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Building Laboratory Excellence

Vers l'excellence dans les laboratoires

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A Submission to the Expert Panel Reviewing Canadian Environmental Assessment Processes

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The Canadian Association for Laboratory Accreditation Inc. (CALA) is a not-for-profit member-based association that instills public confidence in laboratory test results by providing internationally recognized accreditation, proficiency testing and training services. On behalf of CALA, thank you for the opportunity to contribute CALA's ideas and suggestions toward improving/strengthening environmental assessment processes in Canada.

BACKGROUND

Environmental Assessment has been broadly defined as a planning & decision-making tool used to both anticipate adverse environmental effects before they occur and provide plans to follow up, mitigate and monitor these effects.

Environmental Assessment can also be described as an exercise in projecting (largely through mathematical modeling) potential environmental and human health impacts of planned projects. These complex models use as their foundation, laboratory analytical data from field samples (water, sediment, biota and air). These laboratory data are coupled with assumptions regarding future environmental conditions (temperature, precipitation, climate change, etc.) to predict future environmental quality, often into the far future (e.g. 2165 for Shell Jackpine oil sands project http://www.ceaa.gc.ca/050/documents/p59540/90873E.pdf (pg. 70)

CALA believes that accreditation should be a key building block within the Environmental Assessment (EA) Process.

If laboratories conducting chemical analyses are required to be accredited, then indigenous peoples, the general public, governments and industry will have a higher degree of confidence in the foundational data, and hence the overall conclusions of the EA process.

Equally important to the EA process is the post-EA follow-up monitoring activities. Such monitoring and associated accredited analytical testing should/will be able to demonstrate that the EA was reasonably accurate and that the proponent was operating and managing the project to be within the predicted environmental quality targets.

Data integrity throughout this process is vital for public confidence, yet this element has generally been left to the judgment of the proponents' consultants. Some jurisdictions (BC:

Contaminated Sites Regulations adopted a 'Qualified Professional' designation to establish accountability for quality control and data integrity https://csapsociety.bc.ca/ and CALA supports this approach as outlined in the submission to the Expert Panel by the College of Applied Biology dated December 6, 2016. http://eareview-examenee.ca/wp-content/uploads/uploaded_files/college-of-applied-biology-submission-to-environmental-assessment-review-panel.pdf

A top priority of the Government of Canada is to immediately review Canada's environmental assessment processes to regain public trust and help get resources to market and introduce new and fair processes that will in part:

- Restore robust oversight and thorough environmental assessments of areas under federal jurisdiction, while working with the provinces and territories to avoid duplication;
- Ensure decisions are based on science, facts and evidence and serve the public's interest;

CALA appreciates that government bodies and regulators are constantly being called upon to make decisions related to:

- Protecting the health and welfare of consumers and the public
- Protecting the environment
- Developing new regulations and requirements
- Measuring compliance with regulatory and legal requirements
- Allocating resources, both technical and financial

In order to make informed decisions, governments/regulators must have confidence in the data being generated in support of the environmental assessment process. It is CALA's opinion that using accredited laboratories can help to both establish and assure this confidence.

Using an accredited laboratory benefits governments and regulators by:

- Increasing confidence in data that is used to establish baselines for key analyses and decisions
- Reducing uncertainties associated with decisions that affect the protection of human health and the environment
- Increasing public confidence, because accreditation is a recognizable mark of approval
- Eliminating redundant reviews and improving the efficiency of the assessment process (which may reduce costs)

A laboratory that is accredited by an internationally recognized accreditation body, has formally demonstrated that it has a prescribed level of technical competence to perform specific types of testing. The result of undergoing the accreditation process is an assurance that the laboratory is capable of producing data that is accurate, traceable and reproducible – all of which are critical components in governmental decision-making.

An early CALA-Standards Council of Canada joint study from 2001 illustrated that accredited laboratories produced more consistent and competent results than non-accredited laboratories. http://www.archives.gov.on.ca/en/e_records/walkerton/part2info/publicsubmissions/pdf/SCC-CAEAL14mar.pdf
In a more recent (2003-2015) examination of CALA data (currently being submitted for publication) shows that non-accredited laboratories were 1.8 times more likely to have unsatisfactory performance in Proficiency Testing than accredited laboratories. A similar study undertaken in Brazil also shows the positive influence that accreditation has on a laboratory's performance. http://link.springer.com/article/10.1007/s00769-015-1181-9

CALA believes that using accredited laboratories to carry out any testing required during the environmental assessment process will help to achieve the government's goals of improving/strengthening Canada's environmental assessment processes and:

- Regaining public trust
- Restoring robust oversight and
- Ensuring decisions are based on science, facts and evidence

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RECOMMENDATION:

To this end, CALA recommends the following requirements be included as integral components of Canada's Environmental Assessment Processes:

In order to ensure that a laboratory providing external testing as part of an environmental assessment has:

- ***Met the relevant international standard***
- ***Met the requirements of the International Laboratory Accreditation Cooperation (ILAC) [3] for competence AND***
- ***Is providing reliable data and reports:***

1. ***The laboratory shall be accredited in accordance with the requirements of ISO/IEC 17025 [1], General requirements for the competence of testing and calibration laboratories.***
2. ***The laboratory's scope of accreditation to ISO/IEC 17025 shall include each of the test methods required for any testing work being specified.***
3. ***The accreditation of the laboratory shall be issued by an accreditation body (AB), operating in accordance with ISO/IEC 17011 [2], General requirements for accreditation bodies accrediting conformity assessment bodies and said AB is a Signatory to the ILAC Mutual Recognition Arrangement (MRA) [3].***

FOOTNOTES:

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[1] ISO/IEC 17025 – The global standard for laboratory competence

The general requirements for laboratory competence are described in the ISO/IEC 17025 standard. This standard establishes a global baseline for the accreditation of all types of laboratories. Since its origin in the late 1970s, ISO/IEC 17025 (formerly known as ISO Guide 25) emphasizes competence of laboratories to perform specified tests, not just mere compliance with requirements.

Formal recognition of such competence generally requires that laboratories obtain accreditation. Accreditation involves on-site and performance assessments as well as ongoing proficiency testing. Assessment of competence requires persons (known as assessors) who understand the requirements of the standard and have a sufficient depth of understanding about the specified tests to make judgments of competence.

Several Principles are embedded in the requirements of ISO/IEC 17025 as follows:

Responsibility. A laboratory must have personnel who have the authority to execute specific functions within its overall scope of work—and can demonstrate accountability for their results.

Scientific Approach. A laboratory should carry out its work based on accepted scientific principles, preferably following consensus-based methods or standards, and deviations from accepted methods must be substantiated in a manner considered generally acceptable by experts in the field.

Objectivity/Impartiality. The results produced by the laboratory should be based on measurable quantities. The pursuit of reliable results through the use of accepted scientific principles is the primary and overriding influence on the persons carrying out the testing. All other influences are secondary and not permitted to take precedence.

Metrological Traceability. The results produced by the laboratory are based on a recognized system of measurement that derives from accepted known quantities (SI system, if units of measurement) or other well-characterized references. The chain of comparison of measurements between these accepted, known 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.

Reproducibility. The test methods used by the laboratory to produce results will produce results within an acceptable spread or range during future testing and within the constraints of using the same procedures, equipment, and persons used for a prior execution of the test.

Transparency. The processes within a laboratory producing objective results must be open to external as well as internal scrutiny, so that factors that may adversely affect the laboratory's pursuit of objective results based on scientific principles can be easily identified and mitigated.

Capacity. A laboratory must have the resources (people with the required skills and knowledge; environment with the required facilities, equipment and instruments; procedures to ensure consistency of test processes; and quality control for the key steps in the testing processes) necessary to carry out the tests and produce reliable results.

While these principles do not cover every requirement of the standard, they are comprehensive enough to allow laboratories and assessors to appreciate the reasons behind most of the individual requirements of the standard. They enable assessors to exercise their professional judgment in evaluating whether a laboratory meets the requirements for recognition of its competence to perform specified tests.

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[2] ISO/IEC 17011 –The global standard for the competence of Accreditation Bodies

The general requirements for accreditation bodies accrediting conformity assessment bodies are described in the ISO/IEC 17011 standard. This standard establishes a global baseline for the requirements of accreditation bodies. Peer evaluation mechanisms have been created at both regional and international levels, through which assurance is provided that accreditation bodies are operating in accordance with this international standard. Accreditation bodies that have passed such an evaluation can become members of Mutual Recognition Arrangements (MRA). Through regular re-evaluations, the continued adherence to ISO/IEC 17011 is assured.

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[3] The International Laboratory Accreditation Cooperation (ILAC) and the ILAC Mutual Recognition Arrangement (MRA)

ILAC is the international organization for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies including testing laboratories (using ISO/IEC 17025).

Accreditation is the independent evaluation of conformity assessment bodies (e.g. laboratories) against recognized standards to carry out specific activities to ensure their impartiality and competence.

Through the rigorous application of both national and international standards, government, procurers and consumers can have confidence in the laboratory test results provided.

Accreditation Bodies that have been peer evaluated as competent, become Signatories to both Regional and International Mutual Recognition Arrangements (MRAs) to demonstrate their competence globally. These recognized Accreditation Bodies (example: CALA) then assess and accredit laboratories to the relevant standards.
MRA Signatories such as CALA facilitate a one-stop process that includes recognition, promotion and acceptance of each other's accredited laboratories.

These international MRAs support the provision of local or national services, such as providing safe food, clean drinking water or maintaining an unpolluted environment. In addition, MRAs enhance the acceptance of both products and services as they move across national borders, thereby creating a framework to support international trade through the removal of technical barriers.
The overwhelming international success of MRAs has resulted in the tagline:

Accredited Once, Accepted Everywhere!!