

P02-03 – CALA Program Description – Proficiency
Testing Policy for Accreditation
Revision 1.4 – December 01, 2011



CALA

Laboratory Accreditation

TABLE OF CONTENTS

1.0 SCOPE	1
2.0 BACKGROUND	1
3.0 POLICY	1
3.1 Proficiency Testing (PT) Coverage Requirement.....	1
3.2 Laboratory PT Plan.....	3
3.3 Requirements for Granting Accreditation.....	3
3.4 Requirements for Maintaining Accreditation.....	3
3.5 Requirements for Shellfish Testing	4
3.6 Multi-species Toxicology Appendices.....	4
4.0 REFERENCES	4

CALA PROGRAM DESCRIPTION - PROFICIENCY TESTING POLICY FOR ACCREDITATION

1.0 SCOPE

This policy applies to all laboratories accredited by CALA.

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 7.15.3) requires CALA to,

...ensure that its accredited laboratories participate in proficiency testing or other comparison programmes, where available and appropriate, and that corrective actions are carried out when necessary. The minimum amount of proficiency testing and the frequency of participation shall be specified in cooperation with interested parties and shall be appropriate in relation to other surveillance activities.

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.

Where PT is available and appropriate, 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:

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 two studies per year, four samples per study, provided as ready-to-analyze samples (i.e., not 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 used for 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 conduct an inter-analyst comparison at least once per year.

- These studies shall be examined during site assessments.
- The laboratory shall establish 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. 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 Multi-species Toxicology Appendices

Laboratories must demonstrate proficiency for a minimum of one of the test species, where there is more than one species listed under a method. It is preferable that different species are used in the annual demonstration of proficiency, if possible.

4.0 REFERENCES

- 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.*