Requirements, regulation and criteria for the competence of testing laboratories (LA-R-03)

Bureau of Laboratory Accreditation

Department of Science Service

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Introduction

This document defines the regulations according to ISO/IEC 17025 to be met by testing laboratories 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.

It is the policy of BLA-DSS to provide testing laboratory accreditation service according to ISO/IEC 17025 in the scopes of Physical Testing, Chemical Testing and Biological Testing. This document can be downloaded on the website http://bla.dss.go.th

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1. Scope

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

2. Definitions

2.1 Laboratory accreditation means the formal recognition that a laboratory is technically competent to carry out specific tests.

2.2 Applicant means the entrepreneur or assignee who requests for accreditation, scope extension or certification extension.

2.3 Accredited laboratory means the laboratory that has already passed assessment, and is approved for accreditation by the Laboratory Accreditation Committee.

2.4 Externally provided products and services means an organization or a company or individual personnel who provide products and services conform to the laboratory's established requirements or, to the relevant requirements. Externally provided products and services are, for example, seller, subcontractors and proficiency testing providers.

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 testing laboratory accreditation.

2.9 Laboratory means body that performs one or more of the following activities: testing, calibration and sampling associated with subsequent testing or calibration

2.10 Decision rule means rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

2.11 Remote assessment means the assessment of the physical location or virtual site of a conformity assessment body, 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 laboratory 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, in associated temporary or mobile facilities or at a customer's facility of the operation.

3.2 The laboratory shall establish quality system, which meets the requirements of ISO/IEC

17025 and Requirements, regulation and criteria of the BLA-DSS that laboratory 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 laboratory is part of a larger organization, it may be more 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) develop a PT plan according to laboratory needs, and/or participate in any appropriate program of proficiency testing or interlaboratory comparison that the BLA-DSS deem necessary. The BLA-DSS requires laboratories to participate in at least one program of proficiency testing scheme (or interlaboratory comparison) each major sub discipline in a relevant scope when an appropriate scheme is available within its proposed scope of accreditation before accreditation is granted and at least one program every 2 years after accreditation. It is the responsibility of the laboratory to ensure that the scheme operates in accordance with the requirements of ISO/IEC 17043. Where results from the proficiency program do not meet defined criteria, the laboratory shall determine the root cause of nonconformity and undertake appropriate corrective action with the assigned time frame.

Where the evidence from the participation of proficiency testing scheme and/ or interlaboratory comparison casts doubts on the competence of the laboratory and the laboratory does not undertake appropriate corrective action with the assigned time frame. The BLA-DSS may refuse accreditation to the applicant laboratory for the defined test or tests or may suspend or withdraw accreditation for the defined test or tests from an existing scope of accreditation until additional evidence is supplied. The BLA-DSS reserves the right to require the accredited laboratory in participating in the Proficiency Testing Schemes as BLA-DSS assigned.

3.3 In case of the laboratory has a policy of sampling or when it carries out sampling of substances materials or products for subsequent testing. Sampling may be performed by the laboratory itself, or by other units under the same organization, or by external providers. In case of the laboratory do not perform the sampling itself, the units or external providers who provide this service to the laboratory has to be assessed for the competence according to the ISO/IEC 17025 requirements. In such case, the laboratory is required to give the sampling information in the report.

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

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

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

3.7 The BLA-DSS shall conduct the initial assessment of the applicant laboratory and inform the assessment report. The laboratory shall be invited to respond to the recommendations and describe the specific actives taken or planned to be taken within 15 working days and shall discharge the nonconformities within 3 months. If corrective action is not received within the agreed timescale, the BLA-DSS may allow the laboratory 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.

In case of the surveillance assessment, the reassessment and the extension of the scope the laboratory 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 laboratory 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 When a new edition of ISO/IEC 17025 is published, the BLA-DSS will establish and communicate a transition period for accredited laboratories to implement the new requirements. The implementation of the transition will be evaluated by the BLA-DSS during surveillance or reassessment visits, depending on the accreditation cycle.

3.8 The BLA-DSS will issue a certificate and a scope of accreditation to the laboratory. 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 laboratory 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 the BLA-DSS Director.

3.9 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.

3.10 The monitoring of compliance with the requirements of ISO/IEC 17025 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.

3.11 The frequency with which the laboratory 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 laboratory, 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.

3.12 An accredited laboratory 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.

3.13 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 laboratory 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 laboratory is required to comply with such changes and provide evidence, when asked, to demonstrate that the changes have been made.

3.14 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 laboratory 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 laboratory 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.

3.15 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 laboratory's status or operation that affects the laboratory's capability.

3.16 The BLA-DSS under the consideration of LAC may, at its discretion, suspend accreditation when the laboratory fails to comply with ISO/IEC 17025 and the requirements, regulation and criteria for the competence of testing laboratories. The maximum allowed period of suspension shall not exceed 6 months, the BLA-DSS may formally withdraw accreditation if the laboratory fails to demonstrate compliance with ISO/IEC 17025 or the requirements of the BLA-DSS within the agreed timescale.

3.17 The BLA-DSS may immediately suspend the certificate or reduce the scope of the accreditation when the laboratory fails to comply with the requirements of ISO/IEC 17025 and the requirements of the BLA-DSS.

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

a) the laboratory becomes bankrupt
b) the management of the laboratory fails in any respect to comply with the requirements, regulation and criteria for the competence of testing laboratories
c) the laboratory ceased to provide the service within the scope of accreditation
d) the laboratory cannot maintain the ability to perform any task within the scope of accreditation
e) the laboratory 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 laboratory submits 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 laboratory may reapply for accreditation 6 months after the date of termination.

3.19 The accredited laboratory 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 laboratory may cancel the application by informing the BLA-DSS in writing. The paid fees are not refundable.

4. Conditions to be met by testing laboratories

4.1 Impartiality, independence and integrity

a) the laboratory and its personnel shall be free from any commercial, financial
and other pressures which might influence their technical judgement

b) the laboratory shall not allow external persons or organisations to influence the results of tests performed by the laboratory

c) the laboratory shall not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its testing activities.

4.2 Cooperation with the BLA-DSS

The laboratory 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 17025 and these regulations. This cooperation shall include

a) allowing the BLA-DSS and its representatives access to relevant areas of the laboratory for the witnessing of tests

b) undertaking any reasonable checks to enable the BLA-DSS to verify the competence of the laboratory

c) preparation and demonstration any tests 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 and record, including, but not limited to, test reports

and certificates, internal audit and management review records, proficiency testing results 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 laboratory's accredited testing 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 laboratory shall

a) at all times comply with the requirement of ISO/IEC 17025 and these regulations, including the conditions prescribed by the BLA-DSS for the use of the BLA-DSS accreditation symbol (LA-R-04) or reference to BLA-DSS accreditation

b) claim that it is accredited only in respect of the testing services 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 laboratory personnel, locations, equipment, information, documents and records including witnessing of laboratory activities when requested by the BLA-DSS

d) arrange the laboratory activities at their client site in order to assess the laboratory's performance, in case of on-site 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 laboratory immediately discontinue its use of the accreditation symbol according to LA-R-04 and/or reference to accreditation on test reports, 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) endeavour to ensure that any properly authenticated complaints from third parties are promptly investigated and resolved in accordance with the laboratory'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- define documented procedures.

5. Notification of change

5.1 The laboratory shall inform the BLA-DSS immediately of any change in any aspect of the laboratory's operation or status that affects the laboratory's compliance with the accreditation criteria and regulations or otherwise affect the laboratory'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 laboratory's location or premises

e) personnel, equipment, working environment or anything affecting significantly laboratory 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.