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Accreditation Services

Requirements & Guidance – Proficiency Testing for Testing and Medical Laboratories

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Canada

Standards Council of Canada
55 Metcalfe St., Suite 600
Ottawa, ON K1P 6L5

Telephone: + 1 613 238 3222
Fax: + 1 613 569 7808
accreditation@scc.ca
www.scc.ca

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Introduction

The Standards Council of Canada (SCC) recognizes the importance of proficiency testing (PT) in demonstrating the competence of laboratories to achieve consistent and reliable results. SCC supports the use of appropriate PT programs which meet the essential requirements of ISO/IEC 17043, *Conformity assessment -- General requirements for proficiency testing*. This document sets out the requirements for, and gives guidance to laboratories and SCC assessment teams, on the use of PT activities in the accreditation process of laboratories. It also aims to assist SCC assessors to consistently apply SCC PT policies. It describes SCC's policy on the use of PT activities in its assessment and accreditation process. It complies with the general minimum PT requirements outlined in ILAC-P9, *ILAC Policy for Participation in Proficiency Testing Activities*. This document also addresses specific PT benchmark participation frequency guidelines for accredited laboratories under specific program specialty areas (PSAs) (see Annexes). It emphasizes the need for a PT participation plan which has been formulated by SCC and its applicant laboratories, and the specific PT requirements for each of its PSAs. This document also outlines the SCC requirements regarding the minimum level and frequency of participation in PT by its accredited laboratories. In addition, this document highlights the needs for a laboratory to regularly review its PT procedures and PT plan in response to changes in staffing, methodology, instrumentation, or any other relevant changes.

SCC evaluates the PT participation and performance of its accredited laboratories through its accreditation process in order to ensure that the participation in PT activities of laboratories is effective, and that corrective actions are carried out when PT participation is not satisfactory.

SCC assessment teams review the laboratory's PT participation and performance during the assessments as well as the adequacy of corrective action taken when a laboratory's PT performance is not satisfactory. The evaluation of PT participation and performance of laboratories by SCC assessment teams is reviewed during the accreditation decision-making process.

SCC assessment teams ensure that when any unsatisfactory PT results are received by a laboratory, the laboratory provides evidence of root cause analysis of the unsatisfactory result, corrections (where appropriate), and corrective action. Repetitive unsatisfactory PT results may lead to suspension or withdrawal of accreditation.

SCC recognizes that there are some specific forms of testing that do not lend themselves to PT. In such cases, SCC and the laboratory shall discuss and agree on suitable alternative means or other mechanisms by which performance may be assessed and monitored. Other mechanisms, such as in-house proficiency programs, blind splits, interlaboratory comparisons (ILCs), etc., shall be used to evaluate the laboratory performance. The annexes of this document define specific PT requirements relevant to various SCC PSAs as well as any PT requirements set by regulators, industry or professional sectors, Regional Cooperation bodies, or other interested parties.

Note that these requirements and guidance do 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.

Definitions

Satisfactory performance: acceptable results on the majority of samples analyzed over one (1) year.

References

- ISO/IEC 17011:2004, *Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies*
- ISO 15189:2012, *Medical laboratories -- Requirements for quality and competence*
- ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*
- ISO/IEC 17043:2010, *Conformity assessment -- General requirements for proficiency testing*
- ILAC P9:2014, *ILAC Policy for Participation in Proficiency Testing Activities*
- APLAC PT006:2010, *Proficiency Testing Frequency Benchmarks*

Requirements

Laboratories shall provide evidence of compliance with the requirements in this document. The guidance statements are included to provide clarification. They explain or interpret certain requirements in this document to ensure that the requirements are applied in a consistent manner. The clauses below and in each annex are aligned with those of ISO/IEC 17025:2005 or ISO 15189:2012 as they apply to medical testing laboratories.

PT Requirements		
Clause	**Requirements**	**Guidance**
5.9.1.1	SCC requires all laboratories to participate in one (1) PT activity prior to gaining accreditation, and one activity relating to each major sub-discipline of the laboratory's scope of accreditation within each four-year (4-year) period (each four-year [4-year] period includes two [2] reassessment visits and two [2]	SCC supports the use of appropriate PT programs which meet the essential requirements of ISO/IEC 17043:2010; therefore SCC-accredited laboratories should use PT programs which conform to the operational procedures detailed in ISO/IEC 17043:2010.

	annual surveillance questionnaires). The Laboratory shall report to SCC prior to each assessment all the PT programs to which they subscribe. Annual participation in PT is required where available and appropriate.	Laboratories may deviate from scheduled PT rounds where appropriate. In such case, laboratories must provide justification. Major sub-disciplines are those described in APLAC PT 006:2010.
5.9.1.1.1	Laboratories shall develop, document, and implement a PT participation plan that meets the requirements of their scope of accreditation and any associated regulatory requirements. As well, the plan submitted by the laboratory shall reflect all matrices analyzed and the analytical principles used. The plan shall ensure sufficient frequency of participation and coverage to adequately address the laboratories scope of activities. The plan shall include any commercially available participation and any ILCs, as applicable. In cases where the laboratory can demonstrate equivalency of matrices, covering one of the equivalent matrices is sufficient.	A PT participation plan should contain as a minimum: • the discipline(s) or major area(s) of expertise • the PT program (PT, ILC …) and the scope • the provider name • the scheduled dates • the minimum level and frequency of participation in PT The plan should also allow the PT results and any relevant remark to be included to identify that laboratory results are known so that the plan can help with the assessment of the laboratory performance. Equivalency of matrices should be documented.
5.9.1.1.2	When appropriate PT is not available, the laboratory shall provide evidence of a recent extensive search for such PT. The laboratory shall be documenting the search for PT.	
5.9.1.1.3	Laboratories shall analyze the PT samples using the testing discipline listed in their Scope of Accreditation. If their scope contains more than one (1) accredited testing discipline or analytical technique for the same measurand in any PT test group, then each test shall have its own PT result.	Appropriate PT activity includes international or national ILCs, or PT approved by the accreditation body itself. Preference should be given to international ILCs (i.e. APLAC, IAAC or equivalent) where these are available.

5.9.1.2	For any unsatisfactory results received by the laboratory, the laboratory shall provide evidence to SCC of root cause analysis of the unsatisfactory result, corrections (where appropriate), and corrective action.	This evidence should take the form of a corrective action report (CAR), and should only be submitted to SCC in preparation for an assessment activity, or as part of an Annual Surveillance Questionnaire response. Should the submitted evidence not be acceptable, SCC shall take additional actions as appropriate. Additional actions may include full or partial suspension or withdrawal of the accredited test method.

Note: Should any requirement listed in a program-specific annex contradict those of the main document, the program-specific requirement shall take precedence.

Annex A: Agriculture Inputs, Food, Animal Health and Plant Protection (AFAP) Testing Laboratories

As a regulatory authority, the Canadian Food Inspection Agency (CFIA) may, when appropriate, specify a PT, ILC, or blind test item for mandatory or recommended participation by applicant or accredited laboratories. SCC will take into account this requirement when reviewing results during assessments.

Applicant and accredited laboratories under the PSA-AFAP shall provide SCC with a PT plan that also documents the specific PT schemes in which the laboratory participates for accredited tests. The laboratory shall document efforts to search for PT providers to cover their scope of testing; however, not all analytes or matrices are necessarily included in a proficiency program for multi-analyte methods. Where feasible, a laboratory will participate in more than one PT program to cover as many or all of the analytes in the multi-analyte method(s) on the scope.

Where these are not available, ILCs would be chosen. Internal and/or external sample exchanges or round-robins could be selected in the absence of accredited PT schemes or pertinent ILCs. As much as possible, externally derived materials shall be used. When these are not relevant to the scope of testing, internal performance-based data may be appropriate, such as the regular use of certified reference materials and/or internal quality control activities using secondary reference materials that replicate tests using the same or different methods or correlation of results between laboratories, provided that they are technically sound and be reflected in laboratory PT plan.

Additional PT Requirements		
Clause	**Requirement**	**Guidance**
A.5.9.1.1	A minimum of one (1) successful PT activity is required prior to gaining accreditation. The laboratory shall have satisfactory internal performance data to support its competence within the sub-discipline. Otherwise procedures for unsatisfactory PT performance shall apply.	This should be reflected in the laboratory's developed PT plan. Enrollment in suitable PT programs for initial accreditation is evaluated and determined to be acceptable by SCC.
A.5.9.1.2	The laboratory is required to develop and document a PT plan describing its frequency of PT participation for the sub-disciplines/ test methods and	EA-4/18 INF 2010, *Guidance on the level and frequency of* proficiency testing *participation*, may be consulted for examples of grouping in PT plans.

	materials/matrices/product types over a one-year (1-year) period. The laboratory's rationale for grouping in the PT plan shall be documented.	
A.5.9.1.3	The plan shall be reviewed and updated as needed, or annually at a minimum.	
A.5.9.1.4	Laboratories may be required to participate more frequently in PT when the developed plan is deemed insufficient in regards to suitable coverage of the scope or planned frequency. Requirements for participation may be influenced by: • the laboratories past performance in PT • nature of the methodology or the testing specialty area • the nature of technical deficiencies identified during an assessment visit • the nature and number of non-conformities within the laboratory management system	
A.5.9.1.5	The laboratory shall ensure that PT samples are distributed amongst qualified personnel who are routinely engaged in testing and are from multiple locations. In specific testing sub-disciplines within the PSA, PT samples may be used to certify analysts. Individual participation is mandatory to conduct the regulatory testing.	Treat PT samples in the same manner as routine test samples to the extent possible. The laboratory should ensure that PT samples are analyzed at all locations where testing routinely occurs and are distributed amongst qualified personnel routinely engaged in testing. When there is a regulatory requirement for analyst certification for specific tests, the PT round should be completed individually.
A.5.9.1.6	If the PT sample concentration for any measurand falls below the test method detection limit, the	

	laboratory shall advise the PT provider for that specific measurand/test method in that specific PT sample.	
A.5.9.1.7	The laboratory shall advise SCC of circumstances where it is not possible to find a PT scheme which has at least 10 participants.	For ILC, there shall ideally be a minimum of 10 participants who report results for the measurand in any particular PT round. When the laboratory cannot find a PT scheme which has at least 10 participants, the results of these schemes will be evaluated with due attention on a case-by-case basis and may require additional PT and/or quality control activities by the laboratory. The minimum number of PT participants is usually known by the PT Provider.
A.5.9.1.8	To pass a set of PT samples, analysis shall be completed and results reported within the time period specified by the PT coordinator of the PT provider after receipt of each PT round of samples by the laboratory.	To pass a set of PT samples, a laboratory is expected to complete analysis and report results reported within the time period specified by the PT organizer.
A.5.9.1.9	Laboratories shall keep all PT provider final reports and documents relating to their scope under this PSA for a minimum of five (5) years.	Although laboratories are only required to respond formally to unsatisfactory ratings, i.e. Z scores > 3, it is recommended that laboratories receiving questionable results (Z score between 2 and 3) investigate and take action as needed. Repetitive questionable results should be investigated.

Annex B: Environmental Testing Laboratories

This annex contains the specific requirements for the evaluation of environmental testing laboratory performance by PT.

ADDITIONAL PT REQUIREMENTS FOR ENVIRONMENTAL LABORATORIES		
Clause	**Requirements**	**Guidance**
B.5.9.1.1	**General Criteria for PT**	
B.5.9.1.1.1	Accreditation in this PSA-Environmental Testing (ET) program requires ongoing continued participation and demonstrated satisfactory performance in acceptable PT scheme(s) for all environmental tests appearing in the laboratory's Scope of Accreditation, where such PT scheme(s) exist and are appropriate. It is recognized that for some specialized tests a formalized PT scheme may not exist and, therefore, other mechanisms, such as in-house proficiency programs, blind splits, ILCs, etc., shall be used to evaluate the laboratory performance.	
B.5.9.1.1.2	All procedures associated with the handling and testing of PT samples (items) by the laboratory shall be carried out to the extent possible in a manner identical to routine method(s) of testing that applied to customer samples.	
B.5.9.1.1.3	Laboratories shall analyze the PT samples using the test method listed in their Scope of Accreditation. If their scope contains more than one (1) accredited test method or analytical technique for the same measurand in any PT test group (e.g. zinc in water by FAAS and also ICP and/or ICP/MS) then each test shall have its own PT result.	
B.5.9.1.1.4	If the PT sample concentration for any measurand falls below the test method	

	detection limit, the laboratory shall advise the PT coordinator for that specific measurand/test method in that specific PT sample.	
B.5.9.1.2	**PT Requirements**	
B.5.9.1.2.2	The laboratory shall participate as follows:	
B.5.9.1.2.2 a)	Each PT round shall contain sample sets consisting of a minimum of two (2) samples per test group offered. These sample sets shall have two (2) different concentrations spanning a predetermined concentration range that covers the concentration range of the accredited test requested.	i) An acceptable PT scheme having generally equivalent frequency (e.g. two [2] sample sets per round twice per year) is acceptable, provided that over the course of one (1) year the concentrations span a predetermined concentration range that covers the concentration range of the accredited test. ii) Where specific environmental regulatory requirements stipulate additional PT requirements (e.g. more samples/set or higher frequency of PT rounds) those regulatory requirements shall be met to maintain accreditation.
B.5.9.1.2.2 b)		If participation frequency of two (2) sample sets per round twice per year (2x2) is not available, then one (1) sample twice per year (1x2) is sufficient to maintain accreditation.
B.5.9.1.2.2 c)	There shall be a minimum of 10-participant (i.e. n ≥ 10) reported results for that measurand in any particular proficiency testing round.	The laboratory shall identify circumstances to SCC where it is not possible to find a PT scheme which has n ≥ 10 for that specific measurand in that particular matrix. SCC may give special consideration to these situations.

B.5.9.1.2.3	To pass a set of PT samples, analysis shall be completed and results reported within the time period specified by the PT coordinator after receipt of each PT round of samples by the laboratory.	
B.5.9.1.2.4	A laboratory that fails the first set of PT samples is to ask for a replacement set of samples, after appropriate root cause analysis and corrective action has been taken.	
B.5.9.1.2.5	If the replacement set of PT samples is not analyzed satisfactorily, further corrective action(s) shall be taken.	SCC strongly suggests a thorough investigation of the root cause of these failures and the appropriate corrective action(s) be taken prior to requesting the third set of PT samples.
B.5.9.1.3	**The "2 x 2 Performance-Based PT Program"**	
B.5.9.1.3.1	This **"2 x 2 performance-based PT program" shall be reflected in the laboratory's developed PT plan and** requires participation as follows:	When developing its PT plan, the laboratory should take in to consideration the "2 x 2 performance-based PT program."
B.5.9.1.3.1 a)	The laboratory shall, for each accredited test, seek and be granted prior approval from SCC to convert to this program for that specific accredited test.	
B.5.9.1.3.1 b)	Participation in a minimum of two (2) PT rounds annually for each test approved for this program from an SCC-acceptable PT provider(s).	
B.5.9.1.3.1 c)	Each PT round contains sample sets consisting of two (2) samples per test group offered. These sample sets shall have different concentrations for each measurand and concentrations that are above the laboratory's declared detection limit for the measurand for all samples.	
B.5.9.1.3.1 d)	A minimum of four (4) PT samples per year for each accredited test approved for this program. These sample sets over two (2) PT rounds shall have different concentrations spanning a	i) An acceptable PT scheme having generally equivalent frequency (e.g. one [1] sample set per round, four [4] times per year) is acceptable, provided that over the course of one (1) year the

	predetermined concentration range that covers the concentration range of the accredited test. All PT samples shall be above the laboratory's declared detection limit for the measurand for all four (4) PT samples.	concentrations span a predetermined concentration range that covers the concentration range of the accredited test. ii) Where specific environmental regulatory requirements stipulate additional PT requirements (e.g. more samples/set or higher frequency of PT rounds) those regulatory requirements shall be met to maintain accreditation.
B.5.9.1.3.1 e)	A minimum of 10-participant (i.e. n ≥ 10) reported results for that measurand in any particular PT round.	
B.5.9.1.3.2	To pass a set of PT samples, laboratories shall correctly report, for each accredited test, the measurand(s) result or identification along with the specific test method employed within the timelines outlined by the PT provider.	
B.5.9.1.3.3	PT results are due within the time period specified by the PT coordinator after receipt of proficiency testing samples by the laboratory.	
B.5.9.1.4	**PT Program Responsibilities**	
B.5.9.1.4.1	Applicant and accredited laboratories shall identify in their developed PT plan to SCC the specific ET PT provider(s) and the specific PT scheme(s) the provider(s) will employ for accredited environmental tests and associated specific measurands under this PSA-ET program subject to the conditions below.	
B.5.9.1.4.2	For multi-measurand test methods, not all of the measurands may be included in a specific PT provider's test group. If the measurand is available from any SCC-acceptable PT provider, the laboratory shall be required to participate in PT rounds from more than one (1) PT provider if necessary to cover all the measurands in the multi-	

	measurand method(s) in their scope with SCC.	
B.5.9.1.4.3	The laboratory shall obtain specific SCC prior-approval of specific scheme(s) the PT provider(s) will employ for their accredited scope of ET under this PSA. Once approved, the laboratory shall not change their “current” PT provider(s) without obtaining prior approval from SCC.	SCC supports the use of appropriate PT programs which meet the essential requirements of ISO/IEC 17043, where applicable. SCC assessment teams will ensure (during the pre-assessment document review and during the assessment or during Annual Surveillance Questionnaire review) that further and ongoing activity is appropriate to the scope of accreditation and consistent with the PT participation plan.
B.5.9.1.4.4	If the PT sample concentration for any measurand falls below the test method detection limit, the laboratory shall clearly indicate this by reporting either a “<” or “< DL” on their PT report for that specific measurand/test method in that specific PT sample.	
B.5.9.1.4.5	Laboratories shall keep all final “PT performance report” documents (however named) from the PT provider relating to their scope under this PSA-ET for a minimum of five (5) years. They shall provide copies of any final “PT performance evaluation report” to SCC when requested by SCC.	

Annex C: Forensics

Please note that proficiency testing requirements for forensics laboratories can be found in the current version of SCC Requirements and Guidance for the Accreditation for Forensic Testing Laboratories, available at www.scc.ca.

Annex D: Mineral Analysis

This annex contains the specific requirements for the evaluation of mineral analysis laboratory (MAL) performance by PT under PSA-MAL, and also describes requirements for participating in other PT programs.

Additional PT Requirements for MLAs		
Clause	**Requirements**	**Guidance**
D.5.9.1.1.1	**Multi-analyte methods** A method may be used to determine more than one measurand. The PT program shall cover all measurands included in the scope of accreditation.	In some cases it may be difficult to include all measurands in a PT program, for example, no PT program may exist for some measurands or PT programs will include different measurands in successive rounds. In such cases, the laboratory needs to follow the requirements in 5.9; however, in addition, they may group measurands together according to certain characteristics common to the group, such as volatility, solubility. distribution, wavelength, sensitivity, or mass and use one measurand as a surrogate for others that behave similarly. The justification for this grouping shall be documented.
D.5.9.1.1.2	All procedures associated with the handling and testing of PT items by the laboratory shall be carried out to the greatest extent possible in a manner identical to routine method(s) of testing used for testing customer samples. Laboratories shall analyze the PT items using the test method listed in their Scope of Accreditation. If their scope contains more than one accredited test method or analytical technique for the same measurand (e.g. zinc in sediment by AD2/FAA and also by AD3/ICPE and/or by AD3/ICP-MS) then each accredited test shall have its own PT result.	
D.5.9.1.1.3	If the PT sample concentration for any	

	measurand falls below the test method detection limit, the laboratory shall clearly indicate that to the PT coordinator. This result will be considered to meet the requirement for having participated in the PT round.	
D.5.9.1.1.4	In the case where the concentration is outside the range for the accredited method, the laboratory will not be required to analyze the PT item. The laboratory should report to the PT coordinator that the item is outside the accredited method range. For example, a mineral concentrate sample will not be done using an exploration test method.	
D.5.9.1.1.5	Although laboratories will be required only to respond formally to unsatisfactory ratings, i.e. Z scores > 3, it is recommended that laboratories receiving questionable ratings (Z score between 2 and 3) investigate and take action if needed. Laboratories shall keep all final report documents from their PT provider relating to their scope under this PSA-MAL for a minimum of three (3) years. They shall provide copies of any preliminary reports or final reports to SCC when requested by SCC.	
D.5.9.1.2	**PT Participation**	
D.5.9.1.2.2	**After becoming accredited** Once accredited, the laboratory shall maintain demonstrated satisfactory performance in the designated PT scheme for each accredited test on the scope. For the PSA-MAL this requires:	
D.5.9.1.2.2 a)	Participation in a minimum of two (2) PT rounds annually for each accredited test.	
D.5.9.1.2.2 b)	Each PT round contains sample sets generally consisting of four (4) samples.	

	These sample sets will generally have four (4) (except for Pt and Pd which should generally have two [2]) different concentrations spanning the normal target concentration range outlined below.	
D.5.9.1.2.2 c)	There will generally be eight (8) PT results per year required per accredited test. This is subject to the multi-element situation described above.	
D.5.9.1.2.2	**Laboratory reporting to SCC** For any unsatisfactory measurand result, laboratories shall provide to their SCC Account Manager evidence that the corrective action report (CAR) has been initiated. This shall be submitted within 10 working days from the first date of receiving the preliminary report from the PT provider. Laboratories failing to accurately report their performance in any PT round within this timeline may be subject to suspension.	
NOTE: If a laboratory fails two (2) consecutive PT rounds, the laboratory may choose voluntary withdrawal, or SCC may take actions to suspend following the Accreditation Services Program Overview. SCC will consider several factors in determining whether the suspension of a test from the scope of an accredited laboratory is necessary: *a) unsatisfactory performance in two (2) consecutive rounds* *b) failure to participate in a PT round* *c) failure to take immediate corrective action on unsatisfactory PT performance* *d) failure to properly correct the unsatisfactory PT performance in a timely manner* *e) failure to report unsatisfactory PT results to SCC within the timelines set above* *f) failure to accurately report unsatisfactory performance* g) *failure to treat PT items as routine samples*		
D.5.9.1.3	**Other PT Programs**	
D.5.9.1.3.1	**Prior to becoming accredited** Prior to becoming accredited, a laboratory shall successfully complete two (2) successive PT rounds for each test for which accreditation is requested. The laboratory must	.

	successfully complete the first round before applying for accreditation and the second successive round must be successfully completed before accreditation is granted.	
D.5.9.1.3.2	**After becoming accredited** Once accredited, in order to remain accredited, the laboratory shall maintain demonstrated satisfactory performance in the designated PT scheme, for each accredited test on their scope.	The PT data and results will be examined by the assessor during the accreditation assessment.

Annex E: Medical Testing

This annex documents the Medical Testing Laboratories program policy for ILCs in accredited and applicant laboratories.

Formal ILCs are commonly referred to as PT/external quality assessment (PT/EQA). Both participation and performance in such activities are evaluated by SCC.

This position statement:

- is in compliance with ILAC P9:06/2014, *ILAC Policy for Participation in Proficiency Testing Activities*, and ISO/IEC 17011:2004, *Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies*, clause 7.15.3
- describes the importance of PT/EQA as a tool to demonstrate technical competence in applicant and accredited laboratories
- describes the requirements for the minimum level and frequency of participation in PT/EQA
- outlines how information from applicant and accredited laboratories will be used in the decision-making process

Within the Medical Testing Laboratories program, PT/EQA is considered an important tool in demonstrating laboratory technical competence.

In applicant and accredited laboratories, the laboratory director is responsible for ensuring that formal comparison programs (such as PT/EQA) are in place to adequately challenge the performance for all tests included in the scope of accreditation. When a formal interlaboratory program is not available, laboratory management shall develop a mechanism for deciding the acceptability of methods not otherwise evaluated. This is to be included in a PT plan.

PT/EQA is defined as a formal ILC program that provides challenges of undisclosed assay value or content, and also provides the laboratory with an evaluation of the laboratory performance on submitted results, e.g., provide comparison of results for like methods and different methods with a score and/or judgment of performance.

Additional Requirements for Medical Testing Laboratories		
Clause	**Requirements**	**Guidance**
E.5.9.1.2	**Required Participation Frequency**	
E.5.9.1.2.1	PT/EQA programs shall provide a minimum of four (4) sample challenges in a 12-month period for each discipline on the scope of accreditation.	

E.5.9.1.2.2	It is the responsibility of the laboratory director or its designate to ensure that the testing schedule adequately challenges test performance, e.g., that testing is spread throughout the year.	When formal PT/EQA programs are not available, the alternative shall occur with the same frequency.
E.5.9.1.3	**Use of Laboratory Information Regarding Participation and Performance**	
E.5.9.1.3.1	Applicant and accredited laboratories shall provide information demonstrating participation in acceptable PT/EQA for all examinations included within the proposed scope of accreditation.	
E.5.9.1.3.2	Applicant and accredited laboratories shall demonstrate satisfactory performance on the majority of samples for the previous period of review.	
E.5.9.1.3.3	Applicant laboratories shall demonstrate successful PT participation prior to assessment.	
E.5.9.1.3.4	Accredited laboratories shall demonstrate the above at reassessment.	
E.5.9.1.3.5	In order to obtain and retain accreditation, laboratories shall demonstrate acceptable PT/EQA participation (or an acceptable alternative) and that corrective actions are effective in correcting unsatisfactory performance.	