P02-03 – CALA Program Description – Proficiency Testing Policy for Accreditation

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CALA
Laboratory Accreditation

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CALA PROGRAM DESCRIPTION – PROFICIENCY TESTING POLICY FOR ACCREDITATION

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 participation in either or both proficiency testing and interlaboratory comparisons.

Additionally, ILAC P9:06/2014 *ILAC Policy for Participation in Proficiency Testing Activities* 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 regard to laboratories accredited by CALA.

3.0 POLICY

All applicant/accredited laboratories shall demonstrate their technical proficiency by their satisfactory participation in a suitable proficiency testing activity.

3.1 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.

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 approved provider.

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

3.1.1 Option i

If the analyte is covered within the CALA PT Program then the laboratory shall use either CALA PT or comparable PT from an approved PT Provider.

- Comparable PT is defined as PT that includes the same number of samples, at the same frequency, as is found in the CALA PT program, and in a ready to analyse format (i.e., not provided as concentrates).
- PT results shall be reported using the CALA Web-Data-Entry.
- CALA PT shall be evaluated as per PT15-03 – *CALA PT Program – Procedures.*
- Comparable PT shall be evaluated using the assigned value from the PT report and the regression equations established from CALA PT; z scores and composite scores shall be determined as per PT15-03 – *CALA PT Program - Procedures*.
- Unacceptable performance shall be handled as described in PT15-03 – CALA PT Program - Procedures and P02-01-*CALA Program Description*.
- 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.

3.1.2 Option ii

If the analyte is not covered within the CALA PT Program, but is offered in the catalogue of an approved PT Provider, the laboratory shall participate in at least two studies per year, with a minimum of one sample per study.

- The outcomes of each study shall be reported using the CALA Web-Data-Entry system.
- Unacceptable performance shall be handled as described in PT15-03 – *CALA PT Program - Procedures* and P02-01-*CALA Program Description*.
- 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.

3.1.3 Option iii

This option is no longer valid.

3.1.4 Option iv

If option i and option ii are not applicable, the laboratory shall participate in at least one formal study per year from a PT Provider (e.g., NAPT, New York State, EPA, etc.).

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

3.1.5 Option v

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

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

3.1.6 Option vi

If options i, ii, iv, or v are not applicable, the laboratory shall develop and implement a procedure to demonstrate analyst proficiency. Procedures include, but are not limited to, inter-analyst comparisons, analysis of a blind reference material, or 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.

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

3.2 Laboratory PT Plan

3.2.1 Submitting a PT Plan

A laboratory seeking accreditation for any analyte shall submit a PT Plan to CALA detailing how they are going to comply with the CALA PT requirements. A completed *Scope of Testing Template* that is included in the appendices of the application documents (e.g., P04-03 *CALA Application for New Accreditation*), is the form in which a laboratory communicates its PT Plan for any new method. Upon review by CALA, and any required clarification, CALA and the laboratory shall agree to the plan.

3.2.2 Notification of Change

The laboratory shall notify CALA of any changes to their PT Plan.

3.3 Requirements for Granting Accreditation

Prior to gaining accreditation for an analyte, a laboratory shall complete, to CALA's satisfaction at least one proficiency testing activity as per 3.1 above. 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). For new (applicant) laboratories, it is strongly recommended that one round of PT is completed prior to the initial site visit.

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 3.1 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 approved provider to meet the requirements in section 3.1, 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 PT comparable to CALA PT (option i) or option ii PT, the first study in a calendar year shall be completed and reported by July 31. The second study in the year shall be completed at least four months after the first study and be reported by December 31, of the same year.

3.4.3 Ongoing Surveillance

CALA shall have a surveillance procedure whereby it requests copies of the official PT reports from a random selection of laboratories. Failure to submit these reports, or any evidence of falsification of PT data shall result in suspension of the affected analyte(s). As well, laboratories using non-CALA option i PT may be requested to provide copies of PT instruction sheets from the approved provider to demonstrate that they are being provided as ready to analyze samples. Laboratories using option ii may be further requested to provide copies of corrective action reports as demonstrated evidence that corrective actions are carried out when necessary.

3.5 Requirements for Shellfish Testing

If pursuing accreditation for shellfish product testing under the Canadian Shellfish Sanitation Program (CSSP), participation in the USFDA program is mandatory.

3.6 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 a different species on the list is chosen, 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.

3.7 International 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 REFERENCES

- ILAC P9:06/ 2014 ILAC *Policy for Participation in Proficiency Testing Activities*.
- P02-01 – *CALA Program Description.*
- P02-02 – *CALA Program Description – Fee Schedule.*
- P02-04 – *CALA Program Description – PT Catalogue.*
- P02-05 – *CALA Program Description - List of Approved PT Providers.*
- PT15-01 - *CALA PT Program – Scheme.*
- PT15-02 – *CALA PT Program – Policies.*
- PT15-03 – *CALA PT Program – Procedures.*
- A118 - *Laboratory Proficiency Testing Plan.*