



**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**  
Department of Standards Malaysia

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## **Introduction**

### **Preamble**

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. This document does not re-state all the requirements of MS ISO/IEC 17043. The numbering of its clauses follows that of MS ISO/IEC 17043. PTPs shall comply with all of the relevant requirements in MS ISO/IEC 17043 and Specific Criteria for Accreditation of Proficiency Testing Providers (SC 1).

PTPs shall comply with any relevant statutory or legislative requirements.

### **Purpose**

This document provides supplementary requirements for accreditation of PTPs to MS ISO/IEC 17043.

The specific requirements set out in this document are additional to and/or amplification on the requirements described in MS ISO/IEC 17043.

### **Authorship**

This document is developed by Technical Working Group (TWG) 51 of Standards Malaysia.

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.

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

3        **Terms and definitions**

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 and calibration activities to support its PT scheme(s), accreditation to MS ISO/IEC 17025 or MS ISO 15189 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 that participate regularly and successfully in relevant international interlaboratory comparisons performed by *Bureau International des Poids et Mesures* (BIPM) and/or regional metrology bodies. A reference material producer accredited to ISO Guide 34 in combination with MS ISO/IEC 17025 is also considered as a competent supplier.

4.2      **Personnel**

Relevant technical personnel shall have demonstrated competence to make necessary measurements (e.g. homogeneity and stability testing on test items).

Job description for key personnel of the PTP shall be clearly documented in terms of their duties and responsibilities.

PT reports shall be signed by a signatory nominated by the PTPs and approved by Standards Malaysia for signing such reports for specific PT schemes. 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.

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;
  - 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.

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**

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 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**

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 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 Measurement Standards Laboratory (NMSL) or a National Metrology Institute that is a signatory to the *Comite International des Poids et Mesures* (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 Organization**

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**

As in MS ISO/IEC 17043

**5.4 Review of requests, tenders and contracts**

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 or ISO Guide 34 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**

As in MS ISO/IEC 17043

**5.7 Service to the customer**

As in MS ISO/IEC 17043

**5.8 Complaints and appeals**

As in MS ISO/IEC 17043

**5.9 Control of nonconforming work**

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**

As in MS ISO/ IEC 17043

**5.12 Preventive actions**

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**

As in MS ISO/ IEC 17043

5.15 **Management reviews**

The effectiveness of the PTP management system shall be reviewed at least once a year.

### 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 Guide 34, *General requirements for the competence of reference material producers*
- [6] PT1 document, *Accreditation of Providers of Proficiency Testing Schemes for Laboratory Testing under United Kingdom Accreditation Service*
- [7] HOKLAS 017 (2<sup>nd</sup> Edition) document, *Technical Criteria for Accrediting Proficiency Testing Providers under Hong Kong Accreditation Service*
- [8] NABL 181, *Specific Criteria for PT Provider Accreditation*
- [9] *Proficiency Testing Scheme Providers - ISO/IEC 17043 Application Document – Supplementary Requirements for Accreditation (NATA)*
- [10] *Procedures Manual: Application Criteria Standard NMX-EC-17043-IMNC-2010 (ema)*

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