for avoiding deterioration, loss or damage to test or calibration items during storage, handling and preparation.

- Quality Control

The laboratory must have quality control procedures for monitoring tests or calibrations. The procedure may include the regular use of certified reference materials, internal quality control materials, participation in proficiency-testing programs, retesting of retained samples, and correlation of sample characteristics.

Quality control data must be recorded so that trends are detectable and where possible, statistical techniques are applied to evaluate the results. If the data are outside pre-determined criteria, action will be taken to correct the problem and prevent erroneous results from being reported.

- Reporting the Results

All the results of each test or calibration occurring at the laboratory will be reported accurately and clearly in a report or calibration certificate in a format that meets the requirements of the customer. If the test report contains data from subcontractors, these results will be clearly identified and the subcontractor will issue the calibration certificate.