



STANDARDS
MALAYSIA

SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)
LABORATORY ACCREDITATION SCHEME OF MALAYSIA



SAMM POLICY 4 (SP4) -
POLICY FOR PARTICIPATION IN PROFICIENCY TESTING
ACTIVITIES

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JABATAN STANDARD MALAYSIA
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1 INTRODUCTION

Proficiency testing (PT) is used as part of the assessment process to assess the ability of laboratories/inspection bodies to perform competently tests/calibration/inspection 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.

2 AIM AND SCOPE OF APPLICATION

- 2.1 This document outlines the policy of the Department of Standards Malaysia (Standards Malaysia) with regards to PT participation requirements imposed upon applicant and laboratories accredited under the *Skim Akreditasi Makmal Malaysia* (SAMM) and where feasible and applicable, applicant and inspection bodies accredited under the Malaysia Inspection Bodies Accreditation Scheme (MIBAS).
- 2.2 This policy document should be read in conjunction with the relevant Specific Criteria, Specific Technical Requirement and policy documents governing the SAMM/MIBAS scheme.
- 2.3 For medical testing laboratory, this document shall be read together with SC 2 - Specific Criteria for Accreditation in the Field of Medical Testing. In the field of medical testing the term “external quality assessment” is used for proficiency testing.
- 2.4 For medical molecular testing laboratory, this document shall be read together with SC 2.1 – Specific Criteria for Accreditation in the Field of Medical Molecular Testing.

3 TERMS AND DEFINITIONS

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

- a) **Proficiency testing**
Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.
- b) **Interlaboratory comparison**
Organisation, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.
- c) **Proficiency testing provider**
Organisation which takes responsibility for all tasks in the development and operation of a proficiency testing scheme.
- d) **Outlier**
Observation in a set of data that appears to be inconsistent with the remainder of that set.

e) **Measurement audit**

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

f) **Branch laboratory**

(A) permanent laboratory(ies) at a different location managed by the central laboratory/office with the same management system and owned by the same legal entity.

4 PARTICIPATION IN PROFICIENCY TESTING ACTIVITIES

4.1 General

Applicant and accredited laboratories/inspection bodies under SAMM/MIBAS shall demonstrate their technical ability by satisfactory 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.

4.2 PT programmes

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

4.3 PT activities

- a) An applicant laboratory/inspection body 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 laboratory/inspection body shall achieve satisfactory performance in all the PT activities it has participated, before accreditation can be considered.
- b) An accredited laboratory/inspection body shall participate in at least one available PT activity relevant to its scope of accreditation for each field within one accreditation cycle. The laboratory/inspection body shall achieve satisfactory performance in all the PT activities it has participated.
- c) The minimum requirement of one PT participation shall also apply to a laboratory/inspection body applying for an extension of scope of accreditation:
 - i) in a new field(s);
 - ii) 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.

- d) In addition to the minimum requirements (a), (b) and (c), the laboratory/inspection body shall plan and participate in as many PT activities 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 one accreditation cycle.
- e) The participation of a laboratory/inspection body in a PT activity shall be selected, depending on its availability and taking cost into account, according to the following decreasing order of preference:
 - i) International/Regional/National PT programmes organised by International/Regional cooperation bodies, accreditation bodies, PT providers including those mandated by regulators. This includes Measurement Audits.
 - ii) Formal interlaboratory comparison programmes involving several independent laboratories/inspection bodies (e.g. organised by association, professional bodies, etc.).
 - iii) Less formal interlaboratory comparison programmes between two or more accredited laboratories/inspection bodies initiated by the laboratory/inspection body. 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 testing laboratories/inspection bodies where accredited testing laboratories/inspection bodies are not available for the interlaboratory comparison programmes, the use of non-accredited testing laboratories/inspection bodies may be considered.
- f) Standards Malaysia reserves the right to request the laboratory/inspection body to participate in additional PT should the situation arises in the following circumstances and not limited to:
 - i) Change of scope of accreditation (e.g. due to changes of test method or techniques); and/or
 - ii) Laboratory/inspection body's PT performance.

4.4 PT participation plan

- 4.4.1 An applicant laboratory/inspection body shall submit its PT participation plan for the first accreditation cycle during compliance assessment.

An accredited laboratory/inspection body shall prepare a PT participation plan for the next accreditation cycle during reassessment.

The plan shall cover all the PT activities, the laboratory/inspection body including branch 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. Laboratories/inspection bodies are obliged to inform Standards Malaysia of any changes to this plan.

4.4.2 The following aspects should be taken into consideration when determining the suitability of a laboratory/inspection body'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 one accreditation cycle. [Please see 4.3 d) also].

Note:

1. For a medical testing laboratory, the laboratory shall comply with the requirements of SC 2.
2. For a medical molecular testing laboratory, the laboratory shall comply with the requirements of SC 2.1.

- b) The level of risk presented by the laboratory/inspection body, the sector in which they operate or the methodology they are using. This can be determined, for example, by considering:

- 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)

4.5 Obligations of the laboratories/inspection bodies

- a) It is the laboratory/inspection body's responsibility to seek for the relevant PT programme related to its scope of accreditation.
- b) The laboratory/inspection body shall participate in any PT programme when directed by Standards Malaysia. If the laboratory/inspection body is unable to participate it may seek for exemption from Standards Malaysia. Standards Malaysia may grant exemption of participation in a PT subject to Director of Accreditation's discretion.
- c) Refusal to participate may result in full or partial suspension of the laboratory/inspection body's scope of accreditation.

- d) PT samples/artefacts shall not be subcontracted to another laboratory/inspection body for analysis/measurement.
- e) The laboratory/inspection body shall afford Standards Malaysia 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 laboratory/inspection body. The verification exercise will be conducted during assessment.

4.6 Consequences of poor performance

- a) If the laboratory/inspection body obtains unsatisfactory result in a PT programme, it shall carry out appropriate corrective actions and take part in the next available PT programme and demonstrate acceptable performance.
- b) If the laboratory/inspection body continues to obtain unsatisfactory result Standards Malaysia may initiate further actions which may include, but not limited, to the following:
 - i) Direct the laboratory/inspection body to participate in additional PT; and/or
 - ii) Conduct a verification assessment; and/or
 - iii) Increase frequency of assessment (shorter interval); and/or
 - iv) Full or partial suspension of the laboratory/inspection body's scope of accreditation.

4.7 Confidentiality

All information supplied by a laboratory/inspection body as part of a PT programme is treated as confidential. This information is made available to relevant Standards Malaysia assessors, Laboratory Accreditation Evaluation Panel (LAEP)/Inspection Accreditation Evaluation Panel (IAEP) members and international evaluators from Asia Pacific Accreditation Cooperation (APAC).

4.8 Participation fees

Laboratories/inspection bodies shall bear all costs, participation charges or fees incurred in the participated PT activities.

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. Electrical
4. Thermal
5. Mechanical
6. Non-Destructive Testing (NDT)
7. Radioactivity
8. Veterinary
9. Forensic Science
10. Information and Communication Technologies (ICT)
11. Others

Fields of Calibration

1. Heat and Temperature
2. Electrical
3. Mass and Mass-Related Quantities (density, pressure, force, torque, hardness, viscosity, flow, and volume)
4. Optical and Photometric
5. Dimensional
6. Acoustic & Vibration
7. Radioactivity
8. Others

Fields of Medical Testing

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

Fields of Inspection

1. NDT Inspection
2. Welding Inspection
3. Vehicle Inspection
4. Shop Inspection
5. Manufactured Goods
6. Factory Audits
7. Electrical Products
8. Others

Bibliography

- a) ISO/IEC 17011, Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies
- b) ILAC P9, ILAC Policy for participation in proficiency testing activities
- c) MS ISO/IEC 17043, Conformity assessment – General requirements for proficiency testing
- d) MS ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
- e) MS ISO 15189, Medical laboratories – Requirements for quality and competence
- f) MS ISO/IEC 17020, Conformity assessment – Requirements for the operation of various types of bodies performing inspection
- g) EA-4/18, Guidance on the level and frequency of proficiency testing participation
- h) A2LA R103 – General requirements: Proficiency testing for ISO/IEC 17025 laboratories
- i) IANZ Specific Criteria for accreditation Metrology and Calibration
- j) SC 2 – Specific criteria for accreditation in the field of medical testing
- k) SC 2.1 - Specific criteria for accreditation in the field of medical molecular testing