



Requirements, regulation and criteria for the competence of proficiency testing providers (LA-R-06)

Bureau of Laboratory Accreditation

Department of Science Service

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Introduction

This document defines the regulations to be met by proficiency testing providers (PTPs) applying for, and accredited by, the Bureau of Laboratory Accreditation, Department of Science Service (BLA-DSS). It additionally includes any requirements imposed by the Asia Pacific Accreditation Cooperation (APAC) through its document APAC MRA 001. The requirements for accreditation are laid down in ISO/IEC 17043: 2010 Conformity assessment- General requirements for proficiency testing.

It is the policy of BLA-DSS to extend the accreditation scope to proficiency testing providers in the scope in the fields of testing, calibration and medical testing. This document may be amended and the latest version is uploaded to the website of BLA-DSS.

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1. Scope

This document is applicable to all applicants and accredited PTPs of the Bureau of Laboratory Accreditation, Department of Science Service.

2. Definitions

- 2.1 Proficiency testing provider accreditation means the formal recognition that PTP demonstrates its competence in implementation of proficiency testing programs.
- 2.2 Applicant means the entrepreneur or assignee who requests for accreditation, scope extension or certification extension.
- 2.3 Accredited Proficiency testing provider means the PTP that has already passed assessment, and is approved for accreditation by the Laboratory Accreditation Committee.
- 2.4 Subcontractor means an organisation or person that is contracted to undertake specific activities relating to the provision of the scheme for a proficiency testing provider.
- 2.5 The Laboratory Accreditation Committee, hereinafter called “the Committee or LAC” is responsible for making the decisions on accreditation and commit to consideration of the competence of laboratory accreditation according to ISO/ IEC 17025 or PTP accreditation according to ISO/IEC 17043 or RMP accreditation according to ISO 17034 that require for the decision making process and service to consultations.
- 2.6 The Appeal Committee, hereinafter called “the AC” is responsible for investigating appeals against accreditation decisions made by the BLA-DSS and assigning the safeguard impartiality.
- 2.7 The BLA-DSS means the Bureau of Laboratory Accreditation, Department of Science Service.
- 2.8 Certificate means the certificate of the proficiency testing provider accreditation.
- 2.9 Remote assessment means the assessment of the physical location or virtual site of a proficiency testing provider, using electronic means

NOTE 1: On entry: a virtual site is an online environment allowing persons to execute processes, e.g. in a cloud environment.

NOTE 2: Examples of remote assessment include: webinars/web meetings, teleconferences, online video/audio services, remote access to organization's data processing and management systems, databases, etc.

3. General requirements

3.1 The granting, maintenance, extension and renewal of accreditation will only be afforded to a PTP which

- a) is a legal entity
- b) has not had its accreditation withdrawn within the last 6 months
- c) has permanent site, at a site away from its permanent facilities or associated temporary facilities of the operation.

3.2 The PTP shall establish and maintain quality system, which meets the requirements of ISO/IEC 17043 and Requirements, regulation and criteria of the BLA-DSS that PTP shall

- a) carry out internal audits for all activities within a year cycle that perform at the permanent address or outside its premise
- b) perform management reviews at least once per year. Where a PTP is part of a larger organization, it may be most appropriate to hold a separate management review to cover all activities within the scope
- c) maintain all records for a minimum of 5 years.
- d) conduct a proficiency testing program of its applied, accredited or relevant scope approved by BLA-DSS.
- e) ensure the organization whose PTP works will be subcontracted has been accredited by an accreditation body recognised by BLA-DSS. Where the subcontractor is not accredited for such works, PTP shall assess the competency of the subcontractor through on-site visits, and the subcontractor shall be required to carry out demonstration of the activities as requested by the PTP. In the proficiency testing report, the accredited PTP shall specify the activities performed and the results obtained by such

subcontractor. The accredited PTP shall not disclose the performance of any of its customers to any of its contractors without prior written approval from the customer. BLA-DSS reserves the right to assess the work of subcontractor to ensure their competency

- f) ensure that their own testing laboratory and subcontractors involved in testing associated with conduction of proficiency testing provider to meet the requirement of ISO/IEC 17025 or ISO 15189 and LA-R-03 clause 3.2d .
- g) frequency conduct of all schemes at least 1 round within 4 years.

3.3 The BLA-DSS has policy to assessment on site and may provide a remote assessment policy and rules when there is a necessary situation.

3.4 The BLA-DSS may conduct the preassessment not more than 1 month after receiving the application to examine the readiness of the PTP for further assessment.

3.5 The BLA-DSS may conduct the initial assessment of the applicant PTP within 6 months of the preassessment. In case of the preassessment is not conducted, within 6 months the applicant PTP is not ready for the initial assessment the BLA-DSS will cancel the application. Where the PTP requires a longer timescale to implement necessary changes to its management system, the PTP shall informed the reason in writing with appointing the timescale to the BLA-DSS for considering as appropriate.

3.6 The BLA-DSS shall conduct the initial assessment of the applicant PTP and inform the assessment report. The PTP shall be invited to respond to the recommendations and describe the specific actions taken or planned to be taken within 15 working days and shall be discharged the nonconformities within 3 months. If corrective action is not received within the agreed timescale, the BLA-DSS may allow the PTP to extend the timescale consecutive 1 month and up to the maximum period of 6 months (where appropriate) from the closing meeting date of the initial assessment. The reason for the extension shall be communicated to the BLA-DSS in writing.

The BLA-DSS shall conduct of assessment of the applicant PTP in the preparation of proficiency test items and packaging, labeling and distribution of proficiency test items in the applied or accredited scope. These activities were witnessed in the actual operation (if possible) and completed by applicant PTP at least 1 operation in a cycle of accreditation.

In case of the surveillance assessment, the reassessment and the extension of the scope the PTP shall be invited to respond to the recommendations and describe the specific actives taken or planned to be taken within 10 working days and shall discharge the nonconformities within 1 month. If corrective action is not received within the agreed timescale, the BLA-DSS may allow the PTP to extend the timescale consecutive 1 month and up to the maximum period of 4 months (where appropriate) from the closing meeting date of the assessment. The reason for the extension shall be communicated to the BLA-DSS in writing.

NOTE : Assessment during the transition period to the new edition of the standard for accredited PTPs.

1) Where an accredited PTP requests assessment in accordance with the previous edition of the standard, BLA-DSS shall conduct a surveillance. The PTP shall subsequently request reassessment to the new edition, and accreditation shall be granted within the specified transition period.

2) Where an accredited PTP requests accreditation to the new edition of the standard, BLA-DSS shall conduct a reassessment.

3.7 The BLA-DSS will issue a certificate and a scope of accreditation to the PTP. The certificate is valid for a cycle of 4 years, effective from the day following the date specified on the certificate. In case of the certificate is changed before the expired date, the expired date of the new certificate is the same date of the previous issue.

Unless accreditation is withdrawn or terminated by the BLA-DSS, the new certificate of accreditation is issued following the successful completion of a reassessment visit.

In case of the PTP certificate expired during the period of reassessment or reassessment and the extension, the BLA-DSS has conducted assessment and

followed up nonconformities in complete, the expiration date will be automatically extended until the process of reassessment or reassessment and the extension is finished. The extension scope will be accredited after have been granted by LAC.

- 3.8 The BLA-DSS will specify the procedures by which application for accreditation should be made, the conditions for granting, maintaining, extending and renewal of accreditation and the conditions under which accreditation may be reduced, refused or withdrawn.
- 3.9 The monitoring of compliance with the requirements of ISO/IEC 17043 and these regulations will be conducted in accordance with defined procedures. These procedures will be based on regular inspections by trained personnel acting on behalf of the BLA-DSS.
- 3.10 The frequency with which the PTP is normally subject to surveillance and reassessment will be prescribed by the BLA-DSS. It is the policy of the BLA-DSS to conduct surveillance visits at intervals of approximately 18-22 months and reassessments every 4 years from the assessment. In case of any change that affects the quality management system and the competence of the PTP, the BLA-DSS reserves the right to carry out additional and extraordinary visits and to require surveillance and reassessment visits at intervals other than those prescribed.
- 3.11 An accredited PTP may, at any time, request to extend the scope of its accreditation by informing in written and submitting a completed Supplementary document form to the BLA-DSS, 45 days in advance of the assessment.
- 3.12 The BLA-DSS reserves the right to change, at any time, any of these regulations or any of the relevant criteria prescribed by the BLA-DSS. The PTP shall be given due notice of any intended changes and will be given such time, as deemed reasonable by the BLA-DSS, to carry out the necessary adjustments. The PTP is required to comply with such changes and provide evidence, when asked, to demonstrate the changes have been made.

3.13 All information gained by the BLA-DSS and its representatives in the granting, maintenance and renewal of accreditation will be treated as confidential between the PTP and the BLA-DSS. Such information will be handled on a strict 'need to know' basis and will not, subject to the regulation of the Royal Thai government, be divulged without the express written instructions of the PTP management. All personnel of the BLA-DSS and those involved in the assessment and decision making process are required to sign confidentiality agreements with the BLA-DSS. The BLA-DSS is only responsible for consequences resulting from the direct actions of the BLA-DSS staff and its assessors.

3.14 The BLA-DSS under the consideration of LAC may reduce the scope of an accreditation when there is any change in any aspect of the PTP's status or operation that affects the competence in operating the proficiency testing program.

3.15 The BLA-DSS under the consideration of LAC may, at its discretion, suspend accreditation when the PTP fails to comply with ISO/IEC 17043 and the requirements, regulation and criteria for the competence of proficiency testing providers. The maximum allowed period of suspension shall not exceed 6 months, the BLA-DSS may formally withdraw accreditation if the PTP fails to demonstrate compliance with ISO/IEC 17043 or the requirements of the BLA-DSS within the agreed timescale.

3.16 The BLA-DSS may immediately suspend the certificate or reduce the scope of the accreditation when PTP fails to comply with the requirements of ISO/IEC 17043 and the requirements of the BLA-DSS.

3.17 The BLA-DSS under the consideration of the LAC may, at its discretion, withdraw accreditation, if

- a) the PTP becomes bankrupt
- b) the management of the PTP fails in any respect to comply with the requirements, regulation and criteria for the competence in the proficiency testing program

- c) the PTP ceases to provide the service within the scope of accredited proficiency testing program
- d) the PTP cannot maintain the ability to operate the PT program within the scope of accreditation
- e) the PTP is unable to maintain the ability to perform any task within the scope of accreditation after been suspended 2 times within 2 years.
- f) the PTP submit any fraudulent behaviour, falsification of information or deliberate violation of accreditation requirements evidence to inform BLA-DSS. The application or assessment process to be ceased or terminated in writing.

The PTP may reapply for accreditation 6 months after the date of termination.

3.18 The accredited PTP may ask for resignation of accreditation by informing the BLA-DSS in writing not less than 30 days before the date of the resignation. The applicant PTP may cancel the application by informing the BLA-DSS in writing. The paid fees are not refundable.

4. Conditions to be met by PTP

4.1 Impartiality, independence and integrity

- a) the PTP and its personnel shall be free from any commercial, financial and other pressures which might influence their technical judgement
- b) the PTP shall not allow external persons or organisations to influence the results of tests performed by the PTP
- c) the PTP shall not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its proficiency testing program activities.

4.2 Cooperation with the BLA-DSS

The PTP shall afford the BLA-DSS and its representatives such reasonable accommodation and cooperation as necessary, to enable the BLA-DSS to monitor

compliance with the accreditation requirements of ISO/IEC 17043 and these regulations. This cooperation shall include

- a) allowing the BLA-DSS and its representatives access to relevant areas of the PTP for the witnessing of its activities
- b) undertaking any reasonable checks to enable the BLA-DSS to verify the competence of the PTP
- c) preparation and demonstration any activities requested by the assessors that form part of the proposed or accredited scope of accreditation
- d) preparation, packaging and dispatch of any items or documentation required by the BLA-DSS for verification purposes
- e) permitting scrutiny by the BLA-DSS and its representatives of its quality system documentation including, but not limited to, planning document, final reports, internal audit and management review records etc.
- f) assisting the BLA-DSS and its representatives in the investigation and resolution of any properly authenticated complaints made by third parties about the PTP's accredited activities.
- g) accredited CAB shall have a commitment to their clients to provide, on request, access to BLA-DSS assessment teams to assess the conformity assessment body's performance when carrying out conformity assessment activities on the client's site (if applicable).

4.3 Duties arising from the use of accreditation

The accredited PTP shall

- a) at all times comply with the requirement of ISO/IEC 17043 and these regulations including the conditions prescribed by the BLA-DSS for the use of the BLA-DSS accreditation symbol or reference to BLA-DSS accreditation
- b) claim that it is accredited only in respect of the proficiency testing program for which it has been granted accreditation and which are carried out in accordance with these regulations
- c) cooperate with the BLA-DSS to verify the fulfilment of requirements for accreditation such as allowing the BLA-DSS and its representatives access

to relevant areas of the PTP personnel, locations, equipment, information, documents and records including witnessing of proficiency testing activities when requested by the BLA-DSS

- d) arrange the proficiency testing activities at their clients site in order to assess the PTP's performance, in case of on-site proficiency testing or client site
- e) pay such fees for application of accreditation, initial assessment, surveillance, extension scope assessment, reassessment, additional assessment and other services as shall from time to time be determined by the BLA-DSS according to LA-R-02
- f) not use its accreditation in such a manner as to bring the BLA-DSS into disrepute, and shall not make any statement relevant to its accreditation which the BLA-DSS may reasonably consider to be misleading
- g) upon suspension, withdrawal or resignation of its accreditation the accredited PTP immediately discontinue its use of the accreditation symbol according to LA-R-04 and/or reference to accreditation on the report, all documentation and publicity materials
- h) notify the clients when the accreditation is reduced, suspended, withdrawn, resigned or changed in the legal entity
- i) on withdrawal or resignation of its accreditation return the certificate within 1 month
- j) ensure that where the accreditation symbol or accreditation statement is used in a report it shall not be used in such a way as to imply that the BLA-DSS accepts responsibility for the activities carried out under the scope of accreditation
- k) endeavor to ensure that any properly authenticated complaints from third parties are promptly investigated and resolved in accordance with the PTP's policies and procedures for the handling of complaints
- l) notify the BLA-DSS, in writing, of its intention to maintain its accreditation at least 45 days in advance of the reassessment

- m) ensure that the subcontractor operates a quality control system and carries out the subcontracted activity, according to well-defined documented procedures.

5. Notification of change

5.1 The PTP shall inform the BLA-DSS immediately of any change in any aspect of the PTP's operation or status that affects the PTP's compliance with the accreditation criteria and regulations or otherwise affect the PTP's capability or scope of activity.

Such changes include

- a) law, business or organisation status
- b) the organisation and management, such as key management person
- c) policy or procedures significantly affecting the quality system and/ or the scope of accreditation
- d) the PTP's location or premises
- e) personnel, equipment, working environment or anything affecting significantly PTP management system
- f) authorized signatories.

6. Complaint and appeal

6.1 A complaint and appeal shall be implemented according to LA-I-05.

6.2 An appeal against the refusal, suspension or termination of accreditation, and disputes concerning the interpretations of the accreditation criteria and these regulations, will be dealt with by the AC according to LA-I-05.

6.3 An appeal against any decision shall be submitted, in written form, within 30 days of formal notification of decision to the Chairman of the AC. The Chairman of the AC assigns the Special Appeal Committee "SAC" to consider the appeal.

6.4 The SAC is responsible for submitting the consideration result to the AC who is responsible for making the final decision.

6.5 The AC shall prepare document concerning the appeal and is required to complete the process, including reporting the outcome to the appellant, within 60 days of the date of receipt of the appeal.

6.6 Whilst an appeal is in process, the previous decision of the committee is enforced.