財團法人全國認證基金會
Taiwan Accreditation Foundation

Laboratory and Inspection Body Accreditation Service Manual

Laboratories and Inspection Bodies
Application information
TAF-CNLA-A01(21)

In the event of any difference between the Chinese and English versions, the Chinese version of this document shall govern.

Description

The Taiwan Accreditation Foundation (hereinafter referred to as TAF) is a non-profit organization that provides comprehensive and professional accreditation service. It is also the only accreditation body in Taiwan recognized by international accreditation organizations. TAF has established a conformity assessment system that complies with international standards, and provides impartial, independent and transparent accreditation service by utilizing the capacity of relevant technical groups and professional assessment manpower in Taiwan. TAF promotes international accreditation of conformity assessment bodies (laboratories, inspection bodies, proficiency testing provider (PTP), reference material producer (RMP) and certification bodies) in various fields in Taiwan for improving their quality and technical capabilities. TAF is also committed to talent training and information promotion and strengthening of accreditation credibility to meet the needs of clients (government, industry and commerce, consumers, etc.), promote and enhance industry and national competitiveness as well as consumer welfare.

TAF is a member of the International Laboratory Accreditation Cooperation (ILAC) and the Asia Pacific Accreditation Cooperation (APAC), and has signed the Mutual Recognition Arrangement (MRA) on behalf of Taiwan. Test/calibration/inspection reports (or certificates) issued by the TAF-accredited laboratories and inspection bodies are accepted by the international accreditation bodies that signed the MRA.

TAF is an impartial, independent, and transparent accreditation body. For planning, formulation, and review of accreditation-related documents, TAF seeks public opinions through announcement on the TAF website and the members-only area on the TAF member network. TAF also invites TAF technical committee members or external experts to formulate and/or review documents, and adopts the above necessary review methods based on the nature of the documents so that the views of various communities can be included. The issuance and implementation of new documents are also announced on the TAF website and members-only area in the accreditation service information system.

Disclaimer: **The intellectual property rights of this document belong to TAF. No one may use, modify, reproduce, publicly broadcast, modify, disseminate, distribute, publish, decompile, disassemble or sell without prior written agreement from TAF.**

Taiwan Accreditation Foundation
Taipei Office
TEL: 02-2809 0828 FAX: 02-2809 0979
ADDRESS; 23F., No. 27, Sec. 2, Zhongzheng E. Rd., Tamsui Dist., New Taipei City 25170
Hsinchu Office
TEL: 03-533 6333 FAX: 03-533 8717
ADDRESS: 2F., No. 95, Beida Rd., North Dist., Hsinchu City 30044
Website URL: www.taftw.org.tw

Table of Contents

Page No.

Foreword 1

1. Objective 1

2. Scope 1

3. Introduction to TAF 1

4. Definition of terms 3

Part I Description of Laboratory and Inspection Body Accreditation Service 9

5. Mission, goals and principles 9

6. Accreditation objects 10

7. Accreditation field 12

8. Accreditation program 15

9. Accreditation criteria 15

10. Accreditation number and accreditation certificate 16

11. Accreditation symbols 18

12. Rights and obligations 20

13. Accreditation fees 20

14. Proficiency testing 21

15. Website resources and service description 21

16. Publications 22

17. Assessment manpower resources 23

18. Directory of accredited bodies 23

19. Mutual recognition and cooperation 24

20. Complaints 25

21. Appeal 26

Part II Instructions on Accreditation Assessment 26

22. Accreditation process (initial, renewal and extending) 28

23. Application operation (initial, renewal and extending) 29
24. Assessment operations (initial, renewal and extending).....33
25. Assessment Review(initial, renewal and extending) 39
26. Accreditation decisions (initial, renewal and extending).....40
27. Notices 41
Part III Amendment, Maintenance of Accreditation and Termination of Relationship 44
28. Amendment ofAccredited laboratory/inspection body 44
29. Maintenance of Accreditation.....46
30. Suspension, reduction and withdrawal/revocation 50

Note: The underline parts in this document are the main revision of this version.

This document shall take effect from the date of issuance, and the provisions of this version shall apply from the implementation date onward.

Foreword

1. Objective

This document is the principles and procedures for the implementation of laboratory and inspection body accreditation service by the Taiwan Accreditation Foundation (hereinafter referred to as TAF). It shall be followed by the TAF staff, assessors and applicants/accredited laboratories or inspection bodies to facilitate application and maintenance of accreditation. This document is also an important reference for users of accredited laboratories and inspection bodies, as well as the domestic and foreign competence authorities, to understand and trust the accreditation services of TAF.

2. Scope

This document is applicable to the TAF accreditation service for laboratories and inspection bodies.

3. Introduction to TAF

3.1 Legal basis

TAF completed the registration of foundation according to the Law of the Republic of China, and received the certificate of foundation registration from the Taiwan Taipei District Court in September 2003.

The highest operation principle of Taiwan Accreditation Foundation is based on Contributions Articles of Taiwan Accreditation Foundation (TAF-AR-01), and the Laboratory Accreditation service was formally established and started from October 1st of the same year. In 2004, the Inspection Body accreditation service was added; in 2007, the Proficiency Testing Provider accreditation service was added; and in 2011, the Reference Material Producers accreditation service was added.

3.2 Scope of services

The TAF's accreditation services covers the accreditation of management system certification bodies, product certification bodies, personnel certification bodies, validation and verification bodies, laboratories, inspection bodies, proficiency testing providers (PTPs), reference material producers (RMPs), health examination units, point-of-care (POCT) management unit, and biobanking, as well as other business related to accreditation, such as the R&D of forward-looking accreditation capacity, OECD Good Laboratory Practice (GLP) Compliance Monitoring Program, international affairs, and talent training and promotion.

3.3 Financial sources

Funds for the TAF operation come from:

(1) Revenue from research and development budget and accreditation services;
(2) Subventions from government authorities or budget from the specific service programs commissioned by the government authorities or agencies;
(3) Donations from public or private organizations or individuals;
(4) Interest earnings from the TAF fund;
(5) Other income related to the business implementation.

3.4 TAF organization

3.4.1 Organizational structure

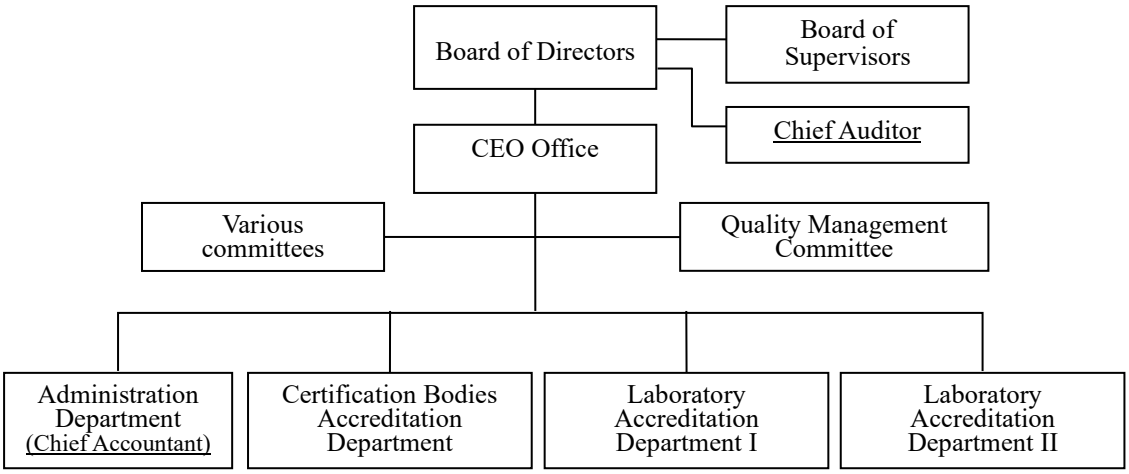
The TAF organization includes Board of Directors, supervisors, Chief Executive Officer Office (CEO officer), Administration Department, Laboratory Accreditation Department I (LA I), Laboratory Accreditation Department II (LA II), Certification Bodies Accreditation Department (CBA), Quality Management Committee and various committees.

The Board of Directors and the Board of Supervisors are the core of TAF's highest management. The Chairman of the Board of Directors is the legal responsible person of TAF, responsible for signing the accreditation certificate issued by TAF. The CEO oversees all businesses of TAF according to the resolution of the Board of Directors. The Laboratory Accreditation Department I and the Laboratory Accreditation Department II are in charge of the accreditation of laboratories, inspection body, proficiency testing provider (PTP), reference material producer (RMP), health examination units, point-of-care (POCT) management unit, biobanks, and Good Laboratory Practices (GLP) National Compliance Monitoring Program. The Certification Bodies Accreditation Department is responsible for the accreditation of various certification bodies. The Administration Department handles the TAF legal affairs, public relationship, information system, personnel affairs and accounting, educational training, planning, control and promotion of accreditation service. The Quality Management Committee is in charge of the implementation and promotion of the TAF quality management activities. Depending on business needs, the CEO Office can set up various committees. For example, the Technical Committee is the committee related to accreditation service. Its main task is to review technical

documents, such as technical criteria and guidelines, as well as technical affairs consultation.

3.4.2 Organization chart

The TAF organization chart is as shown below:



3.5 TAF logo

TAF logo (below) is registered with the Intellectual Property Office of the Ministry of Economic Affairs. The conformity assessment bodies (CAB) should not use it in any documents or publicity at will. The accredited CABs can use accreditation symbol and should be in accordance with Chapter 11 of this document.

4. Definition of terms

In consideration of the common terminologies used by the ISO/IEC 17011:2017 *"Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies"* and international laboratory accreditation organizations, the terminologies used in the TAF laboratory /inspection body accreditation services shall be defined as below. For laboratory related terms, please refer to *"General requirements for the competence of calibration and testing laboratories"* (TAF-CNLA-R01) and ISO 15189 "*Medical laboratories - Particular requirements for quality and competence* (TAF-CNLA-R02*)*. For inspection body related terms, please refer to ISO/IEC 17020:2012

"Conformity assessment — General criteria for the operation of various types of bodies performing inspection" (TAF-CNLA-RI01*)*.

(1) Conformity assessment: demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.

(2) Conformity assessment body: a body that can provide conformity assessment services and that can be the object of accreditation.
Note: Laboratories and inspection bodies are conformity assessment bodies.

(3) Accreditation: third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

(4) Accreditation body: a regulatory authority that performs accreditation

(5) Accreditation criteria: the set of requirements that an accreditation body requires an applicant conformity assessment body to satisfy before granting accreditation

(6) Accreditation body logo: logo used by an accreditation body to identify itself.

(7) Accreditation symbol: symbol issued by an accreditation body to be used by accredited conformity assessment bodies to indicate they are accredited.

(8) Accreditation certificate: official document specifying the grant of a defined scope of accreditation

(9) Accredited laboratory/accredited inspection body: a laboratory/an inspection body that has been accredited, also known as an approved laboratory/inspection body.

(10) Accreditation scope: range or characteristics of objects of conformity assessment covered by formal attestation of the competence of a laboratory (calibration/testing/medical testing*) or an inspection body
*Note: Medical testing refers to the activities of medical laboratories as defined in ISO 15189.

(11) Laboratory/inspection body code: specific code assigned to a laboratory/an inspection body for identification from the application process to the maintenance period of accreditation. After the laboratory/inspection body is accredited, the code automatically becomes a valid accreditation number.

(12) Initial accreditation: the first time a laboratory/an inspection body submits an application for accreditation.

(13) Extending accreditation: an accredited laboratory/inspection body's application may apply for an extension of the scope of accreditation before the accreditation status expires.

Note 1: Refer to Chapter 10 for the accreditation items in the fields of calibration/testing/medical testing/inspection accreditation.

Note 2: When the extending accreditation scope involves partial changes in the original accreditation items, an application for amendments shall be submitted (see Chapter 28 of this document)

(14) Renewal accreditation: an accredited laboratory/inspection body submits an application for renewing accreditation status.

Note: When applying for renewal, the applicant can also apply for adding accreditation items or amending the original accreditation scope.

(15) Laboratory/inspection body assessment: The process by which an accreditation body assess the competence of a laboratory/an inspection body within a certain defined accreditation scope in accordance with particular standards and (or) other normative documents.

Note: (a) The competence of a laboratory/an inspection body shall be assessed in terms of its overall operational competence, including personnel competence, environmental facilities, validity of measurement or testing method and the validity of measurement or testing results.

(b) An assessment to confirm the improvement of a laboratory/an inspection body on non-conformity is called follow-up; an assessment to confirm the amendment of a laboratory/an inspection body is called a verification visit.

(c) An assessment to confirm whether a laboratory/an inspection body continues to meet the accreditation criteria and comply with the Regulations on Rights and Obligations is called surveillance assessment.

(16) Assessment team: a group of persons appointed by the accreditation body to perform an assessment. According to their tasks, their mission can be divided into the following three types:

(a) Lead assessor: A person who is assigned by TAF to lead and coordinate an assessment in an assessment team

(b) Assessor: a person who is registered with TAF and performs an assessment

(c) Technical expert: a person who works with an assessment team to perform an assessment. He/she is a person with specific knowledge and expertise related to the technical item (scope) and assigned by TAF but not registered with TAF as an assessor.

(17) Observer: A person who, for a specific purpose, such as observing, studying, assessing the performance of assessors, and evaluating the operation of TAF, accompanies the assessors at an assessment site but does not perform assessment.

(18) Laboratory head, laboratory director/ inspection body head: person who is authorized and appointed by an applicant to be responsible for the management of the laboratory/inspection body (Note) at the time of accreditation application. After assessment and accreditation, the person is responsible for supervising the laboratory/inspection body's compliance with the TAF's relevant regulations.

Note: An inspection body may be an organization or a department/unit involving in inspection work within an organization.

(19) Approval signatory: person authorized and appointed by an applicant to be responsible for technical affairs and issuance of a calibration/testing report or inspection report during accreditation application in the calibration/test/civil engineering field or inspection body accreditation. After granting accreditation, the person is qualified for signing calibration/testing reports or inspection reports.

(20) Reviewer: composed of senior assessors and assessors registered with TAF or people with specific technical competence and the competency criteria meet the qualification requirements for reviewing assessment work

(21) Surveillance: activities, other than assessment for accreditation renewal, that monitor whether an accredited laboratory/inspection body continues to meet the accreditation criteria and comply with the Regulations on Rights and Obligations.

Note: Surveillance includes surveillance assessment and other surveillance activities, such as:

(a) An accreditation body proposes relevant accreditation concerning to a laboratory/an inspection body;

(b) Review the statement of a laboratory/an inspection body regarding the accreditation scope;

(c) Request a laboratory/an inspection body to provide documents and records (e.g., audit report, statistic data, original data, reports, internal quality control results, complaint records, management review records and measurement traceability records).

(d) Monitor the technical competence of a laboratory/an inspection body (e.g., results of proficiency testing)

(22) Warning: a decision given when there is a violation of the TAF accreditation criteria, requirements, or relevant regulations but having not reached the level of suspension, reduction, withdrawal, or revocation. The decision includes a warning and a deadline for improvement.

(23) Suspension: a decision to suspend the qualification of the accredited laboratories/inspection bodies for all or part of the scope of accreditation obtained from TAF for a specific timeframe.

Note: An accredited laboratory/inspection body or TAF can propose suspension. The accredited laboratory/inspection body under suspension shall reinstate the accredited status within a specified time limit.

(24) Reducing: a decision to invalidate a part of qualifications obtained by the accredited laboratories/inspection bodies within the scope of accreditation from TAF.

(25) Withdrawal: a decision to invalidate all the qualifications obtained by the accredited laboratories/inspection bodies within the scope of accreditation from TAF.

Note: An accredited laboratory/inspection body or TAF can propose withdrawal. If an accredited laboratory/inspection body has been withdrawn for the accreditation and wishes to be accredited again, it must resubmit an initial accreditation application.

(26) Revocation: a decision to retroactively invalidate all qualifications obtained by the accredited laboratories/inspection bodies within the entire scope of accreditation from TAF due to a violation of the TAF accreditation criteria, requirements, or relevant regulations.

(27) Expiration without renewal: the accreditation certificate of an accredited laboratory/inspection body expires and no application is filed for renewal accreditation.

(28) Retention: the whole or part of the items in a laboratory/an inspection body that is not approved according to the assessment team’s accreditation recommendation or the TAF’s accreditation decision.

(29) Complaint: A non-appeal expression of dissatisfaction to an accreditation body by an individual or organization for the behavior of accredited laboratory/accredited inspection body

(30) Appeal: a request for reconsideration submitted by a laboratory/an inspection body to TAF regarding the accreditation decisions that are unfavorable to its accreditation status as well as being punished for violating the "Regulations on Rights and Obligations".

Note: Unfavorable accreditation decisions include decision on granting, maintaining, extending, warning, reducing, suspending, withdrawing, and revoking accreditation.

(31) Punishment: a decision of TAF to impose warning, suspension, reduction, withdrawal, or revocation of the accreditation scope and qualification of specific accreditation number based on the severity of the violation of the TAF accreditation criteria, requirements, or relevant regulations.

Part I Description of Laboratory and Inspection Body Accreditation Service

5. Mission, goals and principles

5.1 TAF uses a set of accreditation process to determine the competence of a laboratory/ inspection body to conduct specific tasks and grants an open and official recognition. The said competence is based on the compliance with accreditation criteria. The open and formal acknowledgment is through issuance of accreditation certificate and registration of accredited laboratories/accredited inspection bodies to a directory on the TAF website.

5.2 The mission of TAF is to provide impartial, objective and independent third-party laboratory/inspection body accreditation services that meet the needs of social and economic development and the social expectation at home and abroad. The main objectives are:

(a) Promote the use of service provided by accredited laboratories/inspection bodies by people from all walks of life at home and abroad;

(b) Assist laboratories/inspection bodies to improve operational benefit and efficiency and thus to make them more competitive.

5.3 Accreditation principles

TAF performs laboratory and inspection body accreditation service by upholding the following five accreditation principles:

(a) Ensure compliance with ISO/IEC 17011

ISO/IEC 17011 is an international standard for regulating accreditation bodies and is also a basic requirement for signing mutual recognition with International Laboratory Accreditation Cooperation (ILAC). TAF is committed to ensuring that laboratories and inspection bodies meet the requirements of ISO/IEC 17011.

(b) Accreditation criteria are based on international standards

The accreditation criteria adopted or formulated by TAF are based on international standards, such as ISO/IEC 17025, ISO 15189, ISO/IEC 17020 or related documents of relevant international organizations.

(c) Maintenance of accreditation credibility

TAF upholds the spirit of fairness and impartiality when issuing an accreditation certificate after ensuring that a laboratory/an inspection body meets accreditation criteria through actual verification. There is no discrimination. TAF also requires

the accredited laboratory and inspection body to maintain the credibility of accreditation together.

(d) Implementation of professional assessment

The assessment of laboratories and inspection bodies is a professional assessment, which emphasizes that the assigned assessment team must have the technical expertise corresponding to the assessment scope; at the same time, through sharing and discussing the professional experience between assessors and the personnel of facilities under assessment, the assessment values are created.

(e) Encourage autonomous management

The benefits arising from accreditation can only be acquired and sustained under the autonomous management of the laboratories and inspection bodies. Therefore, TAF encourages and assists the laboratories and inspection bodies to be committed to autonomous management.

6. Accreditation objects

6.1 Objects of laboratory accreditation

6.1.1 For all laboratories of military, public, private and academic research institutions legally registered at home and abroad, regardless of the size, the responsible people of the laboratories can apply for laboratory accreditation as long as the laboratories have dedicated technical personnel and use specific instrument and equipment to perform calibration, testing and medical testing in appropriate space in accordance with the established management system, and issue reports. The latest legal certification documents approved by competent authority for establishment or change shall be submitted during application (for medical laboratories, license to practice is the legal certification documents).

6.1.2 The definition of a laboratory refers to the units of the same organization, under the same management system and in the same accreditation field (see Section 7.1 for the definition of field) under the same economy, and applying for accreditation in the same application. This definition is not applicable to those under an accreditation program or otherwise specified by regulatory authority.

6.1.3 A laboratory can carry out its main activity within its accreditation scope at multiple locations, as explained below:

(1) Base or Headquarters: is set up at a dedicated fixed location where main activities are carried out. The main activities refer to formulation of laboratory

policy/procedures, contract review, complete testing/calibration, partial testing/calibration, activities that might significantly affect testing/calibration results, and sampling in Section 7.3 of ISO/IEC 17025. A laboratory can only set up one headquarters.

Note: This address is presented on the first page of an accreditation certificate.

(2) Testing/Calibration Site: A permanent location other than the laboratory's headquarters. A great number of main activities of specific technical items or main activities of specific technical items that are performed within a specific time period as specified by a contract can be performed at this location. The restrictions on setting up this testing/calibration site (such as the distance between the site and the laboratory headquarters) shall meet the requirements of various TAF accreditation programs or the management regulations of the corresponding competent authority.

Note: This address shall be shown in the accreditation item field on the continuation page of the certificate.

(3) Site away from permanent facilities: non-permanent locations other than the laboratory headquarters and testing/calibration site. This location can be sites commissioned by clients or mobile equipment that performs calibration or testing service.

Note 1: The accreditation item on the continuation page of the accreditation certificate shall properly present this information, for example, on-site testing or on-site calibration.

Note 2: Please refer to the Technical Criteria for the Accreditation of Site Calibration Laboratories (TAF-CNLA-T03) and Technical Criteria for the Accreditation of On-Site Testing Laboratories (TAF-CNLA-T20) for on-site calibration and on-site testing.

6.2 Objects of inspection body accreditation

6.2.1 For all military, public, private and academic research institutions or their affiliated units, regardless of the size, the responsible people of the institutions can apply for inspection body accreditation as long as the institutions have dedicated management and inspection technical personnel who can perform inspection tasks in accordance with established management, provide professional determination/verification on testing results and issue inspection reports.

6.2.2 The definition of an inspection body refers to the units of the same body under the same economy, using the same management system, and applying for accreditation in the same application. The latest legal certification documents approved by competent authority for establishment or change shall be submitted during application.

6.3 For applications from overseas laboratories/inspection bodies, in addition to the regulatory requirements, TAF will inform the application laboratory/inspection body of information about ILAC mutual recognition agreement (MRA) based on TAF's obligation as a member of ILAC. If the applicant decides to apply to TAF, TAF will inform the relevant accreditation body that signed ILAC MRA in the applicant's home country with the consent of the applicant, and TAF will proceed in accordance with the Cross Frontier Accreditation-Principles for Cooperation (TAF-CNLA-G14).

7. Accreditation field

7.1 Laboratory accreditation:

The laboratory accreditation service provided by TAF includes four accreditation fields (Note 1): calibration, testing, medical and civil engineering testing. The technical categories included in each field are as follows:

Note 1: If the laboratory application items are multidisciplinary, they shall be applied separately, and TAF reserves the right to change the accreditation field applied.

- Calibration field (field code K, Note 2)

  Length (technical code KA), Vibration/Volume (technical code KB), Mass/Force (technical code KC), Pressure/Vacuum (technical code KD), Temperature/Humidity (technical code KE), Electrical (technical code KF), Electromagnetic (technical code KG), Flow (technical code KH), Chemical (technical code KI), Time and frequency (technical code KJ), Ionizing Radiation (technical code KK)

  Note 2: A code in the calibration field contains 6 alphanumeric characters, for example, KA1001, wherein KA is length, the third and fourth characters 10 are endpoint standards, and the fifth and sixth characters 01 are gauge block.

- Testing field (field code W, Note 3 and Note 4)

Acoustics and Vibration (technical code A), Biological (technical code B), Chemical (technical code C), Electrical (technical code E), Ionizing radiation (technical code I), Mechanical (technical code M), Non-destructive testing (technical code N), Optical (technical code O), Temperature and Heat (technical code T), Forensic science (technical code Z).

- Civil engineering testing field (field code L, Note 3 and Note 4)

  Civil engineering (technical code L)

  Note 3: In the testing field and civil engineering testing field, the accreditation scope of each laboratory is based on items to be tested and name of test. These names are mainly from laboratories' expression of how they want to be accredited by TAF and how they want to be shown on accreditation certificates. These names are not uniformly expressed in TAF, and they do not necessarily have a one-to-one correspondence with the codes.

  Note 4: The item code in the testing field and civil engineering field is composed of four units: large category code of item to be tested (two digits), small category code of item to be tested (two digits), technical field code (one alphabetic character), and test item code (three digits). Large category code and small category code form a coding system for items to be tested. For example, 0101, the former 01 is large category code, referring to metal and alloy material and products; the latter 01 is small category code, referring to iron-based material. The technical field code and test item code form a coding system for test items. For example, L001, L is for construction and 001 is for fineness.

- Medical field (field code H, Note 5 and Note 6)

  Anatomical Pathology (technical code: HA), Clinical biochemistry (technical code: HB), Transfusion medicine (technical code: HC), Hematology (technical code: HD), Clinical immunoserology (technical code: HE), Clinical microbiology (technical code: HF), Clinical toxicology (technical code: HG), Clinical microscopy (technical code: HH), Cytogenetics (technical code: HI), Genetics and molecular pathology (technical code: HJ), Nuclear Medicine (technical code: HR), Diagnostic Radiology (technical code: HS).

Note 5: The item code in the medical field contains six alphanumeric code. For example, HA0101, wherein HA is anatomic pathology, 01 in the 3rd and 4th characters refers to slice, and 01 in the 5th and 6th character refer to small biopsy.

Note 6: When applying for a specific item in the medical field, an applicant should pay attention to the Essential Application Items for the Corresponding Professional Fields of Medical Laboratories Applying for Accreditation (TAF-CNLA-J09). Please refer to the corresponding notice on the TAF website. Subsequent revisions to the necessary application items for relevant professional disciplines will be posted and updated as “accreditation announcement” at any time on the TAF website.

7.2 Inspection body accreditation (code I, Note 7 and Note 8)

The inspection body accreditation services provided by TAF are divided into ten large category code based on the technical categories, as explained below:

01 Factory (Site) Inspection
02 Non-destructive Inspection
03 Fume Hood/Facility Inspection
04 Rail System and Product Inspection
05 Hazardous Equipment Inspection
06 Playground Equipment Inspection
07 Construction and Civil Engineering
08 Electrical Equipment
09 Fire equipment
10 Environment

Note 7: An inspection item code in the inspection body accreditation contains 5 alphanumeric characters. The item code is composed of three units: large category code of inspection technique (two digits), small category code of inspection technique (two digits), technical field code (one alphabetic character). Large category code and small category code form a coding system for inspection technique. For example, 0101, the former 01 is large category code, referring to Factory (Site) Inspection; the latter 01 is small category code, referring to BSMI Regulations Governing Registration of Product Certification/Voluntary Product Certification-electronic products.

The technical field code and inspection technique large/small category code form a coding system for inspection items. For example, 0101E, E is for Electrical technical code.

Note 8: When applying for Inspection body accreditation, please refer to "Accreditation Item Coding – Inspection body (TAF-CNLA-DI01)".

8. Accreditation program

8.1 To enhance accreditation value and reduce repetitive assessment accreditation, TAF welcomes competent authorities/industry groups willing to use accredited laboratories/inspection bodies to contact TAF.

8.2 Accreditation service that meets the needs of specific purposes, such as regulations, mutual recognition agreements with foreign authorities, and specific users, such as government authorities and industry groups, will be presented in the form of accreditation program as a basis of cooperation among TAF, specific users and relevant facilities under assessment. These programs may have different regulations and/or operation based on applicants' qualification and application materials, accreditation criteria, assessment team members and surveillance assessment frequency. Please refer to each accreditation program for details.

8.3 The accreditation certificate should explicitly indicate to which accreditation program the organization is accredited and its accreditation scope. Such information may be accessed via accreditation directory of each accreditation program on TAF website.

9. Accreditation criteria

9.1 TAF accreditation criteria are divided into the following three categories based on their attributes.

(a) Common criteria: these criteria are requirements that shall be met for signing and maintaining mutual recognition agreement with ILAC and Asia Pacific Accreditation Cooperation (APAC) (Note), for example, ISO/IEC 17025, ISO 15189, ISO/IEC 17020 or proficiency testing, measurement traceability, measurement uncertainty, accreditation symbols usage and promotion. In general, such criteria apply to all laboratories and inspection bodies unless otherwise specified.

Note: Under the trend of integration of international accreditation systems, the Asia-Pacific Laboratory Accreditation Cooperation (APLAC) and the Pacific Accreditation Cooperation (PAC) in the Asia-Pacific region merged at the end of 2018, and the Asia-Pacific Accreditation Cooperation (APAC; www.apac-accreditation.org)) was formally established on January 1, 2019.

(b) Technical criteria: these criteria are based on technical matters and usually define the applicable laboratories/inspection bodies.

(c) Specific criteria: These criteria are primarily for the needs of specific (potential) customers, such as government authorities or groups. When a specific customer is a government authority with relevant regulations, the relevant provisions of such regulations are directly included in TAF's specific criteria, but will not be included in the TAF's list of accreditation criteria. Usually, such criteria define the applicable laboratories/inspection bodies.

Note: In certain matters, such as personnel qualifications, use of accreditation symbols and record keeping, the technical criteria and/or specific criteria have more specific requirements compared to common criteria. Therefore, the applicable laboratories and inspection bodies defined by the technical criteria and specific criteria shall pay special attention to the requirements of technical criteria and/or specific criteria.

9.2 The draft of TAF accreditation criteria will be announced on the TAF website and the members area (for use by laboratories, assessors, and assessment case review panel) during formulation/amendment period to seek opinions from all walks of life. In addition, TAF also issues accreditation announcement of specific topics or regulatory provisions to explain and clarify accreditation criteria. This type of accreditation announcements are also accreditation criteria.

9.3 Technical data, such as relevant standards/procedures/methods used by laboratories or inspection bodies, are also one of the accreditation criteria.

10. Accreditation number and accreditation certificate

10.1 Laboratory/inspection body number is a specific number assigned to a laboratory/an inspection body when TAF accepts the laboratory/inspection body's application for initial accreditation. The applicant is notified during application, and it is an identification code from application to accreditation. A laboratory/an inspection body

shall inform the laboratory/inspection body number when inquiring about assessment accreditation so that TAF can confirm and respond promptly. Once the laboratory/inspection body is granted accredited, this number will be automatically converted to accreditation number.

10.2 An accreditation certificate is an official document used by TAF to acknowledge that a laboratory/an inspection body has specific competence. The accreditation certificate is valid for three years. Once an applicant is assessed and approved through accreditation decision, and paid relevant fees, an accreditation certificate will be issued in two versions, Chinese and English, after signing by TAF President.

10.3 The first page of a laboratory accreditation certificate contains organization name, laboratory name, laboratory address, accreditation basis (accreditation criteria), accreditation number, date of initial accreditation, valid accreditation period and accreditation scope (e.g., certain field and/or accreditation program). The appendix of the accreditation certificate contains accreditation content, including accreditation number, name of laboratory head and accreditation item. Each accreditation item must include name of item to be tested/calibrated or name of specimen, relevant information of testing/calibration method or medical testing method, report approval signatory (except for medical field). For the calibration field, it also contains calibration scope, maximum working standard and smallest uncertainty. If necessary, other relevant information, such as testing scope, measurement conditions and testing/calibration site, are also shown. Accredited items of accreditation program will be separated from other field by a heading indicating the accreditation program.

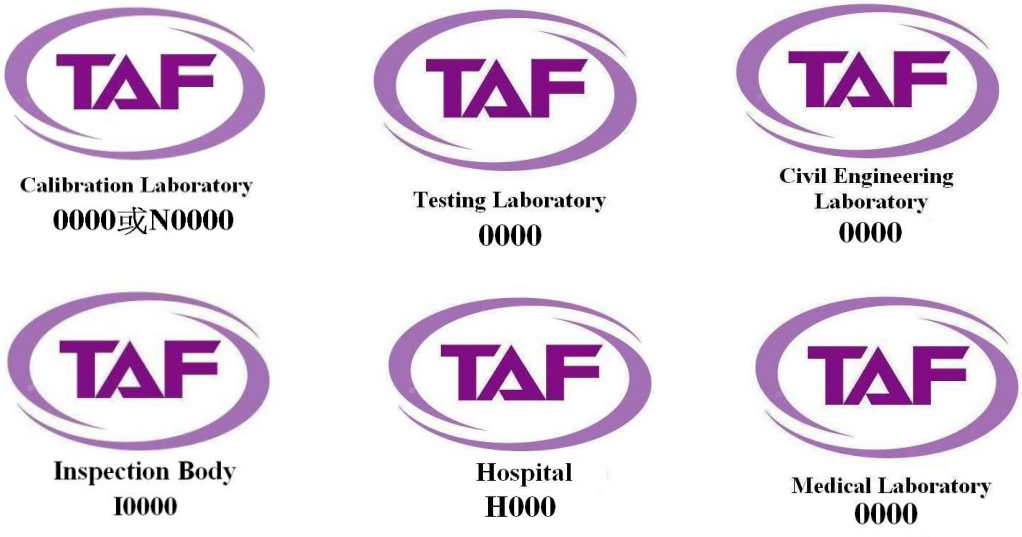
10.4 The first page of an inspection body accreditation certificate contains institution name, inspection body name, inspection body address, accreditation basis (accreditation criteria), accreditation number, date of initial accreditation, valid accreditation period and accreditation scope (e.g., a certain technical field). The appendix of the accreditation certificate contains accreditation content, including accreditation number, type of institution, name of inspection body head and accreditation item. Each accreditation item must include technical classification, inspection item, inspection type and scope, inspection method and procedures. Accredited items of accreditation program will be separated from other field by a heading indicating a certain accreditation program.

10.5 For principles for indicating section and version for testing/inspection standard methods of accreditation scope, please refer to the Version Designation

Requirements for Standard Methods (Including Specific Chapters) within the Scope of Laboratory Accreditation (TAF-CNLA-J12).

11. Accreditation symbols

11.1 According to the field or category of laboratory accreditation and inspection body accreditation, TAF has the following accreditation symbols. The numbers at "0000" position represent accreditation number. Please refer to the Instructions for Making TAF Accreditation Symbols and Good Laboratory Practice (GLP) Compliance Registration Symbols (TAF-AR-11).



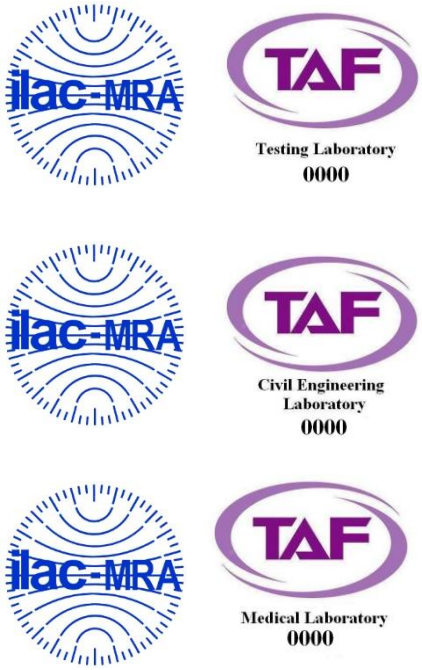
11.2 All accredited laboratories/inspection bodies have the right to use the above corresponding symbols within the valid accreditation period without additional application to TAF for approval. Applicants who have applied to TAF for accreditation may not use the TAF accreditation symbols until they are accredited. The rules for the use of accreditation symbols by accredited laboratories/accredited inspection bodies are set out in the Requirements for Use of Accreditation Symbols and Declaration of Accreditation Status (TAF-CNLA-R03). Accredited laboratories in the calibration field and civil engineering testing field or in an accreditation program shall also follow the specific regulations of such field and relevant provisions in each accreditation program.

11.3 To improve the global acceptance of conformity assessment bodies (CABs), the International Laboratory Accreditation Cooperation (ILAC) issued the Accredited CAB Combined ILAC MRA Mark, as shown below. This mark is a combination of the ILAC Mutual Recognition Arrangement (MRA) mark and the accreditation

symbol. TAF has signed the Agreement for Using ILAC MRA mark (ILAC R7-F1). If the TAF-accredited laboratories and inspection bodies intend to use the Accredited CAB symbol Combined ILAC MRA Mark, the laboratories/inspection bodies shall be familiar with Rules for the Use of the ILAC MRA Mark (ILAC-R7:05/ 2015), and can only use the ILAC MRA Mark after signing Accredited CAB symbol Combined ILAC MRA Mark Use Agreement (TAF-CNLA-B03) with TAF. The scope of application is for use of accredited laboratories (including calibration, testing, civil engineering testing and medical field) and accredited inspection bodies. The sample of the combination mark is as follows:

Accredited laboratories

Note: The accreditation code in the calibration field is composed of four numbers 0000. “N” is the code of the National Measurement Laboratory. N0000 is the full code, with “N” as the identification code.



Note: Accredited hospital under the Accreditation Program for Foreign Labour Physical Check after Entry are not applicable to the usage of accredited symbol Combined ILAC MRA Mark.

Accredited inspection bodies

11.4 When entrusting a TAF-accredited body to perform relevant calibration, testing, medical testing or inspection, please request a report with an accreditation symbol to ensure the reliability of the calibration, testing, medical testing and inspection results. If you entrust a foreign laboratory to perform testing, calibration, please request the Accredited CAB Symbol Combined ILAC MRA Mark.

12. Rights and obligations

For the rights and obligations between TAF and bodies that are applying for accreditation or have been accredited, please see the “Regulations on Rights and Obligations” (TAF-AR-10). If an applicant requests for something that is not stated in the Regulations on Rights and Obligations and TAF believes that such request will render the assessment non-performable, TAF has the right to stop the accreditation process or return the application of the laboratory/inspection body that has not been accredited. In the case of laboratories/inspection bodies that have been accredited, in addition to the above-mentioned measures, TAF may proceed with Chapter 30 of this document depending on the circumstances.

13. Accreditation fees

13.1 For fees related to application for TAF laboratory and inspection body accreditation, such as application fee, assessment fee, certificate fee and annual fee, please refer to the Fees Schedule and Method of Payment (TAF-CNLA-C02).

13.2 An applicant should pay the relevant fees during the application period or during the accreditation maintenance period. If there is a delay, TAF will directly cease the applicant’s application or withdraw the accreditation status.

14. Proficiency testing

14.1 Proficiency testing helps laboratories to improve technical competence and ensure quality of measurement. TAF encourages the laboratories to participate in relevant proficiency testing and encourage relevant professional bodies to conduct proficiency testing. According to ISO/IEC 17011 and the International Mutual Recognition Agreement, proficiency testing is one of the tools for an accreditation body to judge the technical competence of a laboratory.

14.2 Under the requirements of meeting international standards and the International Mutual Recognition Agreement, after considering limited proficiency testing resources and the opinions of relevant bodies (including laboratories and proficiency testing providers), TAF formulated the Requirements for Proficiency Testing Activities (TAF-CNLA-R05), which stipulates that laboratories should develop a proficiency testing program, proficiency testing items, minimum requirements of frequency/quantity and periodic review of participation.

15. Website resources and service description

15.1 The TAF website (https://www.taftw.org.tw)which provides relevant information about TAF to the public, including the directory of accredited bodies, service contacts for various accreditation service, guidance for accreditation application, announcements and publications.

15.2 In order to improve the efficiency of accreditation service, an accreditation service integration platform and TAF members area have been fully established for use by applicants, assessors, assessment case review panel, as a platform for assessment application and exchange of relevant information.

15.3 The functions provided in the user area include basic data maintenance, document downloading, assessment processing information, online application submission, educational training, relevant information report, payment record inquiry, historical record area, bulletin board and message notification. The functions provided in the assessor area include basic data maintenance, document downloading, educational training, assessment material access, payment inquiry and assessment on-line operation.

15.4 To ensure smooth on-line operation, an applicant must read the Internet Account and Password Application Information for Laboratories Applying for Accreditation (TAF-CNLA-C03) to make sure the applicant has appropriate IT equipment and

agrees to comply with relevant regulations before applying for network account and password. The application/confirmation made by a laboratory/an inspection body on the Internet is equivalent to the decision of the body. The applicant is requested to prudently authorize and manage the account. Relevant application forms and instructions are available on the TAF website.

15.5 The TAF documents and case information on the accreditation service integration platform and operation screens of relevant functions are for the purpose of assisting applicants in applying for accreditation and maintaining accreditation. They are TAF's intellectual properties and confidential information. No one can disclose them or make them known to the public without the consent of TAF. If an applicant discloses any key information regarding its accreditation case during the process of application, which may affect the impartiality of the accreditation assessment or review, TAF has the right to stop the accreditation process or return the application of the laboratory/inspection body that has not been accredited. In the case of laboratories/inspection bodies that have been accredited, in addition to the above-mentioned measures, TAF may proceed with Chapter 30 of this document depending on the circumstances.

16. Publications

16.1 Application information for laboratory/inspection body accreditation, such as accreditation service manual, accreditation program, application forms, fee schedule and accreditation items, are available on the TAF website and can be downloaded and printed.

16.2 The list of TAF accreditation criteria and guidelines documents for laboratory/inspection body accreditation is available on the TAF website. If you are interested in purchasing these materials, please fill out the purchase order form on the website and fax the proof of wire transfer receipt to 03-5358662 or e-mail it to TAF Administration Department. Laboratories and inspection bodies that have applied for the Internet service operation can check the document download area in the user area and download the materials.

16.3 When TAF revises accreditation criteria and accreditation application documents for laboratories/inspection bodies, TAF will release the draft on the TAF website for public opinion. The issuance and implementation of new documents will also be announced on the TAF website.

16.4 When the documents of accreditation criteria for laboratory/inspection body accreditation are released or updated, TAF will notify the relevant accredited laboratories/inspection bodies and assessors by sending on-line notification from accreditation service integration platform or notification in writing.

16.5 Please respect the intellectual property rights of TAF and use the TAF publications appropriately. The publications may not be copied or sold without the TAF's authorization.

16.6 The TAF’s operating procedures and relevant forms, including assessment forms, are TAF’s internal materials, which are not provided to personnel/bodies that are not involved in assessment accreditation.

17. Assessment manpower resources

17.1 TAF has invited professionals with specific skills in the industry, government, academia and research institutions as assessors. TAF will categorize assessors into three categories: assessors, senior assessors and assessors-to-be based on the specific skills requirement by assessments and their duties, and has developed a training, registration, appointment and evaluation system. In addition, TAF has also issued identification cards to the TAF assessors-to-be, assessors and senior assessors.

17.2 In general, in an assessment team, the role of lead assessor is taken by a senior assessor, who assesses the management requirements of assessment accreditation criteria and relevant regulations and is responsible for on-site assessment and assessment results. Assessors assess the technical requirements of accreditation criteria and relevant regulations. When there is no one in the (senior) assessor database has the required technical expertise, or for other reasons, the assessment team will include technical experts to assess specific technical competence and assist assessors/senior assessors to complete the assessment. The Policy on the Use of Technical Experts in an Assessment (TAF-CNLA-R11) will be followed when using the technical experts.

17.3 Lead assessors, assessors and technical experts represent TAF rather than organizations they work for during assessment.

18. Directory of accredited bodies

18.1 The directory of accredited bodies contains basic information, accreditation scope, contact information and other information of accredited laboratories/inspection

bodies. TAF directory of accredited bodies is directly posted on the TAF website with various types of listing and inquiry functions. No separate directory in print will be issued.

18.2 As the accreditation status may change, the TAF directory is updated timely. The accredited laboratories/inspection bodies that are suspended are placed in the "suspension" area, and will be removed from the suspension area once they resume their accreditation status. In addition, the accredited laboratories/inspection bodies that are suspended, reduced, withdrawn/revoked by TAF, as well as non-accredited laboratories/inspection bodies that misuse the TAF accreditation symbol in test reports/calibration certificates, will be publicly placed in the "penalty list".

18.3 There is a respective corresponding directory area for the accredited laboratories/inspection bodies in accreditation programs. The TAF directory of accredited bodies is also linked to the websites of several competent authorities.

19. Mutual recognition and cooperation

19.1 To expand the scope of accreditation services, enhance accreditation value, and promote the international acceptance of calibration/test reports or inspection reports issued by domestic laboratories/inspection bodies, TAF actively promotes international mutual recognition activities, as well as cooperation with various professional groups/regulatory authorities. The TAF was one of the first bodies signing the APLAC MRA for laboratory accreditation in 1997, and obtained global international mutual recognition in 2000 through signing ILAC MRA (www.ilac.org) with regional recognition alliances, such as APLAC and European Accreditation (EA).

19.2 TAF added inspection body accreditation to the scope of signing APLAC MRA in 2005, and obtained global international mutual recognition in 2012 through signing ILAC MRA with regional recognition alliances, such as APLAC, EA and Inter American Accreditation Cooperation (IAAC). In 2007, TAF added ISO 15189 medical laboratory accreditation to APLAC MRA. In 2013 and 2014, TAF also added ISO 17034 Reference Material Producers accreditation and ISO/IEC 17043 Proficiency Testing Provider accreditation to APLAC MRA. In 2019, proficiency testing providers were added to the scope of ILAC MRA, and TAF became one of the first batch accreditation bodies that signed the international mutual recognition agreement. In 2020, reference

material producers were added to the scope of ILAC MRA, and TAF became one of the accreditation bodies that signed the international mutual recognition agreement.

19.3 TAF's accreditation is widely used by various competent authorities in Taiwan, including, Bureau of Standards, Metrology and Inspection, Ministry of Economic Affairs; Public Construction Commission Executive Yuan; National Communications Commission, Executive Yuan; Taiwan Centers for Disease Control; National Treasury Administration, Ministry of Finance; Ministry of Environment, Central Weather Administration, Ministry of Transportation and Communications; Occupational Safety and Health Administration, Ministry of Labor, Executive Yuan; Public Construction Commission Executive Yuan; Energy Administration, Ministry of Economic Affairs; and Industrial Development Administration, Ministry of Economic Affairs. Any update will be announced on the TAF website.

19.4 TAF actively signs Memorandums of Understanding (MoU) with professional associations (societies) in Taiwan. The content focuses on the development, promotion, application and education of accreditation technologies for technical exchanges and cooperation. The information of the professional associations (societies) that signed MoU with TAF is available on the TAF website. New associations (societies) that are added to the list will be announced on the TAF website.

20. Complaints

20.1 TAF will provide accreditation service wholeheartedly. If it is not perfect, individuals or organizations can express their dissatisfaction to TAF regarding the accreditation business and administrative management and they can expect that TAF will respond.

20.2 The window for complaints about TAF accreditation service is the Administration Department. Complaints shall be made in writing and can be faxed (02-2809-0979), e-mailed (taf_service@taftw.org.tw) or mailed (23F, No. 27, Section 2, Zhongzheng East Road, Tamsui District, New Taipei City, 25170) to TAF. Name of the complainant, organization (if any) and valid contact information, defendant, complaint content and relevant supporting documents shall be included. If the above-mentioned information is not provided (including anonymous accusation, fake contact information or information) or if the complaint is made verbally, TAF will not proceed with it.

20.3 If a complaint against an accredited laboratory/inspection body is not within the scope of the rights and obligations of TAF and the body, TAF will not proceed with it. For complaints about accredited laboratories/inspection bodies, TAF will forward them to the corresponding laboratories/inspection bodies when appropriate, and the laboratories/inspection bodies shall reply to TAF after they assist in investigation and solve the problem.

20.4 After receiving a complaint, TAF will confirm whether the complaint is valid and inform the complainant of the proceeding. An investigation will be done within 30 working days after TAF proceed with the complaint case and TAF will inform the complainant of the investigation results by mail.

21. Appeal

21.1 If an applicant or an accredited laboratory/inspection body believes that the TAF's accreditation decision is not in favor of the accreditation status it intends to obtain, it may appeal to TAF after expressing its unwillingness to accept and objection while requesting a new decision.

21.2 A laboratory/an inspection body may appeal to TAF within 30 days from the next day when a decision becomes effective. The appeal documents, including name, valid contact information, reasons for appeal and relevant supporting materials, shall be mailed to Taiwan Accreditation Foundation (23F, No. 27, Section 2, Zhongzheng East Road, Tamsui District, New Taipei City, 25170). If the above-mentioned information is not provided or an appeal is filed after the deadline, TAF will not proceed with the appeal.

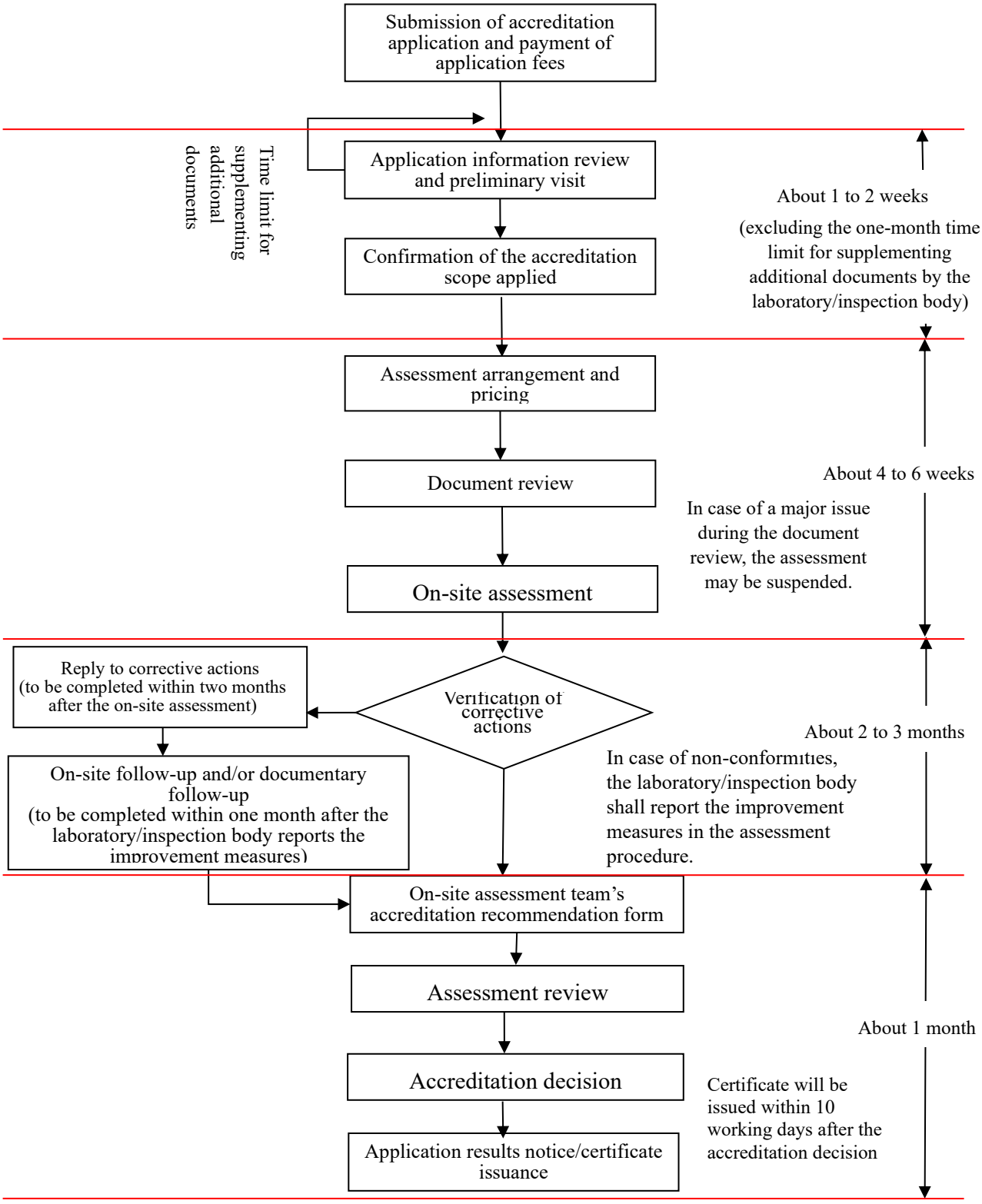
21.3 The appeal investigation committee will investigate and hold a meeting within 30 working days after the appeal is a processed. If the appellant or his/her representative does not attend the investigation meeting without a justifiable reason, the appeal investigation committee may conclude the meeting and provide suggestions based on facts found during the investigation. TAF will make a decision based on the conclusion and suggestions of the appeal investigation committee and reply to the appellant about the TAF decision on appeal by mail.

21.4 During the appeal investigation period, the TAF accreditation decision remain valid and is not affected by the appeal. However, if necessary, the TAF accreditation assessment may be suspended.

21.5 If the complainant disagrees with the TAF's decision on the appeal, the complainant may appellant again by submitting new reasons and new evidence in writing within 10 days after receiving the notice of appeal decision (However, reappeal is limited to once).

Part II Instructions on Accreditation Assessment

22. Accreditation process (initial, renewal and extending)



Note: The estimated time in the right column of this process is based on the time spent by most of the accreditation assessments in the past. The actual time should be determined on a case-by-case basis.

23. Application operation (initial, renewal and extending)

23.1 Any organization that meets the application qualifications in Chapter 6 of this document may submit a laboratory/an inspection body accreditation application by the representative of the organization. If the applicant is an overseas entity, documents showing that the statutory documents are notarized by a local court or an overseas representative office shall be submitted.

23.2 The head of laboratory/inspection body is the authorized and appointed person responsible for the management of the laboratory/inspection body when the body applies for accreditation. The body authorizes the head of laboratory/inspection body to represent the body in conducting various accreditation activities with TAF. Please see the Requirements for Laboratory/Inspection Body Head (TAF-CNLA-R07) for the responsibilities and requirements of the head of laboratory/inspection body during laboratory accreditation. Before the applicant submits the accreditation application, the head of laboratory/inspection body shall read this document and relevant accreditation criteria, announcements and documents carefully. In case of application for an accreditation program, please pay attention to relevant special regulations and well prepare for the accreditation application.

23.3 Before an organization submits a laboratory/inspection body accreditation application, the laboratory/inspection body shall have at least one internal audit and management review. The laboratory/inspection body shall keep at least two reports and supporting records for each accreditation item applied, and the laboratory shall have participation record that meets the Requirements for Proficiency Testing Activities (TAF-CNLA-R05).

23.4 When applying for the initial accreditation of the laboratory/inspection body, the applicant should complete the virtual account information on TAF network platform, fill out the Accreditation Application Form-Laboratory/Inspection Body (TAF-CNLA-B01 and TAF-CNLA-BI01), the Information System User Account Application Form (TAF-CNLA-B06), prepare all documents and materials listed in that application form, and a photocopy of evidence showing that the application fee has been paid, and submit the above to TAF Hsinchu Office at 2F, No. 95, Beida Road, Hsinchu City 30044 by registered mail with a note “initial accreditation” on the envelope. Laboratories/inspection bodies that already have the members area

account and password can apply for renewal, extending and amendment in the members area.

23.5 Simplified assessment of a laboratory's extending application

23.5.1 To encourage the extending application and improve the efficiency of assessment, accredited laboratories who meet the following conditions can apply for simplified assessment for the parts that do not directly involve in extending when applying for extension.

(1) The extending application is filed within six months from the date of the opening meeting of the previous laboratory assessment (excluding surveillance assessment, verification visit, follow-up and simplified extending assessment)

(2) The applicant shall fully prepare for all operations of the extending application, including fee payment, completeness and readiness of application materials and assessment preparation, and the on-site assessment can be conducted within two months after the extending application date.

23.5.2 A simplified assessment is a simplification for management system requirements, for example, organization, quality system, document control, internal audit and management review, which can be simplified for this assessment based on the results of the last assessment.

23.5.3 TAF may decide whether to proceed with a simplified assessment on a laboratory's extending application based on the laboratory's preparation for extending application and the conclusions of the previous assessment.

23.6 Combined handling of laboratory extending and surveillance assessment

If a laboratory wishes to combine extending assessment and surveillance assessment, the laboratory shall contact TAF in advance in the month of the planned surveillance assessment so that TAF can make a suitable plan and arrangement. To ensure smooth operation, the laboratory shall submit the extending application one month before the date of surveillance assessment and the assessment shall be carried out within two months after the application so that the extending and surveillance assessment can be combined.

23.7 Application for renewal accreditation

23.7.1 Before its accreditation certificate expires, a laboratory/an inspection body may apply for renewal accreditation. TAF will remind the laboratory/inspection

body one month before the expiration date, and TAF will not accept an application for renewal accreditation after the expiration date. If the laboratory/inspection body wants to be accredited again, it shall apply for initial accreditation.

23.7.2 The validity date of an accreditation certificate is important to the accreditation qualification of a laboratory/an inspection body. During the period when the accreditation certificate expires but another accreditation certificate is not yet acquired, the laboratory/inspection body is no longer a TAF-accredited laboratory/inspection body. Therefore, accredited laboratories/inspection bodies shall pay attention to renewal application and relevant assessment as well as the accreditation status and use of accreditation symbols. When the accreditation status expires but new accreditation status is not yet granted, the laboratory/inspection body may not continue to use the accreditation symbols and claim valid accreditation status in any way.

23.7.3 Because it takes time to renew accreditation, it also requires the laboratory/inspection body to cooperate with TAF to complete the renewal. Therefore, to ensure the rights of an accredited laboratory/inspection body, please complete a renewal application six months before the accreditation certificate expires, and attach materials that shall be submitted. In case of wide accreditation scope or accreditation program, the applicant shall apply early, follow TAF's schedule and complete the required matters within the relevant time limit to ensure that the validity of the accreditation certificate can be continued.

23.8 After receiving an application for accreditation from a laboratory/an inspection body, TAF will assign a receipt number. For the laboratory/inspection body who applies for initial accreditation, TAF will assign a laboratory/an inspection body number. When contacting TAF, if the laboratory/inspection body can indicate the laboratory/inspection body number, it will help TAF to reply and contact.

23.9 The focus of an application review is on the qualification of an applicant and the readiness of information form and application forms & documents, compliance with the information of Section 23.3 and confirmation of the completion of the application.

23.10 If there is any doubt or deficiency or non-conformity about the applicant's qualification and the application documents or materials provided by the applicant,

TAF will inform the applicant of supplementation/correction of the information/description or return the application without further processing, and the application fee will not be returned. The time limit for supplementing/correcting the information/description is one month (this period includes the time when the laboratory/inspection body can revise the information form in the members area). Those who have not completed the correction/description within this time limit will not be accepted and the application will be returned without further processing.

23.11 When the readiness and completeness of the application documents and materials meet the predetermined level, TAF staff will conduct a preliminary visit in the laboratory/inspection body to confirm the accreditation requirements, understand the preparation status and confirm the accreditation scope applied. For a laboratory/an inspection body that applies for initial accreditation, the preliminary visit is to interview the head of laboratory/inspection body in the laboratory/inspection body. If the laboratory/inspection body expresses that it is not necessary to visit the site for preliminary visit, TAF will consider to conduct the preliminary visit by phone/fax/e-mail. For a laboratory/an inspection body applying for renewal and extending accreditation, the preliminary visit will mainly be conducted through telephone/fax/e-mail. TAF will determine whether it is required to conduct an on-site preliminary visit in the laboratory/inspection body.

23.12 The accreditation scope applied will be confirmed by an application confirmation form signed by both TAF and the head of laboratory/inspection body. If it is processed on-line, the confirmation shall be made through clicking the confirmation button. TAF will arrange assessment and assign tasks to the assessment team accordingly. TAF neither authorize the assessment team to accept the addition or amendment of laboratory head/inspection body head, application confirmation form and approval signatory, nor authorize the assessment team to accept the addition of accreditation items and calibration/testing/testing method. Therefore, laboratories/inspection bodies are requested to carefully confirm the accreditation application confirmation form.

23.13 If accreditation requirements of a laboratory/an inspection body or accreditation scope exceed TAF’s resources and capacity, TAF will reject the application and refund the application fee.

23.14 Upon completion of the application review, TAF will inform the laboratory/inspection body of the interval between the scheduled assessment dates (usually 4 to 6 weeks after the notification of application acceptance). The laboratory/inspection body is requested to prepare for the assessment.

24. Assessment operations (initial, renewal and extending)

24.1 The main focus of the assessment arrangement is to assemble an assessment team, inform the laboratory/inspection body of the assessment arrangement and payment of assessment fee.

24.2 An assessment team is assembled according to the accreditation scope for application confirmed during the application review stage (i.e., the application confirmation form), assessment manpower resources (see Chapter 17 of this document), time and principle of conflict of interest prevention (e.g., assessors/technical experts had no employment relationship or were not involved in any business activities with the laboratory/inspection body to be assessed or its affiliates). In addition, TAF will also consider the number of staff in the laboratory/inspection body, number of application items and testing site (Note 1) and distance when arranging the number of assessment team members and the number of assessment days.

Note 1: For initial, renewal and extending application, all testing sites of the laboratory/inspection body must be confirmed by on-site assessment. If the items of the same overseas sites (including sites in China) have been confirmed on site during the extending application and the assessment is within six months from the date of the on-site assessment for renewal, TAF may make adjustment based on the TAF's confidence in the laboratory's ability in maintaining the accreditation status.

24.3 TAF will issue a notice of assessment arrangement to inform the laboratory/inspection body of the name of assessment team members and the institutions they work for, division of labor of the assessment team, assessment date and schedule as well as the matters to be prepared by the laboratory/inspection body.

24.4 If the assessment is an assessment for an accreditation program (e.g., accreditation program for laboratories testing communication equipment), the assessment team may include a representative of the competent authority. This representative is

responsible for the assessment of relevant items and may report the assessment results to the competent authority.

24.5 If a laboratory/inspection body has any comments on an assessment arrangement, the head of laboratory/inspection body or the contact person authorized by the head of laboratory/inspection body (Note 2) shall inform TAF within one week; otherwise, it is deemed that the laboratory/inspection body agrees with TAF's assessment arrangement. If comments are raised afterwards, TAF may charge administrative processing fees according to the complexity of change. The laboratory/inspection body shall evaluate and be responsible for the additional time required for operation and the impact incurred due to the change. If it involves comments to the members of the assessment team, the head of laboratory head/inspection body shall state reasons in writing and provide relevant supporting information.

Note 2: This contact person is the contact person listed in the Laboratory/Inspection Body Information Form (TAF-CNLA-B02, TAF-CNLA-B04, TAF-CNLA-BI03); for a laboratory/an inspection body using the on-line system, the contact person is the contact person listed in the on-line account and password application form (see Chapter 15).

24.6 For an objection against assessment team members, if it involves personal behavior of an assessor, TAF will reply after verification with the relevant supporting materials provided by the laboratory/inspection body; if it does not directly involve personal behavior of an assessor, for example, business competition between the institution the assessor is working for and the laboratory/inspection body under assessment, TAF will weigh the degree of acceptance for the objection and then reply. If there is no suitable candidate in the TAF database, TAF will assign a foreign expert with the consent of the laboratory/inspection body (Note 3). Because the pricing of foreign expert varies, TAF will make arrangement after the consent of the facility under assessment. If TAF and the laboratory/inspection body fail to reach an agreement, and as a result, the assessment work cannot be carried out, TAF will return the application materials to the laboratory/inspection body.

Note 3: The foreign expert is usually an assessor or technical expert of a foreign accreditation body with mutual recognition with TAF.

24.7 Assessment fee notice will be sent together with assessment arrangement notice. Please see the Fees Schedule and Method of Payment (TAF-CNLA-C02) for valuation method and payment method.

24.8 To train assessors, evaluate the performance of the assessors, or establish/maintain recognition at home and abroad, TAF may assign an observer to go to a laboratory/an inspection body with an assessment team. When an observer is arranged, TAF will inform the name of the observer and the institution he/she works for in advance. An objection, if any, will be handled in accordance with the principle in Section 24.6.

24.9 Assessment

24.9.1 The focus of assessment during the assessment stage includes document review, on-site assessment, confirmation of improvement of non-conformities and proposal of accreditation recommendation for the assessment team to implement.

24.9.2 TAF may hold an assessment coordination meeting to discuss an assessment if necessary.

24.10 Document review

24.10.1 Document review is review of relevant documents of a laboratory/an inspection body by an assessment team to evaluate whether the documentation system of the laboratory/inspection body complies with the accreditation criteria.

24.10.2 The results of document review will be sent to the laboratory/inspection body. Non-conformity will be issued if a major issue is identified during the document review. The laboratory/inspection body shall report implementation work of correction action in writing, which may include revision of relevant documents. The verification of improvement and corrective actions must be confirmed by the assessment team before an on-site assessment is carried out. In this case, the on-site assessment originally scheduled may be suspended. If there are no major problems, the results of the document review will be verified during the on-site assessment. If the problems are not resolved, the assessment team may classify them as non-conformities.

24.11 On-site assessment

24.11.1 The scope of on-site assessment is the scope of accreditation confirmed during the application review stage (Chapter 23 of this document).

24.11.2 A laboratory/inspection body shall ensure that relevant documents of the laboratory/inspection body used by an assessment team during on-site assessment is the latest version, and shall provide the assessment team with support within the scope of assessment, for example, reservation of a meeting room, personnel arrangement for corresponding assessors, arrangement of transportation between different assessment sites, to facilitate smooth conduct of the on-site assessment.

24.11.3 An on-site assessment begins with an opening meeting and ends with a close meeting. During the assessment, the assessment team will conduct personnel interview, verify records/reports, on-site witness, comparison of measurement results and equipment facility checks. On-site assessment is required for all sites performing calibration, testing, medical testing or inspection. The lead assessor will lead the assessment team to orally report the assessment results to the laboratory/inspection body head and its main technical personnel. The on-site assessment report shall be completed on the spot. The lead assessor shall bring the original copy back to TAF, and the laboratory/inspection body shall keep the photocopy. TAF is responsible for all content of the assessment report. If a different conclusion arises during assessment report review, TAF will inform the facility under assessment in writing and explain the reasons for coming up with the different conclusion.

24.11.4 Please see Guidelines for Determining and Processing of Non-conformity (TAF-CNLA-G05) for the TAF's handling and description of non-conformities. If TAF regard that the way for verifying nonconformity implementation needs to be adjusted after reviewing the on-site assessment report, TAF has the right to make an adjustment and will inform the CAB, corresponding assessor and team leader of assessment team.

24.11.5 In case of absence of important personnel who have significant impact on laboratory/inspection body activities, such as head of laboratory/inspection body, approval signatory, management related to quality technology and calibration/testing/medical testing/inspection personnel or failure to demonstrate important equipment on-site in result of being unable to

comply with the criteria, the assessment team may determine it as a non-conformity for the scope involved and request onsite follow-up.

24.11.6 For serious non-conformities that cannot be effectively improved within a short period (two months), the lead assessor shall record this situation in the on-site assessment report after the consent of the laboratory/inspection body, and keep the corresponding items (not approved).

24.11.7 The head of laboratory/inspection body shall sign in the relevant field in the non-conformity record form to acknowledge the assessment team's finding during the on-site assessment. If the head is not clear about the content, he/she shall ask the assessment team for further explanation.

24.11.8 If there is any disagreement on non-conformities, the laboratory/inspection body shall present evidence on-site or supplement relevant materials. If the laboratory/investigation body still disagrees with the non-conformities proposed by the assessment team, it should indicate what evidence was presented on-site or what materials were supplemented in the non-conformity record form, and indicate it in the on-site assessment report. TAF will handle this objection.

24.11.9 A laboratory/inspection body that has any non-conformity identified during an on-site assessment shall make improvement. The laboratory/inspection body shall submit the materials related to implementation work of corrective action for the non-conformities within two months after the on-site assessment date. If the facility under assessment fails to submit the implementation work of corrective action in time, the assessment case will enter the decision-making stage directly. If the laboratory/inspection body is in the "suspension of accreditation" stage, it will not be subject to the two-month deadline, but will be handled in accordance with suspension (for reinstatement, the laboratory/inspection body shall submit an application for reinstatement of accreditation status).

24.11.10 If major matters that might violate the Regulations on Rights and Obligations (TAF-AR-10) is identified from on-site assessment materials of a laboratory/inspection body or other sources, TAF will address it (see Chapter 28 of this document). In case of "suspension of accreditation," TAF will suspend the assessment depending on the situation and reinstate the accreditation after the laboratory/inspection body voluntarily applies for

reinstatement in accordance with Section 30.4. If the suspension of accreditation is only for a few items, the assessment can continue on the items that are not affected. The items under “suspension of accreditation” will be handled in accordance with suspension, i.e., the laboratory/inspection body shall apply for reinstatement of accreditation when it wishes to reinstate the accreditation status. In addition, the laboratory/inspection body may choose to abandon the said items and apply for extending accreditation. Please see Chapter 30 of this document for suspension, withdrawal/revocation or reduction.

24.12 Confirmation for the corrective action of non-conformity

24.12.1 There are two ways to confirm the corrective action of non-conformity. One is document review and the other is on-site follow-up. The (lead) assessor/technical expert shall tick in the way of confirmation to be implemented in each nonconformity form. The deadline for laboratories/inspection bodies to submit corrective actions is within two months from the date of the close meeting of the assessment. If it is overdue, it will not be able to submit corrective actions. The assessment team shall confirm the improvement situation according to the corrective actions. When it is necessary to arrange an on-site follow-up to confirm the improvement, the laboratories/inspection bodies shall submit corrective actions in writing according to the aforesaid period. And the on-site follow-up should be completed within three months from the date of the close meeting of the assessment. When the laboratories/inspection bodies have force majeure factors (such as: natural disasters, incidents, strikes, government bans, etc.), an extension can be applied to TAF in writing one week before the overdue period and can be extended by one month when TAF agrees.

24.12.2 On-site follow-up be conducted no more than once. TAF reserves the right to change the document review to on-site follow-up.

24.12.3 If it is determined that on-site follow-up is required, TAF will issue an assessment arrangement notice and an assessment fee payment notice according to the on-site assessment report. The laboratory/inspection body is requested to pay the fee and prepare for the on-site follow-up in advance. The preparation may include uploading written supporting documents to the non-conformity record form in the members area. The purpose is to ensure

that the laboratory/inspection body is well prepared for the on-site verification.

24.12.4 The confirmation for the corrective action of non-conformity, in principle, shall be carried out by the original corresponding (lead) assessor/technical expert. However, for some reasons, if it cannot be carried out by the original corresponding person, it will be carried out by the lead assessor or TAF staff.

24.12.5 TAF will inform the laboratory/inspection body of the confirmation results of the corrective action of non-conformity after the written review. The results of the on-site follow-up will be delivered orally by the (lead) assessor/technical expert on the spot. The onsite follow-up report shall be completed on the spot. The original copy will be brought back by the (lead) assessor/technical expert, and a photocopy is retained by the laboratory/inspection body. When the corrective action of non-conformity has not been approved, if the non-conformity is about the overall management system of the laboratory/inspection body that cannot meet the accreditation criteria, the laboratory/inspection body will not be accredited. If only a specific application item is involved, the application item will not be granted.

24.13 Proposing accreditation recommendation

24.13.1 The lead assessor shall compile the materials of document review, on-site assessment and confirmation of improvement on non-conformity after the assessment ends and submit the assessment team’s accreditation recommendation form to TAF.

24.13.2 The lead assessor can report the assessment team’s accreditation recommendation form to the laboratory/inspection body in the assessment close meeting if it is practical, for example, no non-conformity or all non-conformities have been verified during the on-site follow-up; otherwise, TAF will inform the laboratory/inspection body of the assessment team’s accreditation recommendation in writing or in the members area.

24.13.3 A decision will be made after TAF review the on-site assessment report, on-site follow-up report, confirmation results of improvement on non-conformity and assessment team’s accreditation recommendation form.

25. Assessment review (initial, renewal and extending)

25.1 TAF will invite two or more assessment cases reviewers to review the assessment team's assessment results and accreditation recommendation based on their accreditation expertise. In general, the assessment review is conducted in writing and, if necessary, in the form of a meeting, where the lead assessor will brief report the results of the assessment.

25.2 Before inviting and appointing the assessment review team, TAF shall inform the laboratory/inspection body under assessment of the list of assessors corresponding to the technical area (including names and organization they work for). If there is any conflict of interest, the head of laboratory/inspection body or the contact person authorized by the head of laboratory/inspection body (see Chapter 24, Note 2) shall contact TAF within 3 working days after the notification date. Otherwise, it is deemed that the laboratory/inspection body agrees with the TAF's arrangement for decision-making review.

25.3 If necessary, TAF will ask the assessment team to provide documentary or oral explanation or ask the laboratory/inspection body to provide the relevant information. These materials will be incorporated into the assessment results as a basis for accreditation decision.

26. Accreditation decisions (initial, renewal and extending)

26.1 TAF will compile the comments of the review panel of assessment cases along with the reports and results related to the assessment, and then make an accreditation decision.

26.2 If the review panel has doubts about the laboratory/inspection body's conformity with the accreditation criteria and such doubts are sufficient to affect the accreditation decision, the review panel can inform the laboratory/inspection body of on-site verification. The laboratory/inspection body is not required to pay for this onsite verification. The accreditation decision will be made after the review panel receives the results of the on-site verification.

26.3 An accreditation decision is a decision on whether to grant the accreditation to a laboratory/an inspection body. TAF will inform the accreditation decision by on-line notification or in writing. If an accreditation status is granted, an accreditation certificate will be enclosed in the notice. If the laboratory/inspection body has any objection on the accreditation decision when receiving the notice of accreditation

decision, the laboratory/inspection body may appeal (please see Chapter 21 of this document).

26.4 If a laboratory/an inspection body is accredited, the next possible activity, such as the date of scheduled surveillance assessment or reminder for submitting an application for renewal, will be announced in the accreditation decision notice. Sometimes, it also includes information, such as audit highlights or suggestions arising from that assessment.

26.5 In order to know the extent to which the laboratory/inspection body is satisfied with the accreditation service, the laboratory/inspection body will be asked to fill out a questionnaire for the satisfaction survey when it is noticed of the results of initial accreditation, renewal accreditation and extending accreditation, as well as at other appropriate timings. This questionnaire is designed to improve the laboratory/inspection body's accreditation service. Laboratories/inspection bodies are requested to express their feelings and opinions of the accreditation service. The laboratories/inspection bodies are also welcomed to take this opportunity to express their views.

27. Notices

27.1 If a laboratory/inspection body has no intention to continue the assessment for some reasons, it can inform TAF by a letter, and work related to that application will be stopped.

27.2 The materials provided by a laboratory/an inspection body shall be true. If there is evidence showing that the laboratory/inspection body provided false or misleading information in application documents, TAF may stop the accreditation process or return the application depending on the situation. The application fee will not be refunded. The laboratory/inspection body may not submit the same application within three years from the day following the notification of rejection of the previous application. If the laboratory/inspection body is an accredited laboratory/inspection body, it will be handled in accordance with Chapter 30 of this document.

27.3 TAF may decline or reject an application if it discovers or has reasonable grounds to believe that the laboratory/inspection body falls into one of the following situations, and the application fee will not be refunded. If the laboratory/inspection body is an accredited laboratory/inspection body, it will be handled in accordance with Chapter 30 of this document. In the case of serious situation, TAF may not proceed with the

laboratory/inspection body's initial application within 3 months from the next day the decision becomes effective.

(1) Attempt to influence the impartiality of the accreditation of TAF through improper means or for improper gains.
(2) Deliberate violation or evasion of accreditation criteria, requirements, and relevant regulations prescribed by TAF.
(3) Involvement in circumstances that may affect the impartiality of TAF or the laboratory/inspection body.
(4) Outstanding accreditation-related fees owed by the laboratory/inspection body.

27.4 A laboratory/inspection body may not submit the same application within one year from the day following the notification of the second decline or rejection provided that the accreditation applications for the same accreditation scope (category or method) have been declined or rejected twice consecutively.

27.5 After the scope of application is confirmed (Section 23.12 of this document), if a laboratory/an inspection body wishes to add accreditation items, it shall submit an application in accordance with Section 23 of this document. The former application will be incorporated into the latter application, and the subsequent operation will be application review. If there are prescribed amendment to the laboratory/inspection body, the laboratory/inspection body shall apply for amendments (please see Chapter 28 of this document).

27.6 Within three months after the application is accepted, if the laboratory/inspection body is not ready for on-site assessment, the application will be invalid, any paid fees will not be refunded. If the applicant is still willing to apply for accreditation, it shall submit an application again.

27.7 Assessment fee shall be paid within one month. If a laboratory/an inspection body fails to pay the fee in time, TAF may inform the applicant of the cancellation of the application. If the laboratory/inspection body wishes to be accredited again, it shall submit an application again.

27.8 In the case of special events, such as natural disasters, disease outbreaks, man-made disasters, and safety problems, which affect the normal operation of accreditation activities, TAF may announce contingency countermeasures, and when appropriate, TAF will notify the affected laboratories/inspection bodies individually. The laboratories/inspection bodies shall cooperate and continue to comply with accreditation criteria and various management regulations. The

laboratories/inspection bodies are subject to suspension, withdrawal/revocation, or scope reduction if they cannot continue to comply with the criteria and regulations. Please see Chapter 30 of this document.

Part III Amendment, Maintenance of Accreditation and Termination of Relationship

28. Amendments by accredited laboratory/inspection body

28.1 In the case of any of the following changes, an accredited laboratory/inspection body shall voluntarily apply for amendment in the members area on the TAF accreditation service integration information platform. For the inspection bodies that do not have access to the members area, please fill out the application form (TAF-CNLA-BI05), provide amendment information, and mail them to TAF Hsin-Chu Office (Address: 2F, No. 95, Beida Road, East District, 30044) by a registered mail. The application shall be made within thirty (calendar) days from the day following the change.

(1) Amendment of ownership, name or address of the organization to which the laboratory/inspection body belongs, including amendment of laboratory ownership (Section 28.3 of this document);

(2) Amendment of the responsible person of the organization to which the laboratory/inspection body belongs;

(3) Amendment in the content of accreditation certificate (if it is to add accreditation items, please apply for extending accreditation, rather than application for amendment; if it is to delete accreditation items, please apply for reducing accreditation)

(4) Amendment of laboratory/inspection body head, approval signatory, person in charge of laboratory quality, or inspector of inspection body;

(5) Amendments of laboratory/ inspection body address, environment and equipment;

(6) Amendment of designated person in the accreditation program, for example, the technical supervisor of product specific program (the main person that ensures the effectiveness of a technique) or quality control supervisor (the main person that manages quality);

(7) Application or termination of accreditation program (cases involving an extension of accreditation item, an extending accreditation application shall be submitted);

(8) Termination of operations for more than 30 (calendar) days or other amendments that might affect the competence or operation of the laboratory/inspection body;

(9) Withdrawal of accreditation status of the laboratory/inspection body;

(10) Suspension of accreditation status of the laboratory/inspection body or reinstatement of accreditation status. (See Section 30.6 of this document)

28.2 For accredited laboratories and inspection bodies that use Internet, the designated users are important contact people between the laboratories/inspection bodies and TAF for assessment accreditation-related matters. In the event of user change or contact information change, the applicant should re-submit the Information System User Account Application Form (TAF-CNLA-B06) within 30 days after the change occurs and mail the application form to TAF Hsinchu Office by registered mail.

28.3 If the principal part of TAF-accredited laboratory/inspection body changes because of division, merger, or other reasons of the organization to which TAF-accredited laboratory/inspection body belongs, the accreditation status of the originally accredited laboratory or inspection organization shall not be transferred along with the amendment, and the relationship, rights, and obligations between the original organization and TAF due to accreditation will be terminated. If the new organization wishes to be accredited by TAF, it must apply for initial accreditation by itself. TAF will weigh the changes in the laboratory/inspection body and adjust the scale of on-site assessment.

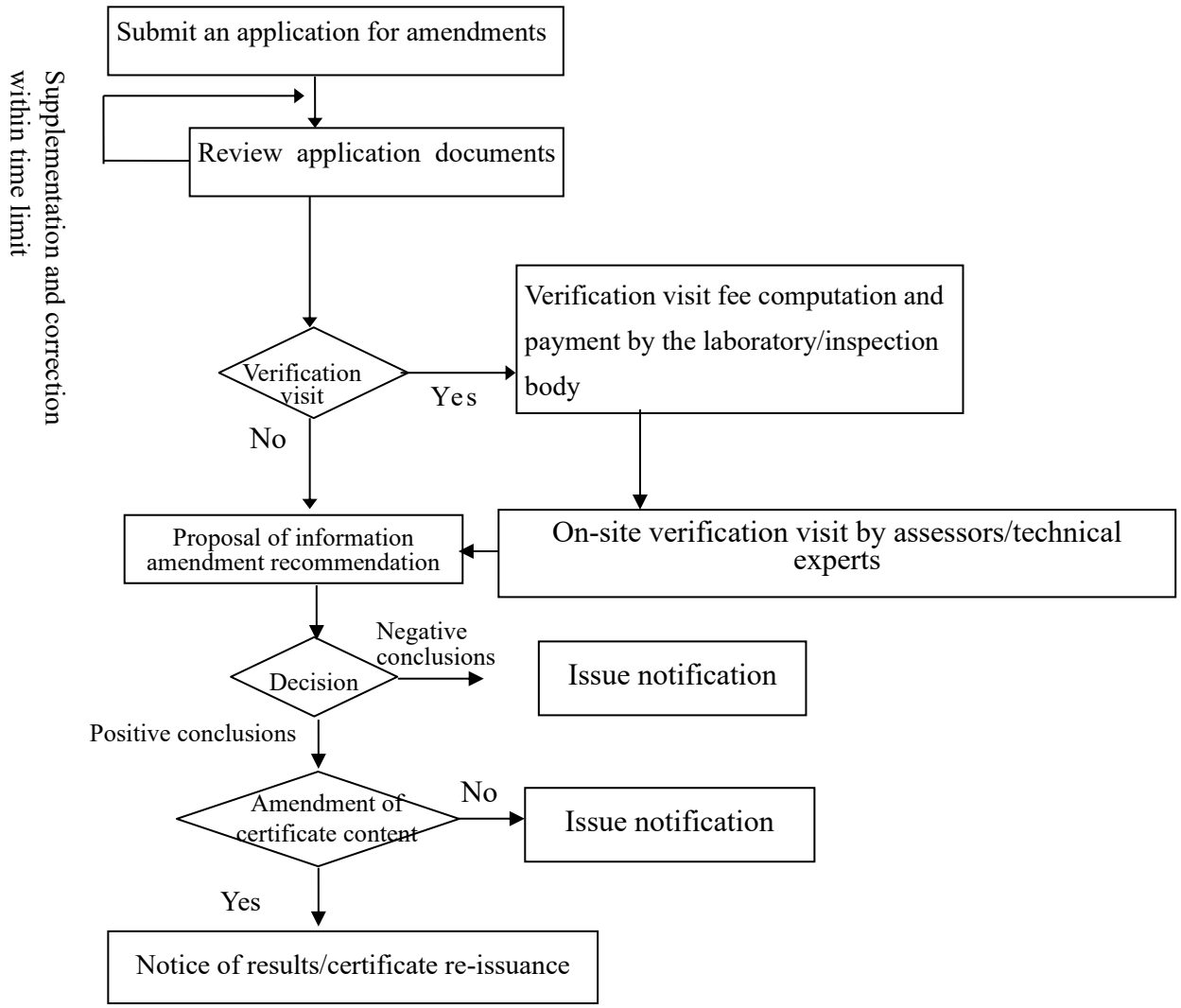
28.4 After receiving the application for amendments, TAF will review whether the application documents are complete and ready. If the application documents are insufficient or the laboratory/inspection body's further explanation is required, TAF will notify the laboratory/inspection body to supplement the materials.

28.5 For amendments mentioned in Section 28.1 (2)-(10), TAF will decide whether to arrange a verification visit or document review based on the amendments after the application materials are complete and ready. The procedures are shown in Section 28.7. For changes that involve the address of the laboratory/inspection body, please see the Policy on the Address Amendment of Accredited Laboratory/Inspection Body (TAF-CNLA-R09) for handling and instructions. If a verification visit by an assessor and/or technical experts is required (see Chapter 24), TAF will inform the laboratory/inspection body of the verification visit assessment fee and ask the laboratory/inspection body to pay the fee. Please see the Fees Schedule and Method of Payment (TAF-CNLA- C02) for fee standards and payment method.

28.6 TAF will inform the laboratory/inspection body of the approval results of the application for amendments by on-line notification or in writing (see Chapter 26). If the laboratory/inspection body's application for amendments involves a change in the scope of accreditation and requires a certificate to be renewed, TAF will inform the laboratory/inspection body of certification fee payment and issue a new accreditation

certificate. Meanwhile, the laboratory/inspection body is asked to send the original accreditation certificate back to TAF or destroy it by itself.

28.7 Process



29. Maintenance of accreditation

29.1 To maintain the accreditation, accredited laboratories/accredited inspection bodies should continue to comply with the accreditation criteria (see Chapter 9), abide by TAF's Regulations on Rights and Obligations, and pay relevant fees. These requirements apply throughout the suspension period as well.

29.2 During the maintenance of accreditation, TAF will ask the accredited laboratories/accredited inspection bodies to participate in various surveillance activities, including seminars for the accredited laboratory/inspection body heads, technical seminars, surveillance assessments, participation in proficiency testing activities according to the proficiency testing plans, survey of provision of calibration,

testing and inspection in order to surveil the accredited laboratories/accredited inspection bodies' maintenance of accreditation. The above-mentioned surveillance activities will be carried out in an integrated manner in accordance with the degree of confidence of the accredited laboratories/accredited inspection bodies in maintaining accreditation.

29.3 Seminars for the accredited laboratory/ inspection body heads

The seminars for the accredited laboratory/inspection body heads provide an overview of the past year's accreditation outcomes, key directions for future initiatives, relevant important measures, document updates, and essential activities to assist the laboratory/inspection body heads in maintaining accreditation. In principle, it is held once a year, with the possibility of additional sessions as needed. The accredited laboratory/inspection body heads are requested to inform relevant personnel of the content of the forum and ensure the laboratories/inspection bodies meet the relevant requirements. If the heads are unable to attend the forum, please assign a proxy to participate in the event and convey the relevant information. The attendance of the accredited laboratories/inspection bodies heads in the forum will be included in the laboratory/inspection body surveillance records. The briefing materials for this forum will be provided in the members area. The heads of the laboratory/inspection body are encouraged to use these materials to make the accreditation requirements clear to the relevant personnel of the laboratories/inspection bodies.

29.4 Technical seminar

Technical seminars are the TAF's important activities to explain relevant technical criteria, formulation of important technical measures, and distribute relevant technical documents and assist approval signatories to maintain accreditation of technical competence. It focuses on the discussion of specific technical matters, and relevant approval signatories will be invited to participate in the technical seminars. The approval signatories are responsible for informing relevant laboratory personnel of the content of the technical seminars, and ensure the laboratories comply with the relevant requirements. The attendance of the approval signatories in the technical seminars will be included in the laboratory/inspection body surveillance records.

29.5 Surveillance assessment

29.5.1 Surveillance assessment is an on-site assessment carried out to ensure that the laboratories/inspection bodies maintain the accreditation status. TAF will arrange regular surveillance assessments for the TAF-accredited

laboratories/inspection bodies, a surveillance assessment will be carried out every year for the laboratories/accredited inspection bodies accredited for the first time, while for laboratories/inspection bodies with renewal accreditation, in principle, at least one surveillance assessment will be carried out for accreditation in the three-year accreditation cycle. When the laboratory has an accreditation program and its frequency or method of surveillance assessment is different, it will be specifically described in the accreditation program. For the arrangement of the surveillance assessment, TAF may carry out the assessment in part or all testing sites of the laboratory/inspection body separately depending on the laboratory/inspection body's accreditation status.

29.5.2 TAF will increase the frequency of surveillance assessment of individual laboratories/inspection bodies based on its degree of confidence on the accredited laboratories/inspection bodies' maintenance of accreditation and the purpose of accreditation surveillance. The laboratories/inspection bodies shall cooperate with TAF regarding various activities in accordance with the Regulations on Rights and Obligations. The above-mentioned situations include but are not limited to the followings:

(a) Change of TAF accreditation criteria or rules
(b) Appeal or complaint;
(c) Requirement by competent authorities in accreditation programs;
(d) To understand the operation of conformity assessment bodies (e.g., performance of proficiency testing activities, issuance of reports and use of accreditation symbol by the laboratory/inspection body)
(e) Calibration/testing/medical testing/inspection results or reports are likely to affect public credibility and safety crisis;
(f) Others (e.g., accreditation qualification may be affected)

29.5.3 Based on accreditation risk management, TAF has different surveillance assessment plans for accredited laboratories/inspection bodies in an accreditation cycle in order to confirm that they continue to conform with international standards, TAF accreditation criteria and management regulations. In principle, surveillance assessments are planned in accordance with Section 29.5.1. However, when the accreditation risk increases, the TAF will increase the frequency of surveillance assessment.

29.5.4 The laboratory/inspection body under assessment shall be informed of the TAF's regular surveillance assessment in writing /by online notice at least seven working days before the implementation date. If the laboratory/inspection body under assessment has any comments on the assessor or assessment date, it shall inform the TAF's case officer three working days prior to the assessment date. However, if there are special regulations in the accreditation criteria or if the laboratories/inspection bodies provide misleading information, violate governmental laws, endanger public interests, which likely affects TAF's impartiality and trust of the accreditation or the qualification of international mutual recognition, TAF may inspect the laboratories/inspection bodies without the aforementioned advanced notice, and the laboratories/inspection body may not reject, restrict or hinder. If the laboratories/inspection bodies do not cooperate without justifiable reasons, TAF will handle it in accordance with the Regulations on Rights and Obligations. To ensure the objectivity of the fact verification, TAF may record it or film it for evidence when carrying out the non-announced surveillance assessments.

29.5.5 When carrying out the surveillance assessment, the assessors will also check the use and promotion of accreditation symbols as well as improvement on non-conformity in addition to checking the maintenance of accreditation status of an accredited laboratory/inspection body in accordance with accreditation criteria. The verification methods of on-site assessment include procedural record verification, key personnel interview and on-site observation/implementation/witness, which will be arranged according to the situation. The surveillance assessment report will be completed on site. Handling and verification of on non-conformity improvement and implementation of corrective actions is described in Chapter 24 of this document. If the non-conformity meets the condition of suspension, withdrawal/revocation or reducing accreditation, TAF will proceed with it. Please see Chapter 30 of this document for suspension, withdrawal/revocation or reduction.

29.5.6 TAF does not authorize assessors to verify the change of accreditation scope of an accredited laboratory/inspection body during surveillance assessment. If there is any change to the accreditation scope, the accredited laboratory/inspection body shall apply for amendment or extending before the deadline. If practicable, the surveillance assessment may be carried out in conjunction with the

assessment cases for extending application (Chapter 23) or amendment application (Chapter 28) of the accredited laboratory/inspection body.

29.6 Survey on service of calibration, testing, medical testing and inspection results.
At the beginning of each year, TAF will send a calibration/testing/medical testing/ inspection result service data sheet to survey the TAF-accredited laboratories/inspection bodies' service regarding calibration/testing/medical testing/inspection result service and use of accreditation symbol in the previous year. The results of this survey are one of the records of surveillance activities.

30. Suspension, reduction and withdrawal/revocation

30.1 The TAF's warning, suspension, reduction and withdrawal/revocation of laboratory/inspection body accreditation are handled in accordance with the Regulations on Rights and Obligations (TAF-AR-10) between TAF and accredited laboratories/inspection bodies.

30.2 When a laboratory/inspection body accredited by TAF cannot maintain accreditation and intends to suspension, reduction and withdrawal, it shall voluntarily apply for amendments (see Chapter 28 of this document). When TAF finds out that the laboratory/inspection body has violated the TAF's Regulations on Rights and Obligations or accreditation criteria during activities related to laboratory/inspection body accreditation management, TAF will verify the situation by document review, on-site verification visit or meeting, and then make an accreditation decision after clarifying the situation. TAF will formally inform the laboratories/inspection bodies of the matters that need to be cooperated with for verification. If the laboratories/inspection bodies fail to cooperate without legitimate reasons, TAF may make an accreditation decision based on the evidence obtained. If the violation meets the condition of suspension, reduction or withdrawal/revocation, TAF may reject the laboratory/inspection body's voluntary application for suspension, reduction or withdrawal. TAF will inform the laboratory/inspection body of the TAF's decision on warning, suspension, reduction and withdrawal/revocation of laboratory/inspection body accreditation in writing. If there is any objection to the TAF's decision, the laboratory/inspection body can file an appeal (see Chapter 21 of this document).

30.3 If the suspension/reduction and withdrawal/revocation of laboratory/inspection body accreditation involves public interest, TAF may release the handling and process on the TAF website and inform the relevant bodies.

30.4 When the accreditation status is suspended, reduced, and withdrawn/revoked, the laboratory/inspection body shall inform the affected customers of the relevant consequences immediately without unreasonable delay. If it involves relevant competent authorities, notification to them shall also be made. The maximum period for fulfilling the notification obligation shall not exceed thirty (calendar) days. The laboratory/inspection body shall retain records of the aforementioned notifications. Upon written notice from TAF, the laboratory/inspection body shall provide relevant notification records to TAF within seven working days. Failure to do so by the deadline is considered a failure to fulfill the notification obligation. If the laboratory/inspection body violates the notification obligation, TAF may impose a penalty of One Thousand New Taiwan Dollars (NT$1,000) per day from the laboratory/inspection body until the notification is completed, and decline to process any application from the laboratory/inspection body.

30.5 Warning

When a laboratory/inspection body violates certain matters of the TAF's Regulations on Rights and Obligations, but the violation is not serious enough for suspension, reduction and withdrawal/revocation, TAF may send an official letter for warning and request it to improve within a time limit.

30.6 Suspension of accreditation

30.6.1 During suspension of accreditation, the rights of the laboratory/inspection body shall be ceased immediately. In particular, the laboratory/inspection body may not use the accreditation symbols and declare/state its accreditation status. The laboratory/inspection body’s information on the TAF website will be moved from the directory of accredited bodies to the list of suspended laboratories/inspection bodies. The period of suspension may not be longer than six months. If the accreditation status cannot be reinstated by the accreditation certificate's expiry date or before the suspension period ends, TAF may directly withdraw the laboratory/inspection body’s accreditation status and inform the laboratory/inspection body in writing.

30.6.2 Reinstatement of accreditation status

(1). If a laboratory/an inspection body wishes to reinstate its accreditation status after the reason for suspension of accreditation no longer exists, the laboratory/the laboratory/inspection body shall inform TAF by applying for amendments (Chapter 28) in writing or by on-line application. The

laboratory/inspection body shall complete the application for reinstatement and attach improvement materials three months before the suspension expires. If additional improvement materials are required, the laboratory/inspection body shall complete supplementation of all improvement materials one month before the suspension period expires. TAF will confirm whether the accreditation status can be reinstated based on the materials submitted.

(2). If the laboratory/inspection body violates certain matters in the Regulations on Rights and Obligations, and the laboratory/inspection body is suspended after a disposal, TAF will not accept the suspended laboratory/inspection body's application for reinstatement within two months after the suspension becomes effective. The laboratory/inspection body can only apply for reinstatement from the third month after the suspension becomes effective and shall complete all supplementation and correction of all improvement materials one month before the suspension period ends. TAF will confirm whether the accreditation status can be reinstated based on the materials submitted. In case the laboratory/inspection body fails to restore eligibility by the accreditation certificate's expiry date or before the expiration of the suspension period, when the suspension involves the entire or a part of the accreditation scope, TAF may directly withdraw or reduce the scope of accreditation with no advance notice when the deadline is reached.

(3). When the laboratory/inspection body submit an application for reinstatement after being imposed a punishment of suspension by TAF, the laboratory/inspection body shall provide evidence of completion of correction for the previous nonconformity. At the same time, documentary evidence certifying that notification has been provided to affected third parties or relevant competent authorities as per Chapter 30.4 shall be submitted. However, this requirement does not apply to applicants who submit their application more than six years after the punishments by TAF.

(4). A laboratory/an inspection body must apply for renewal accreditation and restore eligibility before its accreditation certificate expires if the laboratory/inspection body's accreditation certificate will expire within six months after suspension becomes effective; otherwise, the

laboratory/inspection body must re-apply for initial accreditation after the accreditation certificate expires.

30.6.3 If the reason for suspension of the laboratory/inspection body affects the accreditation scope, TAF may arrange a verification visit (Section 28.4) to confirm whether the reason for suspension has disappeared. Upon confirmation, TAF will inform the laboratory/inspection body of the accreditation status reinstatement in writing, and the laboratory/inspection body's information on the TAF website will be moved back to the directory of accredited bodies.

30.7 Reduction

30.7.1 Upon receipt of TAF's notice for cancellation of partial accreditation scope, the laboratory/inspection body shall immediately stop using the accreditation symbols in the item/scope, as well as any declaration/statement of accreditation status. The new accreditation certificate will be sent along with the notice of reduction. The laboratory/inspection body shall return the original accreditation certificate to TAF or destroy it by itself. If the laboratory/inspection body wishes to be accredited for that scope, it must apply to TAF for extending accreditation.

30.7.2 If the accreditation scope of a laboratory/an inspection body is reduced after a disposal, TAF will not accept the laboratory/inspection body's extending application for the same reducing scope that is reduced within six months from the effective date of the punishment of reduction. However, if there are regulations, TAF's accreditation service manual, specific service plans, or regulations from the competent authority that stipulate otherwise, those provisions will take precedence. TAF may also handle cases within the scope of reduction in accordance with such provisions.

30.7.3 When the laboratory/inspection body submit an application for extending accreditation within the same scope of reduction after a prior reduction, the laboratory/inspection body shall provide evidence of completion of correction for the previous nonconformity. At the same time, documentary evidence certifying that notification has been provided to affected third parties or relevant competent authorities as per Chapter 30.4 shall be submitted. However, this requirement does not apply to applicants who submit their application more than six years after the punishments by TAF.

30.8 Withdrawal and revocation of accreditation

30.8.1 Upon receipt of TAF's written notice of withdrawal or revocation, a laboratory/an inspection body shall immediately stop using accreditation symbols and declaring/stating any accreditation status. If the laboratory/inspection body wishes to be accredited again, it must apply to TAF for initial accreditation. No other forms of accreditation status reinstatement will be accepted. The laboratory/inspection body shall send the accreditation certificate back to TAF or destroy it by itself.

30.8.2 After withdrawal of accreditation, if the laboratory/inspection body has paid the annual fee for that year, TAF may refund the fee based on the ratio of the remaining months. Please see the Fees Schedule and Method of Payment (TAF-CNLA-C02) for refund.

30.8.3 TAF does not accept accreditation applications from any applicant on whom withdrawal or revocation is imposed within six months from the effective date of the punishment. This restriction does not apply to applications for other accreditation programs (See Note). However, if there are regulations, TAF's accreditation service manual, specific service plans, or regulations from the competent authority that stipulate otherwise, those provisions will take precedence. TAF may also handle cases within the scope of withdrawal or revocation in accordance with such provisions.

Note: ISO/IEC 17025 (CNS 17025) is applicable to the accreditation of testing laboratories and calibration laboratories. The accreditation applications of the aforementioned testing laboratories and calibration laboratories are considered as different certification schemes.

30.8.4 If the laboratory/inspection body wishes to regain the accreditation status after the same scope (item or method) being withdrawn or revoked by TAF, the laboratory/inspection body shall provide evidence of completion of correction for the previous nonconformity. At the same time, documentary evidence certifying that notification has been provided to affected third parties or relevant competent authorities as per Chapter 30.4 shall be submitted. However, this requirement does not apply to applicants who submit their application more than six years after the punishments by TAF. When the laboratory/inspection body apply to TAF for initial accreditation, TAF may confirm the completion of correction at the application stage, and may hold a meeting to confirm it when necessary. If the applicant is not willing to cooperate or has not completed the correction for the

previous non-conformities, TAF may return the application and refuse the application for initial accreditation.

30.8.5 TAF does not accept accreditation applications from any laboratory/inspection body on whom withdrawal or revocation is imposed, within three years from the day following the effective date of the punishment, using the original accredited registration address or testing site.

30.9 Application submitted under another name or in another manner by the laboratory/inspection body who has been imposed a punishment of reduction, withdrawal, or revocation by TAF, in attempt to circumvent the provisions of evidence of completion of correction for the previous nonconformity (see Chapter 30.4),TAF may decline or reject an application, and the application fee will not be refunded.

30.10 The laboratory/inspection body may not submit the same accreditation scheme application to TAF within one year from the day following the notification of the decline or rejection of its application for accreditation submitted after a punishment by TAF of reduction, withdrawal, or revocation on the grounds of failure to correct the issues leading to the previous punishment.