



**MINISTRY OF INVESTMENT, TRADE AND INDUSTRY
DEPARTMENT OF STANDARDS MALAYSIA**

**ACCREDITATION POLICY 6 (AP6) -
POLICY FOR PARTICIPATION IN PROFICIENCY
TESTING ACTIVITIES**

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**JABATAN STANDARD MALAYSIA
DEPARTMENT OF STANDARDS MALAYSIA**

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Introduction

Proficiency testing (PT) is used as part of the assessment process to assess the ability of conformity assessment bodies (CABs) to competently perform tests/calibrations/inspections for which accreditation is held. The requirements of this document are derived from the requirement of ILAC P9 - ILAC Policy for Participation in Proficiency Testing Activities.

1 Scope

1.1 This document outlines the policy of the Department of Standards Malaysia (JSM) with regards to PT participation requirements imposed upon applicants and laboratories accredited under the *Skim Akreditasi Makmal Malaysia* (SAMM) and Primary Healthcare Laboratory Accreditation Scheme (PHLAS) and where feasible and applicable, applicants and inspection bodies accredited under the Malaysia Inspection Bodies Accreditation Scheme (MIBAS).

1.2 This policy document shall be read in conjunction with the relevant Specific Criteria, Specific Technical Requirement and policy documents governing the SAMM, MIBAS and PHLAS.

2 Normative reference

2.1 ISO/IEC 17011, Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies.

2.2 ISO/IEC 17043, Conformity assessment - General Requirements for the competence of proficiency testing providers.

2.3 ILAC P9, ILAC Policy for participation in proficiency testing activities.

Note: Unless otherwise specified, reference to the latest edition of the document applies.

3 Definitions

For the purpose of this document, the following terms and definitions apply.

3.1 Proficiency testing

Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

[Source: ISO/IEC 17043:2023]

3.2 Interlaboratory comparison

Design, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

[Source: ISO/IEC 17043:2023]

3.3 Proficiency testing provider

Organisation which takes responsibility for all activities in the development and operation of a proficiency testing scheme.

[Source: ISO/IEC 17043:2023]

3.4 Outlier

Member of a set of values which is inconsistent with other members of that set.

[Source: ISO/IEC 17043:2023]

3.5 Measurement audit

A well characterised and calibrated artifact is usually sent to only one laboratory where their results are compared to a reference value which is normally supplied by a national metrology institute.

3.6 Central Conformity Assessment Body (CAB)

The premise where the management system is managed and administered. A Central CAB may or may not conduct conformity assessment activities. The Central CAB manages one or more branches or sites at which conformity assessment activities are carried out. All branches or sites are under the same legal entity with the Central CAB and implement the same management system.

3.7 Branch

Branch is a premise at a different location conducting conformity assessment activities, which is controlled and managed by the Central CAB. Branch implements the same management system and is owned by the same legal entity as the Central CAB. Branch may manage one or more sites.

4 Participation in proficiency testing activities

4.1 General

Applicant and accredited conformity assessment bodies (CABs) under SAMM/MIBAS/PHLAS shall demonstrate their technical ability by demonstrating satisfactory performance through participation in PT activities, where available.

In the context of this document PT activities include Proficiency Testing (PT), Interlaboratory Comparison (ILC), External Quality Assessment (EQA) and Measurement Audit (MA) programmes.

4.1.1 The requirements for applicant and accredited CABs in participation of proficiency testing activities are as follow: -

- a) It is the CAB's responsibility to seek for the relevant PT activity related to its scope of accreditation.
- b) Proficiency test items shall not be subcontracted to another CAB for analysis/measurement.
- c) The CAB shall afford JSM and its assessors, access to records pertaining to PT activities and shall allow such persons to verify the appropriateness and effectiveness of the corrective actions and/or preventive action(s) implemented by the CAB. The verification exercise will be conducted during assessment.
- d) The CAB shall bear all the costs, participation charges or fees incurred in the participated PT activities.

- e) The CAB shall participate in any PT programme when directed by JSM. Refusal to participate may result in full or partial suspension of the CAB's scope of accreditation.

4.2 PT programmes

Acceptable PT programmes are preferably those operating in accordance to ISO/IEC 17043. Information on PT programmes can be accessed through JSM website at www.jsm.gov.my.

4.3 Hierarchy of PT activity participation

4.3.1 The participation of a CAB in a PT activity shall be selected, depending on its availability and taking cost into account, according to the following decreasing order of preference:

- a) International/Regional/National PT programmes organised by International/Regional cooperation bodies, PT providers including those mandated by regulators. This includes Measurement Audits.
- b) Formal interlaboratory comparison programmes involving several independent CABs (e.g. organised by associations, professional bodies, etc.).
- c) Less formal interlaboratory comparison programmes that consists of a minimum of three (3) CABs. The other participating CABs shall be accredited. For a calibration laboratory, the laboratory shall select participating laboratories with accredited Calibration and Measurement Capability (CMC) better than or of equivalent to its own.

Note: In the case of unavailability of accredited testing laboratories/inspection bodies for the interlaboratory comparison programmes, the use of non-accredited testing laboratories/inspection bodies may be considered.

4.4 PT activities

4.4.1 An applicant CAB or applicant for extension of accreditation for branch shall participate in at least one available PT activity relevant to its applied scope for each field. The fields of accreditation are as listed in Annex A. The CAB shall achieve satisfactory performance in all the PT activities it has participated before accreditation can be considered.

4.4.2 An accredited CAB shall participate in at least one available PT activity relevant to its scope of accreditation for each field within three (3) years. The CAB shall achieve satisfactory performance in all the PT activities it has participated.

Note: For medical testing laboratories, the term 'external quality assessment' or 'interlaboratory comparison' is used for proficiency testing

4.4.3 The minimum requirement of one PT participation shall also apply to a CAB applying for an extension of scope of accreditation:

- a) In a new field(s);

- b) In the same field of testing or calibration or inspection (where applicable) that involves different materials/matrices/product types, parameters or technique and/or that requires a significantly different level of technology/skill/competency.

4.4.4 In addition to the minimum requirements of clause 4.4.1, 4.4.2 and 4.4.3, the CAB shall plan PT activities and participate in as many as possible in the same field based on material or parameter tested or technique used or level of skill/competence required for better representation of PT participation within three (3) years.

4.4.5 JSM reserves the right to request the CAB to participate in additional PT activities should the situation arises in the following circumstances and not limited to:

- a) Change of scope of accreditation (e.g. due to changes of test method or techniques); and/or
- b) CAB PT performance

4.5 PT participation plan

4.5.1 An applicant CAB shall submit its PT participation plan during compliance assessment.

An accredited CAB shall submit a PT participation plan during reassessment.

The plan shall cover all the PT activities, the CAB including branches it intends to participate/undertake over the accreditation cycle. The PT participation plan will be reviewed and endorsed by the assessment team to ensure its suitability. CABs are obliged to inform JSM of any changes to this plan.

4.5.2 The following aspects should be taken into consideration when determining the suitability of a CAB's level and frequency of participation:

- a) The material or parameter tested or technique used or level of skill / competence required in each of the fields under its scope of accreditation and that the PT activities shall cover all the fields within three (3) years. (see 4.4.4).
- b) The level of risk presented by the CABs, the sector in which they operate or the methodology they are using. This can be determined by considering the following examples but not limited to:
 - i) Number/type of tests/calibrations/measurements undertaken;
 - ii) Turnover of technical staff;
 - iii) Experience and knowledge of technical staff;
 - iv) Source of traceability (e.g. availability of reference materials, national standards, etc.);
 - v) Known stability/instability of the measurement technique;
 - vi) Significance and final use of testing/calibration data (e.g. forensic science represents an area requiring a high level of assurance).

4.6 Consequences of unsatisfactory results of PT activities

4.6.1 If the CAB obtains unsatisfactory results in a PT activity, it shall carry out appropriate corrective actions. The effectiveness of corrective actions will be verified in the next assessment.

4.6.2 If the CAB continues to obtain unsatisfactory results, JSM may initiate further action which may include but not limited to the following:

- a) Direct the CAB to participate in additional PT activities; and/or
- b) Conduct a verification assessment; and/or
- c) Increase frequency of assessment (shorter interval); and/or
- d) Full or partial suspension of the CAB's scope of accreditation.

4.7 Confidentiality

All information supplied by a CAB as part of a PT activity is treated as confidential. This information is made available to relevant JSM assessors, Accreditation Evaluation Panel (EP) members and international evaluators from Asia Pacific Accreditation Cooperation (APAC).

Annex A – List of Fields

The detailed breakdown of the scope of accreditation/classes of test or product/discipline under the fields listed below is as specified in the respective Specific Criteria/Specific Technical Requirements.

Fields of Testing

- 1) Chemical
- 2) Biological
- 3) Microbiological
- 4) Genetically Modified Organism (GMO)
- 5) Nucleic Acid
- 6) Bioefficacy
- 7) Thermal
- 8) Radioactivity
- 9) Forensic Science
- 10) Electrical, Radio Frequency and Electromagnetic Compatibility
- 11) Mechanical
- 12) Non-Destructive Testing (NDT)
- 13) Physical
- 14) Veterinary
- 15) Toxicity
- 16) Information Technology Security Evaluation and Testing: Common Criteria
- 17) Software Testing
- 18) Network Testing
- 19) Others

Fields of Calibration

- 1) Heat and Temperature
- 2) Electrical
- 3) Mass
- 4) Density
- 5) Pressure
- 6) Force
- 7) Torque
- 8) Hardness
- 9) Viscosity
- 10) Flow
- 11) Volume
- 12) Gravity
- 13) Optical and Photometric
- 14) Dimensional
- 15) Acoustic & Vibration
- 16) Radioactivity
- 17) Others

Fields of Medical Testing

- 1) Cytopathology
- 2) Histopathology
- 3) Chemical Pathology
- 4) Haematology
- 5) Medical Microbiology
- 6) Assisted Reproductive Technology
- 7) Cytogenetics
- 8) Medical Molecular Testing
- 9) Others

Fields of Inspection

- 1) Automotive
- 2) Engineering Inspection
- 3) Manufactured Good (Preshipment & Postshipment)
- 4) Non-Destructive Testing (NDT) Services
- 5) Building & Construction
- 6) Industrial Waste inspection
- 7) Cargo Inspection
- 8) Factory Audits
- 9) Electromagnetic Radiation
- 10) Electrochlorination System
- 11) Road Safety Inspection (RSI)
- 12) Others

Bibliography

- a) MS ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
- b) MS ISO 15189, Medical laboratories - Requirements for quality and competence
- c) MS ISO/IEC 17020, Conformity assessment - Requirements for the operation of various types of bodies performing inspection
- d) EA-4/18, Guidance on the level and frequency of proficiency testing participation
- e) A2LA R103 - General requirements: Proficiency testing for ISO/IEC 17025 laboratories
- f) IANZ Specific Criteria for accreditation Metrology and Calibration