

A06 – CALA Accreditation Program, Policies and
Procedures
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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 17011:2004, *Conformity assessment-General 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,

...clearly describe its accreditation activities, referring to the relevant International Standards, Guides or other normative documents.

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

3.0 POLICY

To attain and maintain accreditation, applicant and accredited laboratories must conform to ISO/IEC 17025:2005 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 - *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; and,*
- P03 - *CALA Publicity Policy.*

3.1 Pre-Assessment Policies and Procedures

3.1.1 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.

3.1.2 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 the following are not accredited by CALA:

- Stand-alone preparation methods; and,
- Aggregate analytes (i.e., results generated by the manipulation of other test results; e.g., hardness by calculation). See A116 - Calculations.

For a list of the toxicology methods that can be assessed and accredited, please refer A110- *Assessment and Accreditation of Toxicology Methods* on the CALA web site.

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.

3.1.3 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.

3.1.4 Information Required Prior to an Assessment

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

- One (1) hard copy of the quality manual;
- The requested number of CD-ROMs, which contain:
 - The test methods and any supporting operational procedures;
 - Method validation for all analytes on the proposed scope of testing;
 - Internal audit and management review records; and,
 - An electronic copy of the quality manual.
- A completed copy of A02-CALA Rating Guide.

CALA will notify the applicant, in writing, as to the number of CD-ROMs required prior to the deadline for submission of documents and records to CALA.

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

- One (1) hard copy of the quality manual;
- The requested number of CD-ROMs, which contain:
 - The test methods and any supporting operational procedures;
 - Method validation for new analytes on the proposed scope of testing; and,
 - An electronic copy of the quality manual.
- A completed copy of A18 – Quality Manual Cross Reference Form.
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CALA will notify the laboratory, in writing, as to the number of CD-ROMs required prior to the deadline for submission of documents and records to CALA.

All documents provided are treated as confidential. The hard copy of the quality manual and one (1) copy of the CD-ROM of test methods, supporting procedures and method validation are retained on file at CALA.

3.1.5 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.).

3.2 On-Site Policies and Procedures

3.2.1 Frequency of Reassessments

Following the initial assessment, a reassessment is carried out one year later; thereafter, regular reassessments are carried out every two years, plus or minus three months. The three-month window cannot carry over into the next calendar year.

3.2.2 Method Requirements

For a method to be assessed, there must be:

- Method validation 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.

3.2.3 Equipment Requirements

Equipment should be operational at the time of the assessment, and an assessor can ask for the equipment to be turned on and operated, or ask that all or part of a method be demonstrated.

3.2.4 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.

3.2.5 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.

3.2.6 Types of Findings

Required Actions - A: A nonconformance 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).

Required Actions - B: A non-conformance 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 Required B item 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 Non-conformances: If any non-conformities seriously call accredited test results being reported to customers into question, document the nonconformity, grade it as Required 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.

3.3 Post-Assessment Policies and Procedures

3.3.1 Submission of Responses

Laboratories must respond to any non-conformances 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 non-conformances, laboratories must use the form and format as described in A83 – *Responses to Required Actions*.

Objective evidence must be submitted for every Required A item. 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 Required B items, 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 with all the Required Actions A and document action taken or planned action for all Required Actions B.

3.3.2 Failure to Submit Responses

Should a laboratory fail to submit responses to non-conformances, 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.

3.4 Scope Extensions

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

- A copy of the test method;
- Supporting method validation data;
- 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. The Accreditation Council must approve the addition of any new appendices.

3.5 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.

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;
- Required Actions A from previous visits are recurring;
- Information indicates that a laboratory no longer complies with the requirements of accreditation.

Verification Assessments: Verification assessments may be conducted:

- to confirm that the laboratory has completed all of the Required Actions 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; and,
- 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).

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 Required Actions A are identified during a verification visit, the laboratory has ten (10) calendar days from the closing meeting to respond satisfactorily.

3.6 Changes of Location

As per the *Terms and Conditions of Accreditation*, a lab 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 lab expects to be reporting results to clients; and,
- the laboratory must undergo a verification visit within 3 months of the move.
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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.

3.7 Seasonal Laboratories

A seasonal laboratory is defined as a laboratory that functions less than six (6) consecutive months per year. Seasonal laboratories must meet the following conditions:

- the accredited scope will remain on the web site year-round and a note is put on the scope at the end of the season;
- 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 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;
- laboratories must successfully participate in one Proficiency Testing (PT) round per season, within 30 days of start-up (the laboratory may apply in writing for an extension);
- if the laboratory fails the PT, the accreditation status goes to Possible Suspension and lab must fast-track within 30 days; if the lab does not submit results or fails again, the analyte is suspended.

3.8 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 will 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).