

ACCREDITATION OF LABORATORIES IN CANADA WITH A FOCUS ON DRINKING WATER TESTING LABORATORIES

Background

The Ontario government has recently introduced a regulation to require that laboratories conducting the testing of drinking water sources be accredited for the conduct of those tests. Further, the regulations call for this accreditation to be delivered by the Standards Council of Canada / Canadian Association for Environmental Analytical Laboratories (SCC/CAEAL) program for the accreditation of environmental testing laboratories.

Purpose

The purpose of this paper is to provide information on the subject of laboratory accreditation in Canada and, in particular, how it applies to the accreditation of water testing laboratories. The paper will address:

- The part accreditation plays in achieving and maintaining confidence in laboratory test results
- The Standards Council of Canada (SCC) – the national accreditation body
- The Canadian Association for Environmental Analytical Laboratories (CAEAL) – the SCC Partner providing assessment and re-assessment services to environmental laboratories leading to SCC accreditation/re-accreditation
- The national and international recognition provided by SCC/CAEAL accreditation.

What is Accreditation?

Accreditation: *is the formal recognition of the competence of a laboratory to carry out specific tests.*

Accreditation is given only to those laboratories that demonstrate competence in their field of testing and conform to ISO/IEC 17025: *General Requirements for the Competence of Testing and Calibration Laboratories*, by providing evidence that they have:

- the personnel with the skills and knowledge;
- the environment with the facilities and equipment;
- the quality control; and
- the procedures,

in order to produce competent test results.

Evidence of this conformance is acquired during a full technical assessment and must satisfy the assessor who is, in this instance, an expert in the field of water quality testing.

Accreditation is maintained only by those laboratories that:

- continue to demonstrate competence through inter-laboratory comparison of sample test results (proficiency testing) held twice yearly; and
- successfully complete full technical assessments every two years.

Accreditation is voluntary (unless mandated by legislation or regulation). There are currently 112 laboratories accredited through the SCC/CAEAL accreditation program and almost all of these conduct testing of analytes in a water matrix.

What does Accreditation provide?

To the laboratory, accreditation provides only recognition of competence. To all others, laboratory accreditation provides confidence in the ability of the laboratory to produce competent results. From the International Laboratory Accreditation Cooperation (ILAC) Guide 10:1996;

“Laboratory accreditation is the best mechanism to provide assurance to customers on the quality and competence of the laboratory. Confidence in accreditation is obtained by a transparent system of control over the accredited labs and an assurance given by the accreditation body that the accredited laboratory constantly fulfils the accredited criteria.”

To illustrate the advantages of accreditation, Figure 1 below shows the differences in performance of laboratories in six rounds (three years) of the CAEAL Proficiency Testing Program, based solely on whether or not they were accredited. Six proficiency-testing studies performed (over three years) using five testing parameters, namely Biochemical Oxygen

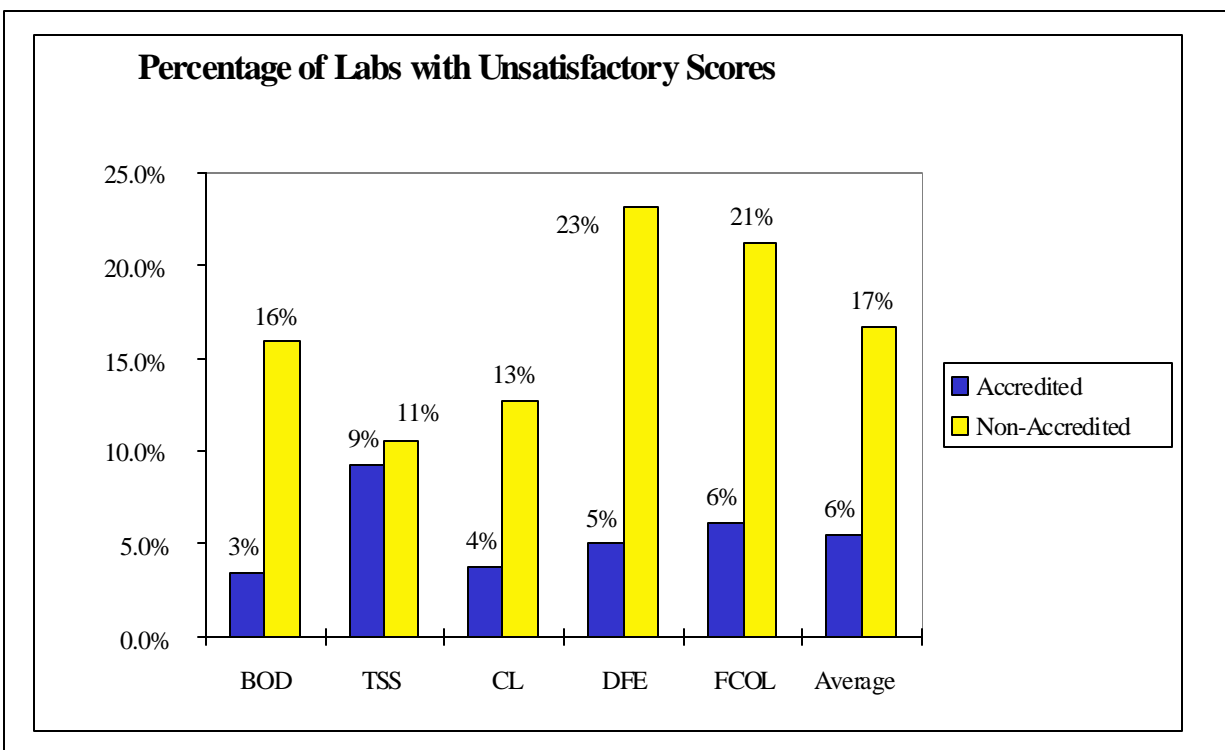


Figure 1: Comparative Performance of Accredited vs. non-Accredited laboratories.

Demand, Total Suspended Solids, Chloride, Dissolved Iron and Fecal Coliform. Five hundred and twenty-eight results from accredited laboratories were compared with the same number of results from non-accredited laboratories that received identical proficiency testing samples. It

was found that accredited laboratories achieved higher scores, a greater number of perfect scores, and fewer unsatisfactory scores (as illustrated in Figure 1) in each of the five parameters. The conclusion is an obvious one: accredited laboratories produce more consistent and competent results than non-accredited ones.

Who accredits water testing laboratories in Canada?

The SCC and CAEAL jointly deliver accreditation services to environmental laboratories. Accreditation, as mandated by *The Standards Council of Canada Act* is granted solely by the SCC upon recommendation from CAEAL. To ensure that the entire process meets the relevant international requirements, ISO/IEC Guide 58, the SCC conducts an audit annually on the CAEAL portion of the program. Concomitantly, the SCC agrees to undergo similar assessment from international peer organisations to ensure their continued conformance to these same requirements.

How are assessments carried out?

An assessment to ISO/IEC 17025 covers the laboratory's overall quality system and assesses their technical competence to conduct the specific tests for which they seek accreditation.

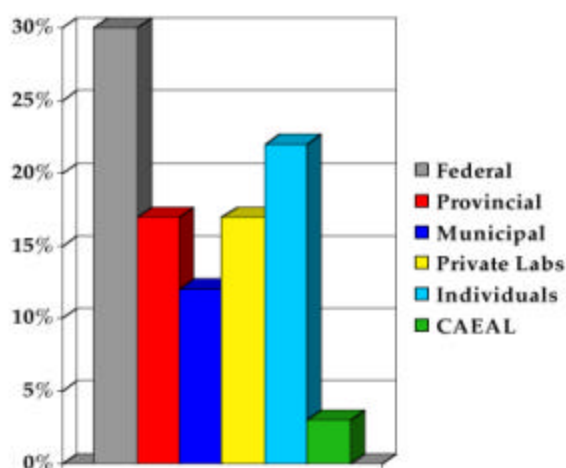


Figure 2: Sources of Environmental Assessors

Two to four trained assessors typically conduct assessments over a period of 3-4 days. In addition, assessors will assess an applicant or accredited laboratory against test-specific criteria within documentation that is supplementary to CAN-P-4D. This documentation may include test methods and other technical or regulatory testing requirements. Normally, water testing laboratories are assessed and accredited for specific tests, defined as *a unique combination of analyte, matrix and method*. Water testing technical experts, who are trained in the processes of laboratory assessment, carry out all the assessment and the re-assessment work on a volunteer basis.

There are 86 trained assessors in the SCC/CAEAL program and 47 of these are employed by federal, provincial and municipal regulatory agencies. Other assessors are from private-sector laboratories and some are individuals without specific business affiliation.

What is the Accreditation Process?

Upon completion of the assessment, the team will leave a list of corrective actions to be instituted by the laboratory within a specified timeframe and to the satisfaction of a scientific panel (the CAEAL Advisory Panel). When all corrective actions have been completed by the laboratory, to the satisfaction of the CAEAL staff and the Advisory Panel, the application is balloted to the CAEAL Board. When this is complete, the SCC accreditation approval process is then initiated. For new accreditations, the successful applicant will receive an Accreditation Certificate signed by the Chair of the SCC Board along with a congratulatory

letter. Subsequently, for accreditation scope extensions, the CAEAL Board makes the approval decision. For re-accreditation every two years, the Director of Conformity Assessment acts on behalf of the SCC in renewing the accreditation following receipt of a CAEAL Board recommendation.

How is laboratory competence monitored through Proficiency Testing (PT)?

In order for a laboratory to acquire and maintain accreditation, it must successfully participate in the CAEAL PT Program, for those parameters offered in the CAEAL Pt program. Proficiency testing, or sometimes referred to as inter-laboratory comparisons, seeks to determine the technical competence of a laboratory. There are currently 281 laboratories in the CAEAL PT Program. Laboratories must analyse 4 concentrations, twice a year for each type of test listed on their scope of accreditation. Laboratory performance is evaluated statistically. When a laboratory returns successful results, CAEAL grants a Certificate of Proficiency and includes the laboratory in a directory on the CAEAL website. In one instance, a provincial ministry also receives these results, in order to more proactively monitor the performance of laboratories conducting testing for regulatory compliance.

When a laboratory fails to perform satisfactorily, the laboratory receives a warning letter of suspension of PT recognition for that test. Should the next round of PT samples produce a similar failure, the laboratory accreditation for that test is suspended by the SCC on a recommendation from CAEAL. A third failure results in mandatory withdrawal by the SCC of that specific test from the laboratory's scope of accreditation. Verification visits, outside the normal assessment cycle, may also provide indication that individual tests should be suspended or the accreditation withdrawn.

What testing parameters are covered by PT?

The following represents the PT parameters that currently form part of the CAEAL PT Program, most of which (except TSS and BOD) are all affected by at least some of the current and proposed provincial drinking water regulations:

- Major Ions,
- Metals/Metal Hydrides,
- Total Kjeldahl Nitrogen / Total Phosphorous, (TKN/TP)
- Total suspended solids, (TSS)
- Biochemical oxygen demand, (BOD)
- Turbidity,
- Coliforms,
- Organochlorine pesticides and polychlorinated biphenyls, (OCP/PCB)
- Polycyclic aromatic hydrocarbons, (PAH)
- Trout lethal concentration 50, (Trout LC50)
- Daphnia lethal concentration 50, (Daphnia LC50)
- Microtox inhibition concentration 50, (Microtox IC50)

- Cyanide (Strong acid dissociable), CN(SAD)
- pH,
- benzene, toluene, ethyl benzene, xylene / trihalomethanes, (BTEX/THM)
- Mercury

Who are the Partners in Accrediting Water Testing Laboratories?

The Standards Council of Canada (SCC) – The SCC is a statutory Crown corporation that was created by an Act of Parliament in 1970. The mandate of the SCC is in *The Standards Council of Canada Act*: "to promote efficient and effective voluntary standardisation in Canada, where standardisation is not expressly provided for by law and in particular, to:

- promote the participation of Canadians in voluntary standards activities,
- promote public-private sector co-operation in relation to voluntary standardisation in Canada,
- co-ordinate and oversee the efforts of persons and organisations involved in the National Standards System,
- foster quality, performance and technological innovation in Canadian goods and services through standards-related activities and
- develop standards-related strategies and long-term objectives,

in order to advance the national economy, support sustainable development, benefit the health, safety and welfare of workers and the public, assist and protect consumers, facilitate domestic and international trade and further international co-operation in relation to standardisation."

As a part of its overall mandate, the SCC represents Canada in international standards organisations such as the International Organization for Standardization (ISO) and the International Laboratory Accreditation Cooperation (ILAC). In addition, it accredits standards development organisations, certification organisations, quality and environmental management systems registrars, auditor course providers, auditor certifiers, and testing and calibration laboratories. It is this last one that is the subject of this paper.

The SCC mandate is furthered through the National Standards System (NSS) made up of volunteers involved in Canadian Advisory Committees (CACs) and Canadian Sub-Committees (CSCs), members of the Standards Council and its advisory committees, the Standards Council itself (the Secretariat), and all organisations accredited by the Standards Council. Like all organisations representing a disparate group of stakeholders, the SCC takes pride in its role as a facilitator of public-private sector partnerships. The Program for the Accreditation of Laboratories (PALCAN) is one such effort and is the program, through which, the SCC recognises the competence of water testing laboratories.

PALCAN provides formal recognition of the competence of a laboratory to manage and perform specific tests or types of tests listed in the scope of accreditation approved by the Council. PALCAN currently accredits laboratories in the following fields of testing: Acoustics & Vibration, Biological, Calibration, Chemical, Electrical/Electronic, Ionising Radiation, Mechanical, Non-destructive Evaluation, Optics & Optical Radiation, Physical, Thermal & Fire.

All environmental testing, including water testing, falls into one of the biological or chemical fields of testing.

Beginning in 1981, PALCAN has grown to a client base of 330 applicant or accredited laboratories. In 1994, CAEAL signed the first full partnership agreement with the SCC, preceding the National Research Council / Calibration Laboratory Assessment Services (NRC/CLAS) and the Bureau de normalisation du Québec (BNQ) by nearly four years. Under the terms of the SCC/CAEAL Accreditation Partnership Agreement, CAEAL carries out site assessments and re-assessments and operates a proficiency-testing program. The granting and maintenance of accreditation is under the authority of the SCC on the recommendation of CAEAL. Accreditation itself is based on satisfactory participation in the site assessment program plus satisfactory participation in proficiency testing, where such testing is offered as part of the accreditation.

PALCAN's delivery of accreditation follows international criteria and guidelines established by ISO and by ILAC.

The Canadian Association for Environmental Analytical Laboratories (CAEAL) – was formed in 1989 as a non-profit private-public partnership. Following the identification of a need for a national proficiency testing program in 1988 by Environment Canada, the Ontario Ministry of the Environment and some private sector laboratories, public consultation across Canada resulted in the creation of the Association. The original application for incorporation contained the signatures of all three original stakeholders.

CAEAL was formed to provide quality assurance programs for laboratories conducting environmental testing, including tests involving the suitability of drinking water. The original testing parameters of concern to the founding stakeholders were all in water matrices, and water is still the most prevalent testing matrix in published scopes of accreditation and for the PT Program parameters.

CAEAL is an association of 450 environmental analytical laboratories and individuals. It is governed by a Board of Directors, which includes one public sector and one private sector representative elected by the membership from each of five geographic Regions in Canada, for a total of ten elected board members.

Current laboratory participation in the joint SCC/CAEAL accreditation program and the CAEAL PT program is as follows:

<i>Accreditation Program (includes PT Program)</i>			<i>PT Program only</i>		<i>Total</i>
	<i>Public/Private</i>		<i>Public/Private</i>		
BC	2	11	15	52	80
Prairie	6	20	5	18	49
Ontario	13	45	11	32	101
Quebec	1	1	1	1	4
Atlantic	2	10	4	18	34
Northern	1	-	1	1	3
International	-	-	1	9	10
Sub-Total	25	87	Sub-Total	38	131
Total	112		169		281

The accredited laboratories are identified on the SCC website: <http://www.scc.ca> while the laboratories recognised for PT performance are listed on the CAEAL website at: <http://www.caeal.ca>

Recognition of Program Integrity

Both SCC and CAEAL believe strongly that technical competence should remain the only real basis for establishing confidence in a laboratory's ability to produce reliable results. Accreditation of water testing laboratories remains the best method of demonstrating this competence.

Both the SCC and CAEAL participated in the three year effort to obtain recognition of the program from the Asia Pacific Laboratory Accreditation Co-operation (APLAC), which resulted in acceptance of Canada (through the SCC) as a full signatory of the APLAC Mutual Recognition Arrangement (MRA) in 2000. Shortly thereafter, the SCC signed the same type of arrangement as a member of the International Laboratory Accreditation Cooperation (ILAC), providing demonstrated equivalence to similar programs around the world. At the time of signing, there were 37 Accreditation Bodies in the ILAC MRA.

Finally, the SCC and CAEAL were recently approached by the World Health Organization's Pan American Health Organisation (PAHO) to jointly deliver accreditation services in Central and South America. The joint effort specifically targets water testing laboratories and PAHO selected the Canadian model as the preferred option.

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