A06 - CALA ACCREDITATION PROGRAM, POLICIES AND PROCEDURES

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CALA

Trust, measured accurately

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1.0 SCOPE

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

2.0 BACKGROUND

The Accreditation Program 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. As part of the accreditation process, laboratories undergo a site assessment where conformance to ISO/IEC 17025 (*General Requirements for the Competence of Testing and Calibration Laboratories*) is assessed. Accreditation itself is based on satisfactory participation in an assessment, plus satisfactory compliance with P02-03 - CALA *Program Description – Proficiency Testing Policy for Accreditation*.

Ontario MOE/CALA Accreditation Agreement: The Ontario *Safe Drinking Water Act* (OSDWA), 2002, and related regulations provide requirements for drinking water testing in the Province of Ontario. One of the requirements under the Act is that laboratories testing Ontario drinking water samples must be licensed, and one of the conditions of licensing is accreditation. Section 66(1) of the Act allows the Minister to enter into an accreditation agreement for this purpose. To this end, the *Agreement for the Accreditation of Drinking-Water Testing Laboratories* between the Ontario Ministry of the Environment and CALA came into effect on August 01, 2008. Those pursuing a license may apply for accreditation by CALA using one of the applicable "P04 – CALA *Application Form*" Series documents.

Canadian Food Inspection Agency (CFIA/CALA Accreditation Agreement: The Canadian Food Inspection Agency (CFIA) is an agency under the Canadian Ministry of Agriculture and Agri-Food. The agency is dedicated to safeguarding food, animals and plants, which enhances the health and wellbeing of Canada's people, environment and economy. The CFIA is responsible for the administration and enforcement of numerous Acts and Regulations (http://www.inspection.gc.ca).

Many laboratories in Canada conduct testing in response to legislation that is enforced by the 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 the 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.

Laboratories applying for accreditation of this field of testing generally follow the same procedure for assessment and accreditation, with the following notable differences:

- The CFIA may specify Proficiency Testing (PT) requirements;
- Assessors either work for or are approved by the CFIA; and,
- There are some applications of ISO/IEC 17025 that are specific to this field of testing.

Disclaimer: Accreditation under ISO/IEC 17025 is a demonstration of confidence in the laboratory's technical competence. It is not a guarantee. It does not imply the acceptance by CALA of any responsibility toward any person or organization for the effects of the services provided by an accredited laboratory.

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 POLICIES AND PROCEDURES

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;

- P07-2017 – CALA Application of Requirements in ISO/IEC 17025:2017;
- P03 - CALA Publicity Policy; and,
- A12 – CALA Policy on Reference Methods.

Note: Where there are inconsistencies among the documentation sources noted above, the provisions of ISO/IEC 17025 shall prevail.

A new version of ISO/IEC 17025 was published on November 29, 2017. Any reference to ISO/IEC 17025 throughout this document refers to the most current version of the standard

4.1 The Application Process

P04-03-CALA Application for New Accreditation describes the application process and is readily available on the CALA web site at www.cala.ca.

Laboratories may apply for accreditation by submitting a completed application via the CALA Association Management System(CAMS).

As part of the application process, applicant and accredited laboratories must:

- Agree to the terms and conditions of accreditation;
- Provide key documentation according to the timelines specified; and,
- Provide summary information on all tests for which accreditation is sought. This summary information is used to identify the Proposed Scope of Testing and includes information on the matrix, the analyte, the test method, and the test method reference.

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. Additionally, CALA reserves the right to decline applications for services to laboratories in countries where travel by staff, volunteers, or other agents on behalf of CALA would put individuals at risk. At any point in the application or initial assessment process, if the laboratory provides false information, conceals information, or there is evidence of fraudulent behaviour, CALA reserves the right to reject the application.

4.2 Pre-assessments

Applicants to the CALA Accreditation Program may request a pre-assessment, which is generally conducted by CALA staff or more experienced lead assessors. 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.

4.3 Policies and Procedures Prior to the On-Site Visit

4.3.1 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.

4.3.2 Language Requirements

The working language at CALA is English, however, services in French are available on request. Most documents are provided only in English, although a few checklists are available in French and Spanish.

4.3.3 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.

4.3.4 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.

A team of qualified professionals, drawn mostly from member laboratories, conducts site assessments. For testing conducted under legislation enforced by the CFIA, assessors are either drawn from or approved by the CFIA. All candidate assessors participate in a formal training program to ensure fair and equitable application of the rating criteria used in the assessment process. The training program includes participation in a course on the Assessment of Laboratory Quality Systems (or equivalent), together with biennial (refresher) courses on the application of A02 - Rating Guide. All assessors must commit to adhering to Q05 – *CALA Code of Ethics and Q14 – Conflict of Interest and Confidentiality Code.*

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.

It is the responsibility of the Lead Assessor to coordinate the exact days that the team will be on-site.

4.3.5 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.
- Completed A02: 2017 Assessment Rating Guide (provided by CALA with proof of purchase of ISO/IEC 17025)
- 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 CAMS portal.

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 CAMS portal.

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

4.3.6 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.).

4.4 On-Site Policies and Procedures

4.4.1 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 (2) years. 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.

4.4.2 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.

4.4.3 Assessment Process

Assessors perform the assessments using various assessment techniques, including:

- Interviewing laboratory staff;
- Examining laboratory records;
- Reviewing technical documentation;
- Assessing facilities and equipment; and,
- Assessing the conduct of testing (i.e., the assessor may ask to witness part or all of a test method).

New laboratories (applicants) will generally have all appendices on a proposed scope of testing assessed.

During reassessments, a representative sample of accredited appendices will normally be assessed in detail. Sampling will ensure that all areas of competency are assessed, and may include spot-checks of appendices not being assessed in detail. Any new appendices being added to the scope will be assessed, as well as any appendices licensed under the *Ontario Safe Drinking Water Act* (OSDWA). CALA reserves the right to assess 100% of the scope; even if an appendix was not initially selected for assessment, the team does have the authority to assess other appendices while on-site.

4.4.4 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.

4.4.5 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.

4.4.6 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.

Serious Nonconformities: If any nonconformity seriously calls accredited test results being reported to customers into question, the nonconformity will be graded as an "A" item.

A response sooner than 45 days may be required, or the analyte(s) may be suspended.

4.4.7 Assessment Reports

At the end of the assessment, the Assessment Team provides the laboratory with a copy of an assessment report that summarizes the results of the assessment. CALA staff review and edit this report for consistency and validity, and a final report is issued.

The final report definitively identifies the nonconformities that must be addressed in the required timeframe prior to a recommendation for granting or maintenance of accreditation.

New (applicant) laboratories have a maximum of 90 days and accredited laboratories have a maximum of 45 days to:

- Provide evidence that all nonconformities graded as "A" have been addressed; and,
- Document the action taken or planned action for nonconformities graded as "B".

4.4.8 Disputes and Appeals

Assessment findings may be disputed or appealed. Refer to Q28 – *Disputes and Appeals Within CALA Programs*, on the CALA web site for details on the disputes and appeals process.

4.5 Post-Assessment Policies and Procedures

4.5.1 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".

Implementation of corrective actions in response to non-conformities may be subject to on-site verification by CALA or, in serious cases, a reassessment for cause may be carried out.

4.5.2 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 again 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.

4.5.3 Evaluation and Approval

Responses to any findings are reviewed initially by CALA staff. The file then undergoes a review by a panel of the Advisory Panel and the laboratory may be requested to provide further documentation to close out any identified nonconformities. A panel of the CALA Accreditation Council performs a final review (and again, may request further information) and approves the granting or maintenance of accreditation.

CALA formally advises the laboratory of the decision as to whether or not accreditation has been granted. An approved scope of testing is issued to the laboratory and posted on the CALA website at the time of accreditation, subsequent to each re-assessment, and in the event of scope changes due to extensions, suspensions or withdrawals. Scopes will be copied to the appropriate regulatory authority, as required.

4.5.4 Certificates of Accreditation

Certificates of Accreditation are issued by CALA as the result of a decision by the Accreditation Council, following an assessment or reassessment, and are valid for 2.5 years.

4.6 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. An abbreviated visit will be required if

the changes are major, including but not limited to a new competency, new equipment, or a new field of accreditation.

4.7 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 management system per se is not assessed, but if there are any findings related to the 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.

Pre-assessment Visit: Applicant may request a pre-assessment visit to identify any significant gaps and to gain an understanding of the laboratory's state of readiness for accreditation. Typically, only one assessor is assigned for a pre-assessment.

4.8 Changes at an Accredited Laboratory

As per P04-01 – *CALA Terms and Conditions of Accreditation*, a laboratory must notify CALA of any changes to ownership or organization including changes in 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. 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 management 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.

Other types of changes may also be subject to on-site verification.

4.9 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 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.

4.10 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.

4.11 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.

4.12 Group Accreditation

Network laboratories operating from more than one location and operating under a single management system may qualify for CALA group accreditation. As group accreditation is based on a single management system it will minimise duplication of the assessment of all elements of the system at each site allowing for a more efficient use of laboratory resources. In some cases, this will lead to a reduction in assessor resources deployed by CALA resulting in reduced cost to the laboratory. Refer to A143 - CALA Policy on Group Accreditation.

4.13 Surveillance Questionnaires

In the intervening year between biennial site assessments, laboratories must complete and submit a surveillance questionnaire by a required due date. The questionnaire covers activities or changes related to the accredited scope of testing since the last site assessment.

4.14 Suspension and Withdrawal of Accreditation

Accreditation will be suspended automatically, in whole or in part, subsequent to its having been granted:

I. if a laboratory fails two successive PT studies for a specific analyte in those cases where the laboratory is meeting the CALA PT Policy with options (i) or (ii);
II. if a laboratory fails to submit a satisfactory PT corrective action report within the specified timeframe;
III. if a laboratory fails to pay all fees that are owed to CALA;
IV. if a laboratory fails to respond to requests for information related to non-conformances identified on an assessment report; or,
V. upon expiration of the accreditation certificate.

When a laboratory fails to achieve an acceptable PT score on the third set of successive PT samples, CALA accreditation will be automatically withdrawn. Reinstatement of accreditation will only be considered following a formal request for reinstatement. An acceptable Corrective Action Report (CAR), recent re-validation data, satisfactory participation in PT, and any other information required to make a decision on reinstatement must support a formal request for reinstatement.

Accreditation may be recommended for suspension subsequent to its having been granted, when:

VI. a laboratory fails to comply with the terms and conditions of accreditation;

VII. a laboratory fails to submit a satisfactory response or additional information required to complete a response within the timeframe pre-determined by CALA, as communicated to the laboratory; or,

VIII. CALA receives substantiated information on the lack of validity of a test method.

In severe cases of non-compliance, the Accreditation Council may immediately suspend or withdraw the accreditation, in whole or in part. Such cases might involve, though may not be limited to: failure to comply with the requirements of the latest version of ISO/IEC 17025; failure to demonstrate competency in those tests for which accreditation has been granted; misrepresentation of the laboratory's accreditation status; violation of the CALA Code of Ethics; evidence of fraudulent behaviour; provision of false information; or, concealing information.

If suspended, the laboratory receives written notice from CALA that accreditation for the test in question is suspended, and the CALA web site is updated accordingly. Amended scopes will be copied to the appropriate regulatory authority, where required.

If the laboratory is not re-instated in whole, or in part, after 90 days, a recommendation for withdrawal of accreditation will be forwarded to the CALA Accreditation Council.

4.15 Termination of Accreditation

Accreditation is deemed terminated if it is either withdrawn or voluntarily relinquished. If a laboratory wishes for whatever reason to voluntarily relinquish its accreditation, either in whole or in part, it may do so by providing written notice to CALA. Termination of accreditation, either in whole or in part, does not preclude a laboratory from applying for accreditation at a later date. Any re-application is evaluated under the same requirements and procedures applicable to every other applicant laboratory. If voluntarily relinquishing accreditation, adherence to all requirements, including participation in Proficiency Testing (PT), must be maintained up until the date of termination.

4.16 Transfer of Accreditation

Any laboratory currently accredited by an accreditation body other than CALA, can apply for accreditation by CALA providing that the conditions described under P26 - *CALA Policy on Transfer of Accreditation* are fulfilled.

4.17 Joint Assessments

A laboratory may request a joint assessment if they are accredited by or are seeking to be accredited by more than one accreditation body. Every effort will be made to accommodate this request. If the other accreditation body is signatory to ILAC (International Laboratory Accreditation Cooperation), there may be opportunities to streamline the process further by

one accreditation body assessing the management requirements. In this case, if a coordinated visit can be arranged, the laboratory must still meet all CALA requirements.

5.0 REVISION HISTORY

Revision Number	Revision Date	Nature of Revision
1.13	February 14, 2019	Section 4.0- removed reference to A96- Use of IT in Accredited Laboratories
		Section 4.0- Removed reference to PT 15-02 CALA PT Program-Policies
		Section 4.4- Added clarification as to when a scope extension request will result in an abbreviated visit.
		General- refreshed wording to reflect wording in ISO/IEC 17025:2017
1.14	November 20, 2019	Incorporated requirements from P02-01 – CALA Program Description
		Clarified that the reassessment must occur prior to the anniversary date of the reassessment (not 2 years +/- 3 months).
1.15	July 8, 2022	Removed all references to documents being provided on CD-ROM.
1.16	March 29, 2023	Removed references to FTP throughout. 4.12 Add reference to Group accreditation.