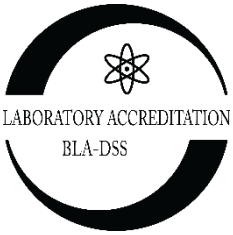

Requirements, regulation and criteria for the competence of reference material producers (LA-R-08)

Bureau of Laboratory Accreditation

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Introduction

This document defines the regulations to be met by reference material producers (RMPs) 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 17034 General requirements for the competence of reference material producers.

It is the policy of BLA-DSS to extend the accreditation scope to reference material producers. This document may be amended and the latest version is uploaded to the website of BLA-DSS.

Content

1. Scope

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

2. Definitions

2.1 Reference material producer accreditation means the formal recognition that RMP demonstrates its competence in implementation of reference material.

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

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

2.4 Subcontractor means a technically competent body that undertakes aspects of the processing, handling, homogeneity and stability assessment, characterization, storage or distribution of the reference material.

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 reference material producer 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 RMP which

a) is a legal entity

b) has not had its accreditation withdrawn within the last 6 months

c) has a permanent site or at other sites (including associated temporary or mobile facilities) of operation.

3.2 The RMP shall establish and maintain quality system, which meets the requirements of ISO 17034 and Requirements, regulation and criteria of the BLA-DSS that RMP 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 a year. Where a RMP 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 process of reference material production of its applied, accredited or relevant scope approved by BLA-DSS.

e) ensure that the organization whose RMP works will be subcontracted has been accredited by an accreditation body recognised by BLA-DSS. Where the subcontractor is not accredited for such works, RMP 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 RMP. A RMP shall specify the subcontracted works. 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 production of reference material to meet the requirement of ISO/IEC 17025 or ISO 15189 as defined in LA-R-03 clause 3.2 d.

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

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

3.5 The BLA-DSS may conduct the initial assessment of the applicant RMP within 6 months of the preassessment. In case of the preassessment is not conducted, within 6 months the applicant RMP is not ready for the initial assessment the BLA-DSS will cancel the application. Where the RMP requires a longer timescale to implement necessary changes to its management system, the RMP shall be informed the reason in writing with appointing the timescale to the BLA-DSS for considering as appropriate. It is the responsibility of the case officer in conjunction with lead assessor and Head of LAS to decide whether any further assessment is required before an initial assessment takes place.

3.6 The BLA-DSS shall conduct the initial assessment of the applicant RMP and inform the assessment report. The RMP 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 discharge the nonconformities within 3 months. If corrective action is not received within the agreed timescale, the BLA-DSS may allow the RMP 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 assess the operation process, homogeneity and stability testing, packaging, labelling certification, distribution of RMs and any other related activities in

the applied or accredited scope. These activities were witnessed the actual operation (if possible) at least 1 operation in a cycle of accreditation.

In case of the surveillance assessment, the reassessment and the extension of the scope, the RMP shall be invited to respond to the recommendations and describe the specific actions taken or planned to be taken within 10 working days and shall discharge the nonconformities within 1 months. If corrective action is not received within the agreed timescale, the BLA-DSS may allow the RMP 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 RMPs.

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

2) Where an accredited RMP 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 RMP. 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 RMP 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 17034 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 RMP 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 RMP, 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 RMP 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 RMP 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 RMP 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 RMP 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 RMP 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 RMP's status or operation that affects the competence in operating the reference material production.

3.15 The BLA- DSS under the consideration of LAC may, at its discretion, suspend accreditation when the RMP fails to comply with ISO 17034 and the requirements, regulation and criteria for the competence of RMP. The maximum allowed period of suspension shall not exceed 6 months, the BLA- DSS may formally withdraw accreditation if the RMP fails to demonstrate compliance with ISO 17034 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 RMP fails to comply with the requirements of ISO 17034 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 RMP becomes bankrupt

b) the management of the RMP fails in any respect to comply with the requirements, regulation and criteria for the competence of RMP

c) the RMP ceases to provide the service within the scope of accredited RMP

d) the RMP cannot maintain the ability to operate the RM production within the scope of accreditation

e) the RMP 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 RMP 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 RMP may reapply for accreditation 6 months after the date of termination.

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

4. Conditions to be met by RMP

4.1 Impartiality, independence and integrity

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

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

c) the RMP shall not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its reference material production activities.

4.2 Cooperation with the BLA-DSS

The RMP 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 17034 and these regulations. This cooperation shall include

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

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

c) preparation and demonstration any activities requested by 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, RMP production, certificate, 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 RMP'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 RMP shall

a) at all times comply with the requirement of ISO 17034 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 reference material 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 RMP activities when requested by the BLA-DSS

d) arrange RMP activities at their clients site in order to assess the RMP's performance, in case of on-site RMP 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 RMP immediately discontinue its use of the accreditation symbol according to LA-R-04 and/or reference to accreditation of certification, all documentation and publicity materials

h) notify the clients when the accreditation is reduced, suspended, withdrawn, resigned or changed in the legal entity

g) on withdrawal or resignation of its accreditation return the certificate within 1 month

h) ensure that where the accreditation symbol is used in a report or certificate 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

i) endeavor to ensure that any properly authenticated complaints from third parties are promptly investigated and resolved in accordance with the RMP's policies and procedures for the handling of complaints

j) notify the BLA- DSS, in writing, of its intention to maintain its accreditation at least 45 days in advance of the reassessment

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

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