



## ACCREDITATION SCHEME FOR PROFICIENCY TESTING PROVIDERS

### **PTP 001**

## **Requirements for the Application of ISO/IEC 17043**

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## **1. INTRODUCTION**

- 1.1 This document PTP-001, "*Requirements for the Application of ISO/IEC 17043*" provides the policies and guidance for organisations in their application of ISO/IEC 17043: 2010.
- 1.2 This document forms part of the SAC-PTP criteria for accreditation of organisations for all scopes of proficiency testing using ISO/IEC 17043. The document should be read in conjunction with ISO/IEC 17043, SAC 01 "*Terms and Conditions for Accreditation*" and SAC 02 *Rules for Use of SAC Accreditation Marks and Mutual Recognition Arrangement (MRA) Marks*.

## **2. TECHNICAL REQUIREMENTS**

### **2.1 Clause 4.1 General**

- 2.1.1 Testing and measurement activities carried out by a proficiency testing provider (PTP) shall meet the requirements of ISO/IEC 17025 or ISO 15189 (for medical tests).
- 2.1.2 When reference materials are used by a proficiency testing provider, they shall be produced by competent reference material producers. Competent reference material producers are National Metrology Institutes or Designated Institutes. A reference material producer accredited to ISO 17034 in combination with ISO/IEC 17025 is also considered as a competent supplier. Where such competent suppliers are not available for fields such as for Non-Destructive Testing, reference test specimens manufactured by industry recognised organisations may be acceptable.
- 2.1.3 The applicant PTP is required to submit a completed proficiency testing programme for each of the intended scope of application.

### **2.2 Clause 4.2 Personnel**

#### **2.2.1 Coordinator**

An applicant or accredited proficiency testing provider shall nominate an individual as the coordinator for each proficiency testing scheme included in its scope of accreditation. Among other duties, the coordinator shall participate in the preparation and endorsement of the report(s) for the relevant scheme(s)

- 2.2.2 The responsibility of the coordinator shall be clearly documented. In cases where an external coordinator is used, there shall be written agreement between the coordinator and the proficiency testing provider defining the tasks for which the coordinator shall be responsible. In such a case, the coordinator shall report directly to the proficiency testing provider and is not considered a subcontractor.

2.2.3 The nominated coordinator shall have appropriate training, qualifications and experience in the field of the specific scheme. The person shall possess the following minimum qualifications and experience:

- a) A bachelor's degree in the relevant area;
- b) Experience in organising at least 3 inter-laboratory comparison programmes over the last 5 years; and
- c) Working knowledge in the areas of statistical evaluation of data and measurement uncertainty.

Before appointing a potential coordinator, the applicant or accredited proficiency testing provider shall assess and confirm the competence of the candidate. Such assessment and their results shall be recorded. During SAC assessment, the coordinator shall be available for assessment. SAC shall be informed immediately when there is a change of coordinator for a particular scheme.

2.2.4 Personnel for authorising reports

The person authorised to issue interim and final proficiency testing reports shall be either employed by, or under contract to, the provider. Before authorising the issue of the report(s), the person shall ensure that the content of the report is endorsed by the coordinator, and there is adequate access to advice and assistance from experts or its advisory groups, where necessary.

### **2.3 *Clause 4.3 Equipment, accommodation and environment***

2.3.1 A proficiency testing provider shall have documented procedures for handling, maintaining stability and storage of proficiency test items. It shall be equipped with facilities that are suitable for handling the proficiency test items. All units of proficiency test items shall remain uniquely identifiable at all times.

2.3.2 When microbiological tests are undertaken for the proficiency test items, the layout of the testing facility should generally provide for sample receipt, washing up and sterilisation, media preparation and general testing areas, and should be designed to minimise potential contamination of samples and to ensure protection of testing staff. Proficiency testing providers involved in handling pathogenic organisms need to take special environmental precautions.

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

### **2.4 *Clause 4.4 Design of proficiency testing schemes***

No additional requirement.

**2.5 Clause 4.5 Choice of method or procedure**

No additional requirement.

**2.6 Clause 4.6 Operation of proficiency testing schemes**

No additional requirement.

**2.7 Clause 4.7 Data analysis and evaluation of proficiency testing scheme results**

2.7.1 The evaluation of participant performance shall be conducted by the proficiency testing provider itself. If data analysis is subcontracted, confidentiality of participants' identities shall be maintained and shall not be disclosed to the subcontractors. All original results provided by participants, processed data and analysed results shall be returned by the subcontractors to the proficiency testing provider for further evaluation of participants' performance.

**2.8 Clause 4.8 Reports**

2.8.1 The preparation, approval and issue of interim report for each round and the annual summary report of a continuous proficiency testing scheme or the final report of a one-off scheme included in the scope of accreditation shall be carried out by the accredited proficiency testing provider and shall not be subcontracted.

2.8.2 When technical comments other than on the performance of participants are made in proficiency testing reports, they are not covered under the scope of accreditation of the proficiency testing provider. Where such comments are included in accredited proficiency testing report, a clear and explicit disclaimer shall be given in the report that they are not covered under the scope of accreditation.

**2.9 Clause 4.9 Communication with participants**

2.9.1 The proficiency testing provider shall have documented procedures for handling participants that are found to be involved in falsification and collusion of results.

**2.10 Clause 4.10 Confidentiality**

2.10.1 The proficiency testing provider should inform subcontractors and external coordinators that they are not allowed to retain any form of the information and processed data.

### **3. MANAGEMENT REQUIREMENTS**

#### **3.1 *Clause 5.1 Organisation***

- 3.1.1 It is the responsibility of a proficiency testing provider to carry out its work in accordance with the relevant laws and regulations of Singapore or of the country where the proficiency testing provider is located. Assessment of the proficiency testing provider's compliance with the relevant regulatory requirements is however outside the scope of SAC accreditation schemes.
- 3.1.2 An applicant or accredited proficiency testing provider shall be a legal entity and take responsibility for all activities involved in the operation of the proficiency testing scheme included in its scope of accreditation.
- 3.1.3 A proficiency testing provider's scheme could be designed for any field of testing for any purpose for participants to satisfy the SAC proficiency testing requirements. Each scheme shall be listed separately under its scope of accreditation, for instance, a scheme for chemical testing of construction materials, and another scheme for steel testing, etc.
- 3.1.4 Where a proficiency testing provider is part of a larger organisation, the organisational arrangements should be such that departments having conflicting interests, such as operation, commercial marketing or financial should not adversely influence the provider's compliance with the requirements of this document. In this regard, the proficiency testing provider should particularly take note of ISO/IEC 17043 clause 5.1.4 if it also provides testing or calibration services to external customers. Suitable firewall shall be established to ensure that all information on the performance of participants is not disclosed to anyone including staff members who may have a conflict of interest. Furthermore, the proficiency testing provider shall provide evidence that its proficiency testing schemes are conducted with impartiality.
- 3.1.5 Where the proficiency testing provider's laboratory is also a participant of the concerned proficiency testing scheme, there shall be documented procedures and mechanisms established to prevent collusion and falsification of results; and the personnel involved in the operation of the proficiency testing scheme shall be different from the personnel participating in the scheme.

#### **3.2 *Clause 5.2 Management system***

No additional requirement.

#### **3.3 *Clause 5.3 Document control***

No additional requirement.

#### **3.4 *Clause 5.4 Review of requests, tenders and contracts***

No additional requirement.

### **3.5 Clause 5.5 Subcontracting services**

3.5.1 If a proficiency testing provider subcontracts any of its activities for the production, testing, measurement, sampling, storage, and distribution of the proficiency test items (i.e. PT materials/samples or measurement artefacts), or for data processing and distribution of the proficiency testing records, the work and responsibilities of each subcontractor shall be clearly defined and documented.

3.5.2 The subcontractors

An applicant or accredited proficiency testing provider shall ensure that the subcontractor responsible for the testing/measuring activities, or other activities which have an impact on the quality of its proficiency testing schemes, carries out the subcontracted activities according to well-defined documented procedures and meets the accreditation requirements in ISO/IEC 17043.

3.5.3 On-site assessment

It should be emphasised that accreditation is granted to the proficiency testing provider, not to its subcontractors. In this regard, the proficiency testing provider shall have a written agreement with its subcontractors which requires its subcontractors not to represent themselves to anybody that they are accredited with respect to the subcontracted activities. It is an obligation of an accredited proficiency testing provider to ensure that its subcontractors follow the relevant accreditation requirements and regulations. The assessment team may recommend suspension of the accreditation when the proficiency testing provider fails to ensure that its subcontractors follow any of the SAC accreditation regulation or requirement relevant to the situation concerned.

### **3.6 Clause 5.6 Purchasing services and supplies**

3.6.1 There are three commonly encountered situations where a proficiency testing provider needs to seek external services and supplies:

- a. Acquisition/Purchase of consumables or perishable items relating to the production of proficiency test items, e.g. media, chemical reagents, blood products, biological samples, reference materials:

There shall be documented criteria on the selection of supplies and records of evaluation of the selected supplies. Records shall be kept of the different brands/ batch/ lot of those items which bear a critical influence of the test or examination results. The records should, where appropriate, include results of the acceptance tests on each new batch/lot prior to use. When a particular brand shows an undesirably high rejection rate, consideration should be given to excluding it from the list of acceptable source of supplies.

b. Acquisition/Purchase of equipment:

Separate records shall be kept for each manufacturer supplying major items of equipment. The records should include results of the acceptance tests and the subsequent maintenance history of their equipment. Manufacturers whose equipment consistently do not meet their stated performance specifications and/or show undesirably high proportion of equipment down time and/or are not supported by good after-sales service should be noted and their names removed from the list of acceptable suppliers.

It is further recommended that when choosing a supplier of service or equipment, priority should be given to those certified to ISO 9001 by an accredited certification body.

c. Delivery/Courier of proficiency test items:

There shall be documented procedures for delivery/courier of proficiency test items. These procedures shall be communicated to the delivery/courier service providers.

There shall be documented criteria and evaluation of the delivery/courier service providers. Delivery/courier service providers whose performance consistently do not meet criteria should be noted and their names removed from the list of acceptable suppliers.

3.6.2 Applicant and accredited proficiency testing providers shall take note that the requirements given in Section 3.6 are, where relevant, also applicable to the purchasing of external services.

**3.7 Clause 5.7 Service to the customer**

3.7.1 Feedback from all clients, including internal clients, should be sought.

**3.8 Clause 5.8 Complaints and appeals**

3.8.1 Resolution of complaints

Proficiency testing providers shall note that when a complaint involving a SAC accredited proficiency testing scheme is not satisfactorily resolved within 90 days from the date of its receipt, they are required to notify SAC the nature of the complaint immediately.

**3.9 Clause 5.9 Control of nonconforming work**

No additional requirement

### **3.10 Clause 5.10 Improvement**

3.10.1 Facilities should be able to show evidences of how continuous improvement is sought in the work place.

### **3.11 Clause 5.11 Corrective actions**

No additional requirement

### **3.12 Clause 5.12 Preventive actions**

No additional requirement.

### **3.13 Clause 5.13 Control of records**

No additional requirement.

### **3.14 Clause 5.14 Internal audits**

3.14.1 The internal audit schedule shall cover all the elements of the management system over a twelve-month period. The audit should determine if:

- a. Procedures described in the management system are being followed;
- b. Objectives (as defined in the management system) are being achieved;
- c. Designated duties are being carried out satisfactorily and
- d. There are opportunities for improvements

3.14.2 The facility is encouraged to use PTPFM03 PTP assessment checklist to ensure that all aspects of ISO/IEC 17043 are covered during the Internal Audit. It is also a good practice to record accordingly all evidences audited.

3.14.3 The corrective actions submitted to address the findings of internal audit shall be verified and accepted by the relevant internal auditor.

3.14.4 The facility is required to have its internal audit report ready by the on-site assessment.

### **3.15 Clause 5.15 Management reviews**

3.15.1 The effectiveness of the management system shall be reviewed by the facility's management at least once every twelve months.