ACCREDITATION SERVICES

SCC Requirements & Guidance – Proficiency Testing for Laboratories (Testing and Medical)

Version 4

Standards Council of Canada

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Introduction

The Standards Council of Canada (SCC) recognises the importance of proficiency testing in demonstrating laboratory competence (testing and medical, ISO/IEC 17025 and ISO 15189 respectively) to achieve consistent and reliable results. This document complies with the general requirements outlined in ILAC-P9, ILAC Policy for Participation in Proficiency Testing Activities.

NOTE: unless specified otherwise, when this document refers to “laboratories”, it implies both testing and medical laboratories.

This document sets out the requirements for, and gives guidance to, laboratories on the use of PT activities in the accreditation process. It also aims to provide guidance and assistance to SCC assessment teams in the consistent application of this SCC PT Requirement and Guidance (RG) document.

SCC evaluates the performance of results to participation in a PT scheme of its accredited laboratories through its accreditation process in order to ensure that the PT activities are effective, and that corrective actions are carried out when necessary. The evaluation of PT activities and performance is done by SCC assessment teams. It is also reviewed and evaluated during the accreditation decision-making process.

NOTE: The evaluation of PT participation, performance and corrective action (where necessary) is done during on-site activities and during review of annual surveillance questionnaires. See the *SCC Accreditation Program Overview* for program specific requirements and accreditation cycles.

It is up to the laboratory to determine its level of participation by identifying within its scope the number of specific proficiency tests that needs to be considered for participation. The level of participation shall be such as to ensure compliance with this document.

When a test/method/technique has been identified for participation, the laboratory shall refer to section 8 of this document for SCC requirements of participation frequency.

- For testing laboratories, the frequency requirements are outlined by specific Program Specialty Areas (PSAs) and/or by discipline. See table 8.1 for the list of disciplines and PSAs.
- For medical laboratories, the frequency requirements will be outlined by specific disciplines. See table 8.2 for the list of disciplines.

NOTE: For testing laboratories (ISO/IEC 17025), if there are requirements in an additional SCC RG document, which are specific to a PSA (e.g. R&G for Forensic Testing Laboratories), then those requirements are in addition to those included in this document.

This document also emphasizes the requirement for a PT participation plan (PT Plan) and highlights the need to periodically review the PT plan in response to changes in staffing, methodology, instrumentation, or other relevant changes.

SCC recognizes that there are some specific forms of testing that do not lend themselves to PT. In such cases, SCC expects the laboratory to adopt a suitable alternative means or other mechanisms by which performance may be assessed and monitored. Other mechanisms include interlaboratory comparisons (ILC), blind in-house proficiency programs.

Since SCC supports the use of appropriate PT programs that meet the essential requirements of ISO/IEC 17043, *Conformity assessment -- General requirements for proficiency testing*, it is expected that, where feasible, the use of such PT providers will be prioritized.

SCC recognises that specific requirements, providers and participation frequency may be dictated by regulators or by the industry professional sectors.

Laboratories shall provide evidence of compliance with the requirements in this document. The guidance statements are included to provide clarification and explanation of some requirements listed in this RG document.

According to ISO/IEC 17025:2017, a laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:

a) participation in proficiency testing;

b) participation in interlaboratory comparisons other than proficiency testing.

According to ISO 15189:2022 (7.3.7.3), the laboratory shall monitor its performance of examination methods, by comparison with results of other laboratories. This includes participation in EQA programmes appropriate to the examinations and interpretation of examination results, including POCT examination methods interlaboratory

ISO/IEC 17011:2017 requires accreditation bodies to take into account during assessments and during the decision-making process the review of performance in proficiency testing and other interlaboratory comparisons.

ILAC-P9:06/2014 states that Accreditation Bodies (ABs) seeking to sign or seeking to maintain their status as a signatory to the ILAC Multilateral Recognition Arrangement (MRA) shall demonstrate the technical competence of their accredited calibration and testing laboratories. One of the elements by which accredited laboratories can demonstrate technical competence is by satisfactory participation in PT activities where such activities are available and appropriate.

1. Scope

This RG document sets out the requirements and guidance for PT participation for testing (ISO/IEC 17025) and medical (ISO 15189) laboratories.

This RG document does not apply to calibration laboratories. Calibration laboratories should refer to National Research Council Canada's *Calibration Laboratory Assessment Service* (*CLAS) Document 7 - CLAS Requirements for Proficiency Testing* for any requirements and guidance.

2. Normative References

The following referenced documents are essential for the application of this document. The latest edition of the referenced document (including any amendments) applies.

- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
- ISO 15189, Medical laboratories - Requirements for quality and competence
- ISO/IEC 17011, Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies
- ILAC P9, ILAC Policy for Participation in Proficiency Testing Activities
- EA-4/18, Guidance on the level and frequency of proficiency testing participation
- ISO/IEC 17043, Conformity Assessment - General requirements for proficiency testing
- JCGM 200, International vocabulary of metrology – Basic and general concepts and associated terms (VIM)
- SCC Accreditation Program Overview (POV)

3. Definitions

Proficiency testing (PT): evaluation of participant performance against pre-established criteria by means of interlaboratory comparison. [ISO/IEC 17043:2010]

Interlaboratory comparison (ILC): is the organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions. [ISO/IEC 17043:2010 and ISO/IEC 17025:2017]

Product: The item that the measurement technique is being applied. (e.g. soil, vegetables, serum, polystyrene, concrete) [EA-4/18]

Property: The quantify being measured. (e.g. arsenic, fat, creatinine, Escherichia coli, length, hardness, force) [EA-4/18]

Intralaboratory proficiency testing:

- Internally prepared sample(s) where the quantity being measured in a given product is known. Although the quantity being measured is known internally, the analyst(s) should be performing blind testing (should be unaware of the amount prior to analysis).
- Use of sample which has tested positive in the past and where the quantity being measured is known (where applicable).

Proficiency Testing Plan (PT Plan): is a documented schedule demonstrating the level of participation, the oversight and management of the PT program, it demonstrates compliance outlined in this document. See section 5.

Measurement Technique: The process of testing/calibrating/identifying the property, including any pre-treatment required to present the sample, as received by the laboratory to the measuring device. (e.g. ICP-MS, Rockwell Hardness, PCR, Microscopy, force Measurement) [EA-4/18]

Sub-discipline: An area of technical competence defined by a minimum of one Measurement Technique, Property and Product, which are related. (e.g. Determination of Arsenic in soil by ICP-MS). [EA-4/18]

Level of Participation: the number of sub-disciplines that an organisation identifies within its scope, and therefore the number of specific proficiency tests that should be considered for participation. [EA-4/18]

External quality assessment (EQA): term that is used in Medical Laboratories to describe a method that allows for comparison of a laboratory's testing to a source outside the laboratory.

Point-of-care testing (POCT): term that is used in medical laboratories. It is defined as medical diagnostic testing performed in close proximity to where the patient is receiving care. POCT is performed outside of the laboratory.

4. General

Laboratories shall provide evidence of conformity to the requirements of this document. The guidance statements are intended to clarify, explain, or interpret certain additional requirements to ensure that they are applied in a consistent manner. The additional requirements listed in each section are to be applied to conform to clause 7.7.2 of ISO/IEC 17025 or clause 7.3.7.3 External quality assessment (EQA) of ISO 15189.

Section	Requirement	Guidance
4.1	Where PT is available and appropriate, a minimum of one (1) successful PT activity is required for each accredited test prior to it being added to the scope of accreditation. For flexible scopes, a minimum of one (1) successful PT activity is required for each technique prior to it being added to the scope of accreditation. The pre-accreditation participation shall be as described in section 8.	This applies to new applicants (not yet accredited by SCC) and for requested scope extensions. A participation in a PT does not always mean one sample, see section 8 for what is expected prior to being accredited. Successful/Unsuccessful outcome to participation in a PT scheme is to be assessed and determined by the PT provider. It is strongly advised that before seeking accreditation, the laboratory first enrolment for participation in a PT scheme be done in a timely manner in order to avoid potential delay in obtaining accreditation. Plan for time to resolve any potential unsuccessful result(s) on the first participation.
4.2	Once accredited, demonstration of continued satisfactory performance for accredited tests and/or techniques included on the scope of accreditation is required. The laboratory shall determine its PT level of participation taking into account all requirements listed in section 5.	Repetitive unsatisfactory PT results can lead to suspension or withdrawal of partial/full accreditation. See section 5 for the determination of PT frequency and for the elaboration of the PT plan. A PT participation may cover more than one accredited test if method equivalency can be demonstrated (see sections 6.1 and 6.3 for testing labs, see section 7.1 for medical labs).
4.3	When a test/technique has been identified for participation, the laboratory shall refer to section 8 of	For testing laboratories, the frequency requirements are outlined by specific Program Specialty Areas (PSAs)

	this document for SCCs requirements of participation frequency.	and/or by discipline. See table 8.1 for the list of disciplines and PSAs. For medical laboratories, the frequency requirements will be outlined by specific disciplines. See table 8.2 for the list of disciplines.
4.4	Where an appropriate PT (or ILC) is not available, evidence of recent searches shall be available. When appropriate PT is not available, evidence of renewed periodic searches shall be available. Next anticipated search date shall be documented in the PT plan (see section 5).	There are several ways that a laboratory can demonstrate evidence of having searched for an appropriate PT scheme, these include (but not limited to): • Communication/inquiry with PT providers • Internet searches including PT search engines such as eptis (international database found at www.eptis.org) • Communication/inquiry with peers demonstrating an attempt to initiate an informal bilateral comparison with other laboratories
4.5	For all unsatisfactory results identified by the PT provider, the laboratory shall initiate an investigation and any necessary corrective actions as per internal procedure(s).	When there are unsatisfactory PT results, retesting of retained samples (where applicable) should be considered. Ordering a replacement/additional PT participation should also be considered especially if an associated corrective action remains unresolved.
4.6	Original PT performance reports provided by the PT providers shall be made available during assessments and shall be retained for at least 5 years. Evidence of cancelled PT by the provider shall be retained for at least 5 years.	It is up to the PT provider to determine if a PT scheme is cancelled. Example: a PT provider may determine that there is an insufficient number of participants for a given PT scheme.
4.7	Where regulatory requirements [*e.g. requirements from the Canadian Food*	

	Inspection Agency (CFIA)] stipulates a participation, which is different than what is listed in this document, then the participation shall be that of the highest required frequency.	

5. Proficiency Testing Plan (PT plan)

Applicability, section 5: This section applies to Testing Laboratories (ISO/IEC 17025) and Medical Laboratories (ISO 15189).

Section	Requirement	Guidance
5.1	Laboratories shall develop, document and implement a PT Plan.	The format to be used is at the discretion of the laboratory. Example: use of spreadsheet, word processing application, etc.
5.2	The PT plan shall be developed in such a way as to demonstrate compliance with this document. It shall cover the scope of accreditation and shall contain the minimum following information: • The scope listing(s) • PT provider name • Participation frequency • Product and property measured • Scheduled dates of participation (where available) • Where PT is not available, the PT plan shall list what other mechanisms are used to evaluate performance (ILC, Intra-laboratory proficiency testing, etc.) • See section 6.2 for testing labs, see section 7.2 for medical labs.	For testing laboratories, the scope of accreditation is presented as test methods or as techniques (in the case of flexible scope). For medical laboratories, the scope of accreditation is presented as disciplines, each discipline may contain sub-disciplines. The PT plan should allow for the addition of results and any relevant remark(s). For unsatisfactory results, the plan should include a reference to the associated investigation and any applicable corrective action.
5.3	The PT plan shall outline the participation for the entire scope of accreditation. Frequency of	Laboratories should identify sub-disciplines within the scope of accreditation when determining the

	participation shall be scheduled in such as way where it does not exceed a 4-year period. The PT plan shall be elaborated in such a way where the participation ensures that all measurement techniques are evaluated annually. • If the scope of accreditation contains more than one measurement technique for the same property, (e.g. zinc in sediment by FAA and also by ICP-MS) then each accredited test shall have its own PT participation. The determined participation frequency shall be based on a sampling strategy which is elaborated taking into account the evaluation of risk.	frequency of participation and when elaborating the PT plan. To aid in this exercise, see EA-4/18, *Guidance on the level and frequency of proficiency testing participation* The level of risk presented by the laboratory, the sector in which they operate or the methodology they are using. This can be determined, for example, by considering: • Number of tests/calibrations/measurements undertaken • Turnover of technical staff • Experience and knowledge of technical staff • Source of Traceability (e.g. availability of reference materials, national standards, etc.) • Known stability/instability of the measurement technique • Significance and final use of testing/calibration data (e.g. forensic science represents an area requiring a high level of assurance).
5.4	**For multi-property and/or multi-product tests:** *If necessary*, the laboratory shall participate in more than one PT scheme over a four (4) year period in order to maximize the coverage of all or as many of the measured properties and/or products. The participation method for optimum property and product coverage shall be documented in the PT plan.	*If necessary,* means that there is no PT scheme which offers participation for all properties to be measured which are included on the scope (or proposed scope) of accreditation. Example: the selection of different food commodities from year to year. For product equivalency requirements, see sections 6.1 for testing labs, see section 7.1 for medical labs.

5.5	The PT plan shall be reviewed and updated as needed, or annually at a minimum.	Examples of reasons why the PT plan could be reviewed and updated: • Change of staff • Change of methodology • Change of instrumentation • Scope extensions or reductions • Other relevant change It is recommended that the PT plan be reviewed for continued suitability at annual management reviews.
5.6	Where inappropriate and when PT or ILC is not available, this shall be documented in the PT plan. The PT plan shall indicate the date where the laboratory anticipates renewing the search.	New PT schemes, ILCs and related opportunities become available on a regular basis, a renewed search can provide positive results where it had proven negative in the past.

6. Testing Laboratories (ISO/IEC 17025)

Applicability, section 6: This section applies to all Testing Laboratories including those under the following PSAs: Agriculture, food, animal health and plant protection (AFAP), environmental testing, forensic testing, mineral analysis testing and test method development and non-routine testing [non-routine testing section only (NRT)].

NOTE: for IT Security Evaluation and Testing (ITSET), see *SCC Requirements and Guidance for the Accreditation of Information Technology Security Evaluation and Testing Facilities*.

Section	Requirement	Guidance
6.1	Testing laboratories shall participate in PT schemes as described in section 5.3 for all tests (or all techniques in the case of flexible scopes) listed on their scope of accreditation where available and appropriate. • For quantitative tests, PT shall be within the appropriate concentration range (where applicable).	In the case where the concentration is outside the range for the accredited test, the testing laboratory

	• PT shall be in the appropriate product. ○ *In cases where the laboratory can demonstrate equivalency of product, covering one of the equivalent product will be acceptable. (see 6.3)* • PT shall be above the test methods detection limit. When performing test method development and non-routine testing (TMDNRT), the participation in appropriate proficiency testing is required. Where there is no proficiency testing participation, the rationale shall be recorded on the PT plan (see *SCC Requirements and Guidance for Accreditation of Laboratories Engaged in Test Method Development and Non-Routine Testing*).	will not be required to participate in the PT. Demonstration of product equivalency can be done through method validation data. It is recognised that the timing of the NRT project might not match the PT providers schedule.
6.2	SCC expects the use of appropriate PT programs that meet the requirements of ISO/IEC 17043. The Testing Laboratory shall consider the following order of priority: 1. Participation in a PT from a PT provider accredited to ISO/IEC 17043. 2. Participation in a PT from a non-accredited PT provider. 3. Participation in ILC. 4. Intralaboratory proficiency testing**.** – Use of blind testing is required. The selected option shall be documented in the PT plan.	

	When PT is not available, the chosen alternative shall occur with the same frequency as described in section 8.1.	It is recognised that following the same frequency as described in section 8.1 might not be possible when the alternative is an ILC.
6.3	When a testing laboratory determines that a PT may be used to cover multiple accredited tests, the testing laboratory shall be able to demonstrate through documented evidence the test method equivalency.	Demonstration of test method equivalency can be done through method validation data.
6.4	All procedures associated with the handling and testing of PT shall be carried out in a manner identical to accredited procedures/test methods used for testing customer samples. PT shall be analysed at locations where testing routinely occurs and shall be distributed amongst qualified personnel routinely engaged in laboratory testing activities. The analyses of PT shall not always be performed by the same qualified person.	If possible, testing Laboratories should add PT to a routine set of samples as opposed to running the PT separately and independently. PT may be used in the analyst qualification process.

7. Medical Laboratories (ISO 15189)

Applicability section 7: This section applies to Medical Laboratories

Section	Requirement	Guidance
7.1	Medical laboratories shall participate in PT/EQA schemes for all discipline/measurement technique listed on their scope of accreditation where available and appropriate. • For quantitative tests, PT/EQA shall be within the appropriate concentration range (where applicable). • PT/EQA shall be in the appropriate product. ○ *In cases where the laboratory can demonstrate equivalency of product, covering one of the equivalent products will be acceptable.* • PT/EQA shall be above the test methods detection limit. PT/EQA participation shall include all types of POCT. • If the laboratory uses several equipment and/or measurement techniques for a given POCT, the PT/EQA participation shall be based on a sampling strategy which is elaborated taking into account the evaluation of risk (for guidance, see section 5.3).	In the case where the concentration is outside the range of the medical laboratory's testing activities, the medical laboratory will not be required to participate in the PT/EQA. Demonstration of product equivalency can be done through method validation data.
7.2	SCC expects the use of appropriate, recognised PT/EQA programs which	It is recognised that following the same frequency as described in

	are recognised within the medical laboratory industry. The Medical Laboratory shall consider the following and select the first available option: 1. Participation in a PT/EQA which is recognised within the medical laboratory industry or which is from a PT provider accredited to ISO/IEC 17043. 2. Participation in a PT/EQA from a non-accredited provider. 3. Participation in ILC. 4. Internally developed PT/EQA program. – Use of blind testing is required. The selected option shall be documented in the PT plan (see section 5). When PT/EQA is not available, the chosen alternative shall occur with the same frequency as described in section 8.2. • If the frequency described in section 8.2 can not be observed, the medical laboratory shall have a documented justification.	section 8.2 might not be possible when the alternative is an ILC.
7.3	It is the responsibility of a member of the management team (or its designate) to ensure that the testing schedule adequately challenges test performance, e.g., that testing is spread throughout the year.	
7.4	When a medical laboratory determines that a PT/EQA may be used to cover multiple disciplines/measurement techniques, the medical laboratory	Demonstration of test method equivalency can be done through method validation data.

	shall be able to demonstrate equivalency through documented evidence.	
7.5	All procedures associated with the handling and testing of PT/EQA shall be carried out in a manner identical to routine procedures/test methods used for testing of patient samples. PT/EQA shall be analysed at locations where testing routinely occurs and shall be distributed amongst qualified personnel routinely engaged in laboratory testing. PT/EQA analysis shall not always be performed by the same qualified person.	Medical Laboratories should add PT to a routine set of samples as opposed to running the PT separately and independently. PT/EQA may be used in the analyst qualification process.

8. Participation Frequency

Applicability, section 8: This section applies to Testing Laboratories (ISO/IEC 17025) and Medical Laboratories (ISO 15189).

NOTE: SCC may require more PT participation than what is listed below.

Examples where additional PT participation may be required:

- If serious and/or critical nonconformities are identified during an assessment.
- nature and/or number of nonconformities identified during an assessment.
- complaint received.
- previous unresolved poor PT performance.

8.1 Testing Laboratories (ISO/IEC 17025)

PSA/Discipline	Successful PT Participation requirement PRIOR to being accredited	Continued PT participation AFTER being accredited	Guidance
AFAP (PSA)	1	One round per year per sub discipline.	

		Where CFIA mandates participation in a specific PT program and/or demonstrated proficiency per analyst, the laboratory shall participate as required.	
Environmental Testing Laboratories (PSA)	1 x 2	2 x 2/year	A 1 x 2 PT scheme consists of 1 PT participation having a minimum of 2 samples each of different and appropriate concentration/amount (see 6.1). • If a 1 x 2 PT scheme is not available, then a participation of 1 sample prior to accreditation is sufficient. A 2 x 2 PT scheme consists of 2 PT participation annually. Each PT participation has a minimum of 2 samples each of different and appropriate concentration/amount (see 6.1). • If a 2 x 2 PT scheme is not available, then a participation of 2 samples/year is sufficient.
Mineral Testing Laboratories (PSA)	1 x 2	2 x 2/year	

Test Method Development and Non-Routing Testing (TMD-NRT) (PSA)	1	1/year during the life span of the NRT project.	Due to the nature of this PSA a participation prior to being accredited may not be feasible. Also, see SCC Requirements and Guidance for Accreditation of Laboratories Engaged in Test Method Development and Non-Routine Testing.
Chemical, other (discipline)	1	1/year	1 participation per year
Biological, other (discipline)	1	2/year	2 participations per year. Each participation having a minimum of one sample.
Forensic Testing (PSA)	*See SCC Requirements and Guidance for the Accreditation for Forensic Testing Laboratories.*		
ITSET (PSA)	*See SCC Requirements and Guidance for the Accreditation of Information Technology Security Evaluation and Testing Facilities.*		
Electrical (discipline)	1	1/year	1 participation per year.
Building Products (discipline)	1	1/year	
Non-Destructive Testing (discipline)	1	1/year	
Construction Material (discipline)	1	1/year	
Mechanical Testing (discipline)	1	1/year	
Toy and Children's Product (discipline)	1	1/year	

8.2 Medical Laboratories (ISO 15189)

Discipline	Successful PT/EQA Participation requirement PRIOR to being accredited	Continued PT/EQA participation AFTER being accredited	Guidance
Anatomical Pathology	2	4/year	4 participation/year: Each participation having a minimum of one sample.
Biochemistry	2	4/year	
Cytology	2	4/year	
Genetic/Cytogenetics	2	4/year	
Hematology	2	4/year	
Immunology	2	4/year	
Maternal serum screening	2	4/year	
Microbiology	2	4/year	
Molecular Biology	2	4/year	
Mycology	2	4/year	
Parasitology	2	4/year	
Transfusion medicine	2	4/year	
Virology	2	4/year	

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