

PT15-02 – CALA PT Program - Policies
Revision 1.3 – June 2011



CALA
Proficiency Testing

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CALA PT PROGRAM - POLICIES

1.0 SCOPE

The following are the general policies with regards to proficiency testing that apply to participants and CALA. The Terms and Conditions of Accreditation and/or Proficiency Testing (P04 - *CALA Application Form*), signed by all PT participants, require compliance with the policies and procedures in this section.

All documents referred to in this document may be found on the CALA web-site library (www.cala.ca/library.html).

2.0 POLICIES

2.1 Changes To PT Participation

All correspondence relating to changes to a participant's PT registration shall be received by CALA no later than four (4) weeks prior to the scheduled sample shipping date. This schedule is posted on the CALA web site. (www.cala.ca/pt_ship_schedule.html).

All requests for changes and additions shall be made following the procedures outlined under *Requesting Changes to Scope of Testing and PT Registration* on the CALA web site (www.cala.ca/progdocs.html).

2.2 Sample Analysis

With the exception of specific instructions provided on the web site (www.cala.ca/Instructions.html), PT samples shall be processed using the same workflow and level of effort as afforded the majority of client samples analysed using the CALA registered method (i.e., treated as routine). As well, participants may not collude with other participants, either within the same laboratory or between different laboratories, and may not falsify results or other information provided to CALA.

Participants found to not treat their PT samples as routine are issued a warning and may have their PT status advanced to the next level (e.g., Possible Suspension to Suspension).

Suspected collusion or falsification is investigated by the PT Manager. Refusal by a participant to participate in this investigation, or confirmation of collusion or falsification of PT study data shall result in withdrawal of PT recognition and, if accredited, shall also result in withdrawal of accreditation.

2.3 Reporting The Results

Results shall be submitted to CALA using the Web-Data-Entry System by midnight of the due date indicated on the published PT schedule (www.cala.ca/pt_ship_schedule.html).

C20 Asbestos results shall be submitted directly to the Collaborator responsible for preparing the samples by the deadline indicated by the Collaborator.

Results that are submitted using a method other than the one registered with CALA shall be assigned a PT score of zero for the registered test and a new PT registration shall be made for the new method.

For accredited laboratories, the test method used to analyze the PT sample shall also match the method listed on the Scope of Accreditation associated with that laboratory.

An analyte for which a participant has failed to submit data by the deadline shall be assigned an unacceptable PT score. Reporting a zero for any chemistry result shall be treated as a non-submitted result.

The test method (as defined in the Application Form) shall be indicated on the web-data-entry Report Form, along with any sample preparation procedures. The type of media used shall be recorded for microbiology tests.

Results shall be reported in the units specified on the web-data-entry Report Form, using the number of significant digits appropriate for the method.

2.4 Reporting Transcription Errors In Asbestos PT

Participants in PT for C20 (asbestos), delivered in partnership with the Asbestos Quality Assurance Program (AQAP), may submit a *transcription error request* whenever a transcription error is discovered. The participant may submit these only when the Collaborator is the source of transcription errors in their preparation of the *Preliminary Asbestos PT Reports*.

2.5 PT Sample Replacement

A participant shall notify the Collaborator, using the non-conformance form on page two of the appropriate PT Instruction Sheet, within 24 hours of sample receipt if a sample is missing or arrives compromised. The Collaborator shall send another sample set, at no cost to the participant or to CALA. Please note, replacement samples may not be available for some test groups due to the very short analytical hold time (e.g., C05 microbiology).

After twenty-four hours of sample receipt, or if a participant compromises the sample after it has been delivered, the participant may request (in writing) a replacement sample set. When feasible, CALA shall instruct the Collaborator to ship another sample set to the participant. The regular sample fee applies to each replacement sample.

2.6 Duplicate Samples and Duplicate Methods

If the normal sample quantity is insufficient the participant may request that additional sets of a particular CALA PT sample be added to their ongoing registration. The laboratory will be invoiced the *Extra Volume* fee listed in *P02-02-Program Description – Fee Schedule*.

When a participant wishes to receive CALA recognition for more than one analytical method of the same analyte, an additional set of samples shall not be shipped unless specifically requested. A fee of 50% of the full fee shall be applied to cover admin and PT evaluation.

2.7 Remedial Actions

Whenever a participant receives a *Possible Suspension, Suspension, or Withdrawal* they shall submit a completed corrective action report (CAR) to CALA for review. Participants may use their own form or may use the form that is available on the CALA web site (www.cala.ca/carform.html). If a laboratory is using its own form, please ensure that the CALA laboratory number is included.

Each CAR shall contain a description of the failure, the factors investigated, the root cause identified, and a corrective action that will reduce the risk of subsequent PT failure.

Failure to provide a satisfactory corrective action report shall result in a further advancement to *Suspension* or *Withdrawal* of PT recognition. For accredited laboratories this shall also result in a *Suspension* or *Withdrawal* of accreditation for the affected analyte.

When these corrective action reports are reviewed, the Proficiency Testing Manager does not make a judgment on the accuracy of the root cause or the appropriateness of the corrective action. Rather the appropriateness of the report will be based on:

- the thoroughness of the investigation;
- whether the identified root cause is deemed to be a legitimate root cause or is simply the immediate cause. For example, transcription error is not a root cause but an inadequate data verification process could be; and,
- whether the indicated corrective action is likely to prevent recurrence. For example, wording such as will ensure or analyst will take more care does not indicate how this will be done. Corrective actions generally involve actions such as modifications to documentation or changes to training plans, etc.

Each *Suspension/Withdrawal* notice triggers a *Suspension/Withdrawal* fee. Refer to *P02-02-Program Description – Fee Schedule* for more information regarding PT *Suspension* and *Withdrawal*. This fee is intended to offset the administrative cost of modifying directories/scopes and reviewing the corrective action reports.

2.8 Fast Tracking Of PT Recognition

Participants seeking proficient status, or wishing to have their proficiency status reinstated, before the next scheduled CALA study, may use the Fast-Track process through an approved PT Provider (P02-05–*Program Description – List of Approved PT Providers*).

To proceed with Fast-Tracking, the following procedure shall be followed:

- the participant shall obtain, from an approved PT Provider, a minimum of four different samples with concentrations comparable to those in the CALA program;
- the PT provider shall submit the final report directly to CALA;
- CALA shall calculate z scores and a combined PT score using the participant’s reported results, the PT provider’s assigned values, and standard deviations estimated using the CALA regression equations (PT15-05–*CALA PT Program – Regression Equations*); and,
- An acceptable combined score (> 70) shall result in the granting or reinstatement of proficient status.

Unacceptable Fast-tracking exercises shall be treated in the same fashion as CALA PT failures, including the issuing of invoices for any *Suspension/Withdrawal* fee that may arise.

Before an accredited laboratory can use fast-tracking to regain status after a withdrawal, they must also submit an acceptable corrective action report and recent re-validation data.

If a participant using Fast-Tracking is unsuccessful, they shall submit an acceptable corrective action report before using the Fast-Tracking option again.

2.9 Disputes And Appeals

Within 30 days of receiving any PT decision (e.g., *Suspension/Withdrawal* notice), the participant may dispute the decision to CALA. The dispute shall be investigated by CALA staff and shall be limited to investigating whether or not CALA procedures were followed. If a participant disagrees with the dispute decision it may appeal the decision to a panel of the Board of Directors. The decision of the Board is final.

Requests for disputes /appeals shall be made in writing, clearly stating that the participant is disputing/appealing a PT decision, and shall provide adequate information to support the dispute/appeal.

A more detailed description of the dispute/appeal process is found in Q28–*Disputes and Appeals Within CALA Programs*.

2.10 Notification Of PT-Related Errors

If an error is made by CALA during the conduct of a PT, CALA shall correct the error and notify all of the participants in the study for the affected analyte. The notification shall contain details regarding the error and a description of the actions taken by CALA to resolve the issue and to prevent its recurrence.

If the error results in the re-issuing of PT reports, the re-issued reports shall be clearly indicated as being revised from the original report.

2.11 International Sample Shipments

PT samples shall be sent by courier to international participants. CALA consults with the Collaborator to find the best courier solution to keep the costs low for all the participants in the study. Refer to the Fee Schedule in P02-02 – *CALA Program Description – Fee Schedule* for details regarding international pricing.

2.12 Participation In International PT Studies

Laboratories accredited by CALA shall participate in international PT (e.g., APLAC PT studies) if requested by CALA. Laboratories selected to participate in these studies shall be selected at random from those accredited laboratories that are accredited for the analytes in the study.

Laboratories that obtain unacceptable scores on international PT shall submit corrective action reports to CALA demonstrating appropriate investigation, and corrective action.

2.13 Release of PT Study Assigned Results

Although approximate concentration ranges are provided in P02-04-*CALA Program Description – PT Catalogue*, study specific design and assigned values (target value and standard deviation) will not be released until the study has been closed and the official PT report issued.

2.14 Participant Use of Proficiency Testing Reports

As per P03 – *CALA Publicity Policy*, participating laboratories shall not duplicate or post copies of CALA Proficiency Testing Reports for marketing or advertizing purposes. Laboratories may, however, provide copies of CALA Proficiency Testing reports if required in response to a request for proposal, bid or quotation. When this occurs, the participant must include all of the report pages.