



STANDARDS
MALAYSIA

**MALAYSIA PROFICIENCY TESTING PROVIDER ACCREDITATION
SCHEME (MyPTP)**

**SC 1 - SPECIFIC CRITERIA FOR ACCREDITATION OF
PROFICIENCY TESTING PROVIDERS**

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(Supplementary to MS ISO/IEC 17043)



MS ISO/IEC 17043

**JABATAN STANDARD MALAYSIA
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Introduction

MS ISO/IEC 17043 specifies the general requirements for the competence of proficiency testing providers (PTPs). These requirements are designed to apply to all fields of proficiency testing (PT) and therefore need to be interpreted with respect to the type of PT concerned and the techniques involved.

This document defines specific criteria for the assessment and accreditation of PTPs. It shall be read in conjunction with MS ISO/IEC 17043. PTPs shall comply with all of the relevant requirements in MS ISO/IEC 17043 and any relevant statutory or legislative requirements.

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

1 Scope

This document shall apply to the accreditation of PTPs and shall be read in conjunction with MS ISO/IEC 17043.

2 Normative references

The following referenced document is indispensable for the application of this document.

MS ISO/IEC 17043:2010, Conformity assessment - General requirements for proficiency testing.

3 Terms and definitions

Same as in MS ISO/IEC 17043.

4 Technical requirements

4.1 General

Where a PTP or its subcontractor(s) is involved in carrying out testing, calibration and inspection activities to support its PT scheme(s), accreditation to MS ISO/IEC 17025 or MS ISO 15189 or MS ISO/IEC 17020 as appropriate for those activities is sufficient evidence for demonstration of competence.

When reference materials are used by a PTP or its subcontractor(s), they shall

be produced by competent reference material producers. Competent reference material producers are 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). Reference Material Producers (RMPs) that meet the requirements of ISO 17034 are considered to be competent.

4.2 Personnel

- a) Relevant technical personnel shall have demonstrated competence to make necessary measurements (e.g. homogeneity and stability testing on test items).
- b) Job description for key personnel of the PTP shall be clearly documented in terms of their duties and responsibilities.
- c) PT reports shall be authorised by a signatory nominated by the PTPs. The approved signatory shall be either employed by, or under contract to, the PTP. The person shall have in-depth understanding of the operation of the PT schemes and the relevant MyPTP requirements. It is the responsibility of PTP to ensure the competency and the authorisation of approved signatory.
- d) The PTP shall have a procedure for determining the competence criteria and the approval process of the signatories. Competence criteria shall be determined with regard to qualification, training, experience and a satisfactory knowledge of the requirements of the PT activities.
- e) An accredited PTP shall maintain the list of their current approved signatories.
- f) An approved signatory listed by a PTP will be verified by Standards Malaysia assessors during compliance assessment or extension of scope assessment.
- g) During surveillance assessment or reassessment, Standards Malaysia assessor(s) shall review the list of approved signatories and if necessary, assess their competency.
- h) The approved signatory shall meet the following requirements:
 - i) Legal requirements that may be applicable;
 - ii) Qualification and experience:

- Degree in science or relevant technical discipline with at least 12 months working experience in relevant fields/PT;
 - Working at least 3 months in the current PTP and be knowledgeable of its management system;
- iii) Relevant knowledge:
- Technical knowledge and understanding of MS ISO/IEC 17043 and all related MyPTP requirements and relevant regulatory requirements;
 - Knowledge of statistical methods; and
- iv) Knowledge and understanding of technical and operational requirements of the PTP.
- i) When external advisory groups (or however named) are used, written arrangements shall be made. Such arrangements shall include, amongst others, the roles, functions, responsibilities and authorities of the groups, their establishment and operation procedures as well as the arrangements on how the advice is to be acted upon by the PTP. There shall be effective communication between the PTP and its advisory groups. The relationship between these groups and the PTP shall be clearly defined and shown in the organisation and management structure.

4.3 Equipment, accommodation and environment

The PTP may make use of its own testing and measurement facilities or the testing or measurement services provided by its subcontractors. See also the specific criteria in clause 5.5.

The PTP shall ensure that there is adequate space provided and designed for the proper and safe operation of the PT scheme. In addition, appropriate environmental conditions shall be maintained and controlled to ensure the integrity and stability of the proficiency test items during the various stages of operations of the PT scheme. Where these activities are sub-contracted it is the responsibility of the PTP to ensure that similar conditions are maintained at the subcontractor's site.

The PTP shall implement a system that the equipment used for manufacturing, handling, calibration and testing of proficiency test items are all properly calibrated, verified and maintained.

The PTP shall comply with relevant national safety regulations for the safe handling, storage and disposal of toxic and hazardous materials.

4.4 Design of proficiency testing schemes

The designing of a PT scheme covers the planning of the scheme, preparation of proficiency test samples, conducting homogeneity and stability studies, statistical design and finally assigning the values.

4.4.1 Planning

The planning of a PT scheme cannot be subcontracted by a PTP. However, the PTP can seek input and advice from experts or an advisory group (however named) on the planning requirements and other matters related to PT schemes. However, the final decision and judgment on the use of such input and advice shall be the prerogative of the PTP. Should the PTP decide not to follow the advice of the advisory group, the rationale for such a decision shall be recorded. The experts and members of the advisory group may be experts with the necessary technical expertise and experience from the PTP's own organisation or from an external source.

4.4.2 Preparation of proficiency test items

Same as in MS ISO/IEC 17043.

4.4.3 Homogeneity and stability

In the case where the proficiency test items are not feasible to be subjected to homogeneity and stability testing, the PTP shall document the reason or justification for not doing so.

Wherever possible, homogeneity testing shall be conducted after the proficiency test items have been packaged in its final form and prior to its distribution. Where homogeneity testing is conducted at any time other than post-packaging of the final form, the reasons for this departure must be justified and recorded.

In cases where materials are not sufficiently homogenous or stable and they are the best available to prepare the proficiency test items, the uncertainties of assigned values or the evaluation of the performance of the participants shall include consideration for this.

4.4.4 Statistical design

Same as in MS ISO/IEC 17043.

4.4.5 Assigned values

Assigned values for calibration PT schemes shall demonstrate metrological

traceability to national or international standards in accordance with SAMM Policy 2 “Policy on the Metrological Traceability of Measurement Results” in the case where results of test, measurement and calibration standard/equipment are used in the determination of the assigned values.

Where reference materials are used by a PTP the assigned values shall demonstrate suitable traceability through:

- a) reference material producers accredited by Standards Malaysia or one of Standards Malaysia’s mutual recognition arrangement (MRA) partners, when the MRA recognition covers reference material producers and the results are reported on an endorsed report/certificate; or
- b) 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 where there are no readily available reference material producers as described in a) and b),

- c) 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.

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 PTP shall document the justification or reasons in cases where metrological traceability need not be demonstrated.

The assigned value(s) shall not be disclosed to participants until after the results have been collated. In some cases, it may be appropriate to advise target ranges prior to testing.

4.5 Choice of method or procedure

Where participants are permitted to use a method of their choice, the PTPs shall, where appropriate, request details of the method used to permit comparison and comment on the results obtained by different test methods.

4.6 Operation of proficiency testing schemes

All documented instructions to the participants shall be included in the document control system of the PTP.

The PTP shall ensure that the integrity of proficiency test items is protected at all times before the distribution and transportation of the proficiency test items. Where the conditions of storage and transportation of the proficiency test items could affect the results of the PT they shall be monitored and recorded.

Where the proficiency test items require special precaution in handling the PTP shall mark or label the precautions securely on the packaging. For the distribution and delivery of proficiency test items, there shall be documented instructions regarding proper labelling, packaging and environmental condition during transportation.

Where the PTP is distributing proficiency test items to participants, the packaging and process of distribution shall comply with relevant national, regional or international safety and transport requirements where applicable. The PTP shall have on file the current details of such relevant regulations. These documents shall form part of the document control system of the PTP.

4.7 Data analysis and evaluation of proficiency testing schemes results

Data analysis and processing may be subcontracted by the PTP. In such a case the confidentiality of the participants' identities shall be maintained and shall not be disclosed to the subcontractor.

4.8 Reports

All preliminary and/or final report shall be authorised by an approved signatory of the PTP.

When technical comments other than those relating to the performance of the participants are included in PT reports there shall be a clear and explicit disclaimer stated in such reports that such comments are not covered under the scope of accreditation of the PTP.

4.9 Communication with participants

The PTP 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. Records of communication with participants shall be maintained with controlled access to authorised personnel.

4.10 Confidentiality

The confidentiality of participants' identities is often achieved by the use of randomly assigned 'participant codes', which may be different for each PT round.

In general, all information on a participant's performance shall not be revealed to any third party without the explicit permission from the participant except where applicable laws or regulations stipulate such disclosure. The PTP shall maintain records of the identity of the person(s) and/or parties to whom such disclosure has been made.

5 Management requirements

5.1 Organisation

If the PTP is part of a larger organisation, procedures shall be documented to ensure that departments with potential conflict of interests in the operation and activities of the PT are identified and do not adversely affect the impartiality of the conduct of PT. An organisation chart showing the PTP's overall organisational set up, its relation with the parent organisation, lines of responsibilities including its relationship with subcontractors shall be documented.

With regards to requirement of clause 5.1.4 of MS ISO/IEC 17043 if the parent organisation is also providing testing, calibration or inspection services to external customers, procedures shall be established to ensure that confidentiality on the performance of the participants shall be maintained and not disclosed to anyone including staff members who may have a conflict of interest.

5.2 Management system

In the case of a PTP that is part of a larger organisation with a range of other operations the management system may be established as a separate independent quality manual or as a manual extracted from the parent organisation overall quality manual and expanded to specifically address the PTP activities.

The PTP management system shall clearly describe the roles and relationship of the PTP with other relevant parties, including its subcontractors.

5.3 Document control

Same as in MS ISO/IEC 17043.

5.4 Review of requests, tenders and contracts

Same as in MS ISO/IEC 17043.

5.5 Subcontracting services

While the PTP shall not subcontract the planning of the PT scheme, evaluation of performance and the authorisation of the final report it can make use of advice and assistance obtained from experts, advisors or steering group that it has consulted with. (See specific criteria for clause 4.4.1 also).

Accreditation of a subcontractor to MS ISO/IEC 17025, MS ISO 15189, MS ISO/IEC 17020 or ISO 17034 with the appropriate scope is accepted as a demonstration of technical competence.

In the case where a non-accredited subcontractor is used the PTP shall satisfy itself that the subcontractor's experience and technical competence are adequate for the assigned work. The PTP shall establish procedures for the selection of such subcontractors and maintain records of the assessment of the subcontractors against the relevant clauses of MS ISO/IEC 17043 and other appropriate standards for the subcontracted work in question. (See specific criteria for clause 4.1 also).

5.6 Purchasing services and supplies

Same as in MS ISO/IEC 17043.

5.7 Service to the customer

Same as in MS ISO/IEC 17043.

5.8 Complaints and appeals

Same as in MS ISO/IEC 17043.

5.9 Control of nonconforming work

Same as in MS ISO/ IEC 17043.

5.10 Improvement

The feedback from the PTP's customers shall also be used and analysed for the improvement of its management system.

5.11 Corrective actions

Same as in MS ISO/ IEC 17043.

5.12 Preventive actions

Same as in MS ISO/IEC 17043.

5.13 Control of records

The PTP shall establish and maintain procedures for the proper management of quality and technical records related to its operation.

Records shall be retained by the PTP for a period as specified in MyPTP Policy 1 (PP1) unless otherwise prescribed by legislation or contractual obligation, or in the case of measurement standards and/or equipment records, the maximum recalibration interval of the measurement standards and/or equipment (whichever is the longer).

As far as practicable, all raw data or observations shall be indelible and recorded in such a manner that prevents amendment. 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.

5.14 Internal audits

Same as in MS ISO/ IEC 17043.

5.15 Management reviews

The effectiveness of the PTP's management system shall be reviewed once in 12 months.

Bibliography

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