MINISTRY OF INVESMENT, TRADE AND INDUSTRY
JABATAN STANDARD MALAYSIA

SC 1 - SPECIFIC CRITERIA FOR ACCREDITATION OF PROFICIENCY TESTING PROVIDERS

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(Supplementary to MS ISO/IEC 17043)

MALAYSIA PROFICIENCY TESTING PROVIDER ACCREDITATION SCHEME (MyPTP)

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Introduction

This document defines the specific criteria for the accreditation of proficiency testing (PT) providers. It shall be read in conjunction with MS ISO/IEC 17043, relevant accreditation policies and criteria of Department of Standards Malaysia (JSM) as well as any applicable regulatory requirements.

The clause numbers in this document correspond to the clauses of MS ISO/IEC 17043 but since not all clauses require supplementary requirements, the numbering may not be continuous.

1 Scope

The specific criteria contained in this document sets out the supplementary requirements to those of MS ISO/IEC 17043.

2 Normative references

i) MS ISO/IEC 17043:2023 - Conformity assessment - General requirements for the competence of proficiency testing providers.

ii) SAMM Policy (SP) 2 - Policy on the Metrological Traceability of Measurement Results.

iii) Accreditation Policy (AP) 2 - Terms and Conditions Governing the Department of Standards Malaysia’s Accreditation Schemes.

3 Terms and definitions

Same as MS ISO/IEC 17043.

4 General requirements

4.1 Impartiality

Same as MS ISO/IEC 17043.

4.2 Confidentiality

Same as MS ISO/IEC 17043.

5 Structural requirements

5.5 a) The PT provider shall clearly describe the roles and relationships of the PT provider with other relevant parties, including its external providers.

6 Resource requirements

6.1 General

6.1.2 Measurement or tests conducted under the responsibility of the PT provider related to PT item characterisation and/or assessing homogeneity and stability, shall be conducted by an accredited MS ISO/IEC 17025 laboratory and/or in the medical area, by an accredited MS ISO 15189 laboratory, unless the PT provider has valid reasons for not doing so.

6.1.3 Where the PT item is a material that meets the definition of reference material, it shall be provided by an accredited ISO 17034 reference material producer and/or in the medical area, reference material compliant to ISO 15194 shall be used, unless the PT provider has valid reasons for not doing so.

6.2 Personnel

6.2.5 The approved signatory shall meet the following requirements:

i) Qualification and experience:
   1) Degree in science or relevant technical discipline with at least 12 months working experience in relevant fields. For PT schemes in the areas of calibration and testing, working experience shall include laboratory experience; and
   2) Working at least 6 months in a PT provider(s) including at least 3 months in the current PT provider.

ii) Relevant knowledge:
   1) Knowledge and understanding of the requirements of MS ISO/IEC 17043 and all related accreditation criteria including this document;
   2) Knowledge and understanding of PT provider management systems; and
   3) Knowledge of relevant statistical methods.

iii) Relevant regulatory requirements, if any.

6.3 Facilities and environmental conditions

Same as MS ISO/IEC 17043.

6.4 Externally provided products and services

6.4.2 The PT provider shall document procedures to ensure that only suitable and competent external providers are used for the tasks to be assigned to them.

For testing and calibration services, external providers fulfilling the requirements of MS ISO/IEC 17025 and/or MS ISO 15189 (or equivalent) in relevant scope are considered to be competent.

7 Process requirements

7.1 Establishing, contracting and communicating the PT scheme objectives

7.1.1 Review of requests, tenders and contracts

Same as MS ISO/IEC 17043.

7.1.2 PT scheme communication

7.1.2.1 The PT provider may issue statements of participation or performance to individual participants. However, the full participant list shall not be published or revealed to other participants to protect confidentiality and avoid potential collusion. In some cases, it may be appropriate to advise target ranges prior to testing. Records of communication with participants shall be maintained with controlled access to authorised personnel.

7.2 Design and planning of a PT scheme

7.2.1 General

7.2.1.1 The design of a PT scheme covers the planning, statistical design and determination of assigned values.

PT provider shall not use external service providers for the design and planning of PT schemes. However, the PT provider can seek input and advice from experts or advisory groups (however named) on the planning requirements and other matters related to PT schemes.

7.2.2 Statistical design

Same as MS ISO/IEC 17043.

7.2.3 Determination of assigned values

Assigned values for PT schemes in the area of calibration shall demonstrate metrological traceability to national or international standards in accordance with SAMM Policy (SP) 2 - Policy on the Metrological Traceability of Measurement Results.

7.2.3.2 In PT schemes where reference materials are used by a PT provider the assigned values shall demonstrate suitable traceability through:

i) Reference material producers accredited by JSM or one of JSM’s Mutual Recognition Arrangements (MRA) partners, when the MRA recognition covers reference material producers and the results of the reference materials are reported on endorsed reports or certificates; or

ii) National Metrology Institutes or Designated Institutes with the relevant calibration and measurement capabilities listed in Appendix C of the International Bureau of Weights and Measures Key Comparison Database (BIPM KCDB) under the International Committee for Weights and Measures Mutual Recognition Arrangement (CIPM MRA); or

iii) Where there are no readily available reference material producers as described in i) and ii), a competent supplier who can demonstrate traceability of its reference material(s) using specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

7.2.3.3 For PT schemes in areas other than calibration, the above criteria for metrological traceability of assigned values shall apply where it is relevant, feasible and applicable. The PT provider shall document the justification or reasons in cases where metrological traceability need not be demonstrated.

7.3 Production and distribution of PT items

Same as MS ISO/IEC 17043.

7.4 Evaluation and reporting of PT scheme results

7.4.1 Data analysis

The PT provider shall be responsible for any data analysis and processing performed by external service providers.

7.4.3 PT reports

All preliminary and/or final reports shall be authorised by an approved signatory of the PT provider.

7.5 Control of the PT scheme process

7.5.3 Surveillance of the processes

After completion of each PT scheme, surveillance of processes shall be conducted once in 12 months or before the following cycle of the PT scheme concerned to ensure the continuous validity and improvement of the PT scheme.

7.6 Handling of complaints

Same as MS ISO/IEC 17043.

7.7 Handling of appeals

Same as MS ISO/IEC 17043.

8 Management system requirements

8.1 General requirements

Same as MS ISO/IEC 17043.

8.2 Management system documentation

Same as MS ISO/IEC 17043.

8.3 Control of management system documents

Same as MS ISO/IEC 17043.

8.4 Control of records

8.4.1 The PT provider shall establish and retain legible quality and technical records related to the PT activities concerned.

Records shall be retained by the PT provider for a period as specified in Accreditation Policy (AP) 2 - Terms and Conditions Governing the Department of Standards Malaysia's Accreditation Schemes unless otherwise prescribed by law or contractual obligations.

As far as practicable, all raw data or observations shall be indelible and recorded in such a manner that prevents alteration. Where data processing systems are used, the raw data shall be retained unless such data are automatically fed directly into the processing system. Evidence of counterchecking data transcribed from recorded raw data shall be available.

8.5 Actions to address risks and opportunities

Same as MS ISO/IEC 17043.

8.6 Improvement

The PT provider shall seek feedback, both positive and negative, from its participants, customers and personnel involved in the PT activities once in 12 months.

8.7 Corrective actions

Same as MS ISO/IEC 17043.

8.8 Internal audits

The PT provider shall conduct internal audits once in 12 months to ensure the management system is effectively implemented and maintained.

8.9 Management reviews

The PT provider management shall review its management system once in 12 months to ensure its continuing suitability, adequacy and effectiveness.

Bibliography

1. MS ISO/IEC 17025 - General Requirements for The Competence of Testing and Calibration Laboratories.

2. MS ISO/IEC 17020 - Conformity Assessment - Requirements for The Operation of Various Type of Bodies Performing Inspection.

3. MS ISO 15189 - Medical Laboratories - Requirements for Quality and Competence.

4. ISO 13528 - Statistical Methods for Use in Proficiency Testing by Interlaboratory Comparisons.

5. ISO 17034 - General Requirements for The Competence of Reference Material Producers.

6. ILAC P9 - ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing.

7. ISO 15194 - In vitro diagnostic medical devices.

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