



ACCREDITATION SCHEME FOR PROFICIENCY TESTING PROVIDERS

PTP 003 Accreditation Process

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TABLE OF CONTENTS

1. THE SCHEME	2
2. DEFINITIONS	2
3. SAC ORGANISATIONAL STRUCTURE	5
Council Committee for Laboratory – Medical and Sciences (CCL-MS)	5
Technical Assessors	5
4. ACCREDITATION PROCESS	6
Introduction	6
Application	6
Preliminary Assessment	6
Initial Assessment	7
Award of Accreditation	8
Routine Surveillance and Renewal Assessment	8
Non-routine Assessment	9
5. KEY PERSONNEL	9
6. MANAGEMENT REPRESENTATIVE	10
7. SAFETY	10
8. ANNEX 1 - LISTING OF ACCREDITATION CRITERIA DOCUMENTS AND GUIDELINES	11

1. The Scheme

- 1.1 The Proficiency Testing (PT) Providers scheme is the national proficiency testing accreditation scheme of the Singapore Accreditation Council (SAC) which is managed by the Enterprise Singapore (EnterpriseSG). The said scheme will be referred to as "SAC-PTP"
- 1.2 The primary objectives of the SAC-PTP scheme are as follows:
- a) to operate the accreditation of proficiency testing providers in accordance to international criteria, such as ISO/IEC 17011 and requirements for mutual recognition arrangements
 - b) to provide by means of assessment, the assurance that the professional practice by accredited proficiency testing providers are in accordance to international standards, such as ISO/IEC 17043
 - c) to ensure that the accreditation processes are carried out with professionalism and integrity
 - d) to strengthen and develop new accreditation fields to meet the needs of stakeholders
 - e) to facilitate trade and market access by establishing and maintaining mutual recognition arrangements (MRAs) with overseas accreditation bodies through the regional and international bodies, such as Asia Pacific Accreditation Cooperation (APAC) and Global Accreditation Corporation Incorporated.
- 1.3 SAC gives formal recognition to proficiency testing providers that have been independently assessed and found to comply with the criteria established. Accreditation is granted for specific scopes of proficiency testing and is not a blanket approval for its total operations.
- 1.4 SAC accredits proficiency testing providers which can demonstrate that they comply with currently accepted standards in particular the requirements of ISO/IEC 17043 "*Competency Assessment – General Requirements for the competency of Proficiency Testing Providers*".
- 1.5 This document should be read in conjunction with SAC 01 *Terms & Conditions for Accreditation*, SAC 02 *Rules for Use of SAC Accreditation Marks and Mutual Recognition Arrangement (MRA) Marks*, ISO/IEC 17043 and any specific requirements that may be published as PTP Technical Notes relating to specific proficiency testing provider's activities.

2. Definitions

- 2.1 Accreditation criteria:

Requirements of SAC expressed in general terms, which address organisation, human and material resources, operating procedures, calibration and quality assurance practices of a laboratory. Such requirements are specified in the documents and technical notes as stipulated in **Annex 1**.

- 2.2 Accredited Proficiency Testing (PT) Provider:
A Proficiency Testing Provider to which SAC accreditation has been granted. The accredited PT Provider is competent to conduct PT schemes.
- 2.3 Assessor:
An individual who carries out some or all functions related to a proficiency testing provider assessment under SAC-PTP.
- 2.4 Coordinator:
Personnel with responsibility for the operation and conduct of the proficiency testing scheme.
- 2.5 Interlaboratory comparisons:
Design, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions
- 2.6 Key Personnel:
Personnel with responsibility for operating a proficiency testing provider facility to monitor all work performed so as to achieve reliable proficiency testing.
- 2.7 Management Representative:
A person nominated by the proficiency testing provider to represent it in all matters relating to SAC accreditation (see Clause 6 for details).
- 2.8 Non-conformity:
Non-fulfilment of a requirement.
- 2.9 Critical Non-conformity:
A critical non-conformity which seriously threatens the credibility of the laboratory accreditation scheme. Gross lack of technical competence, persistent violation of SAC Terms & Conditions, gross lack of commitment of the organisation to quality or compliance with accreditation criteria and existence of serious doubt on the integrity and impartiality of the organisation. A management system breakdown, as indicated by a series of significant non-conformities which seriously threaten the quality of all activities under the system, warrants a critical non-conformity.

Note:

Gross lack of competence may arise from lack of competent staff for key activities, inappropriate environment for key activities, lack of critical equipment, lack of traceability, totally invalid PT scheme, total breakdown of the record or documentation system, lack of or totally ineffective quality assurance procedures or other causes.

2.10 Significant Non-conformity:

A significant non-conformity has serious adverse effect on the validity of an activity, its results or the competence of the organisation or a violation of SAC Terms & Conditions for accreditation.

The existence of a serious doubt on the technical validity of an activity or its results, as indicated by a series of related minor non-conformities is a significant non-conformity. Furthermore, persistence of a minor non-conformity for an extended period of time and without any plausible explanation may be a violation of SAC Terms & Conditions for accreditation, warrants a significant non-conformity.

2.11 Minor Non-conformity:

A minor non-conformity has no serious adverse effect on the validity of the activity, its results or the competence of the organisation.

Note:

Minor non-conformities have a tendency to grow into significant non-conformities if not addressed appropriately at the time.

2.12 Observation:

An assessment finding that does not warrant non-conformity but is identified by the assessment team as an opportunity for improvement.

2.13 Reference material:

Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

2.14 SAC accredited report:

A report that includes a statement by the proficiency testing provider that it is accredited for the scope of proficiency testing schemes conducted and that the proficiency testing schemes has been performed in accordance with the terms and conditions for accreditation under SAC. It shall include the SAC mark and the Certificate Number.

2.15 Schedule of Accreditation:

A schedule issued with the Certificate of Accreditation listing the specific scope of the proficiency testing providers for which accreditation have been granted.

- 2.16 Surveillance:
Routine examination of a proficiency testing provider to evaluate its continued compliance with SAC requirements, normally every twelve-month period.
- 2.17 Suspension of Accreditation:
Process of temporarily making accreditation invalid, in full or for part of the terms of accreditation.
- 2.21 Terms of Accreditation:
The scope of proficiency testing provider for which a it is accredited under SAC.
- 2.22 Withdrawal of Accreditation:
Process of cancelling accreditation in full.

3. SAC Organisational Structure

3.1 Council Committee for Laboratory – Medical and Sciences (CCL-MS)

- 3.1.1 The Council Committee for Laboratory – Medical & Sciences (CCL-MS) oversees the Proficiency Testing Providers scheme. CCL-MS is a specialist committee appointed to support the SAC Council. The CCL-MS is responsible for the formulation of policies, provides guidance and oversees the operation of the Proficiency Testing Scheme, based on ISO/IEC 17043.
- 3.1.2 The CCL-MS is authorised to review, evaluate and approve assessment reports for accreditation of proficiency testing providers for their respective areas, through their Review Committees. The CCL-MS may also co-opt individuals with relevant technical or management expertise as advisors for the review of assessment reports.
- 3.1.3 The term of office for members of the CCL-MS is three years with provision for reappointment.

3.2 Technical Assessors

- 3.2.1 The CCL-MS maintains a panel of technical assessors who are appointed from the ranks of government departments, associations & societies, academic institutions, research organisations, industrial and commercial laboratories. The assessors are chosen on the basis of their professional knowledge and expertise in a particular area of calibration / testing

technology and their ability to examine and evaluate a proficiency testing provider's standard of management and practices.

3.2.2 The assessors conduct on-site assessments of applicants and accredited proficiency testing providers based on the criteria established under SAC-PTP.

3.2.3 The assessment team submits assessment report to its respective Review Committee under the CCL-MS for approval after the assessment.

4 Accreditation Process

4.1 Introduction

4.1.1 Enquiries regarding the SAC Proficiency Testing Providers scheme may be made at the Singapore Accreditation Council.

4.1.2 Proficiency Testing Providers interested to be accredited under SAC may obtain the relevant documents (except ISO/IEC Standards) from SAC website. Application must be made via SAC online system, SACiNet.

4.1.3 A proficiency testing provider is advised to study in detail the SAC Terms and Conditions to ensure that it can substantially meet the accreditation criteria before it lodges an application for accreditation.

4.1.4 The management system of the proficiency testing provider shall be operational for at least two months before SAC conducts an assessment of the proficiency testing provider.

4.2 Application

4.2.1 All applications shall be submitted in SACiNet and be supported with documents containing sufficient information regarding its staff, management system, equipment, calibration, proficiency testing provider's practices, or other information necessary or requested by SAC from time to time for the assessment of the proficiency testing providers.

4.2.2 The applicant shall nominate a management representative to liaise with SAC on all matters relating to accreditation and the applicant shall update any changes in the representative in SACiNet.

4.3 Preliminary Assessment

- 4.3.1 Upon receipt of a duly completed application form in SACiNet and satisfactory supporting documents relating to its management system, equipment, calibration and proficiency testing provider's practices, SAC will arrange for a preliminary assessment if it is requested by the applicant.
- 4.3.2 SAC makes recommendations to the proficiency testing provider on the non-conformities noted and upon full rectification of the nonconformities may recommend the laboratory to proceed with the initial assessment.

4.4 Initial Assessment

- 4.4.1 This is an on-site evaluation of the applicant to determine whether it conforms with the accreditation criteria before an accreditation is awarded.
- 4.4.2 The applicant shall make available personnel such as management representatives and key personnel for interviews during the assessment.
- 4.4.3 SAC will appoint an appropriate assessment team comprising Team Leader, and Technical Assessor/Expert to assess the applied scope for accreditation.
- 4.4.4 The applicant shall demonstrate their ability to plan, design, and operate PT scheme.
- 4.4.5 The applicant will be advised on the assessment findings which include comments on competence and conformity. During the assessment, non-conformities are categorised as "Critical", "Significant" or "Minor". The management representative should ensure that the non-conformities and observations raised are fully understood and acknowledged.
- 4.4.6 The applicant with "critical non-conformities" will not be granted accreditation for the specific PT scheme. However, the proficiency testing provider may request to be re-assessed after rectification of the critical non-conformities.
- 4.4.7 The applicant with "significant" and "minor" non-conformities is given 1 month to submit the corrective action.
- 4.4.8 As part of the corrective action, the laboratory shall submit/upload the relevant evidence and root cause analysis (e.g. Corrective/ Preventive Action Report or Corrective Action Report) in SACiNet.
- 4.4.9 Once the applicant has taken the necessary corrective actions, the assessment team shall review the corrective actions in SACiNet and if necessary, conduct a verification visit to verify the actions taken.
- 4.4.10 A Review Committee comprises appropriate members from the CCL-MS.

4.5 Award of Accreditation

- 4.5.1 The CCL-MS grants accreditation to the applicant upon being satisfied that the laboratory meets the criteria for accreditation.
- 4.5.2 All decisions of the CCL-MS on the granting, extension, reduction, renewal, suspension or withdrawal of accreditation shall, unless expressly provided herein, be final and not called into question by the laboratory.
- 4.5.3 An electronic Certificate of Accreditation will be issued to the accredited proficiency testing provider together with an electronic Schedule giving details of its terms of accreditation. The SAC-SINGLAS Certificate of Accreditation is valid for a period of four years with provision for renewal on expiry.
- 4.5.4 The accredited proficiency testing provider shall pay SAC an annual fee and other assessment and administrative fees as determined by SAC from time to time.
- 4.5.5 All accredited proficiency testing providers will be listed on the SAC website.

4.6 Routine Surveillance and Renewal Assessment

- 4.6.1 SAC shall conduct surveillance assessments on accredited proficiency testing providers to ensure that the standard of practice complying with criteria is maintained. A surveillance assessment shall be conducted normally once every twelve months.
- 4.6.2 A renewal assessment shall be conducted prior to the expiry of the Certificate of Accreditation. The Certificate shall be renewed on the condition that the accredited proficiency testing provider has been found to have maintained the necessary standard of practice during the validity of the Certificate and is capable of maintaining the standard established.
- 4.6.3 The accredited proficiency testing provider may request for an extension or reduction in the terms of accreditation for consideration during the surveillance and renewal assessment. For such requests, the proficiency testing provider shall indicate in SACiNet and upload the supporting documents least 1 month prior to the date of assessment.
- 4.6.4 The proficiency testing provider will be advised on the assessment findings which include comments on competence and conformity. During the assessment, non-conformities are categorised as “Critical”, “Significant” or “Minor”. The management representative should ensure that the non-

conformities and observations raised are fully understood and acknowledged.

- 4.6.5 The proficiency testing provider with “critical non-conformities” may have the scope of accreditation suspended or withdrawn. The proficiency testing provider is given one week to submit a corrective action plan which includes the investigation made, specific actions to be taken, the timeliness for completion of corrective actions. Once the assessment team is satisfied with the corrective action plan, the corrective actions shall be completed 1 month from the last day of assessment.
- 4.6.6 The proficiency testing provider with “significant non-conformities” and “minor non-conformities” is given 1 month to submit the correction action.
- 4.6.7 The proficiency testing provider shall submit the corrective action as described in clause 4.4.8 of this document.
- 4.6.8 Once the proficiency testing provider has taken the necessary corrective actions, the assessment team shall review the corrective actions and if necessary, conduct a verification visit to verify the actions taken.

4.7 Non-routine Assessment

- 4.7.1 The non-routine assessments will include visits made to consider requests for extension in the terms of accreditation, or to investigate complaints made against the accredited proficiency testing provider on areas within the scope of SAC accreditation, if these could not be conducted during the routine surveillance visits.
- 4.7.2 Unannounced assessments are conducted for special reasons such as to investigate a complaint against a proficiency testing provider. SAC reserves the right to conduct unannounced visits when the need arises.
- 4.7.3 SAC may conduct non-routine assessment for reinstatement of accreditation for proficiency testing provider whose accreditation has been suspended or inoperative due to various reasons such as change of premises or loss of all key personnel.

5 Key Personnel

- 5.1 The key personnel shall be competent to make a critical evaluation of test results and be a staff occupying a position in the organisation staff structure which is responsible for the adequacy of proficiency testing scheme.

- 5.2 The key personnel shall ensure the reliability and completeness of the proficiency testing scheme reports for which responsibility is taken on behalf of the accredited proficiency testing provider concerned.
- 5.3 The accredited proficiency testing provider shall ensure that the key personnel be thoroughly conversant with SAC-SINGLAS terms and conditions together with other relevant criteria.
- 5.4 The key personnel should have the relevant qualification and experience in the related field.
- 5.5 All key personnel shall be subjected to review during assessment. It is the responsibility of the accredited laboratory to ensure that key personnel be present when their areas are being assessed, otherwise a separate visit or interview may be required.
- 5.6 For details on the role of the Coordinator as key personnel, please refer to PTP-001 *Requirements for the Application of ISO/IEC 17043* under Personnel.

6 Management Representative

- 6.1 The management representative of proficiency testing provider shall be a full-time staff/permanent employee and will be the contact liaison with SAC.
- 6.2 The management representative shall understand the workings of the proficiency testing provider well and shall be able to make decisions on accreditation matters on behalf of the facility.

7. Safety

- 7.1 Safe working conditions are essential to good laboratory practice and management. The PT provider shall observe all necessary safety precautions to ensure that it has a safe working environment.
- 7.2 SAC will not arrange for on-site assessment if it considers the proficiency testing provider to be unsafe.
- 7.3 It is the proficiency testing provider's responsibility to comply with relevant health and safety requirements.

Annex 1 - Listing of Accreditation Criteria Documents and Guidelines

1. ISO/IEC 17043 Competency Assessment – General Requirements for the competency of Proficiency Testing Providers
2. SAC 01 Terms and Conditions for Accreditation
3. SAC 02 Rules for Use of SAC Accreditation Marks and Mutual Arrangement (MRA) Marks
4. PTP 001 Requirements for the Application of ISO/IEC 17043