



# LABORATORY INTER-JURISDICTIONAL REVIEW TO INFORM THE PROCESS OF UPDATING THE ENVIRONMENTAL DATA QUALITY ASSURANCE REGULATION

*PROVINCE OF BRITISH COLUMBIA, MINISTRY OF ENVIRONMENT*

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## 2.1 COLLABORATOR

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Dr Austin has worked in the laboratory industry for over 17 years. Dr Austin's experience includes project work in clinical laboratories, genetics research and most recently environmental laboratory standards and quality assurance. Since 2013 Joyce has worked for the Ministry of Environment as the Senior Provincial Laboratory Specialist (and unit head). Some of the responsibilities of this position include managing the province's Environmental Laboratory Service Program, leading provincial teams of government, academic and scientific professionals in the development of laboratory standards as well as regulatory initiatives and associated policy. Dr Austin is also responsible for negotiating and managing formal monitoring agreements and contracts for laboratory services, coordinating programs such as the Legal Sampling Program and the Split Sample Program and overseeing quality assurance / quality control for environmental laboratories including audits based on ISO 17025. In addition to these responsibilities Dr. Austin develops and delivers training programs, supervises technical staff, co-chairs the B.C. Environmental Laboratory Technical Advisory Committee, is a provincial representative on the Federal/Provincial Quality Assurance Working Group. Joyce graduated from the University of Victoria in 2013 with a Ph.D. in Biology.

### 3. EXECUTIVE SUMMARY

The Environmental Data Quality Assurance Regulation (EDQAR) is the primary means through which British Columbia (BC) controls the quality of laboratory test data it receives under the many programs of the *Environmental Management Act (EMA)*. It does so by setting out mandatory requirements for laboratories to ensure that the test data they produce is acceptable for the intended data use by the BCMOE.

There is a concern that the EDQAR in its current state fails to provide an acceptable level of data quality assurance.

As it is currently structured, the EDQAR utilizes a process known as proficiency testing to qualify laboratories to provide data to the ministry. Proficiency testing measures a laboratory's data quality by its performance on reference samples. This mechanism for data quality assessment is not a laboratory standard and lacks any mandatory requirements for internal data quality structures or any physical inspection of laboratory operations. In fact, at the present time, there is no requirement under the EDQAR to "pass" the proficiency test evaluation.

A higher level of data quality assurance is provided by *laboratory accreditation*. In this model, a laboratory must demonstrate it has "a management system, are technically competent, and are able to generate technically valid results" (International Standards Organization (ISO) 2005). The standard that is used for this purpose internationally is ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*. It is supported by a worldwide chain of peer-reviewed accrediting bodies that maintain a process of objective and impartial laboratory assessment – including direct physical inspection and audit by technical experts.

A review of the Canadian jurisdictions reveals that British Columbia *is the only province that does not designate ISO/IEC 17025 laboratory accreditation to qualify laboratories, or ISO/IEC 17043 to qualify Proficiency Testing providers*.

In the late 1990's, Ontario went through similar deliberations on laboratory accreditation, and were ultimately driven to move to requiring laboratory accreditation to qualify laboratories by an environmental crisis. This is documented in detail by the Report of the Walkerton Inquiry. The BCMOE should look upon that situation as a "lesson learned" as considerations are made into the optimal strategy for test data quality for the protection of the people and environment of British Columbia.

Several recommendations are presented for consideration in the update of the EDQAR; the predominant recommendation however is the formal adoption of ISO/IEC 17025 laboratory accreditation as the BC policy for laboratory qualification. Adopting this policy

will bring BC in line with other Canadian jurisdictions while ensuring that, the BCMOE will be adequately supported by the provincial laboratory infrastructure in its environmental decision-making.

## 4. INTRODUCTION

In this report, the authors examine laboratory accreditation in all jurisdictions across Canada to inform and guide planning for an update to the BC Environmental Data Quality Assurance Regulation (EDQAR).

### Importance of Data Quality

Decisions involving the environment are being made all the time in the province of British Columbia. A mother may be deciding to use tap water for the preparation of infant formula; a clean-up crew may need to decide on the extent of a spill of diesel fuel; or the province may need to decide on the site or environmental impact of a mine. Each decision maker wants to make the best decision for their family, the land owner or the province. To make the best-informed decision, you need the right information, and in the majority of environmental decisions, laboratory test results provide the bedrock upon which the right information is built. For this reason, it is imperative that the province of British Columbia establish laboratory infrastructure with a high and demonstrable level of quality assurance and the ability to produce accountable and defensible results. Such a system would convey the highest level of confidence achievable while mitigating potential liabilities. In Canada and internationally, this level of rigour is typically achieved through accreditation of testing laboratories to *ISO/IEC 17025 General requirement for the competence of testing and calibration laboratories*.

### Lessons learned from the Walkerton Commission

A seminal event in Canadian environmental history occurred on the 15<sup>th</sup> of May 2000 when agricultural runoff contaminated a ground water well supplying drinking water to the town of Walkerton, Ontario. Seven people died and hundreds were sickened - some with lingering effects to this day. The Walkerton Commission, headed by Justice Dennis O'Connor, reviewed the events and contributing factors in excruciating detail, identifying a litany of failures by many – including the government of Ontario and the Ontario Ministry of the Environment (MOE) - that could have prevented, or at the very least reduced, the impact of this tragedy.

Of particular interest in the context of this report, is the insight provided by the Commission's report into the value of laboratory accreditation. The Commission spent a great deal of time in Parts 1 and 2 of the report examining laboratory accreditation. In Part 1, which examined events prior to the Walkerton event, it was found that Ontario MOE knew about the importance of laboratory accreditation prior to Walkerton, *but chose not to require accreditation*<sup>1</sup> (Walkerton Inquiry, Report of (Part 1) 2002). After Walkerton, the province moved immediately to rectify this error in the creation of O.Reg.

<sup>1</sup> This is documented in the Report of the Walkerton Inquiry Part 1 "10.4.4 The Decision Not to Require Accreditation", p. 378-380

459/00, and the requirement for laboratory accreditation was eventually advanced as Recommendation 41 of the Walkerton inquiry, which was fully integrated into the Ontario Safe Drinking Water Act in 2002. In the words of Justice O'Connor, "Although a quality assurance program adds time, effort and cost to laboratory operations, the improvements in reliability, validity and record keeping more than offset the increased expenditure. As such, drinking water testing should be performed only by accredited laboratories, as currently required under Ontario Regulation 459/00" (Walkerton Inquiry, Part 2 p 268).

In a paper commissioned for the Inquiry - Commissioned Paper 21 *An Overview of Drinking Water Testing Laboratories in Ontario* – Dr. Jane Pagel, vice-president of Corporate and Government Affairs with Jacques Whitford Environment Ltd, conducted a general review of laboratory accreditation and made the following observations:

- Opinion of the Canadian model for laboratory accreditation was quite positive and regarded as a model for accreditation programs generally (Pagel, p.22).
- Accreditation cannot *guarantee* the accuracy of all test data from accredited laboratories, no matter how thorough the assessors and the audit; but it does bring the laboratory closer to perfection (Pagel, p.7).
- Since the analysis of air samples or almost any other type of environmental testing involves health and data quality issues, it makes sense that accredited laboratories be required for this task. (Pagel, p.23).

Dr. Pagel went on to recommend "Phase in mandatory use of accredited laboratories for all parameters as is the case in many other provinces; a phase-in approach would allow smaller laboratories sufficient time to become accredited" (Pagel, p25).

These excerpts from the Walkerton inquiry have relevance for the situation in BC, and should be considered in the context of the EDQAR update.

## 5. DEFINITIONS

The following terms and acronyms are used in the context of this report:

Accreditation – Formal recognition of the competence of a laboratory to carry out specific tests

Scope of Accreditation – The list of tests to which accreditation applies for an individual laboratory

Laboratory Test – A matrix/parameter combination for which there is an associated analytical method, such that when performed in accordance with the instructions, a valid test result is obtained

Regulatory Data – A test result that is used to support a legal requirement such as a regulation, environmental assessment or management, or to satisfy a legal obligation to submit data under an order, permit, licence or approval<sup>2</sup>.

Process Data – A test result that is used for a non-regulatory purpose, such as in-house operations, product quality or other business use.

Proficiency Test – A specific sample or set of samples with a known amount of Analyte that is used to demonstrate that an analytical method produces an acceptable result. The term “proficiency test” or “proficiency testing” is sometimes abbreviated to “PT”.

ILAC – The International Laboratory Accreditation Cooperation (ILAC) is the body that oversees laboratory accreditation activities worldwide. The term “proficiency test” or “proficiency testing” is sometimes abbreviated to “PT”.

CALA – Canadian Association for Laboratory Accreditation, an accrediting body that confers accreditation for environment, food and minerals labs in Canada. CALA is accredited under ISO/IEC 17011 (for Accrediting Bodies) and ISO/IEC 17043 (for Proficiency Test Providers).

SCC – Standards Council of Canada, is the primary agency for standards in Canada. SCC is an ISO/IEC 17011 accrediting body that confers accreditation for several testing and calibration service streams in Canada.

<sup>2</sup> The term for operating permit varies by jurisdiction - permit, approval, certificate of approval, environmental certificate of approval, licence. The term “operating approval” will be used in this document, but should be interpreted to refer to the operating permit terminology in the respected jurisdiction.

CEAEQ – Centre d’expertise en analyse environnementale du Québec, is the primary agency for conformity assessment to ISO/IEC 17025 in the province of Quebec.

ISO/IEC 17011 *General requirements for accreditation bodies accrediting conformity assessment bodies* – The international standard that is used to accredit Accrediting Bodies. Accrediting Bodies confer and manage the accreditation of laboratories in individual regions or countries.

ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* – The international standard that is used to accredit testing and calibration laboratories.

ISO/IEC 17043 *General requirements for proficiency testing* – The international standard that is used to accredit proficiency testing providers.

ISO/IEC 15189 *Medical Laboratories – Requirements for quality and competence* – The international standard that is used to accredit medical laboratories. Medical laboratories can also be accredited through the provincial medical authority.

## 6. OVERVIEW OF LABORATORY ACCREDITATION

### What is laboratory accreditation?

Laboratory accreditation 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 (CALA P02-01, p.1). In a sense, the term “accredited laboratory” is a misnomer, and it is more correctly expressed as “a laboratory accredited for a specific list of analytical methods”. The standard applied to accredit laboratories is ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*, an international standard developed by the International Organization for Standardization (ISO), with the input of industry experts from around the world. ISO/IEC 17025 was developed around a set of fundamental principles. A laboratory wishing to achieve the production of technically valid test data must first successfully articulate and embrace these principles. The eight fundamental principles are:

- **Capacity** – Is the concept that a laboratory has the resources (People with the required skills and knowledge, the environment with the required facilities and equipment, the quality control, and the procedures) in order to undertake the work and produce technically valid results
- **Exercise of Responsibility** – Is the concept that persons in the laboratory have the authority to execute specific functions within the overall scope of work – and that the laboratory can demonstrate accountability for the results of the work
- **Scientific Method** – Is the concept that the work carried out by the laboratory is based on accepted scientific approaches, preferably consensus-based, and that any deviations from accepted scientific approaches can be substantiated in a manner considered generally acceptable by experts in that field
- **Objectivity of Results** – Is the concept that results produced within the scope of work of the organization are mainly based on measurable or derived quantities, and that only persons deemed qualified to do so produce subjective test results, and that such results are noted as being subjective, or are known by experts in that field of testing to be mainly subjective
- **Impartiality of Conduct** – Is the concept that the pursuit of technically valid results using generally accepted scientific approaches is the primary and overriding influence on the work of persons performing tests and calibrations, all other influences being considered secondary and not permitted to take precedence
- **Traceability of Measurement** – Is the concept that the results produced within the scope of work of the laboratory, are based on a recognized system of measurement that derives from accepted, known quantities (SI *Système international d'unités*) or other intrinsic or well characterized devices or quantities, and that the chain of comparison of measurement between these accepted, known quantities or intrinsic devices or quantities, and the device providing the

objective result, is unbroken for the transfer of measurement characteristics, including uncertainty, for the whole of the measurement chain

- **Repeatability of Test** – Is the concept that the test or calibration that produced the objective results will produce the same results, within accepted deviations during subsequent testing, and within the constraints of using the same procedures, equipment and persons used during a previous execution of the test or calibration
- **Transparency of Process** – Is the concept that the technical and supporting processes within the laboratory are open to internal and external scrutiny, so that factors which may adversely affect the laboratory's pursuit of objective results based on scientific method, can be readily identified and mitigated)

In addition, an accredited laboratory must maintain acceptable performance in proficiency testing to maintain accreditation for individual tests. Based on the on-site assessment and acceptable performance in proficiency tests, a laboratory is recognized as meeting the requirements of the standard by the issuance of a certificate and scope of accredited tests. To maintain the accreditation, laboratories must maintain acceptable scores in proficiency tests conducted twice per year, and are subject to on-site assessment every two years.<sup>3</sup>

By using accredited laboratories, customers and regulators have confidence that the measurements being carried out are fit for their intended purpose. In Canada, participation in laboratory accreditation is voluntary unless regulators mandate accreditation in a legal instrument – Act/Statute, Regulation, Policy or Approval – in the respective jurisdiction.

### What is proficiency testing?

Proficiency testing (PT) is a means to measure the ongoing ability of a laboratory to generate acceptable results. In an external proficiency test, a sample or samples (by matrix/parameter) containing the target analyte at known concentrations, is provided to the laboratory for blind<sup>4</sup> analysis by a PT provider. The measured result obtained is returned to the PT provider, who assesses the laboratory's result against the reference value for the analytes. Based on this assessment, a laboratory's performance is rated as acceptable or unacceptable, which provides ongoing assurance that the laboratory can produce valid test results for that matrix/parameter combination. Proficiency testing in this fashion is also known as "interlaboratory comparison".

There is an international standard (ISO/IEC 17043) to accredit proficiency testing providers. Use of ISO/IEC 17043 accredited providers ensures that a high standard for

<sup>3</sup> This is a typical cycle for PT and site assessment, but it may vary between accrediting bodies.

<sup>4</sup> The concentrations of analytes are unknown to the laboratory.

performance and interpretation of proficiency tests is maintained.

In the case where third-party PT providers do not have available a formal PT sample for an analyte, laboratory competence is typically demonstrated by other means such as less formal interlaboratory studies, in-house proficiency testing programs (using certified materials), split samples with another laboratory, or other appropriate QC material.

### How do accreditation and proficiency testing compare as a measurement of laboratory competence?

Figure 1 below is an illustration of the elements of ISO/IEC 17025 that an accredited laboratory must have to receive accreditation:

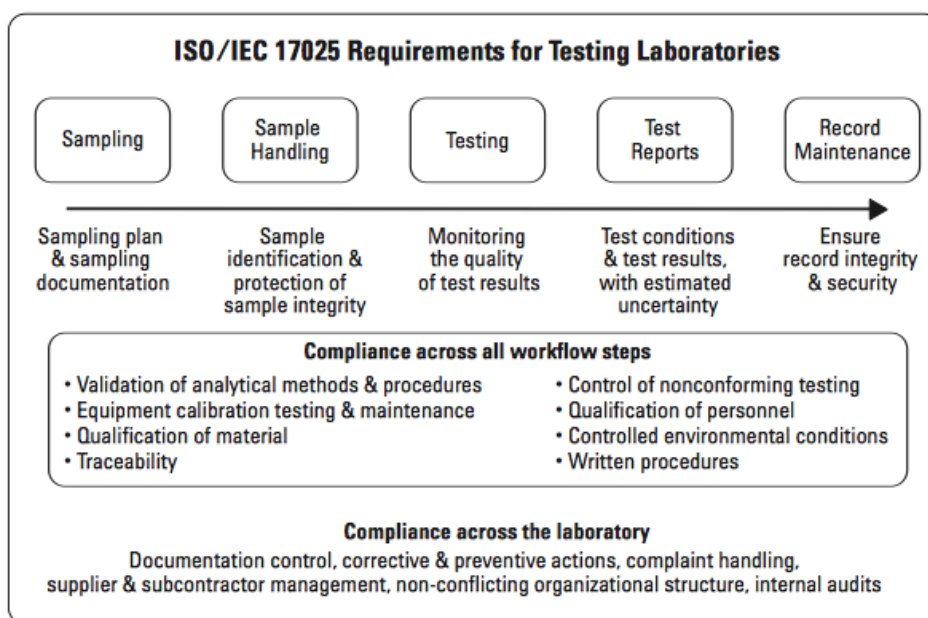


Figure 1. Snapshot of accreditation elements for Testing Laboratories. Source: <http://www.chem.agilent.com/Library/primers/Public/5990-4540EN.pdf>

It includes elements of ethics and confidentiality, documentation and record-keeping, method selection and validation, skills and training of personnel, quality control and result uncertainty, recognition and correction of non-conforming work, internal audits and management reviews – in addition to a periodic assessment by external agencies. As mentioned above, satisfactory performance in proficiency testing is an ongoing requirement to maintain accreditation.<sup>5</sup>

<sup>5</sup> This may vary amongst accrediting bodies in other jurisdictions.

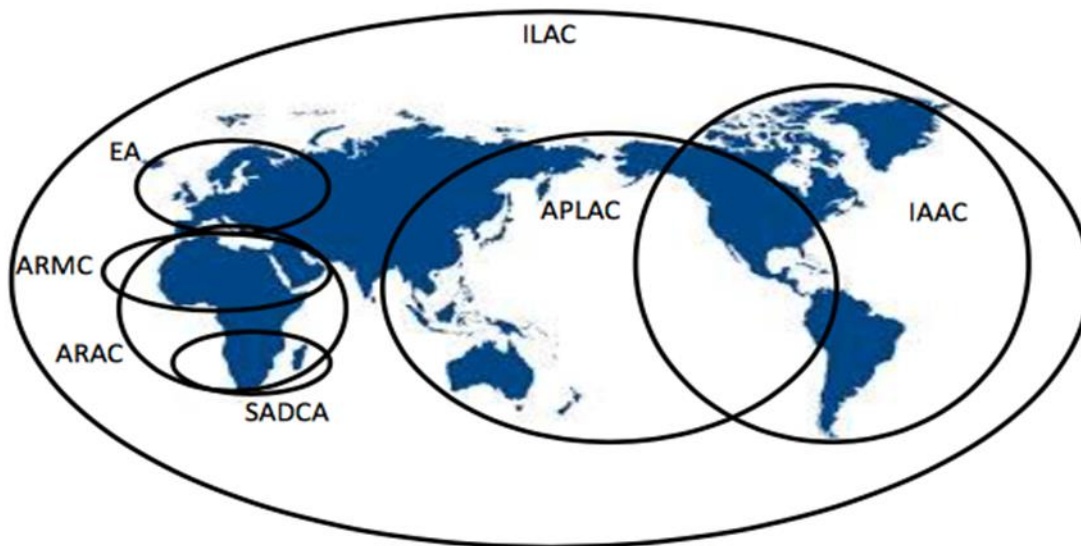


Whereas, laboratory competence that is demonstrated only by performance in proficiency testing is but a small subset of the processes that underpin a fully accredited laboratory. While there may be circumstances where laboratory competence by proficiency testing may be considered adequate, it is no substitute to the rigorous assessment of the laboratory's management and technical underpinnings provided by full ISO/IEC 17025 accreditation.

## Who are the players?

Formal laboratory accreditation is supported by a worldwide network of accreditation professionals (Figure 2). The International Laboratory Accreditation Cooperation (ILAC) is the principal international forum for development of laboratory accreditation practices and procedures. In association with ILAC, specific regions have also established accreditation cooperations, most notably, the Asia-Pacific Laboratory Accreditation Cooperation (APLAC) which oversees laboratory accreditation for Canada (see below). These regional cooperations are members of, and work in harmony, with ILAC. Accrediting bodies are the primary regional authorities that confer laboratory accreditation in their respective regions. They are recognized as such by the regional cooperations. In Canada, the regional cooperation is the Asia-Pacific Laboratory Accreditation Cooperation (APLAC), and the recognized accrediting bodies are the Standards Council of Canada (SCC)<sup>6</sup> and the Canadian Association for Laboratory Accreditation (CALA). There are other accrediting bodies located in the United States and around the world that are recognized accrediting bodies under similar standards to the SCC and CALA.

<sup>6</sup> The SCC is a member of other regional cooperations as well as APLAC.



ILAC – International laboratory Accreditation Cooperation  
 EA – European Cooperation for Accreditation  
 APLAC - Asian Pacific Laboratory Accreditation Cooperation  
 IAAC - Inter-America Accreditation Cooperation  
 SADCA – South African Development Community Accreditation  
 ARAC – African Regional Accreditation Cooperation  
 ARMC – Arabic Accreditation Cooperation

The province of Quebec maintains a parallel but separate laboratory accreditation program as authorized under clause 118.6 of the Quebec Environment Act (discussed below).

Individual laboratories in specific fields of testing will approach an accrediting body with a request to be assessed for conformance. Typically, they will have a list of tests they will want to have assessed. Once accredited, this list of accredited tests is known as the laboratory's Scope of Accreditation.

### How is laboratory accreditation typically conferred?

Laboratory accreditation can be thought of as a chain of conformance stretching from ILAC at the international level, to the individual laboratory down the street. At the top level, ILAC and the regional cooperations will assess the conformity of accreditation bodies to ISO/IEC 17011 *General requirements for accreditation bodies accrediting conformity assessment bodies*. If found to be "in conformance", the two parties will sign a

“Mutual Recognition Arrangement” (MRA), which establishes that the accreditation body meets the requirements of ISO/IEC 17011, the standard for accrediting bodies. In Canada, the “signatory” accreditation bodies are the Standard Council of Canada (SCC) and the Canadian Association for Laboratory Accreditation (CALA).

A “signatory” accrediting body will, upon request from a laboratory, assess the conformity of the laboratory to ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*, the international standard for testing and calibration laboratories. It will do so by sending trained technical assessors to the laboratory site to assess the laboratory’s management and technical processes conformance to the requirements of ISO/IEC 17025. This is accomplished by observation of objective evidence covering each clause of the standard. In addition to the on-site assessment, satisfactory performance in proficiency testing for each matrix/parameter combination is a mandatory requirement. Once the accrediting body is satisfied that a laboratory conforms with all the requirements of ISO/IEC 17025 and it can demonstrate its technical competence through proficiency testing, accreditation is conferred through a certificate and scope of tests to which the accreditation applies. It is at that point that a laboratory can claim to be “ISO/IEC 17025 accredited”.

To maintain accreditation, a laboratory must maintain satisfactory performance on proficiency testing (two rounds per year), and subsequent assessment visit every two years (International Standards Organization 2004). It is important to note that it is accreditation *for a test* that is suspended for unsatisfactory performance in proficiency testing, not the overall accreditation of the laboratory itself.

### **Why require formal laboratory accreditation (what advantages does it confer)?**

As established in the Introduction, decisions should be informed by reliable information. Environmental decisions, especially those that involve human health and safety or environmental health and integrity, typically involve laboratory test data. The use of reliable test data minimizes the risks inherent in a poorly developed environmental decision.

Test data that is generated by an accredited laboratory is buttressed by a chain of international standards and accreditation bodies that specifically address the production, quality and veracity of this test data. Consequently, an accredited laboratory is more likely than a non-accredited laboratory to produce test data that is:

- reliable and “fit for purpose” for the decisions to be taken
- the product of well-established, scientifically based and validated methods
- repeatable and of defined and consistent quality
- comparable to historical data and data from other jurisdictions

- consistent with national and international standards

Several studies conducted to date demonstrate that accredited laboratories out-perform non-accredited laboratories (which rely solely on PT). A recent study performed by Middlebrook 2015 using CALA's database reinforce this statement. CALA is an ISO/IEC 17043 accredited PT provider that services both accredited and non-accredited laboratories. This puts CALA in a unique position to use its large database of PT results to undertake such a comparison.

Middlebrook 2015 developed a database of 1,124,630 participant results consisting of PT results from both accredited and non-accredited labs for the period 2004 – 2015. From this database, the number of participants from each of these categories that produced questionable or unsatisfactory PT results<sup>7</sup> were compared. Figure 3 is a comparison for all analytes in the dataset, and illustrates that accredited laboratories produce a lower percentage of borderline or unsatisfactory PT results than non-accredited laboratories.

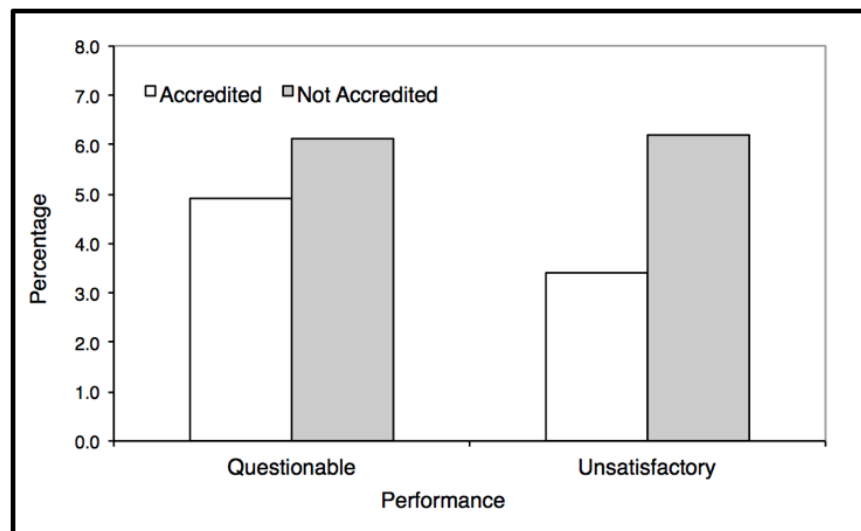


Figure 2. Percentage of Questionable and Unsatisfactory performance by accreditation status for all analytes (Middlebrook 2015)

A further breakdown of this data by test demonstrates similar trends, indicating that the data is not associated with specific tests (data not shown).

<sup>7</sup> The terms “questionable” and “unsatisfactory” are based on statistically-derived PT scores: Questionable means the PT scores that are borderline acceptable, and Unsatisfactory means PT scores that are unacceptable (outside the acceptance limits).

Another relevant information comes from the year-by-year comparison of unsatisfactory PT results between accredited and non-accredited laboratories (Figure 4). This figure clearly illustrates that accredited labs consistently maintain a lower percentage of unacceptable PT scores compared to non-accredited laboratories. It also illustrates the clear benefit that PT participation provides, in the lower percentage of unsatisfactory PT results in both groups the longer they participate in the PT program.

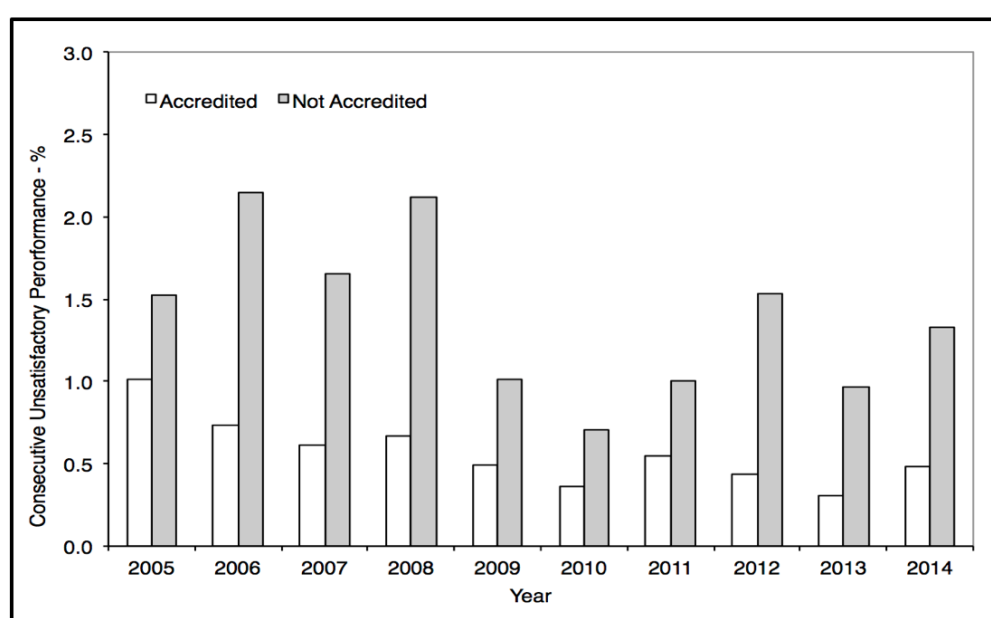


Figure 3. Percentage of consecutive unacceptable performance by year (Middlebrook 2015).

Middlebrook points out that comparison with the database assembled does have some challenges in that the author was unable to unambiguously identify laboratories in the non-accredited group that may have had a non-CALA accreditation, might have lower data quality objectives, or that may have less experience with PT performance (eg. first time PT performers tend to do more poorly in the early rounds). However, based on the size of the database and variety of laboratories involved, the data strongly suggests the differences observed are real.

## 7. LABORATORY QUALIFICATION IN BRITISH COLUMBIA

### **What is the Environmental Data Quality Assurance Regulation (EDQAR)?**

The Environmental Data Quality Assurance Regulation (EDQAR) is a regulation put in place in 1990 to ensure environmental data for use under the Environment Management Act (EMA) is accurate and reliable. The EDQAR applies to all laboratories providing analytical services required for permits or other regulatory purposes under the EMA, in addition to the Ministry's own environmental monitoring, compliance and enforcement activities.

British Columbia maintains a separate program – the Enhanced Water Quality Assurance Program (EWQA) - to qualify laboratories for the analysis of microbiology in drinking water (British Columbia Centre for Disease Control 2013). This program acts on behalf of the province and in partnership with Clinical Microbiology Proficiency Testing (CMPT) to recommend laboratory approval for drinking water testing. It utilizes on-site inspection and satisfactory performance in an approved proficiency testing program to qualify laboratories, which receive a certificate of approval (valid for three years) from the BC Provincial Health Officer. This program was outside the scope of the EDQAR update/jurisdiction review and not studied further.

### **Who are the players?**

#### **BCMOE**

The BC Ministry of Environment (BCMOE) is the primary government authority governing the environment and environmental legislation. It has many programs that utilize environmental test data to inform programs and decisions in many forums. Due to the need to make the right decision, it is in the best interest of the BCMOE and the province to have test data that is reliable and of known quality.

#### **BC-CDC**

The BC Centre for Disease Control public health laboratory is the primary public health and reference diagnostic testing facility for the province. It is responsible for several sectors related to public health, including the Enhanced Water Quality Assurance (EWQA) Program. It maintains a list of laboratories approved by the BC provincial health officer for drinking water microbiology testing.

#### **Commercial Laboratories**

Commercial laboratories are for-profit business whose line of service is laboratory testing. Most major commercial laboratories see the business benefit of formal accreditation and do so voluntarily. Smaller commercial laboratories may not pursue formal accreditation due to the expense.

### **In-house municipal/industrial laboratories**

In-house laboratories are laboratories associated with a plant or industry and are primarily concerned with test data for process control, quality, or other business purposes. Such data would not be subject to EDQAR except for an in-house laboratory that is generating test data to meet the legislated requirement of the plant or industry, in which case the provisions of EDQAR would apply to those tests.

### **Regulated Community**

The regulated community in BC are those municipalities and industries that must abide by the requirements in an order, permit, licence, approval or certificate. In doing so, these entities may need to supply environmental test data to the BCMOE. Their data needs are best addressed through a strong network of in-house or commercial laboratories such that the industries and their samples can be adequately serviced. They are concerned – aside from the cost of the testing service - that their samples be analyzed in a timely way, and the laboratory they have chosen for the service meets the requirements of the BCMOE.

### **How the EDQAR currently works**

In its present configuration, the EDQAR is a legally binding requirement on “persons required to collect samples and submit environmental monitoring data as a requirement of an order, permit, licence, approval or certificate under an enactment administered by the minister”. It imposes a duty to have the sample analyzed by a “qualified laboratory”, and submit the results of the analysis not later than 45 days after the date the sample is collected. A “qualified laboratory” is one that “achieves formal recognition by CALA to carry out specified tests” by participation in the (CALA) Proficiency Testing Program<sup>8</sup>. The identity of qualified laboratories is maintained as the “directory of qualified laboratories” by the ministry.

Since it is a legally binding requirement, laboratories will become “qualified laboratories” by registering with CALA and participating in the Proficiency Testing Program. All BC holders of an order, permit, licence, approval or certificates – in the broadest terms, all industrial, water, wastewater and other operations in the province – will identify a qualified laboratory from the directory and arrange to have the prescribed samples from their operating approval analyzed using this qualified laboratory. Upon receipt of the results, they are forwarded to the ministry to satisfy the requirements of their operating approval and this regulation.

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<sup>8</sup> This is a misunderstanding in the EDQAR. CALA does not provide “formal recognition to carry out specified tests” based on proficiency testing. Such recognition is only provided through laboratory accreditation.

At the present time, there are approximately 58 laboratories registered in the Directory, and only 19 are accredited to ISO/IEC 17025 (Joyce Austin, Personal Communication).

### **Deficiencies in the current EDQAR model**

The approach taken by the EDQAR is dated and has been overtaken by several developments in the field of laboratory testing as outlined below:

#### **In terms of laboratory accreditation**

In its current form, the EDQAR does not designate a laboratory standard to qualify laboratories. Participation in a proficiency testing program may be suitable to identify data quality concerns, *but it is not a laboratory standard*. ISO/IEC 17025 is a formal laboratory standard developed and adopted *internationally* for laboratories – the same type of laboratories intended to be qualified by the EDQAR. Without this requirement, the generation of environmental data may be missing the key principles (described above) that underpin the standard and are proven worldwide to ensure the generation of data of known quality.

In addition, formal laboratory accreditation has become the *de facto* standard between jurisdictions. This has become evident in the attempt by BCMOE to negotiate an equivalency agreement under the Wastewater Systems Effluent Regulation (WSER). Such an agreement will be beneficial to the province by making data generated to meet provincial needs adequate to meet federal needs as well. However, the WSER requires that data be generated by ISO/IEC 17025 accredited facilities, a level not yet prescribed in BC regulations.

#### **In Terms of Proficiency Testing**

The EDQAR depends heavily on proficiency testing to qualify laboratories. Unfortunately, as described below there are several shortcomings in this approach.

- Performance on proficiency testing alone does not provide an adequate measure of “control” within the testing laboratory’s processes. There is no provision to check if the laboratory carries out its work based on the underlying principles of the ISO/IEC 17025 standard. Namely: capacity, exercise of responsibility, scientific method, objectivity of results, impartiality of conduct, traceability of measurement, repeatability of test and transparency of process. *Use of proficiency testing in this fashion is like qualifying a “black box” without knowing whether what is going on inside meets the needs or expectations of BCMOE and accepted industry standards.*
- The EDQAR does not prescribe the requirement to “pass” the proficiency test – only to participate. Theoretically, a laboratory could fail the proficiency test and remain listed as a qualified laboratory. This is not to suggest this actually occurs,

but it is important to understand this as a deficiency of the EDQAR as it is currently structured.

- The EDQAR does not prescribe ISO/IEC 17043 PT providers. This may not be surprising since the accreditation of PT providers under ISO/IEC 17043 is a relatively recent development. It does illustrate, however, how the EDQAR should be updated to reflect developments in this area of international standards.
- The EDQAR designates a sole-source provider of PT programs. The ISO/IEC 17043 standard has enabled the development of several high-quality PT providers in the intervening period since the initiation of the EDQAR. By opening the regulation to other providers, qualified laboratories will have other choices to consider for proficiency testing in terms of test selection, service and cost.

#### **In terms of Data Quality Concerns**

If the BCMOE has a concern with the quality of test data being submitted, it may want or need to take unilateral action to investigate or understand the ramifications of the matter.

- As it is presently configured, there is no provision in the EDQAR to compel a laboratory to provide documentation, records or other supporting material in regards of submitted data.
- There is no provision in the EDQAR for the BCMOE (or designate) to audit a laboratory's operations to confirm that elements of the quality system are present and operating correctly.

## 8. LABORATORY ACCREDITATION IN CANADIAN JURISDICTIONS

### Overview

For the purpose of informing the EDQAR update process, a review of laboratory accreditation in select regulations in the various jurisdictions across Canada was undertaken. The review consisted of a literature search of selected environmental regulations and legal instruments, as well as personal contact with the persons responsible in each jurisdiction.

Early in the examination, it was observed that two approaches are used in the various jurisdictions, which were broadly characterized as the “Protocol Approach” or the “Clause Approach”. The latter was found to be the most common. In limited cases in the far north, the expectation for laboratory accreditation is not formally captured in a legal instrument, but may be present in guidelines or is expected where use of an accredited laboratory is possible. The respective laboratory accreditation information is captured in Figure 5 and reviewed below:

Figure 5. Laboratory Accreditation by Jurisdiction

Via:

ILAC Signatory ISO/IEC 17025 Accreditation X  
Non-ILAC Signatory ISO/IEC 17025 Accreditation (X)  
Proficiency Testing Component &

Select Regulation*	Province													
	BC	AB	QC	NS	NL	CAN	SK	MB	ON	NB	PE	YK	NT	NU
	Protocol Approach Via					Clause Approach								
	Reg	Policy	Act	Policy	Policy									
		Note 5												
Drinking Water	N4	X	(X)	X N1	X/&	N7	X	X	X	X	X	X	N7	
Wastewater (non-WSER)	&	X N3	(X)	X/& N3	X/& N3	X N6	X	X N3		X N3	X	X N3	X N3	N2
Soil/Contaminated Sites	&	X	(X)	X/&	X/&		X		X		X	X	N2	N2
Industrial Dischargers	&	X N3	(X)	X/& N3	X/& N3	N2		X N3	N2	X N3		X N3	X N3	N2
Air	&	X	(X)	X/&	X/&		X		N2				N2	

\* Major Data producing regulations only; not intended to be comprehensive

Note 1: Bacteria and chemistry in DW laboratory accreditation is mandatory with no alternative

Note 2: Guideline recommendation or informal expectation (not legally binding)

Note 3: Incorporates laboratory accreditation requirement in operating approval

Note 4: Laboratory oversight by BC CDC EWQA program

Note 5: Alternate Program utilizing proficiency testing suspended

Note 6: Wastewater Systems Effluent Regulation (WSER); accreditation requirement applies in all jurisdictions

Note 7: Not in a regulation. Some communities do on-site (unaccredited) DW testing; remainder are encouraged to use accredited labs if available.

## Review by Jurisdiction

### Protocol Approach

The protocol approach is typically utilized where a jurisdiction includes alternative options to formal laboratory accreditation to address regional concerns, for example, a proficiency testing option for small laboratories. In Quebec, the protocol involves the maintenance of a *provincial* accreditation program (see below).

### **British Columbia**

The BC Ministry of Environment enacted the Environmental Data Quality Assurance Regulations (EDQAR) in 1990. Details of the EDQAR are outlined in Section 6.

### **Alberta**

Alberta Environment has had the Laboratory Data Quality Assurance Policy (LDQAP) since 2001 (Alberta Environment 2001). In accordance with this policy, “all analytical data required by Alberta Environment and Alberta Sustainable Resource Development must be analyzed by laboratories that are accredited by the Standards Council of Canada (SCC) for the parameters being reported, except as indicated under the policy”. It goes on to identify conditions to be addressed in situations where a lab is providing data consisting of parameters not covered by SCC accreditation, which includes accreditation for other parameters, proficiency testing (if available), and to make documentation available for inspection by the Ministry. It also has a provision for data quality in continuous monitoring or remote sampling equipment.

The LDQAP has a provision for the acceptability of alternate accreditation (by the Alberta College of Physicians and Surgeons of Alberta) for health laboratories that may do testing on environmental matrices (eg drinking water), and a provision for the acceptance of analytical data without SCC accreditation on written approval by a senior authority in the Ministry. The policy is adopted by placement in operating approvals. There is also a provision in the policy for Ministry responsibilities when collecting data, including unit QA/QC manuals, adequate sampling and analytical programs, and data submitted in accordance with the policy.

In 2004, Alberta Environment developed the “Alternate Program” to ensure that all facilities met the objectives of the Laboratory Data Quality Assurance Policy when due to the size of the facility or frequency of the analysis, formal ISO/IEC 17025 accreditation was not reasonable (Alberta Environment 2004). It consisted of the following elements:

- Site evaluation – including the identification and correction of deficiencies.

- Proficiency testing – twice per year with consequences upon PT failure.
- Documentation and test records – equivalent to that required by accreditation including prescribed training of analysts.

The program was prescriptive and complicated. It underwent a trial period of approximately three years, funded by Alberta Environment. The funding was not renewed and the program suspended. It is not active at this time, so the only recourse in Alberta is formal ISO/IEC 17025 laboratory accreditation.

Since the general understanding in Alberta is that test data must be produced by laboratories with formal ISO/IEC 17025 accreditation, virtually all data submitted to meet regulatory requirements is compliant with the policy.

### **Nova Scotia**

For analytical results reported to Nova Scotia Environment (NSE), there is the “Policy for the Accreditation of Laboratories 2006” (Nova Scotia Environment and Labour 2006). This policy describes the requirements for laboratories to be considered acceptable to NSE or by clients who submit analytical data to the department to fulfill data reporting requirements. It incorporates both formal accreditation and acceptable performance in proficiency testing as the working elements. In addition, it specifies that application of these elements by program, so that a laboratory testing for bacteria in drinking water must be formally accredited (in practice, this is extended to all drinking water tests), while in other sectors, a laboratory can elect for either option.

Operationally, it is found that most smaller laboratories opt for the proficiency testing option, where the larger (national) laboratories have formal accreditation. A high percentage of data submitted to the Ministry is compliant with the policy.

### **Newfoundland and Labrador**

The Newfoundland and Labrador Department of Environment and Conservation established the Accredited Laboratory Policy in 2011 (Newfoundland and Labrador Department of Environment and Conservation 2011). This policy requires the use of accredited commercial laboratories for all contract work (for the Ministry) and external data for Ministry programs. It identifies four conditions for acceptance of data:

- Accredited commercial laboratory.
- Accredited in-house laboratory.
- An in-house laboratory that has recognition for proficiency testing, and
- An in-house laboratory where proficiency testing is not available, with approval of the Department upon submission of the standard operating procedure.

From an operational perspective, the majority of laboratories are formally accredited, and only a small number use the proficiency testing option to become a qualified laboratory. It is estimated that 95% of the data submitted to the Ministry is compliant with the policy.

The Quebec Ministère of Développement durable, l'Environnement et Lutte contre les changements climatiques (MDDELCC) maintains a parallel but separate laboratory accreditation program as authorized under clause 118.6 of the Quebec Environment Act which states “*The Minister may, in the cases and on the conditions he determines, accredit a laboratory to make any analyses that may be required for the administration of this Act and the regulations thereunder*”. In this model, it is the Minister that grants laboratory accreditation to Quebec laboratories producing environmental data. This program is overseen by the CEAEQ – Centre d’expertise en analyse environnementale du Québec – a department of the Ministry. The CEAEQ undertakes the assessment of laboratories using the ISO/IEC 17025 standard, but is not itself accredited to ISO/IEC 17011 or a signatory to an ILAC MRA. The CEAEQ will make recommendations to the Minister to accredit laboratories based on conformance with ISO/IEC 17025. Laboratories outside Quebec that wish to produce environmental data for the province, must be separately accredited in accordance with the Quebec accreditation program. Similarly, Quebec labs wishing to produce environmental data for other provinces would have to abide by the requirements of that jurisdiction, in particular, the requirement for the accrediting body to be accredited to ISO/IEC 17011. In the case of federal regulations, those that contain a requirement for laboratory accreditation recognize the Quebec accreditation program by reference in the regulation<sup>9</sup>.

With that understanding, Quebec incorporates the need for 118.6 laboratory accreditation in a variety of regulations, including Quality of Drinking Water (Q-2, r.40), Land Protection and Rehabilitation Regulation (Q-2 r.37) for soil analysis, Regulation Respecting Municipal Treatment Works (Q-2, r.34.1), Regulation Respecting Pulp and Paper Mills (Q-2, r.27) for dischargers, and many others. The regulations will include a clause requiring the use of other ISO/IEC 17025 laboratories, if none of the 118.6

<sup>9</sup> For clarity, laboratory accreditation promulgated under the Quebec Environment Quality Act is referred to as “118.6 laboratory accreditation”.

## Clause Approach

## Canada

An interesting observation is that many other federal organizations, including the Canadian Food Inspection Agency (CFIA) (Canadian Food Inspection Agency 2012) and Canadian Grain Commission (Canadian Grain Commission 2011) have policies prescribing the use of ISO/IEC 17025 accredited laboratories in specific circumstances.

## Saskatchewan

The Saskatchewan Ministry of Environment uses a classical approach to require accredited laboratories for the generation of respective test data, by incorporating the requirement by clause directly in each regulation. Thus, the Waterworks and Sewage Works Regulations (E-10.22 Reg 3) for drinking water and wastewater and the Environmental Management and Protection (Saskatchewan Environmental Code Adoption) Regulations (E-10.22 Reg 2) for site assessments, air and others include such a provision.

### **Manitoba**

Manitoba Conservation and Water Stewardship incorporates the requirement for laboratory accreditation in the Drinking Water Safety Regulation (040/2007). The requirement is also incorporated as a standard clause in the operating approvals for wastewater plants and industrial dischargers.

### **Ontario**

Ontario Ministry of the Environment and Climate Change began incorporating a requirement for laboratory accreditation in regulatory data after the Walkerton incident (see section 4). The Ontario Safe Drinking Water Act incorporates laboratory accreditation, so it applies to all the regulations under the Act. Subsequent environmental regulations that incorporated laboratory regulation are the O.Reg 153/04 Record of the Site Condition, and regulations under the Nutrient Management Act. In some cases, Ontario *recommends* the use of accredited laboratories in guideline documents (MISA Sampling Guide for discharge regulations; air contaminants), but in this form, the requirement is not legally binding. It does not appear that Ontario incorporates the need for laboratory accreditation in operating approvals.

### **New Brunswick**

New Brunswick Environment and Local Government has a requirement for laboratory accreditation only for the Potable Water Regulations – Clean Water Act O.C. 93-979. This requirement is also incorporated in operating approvals for wastewater and industrial waste generators. The province encourages the use of accredited facilities for data generated by itself and for incoming data.

### **Prince Edward Island**

Prince Edward Island Department of Communities, Land and Environment has a requirement for laboratory accreditation in the Drinking Water and Wastewater Facility Operating Regulations (E09-04) as well as for soil analysis under Petroleum Hydrocarbon Remediation Regulations (E09-12). Prince Edward Island maintains an accredited laboratory that is utilized by the islands major dischargers, so do not capture this requirement in operating approvals.

### **Yukon**

Environment Yukon incorporates laboratory accreditation in the regulation for drinking water and for most major environmental data through incorporation in the regulation or

operating approvals. YK is fortunate to have accredited laboratories available regionally that can satisfy this requirement.

### Northwest Territories

The Northwest Territories Department of Environment and Natural Resources applies the requirement for laboratory accreditation to industrial sites through water licenses. Thus, it is applied at mine and oil and gas operations. In most other applications, the requirement for laboratory accreditation is informal but it is a common expectation.

### Nunavut

Nunavut Department of Environment does not have a lot of regulations, but does capture the requirement to utilize accredited laboratories in guideline documents. It is also a policy that they follow as standard practice.

### Observations from Jurisdictional Review

Reviewing the approach and process of the requirement for laboratory accreditation can provide some insight into the updating of the EDQAR. The following characteristics can be pulled from this review:

- Aside from Quebec, BC is the *only jurisdiction that does not utilize ISO/IEC 17025 and ISO/IEC 17011 (or the term ILAC/MRA “signatory”) to qualify laboratories*, and also the only jurisdiction to utilize proficiency test performance as the primary means to qualify laboratories.
- The approaches across the jurisdictions can be grouped into two broad categories – the Protocol Approach and the Clause Approach. In the Clause Approach, a simple clause outlining the requirement for laboratory accreditation is embedded in a legal instrument – usually a regulation or operating approval. The words used may be different depending on the age of the document or the jurisdiction, but the intent is captured in a simple statement, usually quoting ISO/IEC 17025 and ISO/IEC 17011 (or the term ILAC/MRA “signatory”). In the Protocol Approach, a Ministry document or policy captures the rational and program elements of the laboratory accreditation requirement. This is most often used where the program is more complex than a simple clause can express, for example where an option to use proficiency testing performance to qualify laboratories is available. In most jurisdictions, the policy must be referenced in a regulation or operating approval to be legally binding. The most common approach across all jurisdictions is the Clause Approach.
- In terms of the protocol approach, BC is unique in the use of a regulation for this purpose, as opposed to a policy. The Quebec approach is also unique in utilizing a provincial accrediting body.

- Other than BC, the jurisdictions that include a proficiency testing performance options in their program include three provinces where, uptake of this option is mixed – Alberta (suspended), Newfoundland and Labrador (few laboratories – most are accredited) and Nova Scotia (active, mostly small laboratories)
- Quebec maintains a separate accreditation program as described above. It mostly duplicates the services provided by accrediting bodies, although it is not an ILAC MRA signatory. It appears to be very resource intensive and was not investigated further.
- The regulation of drinking water would appear to have the greatest penetration in terms of the requirement for laboratory accreditation, which is not surprising given the direct human health element and the events associated with the Walkerton incident. In a number of jurisdictions (BC, NT), the lead agency is the health authority rather than environment, and laboratory accreditation may reflect a medical laboratory (ISO 15189) rather than an environmental laboratory focus. Investigation of this area was outside the scope of this review. A notable exception to this rigorous focus on drinking water is the absence of a legally binding laboratory accreditation requirement for First Nation's drinking water in the federal jurisdiction.
- An informal approach is taken in the Northwest Territories and Nunavut. In these jurisdictions, the requirement for laboratory accreditation is outlined in guidance documents or is a simple understanding.
- As a side note, it is apparent that words used for the designation of "accredited laboratory" varies widely amongst the jurisdictions. CALA and the SCC have issued a joint memorandum to suggest common and consistent wording for this purpose (Canadian Association for Laboratory Accreditation and Standards Council of Canada 2016). The wording is "a laboratory whose accreditation has been obtained from an accrediting body that is signatory to the ILAC MRA, using the internationally recognized criteria and procedures outlined in ISO/IEC 17025: General requirements for the Competence of Calibration and Testing Laboratories". ECCC has also recognized the importance of this reference and is developing recommended wording for use in federal regulations (Marc Bernier, personal communication).

## 9. UPDATE OPTIONS FOR EDQAR

### Overview

Considering the information discussed thus far - including a brief look at laboratory accreditation and the related process, the summary of shortcomings in the current EDQAR, and the information related to laboratory accreditation in other jurisdictions - it is helpful to extend this information to explore changes that might be beneficial to the EDQAR.

### Laboratory Qualification

Laboratory qualification is the means by which a laboratory – or more specifically, the *competency* of the laboratory – will be judged to be acceptable for the generation of environmental test data of known quality for use by the BCMOE. Based on the jurisdictional review, there are three models to consider.

Laboratory Qualification Model	Description	Advantages	Disadvantages
ISO/IEC 17025 by ILAC Signatory	Formal laboratory accreditation as arranged in Canada by SCC/CALA <sup>10</sup>	<p>Accreditation to a sustainable recognized international standard, through a recognized and high-quality program by an independent third party</p> <p>Strong standard with a high degree of acceptable data quality</p> <p>Shared standard/program with other jurisdictions in Canada</p> <p>Prudent use of resources; minimize duplication of effort to monitor compliance and address deficiencies</p>	Additional cost to non-accredited BC laboratories
ISO/IEC 17025 by non-ILAC Signatory	Similar to 118.6 Laboratory Accreditation in Quebec	Direct control of accreditation program elements and implementation	<p>Cost and resources to maintain provincial accrediting body</p> <p>Duplication of existing national accreditation program</p> <p>Lacks third party independence and oversight</p>

<sup>10</sup> Note that there are numerous ILAC signatory accreditation bodies globally.



Laboratory Qualification Model	Description	Advantages	Disadvantages
Proficiency Testing	Use of proficiency testing performance to qualify laboratories	Minimal imposition/lower cost to laboratory participants	See below

The high quality of ISO/IEC 17025 as a laboratory standard is internationally recognized, and has the greatest potential to deliver high quality environmental test data to BCMOE. It is further supported by the accreditation of accrediting bodies to ISO/IEC 17011, which provide assurance that the body granting the accreditation is itself supported by an internationally conformant management system and is peer reviewed in support of its laboratory accreditation mandate. With these two elements in place, there is an unbroken chain supporting the quality of environmental test data for British Columbia.

**Recommendation 1** – The requirement in BC law for the qualification of laboratories be the use of “a laboratory whose accreditation has been obtained from an accrediting body that is signatory to the ILAC MRA, using the internationally recognized criteria and procedures outlined in ISO/IEC 17025 General requirements for the competence of calibration and testing laboratories”<sup>11</sup> - as the standard for BC environmental data. Furthermore, the requirement should include that the test method (by matrix/parameter) is in good standing (included on the Scope of Accreditation) at the time the test is carried out.

During this review, it was discovered that wording for this purpose is under study by Environment and Climate Change Canada (Environment and Climate Change Canada (ECCC) 2016). Given that this wording has been subject to legal review and to ensure it is consistent with such a reference among jurisdictions, consideration should be given to

<sup>11</sup> This wording is suggested in a joint memo issued by CALA and the SCC (Canadian Association for Laboratory Accreditation and Standards Council of Canada 2016)  
[http://www.cala.ca/RFPs\\_SCC-CALA\\_Joint-Notice\\_2016-11-04.pdf](http://www.cala.ca/RFPs_SCC-CALA_Joint-Notice_2016-11-04.pdf)

adopting the relevant text for the update to the EDQAR. An excerpt of the relevant text is found in the box below:

## Accredited Laboratory

Any analysis or determination performed for the purposes of these regulations must be performed by a laboratory that holds a certificate of accreditation to International Organization for Standardization standard ISO/IEC 17025, entitled *General requirements for the competence of testing and calibration laboratories*.

# Certificate

The certificate referred to must

- (a) Be issued by an accrediting body that is a signatory to the international Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement;
- (b) Cover the specific parameters to which the analysis or determination relates, and
- (c) Be valid at the time that the analysis or determination is performed.

**Recommendation 2** – Since accreditation is by test method (matrix/parameter), and not by facility, the concept of “list of qualified laboratories” be replaced with an explicit reference that disqualifies a laboratory from providing for submission environmental test data not produced by a laboratory test method with a valid accreditation at the time the test was done.

**Recommendation 3** – To reduce the potential for misunderstanding, the legal wording should explicitly require that tests that are subcontracted are subject to this same laboratory accreditation standard outlined above. Subcontracted is to be defined broadly to include any alternate facility that is accredited separately from the subcontracting laboratory.

## The Place of Proficiency Testing

The use of proficiency testing performance to qualify laboratories is of questionable value, since none of the infrastructure supporting the generation of data of known quality is specified within the context of PT participation. That is not to say that data of known high quality is not generated in such situations, but many of the management or technical mechanisms that afford the ability to generate data of known quality on an ongoing basis, and which are useful to recognize and troubleshoot deficiencies, may not be present. This may leave BCMOE in a difficult situation where those support

mechanisms are not available to defend decisions based on environmental data, or in legal situations to defend test data as evidence.

On the technical side, the use of proficiency testing for the qualification of laboratories imposes a significant duty on the BCMOE program administrator to manage the program – as opposed to having the accrediting body do so. At a minimum, this would entail decisions related to acceptability of PT providers, laboratory pass/fail, deficiencies and correction, and receiving and coordinating incoming PT data from multiple sources. It could also lead to time-consuming disputes where disagreements arise. When formal accreditation is the primary means for laboratory qualification, these details are integrated into the accrediting body program, enabling the BC program manager to focus on high level tasks (or reducing the resource requirements).

In addition, it is also important to recognize that this option may impose technical responsibilities on the program administrator. For instance, in the absence of formal accreditation, the program administrator may need to review the Quality Manual or other laboratory documents to assure themselves there is a reasonable expectation of good data quality. In the extreme case, it may be necessary to audit the laboratory to confirm the required elements are in place. In the accreditation scenario, these elements are the purview of the accrediting body, who have technical experts familiar with the standard, the test method in use and the technical requirements that enable them to review laboratory operations effectively, so these resources do not have to be maintained (or contracted) by the BCMOE.

A review of Canadian jurisdictions reveals that it is BC alone that utilizes proficiency testing performance as the primary means to qualify laboratories. Since the majority of laboratories are not accredited, the principles upon which ISO/IEC 17025 is based,

- Capacity
- Exercise of Responsibility
- Scientific Method
- Objectivity of Results
- Impartiality of Conduct
- Traceability of Measurement
- Repeatability of Test
- Transparency of Process

are not demonstrated to be present. Of all the other jurisdictions, only Nova Scotia has an active program to qualify laboratories using proficiency testing performance – mostly for small laboratories. It is apparent, based on observations of the jurisdictional review, that qualification of laboratories using proficiency testing is not common, and it is informative that, based on the experience in these jurisdictions, the laboratory

community can adjust to this reality. This tool may have outlived its usefulness in BC as well, although it may be helpful in exceptional circumstances.

**Recommendation 4** – The laboratory accreditation in the BC program should be limited to formal accreditation as outlined in Recommendation 1, except under exceptional circumstances (see New Laboratories below).

**Recommendation 5** – There should be a phase-in period of two years for Recommendation 4 to come into effect, to enable laboratories to become accredited or adjust their operations to accommodate this requirement.

**Recommendation 6** – If proficiency testing performance is to remain in the EDQAR for any laboratory qualification purpose, the following provisions should be incorporated into the EDQAR:

- Use of ISO/IEC 17043 accredited PT providers is prescribed, and
- Satisfactory (acceptable, pass) performance must be maintained for all analytes whose results are offered for submission for BCMOE programs, and
- Entry be based on a written submission by the laboratory outlining the reason the accommodation is needed, and be considered and approved in writing by the director before any test data is offered for submission, and
- It should be subject to renewal every two years, and
- It should include a provision for laboratory inspection via documentation and/or on-site audit at the director's discretion at cost to the laboratory.

### **Data Coverage**

Data coverage is the laboratory test data that is generated for BCMOE programs that shall be generated by a formally accredited laboratory. Considerations are:

Coverage Option	Laboratory Accreditation Requirement Covers:	Advantages	Disadvantages
Blanket	All data submitted to BC MOE for any environmental program/purpose	<p>Covers all environmental data</p> <p>Ease of interpretation</p> <p>Stakeholder/public consultation process well defined and limited</p> <p>Similar to EDQAR coverage currently; not much change</p>	<p>May be new in some sectors</p> <p>Broad brush may raise objection</p> <p>Potential to increase cost to sites not covered by EDQAR</p>
By Sector/Regulation	Data generated within specific sectors such as drinking water or effluent discharge	Implementation can be focused on major sectors	<p>Subject to interpretation</p> <p>How to decide between important and less important sectors</p> <p>More onerous to change individual regulations</p>
By Operating Entity	Data generated by a specific site or industrial plant	Can be tailored to the operating entity	<p>Many approvals would need to be modified, including many stakeholder and public consultation sessions</p> <p>Requires resources of environmental officers</p> <p>May open negotiation on other elements of the operating approval</p>

In the introduction of this report we established the need to have the right information to inform the right decision for the people and environment of British Columbia. In this context, one should be mindful that it is difficult to predict where and when an environmental crisis may occur, as illustrated by the events during the Walkerton incident. The most prudent path forward is to ensure that all laboratory test data is reliable, so there is no question when important decisions need to be taken.

**Recommendation 7** – Require laboratory accreditation for all test data generated for BCMOE programs, with explicit reference to all legal instruments in BC environmental legislation.



## Legal Instrument

In most circumstances, it is desirable that the requirement for laboratory accreditation be legally binding. There are a number of ways to accomplish this, as evidenced in the variety of legal structures used in the various jurisdictions - each of which has advantages and disadvantages.

Legal Instrument	Description	Advantages	Disadvantages
Free Standing Regulation	A regulation passed by Executive Council	<p>Legally binding</p> <p>Can incorporate a wide variety of matters</p> <p>Wide program coverage based on references within the regulation</p> <p>Update requires change to a single regulation rather than multiple regulations and operating approvals</p>	Time consuming to change or update
Policy Document	A statement or protocol that expresses a requirement	<p>Can incorporate a wide variety of matters</p> <p>Update requires change to a single document rather than multiple regulations and operating approvals</p>	Must be referenced in a legal instrument (eg regulation, operating approval etc.) to be legally binding
Clause in Regulation	Simple statement of requirement	Legally binding	<p>Typically limited to a simple statement(s) of requirements</p> <p>Coverage limited to regulation</p> <p>Update onerous if similar change is required to multiple regulations</p>

Legal Instrument	Description	Advantages	Disadvantages
Clause in Operating Approval	Simple statement of requirement	Legally binding	<p>Typically limited to a simple statement(s) of requirements</p> <p>Coverage limited to approval</p> <p>Update onerous if similar change is required to multiple approvals</p>

Of the variety of mechanisms used across various jurisdictions, it appears that current structure of the EDQAR – a free standing regulation – is the most beneficial in terms of legal standing, flexibility, coverage and update

**Recommendation 8** – The EDQAR be updated in its current form – a regulation – rather than replaced with another mechanism.

### Other Potential Provisions

As a benefit from the jurisdictional review, it is possible to identify other provisions that BCMOE may want to consider for provision in the EDQAR.

### Environmental Test Data Generated by Online/Continuous Measurement

It is a fact that environmental test data for submission to the Ministry may be generated by online or continuous monitoring instrumentation, and there is a minor provision for this in the EDQAR. It is, of course, important that the quality of this data not be overlooked when considering data quality in the context of environmental and health decisions to be taken by the BCMOE. There are two jurisdictions with allowance for online/continuous monitoring equipment in their laboratory accreditation policy. The Nova Scotia policy (Nova Scotia Environment and Labour 2006) outlines that the proponent develop a QA/QC program that is approved by NSEL, and *may require* regular calibration and maintenance of on-line equipment, retention and training of qualified technical staff. The Alberta Environment policy (Alberta Environment 2001) provision for continuous monitoring equipment requires operation “consistent with accreditation standards, including requirements for documentation, equipment calibration and maintenance such as in the Continuous Emissions Monitoring System (CEMS) Code”. These policies may inform the EDQAR update should it be desirable to strengthen the provision for online/continuous measurement.

**Recommendation 9** – The EDQAR include provisions for the quality of test data generated online or with continuous monitoring for submission to BCMOE. As a minimum, consideration be given to incorporate into their operating regime the requirement for qualified technical staff, written operating and maintenance procedures, regular calibration or verification of calibration, and records of operational activities.

### **New Laboratories**

In order that the laboratory accreditation policy is not seen as a barrier to trade, it may be desirable to build in sufficient flexibility to enable new commercial laboratories to be established, but to continue to protect the reliability of BC environmental test data. In the Accredited Laboratory Policy for Newfoundland and Labrador (Newfoundland and Labrador Department of Environment and Conservation 2011) policy, Clause 6 where new commercial laboratories are given a period of one year in which to receive accreditation. The provision requires notice to the Ministry, completion of the accreditation application process, and successful performance on proficiency testing prior to providing for submission of environmental test data. This special provision expires if accreditation is not achieved after one year. This model may be instructive if the BCMOE desires to have a provision for new laboratories in the EDQAR.

**Recommendation 10** – The EDQAR include provisions for establishment of new laboratories in BC. For this purpose, the processes outlined in Recommendation 5 and Recommendation 6 be used as the basis for their operations in BC prior to formal accreditation.

### **Where accreditation or proficiency testing for a parameter is not available**

There may be situations where there is no provision for accreditation of matrix/parameter combination. It will be helpful in this circumstance that the EDQAR have some provision for this situation. The path forward on this may be informed by Clause 4 of the NL Accredited Laboratory Policy (Newfoundland and Labrador Department of Environment and Conservation 2011) that states that in such a circumstance, data will be acceptable from a laboratory that has overall laboratory accreditation and successful performance for proficiency testing of *related* parameters. The Laboratory Data Quality Assurance Policy for Alberta (Alberta Environment 2001) is similar, with the additional requirement to make manuals and test methods available, and to demonstrate the same standards of training, equipment maintenance, and documentation as for accredited parameters. These two models may inform the EDQAR update.

### **Laboratory of special skill or expertise**

It is foreseeable that there may be circumstances in which the BCMOE requires the services of a laboratory with special skill or expertise and for which accreditation or proficiency testing is not available. This is similar to the situation above where there is no accreditation or proficiency testing available, except that the capability may be so specialized that there are no related parameters upon which to base a decision related to data quality. In such a circumstance, it will be prudent if the EDQAR were to contain a provision that enables the BCMOE to qualify such a laboratory on the basis of submission to the BCMOE of qualifying information (quality manual, test methods and associated materials) that can be reviewed to provide a reasonable expectation of data quality.

### **If all else fails provision**

It is difficult to anticipate all data quality situations that may need to be addressed in the future. There may be situations that are without precedent and require flexibility on the part of the BCMOE to be addressed from a data quality perspective. In such a circumstance, it will be helpful if the EDQAR were to contain a provision that enables the Minister to qualify a laboratory on the basis of submission to the BCMOE of qualifying information (quality manual, test methods and associated materials) that can be reviewed to provide a modicum of assurance that the data quality will be controlled and acceptable to BCMOE.

**Recommendation 11** – The EDQAR include a provision for situations where accreditation or third party proficiency testing may not be available. It should be the responsibility of the laboratory to demonstrate the means by which they will ensure data quality. Some suggested means will be to have accreditation of related analytes, the demonstration of internal documentation and quality control performance, or other means, to the satisfaction of the director.

**Recommendation 12** – In the absence of enabling legislation elsewhere, the EDQAR should enable the BCMOE to request/receive documentation, records or to physically inspect a laboratory in relation to test data or laboratory qualification for BCMOE programs. This will enable the BCMOE to act quickly where the quality of test data is suspect, or in emergency situations where time is of the essence.

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## 11. APPENDICES

## Appendix 1

## Representative Example of Laboratory Accreditation Requirement by Jurisdiction

A more comprehensive selection of legislative information is available in the OneNote file associated with this report

Province	Example Document/Link	Clause	Contact
<b>Protocol Approach</b>			
British Columbia	Environmental Data Quality Assurance Regulation <a href="http://www.bclaws.ca/civix/document/id/complete/statreg/301_90">http://www.bclaws.ca/civix/document/id/complete/statreg/301_90</a>	All	Dr. Joyce Austin <a href="mailto:Joyce.austin@gov.bc.ca">Joyce.austin@gov.bc.ca</a>
Alberta	Laboratory Data Quality Assurance Policy <a href="http://aep.alberta.ca/air/legislation/air-monitoring-directive/documents/LaboratoryQualityAssurancePolicy-Oct2001.pdf">http://aep.alberta.ca/air/legislation/air-monitoring-directive/documents/LaboratoryQualityAssurancePolicy-Oct2001.pdf</a>	All	Dr. Donald Reid Drinking Water Quality Coord 780-644-8061 <a href="mailto:donald.reid@gov.ab.ca">donald.reid@gov.ab.ca</a>
	Alberta Environment Laboratory Data Quality Assurance Policy Procedures and Guidelines “Alternate Plan” <a href="http://aep.alberta.ca/water/inspections-and-compliance/documents/LaboratoryDataAssurancePolicyGuidelines.pdf">http://aep.alberta.ca/water/inspections-and-compliance/documents/LaboratoryDataAssurancePolicyGuidelines.pdf</a>	Inactive	Bijan Aidun 780-427-7626



Province	Example Document/Link	Clause	Contact
Quebec	<p>Environment Quality Act  <a href="http://legisquebec.gouv.qc.ca/en/ShowDoc/cs/Q-2">http://legisquebec.gouv.qc.ca/en/ShowDoc/cs/Q-2</a></p> <p>Regulation respecting the quality of drinking water  <a href="http://legisquebec.gouv.qc.ca/en/ShowDoc/cr/Q-2,%20r.%2040">http://legisquebec.gouv.qc.ca/en/ShowDoc/cr/Q-2,%20r.%2040</a></p>	<p>118.6</p> <p>30</p>	<p>Benoit Premont  418-643-1301 x350</p>
Nova Scotia	<p>Policy on Acceptable Certification of Laboratories  <a href="https://novascotia.ca/nse/airlandwater/docs/Policy-AcceptableCertificationOfLabs.pdf">https://novascotia.ca/nse/airlandwater/docs/Policy-AcceptableCertificationOfLabs.pdf</a></p>	All	<p>Angelina Polegato  DW Coordinator  <a href="mailto:Angelina.polegato@novascotia.ca">Angelina.polegato@novascotia.ca</a></p> <p>Brent Baxter  Industrial Management Unit  902-424-2534  brent.baxter@novascotia.ca</p>
Newfoundland and Labrador	<p>Accredited Laboratory Policy  <a href="http://www.env.gov.nl.ca/env/env_protection/lab_policy.pdf">http://www.env.gov.nl.ca/env/env_protection/lab_policy.pdf</a></p>	All	<p>Angela Burrridge, M.Sc.  Senior Environmental Scientist  T 709-729-4273  E <a href="mailto:angelaburrridge@gov.nl.ca">angelaburrridge@gov.nl.ca</a></p>



Province	Example Document/Link	Clause	Contact
<b>Clause Approach</b>			
Canada	Wastewater System Effluent Regulation <a href="http://laws.justice.gc.ca/eng/regulations/SOR%2D2012%2D139/">http://laws.justice.gc.ca/eng/regulations/SOR%2D2012%2D139/</a>	16	Abde Miftah Idrissi Section Manager, Laboratory Services, Science and Technology Branch Tel: 613-993-3322 <a href="mailto:ma.miftahidrissi@canada.ca">ma.miftahidrissi@canada.ca</a>  Marc Bernier Director/ Water Science & Technology Directorate Tel: 506-851-2622 <a href="mailto:Marc.Bernier@canada.ca">Marc.Bernier@canada.ca</a>
Saskatchewan	The Waterworks and Sewage Works Regulations <a href="http://www.publications.gov.sk.ca/details.cfm?p=73309">http://www.publications.gov.sk.ca/details.cfm?p=73309</a>	36	Wes Kotyk, P.Eng. Acting Assistant Deputy Minister, Environmental Protection Division 306-933-6542 (Saskatoon) 306-787-5419 (Regina)



Province	Example Document/Link	Clause	Contact
Manitoba	Drinking Water Safety Regulation <a href="http://www.gov.mb.ca/sd/waterstewardship/odw/reg-info/acts-regs/040-d101.07.pdf">http://www.gov.mb.ca/sd/waterstewardship/odw/reg-info/acts-regs/040-d101.07.pdf</a>	35	Joy Kennedy Water Quality Management Section Tel: 204-945-7908
Ontario	Safe Drinking Water Act <a href="https://www.ontario.ca/laws/statute/02s32">https://www.ontario.ca/laws/statute/02s32</a>  Record of Site Condition <a href="https://www.ontario.ca/laws/regulation/040153">https://www.ontario.ca/laws/regulation/040153</a>	62  47(1)c	Ralph Ruffolo, Ph.D. Senior Litigation Scientist Laboratory Services Branch Phone: 416-235-6358 Email: <a href="mailto:ralph.ruffolo@ontario.ca">ralph.ruffolo@ontario.ca</a>
New Brunswick	Potable Water Regulation – Clean Water Act <a href="http://laws.gnb.ca/en/ShowTdm/cr/93-203//">http://laws.gnb.ca/en/ShowTdm/cr/93-203//</a>	9(1)	David Schellenberg Executive Director Program Operations & Enforcement  Dave.schellenberg@gnb.ca



Province	Example Document/Link	Clause	Contact
Yukon	Protocol for the Contaminated Sites Regulation under the Environment Act <a href="http://www.env.gov.yk.ca/air-water-waste/documents/protocol_2_sample_analysis_aug-12.pdf">http://www.env.gov.yk.ca/air-water-waste/documents/protocol_2_sample_analysis_aug-12.pdf</a>	2.0	Benton Foster, Manager Environmental Health Services 867-667-8370  Jean Beckerton Surface Water Quality Specialist 867-667-3233
Northwest Terr.	Water Supply System Regulations <a href="https://www.justice.gov.nt.ca/en/files/legislation/public-health/public-health.r7.pdf">https://www.justice.gov.nt.ca/en/files/legislation/public-health/public-health.r7.pdf</a>	12(1)	Peter Workman Chief Environmental Health Officer 867-767-9066
Nunavut	Environmental Guideline for Industrial Waste Discharges into Municipal Solid Waste and Sewage Treatment Facilities <a href="http://www.gov.nu.ca/sites/default/files/industrial_waste_discharges_2011.pdf">http://www.gov.nu.ca/sites/default/files/industrial_waste_discharges_2011.pdf</a>	2.1	Alex Brisco Environmental Compliance Manager 867-975-7726 mbrisco@gov.nu.ca

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