

P04-04 – CALA Application for Accreditation Renewal
Revision 1.7 – March 16, 2016



CALA

Laboratory Accreditation

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CALA APPLICATION FOR ACCREDITATION RENEWAL

1.0 INSTRUCTIONS

This application is to be used only by laboratories that are seeking renewal of their CALA accreditation.

Use the following steps to complete the application.

Step 1: Review Your Laboratory Profile

Your current laboratory profile is available at www.cala.ca/cala_directories.html using Directory login password provided by CALA. Review the Laboratory Identification and Laboratory Specifics for accuracy. If any changes are required, print a copy of the relevant form, make the changes on the form and submit it.

Step 2: Review Your Scope of Accreditation

A copy of your current scope of accredited testing is available at www.cala.ca/cala_directories.html using Directory login password provided by CALA. Please update it by:

- reviewing for completeness and accuracy and making any changes necessary directly on the scope of testing; and,
- deleting existing Appendices if you wish to do so.

New methods (appendices) may be added by completing a *Scope of Testing Template* for each new Appendix. Sequentially number all submitted template pages, beginning with the number following the last page number of your existing scope.

Step 3: Review Section 2.0 Documentation Required for Accreditation

This section provides a list of documentation that must be available in order for a site visit to be scheduled.

The Quality Manual, Internal Audit records, Management Review records, Analytical Methods, supporting Procedures (work instructions) and Method Validation Data for any new appendices must be provided to CALA no later than six weeks prior to the assessment. Please keep in mind that the assessment will be facilitated if the assessment team reviews the versions of documents that will be in place at the time of the assessment. All of these must be provided in a CD-ROM format or via FTP (not by email). As well, one (1) hard copy of the quality manual must be submitted and a completed copy of A18-Quality System Document Review Form. Failure to provide these in the required timeframe may result in a

postponement or cancelation of the assessment and the laboratory will incur all associated costs.

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: Review Section 3.0 Date of Assessment

Your assessment will be scheduled within three (3) months of the date provided to you by CALA (sent under a separate cover) and based on the current accredited scope. If there is a period during that window that is problematic, communicate this information to CALA by completing and submitting Section 3.0 of this application.

Step 5: Review Section 4.0 Terms and Conditions

CALA Accreditation Program participants must comply with the terms and conditions (http://www.cala.ca/P04-01-Terms_and_Conditions.pdf). Failure to conform to these terms and conditions may result in suspension or withdrawal of accreditation, in whole or in part.

Step 6: Complete Annex 1: Scope of Testing Template

If there are any new appendices to be added to the Scope of Accreditation, submit a completed Scope of Testing Template for each appendix. Instructions for completion of the template are found in section 5.0.

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: Submit Your Application

Completed applications may be submitted by mail, fax, or scanned and emailed.

If there are no updates or changes, no action is needed.

If there are changes to the existing scope, laboratory contact information or laboratory specifics, they must be included as well. For an estimate on the length of time to complete the process, please refer to A125 - *CALA Accreditation Program Target Timelines*.

Send your completed application to:

CALA
Attention: Program Administrator
102-2934 Baseline Road
Ottawa, Ontario
K2H 1B2

Telephone: (613) 233-5300
Fax: (613) 233-5501
Email: programadmin@cala.ca

2.0 DOCUMENTATION REQUIRED FOR ACCREDITATION

The following documents must be received at CALA no later than six (6) weeks prior to the assessment.

Laboratory Quality Manual.

A completed A18-Quality System Document Review Form.

Test methods and supporting operational procedures.

Method Validation Data for any new appendices.

Internal audit records (for internal audits performed since the last reassessment).

Management review records (for management reviews performed since the last reassessment).

A list of deviations from the reference method (if applicable and not already in the test method procedure). See A12 - CALA *Policy on Reference Methods*.

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

- A copy of ISO/IEC 17025:2005 (<http://www.global.ihs.com/>)
- Organization chart(s) including staff names, job titles and reporting relationships.
- Job descriptions for key management and supervisory positions.
- List of proficiency testing participation.
- List of certified reference materials used.
- Inventory of equipment used.
- Inventory of test methods used.

Key laboratory policies and procedures relating to review and assessment, including:

- | | | | |
|--|--------------------------|---------------------------|--------------------------|
| internal quality control | <input type="checkbox"/> | staff training | <input type="checkbox"/> |
| document control | <input type="checkbox"/> | method validation | <input type="checkbox"/> |
| sample management | <input type="checkbox"/> | confidentiality | <input type="checkbox"/> |
| data management including 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 | <input type="checkbox"/> | complaints | <input type="checkbox"/> |
| sub-contracting (if applicable) | <input type="checkbox"/> | authorizations | <input type="checkbox"/> |

All supporting work instructions, including:

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

All supporting forms used for sample and/or and data management.

Example test reports.

Laboratory records, including, as appropriate:

- | | | | |
|---|--------------------------|---|--------------------------|
| reagent preparation logs | <input type="checkbox"/> | analyst notebooks | <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"/> |
| logs documenting gravimetric, temperature and volumetric traceability | <input type="checkbox"/> | records relating to review and assessment | <input type="checkbox"/> |
| logs documenting reagent and/or dilution water characteristics | <input type="checkbox"/> | method validation | <input type="checkbox"/> |
| Proficiency testing reports | <input type="checkbox"/> | | |

3.0 DATE OF ASSESSMENT

A surveillance assessment must be performed within one (1) year from the initial visit. A full reassessment is conducted every two (2) years from the initial assessment (plus or minus three (3) months). CALA will provide you with the due date for the reassessment in a separate communication. Please indicate preferred dates within your required timeframe:

4.0 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/or Proficiency Testing* and the following applicable statements (choose all that apply):

- This laboratory is a participant in the CALA Proficiency Testing Program, and I agree to terms and conditions found in Section 1.2, P04-01.

- This laboratory is a participant in the CALA Accreditation Program, and I agree to terms and conditions found in Section 1.3, P04-01.

- This laboratory is licensed or applying for a license under the OSDWA, and I agree to terms and conditions found in Section 1.4, P04-01.

- This laboratory conducts testing for legislation enforced by the CFIA, and I agree to terms and conditions found in Section 1.5, P04-01.

Authorized Representative

Signature

Title

Date

DD/MM/YY

5.0 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. If the applicant is using CALA PT to support all or part of its PT requirements, a separate PT application is not required. This information will be obtained from the submitted Scope of Testing Templates.

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.

5.1 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: This refers to P02-03 - CALA *Proficiency Testing Policy for Accreditation*. If CALA PT will be used to support these requirements, the applicant will automatically be registered for the relevant PT. Note that if option (i) is chosen and a PT provider is not designated, the default is the CALA PT and the laboratory will be automatically registered in the CALA PT Program for the applicable analyte(s).

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.

5.2 Laboratories Performing Drinking-Water Testing in Ontario

Laboratories intending to test Ontario drinking water samples must: apply to the Ontario Ministry of the Environment for a license, and ensure that accredited methods are in the *Protocol of Accepted Drinking Water Testing Methods* (http://www.ontario.ca/drinkingwater/stel01_046886.pdf) or are approved by the MOE 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 MOE Laboratory Licensing Administrator at (416) 235-6370.

5.3 Specific Notes

Toxicology Appendices: Please refer to A110 – *Guidelines on Assessment and Accreditation of Toxicology Methods* (www.cala.ca/A110-Toxicology_References.pdf).

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

- If the reference method is following 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*”.

5.4 Proficiency Testing

If option i or option ii Proficiency Testing (PT) is chosen, the Web Data Entry system will be set up so that the laboratory can immediately enter any option i or option ii PT study results. 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.

5.5 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 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.

Test Method - List the main analytical method (e.g., GC/MS).

Method Reference - List the reference method (e.g., MFHPB20). 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., pH) 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 guidance 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 000 - *Salmonella* - 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)			PT Test Group	Status		
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	

Note: if applying for a long list of analytes, a template is available at <http://www.cala.ca/excel-analyte>

Instructions: Ensure that ALL requested information is complete and accurate. This information will appear in your accredited Scope of Testing. When providing the requested information, refer to the instructions in the specific CALA application and use the following guidelines:

- 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 *modified from* 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. NOTE: If option (i) is chosen and a PT Provider is not designated, the default is the CALA PT and the laboratory will be automatically registered in the CALA PT Program for the applicable analyte(s).