A06 – CALA Accreditation Program, Policies and Procedures

Revision 1.12 – May 29, 2018

CALA
Laboratory Accreditation

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CALA ACCREDITATION PROGRAM, POLICIES AND PROCEDURES

1.0 SCOPE

This policy applies to all applicants to the CALA Accreditation Program, and accredited laboratories.

2.0 BACKGROUND

ISO/IEC 17011:2017, *Conformity assessment-Requirements for accreditation bodies accrediting conformity assessment bodies*, is the standard that governs the operation of accreditation bodies such as CALA. This standard (clause 4.6.1) requires CALA to,

"…document the rules and processes for its accreditation schemes, referring to the relevant International Standards and/or other normative documents".

This document details CALA's policies and procedures for applicant and accredited laboratories in the CALA Accreditation Program.

3.0 SAFETY REQUIREMENTS

Non-conformances (Type A and B) will not normally be raised against observed or perceived health and safety activities unless they do not conform to laboratory stated policies and procedures or can be cited against specific and relevant regulations. For example, if there are signs that indicate safety glasses must be worn, and it is observed that they are not being worn, this is a non-conformance against the laboratory's stated policy. However, if an assessor observes what he/she perceives as a clear hazard for laboratory personnel, it should be immediately brought to the attention of laboratory management and documented as a C item on the assessment report.

CALA will not participate in the accreditation of a laboratory that presents known safety hazards to the people who work in the lab, or the people who use the laboratory services.

4.0 POLICY

To attain and maintain accreditation, applicant and accredited laboratories must conform to ISO/IEC 17025 and any CALA-specific accreditation requirements as documented in:

- A06 – *Accreditation Program, Policies and Procedures;*
- P02-03 – *CALA Program Description – Proficiency Testing Policy for Accreditation*;
- A61-01 – *CALA Traceability Policy*;
- P19 - *CALA Measurement Uncertainty Policy*;
- P07 – *CALA Application of Requirements in ISO/IEC 17025*;
- A96 – *Use of IT in Accredited Laboratories*;
- PT15-02 – *CALA PT Program – Policies*;
- P03 - *CALA Publicity Policy*;
- A12 – CALA *Policy on Reference Methods; and,*
- P02-01 – CALA *Program Description*.

4.1 Pre-Assessment Policies and Procedures

4.1.1 International Applicants.

Assignment for international travel is dependent upon the Government of Canada Travel Advisories website (http://travel.gc.ca/travelling/advisories) as follows. There are four levels of advisories:

- Avoid all travel
- Avoid non-essential travel
- Exercise a high degree of caution
- Exercise normal security precautions

Travel Advisory: ***Avoid all Travel***

CALA will not approve travel by CALA Officials into countries that are under an "Avoid all travel" advisory.

Travel Advisory: ***Avoid non-essential travel*** and ***Exercise a high degree of caution***

If a CALA Official elects not to travel to an area under a travel advisory/advice, they will not be expected to travel. CALA will allow other officials who are willing to travel to these areas to undertake the activity after consultation with CALA management.

As well, as per P02-01 CALA *Program Description*, CALA will comply with Government of Canada imposed restrictions on trade, financial transactions or other business that may be in force from time to time.

4.1.2 Language Requirements

The working language at CALA is English. Most documents are provided only in English, although a few key documents are available in French and Spanish.

4.1.3 Proposed Scope of Testing

To attain or maintain accreditation, a laboratory must carry out an analytical test method once every six months. At least one sample (not necessarily a customer sample), reflective of typical matrices run in the laboratory, must be analyzed in this timeframe – not just Proficiency Testing samples or standards.

It is important to note that stand-alone preparation methods are not accredited by CALA.

Any appendices added in the interval between reassessments will appear on the proposed scope of testing for the next upcoming reassessment.

The proposed scope must be finalized two months before the scheduled site (re)assessment. Changes after this date may not be accepted or assessed.

4.1.4 Approval of the Assessment Date and Team

Provided the application is complete, laboratories are scheduled for a visit and are notified of the week of the assessment and the assigned assessment team. It is the responsibility of the Lead Assessor to coordinate the exact days that the team will be on-site. While every attempt is made to ensure that the assigned schedules take into account any limitations noted by the laboratory at the time of application, laboratories are provided the opportunity to vet the assigned assessors, site assessment scheduling, and scope of testing. A request for any such change must be submitted in writing, including the rationale, for review and approval. If the grounds for objection are considered not reasonable or cannot be accommodated, CALA reserves the right to maintain the original schedule and/or assessors. In assigning assessors, CALA (i) avoids known commercial conflicts and (ii) matches assessor expertise with the testing to be assessed. The assigned scope of testing is based on the application information provided by the laboratory.

4.1.5 Information Required Prior to an Assessment

Applicant (New) Laboratories: Applicant laboratories must provide electronic copies of the following either at the time of application or eight weeks prior to the assessment:

- The test methods and any supporting operational procedures;
- Method validation for all analytes on the proposed scope of testing;
- Internal audit records;
- Management review records; and,
- Documents and records to support the full implementation of a management system.
- A completed copy of A18-CALA *Cross Reference to Laboratory Management System*; and,
- A list of deviations from the reference methods, if applicable and if not already included in the test method procedures. See A12 – CALA *Policy on Reference Methods*.

Laboratories are requested to submit the electronic documents and records outlined above using the FTP site. If the FTP site cannot be used for a valid reason, electronic copies of

documents and records may be submitted on CD-ROMs or USB keys; one CD-ROM or USB per assessor on the team must be submitted.

Accredited Laboratories: Accredited laboratories must provide electronic copies of the following either at the time of application or six weeks prior to the reassessment:

- The test methods and any supporting operational procedures;
- Method validation for new analytes on the proposed scope of testing;
- Documents and records to support the implementation of a full management system;
- Internal audit records; and,
- Management review records.
- A completed copy of A18 – Management System Cross Reference Form; and,
- A list of deviations from the reference methods, if applicable and if not already included in the test method procedures. See A12 – CALA *Policy on Reference Methods*.

Laboratories are requested to submit the electronic documents and records outlined above using the FTP site. If the FTP site cannot be used for a valid reason, electronic copies of documents and records may be submitted on CD-ROMs or USB keys; one CD-ROM or USB per assessor on the team must be submitted.

All documents provided are treated as confidential. A copy of the submitted documentation and records are retained on file at CALA.

4.1.6 Cancellation or Postponement of an Assessment

The assessment or reassessment may be cancelled or postponed, and the lab may incur any costs related this cancellation or postponement, if:

- Documents are not submitted according to the required timeline;
- Based on the document review, the Lead Assessor, in consultation with staff, deems that the laboratory is not ready for an assessment;
- Fees have not been paid in accordance with the fee schedule;
- The laboratory presents known safety hazards to the people who work in the lab, or the people who use the lab, or to any other persons; or
- The laboratory requests a major change less than two (2) months prior to the scheduled visit (e.g., vetting an assigned team member, extensive scope changes, etc.).

4.2 On-Site Policies and Procedures

4.2.1 Frequency of Reassessments

A surveillance visit is carried out one year after the initial assessment and a full reassessment is carried out one year after this surveillance visit (i.e., two (2) years after the initial assessment). Thereafter, regular reassessments are carried out every two years, plus three months. The three-month window cannot carry over into the next calendar year unless there are extraordinary events or circumstances. In the event of extraordinary events or circumstance that affect the laboratory or CALA and prevent the scheduled reassessment of

an accredited laboratory, CALA will assess the risk of continuing accreditation. An "extraordinary event or circumstance" is a circumstance beyond the control of the organization, commonly referred to as "Force Majeure" or "Act of God". Examples are war, riot, political instability, geographical tension, terrorism, crime, pandemic, flooding, earthquake, malicious computer hacking, and other natural or man-made disasters.

CALA will make every effort to work with the laboratory to facilitate maintenance of accreditation. There may be alternate methods of assessment to verify continuing system effectiveness. For example, for a short-term basis, the laboratory could be requested to submit internal audit records, management review records, corrective action records, test reports, or other documents and records.

If it appears that it may be an extended period of time before CALA can gain access to the laboratory, alternatives will be investigated. For example, local assessors from other ILAC signatories may be have better access to the laboratory and could be utilized to perform an assessment.

In the scenario where a laboratory has not been able to recuperate from an extraordinary event or circumstance and therefore is no longer able to offer its accredited testing service, either completely or in part, the laboratory is obliged to inform CALA immediately. The same applies to liquidation or bankruptcy.

If after six (6) months an assessment cannot be completed, CALA may have no option but to suspend the laboratory. Should the laboratory wish to transfer to another accreditation body, CALA will work with any local accreditation bodies to facilitate the transfer of accreditation.

4.2.2 Method Requirements

For a method to be assessed, there must be:

- Method validation/verification records (including, but not limited to, method detection limit and estimates of precision, bias, and measurement uncertainty, where applicable);
- Evidence that actual samples, reflective of typical matrices, have been analyzed in a run (to demonstrate that the method has been implemented as documented, and that the method is fit-for-purpose); and,
- An analyst available that is proficient for the method.

Actual samples reflective of typical matrices need not be actual client samples.

4.2.3 Witnessing Requirements

An assessor can ask for the equipment to be turned on and operated, or ask that all or part of a method be demonstrated.

4.2.4 Checklists

Requirements are summarized in checklists that are utilized by assessors during the assessment process to record conformance. The checklists used during the site assessment process are available on the CALA web site except where protected by copyright.

4.2.5 Assessors Drawn from Regulatory Agencies

Some assessors may be drawn from regulatory agencies and authorities having jurisdiction within the public sector. These regulatory personnel, who are experts in the scientific discipline and testing field under assessment, are also required by law to report any contravention of the laws they are duty-bound to enforce. Regulatory requirements that are outside the assessment scope of the CALA Program will not be cited in any assessment or reassessment report authored by a CALA Lead Assessor, but will be reported to the appropriate regulatory agency by the assessor.

4.2.6 Types of Findings

Nonconformities graded as "A": A nonconformity against the standard (ISO/IEC 17025), CALA requirements, the laboratory's own procedures, or a condition that affects the validity of the test result. A response on action taken and supporting evidence of this action is required within the specified timeframe (90 days from the closing meeting for applicants, 45 days from the closing meeting for accredited laboratories).

Nonconformities graded as "B": A nonconformity that is random or infrequent (e.g., a few records are missing or are out of date) or has been deemed a phase-in requirement by CALA, or a condition whereby the laboratory has minimal evidence to support full implementation of the requirement. A response on the action taken or an action plan must be provided, but supporting evidence of this action will not be required. Action taken in response to a non-conformance that is graded as "B" will be reviewed at the next assessment.

Comments - C: Comments may be used to document concerns or highlight areas where the laboratory excels. Use comments judiciously, and always discuss with the laboratory representative. Do not use this option to make suggestions to the laboratory. Comments must link back to ISO/IEC 17025 or CALA policies.

Serious Nonconformities: If any nonconformity seriously call accredited test results being reported to customers into question, document the nonconformity, grade it as an "A" item, and immediately notify the CALA office in writing. Include all relevant information, and if possible, copies of the objective evidence. A response sooner than 45 days may be required, or the analyte(s) may be suspended.

4.3 Post-Assessment Policies and Procedures

4.3.1 Submission of Responses

Laboratories must respond to any nonconformity identified within the following timeframes:

New (Applicant) Laboratories – 90 calendar days from the closing meeting
Accredited Laboratories – 45 calendar days from the closing meeting

When submitting responses to nonconformities, laboratories must use the form and format as described in A83 – *Responses to Nonconformities.*

Objective evidence must be submitted for every nonconformity graded as an "A". Examples include: copies of standard operating procedures (SOPs); photographs; calibration certificates; paid invoices; packaging slips; training records; copies of analytical runs; etc. Written affirmation, without supporting documentation, cannot be accepted as a satisfactory response to a requirement. This includes requirements relating to management reviews and internal audits.

For nonconformities graded as "B", laboratories must document any action taken or a planned action. Evidence of implementation will be reviewed at the next regularly scheduled site assessment.

To be recommended for granting or maintenance of accreditation, a laboratory must conform to all nonconformities graded as "A" and document action taken or planned action for all nonconformities graded as "B".

4.3.2 Failure to Submit Responses

Should a laboratory fail to submit responses to nonconformities, the laboratory will be issued a reminder of the consequences should acceptable responses not be provided by the deadline communicated to the laboratory. If the laboratory still fails to provide responses, the laboratory will be contacted by phone and if responses are still not submitted by the deadline communicated to the laboratory, accreditation will be automatically suspended, in whole or in part.

If the laboratory submits responses and upon review, the responses are deemed not satisfactory, the laboratory is sent a request for additional information and given a maximum of two (2) weeks to submit documentary evidence of conformance. If evidence is still not deemed satisfactory, the laboratory is given an additional maximum of one (1) week to provide the required documents or records. If upon review of this additional information, there are still outstanding issues, a recommendation for suspension of accreditation, in whole or in part, will be forwarded to the CALA Accreditation Council.

4.4 Scope Extensions

The laboratory must make a request, in writing, for a scope extension and submit the following:

- A copy of the test method;
- Method validation, including evidence that staff with the appropriate authority and responsibility has reviewed the data and determined that the method is fit-for-purpose;
- Proficiency Testing (PT) results; and,
- Any other documentation requested by CALA at the time of the application.

Staff and/or the Advisory Panel will review the information and determine if the tests or matrix may be added to an existing accredited appendix, if a separate appendix listing is required, or if a site visit is required. As a general guideline, if the changes are minor (e.g., a filtration step, a simple preparation extraction, a new analyte being added to an existing accredited appendix, or an instrument upgrade for an analyte the lab is already accredited for), the scope extension may proceed based on a document review. If the changes are major and require a new appendix, a site visit will be required.

4.5 Types of Visits

As well as assessments and reassessments, a laboratory may undergo one of the following visits:

Abbreviated Assessment: A site visit to assess new appendices between regularly scheduled reassessments. Generally, one assessor is assigned, and he/she assesses the specific tests for which the laboratory is pursuing accreditation. The quality system per se is not assessed, but if there are any findings related to the quality system, they can be cited. Otherwise, the process and timelines are the same as those documented for assessments and reassessments, with the exception that the SOP and method validation must be submitted at the time of application. Laboratories do have the option to apply for an accelerated abbreviated visit. In this case, it is CALA policy to have an assessor or assessment team on-site within one (1) month of submission of a complete application. The fees do differ for the two options; please refer to P02-02 CALA Program Description-Fee Schedule.

Reassessment for Cause: A laboratory may undergo a reassessment (and be charged, as such) for cause. For cause includes, but is not limited to:

- A laboratory that cannot adequately demonstrate conformance to ISO/IEC 17025 or other CALA requirements in the allotted timeframe without an on-site visit;
- Nonconformities graded as an "A" from previous visits are recurring;
- Information indicates that a laboratory no longer complies with the requirements of accreditation;
- On-going unsatisfactory Proficiency Testing (PT) performance.

Verification Assessments: Verification assessments may be conducted:

- To confirm that the laboratory has effectively implemented corrective actions in response to all the nonconformities graded as "A", generally in response to assessor or Advisory Panel comments received about the assessment or the responses submitted by the laboratory;
- In response to documented complaints; in the event of changes that affect the laboratory's activity and operation (including but not limited to: changes in ownership, personnel or equipment, declaration of bankruptcy); and
- On-going unsatisfactory Proficiency Testing (PT) performance.

Laboratories will be invoiced for verification assessments. In the case of a verification visit as the result of a documented complaint, the laboratory will only incur the cost of the visit if the complaint has been substantiated.

If any nonconformity graded as an "A" is identified during a verification visit, the laboratory has ten (10) calendar days from the closing meeting to respond satisfactorily.

Surveillance Visit: A visit carried out one (1) year following the initial assessment. A surveillance visit is less comprehensive than a reassessment. The duration of the surveillance visit and number of assigned assessors is dependent on the nature and extent of findings from the initial visit and the scope of testing.

4.6 Changes of Location

A relocation or move means that all equipment and all personnel are moving from one location to another location and that the 'old' location ceases to operate as a laboratory.

As per the *Terms and Conditions of Accreditation*, a laboratory must notify CALA of any change to ownership or organization including changes in location. If a laboratory moves locations, the following conditions apply:

- a plan must be submitted at least one month prior to the move (with as much advance notice as possible) that details a schedule of the move, including revalidation, and when the laboratory expects to be reporting results to clients; and,
- the laboratory must undergo a verification visit within 3 months of the move.

If consolidating locations and the methods being moved are due for reassessment, and the final location is not due for reassessment, an abbreviated visit must be carried out on the methods that were moved. This is to ensure that the methods are reassessed every two (2) years, as per program requirements.

If there are wholesale changes in staffing, equipment, methodology, or the quality system, the laboratory may be treated as an applicant laboratory or, at a minimum, undergo an abbreviated, verification, or reassessment prior to the accreditation being transferred to the new location. Responses to any nonconformities must be submitted and approved prior to the accreditation at the new location. The type of visit required will depend on the nature and extent of changes as determined by CALA.

If simply moving accredited methods between buildings under the same accreditation, and all buildings have been assessed previously, a verification visit is not required. Similarly, if a laboratory is simply upgrading existing instrumentation with newer models of the same instrumentation, a verification visit is not required.

If accredited methods are being moved between accredited facilities within the same network, and the new location does not have the competency for similar equipment and methodologies on their scope, an abbreviated visit will be required.

4.7 Mobile and Seasonal Laboratories

A seasonal laboratory is defined as a laboratory that does not operate for at least two (2) consecutive months annually.

A mobile laboratory is defined as a fully equipped, self-contained, transportable testing laboratory capable of performing tests under controlled environmental conditions. A mobile laboratory may be a main laboratory or may be considered an appendix under a main laboratory.

Mobile and seasonal laboratories are subject to the same accreditation requirements as any accredited laboratory, and further, must meet the following conditions:

- the accredited scope will remain on the web site year-round and the nature of the laboratory will be noted on the scope;
- the laboratory requires a start-up plan;
- the laboratory must have readily retrievable records to demonstrate that QC criteria was met at the beginning of the field season or start-up prior to acceptance of customer samples (e.g., duplicate, blank, check standard, spike, etc…); if performance criteria was not be met, full re-validation records must be available; and,
- mobile and seasonal laboratories must comply with P02-03 – CALA Program Description – Proficiency Testing Policy for Accreditation.

Mobile laboratories that are part of an accredited laboratory may be moved to the main permanent facility for assessments, or arrangements may be made to have the assessor travel to the mobile laboratory.

The term “mobile laboratory” implies that the laboratory is moving from location to location on a routine basis; If the mobile unit ceases to be truly mobile (e.g., a contract is continually renewed for an indefinite period of time), or no longer is considered a seasonal/temporary laboratory (e.g., operates annually), the laboratory may be considered a permanent fixed laboratory and be subject to the same policies as an accredited stand-alone facility.

4.8 Multisite Laboratories

Laboratories that operate from more than one location within a city or region may be considered as one accreditable unit subject to approval by CALA. Applicable criteria include:

- Common management;
- Common management system policies and procedures; and,
- Within the same urban area; and,
- Able to have prompt supervisory oversight from the main laboratory, when necessary.

The tests performed at each location are indicated on the scope.

4.9 Key Activities Performed at Different Sites

Laboratories may have methods on the accredited scope where a key activity of the accredited method (e.g., sample preparation) is actually performed at a different location. For the laboratory to claim accreditation for the entire method, including sample preparation, the following criteria must be met:

- All locations are owned by the same organization;
- The location that is accredited for the method is the location that performs the analytical portion of the method*;
- The preparation location participates in Proficiency Testing (PT), where available, to demonstrate technical competency and integrity of samples transferred to the analytical lab;
- All locations undergo a site visit to ISO/IEC 17025 during an initial visit;
- During a reassessment, the location accredited for the method:
    - Provides records demonstrating that the samples prepared at a different location meet contractual or advertised specifications;
    - Provides records demonstrating that the preparation site was part of the internal audit;
    - Provides any further documentation or records as requested, to demonstrate conformance to ISO/IEC 17025, CALA requirements, and laboratory procedures; and,
    - Understands that a reassessment of a preparation location may be scheduled, pending the findings of the assessment team.
- The scope listing indicates that the sample preparation is performed at a different location.

*Note: The facility doing the physical preparation cannot be accredited for the physical preparation alone, because stand-alone preparation methods cannot be accredited by CALA (see Section 3.1.2, above).