



Accreditation process (LA-I-02)

Bureau of Laboratory Accreditation

Department of Science Service

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Introduction

This document gives general information on the process of laboratory, proficiency testing provider and reference material producer preparation for accreditation and accreditation assessment. It is applicable to testing laboratories, proficiency testing providers and reference material producers applying for the accreditation from the Bureau of Laboratory Accreditation, Department of Science Service (BLA-DSS).

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1. Scope

This document is applicable to all laboratories, all proficiency testing providers and all reference material producers applying for the laboratory, the proficiency testing provider and the reference material producer accreditation from the BLA-DSS.

2. Definitions

- 2.1 Accreditation means the formal recognition that a laboratory or a proficiency testing provider or a reference material producers is technically competent to carry out specific tests and scopes.
- 2.2 Applicant means the entrepreneur or assignee who requests for accreditation, scope extension or certification extension.
- 2.3 The Laboratory Accreditation Committee, hereinafter called "the Committee or LAC is responsible for considering the competence of laboratory accreditation to ISO/IEC 17025 or proficiency testing provider accreditation to ISO/IEC 17043 or reference material producer accreditation to ISO 17034 for decisions made for accreditation, as well as provision of consultation and advice related to accreditation activities.
- 2.4 Accredited laboratory or proficiency testing provider or the reference material producer means the laboratory or the proficiency testing provider or the reference material producer that has already passed assessment, and is approved for accreditation from Laboratory Accreditation Committee.
- 2.5 The BLA-DSS means the Bureau of Laboratory Accreditation, Department of Science Service.
- 2.6 Certificate means Certificate of testing laboratory accreditation or Certificate of proficiency testing provider accreditation or Certificate of reference material producer accreditation.

3. Steps of laboratory, proficiency testing provider and reference material producer preparation for accreditation

3.1 Laboratory or proficiency testing provider or reference material producer management appoints a working group for studying ISO/IEC 17025 or ISO/IEC 17043 or ISO 17034

3.2 Laboratory or proficiency testing provider or reference material producer management defines the policy on the quality system management of the laboratory or the proficiency testing provider or the reference material producer.

3.3 Working group establishes quality manual and related documents.

3.4 Laboratory or proficiency testing provider or reference material producer implements quality system as defined in quality manual and related documents.

3.5 Laboratory or proficiency testing provider or reference material producer management appoints internal auditors to ensure that the quality system meets the requirements, is implemented and maintained effectively.

3.6 Laboratory or proficiency testing provider or reference material producer implements the corrective action of nonconformities found from internal audit and improves the quality system efficiency.

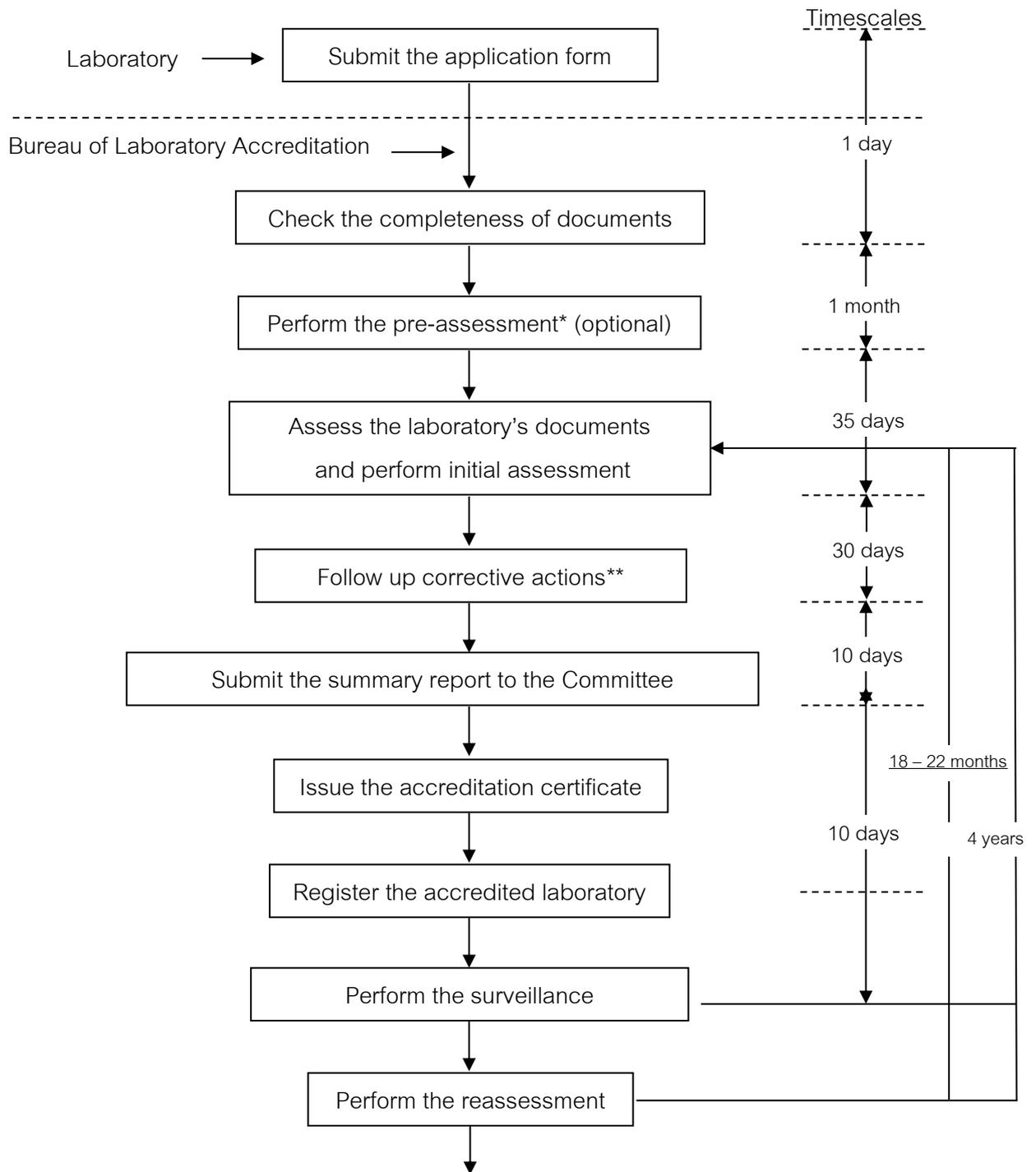
3.7 Laboratory or proficiency testing provider or reference material producer applies the accreditation request to the BLA-DSS.

4. Steps of laboratory, proficiency testing provider and reference material producer accreditation

The laboratory, proficiency testing provider and reference material producer accreditation process of the BLA-DSS are as follows.

- 4.1 Laboratory or proficiency testing provider or reference material producer submits the application form with the supporting documents mentioned in LA-F-01 or LA-F-201 or LA-F-301.
- 4.2 The BLA-DSS checks the completeness of documents.
- 4.3 The assessment team performs the pre-assessment (optional).
- 4.4 The assessment team assesses the laboratory's documents or proficiency testing provider's documents or reference material producer's documents and the laboratory's competence or the proficiency testing provider's competence or reference material producer's competence for the initial assessment.
- 4.5 The assessment team follows up the corrective actions of nonconformities.
- 4.6 The assessment team submits the summary report of assessment to the Committee
- 4.7 The Committee submits the summary report to the BLA-DSS Director for granting of the accreditation.
- 4.8 The BLA-DSS issues the accreditation certificate to the laboratory or to the proficiency testing provider or to the reference material producer.
- 4.9 The BLA-DSS registers the accredited laboratory or the accredited proficiency testing provider or the accredited reference material producer.
- 4.10 The BLA-DSS performs the surveillance.
- 4.11 The BLA-DSS performs the reassessment.

5. Flow chart of laboratory accreditation

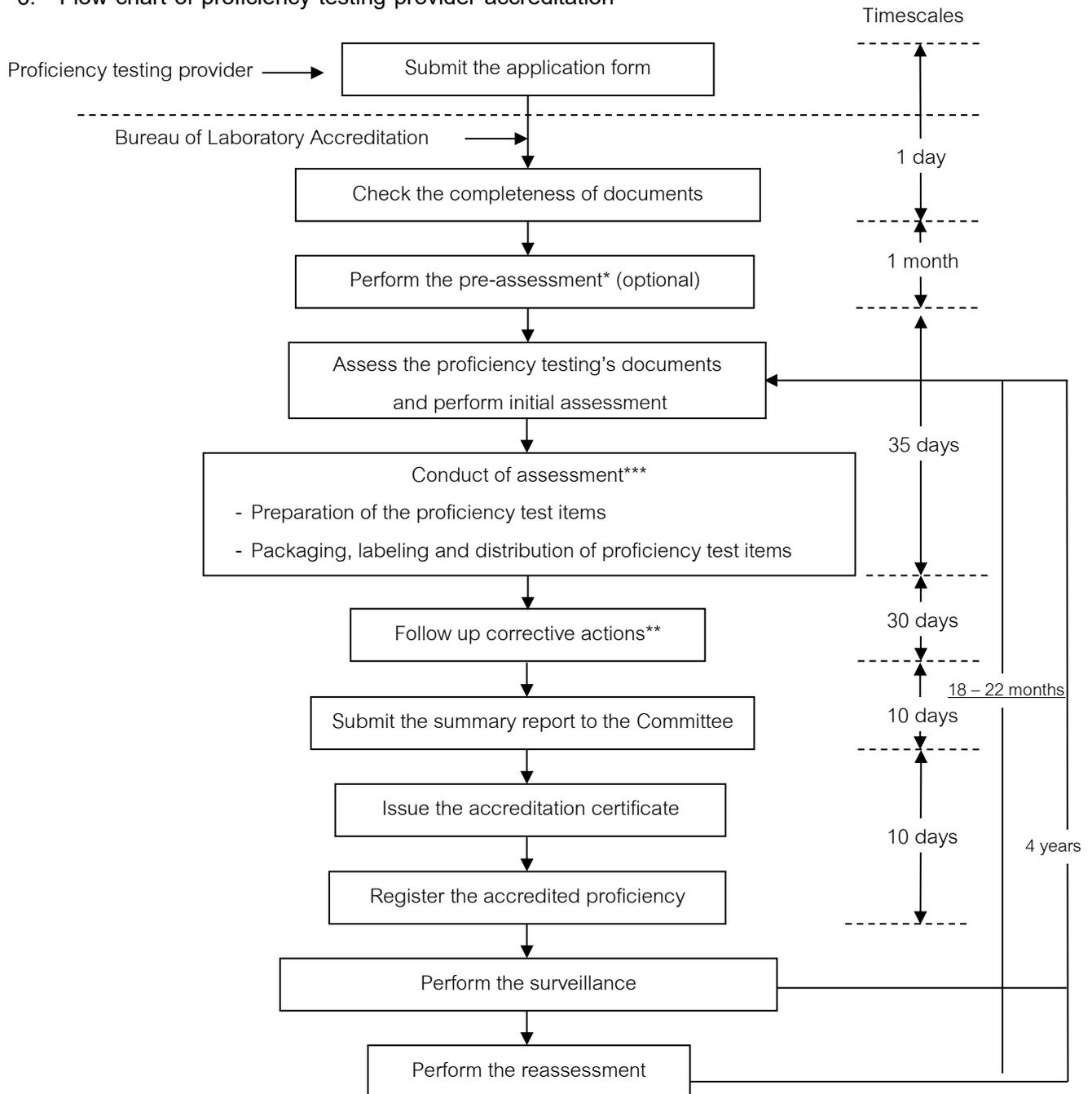


Note : (1) “day” means working day.

(2) * The laboratory shall carry out any actions resulting from the pre-assessment and undergo an initial assessment within 6 months of the pre-assessment.

(3) ** The laboratory shall discharge the non-conformities within 3 months of the initial assessment.

6. Flow chart of proficiency testing provider accreditation



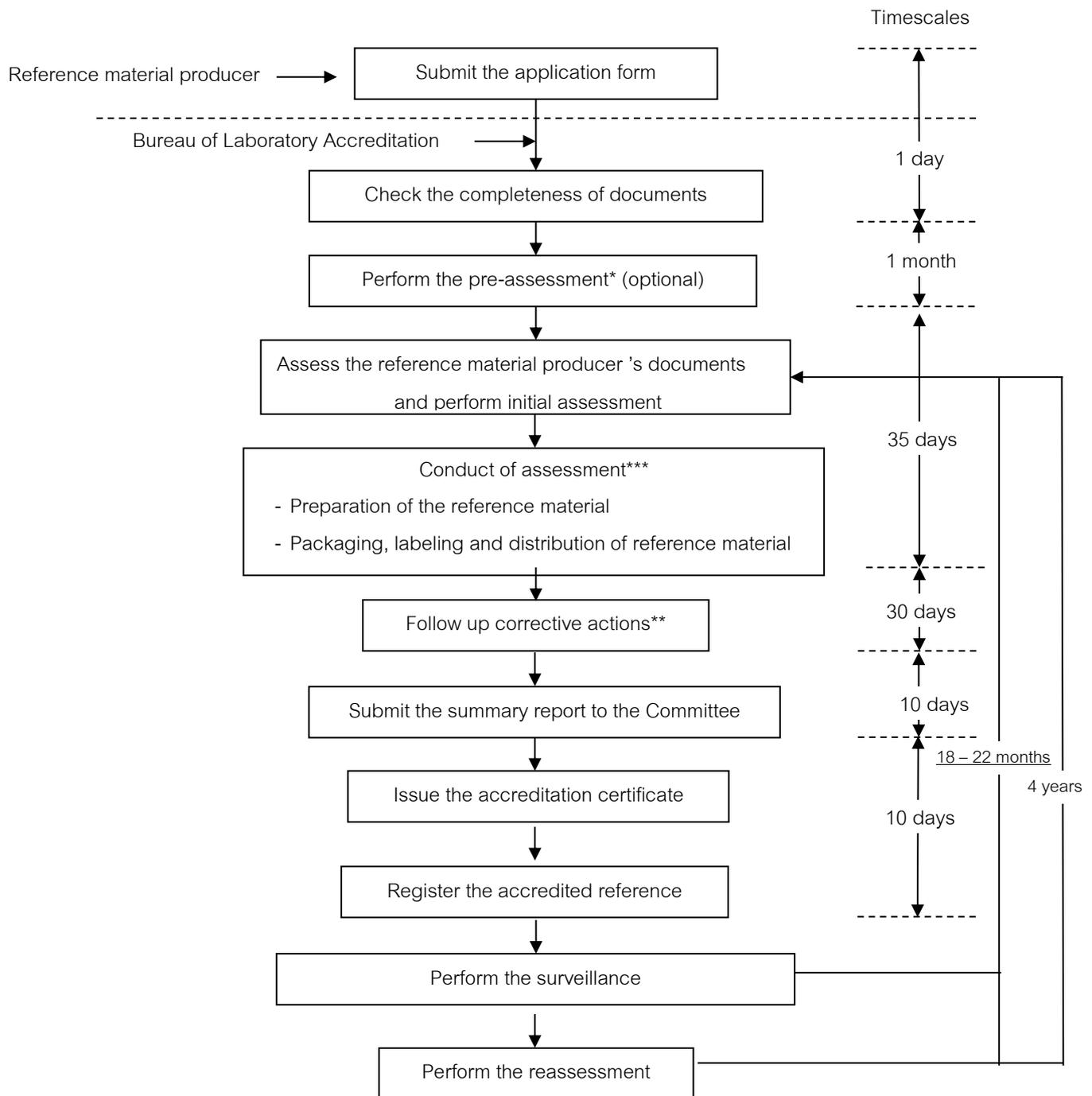
Note : (1) "day" means working day.

(2) * The proficiency testing provider shall carry out any actions resulting from the pre-assessment and undergo an initial assessment within 6 months of the pre-assessment.

(3) ** The proficiency testing provider shall discharge the non-conformities within 3 months of the initial assessment.

(4) *** The BLA-DSS shall conduct additional assessment if they are not performed simultaneously with the assessment.

7. Flow chart of reference material producer accreditation



Note : (1) "day" means working day.

(2) * The reference material producer shall carry out any actions resulting from the pre-assessment and undergo an initial assessment within 6 months of the pre-assessment.

(3) ** The reference material producer shall discharge the non-conformities within 3 months of the initial assessment.

(4) *** The BLA-DSS shall conduct additional assessment if they are not performed simultaneously with the assessment.

8. Accreditation assessment

The BLA-DSS conducts the assessment of the laboratory competence or the proficiency testing provider competence or the reference material producer competence within the scope requested. These assessments are part of laboratory, proficiency testing provider and reference material producer accreditation process complying to ISO/IEC 17025 or ISO/IEC 17043 or ISO 17034 and the Requirements, regulation and criteria for the competence of testing laboratories (LA-R-03) or regulation and criteria for the competence of proficiency testing provider (LA-R-06) or regulation and criteria for the competence of reference material producer (LA-R-08).

Steps of laboratory, proficiency testing provider and reference material producer assessment

8.1 The BLA-DSS appoints the qualified assessment team and notifies the laboratory or the proficiency testing provider or the reference material producer for approval.

8.2 On-site assessment

8.2.1 The Lead Assessor conducts the opening meeting with the laboratory's or proficiency testing provider's or reference material producer's representative by introducing the assessment team, explaining the assessment objective, informing the assessment schedule and confirming the latest quality manual including the necessary resources and other related issues.

8.2.2 The quality system is assessed by assessing the laboratory or proficiency testing provider or the reference material producer quality documents and recording the findings and nonconformity indicators as defined in nonconformity report form.

8.2.3 The technical assessment is assessed by assessing the competence of laboratory in performing test or proficiency testing provider in conduction of the proficiency testing programme or reference material producer in conduction of the reference material process within the scope applied and

recording the findings and nonconformity indicators as defined in nonconformity report form.

8.2.4 The Lead assessor conducts the closing meeting to conclude the assessment, by presenting the quality and technical assessment result to laboratory or proficiency testing provider or reference material producer representatives and answering the questions. The laboratory or proficiency testing provider or reference material producer determines the duration to complete correction activities. In case the assessment team cannot give decision on any findings, the BLA-DSS shall be contacted for final decision.

8.3 Assessment report

- a) assessment team prepares the laboratory or the proficiency testing provider or the reference material producer assessment report and submits to the LAC for consideration
- b) the Committee the report to the BLA-DSS Director for granting of the accreditation
- c) the BLA-DSS notifies the accreditation decision in writing to applicant.

8.4 The BLA-DSS issues the accreditation certificate to the laboratory or the proficiency testing provider or the reference material producer.