



ILAC Policy for Participation in Proficiency Testing Activities

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PREAMBLE

The revision of ILAC P9 was undertaken at a time in which major activities and considerations around PT participation requirements were occurring in a number of areas. These included the preparation of ISO/IEC 17043:2010 *Conformity assessment-General requirements for proficiency testing* [1] and reviews by Regional Bodies, such as EA (through the EA/Eurolab/Eurachem – EEE – PT Working Group) and APLAC, into practical means by which PT needs for the purposes of accreditation should be identified.

It is important to note that this revision of ILAC P9 has removed the previous concept of “major sub-disciplines”, as this concept had been difficult to apply consistently. This change reflects the new trends in the use of PT in accreditation.

By way of explanation a major feature of the EA document *Guidance on the level and frequency of proficiency testing participation* (EA-4/18) [2] is the requirement that laboratories develop a PT plan. This allows laboratories to analyse their own needs and to choose the appropriate “level” and “frequency” of participation.

Another major premise of the EA document is that PT provides only one measure of competence. It indicates that it is also important that PT participation considers the level of risk attached to the testing and calibration activities of the laboratory.

APLAC has also prepared a document, *Proficiency Testing Frequency Benchmarks* (PT 006) [3]. The benchmark frequencies are a result of information obtained through a survey carried out in 2005 of APLAC members on the major sub-disciplines that are required to be covered by PT. The aim of the publication of the benchmark frequencies is to assist accreditation bodies to set their PT policies. While the document adopts a different philosophy to that of the EA document, it does provide regional “benchmarks” for PT frequency rather than a minimum requirement, and can be seen as a complementary concept.

It is also acknowledged that other sources of relevant information regarding PT and PT programs, do exist. One such example is the EPTIS database of PT programs. Accreditation bodies are therefore encouraged to seek a range of sources of information on PT.

PURPOSE

This policy sets out the requirements for accreditation bodies on the use of proficiency testing activities in the accreditation process for laboratories and where relevant, inspection bodies. There may also be regional cooperation documents relevant to proficiency testing which should be consulted.

This document is effective from the date of publication on the ILAC website.

AUTHORSHIP

This document was prepared by the ILAC Proficiency Testing Consultative Group (PTCG) on behalf of the ILAC Arrangement Committee, and was endorsed by the ILAC membership.

1. INTRODUCTION

According to ISO/IEC 17025 [4] a laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. This monitoring may include the participation in interlaboratory comparisons or proficiency testing programmes. Other means may include the regular use of reference materials, or replicate tests or calibrations using the same or different methods. By these mechanisms a laboratory can provide evidence of its competence to its clients, interested parties and the accreditation body.

ISO 15189 [5] also requires that medical laboratories seek confirmation for confidence in their results through participation in suitable interlaboratory comparisons.

2. SCOPE

This policy sets out the requirements for, and gives guidance to accreditation bodies, on the use of proficiency testing activities in the accreditation process of laboratories and where relevant, inspection bodies. It also aims to assist accreditation bodies to consistently define and apply relevant PT policies, thereby providing a tool for harmonization in the process of establishing multilateral and bilateral agreements [6, 7, 8, 9].

In the context of this document, “laboratories” implies all laboratory types – ie testing, calibration and medical laboratories.

3. TERMINOLOGY

- 3.1 Proficiency testing (PT) is the determination of the calibration or testing performance of a laboratory or the testing performance of an inspection body against pre-established criteria by means of interlaboratory comparison [1].
- 3.2 Interlaboratory comparison (ILC) is the organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories or inspection bodies in accordance with predetermined conditions [1].

4. ILAC POLICY

- 4.1 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 (see also 4.6). Where applicable, this also holds for accredited inspection bodies (IBs).

Technical competence can also be demonstrated by successful participation in interlaboratory comparisons that have been organised for purposes other than PT in its strictest sense. For example:

- to evaluate the performance characteristics of a method;
- to characterise a reference material;
- to compare results of two or more laboratories on their own initiative;

- to support statements of the equivalence of measurement of NMIs.

Guidance on the assurance of the quality of inspection activities (as referenced in clause 6.4 of ISO/IEC 17020 [10]) is provided in IAF/ILAC-A4 (2004) clause 6.4 (a-e) [9].

4.2 The minimum PT activity according to a laboratory's or inspection body's (where relevant) scope is:

- evidence of satisfactory participation prior to gaining accreditation where PT is available and appropriate;
- further and ongoing activity that is appropriate to the scope of accreditation and consistent with the PT participation plan. (The main elements of a PT participation plan are provided in 4.3 below.)

Note: Accreditation bodies should support the use of appropriate PT programmes which meet the essential requirements of ISO/IEC 17043 [1], where applicable.

4.3 ABs shall have a policy on the use of PT activities in the assessment and accreditation process. This policy shall include the following:

- a reference to the importance of PT as a tool to demonstrate laboratory and IB competence (where relevant) and to assist in maintaining the quality of the laboratory or IB performance;
- any requirements regarding the minimum level and frequency of participation in PT by accredited laboratories, including the need for a PT participation plan which has been formulated by the laboratory or inspection body (if relevant) and is regularly reviewed in response to changes in staffing, methodology, instrumentation etc;
- how PT participation and performance (in particular constantly poor performance), will be reviewed and utilised during the assessment and accreditation decision-making process. This may also include possibilities of varied surveillance intervals where performance is consistently good.

The policy shall also make reference to the following considerations:

- expectations regarding action by laboratories and inspection bodies (where relevant) in response to poor performance in PT, and any requirements for notification of this performance to the accreditation body;
- any PT requirements set by regulators, industry or professional sectors, Regional Cooperation bodies, or other interested parties.

4.4 Accreditation bodies shall fully document their policies and procedures in relation to the use of PT in accreditation (see also 4.2 and 4.6). In particular, they must be able to evaluate, through the accreditation process, that the participation in PT activities of laboratories accredited by them is effective, and that corrective actions are carried out when necessary.

Accreditation bodies shall also review the PT plans prepared by the laboratory or inspection body (where relevant) with regard to their suitability in relation to the scope of accreditation. Where these plans are not considered to be suitable it may be necessary

for the accreditation body to provide guidance in identifying the required PT coverage (see also 4.5). There may also be circumstances in which PT participation has been mandated for the purposes of accreditation, for example by a regulator, an industry or professional sector, or a Regional Cooperation Body.

4.5 Accreditation bodies may provide information that can assist laboratories in identifying and formulating their PT participation needs and plans. Annex C of ISO/IEC 17043:2010 [1] provides useful information to assist ABs in this task. Assistance may for example include:

- listings or direction to possible sources of PT, and considerations for selecting suitable programs;
- guidance on how to analyse and formulate the particular PT needs of the laboratory or inspection body (where relevant). Guidance provided could:
 - include the need to consider the compatibility of sample type and presentation provided in the PT plan, with those that are most commonly handled by the laboratory in its day to day work;
 - emphasise the fact that PT can be used as a laboratory education and risk management tool;
 - advise the need for PT participation in areas of testing, calibration or inspection (where relevant) that have been mandated for the purposes of accreditation, for example, by another body such as a regulator, industry or professional sector, or Regional Cooperation Body;
 - advise that other activities may be considered as providing useful information on the capability of the laboratory. For example, characterisation of reference materials, information obtained through method validation activities etc.

4.6 It is recognised that there are areas of testing and calibration for which suitable PT does not exist or is not practical. In such cases, the accreditation body and the laboratory shall discuss and agree on suitable alternative means by which performance can be assessed and monitored. This would need to be considered as part of the laboratory's or inspection body's (where relevant) planned PT and/or related activities.

REFERENCES

1.	ISO/IEC 17043:2010	Conformity assessment - General requirements for proficiency testing
2.	EA-4/18:2010	Guidance on the level and frequency of proficiency testing participation
3.	APLAC PT 006:09/08	Proficiency Testing Frequency Benchmarks
4.	ISO/IEC 17025:2005	General Requirements for the Competence of Testing and Calibration Laboratories
5.	ISO 15189:2007	Medical laboratories-Particular requirements for quality and competence
6.	ISO/IEC 17011:2004	General Requirements for Bodies providing assessment and accreditation of conformity assessment bodies
7.	ILAC-G10:1996 (under review)	Harmonised Procedures for Surveillance and Reassessment of Accredited Laboratories
8.	IAF/ILAC A2:2010	IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Single Accreditation Body
9.	IAF/ILAC A4:2004	Guidance on the Application of ISO/IEC 17020
10.	ISO/IEC 17020:2004	General criteria for the operation of various types of bodies performing inspection