



SRI LANKA ACCREDITATION BOARD

For CONFORMITY ASSESSMENT

SPECIFIC CRITERIA FOR

PROFICIENCY TESTING PROVIDERS

Date	Doc. No.	Page/ Section	Description of Change	Revision No.	Approval

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ABBREVIATIONS

APMP	-	Asia Pacific Metrology Programme
IEC	-	International Electro technical Commission
ILAC	-	International Laboratory Accreditation Cooperation
ISO	-	International Organization for standards
MRA	-	Mutual Recognition Arrangement
PTP	-	Proficiency Testing Providers
APAC		Asia Pacific Accreditation Corporation
SLAB	-	Sri Lanka Accreditation Board for Conformity Assessment

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1. INTRODUCTION

- 1.1 The Accreditation Scheme for Proficiency Testing Providers (PTPs) of the Sri Lanka Accreditation Board (SLAB) is based on the requirements laid down in ISO/IEC 17043 conformity Assessment- Requirements for Proficiency Testing. Proficiency Testing covers a wide range of fields including inter-comparison programmes conducted among calibration laboratories as well as National Measurement Institutions.
- 1.2 The requirements stipulated in ISO/IEC 17043 apply to proficiency testing service providers providing all types of proficiency testing programmes and inter-laboratory comparisons in different fields of testing, calibration and inspection. However, in certain instances additional guidance is considered and necessary to take into account the field of proficiency testing, competency level of personnel in the PTPs and the expertise required for different proficiency testing programmes according to the complexities based on the additional criteria published by the International / Regional Accreditation Organizations.
- 1.3 This specific criteria document has been prepared by the Technical Advisory Committee on Proficiency Testing Service Providers and has been authorized for adoption by the Council of the Sri Lanka Accreditation Board (SLAB). PTPs seeking accreditation are required to comply with all the requirements listed in the international standard ISO/IEC 17043. This document supplements International Standard; ISO/IEC 17043 and provides guidance and interpretation of requirements for the accreditation of PTPs , assessors and for potential PTPs preparing for accreditation.
- 1.4 This Specific Criteria document must be used in conjunction with ISO/IEC 17043. It provides an interpretation of the latter document and describes specific requirements for those clauses of ISO/IEC 17043 which are general in nature. Corresponding reference to the clauses in ISO /IEC 17043 is indicated in parenthesis in the text of the document. This document should be read in conjunction with the Rules and Procedures (PT-RGP-02) of SLAB as applicable to PTPs. Further, all PTPs which provide Proficiency Testing Programmes as per ISO/IEC 17043 shall also comply with any national, regional and local laws, regulations and ethical standards as applicable.
- 1.5 This document will be periodically reviewed and updated based on experience gained and developments in technology.

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- 1.6 All accredited Proficiency Testing Providers shall conform to specific requirements stipulated in this document at all times. For an applicant proficiency Testing Provider, accreditation will only be granted after it has demonstrated conformity to the specific criteria for proficiency testing providers and competence to undertake proficiency testing programmes in the relevant field of testing and /or calibration and inspection.

2. **NORMATIVE REFERENCES**

The following referenced documents are indispensable for the application of this document and last edition of the referenced documents including any amendments applies. If there are any discrepancy in requirements described in ISO/IEC 17043 and the other related documents including ISO/IEC 17025: and ISO 15189, the ISO /IEC 17043 shall take precedence.

ISO/IEC 17000:2020: - Conformity Assessment- Vocabulary and General Principles

ISO/IEC 17025:2017: - General Requirements for the Competence of Testing and Calibration Laboratories

ISO 15189:2012/2022: - Medical Laboratories – Requirements for Quality and Competence

ISO 13528: 2022: - Statistical Methods for use in proficiency testing by inter-laboratory comparisons

ISO /IEC Guide 99:2007: - International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM)

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3. TERMS & DEFINITIONS *(ISO/IEC 17043: 2010, Clause 3)*

The terms and definitions given in Clause 3 of ISO/IEC 17043:2010 shall apply.

4. TECHNICAL REQUIREMENTS *(ISO/IEC 17043: 2010, Clause 4)*

4.1 General *(ISO/IEC 17043: 2010, Clause 4.1)*

The development and operation of proficiency testing schemes shall be undertaken by proficiency testing providers having competence to conduct inter-laboratory comparisons and access to expertise with the particular type of proficiency test items. Proficiency testing providers or their subcontractors shall also have competence in the measurement of the properties being determined.

Testing and measurement activities carried out by a proficiency testing provider shall meet the requirements of ISO/IEC 17025 or ISO 15189 or inspections carried out by an inspection body shall meet the requirements of ISO/IEC 17020 and shall demonstrate their competence through accreditation obtained by SLAB or an ILAC MRA partner. It should be noted that all SLAB accredited laboratories shall comply with the requirements stipulated in specific criteria in relation to the field of testing, calibration and inspection.

If proficiency testing provider wishes to operate proficiency testing activities and testing, calibration or inspection activities together, accreditation for laboratories, inspection bodies and proficiency testing shall apply separately for each conformity activity.

When reference materials are used by a proficiency testing provider as PT item, they shall be from competent reference material producers. Reference Material producers are considered as competent if they are National Measurement Institutes or Designated Institutes that participate regularly and successfully in relevant international inter-laboratory comparisons performed by international and/or regional metrology bodies such as APMP. A reference material producer accredited to ISO 17034 in combination with ISO/IEC 17025 is also considered as competent reference materials supplier/ producer.

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4.2 Personnel (ISO/IEC 17043: 2010, Clause 4.2)

The requirements given in Clause 4.2 of ISO/IEC 17043:2010 shall apply.

Proficiency Testing Coordinator

An applicant or accredited proficiency testing service 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 reports for the relevant schemes.

The responsibility of the coordinator shall be clearly documented. In case where external coordinator is used, there shall be a legally enforceable agreement between the coordinator and proficiency testing provider defining the task for which the coordinator shall be responsible. In such a case, coordinator shall report directly to the proficiency testing provider and it is not considered as subcontracting.

The nominated coordinator shall have appropriate training, qualifications and experience in the field of specific scheme. Before appointing a potential coordinator, an applicant or accredited proficiency testing service provider shall assess the competence of coordinator against the minimum qualification criteria set by the proficiency testing service provider and evaluated for the same. Appointment shall be done after competency evaluation based on a process developed including competency requirements set by the proficiency testing service provider. If the coordinator handles technical activities, the competency requirements for Proficiency Testing Coordinator shall include educational qualification at least BSc Degree in the science /engineering or related equivalent qualification as per the field of testing/calibration, knowledge on ISO/IEC 17043, ISO 13528 and relevant accreditation criteria, a minimum of 03 years' experience in relation to PT/ILC activities, technical knowledge and skills required for the specific Proficiency Testing Activities.

Technical Advisory Committees

When external technical expertise is used in technical advisory committees to provide technical inputs to the proficiency testing scheme, a legally enforceable agreement shall be signed between each committee member and proficiency testing provider. Legally enforceable agreement shall cover at least, roles and functions, responsibilities and authorities, terms of reference, procedure for establishment and operation procedures, addressing confidentiality issues and arrangements on how technical advice is to be acted upon by the proficiency testing service provider.

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Minimum qualification and competency requirements for committee members shall be defined by the proficiency testing service provider considering the educational qualification at least BSc Science /Engineering degree or equivalent qualifications, knowledge on ISO/IEC 17043, ISO 13528 and relevant accreditation criteria, minimum 5 years' experience in relation to PT activities, technical knowledge and skills required for the specific Proficiency Testing activities to ensure the committee members are competent enough to carry out their duties and responsibilities.

Proficiency Testing Provider shall evaluate competency of committee members initially before appointing and periodically as per a defined process.

Authorized Signatory

The person authorized to issue interim and final proficiency testing reports under each field of proficiency testing shall be either employed by, or under contract to, the provider. Before authorizing and the issue of the reports, the person shall ensure content of the report is endorsed by the coordinator, and there is adequate access to advice and assistance from experts or its technical advisory committees, where necessary.

The proficiency testing service provider shall ensure that the competence of authorized signatory is conformed to the minimum competence requirements set for the authorized signatory by the proficiency testing service provider, shall cover educational qualifications at least BSc degree in Science/Engineering or equivalent qualifications, knowledge on ISO/IEC 17043, ISO 13528 and relevant accreditation criteria, 3 years minimum experience in relation to PT/ILC activities, technical knowledge and skills required for the specific Proficiency Testing activities .

Appointment shall be done based on the results obtained from the initial competency evaluation and periodic evaluations shall be done in accordance with a documented process.

4.3 Equipment, Accommodation and Environment (ISO/IEC 17043: 2010, Clause 4.3)

The requirements given in Clause 4.3 of ISO/IEC 17043:2010 shall apply.

The proficiency testing provider shall have documented procedures for handling and storage of proficiency testing samples. It shall be equipped with facilities that are suitable for processing the proficiency testing items. All units of proficiency testing items shall remain uniquely identifiable at all times.

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An accredited or applicant proficiency testing provider may use its own testing and measurement facilities or those provided by its subcontractors. If the proficiency testing provider uses equipment or facilities provided by the subcontractor, it should conform to the requirements given under the subcontracting as given in the section 5.5 of this document.

Environmental and accommodation requirements vary greatly depending on the nature of the samples and examination or test to be conducted. Suitability of the accommodation and environmental conditions will be assessed to determine how they affect; -

- a) The integrity of samples tested or examined
- b) The performance of the equipment of the laboratory/ inspection body
- c) Compliance with the conditions set in the test or examination methods
- d) Safety of the staff of the laboratory /inspection body

Consideration of environmental effects on proficiency test items to be examined includes precautions necessary to prevent contamination and degradation. The areas for the sample preparation, preconditioning, testing or examination and storage shall be of adequate size, free from dust and fumes and protected from other environmental factors such as excessive temperature, high humidity, microbial contamination and direct sun light, which may affect the integrity of samples. If proficiency test items require refrigeration before and after examinations, and storage for before and after distribution to participants, refrigerators or freezers of adequate capacity shall be provided. Temperature of the storage facilities shall also be monitored.

Sufficient storage space shall be available to store proficiency test items for the required periods in conditions designed to maintain their integrity.

Factors of the environment that may affect the performance of equipment include corrosion, temperature, humidity vibration, electrical power stability, dust and electromagnetic influences. The location of all items of equipment likely to be affected by these factors shall be chosen to eliminate or minimize any adverse effects.

Accommodation and environmental conditions may also be judged on how it affects staff competence in performing specific activities. There shall be sufficient space available for staff to perform their duties comfortably, with adequate provision of lighting and with precautions taken to minimize noise.

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Adequate space shall also be provided for the proficiency testing provider's clerical and other functions (packing, labeling, reporting, data processing and analysis activities) and separate amenity facilities. All necessary facilities for gas, water, power (suitably established if necessary), waste disposal and for extraction of fumes shall be available and be conveniently located.

Some examination methods also specify features of the environment in which sample preparation, and examination should take place. Where environmental features such as temperature and humidity ranges, airflow rates, illumination levels etc. are specified. These conditions must be met in the relevant testing, examination and sample preparation sections of the proficiency testing provider. Monitoring equipment such as thermometers, hygrometers, psychrometers, thermo hydrographs, and anemometers, shall be available and be operated over the relevant testing, examination and sample preparation period specified by the test methods. The monitoring equipment shall be calibrated by an accredited calibration laboratory as per the calibration programme and intermediate verification shall be performed as per a documented procedure to establish metrological traceability. Records of each activity shall be maintained.

When microbiological testing are being under taken for the proficiency testing items, the layout of the testing facility should generally provide for sample receipt, washing-up and sterilization, media preparation and general testing areas, and should be designed to minimize potential contamination of samples and to ensure protection of testing staff. Proficiency testing providers involved in handling pathogenic organisms need to take special protective precautions.

4.4 Design a proficiency testing programme (ISO/IEC 17043: 2010, Clause 4.4)

The requirements given in Clause 4.4 of ISO/IEC 17043:2010 shall apply.

Planning of proficiency testing schemes shall not be subcontracted. Access to external technical expertise is allowed to obtain technical advice on certain technical aspects provided that the external committee members are agreed to act in accordance with the policies and procedures of proficiency testing provider.

4.5 Choice of method or procedure (ISO/IEC 17043: 2010, Clause 4.5)

The requirements given in Clause 4.5 of ISO/IEC 17043:2010 shall apply.

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4.6 Operation of a proficiency testing scheme (ISO/IEC 17043: 2010, Clause 4.6)

The requirements given in Clause 4.6 of ISO/IEC 17043:2010 shall apply.

Proficiency testing provider is responsible for the distribution and delivery of proficiency testing items, and sometimes the return of the test items which was used for inter-comparisons or examination of mechanical or electrical parameters. In such cases, it shall protect the integrity of proficiency testing items at all times before distribution and during transportation. Documented up to date instructions shall be available to personnel responsible for distribution and delivery regarding proper labeling, packing and environmental condition during transportation.

4.7 Data analysis and evaluation of proficiency testing scheme results (ISO/IEC 17043: 2010, Clause 4.7)

The requirements given in Clause 4.7 of ISO/IEC 17043:2010 and ISO 13528 shall apply.

The evaluation of proficiency testing scheme results to determine performance of participants shall be done by the proficiency testing provider itself. If the data analysis part is subcontracted, confidentiality of participant's identities shall be maintained and shall not disclose to the subcontractors. Therefore, proficiency testing provider shall have coding and decoding systems of original results received from the participants. All original results provided by the participants, processed data and analyzed results shall be returned by the subcontractors to the proficiency testing provider for further evaluation of participant's performance.

4.8 Reports (ISO/IEC 17043: 2010, Clause 4.8)

The requirements given in Clause 4.8 of ISO/IEC 17043:2010 shall apply.

The preparation, approval and issue of interim report for each round and the annual summary report of a continues 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.

Proficiency testing reports which are issued under the SLAB accreditation shall be signed by the authorized signatory nominated by the proficiency testing provider and approved by the SLAB. It is recommended to identify at least two competent persons as authorized signatories for a particular proficiency testing service provider to prevent unnecessary delays in the absence of only one authorized signatory. The authorized signatory may not necessarily to be the same person as the coordinator identified under clause 4.2 of this document. The coordinator, if different from the authorized proficiency testing signatory, shall participate in the preparation and drafting of the report and shall communicate closely with the authorized signatory for the final authorization of report.

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

4.9 Communication with participants (ISO/IEC 17043: 2010, Clause 4.9)

The requirements given in Clause 4.9 of ISO/IEC 17043:2010 shall apply.

It is acceptable for proficiency testing provider to issue statements of participation or performance to individual participants. Feedbacks and inquiries from participants shall be recorded. Technical Feedback shall be reviewed, and if necessary suitable follow up actions shall be taken.

4.10 Confidentiality (ISO/IEC 17043: 2010, Clause 4.10)

The requirements given in Clause 4.10 of ISO/IEC 17043:2010 shall apply.

All information on participant performance and records and information generated at different activities at different steps of the proficiency testing scheme shall not be disclosed to any third party unless prior agreement with concerned parties related to above mentioned activities unless otherwise it requires by laws/ regulations stipulate such disclosure. Therefore, proficiency testing providers shall be knowledgeable on relevant laws and regulations and such requirements shall be informed to the participant at the initial communication in order to prevent issues after disclosing information to regulators.

Where participant's identity and corresponding assign numbers have been disclosed, the proficiency testing provider shall record the identity of the person (s) and parties to whom such disclosure has been made. In such situation, proficiency testing provider shall make conditions to ensure that such information is disclosed within the framework of laws and regulations.

Where the final report contains information of test methods, equipment used and list of participants, there may be a possibility to find out the participant laboratory and assigned number of a particular laboratory. this situation may compromise the confidentiality of the participant results. Therefore, providing above information in the final report, is at the discretion of the PTP.

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5. MANAGEMENT REQUIREMENTS

5.1 Organization (ISO/IEC 17043: 2010, Clause 5.1)

The requirements given in Clause 5.1 of ISO/IEC 17043:2010 shall apply.

Proficiency testing provider or the organization of which it is part, shall be a legal entity that is clearly identifiable and carry out its activities in accordance with the laws and regulation of the relevant country. Where there are requirements laid down for the control limits of parameters for different matrices or materials which come under the regulations, proficiency testing providers shall consider those when organizing proficiency testing programmes.

Proficiency testing providers could design PT programs for any field of testing for any purpose to satisfy the participants' proficiency testing requirements. Each scheme shall be identified separately under the scope of accreditation.

Where proficiency testing provider is a part of larger organization, the organizational arrangements should be such that the departments having conflict of interests, such as operation, commercial marketing or financial should not adversely influence the PTPs' compliance with the requirements of ISO/IEC 17043 and this document. In such situation, proficiency testing provider shall evaluate threats to impartiality arisen from relationships (internal and external) and other means which directly affect the services of proficiency testing provider.

Proficiency testing provider shall define its organization and management structure identifying other functions of the organization and how it links to the parent organization.

Where the proficiency testing service provider's laboratories are 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 proficiency testing scheme shall be different from the personnel participating in the scheme.

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5.2 Management System (ISO/IEC 17043: 2010, Clause 5.2)

The requirements given in Clause 5.2 of ISO/IEC 17043:2010 shall apply.

The management system of the proficiency testing provider need not to be complex and its format will depend on number of factors including the size of organization, number of staff members and the range, volume and complexity of the proficiency testing that it provides.

Implementation of integrated management system for main organization, laboratories and proficiency testing is accepted and SLAB encourages the integrated management systems to minimize the duplication of work in relation to common management requirements, minimize the cost of assessments and save the time. It is necessary to consider conformity of systems with all requirements of applicable management system standards. One quality manager may be appointed for whole system. However, it is recommended to appoint deputies for each component of the system.

Roles and responsibilities of key functions shall be defined in the quality management system documentation. When proficiency testing provider is part of a larger organization, functions of other divisions shall be defined in order to prevent conflict of interest in providing proficiency testing services.

5.3 Document Control (ISO/IEC 17043: 2010, Clause 5.3)

The requirements given in Clause 5.3 of ISO/IEC 17043:2010 shall apply.

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5.4 Review of requests, tenders and contracts (ISO/IEC 17043: 2010, Clause 5.4)

The requirements given in Clause 5.4 of ISO/IEC 17043:2010 shall apply.

When participants enroll in proficiency testing schemes based on the information provided by the PTP, it is considered that they are entering into a contract with the proficiency testing provider. It is recommended to inform terms and conditions for each programme and /or make reference to terms and conditions in information documentation sent to participants at initiation. Participants shall be informed in case of changes to contract or conditions set out in relation to particular proficiency testing programme at any step of the programme.

If the proficiency testing provider is requested to organize a PT program by a regulatory authority or any other interested party, a contract agreement needs to be established between the PTP and the requested party. The PTP shall address this situation in the PTP procedures.

For existing programmes, feedback from customers shall be taken into consideration when reviewing contracts.

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5.5 Subcontracting services (ISO/IEC 17043: 2010, Clause 5.5)

The requirements given in Clause 5.5 of ISO/IEC 17043:2010 shall apply.

If a proficiency testing provider subcontracts any of its activities for the production, testing, measurement, inspections, sampling, storage, and distribution of the proficiency test items (e.g PT materials / samples or measurement artifacts), or for data processing and distribution of the proficiency testing reports, the work and responsibilities of each subcontractor shall be clearly defined and documented in relation to each proficiency testing schemes and shall be provided in the initial documentation sent to the participants along with the invitation.

The proficiency testing provider utilizing advice or assistance from any advisors, experts or steering group or use of testing / measurement facilities obtain from other divisions within the organization of which report to same top management are not considered as subcontracting provided that confidentiality of information and impartiality of activities have been ensured and demonstrated effectively and acceptable to the SLAB in question.

The subcontractors

An applicant or accredited proficiency testing provider shall ensure that the subcontractor responsible for the testing/ measuring activities shall conform to the ISO/IEC 17025 or ISO 15189 requirements as relevant.

PTP should ensure that all other activities which have an impact on the quality of its proficiency testing schemes, operates under suitable conditions.

If the work to be subcontracted is a test or measurement, a subcontractor holding current accreditation by SLAB or any other ILAC MRA partner for the relevant test, measurement or inspection is accepted as having adequately demonstrated its competence to carry out testing or measurement or inspection activities which is relevant to the proficiency testing scheme. Evidences of subcontractor's competence is also assessed during the assessments conducted by the SLAB at different stages of accreditation process such as pre assessments, initial, surveillance and re-assessments. SLAB may visit the subcontractor's premises where PT activities carried out and witnessing of PT activities, as a part of the assessment, if necessary.

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In such circumstances, the proficiency testing service provider shall ensure that its subcontractors will provide necessary cooperation and support to the assessment team, including but not limited to demonstration of the performance of activities, provision of any documents and data related to subcontracted activities and access to files and records during the on-site visits and other assessment activities on request.

Proficiency testing provider shall monitor subcontractor's activities in relation to proficiency testing scheme and periodically evaluate to ensure the compliance of requirements of proficiency testing provider and relevant sections of ISO/IEC 17043 and this documents for subcontractor's work. When evaluating competence of subcontractor, participation in PT programmes, staff competence, traceability sources, and calibration status of equipment, internal quality control programmes and also determination of uncertainty of measurements / calibration measurement capabilities or any other applicable criteria shall be considered for evaluation.

Any nonconformity identified related to subcontractors work in relation to proficiency testing scheme, is considered as nonconformity of proficiency testing provider. Proficiency testing provider is responsible for resolving issues related to particular nonconformity. In case the proficiency testing provider replaces its subcontractor, the new subcontractor shall be qualified as competent subcontractor after an initial competency evaluation. Proficiency Testing provider shall arrange provision to assess subcontractor/s by the accreditation body.

5.6 Purchasing services and supplies (ISO/IEC 17043: 2010, Clause 5.6)

The requirements given in Clause 5.6 of ISO/IEC 17043:2010 shall apply.

Purchasing of consumables

Consumable or perishable items may include media, chemical, reagents, blood products, biological samples, reference materials, etc.

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 of those items which bear a critical influence on the test or examination results. The records should include results of acceptance tests on each new batch 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 sources of supplies.

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Purchase of equipment

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

Service providers

PTP has to evaluate the service providers for continuing suitability.

5.7 Service to the customers (ISO/IEC 17043: 2010, Clause 5.7)

The requirements given in Clause 5.7 of ISO/IEC 17043:2010 shall apply.

The proficiency testing service provider shall seek feedback, both positive and negative, from its customers and also regulatory bodies if applicable. Proficiency testing service provider may conduct customer feedback surveys and review of proficiency testing reports with customers and may address common issues of participant laboratories.

5.8 Complaints and appeals (ISO/IEC 17043: 2010, Clause 5.8)

The requirements given in Clause 5.8 of ISO/IEC 17043:2010 shall apply.

The proficiency testing provider shall ensure the impartiality of appeal handling process. Therefore, those who involve in decision making or any person who has direct relationship with the appeal which made against adverse decision of proficiency testing provider shall not involve in appeal handling process.

5.9 Control of nonconforming work (ISO/IEC 17043: 2010, Clause 5.9)

The requirements given in Clause 5.9 of ISO/IEC 17043:2010 shall apply.

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5.10 Improvement (ISO/IEC 17043: 2010, Clause 5.10)

The requirements given in Clause 5.10 of ISO/IEC 17043:2010 shall apply.

5.11 Corrective Actions (ISO/IEC 17043: 2010, Clause 5.11)

The requirements given in Clause 5.11 of ISO/IEC 17043:2010 shall apply.

5.12 Preventive actions (ISO/IEC 17043: 2010, Clause 5.12)

The requirements given in Clause 5.12 of ISO/IEC 17043:2010 shall apply.

5.13 Control of records (ISO/IEC 17043: 2010, Clause 5.13)

The requirements given in Clause 5.13 of ISO/IEC 17043:2010 shall apply.

Records generated at all levels of the proficiency testing scheme shall be maintained to provide objective evidence to prove ~~that~~ the conformance of proficiency testing schemes with ISO/IEC 17043:2010.

5.14 Internal audits (ISO/IEC 17043: 2010, Clause 5.14)

The requirements given in Clause 5.14 of ISO/IEC 17043:2010 shall apply.

Internal auditors shall be familiar with the ISO/IEC 17043 requirements and other relevant national and international requirements available for statistical analysis, stability testing, homogeneity testing as well as PT item preparation and the test parameters covered by the proficiency testing scheme.

Records of internal audits shall be maintained to provide objective evidence for auditing of all requirements in the ISO/IEC 17043 standard. Therefore, it is recommended to use a comprehensive checklist for the internal audits.

If the proficiency testing provider uses subcontractors' services, internal audit programme shall cover activities of subcontractors and shall audit at least once a year.

5.15 Management reviews (ISO/IEC 17043: 2010, Clause 5.15)

The requirements given in Clause 5.15 of ISO/IEC 17043:2010 shall apply.

The top management of proficiency testing provider including authorized signatory, coordinator and its quality manager shall participate in management review. Reports and recommendations of technical advisory committees and summary of proficiency testing programmes including programmes not conducted shall be reviewed at the management review meeting in order to identify possibilities for re organizing such programmes and also to identify opportunities for improvements.

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Appendix A

(informative)

Types of proficiency schemes

The main text of this Annex B is the text of the Annex A of ISO/IEC 17043:2010.

Appendix B

(informative)

Statistical methods for proficiency testing

The main text of this Annex C is the text of the Annex B of ISO/IEC 17043:2010.

Appendix C

(informative)

Types of proficiency schemes

The main text of this Annex D is the text of the Annex C of ISO/IEC 17043:2010.

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Appendix D

COMPOSITION OF THE TECHNICAL ADVISORY COMMITTEE

SI No	Name	Designation	Status
01	Ms. Chandrika Thilakaratne	Director / CEO	Chairman
02	Dr. H P P S Somasiri	Additional Director General, ITI	Member
03	Ms. Subadra Jayasinghe	PTP Representative – Association of Testing Laboratories	Member
04	Ms. Sujeewa Udakara	Director, Metrology Division, SLSI	Member
05	Mr. S. D. I. Dias	Deputy Director, MUSSD	Member
06	Dr. S. I. Abeygunawardena	Retired Senior Lecturer, University of Kelaniya.	Member
07	Professor Chandrika Nanayakkara	Senior Lecturer, Department of Plant Science, University of Colombo.	Member
08	Ms. S. Muthuratne	Director, Building Material Research & Testing Division, NBRO	Member
09	Dr. Darshana Wickramasinghe	Consultant Microbiologist Medway Foundation Trust, Gillingham, Kent, UK. (Former Consultant Microbiologist at Hambantota General Hospital)	Member
10	Mr. N D S K Fernando and Ms. P S T R Mudalige	AD (Accreditation), SLAB	Co- secretaries

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