

1. Purpose / Scope

This technical rule describes the implementation of international and regional requirements for the inclusion of proficiency tests (PT) into the GAC accreditation process of testing and calibration laboratories, medical laboratories, if applicable, inspection bodies (known as conformity assessment bodies – referred in this policy as CAB).

Benefits of the PT

Proficiency tests are an essential instrument of the quality assurance in laboratories (to comply with requirements of ILAC P9 and ISO/IEC 17025 / ISO 15189 and where applicable under ISO/IEC 17020) and if applicable in inspection bodies. It provides an opportunity to review the validity of the results of the activities for which a CAB is accredited or otherwise seeking accreditation:

The benefits of PT include, but are not limited to, the following:

- ☀ comparison of a CAB's performance with other CABs;
- ☀ evaluation of methods if fit for the purpose, (method's precision and accuracy),
- ☀ contribution to estimation of measurement uncertainty;
- ☀ monitoring of a CAB's long-term performance,
- ☀ staff education, training and competence monitoring;
- ☀ contribution to a CAB's overall risk management process;
- ☀ confidence building with interested parties (e.g., customers, accreditation bodies, regulators)

2. Terms / Definitions

- **Proficiency Testing, PT:** Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO/IEC 17043).
- **Interlaboratory Comparison, ILC:** 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).
- **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).
- **Property:** The quantity being measured (e.g. Arsenic, Fat, Creatinine, Length, Hardness, and Force).
- **Product:** The item that the measurement technique is being applied. (e.g. Soil, Vegetables, Serum, Polystyrene, Concrete).
- **Level of Participation:** The number of categories that an organization identifies within its scope, and therefore the number of specific proficiency tests that should be considered for participation.
- **Frequency of Participation:** Interval for participation in a proficiency test for each category. Intervals may vary however shall be at minimum frequency as defined in the procedure below.
- **Category:** such as chemical, microbiological, mechanical, where 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).
- **Technical adequacy of proficiency tests:** A proficiency test is regarded as technically adequate, if its scope similar to the daily practice in the participating body. In case of specific measurement techniques, for which no exact consistent proficiency test is available, it may be adequate to choose a proficiency test, which is similar to the scope or which covers an important partial aspect of the task.

3. Description

This document summarizes the international requirements and interprets them, if necessary, to ensure a basis for the harmonized procedure of the assessment of laboratories and inspection bodies.

3.1 Requirements for the CAB for participation in proficiency tests/interlaboratory comparisons

It is the responsibility of CABs to check the availability of appropriate PT programs which best matches their activities in the scope of accreditation.

Accredited and applicant conformity assessment bodies are required to participate in suitable PT activities successfully when PT is available.

For some areas of testing and calibration suitable PT does not exist or is not practical or economically not feasible. In such cases, GAC and the laboratory (or where relevant the inspection body) discuss and agree on suitable alternative means by which performance can be assessed and monitored in order to confirm the quality and validity of results. The discussion can involve GAC File Manager /assessment team and the competent staff of the lab. When necessary, the technical support from GAC assessors may be requested.

The alternative measures (as available) that can be acceptable to GAC are as follows but not limited to the following:

- Participate in interlaboratory comparison (ideally involving two other (*bilateral*) or more laboratories),
- Use of certified reference materials (*reference materials may also be acceptable however where practicable, compliance of the reference material procedure with requirements of the ISO 17034 should be established*),
- Use of RPD (relative percent difference), using repeatability and or reproducibility,

❖ Frequency of Participation and Planning

CABs are required to have plan for PT participation that should cover the overall respective scope in span of 4-years (if a CAB has a plan of less years e.g., 3year or 2year plan however covering the overall scope is also acceptable).

Before gaining accreditation, GAC requires successful participation in at least one proficiency test from each category (categories such as chemical, microbiological, mechanical....) where applicable and available.

To be accepted by GAC, results have to be no more than 4 years old from the date of application by the CAB, but also it is required to prove that those results are referring to relevant methods and facilities as requested in the application.

N.B: For calibration, laboratories must participate in PT schemes that are suitable for the claimed CMC in the requested scope (e.g., PT for Mass calibration class M_1 is not acceptable for lab applying for Mass calibration class E_2).

CABs are encouraged to participate in proficiency testing programs as often as possible, the extent and the increased frequency of participation in proficiency tests for a specific category needs to be determined by the CAB considering sectoral and other external requirements for participation in proficiency tests, further aspects should be considered as applicable, such as:

- Requirements on the basis of laws/ regulations in the context of regulatory recognitions/approvals etc.;
- Internal measures for quality assurance as the use of CRM, use control charts, application of different methods for the determination of the same parameter, etc.;
- The potential risk of false results within the respective category;
- The quantity of the performed tests/calibrations/inspections and also the significance and the effect on the final use of the results;
- The qualification of the personnel.

In case of application for extension of the scope, PT requirements stated above are applicable however if the extension of the scope is close to the already accredited scope domain e.g., if accredited for heavy metals and want

to add more metals, likewise Pesticides, or for example accredited for E. coli in water and extending for Coliforms or other likely indicator organisms, the previous participations on accredited domains are acceptable.

❖ Selection of Proficiency Testing Providers and Programmes

CABs must ideally consider and are highly advised to select the PT providers that are accredited to ISO/IEC 17043). Where accredited PT programs are not available, PT Programs provided by non-accredited providers may be considered however when practicable, the compliance of non-accredited PT providers with the requirements of ISO/IEC 17043 should be established.

GAC may also invite its accredited or applicant CABs to participate in the Asia Pacific Metrology Program (APMP) and Asia Pacific Accreditation Cooperation (APAC) joint proficiency testing programs from time to time as and when they are made available. These programs are run with the aim of enhancing the quality and traceability of measurements in various economies of the Asia-Pacific region and support the APAC Mutual Recognition Arrangement (MRA).

❖ Review of Proficiency Testing participation and performance

CAB's PT participation and its performance in the PT programs, any associated corrective actions related to the PT participation, are reviewed by GAC during the assessment (initial assessment and assessments incurred during the cycle of accreditation).

GAC requires the CABs to provide information on PT participation for which data is filled out in the tab-3 of the AC 4.2 sheet used for assessment records.

If a CAB does not participate or participates only partially in PT/ILC, which are available and adequate then it might have consequences for the accreditation of the CAB. In principle insufficient participation in a single proficiency test does not have immediate consequences for the accreditation. Incorrect or insufficient (including those questionable) PT results need to be processed as nonconformity. In case the participation in PT is not sufficient or is continuously unsuccessful, further proficiency tests or additional assessments may be imposed, also a restriction of the accreditation scope may be envisaged.

3.2 Useful links to available proficiency testing programs for member countries

Worldwide PT Database, a PT search engine: (<http://www.eptis.bam.de>)

GSO: <https://www.gso.org.sa/en/conformity/proficiency-testing/>

APAC PT master list: <https://www.apac-accreditation.org/publications/tec2-series/>

4. Applicable documents

- ISO/IEC 17011: Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies
- ISO/IEC 17020: Conformity assessment — Requirements for the operation of various types of bodies performing inspection
- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
- ISO 15189 Medical laboratories - Requirements for quality and competence
- ISO/IEC 17043: Conformity assessment – General requirements for proficiency testing
- ILAC P9: ILAC Policy for Participation in Proficiency Testing Activities
- AC 4.2 Nonconformity Sheet and Assessment report (tab-3)