P02-03 – CALA PROFICIENCY TESTING POLICY FOR ACCREDITATION

Revision 2.2

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TABLE OF CONTENTS

1.0 Scope 1
2.0 Background 1
3.0 Policy 1
3.1 Laboratory PT Plan 2
3.1.1 Submitting a PT Plan 2
3.1.2 Notification of Change 2
3.2 Proficiency Testing (PT) Coverage Requirement 2
3.2.1 Option i 3
3.2.2 Option ii 3
3.2.3 Option iii 4
3.2.4 Option iv 4
3.2.5 Option v 4
3.2.6 Option vi 4
3.3 Requirements for Granting Accreditation 5
3.4 Requirements for Maintaining Accreditation 5
3.4.1 50% Coverage per Appendix 5
3.4.2 Reporting Results for Option i and Option ii 5
3.4.3 Ongoing Surveillance 5
3.5 Toxicology Appendices 6
3.6 Other PT Participation 6
4.0 REVISION HISTORY 7

1.0 SCOPE

This policy applies to all applicant and accredited laboratories in the CALA accreditation program.

2.0 BACKGROUND

ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*, clause 7.7.2, requires that the laboratory monitors its performance by comparison with results of other laboratories, through participation in proficiency testing (PT) and/or interlaboratory comparisons(ILC) other than proficiency testing, where available and appropriate.

Additionally, ILAC P9:01/2024 *ILAC Policy for Proficiency Testing and/or Interlaboratory Comparisons other that Proficiency Testing* sets out specific requirements for accreditation bodies on the use of proficiency testing activities in the accreditation process for laboratories.

This document details CALA's policy on proficiency testing with respect to applicant and accredited CALA laboratories.

3.0 POLICY

All applicant/accredited laboratories shall demonstrate their technical proficiency by their satisfactory participation in a suitable proficiency testing activity or interlaboratory comparison prior to obtaining accreditation and on an ongoing basis for all methods/analytes on their scope where such activities are available and appropriate.

Laboratories shall use a PT provider accredited to ISO/IEC 17043:2023 by an Accreditation Body (AB) signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement(MRA) for Proficiency Testing Providers (PTP), where available and appropriate.

Availability: A PT is considered available, if: a) it is offered by a competent PT provider and the required documents are provided in the national language of the participating body or a language understood by the laboratory; b) if it does not require a development by the PT provider and the results can be provided within a short time in regard to the CAB needs formalized in its PT participation plan. *ILAC P9:01/2024*

Appropriateness: A PT and/or ILC other than PT can be regarded as technically appropriate if the scope of activity being provided is similar to the current practice of the accredited CAB. In the case of specific test or measurement techniques, for which no regular PT and/or ILCs other than PT is available, it may be adequate to choose a PT and/or ILCs other than PT, which is

similar to the scope, or which covers an important partial aspect of the activity. *ILAC P9:01/2024.*

3.1 Laboratory PT Plan

3.1.1 Submitting a PT Plan

A laboratory seeking accreditation for any analyte/method shall submit a PT Plan to CALA detailing how CALA PT requirements will be met while taking risk into account.
A laboratory communicates its PT Plan for any new method through the CAMS. Upon review by CALA, and any required clarification, CALA and the laboratory shall agree to the plan. Laboratories can obtain a copy of their PT plan through the PT section of CAMS. Updates to PT plans are also made through a Change Request in Scope Management of CAMS.

3.1.2 Notification of Change

CALA shall be notified of changes to PT plans through Change Requests in CAMS.

3.2 Proficiency Testing (PT) Coverage Requirement

The PT coverage requirements are designed to provide an acceptable level of coverage while, at the same time, taking cost into account. As such, the coverage required for more commonly performed tests, where PT is readily available, is higher than that for tests that are performed less routinely. Also, in those instances where a regulator specifies the nature and level of proficiency testing, these regulatory requirements supersede accreditation requirements only if the regulatory requirements exceed the accreditation requirements.

Where PT is available and appropriate (e.g., matrix-matched), all analytes appearing in a laboratory's Scope of Accreditation must to CALA's satisfaction, be supported by PT. Laboratories must treat PT samples as "routine" (i.e., defined as the work flow and level of effort followed for the majority of customer samples analyzed using the accredited method).

For each analyte in the laboratory's scope of accreditation, the laboratory shall select the first option that is applicable from the list below. If option iv, v, or vi is chosen, the laboratory must have objective evidence that a search was completed and that there is no option i or ii PT available from an accredited PT provider.

If a PT provider does not provide an evaluation due to data inconsistencies, this will be considered when determining if PT requirements for accreditation have been met.

3.2.1 Option i

For common analytes where proficiency testing is readily available from a PT provider accredited to ISO/IEC 17043 by an accreditation body that is signatory to the International Laboratory Accreditation Cooperation (ILAC) mutual recognition arrangement(MRA) for Proficiency Testing Providers (PTP), a laboratory must choose Option i. The following conditions apply:

- The laboratory shall participate in two PT studies per year;
- Each PT round shall consist of four different samples covering a range of concentrations;
- PT results shall be reported using CAMS including the submission of the PT report, unless prior arrangements have been made with the PT Provider to submit results directly into the CALA database;
- The accredited laboratory shall conduct cause analysis and implement a corrective action for each unacceptable PT result. Records of these may be requested by CALA during assessments;
- A CAR must be completed in CAMS for each suspended and withdrawn analyte;
- It is common in some PT studies to only add 60% of the published analytes to any individual sample. In this case, the laboratory shall report results as indicated in the PT Provider instruction with respect to low level data.

Note: For guidance on Option i analytes and appropriate PT providers, please refer to A139 – CALA Guidance on Meeting Proficiency Testing Requirements.

3.2.2 Option ii

If an accredited proficiency testing provider cannot provide the number of samples per study as specified in Option i, the laboratory shall participate in at least two (2) studies per year, with a minimum of one sample per study. As in Option i, the PT provider must be accredited to ISO/IEC 17043 by an accreditation body that is signatory to the ILAC MRA for Proficiency Testing Providers (PTP).

- PT results shall be reported using CAMS including the submission of the PT report;
- The accredited laboratory shall conduct cause analysis and implement a corrective action for each unacceptable PT. Records of these may be requested by CALA during assessments;
- A CAR must be completed in CAMS for each suspended and withdrawn analyte;
- It is common in some PT studies to only add 60% of the published analytes to any individual sample. In this case, the laboratory shall report results as indicated in the PT Provider instruction with respect to low level data.

3.2.3 Option iii

This option is no longer available, and is maintained for historical record-keeping purposes.

3.2.4 Option iv

If a PT sample from an accredited PT provider is only available once per year or an accredited PT provider is not available (i.e., option i and option ii are not applicable), the laboratory shall participate in at least one formal interlaboratory study per year.

- These studies shall be examined during site assessments.
- If formal acceptable/unacceptable flags are not assigned to interlaboratory studies, the laboratory shall establish criteria for acceptable performance and act accordingly.

3.2.5 Option v

If options i, ii or iv are not applicable, the laboratory shall participate in at least one less formal interlaboratory study per year (e.g., interlaboratory comparisons amongst a multi-site laboratory chain, comparison with a third-party laboratory).

- These studies shall be examined during site assessments.
- If formal acceptable/unacceptable flags are not assigned to interlaboratory studies, the laboratory shall establish criteria for acceptable performance and act accordingly.

3.2.6 Option vi

If a comparison with the results of other laboratories cannot be performed or is not appropriate (i.e., if options i, ii, iv, or v are not applicable), the laboratory shall develop and implement a procedure to demonstrate proficiency. Procedures include, but are not limited to, inter-analyst comparisons, analysis of a blind reference material, or blind matrix spikes. While this procedure should consider bias or accuracy, it is understood that for some empirical and physical tests, a reference material may not be available. Strictly speaking, these procedures are not comparisons between laboratories and may have been performed as part of the method validation/verification or internal quality control (ISO/IEC 17025, 7.7.1); nonetheless, such procedures shall at a minimum be performed once per year as a part of on-going surveillance.

- These studies shall be examined during site assessments.
- The laboratory shall establish and periodically review criteria for acceptable performance, and act on unacceptable flags.

3.3 Requirements for Granting Accreditation

For new (applicant) laboratories, it is strongly recommended that one round of PT is completed prior to the initial site visit. However, while it is recognized that PT schedules may preclude a laboratory from participating prior to the site visit, it is mandatory that the laboratory shall complete, to CALA's satisfaction, at least one proficiency testing/interlaboratory activity prior to gaining accreditation. The laboratory must demonstrate successful participation for all analytes where options i and ii PT are available, regardless of the percentage of coverage in multi-analyte appendices (e.g., ICP or GC). A non-zero Assigned Value is preferred for initial demonstration of proficiency.

3.4 Requirements for Maintaining Accreditation

Subsequent to accreditation, the laboratory shall demonstrate technical competence for each analyte on the scope of accreditation as per 3.2 above with the following clarifications:

3.4.1 50% Coverage per Appendix

For multi-analyte appendices (e.g., ICP or GC), laboratories are not required to seek additional PT for all analytes on an on-going basis if at least fifty percent of the analytes in the appendix are covered by any combination of PT. If a laboratory uses an accredited provider to meet the requirements in section 3.2, it shall report all analytes offered by the provider for the ordered sample if it is on their scope of accreditation, regardless of whether the fifty percent mark has been reached.

3.4.2 Reporting Results for Option i and Option ii

If the laboratory is using option i or option ii PT, the first study in a calendar year shall be completed between January 01 and June 30. The second study in the year shall be completed at least four months after the first study, and be conducted in the period July 01 – December 31. The outcome of the PT shall be reported to CALA in CAMS within thirty days of the PT report date.

3.4.3 Ongoing Surveillance

CALA assessors may request copies of official PT reports from laboratories during assessments. Failure to provide these reports, or any evidence of falsification of PT data shall result in suspension in whole or in part.

3.5 Toxicology Appendices

Very few toxicology tests have official PT testing available that meets either option i or ii. Most toxicology PTs will be conducted as either options v or vi. For option v and vi PTs it is important to establish acceptability criteria prior to testing. A minimum of one (1) sample is required annually.

Where there is more than one species listed under a method, laboratories must demonstrate proficiency for one (1) of the species. In the annual demonstration of proficiency, it is preferable that species are alternated, if possible.

The toxicology PT must match the matrix and test duration and include the standard toxicity endpoints of results that are reported by the lab. For example, for a 14-day *Hyalella azteca* survival and growth sediment test, the results reported at the end of the test are % survival and weight of organisms. It is not acceptable to conduct a PT using a 4-day test with a toxicant in water where the endpoint is only the LC50 or % survival and does not evaluate the growth endpoint. Examples of acceptable PT for *Hyalella* could be: a) two analysts or two labs analysing the same lab prepared sediment sample that has been split (i.e. spiked with toxicant), b) an analyst conducting a spiked sediment sample and comparing the result to a known or literature toxicological value that is based on the same reference method that was used for the proficiency testing, c) two labs or analysts analysing a field contaminated sample that has been split and d) two labs or analysts analyzing a control sediment or soil. Potential acceptance criteria could be: a) two test results must have endpoints within a defined percentage (reasonable fixed value could be based on the uncertainty of biological response), b) both analysts or labs classify a sample correctly as toxic (as defined by the method), c) for multi-concentration test the two LCxxs/ECxxs are not statistically different.

3.6 Other PT Participation

Laboratories in the accreditation program may be required by CALA to participate in proficiency testing studies over and above that outlined in their PT Plan, to meet either Mutual Recognition Arrangement (MRA) or regulatory requirements.

4.0 REVISION HISTORY

Revision Number	Revision Date	Nature of Revision
2.0	January 17, 2020	General - updated wording to better reflect ISO/IEC 17025:2017
		Removed reference to the ex-CALA PT program
		Removed section on CSSP shellfish requirements
		Other additions are highlighted in 'grey'
2.1	January 6, 2022	Included reporting results (including PT reports), PT plans and CARS through CAMS
2.2	April 3, 2024	Updated ILAC P9 reference. Clarified wording on available and appropriate. Minor changes throughout.