DEPARTMENT OF ENVIRONMENT & CONSERVATION

POLICY DIRECTIVE PD:PP2001-01.2

DIVISION: Pollution Prevention Division

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Short Title

This policy may be cited as the *Accredited Laboratory Policy*.

Subject

The use of laboratories with a recognized form of laboratory accreditation and laboratories recognized for proficiency testing by the Department of Environment & Conservation and by organizations providing environmental data to the Department of Environment & Conservation.

Objective

To ensure that environmental information produced by and provided to the Province is comparable, of known quality, and adequate for its intended purpose, thereby providing a reliable and harmonized basis for characterization and management of the Newfoundland & Labrador environment.

Background

In the early 1980's Federal and Provincial laboratories taking part in acid rain studies were asked to participate in a quarterly round-robin. The results were submitted and each laboratory was given a report on how well they had performed. This was the beginning of efforts to improve quality control in Canadian analytical laboratories.

In the late 1980's the Canadian Association for Environmental Analytical Laboratories (CAEAL) was formed. CAEAL took a different approach to laboratory evaluation. Initially CAEAL offered "Certification" for specific chemical parameters. This required the laboratory to submit the analytical results of four performance evaluation samples per parameter. Once the chemical results of the performance evaluation samples were acceptable, certification was granted for the parameter. Re-evaluation was performed every six months to maintain certification.

Certification was an indication of how well a laboratory could perform a specific analysis. Certification was not completely effective and it was well known that laboratories would take special care when analyzing performance evaluation samples. Therefore it was necessary to have a method of evaluating a laboratory's analytical methods, quality assurance and general operating procedures. To meet this need an "Accreditation" scheme was added. Accreditation included the certification process with the addition of:

1) the submission of an analytical methods manual and quality assurance documentation by the laboratory and a
2) site visit, by CAEAL, every two years.

The laboratory's analytical methods manual and quality assurance documentation were reviewed by CAEAL and suggestions were made for changes and improvements. It was mandatory to complete a sample trace in which the documentation of a sample from arrival in the lab, through analysis and any associated quality control checks were verified. Site visits were used to observe the way a laboratory operated and ensured that the laboratory was using the methods and procedures on which accreditation was based. The site visit usually resulted in a list of mandatory and optional changes to be made to the laboratory to improve quality.

Due to the confusion between the terms certification and accreditation, laboratories are now "recognized for proficiency testing" rather than certified.

In 1994, CAEAL and the Standards Council of Canada (SCC) signed a partnership agreement, producing a formal accreditation program. Under the jointly administered program, CAEAL conducted site audits and evaluated each laboratory's performance at regular intervals. CAEAL assessed participating laboratories in accordance with the International Organization for Standardization's (ISO) internationally recognized ISO 17025 standard. The SCC granted accreditation to the laboratory on CAEAL's recommendation. In 2005, CAEAL and the SCC stopped administering the joint accreditation program and each organization continued to offer accreditation independently.

Effective June 23, 2008, CAEAL officially changed its name to CALA, the Canadian Association for Laboratory Accreditation.

CALA and SCC continue to offer accreditation based on the ISO 17025 standard independently of each other and are the only Canadian options for laboratory accreditation. Laboratories can obtain formal laboratory accreditation from accreditation bodies based in other countries. The position of the Department of Environment and Conservation is to accept submissions from laboratories with a recognized form of accreditation.

Reasons for Using Accredited Laboratories

- Accreditation ensures that the laboratory uses proper analytical procedures and has a satisfactory level of performance in analyzing specified chemical parameters.
- Accreditation ensures that data from different laboratories are of known quality and are comparable.
- Accreditation ensures that the laboratory uses proper quality control procedures when performing analytical tests.
- Accreditation ensures that the laboratory results of legal samples are defensible and would stand up to scrutiny in court.

- If the Department does not use accredited laboratories, other governments and agencies will have grounds to question data.

Legislative Authority

This policy has been developed to support regulations, policies and guidance documents under the Environmental Protection Act and the Water Resources Act that contain sections relating to analytical data for the determination of compliance. These regulations include, but are not limited to:

- Air Pollution Control Regulations, NLR 39/04 amended by 94/10.
- Environmental Control Water and Sewage Regulations, NLR 65/03 amended by 23/09.

Policy

1. The Department of Environment & Conservation shall contract only those commercial laboratories which have a recognized form of laboratory accreditation to perform the required analyses. The exception to this policy will be the permissibility to contract commercial laboratories that comply with section 6. The Department of Environment and Conservation does reserve the right to require accreditation at its own discretion irrespective of section 6.

2. The Department of Environment and Conservation shall accept analytical data from all outside sources (i.e. contractors, consultants, the Federal Government, other Provincial Governments, other Provincial Departments and Municipal Governments), other than industrial or municipal in-house laboratories, only if the data is produced by a laboratory which has a recognized form of laboratory accreditation or complies with sections 4, 5 or 6.

3. The Department of Environment and Conservation shall accept analytical data under four conditions:

   (i) if the samples are being analyzed by a commercial laboratory that complies with sections 1 or 6; or
   (ii) if the samples are being analyzed in an accredited in-house laboratory; or
   (iii) if the samples are being analyzed in an in-house laboratory, that this laboratory have recognition for proficiency testing to perform said analyses and comply with section 7; or
   (iv) if the samples are being analyzed in an in-house laboratory and recognition for proficiency testing is not available for a specific parameter, than a standard operating procedure (SOP) for analysis of this parameter be submitted to the Department of Environment and Conservation. This must be submitted and approval received from the Department before analytical results will be accepted and the lab must comply with section 7.

4. If there is no recognition for proficiency testing available for a particular parameter, then data will only be accepted from a laboratory which has overall accreditation and recognition for proficiency testing for related parameters.

5. Notwithstanding section 4, if there is a laboratory that is known to have expertise for a specialized parameter and there is no recognition for proficiency testing for this specialized parameter, then this laboratory can be used even if it does not have accreditation. This should only happen rarely.

6. New commercial laboratories will be given a period of one year in which to receive laboratory accreditation. Notice must be provided to the Department of Environment and Conservation of the company's intention to obtain accreditation. Analytical results will only be accepted from these new commercial laboratories following completion of the application process for a recognized form of laboratory accreditation and successful recognition for proficiency testing for each parameter to be analyzed. Data will cease to be accepted if the laboratory loses recognition for proficiency testing during the accreditation process. If after one year, a new commercial

laboratory fails to attain accreditation, further analytical results from the laboratory will not be accepted by the Department of Environment and Conservation until accreditation is obtained.

Copies of the application to the accreditation body and successful proficiency testing recognition must be sent to the:

Senior Environmental Scientist
Pollution Prevention Division
Department of Environment and Conservation
4th Floor, West Block
Confederation Building
P.O. Box 8700
St. John's, NF
A1B 4J6

7. Industries or municipalities with their own in-house laboratories that are recognized for proficiency to perform analyses or have received Departmental approval to perform analyses for which recognition is not available and are not accredited, will undergo an annual laboratory inspection by a representative of the Department of Environment and Conservation. Companies will be charged a fee for this inspection in accordance with Schedule 1 of this policy as per Section 21 of the Executive Council Act (Chapter E-16.1). Recommendations for improvements of any aspect related to sample analysis must be acted upon within six months in order for analytical results to be continued to be accepted by the Department of Environment and Conservation. If it is determined that these recommendations have not been acted upon, no further environmental data will be accepted by the Department of Environment and Conservation until the laboratory in question satisfies the recommendations or attains accreditation. Until such time as this condition is met, the environmental data must be received from an accredited commercial laboratory.

8. Upon request, the Department of Environment and Conservation must be supplied with all laboratory results as produced in the form and format by the accredited laboratory and must also include the quality control/assurance results, including, but not limited to, detection limits, sample blanks, sample spikes, duplicate and standard reference sample results.

9. This policy will take effect as soon as it is signed by the Minister and shall remain in effect until altered or canceled by the Minister.

SCHEDULE 1

The fee for performing an annual lab inspection is $2000, HST included. The company will be invoiced upon completion of the inspection. Payment must be made to the Newfoundland Exchequer.

DEFINITION OF TERMS

Analytical data: chemical, microbiological, physical or toxicological data.

CALA: Canadian Association for Laboratory Accreditation

CAEAL: Canadian Association for Environmental Analytical Laboratories.

Certification: See Proficiency Testing Recognition.

Commercial laboratory: A third party, independent laboratory performing testing procedures of environmental samples.

ISO: International Organization for Standardization

Performance Evaluation Sample: A characterized sample, having designated reference values, which is used in the evaluation of laboratory performance.

Proficiency Testing: The determination of laboratory testing performance by means of inter-laboratory comparisons. Note that individual agencies may call their Proficiency Testing programs by different titles; e.g. inter-laboratory comparison programs, Performance Evaluation programs, etc.

Proficiency Testing Recognition: The formal recognition of the proficiency of a laboratory to carry out specific tests.

Recognized Form of Laboratory Accreditation: Accreditation obtained from an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Agreement and based on ISO 17025.

Reference Value: Value assigned to a Performance Evaluation sample. This value may be based on any appropriate combination of design value, inter laboratory consensus value or value provided by a laboratory with demonstrated accuracy.

SCC: Standards Council of Canada.

SOP: Standard Operating Procedure