

P04-03 – CALA APPLICATION FOR NEW ACCREDITATION

Revision #1.12

December 23, 2019



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1.0 INSTRUCTIONS

This application is to be used only by laboratories that are seeking accreditation for the first time by CALA.

The following steps must be completed for the application to be considered complete.

Step 1 Complete Section 2.0 Laboratory Identification

This section must be completed with care. The information contained in this section will be used for all communication between CALA and the applicant laboratory. The laboratory may include more than one email contact if desired.

Step 2 Complete Section 3.0 Laboratory Specifics

This information is one of the pieces of information that is retained on file by CALA. It provides a general overview of the size of the laboratory, staffing levels and workload.

Step 3 Complete Section 4.0 Documentation Required for Accreditation

This section provides a list of documentation that must be available in order for a site visit to be scheduled. Please check off all of the documents that your laboratory currently has in its possession.

If method validation records and a person familiar with the method are not available at the time of the site assessment, the method will not be assessed. Method validation records must include evidence that actual samples reflective of typical matrices have been analyzed in a typical run, to demonstrate that the method has been implemented as documented, and that the method is fit-for-purpose. The actual samples need not be client samples.

Step 4 Complete Section 5.0 Preferred Date of Assessment

In section 5.0, enter the dates that your laboratory is available for an assessment.

Step 5 Complete Section 6.0 Terms and Conditions of Accreditation

CALA Accreditation Program participants must comply with the terms and conditions (<http://www.cala.ca/P04-01-Terms and Conditions.pdf>). An assessment will not be scheduled if these terms are not signed by an authorized laboratory official who has authority to bind the organization and returned to CALA.

Step 6 Complete Annex 1: Scope of Testing Template

Section 7.0 provides instructions on the completion of Annex 1 - Scope of Testing Template. A separate template is required for each appendix for which the laboratory is seeking accreditation. If you need further assistance in completing the Scope of Testing, please contact a CALA Accreditation Officer.

Email: assessments@cala.ca

Phone: (613) 233-5300

Fax: (613) 233-5501

Step 7 Optional: Request a Pre-assessment

Applicants to the CALA Accreditation Program may request a pre-assessment, which is generally conducted by CALA staff. A document review is performed and the laboratory undergoes a site visit. The objective of the pre-assessment is to provide an opportunity for the laboratory to gain an understanding of their state of readiness for accreditation. It is not a substitute for an initial assessment and although major gaps between the laboratory's operation and the requirements of ISO/IEC 17025 may be identified, direct advice on how to meet the requirements will not be provided. Should an applicant want a pre-assessment, please submit a request in writing when submitting this completed application.

Step 8 Submit Your Application

Completed applications may be submitted by mail, fax or scanned and emailed. The application sections that must be included in the application are:

Section 2;

Section 3;

Section 4;

Section 5;

Section 6; and,

Annex 1: Scope of Testing Template(s). One for each Method to appear on the scope.

For an estimate on the length of time to complete the process, please refer to A125 – CALA Accreditation Program Target Timelines. Submit your completed application to:

CALA

Attention: Program Administrator

102-2934 Baseline Road

Ottawa, ON K2H 1B2

Telephone: (613) 233-5300

Fax: (613) 233-5501

Email: programadmin@cala.ca

2.0 LABORATORY IDENTIFICATION

CALA File No. (existing clients only)		Membership: <input type="checkbox"/> Yes <input type="checkbox"/> No (See P02-02 - Fee Schedule for benefits)	
Name of Laboratory		Publicly Traded: <input type="checkbox"/> Yes <input type="checkbox"/> No	
		Exchange(s):	Symbol(s):
Name of Parent Institution		Publicly Traded: <input type="checkbox"/> Yes <input type="checkbox"/> No	
		Exchange(s):	Symbol(s):
List other accreditations (if applicable):			
LOCATION OF FACILITY			
Contact		Email	
Street			
City	Province	Postal Code	Country
Phone Number		Facsimile Number	
MAILING ADDRESS		SAME AS (check, if applicable) <input type="checkbox"/> "Location of Facility"	
Contact		Email	
Street			
City	Province	Postal Code	Country
Phone Number		Facsimile Number	
BILLING ADDRESS		SAME AS (check one, if applicable) <input type="checkbox"/> "Mailing Address" <input type="checkbox"/> "Location of Facility"	
Contact		Email	
Street			
City	Province	Postal Code	Country
Phone Number		Facsimile Number	
MANAGEMENT			
Laboratory Manager/Director		Email	
Quality/Management System		Email	
WITHHOLDING TAX (INTERNATIONAL ONLY)		CLIENTS SERVED	
Withholding Tax Required: <input type="checkbox"/> Yes <input type="checkbox"/> No Amount of tax: ____%		<input type="checkbox"/> All Interested Parties <input type="checkbox"/> Specified Clients <input type="checkbox"/> Internal Clients	
HOW DID YOU HEAR ABOUT CALA			
How did you hear about CALA? (Please check all that apply) <input type="checkbox"/> Internet Search <input type="checkbox"/> Conference <input type="checkbox"/> Word of Mouth			
<input type="checkbox"/> Regulatory Requirement <input type="checkbox"/> Email from CALA <input type="checkbox"/> Other _____			

Directory of Accredited Laboratories

This on-line Directory provides information on laboratories in the Accreditation Program and the specific scope of testing for which they have been found to be competent, conforming to the requirements of ISO/IEC 17025:

- Any fields left blank will appear blank in this directory;
- The *Location of Facility* address, as provided on the previous page, is the one that will appear on the Scope; and,
- It is the responsibility of the laboratory to contact CALA should address/contact information change.

Please provide information regarding contact information to appear on the Scope of Accreditation.

INSTITUTION NAME	
Name of Laboratory	as listed on previous page
Name of Parent Institution	<input type="checkbox"/> include "Name of Parent Institution" as listed on previous page
DIRECTORY OF ACCREDITED LABORATORIES	
SAME AS (check, if applicable) <input type="checkbox"/> "Location of Facility" <input type="checkbox"/>	
Contact	Email
Phone Number	Facsimile Number

Canada's Anti-Spam Legislation (CASL)

Canada's new anti-spam law was passed in December 2010 and came into force on July 1, 2014. This law, among other things, will mainly prohibit the sending of commercial electronic messages (CEMs) without the recipient's consent (permission), including messages to email addresses, social networking accounts, and text messages sent to a cell phone.

How does CASL Impact CALA Clients/Laboratories?

Current CALA clients or volunteers will receive emails directly related to the delivery of products and services where there is an existing business relationship (i.e. membership, received program application form or registration form, or active volunteer). However, we require your express consent (permission) to send you CALA SUBSCRIPTION communications via email.

What are CALA SUBSCRIPTION Communications?

CALA SUBSCRIPTION communications are the electronic delivery of up to date CALA information and industry announcements. These subscription communications can include any of the following:

1. **Training Program Information:** receive monthly newsletters, and updates on new and upcoming courses, and exciting e-training opportunities.
2. **Surveys:** feedback obtained from surveys is very important for program and service development and improvements.
3. **Periodic Updates:** contain important information on CALA programs/services, as well as notices, Board updates, industry news and CALA document updates.
4. **General Marketing:** occasionally CALA will forward information on services, products and upcoming events of interest to CALA clients.

For each email identified earlier in this application form, please have the email owner check off all and initial desired CALA SUBSCRIPTION Communications. A person can unsubscribe at any time.

CALA Subscription Selection					
Email Address	Initials of Email owner	1	2	3	4
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3.0 LABORATORY SPECIFICS

Please provide figures, as specified, on laboratory staffing, sample and testing volume, and floor area.

1.	Number of Staff	Management	
		Professional and Technical	
		Other	
		Total	
2.	Total Analysts	Testing*	
		Other	
		Total	
3.	Sample Volume	Total Samples per year	
		% Environmental	
		% Food	
		% Mineral	
		% Petroleum	
		% Other	
4.	Testing Volume	Total Tests per year	
5.	Floor Area (m2)	Testing	
		Other	
		Total	

* Includes all staff involved in the pre-treatment, preparation or analysis of samples.

4.0 DOCUMENTATION REQUIRED FOR ACCREDITATION

The following documents must be received at CALA and reviewed for readiness before an assessment is scheduled:

- Evidence that the laboratory has purchased a copy of ISO/IEC 17025:2017; to purchase, see <http://www.global.ihs.com/>
- Quality Management System documentation (i.e., relevant policies, procedures, and documented processes).
- A completed A18-2017 – Cross Reference to Laboratory Management System.
- Test methods and supporting operational procedures.
- Method Validation Data.
- Internal Audit Records.
- Management Review Records.
- A list of deviations from the reference method (if applicable and if not already in the test method procedure). See A12 – CALA Policy on Reference Methods.
- Demonstration of satisfactory participation in proficiency testing, where available.

If the laboratory has applied for a pre-assessment, all the above documents must be submitted, except that only a representative sample of the test methods, procedures, and method validation packages are required. The exact percentage of test methods, supporting procedures and method validation packages will depend on the nature of the testing. As a general guideline, documents and records do need to be submitted from every discipline (e.g., inorganic chemistry, microbiology, organic testing, etc...) and/or every field (e.g., petroleum testing, mineral testing, mechanical testing, etc...).

In addition, the following documents must be available at the time of the assessment. Please confirm which of them are currently available.

In addition, the following documents must be available at the time of the assessment. Please confirm (using the checkbox) which of them are currently available.

- Competence requirements for each position (e.g., job descriptions).
- List of proficiency testing participation and reports from PT providers.

Key laboratory documents and records, including but not limited to:

<input type="checkbox"/> internal quality control	<input type="checkbox"/> staff training and authorizations
<input type="checkbox"/> document control	<input type="checkbox"/> method verification and validation
<input type="checkbox"/> sample management	<input type="checkbox"/> confidentiality
<input type="checkbox"/> data management and record-keeping	<input type="checkbox"/> equipment maintenance
<input type="checkbox"/> workload management	<input type="checkbox"/> test organism maintenance
<input type="checkbox"/> procurement of goods and services (including services of other testing laboratories)	<input type="checkbox"/> complaints

All supporting work instructions, including but not limited to:

<input type="checkbox"/> sample history requirements	<input type="checkbox"/> test organism history requirements
<input type="checkbox"/> sample pre-treatment procedures	<input type="checkbox"/> test organism culturing and/or holding conditions
<input type="checkbox"/> labware cleaning/sterilization procedures	

Technical records, including but not limited to:

<input type="checkbox"/> reagent preparation logs	<input type="checkbox"/> records of raw data
<input type="checkbox"/> equipment maintenance logs	<input type="checkbox"/> data validation records
<input type="checkbox"/> test organism maintenance logs	<input type="checkbox"/> records of non-conformances
<input type="checkbox"/> certificates of calibration	<input type="checkbox"/> test reports

5.0 PREFERRED DATE OF ASSESSMENT

Attempts will be made to schedule the site visit at a time that is convenient to the applicant laboratory. However, please note that the final date is subject to availability of assessor(s) with the appropriate expertise.

Preferred dates for an on-site assessment:

6.0 TERMS AND CONDITIONS OF ACCREDITATION

Name of Laboratory

CALA File No.

As an Authorized Representative* of this laboratory, I agree to the general terms and conditions found in Section 1.1 of P04-01 – *Terms and Conditions of Accreditation* and the following applicable statements (choose all that apply):

This laboratory is licensed or applying for a license under the Ontario Safe Drinking Water Act (OSDWA), and I also agree to terms and conditions found in Section 1.2 of P04-01.

This laboratory conducts testing for legislation enforced by the Canadian Food Inspection Agency (CFIA), and I also agree to terms and conditions found in Section 1.3 of P04-01.

Authorized Representative *

Signature

Title

Date DD/MM/YY

* An Authorized Representative must have the authority to legally bind the corporation.

7.0 COMPLETING THE SCOPE OF TESTING TEMPLATE

A separate scope of testing template is required for each method (appendix) for which the laboratory is seeking accreditation.

Use the attached *Scope of Testing Template* to prepare an analytical Scope of Testing. Each method (appendix) requires a separate page. Make sufficient photocopies of the template and sequentially number all submitted template pages.

7.1 Explanation of Terms on Scope of Testing Template

In completing a Scope of Testing Template, use the following definitions to provide the required summary information:

Analyte: The parameter that is the quantified output of the method (e.g., Phosphorus, Dichloromethane, etc.).

Analytical Technique: Measurement method (e.g., AA, graphite AA, cold vapor AA, flame emission, ICP/MS, ICP, GC/MS, GC/ECD, GC, HPLC, SIE, IC, colorimetric, auto-color, gravimetric, titrimetric, acute lethality, membrane filtration, etc.). For microbiology tests, the analytical technique is further defined by media type (e.g., membrane filtration (mEndo)).

Appendix: A unique matrix-test method combination that may contain more than one analyte. If the appendix is done outside the scope of the main laboratory (e.g., a field test, mobile unit, etc.), it is considered as a separate appendix. Each mobile unit is considered as a separate unit.

Field of Accreditation: A broad category of accreditation generally differentiated by required expertise (e.g., environmental, mineral, petroleum, food, etc...).

Matrix: A substance or material analyzed for the target analyte. Typical matrices include: (i) water, including fresh water (may include drinking water, ground water, surface water, and precipitation), marine water, and waste water (may include industrial effluent, municipal effluent and process water), (ii) soil, including sediment, (iii) plant tissue, (iv) animal tissue, (v) specific solid or liquid wastes (e.g., oils, sludges, etc.), (vi) airborne materials (in air emissions, the ambient air or workplace), collected by filter or other means, (vii) minerals, rocks, tailings, etc...

Commonly used matrices are: water; fresh water; wastewater; biological tissue; plant tissue; animal tissue; soil; sediment; air filters; charcoal tubes; and waste oil.

Method Reference: Agency or journal method reference abbreviated to the maximum extent possible (e.g., ASTM D1067-70B, EPA 310.1, SM 403, BC MOE D047A007, Anal. Chem 64, 371 (1192), NAQUADAT 19105, etc.). If the method employed by the applicant has been modified from the reference method, include this clarification (e.g., Modified from EPA 624).

OSDWA Check Box: Check this box if you are seeking licensing under the Ontario *Safe Drinking Water Act*.

Proficiency Testing Option: Please refer to the *CALA Proficiency Testing Policy for Accreditation (P02-03)*.

PT Provider: This is the name of the PT Provider that will be used to support the applicant's PT requirements.

Sample Preparation: All procedures such as purging, aeration, pH adjustment, extraction, clean-up, digestion, distillation, etc. carried out on samples (or standards) prior to analysis.

Test Method: Defined, as appropriate, in terms of analytical technique and sample preparation. When sample preparation plays a defining role in recovery, please specify. Examples of analytical technique/sample preparation combinations include ICP - digestion, GC/MS - extraction, Colorimetric - distillation, Hydride AA - digestion, etc.

Test Method I.D.: Unique laboratory I.D. assigned to a test method as part of laboratory document control.

7.2 Laboratories Performing Drinking-Water Testing in Ontario

Laboratories intending to test Ontario drinking water samples must:

- Apply to the Ontario Ministry of the Environment, Conservation and Parks (MECP) for a license, and ensure that accredited methods are in the *Protocol of Accepted Drinking Water Testing Methods* (https://files.ontario.ca/protocol_of_accepted_drinking_water_testing_methods.pdf) or are approved by the MOECP Director;
- Check off the box labeled OSDWA on the Scope of Testing template (Annex 1).

For questions relating to the licensing program, please contact the MECP Laboratory Licensing Administrator.

7.3 Specific Notes

CCME Reference Method for Total Petroleum Hydrocarbons in Soil: Please note the following:

- If the reference method is followed exactly, indicate CCME in the method reference field;
- If all the prescriptive elements are followed and the listed performance-based choices are validated according to the criteria in Appendix 2 and the performance meets the objectives in Section 8, indicate CCME in the method reference field; and,
- If any prescriptive elements are modified, CCME reference cannot be used at all in the method reference field.

If analyzing for petroleum hydrocarbons in water and there is a regulatory or customer requirement to use the fractions in the CCME method, the reference can be listed as “modified from CCME”.

7.4 Proficiency Testing

If option i or option ii Proficiency Testing (PT) is chosen, the CALA Directory will be set up so that the laboratory can immediately enter any option i or option ii PT study results, unless arrangements have been made with a PT provider to automatically transfer PT results to the CALA database. It is incumbent upon the laboratory to do this in a timely manner, as satisfactory PT must be demonstrated before granting of accreditation and not entering the PT results may delay accreditation. It is preferable that this data is entered at least six (6) weeks prior to the assessment.

7.5 Food Testing

Many laboratories in Canada conduct testing for legislation that is enforced by the Canadian Food Inspection Agency (CFIA). Accreditation of testing in these laboratories is governed by the *Agreement Between the CFIA and CALA for the Accreditation of Testing Laboratories*, which came into effect on February 01, 2012. Under this agreement, the CFIA recognizes CALA as an Accreditation Body for Accreditation of Laboratories conducting analyses and tests in all technical fields related to food, feed and fertilizer as per the appropriate Legislation enforced by the CFIA. The responsibilities of each organization are detailed in the Agreement. If applying for accreditation for a test that falls under the CFIA legislation, please note the following:

Field of Accreditation – List “Food”

Appendix Name – List the main analyte or group of analytes (e.g., Salmonella, Pesticides, Coliforms, etc...).

Matrix – List the types of foods (submatrices) that are tested for legislation under CFIA in the laboratory (e.g., meat, eggs, poultry). Also, please list any exclusions (e.g., Milk (excluding Pasteurized Milk)). If there is not enough room in this field, simply note these matrices somewhere else on the page with a clear indication as to what they are, so that they are not confused with analytes. Food Appendices must include at least one submatrix (i.e., labs cannot only list “Food” for the matrix and submatrix).

Test Method – List the main analytical method (e.g., Direct Plating).

Method Reference – List the reference method (e.g., MFLP-58). If the method is followed exactly, do not check the box that says “Modified from”; if this box is checked, the scope listing will say “Modified from MFHPB20”. Note, in cases where there are modifications to the reference method, it is required that the laboratory have a document on file listing the modifications from the reference method (please refer to A12 – CALA Policy on Reference Methods).

Test Method I.D. – List the laboratory’s internal document control number for the method.

Analytes – List the analytes; an appendix may have one (1) analyte (e.g., Aeromonas hydrophila) or several (e.g., a list of pesticides).

NOTE: One reference method may result in two or more appendices (e.g., Pesticides in Meat using GC/MS and Pesticides in Meat using GC/FID).

Proficiency Testing Option – Refer to P02-03 CALA Program Description – Proficiency Testing Policy for Accreditation for requirements on proficiency testing requirements. Circle the option that is applicable for the analyte.

PT Provider – Document the name of the PT provider.

Example Scope Listing

Appendix 001 – Salmonella – Food [Milk Powder, Egg, Cheese, Butter, Evaporated Milk, Meat]

Method: Spread Plate

Reference Method: MFHPB20

Lab ID: SOP 123

Analyte(s): Salmonella

A field of accreditation is a broad category of accreditation, generally defined by required expertise. For example, while some assessors may have expertise to assess both environmental and food testing, some assessors may not have the experience or credentials to assess both types of testing. Practically speaking, this means that two assessors may have to be assigned to cover a proposed scope of testing even if the laboratory is fairly small. It's not unusual that different fields of accreditation have slightly different procedures or require specialized policies or application of the standard, simply due to the nature of the testing.

ANNEX 1: Scope of Testing Template

(Also available in Word format on the CALA Web site www.cala.ca)

GREY BOXED AREAS FOR CALA USE ONLY

<input type="checkbox"/> Check and identify if laboratory address is different than "Location of Facility" identified in Section 2.0.		Template ID			
Facility Name:					
CALA File No. (existing members only)	Field of Accreditation (e.g. Environmental, Mineral, Petroleum, Food)	Page	of		
Appendix Number	Appendix Name (e.g., VOCs)				
Matrix (e.g., Water, Solids, Oil, Food etc.)	Matrix	Test Method (e.g., Purge and Trap/GCMS)			
Method Reference (e.g., EPA 6024) <input type="checkbox"/> "modified from"		Test Method I.D. (e.g., SOP 101.2)			
Analytes	OSDWA Proficiency Testing Option (circle one)	PT Provider	Analytes	OSDWA Proficiency Testing Option (circle one)	PT Provider
	<input type="checkbox"/> i, ii, iv, v, vi			<input type="checkbox"/> i, ii, iv, v, vi	
	<input type="checkbox"/> i, ii, iv, v, vi			<input type="checkbox"/> i, ii, iv, v, vi	
	<input type="checkbox"/> i, ii, iv, v, vi			<input type="checkbox"/> i, ii, iv, v, vi	
	<input type="checkbox"/> i, ii, iv, v, vi			<input type="checkbox"/> i, ii, iv, v, vi	
	<input type="checkbox"/> i, ii, iv, v, vi			<input type="checkbox"/> i, ii, iv, v, vi	
	<input type="checkbox"/> i, ii, iv, v, vi			<input type="checkbox"/> i, ii, iv, v, vi	
	<input type="checkbox"/> i, ii, iv, v, vi			<input type="checkbox"/> i, ii, iv, v, vi	
	<input type="checkbox"/> i, ii, iv, v, vi			<input type="checkbox"/> i, ii, iv, v, vi	
	<input type="checkbox"/> i, ii, iv, v, vi			<input type="checkbox"/> i, ii, iv, v, vi	
	<input type="checkbox"/> i, ii, iv, v, vi			<input type="checkbox"/> i, ii, iv, v, vi	
	<input type="checkbox"/> i, ii, iv, v, vi			<input type="checkbox"/> i, ii, iv, v, vi	
	<input type="checkbox"/> i, ii, iv, v, vi			<input type="checkbox"/> i, ii, iv, v, vi	
	<input type="checkbox"/> i, ii, iv, v, vi			<input type="checkbox"/> i, ii, iv, v, vi	
	<input type="checkbox"/> i, ii, iv, v, vi			<input type="checkbox"/> i, ii, iv, v, vi	
<p>Note: (1) if applying for a long list of analytes, a template is available at http://www.cala.ca/excel-analyte (2) when completing the Matrix area, please reference the Matrix and Sub-Matrix Guide http://www.cala.ca/A136</p> <p>Instructions: Ensure that ALL requested information is complete and accurate. When providing the requested information, refer to the instructions in the specific CALA application and use the following guidelines:</p> <ol style="list-style-type: none"> Appendix Identification: Analytes having a unique matrix – test method combination must be assigned to separate appendices (i.e., separate pages of the template). Analytes: An appendix may contain one or more applicable analytes. Method Ref: Add the words <i>modified from</i> if your method does not follow the Method Reference exactly. Proficiency Testing Option: refer to P02-03-CALA Program Description-Proficiency Testing Policy for Accreditation. <p>NOTE: By choosing PT Canada as a PT provider, your application will be automatically forwarded to PT Canada.</p>					