Regulations Governing Accreditation and Outsourced Accreditation Management of Medical Devices Institutions

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Chapter 1 General Principles

Article 1 These regulations are promulgated pursuant to the Paragraphs 1 and 2 of Article 78 of the Medical Devices Act.

Article 2 Definition of the terms herein employed are as follows:

1. Testing institution: It refers to a testing body (institution), corporation, or group possessing the capacity to implement medical devices testing.
2. Accreditation: It refers to the procedure established under this set of regulations instituted to validate the testing competence of a testing institution for a particular testing item.

Chapter 2 Accreditation Requirements and Procedure for Testing Institutions

Article 3 Testing institutions applying for accreditation shall have their exclusive test laboratory that meets the following requirements:

1. Equipped with the essential test equipment, space, and quality management system, capable of performing tests independently.
2. Complete with a laboratory head, a report signatory, a technical manager, a quality control manager, and the pertinent test personnel possessing the following qualifications:
   (1) Education: Graduates from the undergraduate or graduate program of a local college or university, or a foreign college or university and the academic records of which are recognized in accordance with the Regulations Governing the Assessment and Recognition of Foreign Academic Records by Institutions of Higher Education, with a major in electronics, biomedical engineering, medicine, chemistry, biology, life science, or other related disciplines;
   (2) Work Experience:
      1. for the laboratory head, the report signatory, the technical manager, and the quality control manager, having completed quality management related professional training and at least 3 years of testing related work experience;

2. for test personnel, having completed testing work related training.

The work experience requirements in Item (2)-1 in Sub-paragraph 2 of the preceding paragraph may be offset by the education qualifications in Item (1) in the same sub-paragraph; the master's degree counts for one year, and the doctoral degree counts for two years. Only one degree can be used for offset in case the person holds several degrees on the same level, and only the highest degree can be used in a case.

Article 4 Testing institutions applying for accreditation shall submit an application form, together with the following supporting documents and information to the central competent authority:

1. the certificates manifesting the compliance with the requirements stipulated in the preceding article;
2. documents certifying the testing capability;
3. documents prepared in accordance with the Basic Guidelines Governing the Quality System of Testing Institutions and Laboratories as provided by the central competent authority:
   (1) Quality Manual.
   (2) Standard operating procedures for methods of testing, including the measures for quality control of testing results.
   (3) Assessment report of uncertainty of measurements in case of an application filed for quantitative test item.
   (4) A method validation assessment report on items to be applied for accreditation.
   (5) The template of test report of the accredited test items and the signature format of the report signatory in Chinese.
4. Laboratory location map and the configuration diagram of the test facilities.

Article 5 Where the documents and information stipulated in the foregoing article do not comply with regulations or is found incomplete, the central competent authority shall issue a supplementation request and deadline to the applicant; where requirement is not fulfilled within the prescribed deadline, application shall be denied.

Article 6 The central competent authority shall conduct a document review and on-site assessment on the applications of testing institutions.
Where the on-site assessment finds a deficiency, the testing institutions shall submit a corrective plan to the central competent authority for re-assessment after the end of on-site assessment within 60 days.

Article 7 Where the application passes the assessment stated in Article 4, the central competent authority shall issue the accreditation certificate and make official announcement in acknowledgment thereof.

Article 8 The accreditation certificate shall contain the following information:

1. The title of the testing institution.
2. The title and address of the laboratory, and the full name of the laboratory head.
3. Test items as accredited, test method, test scope, and the report signatory.
4. Year, month, day, and serial number of the accreditation certificate.
5. Validity period of the accreditation certificate.

The testing institution shall display the accreditation certificate in a highly visible place of the premises.

Article 9 The accreditation certificate has a validity period of three years. An application for extension, when necessary, shall be filed between six and eight months preceding the date of expiration. The maximum period of an extension is three years.

The provisions of Articles 4 to 6 shall apply mutatis mutandis to the document, information and procedures required for accreditation period extension application. The documents and information specified in all sections thereof, except for those listed in Paragraph 2 of Article 4, need not be included in the application provided that there is no change in the content since the previous application for accreditation or extension.

If the application for extension filed during the period as specified in Paragraph 1 does not receive a decision of approval or dismissal from the central competent authority within the original accreditation validity period, the validity of the original accreditation is extended to the date of the decision.

Chapter 3 Management of Accredited Testing Institutions

Article 10 In the event of changes in any of the items enumerated under Subparagraphs 1 to 3 of Paragraph 1 of Article 8, the testing institution shall, within the following periods, submit an application for changes to the central competent authority:

1. Change of laboratory address: application shall be filed within 30 days of event.
2. Change of the basis of testing methods: application shall be filed within 90 days of event.
3. Change of test scope due to amendments of the specific specifications and performance of medical devices : application shall be filed within 90 days of the effective date.
4. Change of the title of the testing institution, the title of the laboratory, the name of the laboratory head or the report signatory: application shall be filed within 90 days of event.

For the applications specified above, the central competent authority, when necessary, may conduct on-site review.

Article 11 Relocation based on the Subparagraph 1 of Paragraph 1 of the preceding Article shall be reported to the central competent authority in a relocation plan 15 days prior to the relocation.

The plan mentioned in the preceding paragraph shall include the following items:

1. The time course of relocation.
2. The laboratory's new address and location map.
3. The test instrument list and the test facility configuration diagram.

Article 12 Upon failure to perform the test as specified in the accreditation, the exclusive laboratory of the testing institution shall notify the central competent authority of the event within seven days from the date of the event; and the same applies when the function is resumed.

Article 13 A testing institution shall perform testing based on the quality manual as specified in Item (1) in Subparagraph 3 of Article 4 and the standard operating procedures for methods of testing as specified in Item (2) and shall comply with the following provisions:

1. Sign a written contract of test entrustment with the client when entrusted with a test, indicating the entrusted test items, test methods, test scope, status of accreditation of the entrusted test items, and other matters. For any changes to the entrustment, the content of and the reasons for the changes shall be stated in the contract of test entrustment and verified and recorded by both parties.

2. Accurately record the detailed information of the client and the use purpose of the test report.

3. Accurately record the condition of sample(s) received, including the name, batch number, manufacturing date or expiry date, source, packaging, and quantity of the sample(s). No space or column shall be left blank; moreover, photographs of the sample(s) submitted for testing shall be kept on file.

4. The test report shall indicate the sample information, test item, testing method, test scope, and test results. All information shall be true and accurate.

5. Make clear statements or remarks where the report also contains results beyond the scope of accreditation (including test item, testing method, and test scope).

6. Non-accredited testing methods shall not be used for performing tests on accredited test items; however, this limitation shall not apply where such is requested in a specifically signed contract with the client or in a written request of the client, and such is specified in the test report.
7. The test report shall clearly note the following: "The test report merely reflects the test results of the consigned matters of the client and is not a certification of the legitimacy of the related products."

8. The test report and records of quality control information and raw data shall be kept on file together for at least 3 years.

9. Test reports shall be designed to thwart forgery.

10. The entrusted matter shall not be sub-entrusted to another person without the consent of the client; in the case where consent is granted to sub-entrust the matter to another person, the other person shall be one that possesses the ability to perform the entrusted test items, and the test report shall include the serial number of the test report issued by the sub-entrusted organization or other traceable information.

11. Products of different names, raw material sources, or samples in minimum individual packages shall be tested separately and covered in separated test reports, with no mixture.

12. The results of all the entrusted test items of the same sample listed in the test entrustment contract shall be stated in the same test report.

13. For tests performed on accredited test items, the results shall be stated in a test report in the form recognized by the central competent authority.

Article 14 The central competent authority shall regularly audit the equipment, personnel organization, quality management, operating procedures, testing capacity, and test records of the accredited testing institutions and may require the testing institutions to submit reports of the testing procedures conducted within the accreditation scope. When necessary, the central competent authority may conduct irregular audit.

The central competent authority may require the testing institutions to take, at their own expenses, proficiency testing activities organized by the central competent authority, or administered by other proficiency testing providers as entrusted or recognized by the central competent authority.

Testing institutions are not entitled to evade, obstruct, or refuse the audit procedure, report submission, and proficiency testing participation requirement prescribed in the foregoing two paragraphs.

Article 15 Where the testing institution undergoing the proficiency testing required in the second paragraph of the preceding article fails to pass the proficiency assessment, it shall be obliged to institute corrective actions within 15 days following the date of acceptance of the test assessment notice; moreover, a corrective action report shall be submitted to the central competent authority. The testing institution shall be required to receive the follow-up proficiency testing as per date scheduled by the central competent authority.

Article 16 When a major unforeseen medical devices event happened, testing institutions receiving an emergency mobilization notification from the central competent authority shall be obliged to process the medical devices testing within the prescribed deadline; thereafter, testing institutions shall submit complete sample information and testing results to the central competent authority.

Article 17 In any of the following circumstances of a testing institution, the central competent authority may suspend or abolish its accreditation. Where the accreditation is abolished, the testing institution is not allowed to apply for accreditation within one year:

1. Violation of the provisions of Paragraph 3 of Article 14 of no evading, obstructing, or refusing.
2. False information contained in test statistics, test reports or other documents and information submitted.
3. Other violations of the provisions of this set of regulations causing the central competent authority to deem the testing institution unsuitable for test administration.

Article 18 In any of the following circumstances of a testing institution, the central competent authority may suspend or abolish a part or all of the accredited test items:

1. After obtaining the accreditation according to this set of Regulations, the exclusive laboratory no longer exists or the laboratory does not meet the conditions set out in Article 3.
2. Violation of the provisions of Article 10, with no changes made or no changes made within the time limit.
3. Violation of the provisions of Article 11 or Article 12, with no report or notification submitted within the time limit.
4. Violation of the provisions of any one paragraph of Article 13.
5. Violation of the provisions of Article 15, by failing to submit a corrective action report within the time limit, failing to take the follow-up proficiency test, or failing to pass the test.
6. Closedown or discontinuation of the testing institution.

Chapter 4 Procedure for the Outsourcing of Accreditation Work

Article 19 The central competent authority intending to outsource the accreditation work to a related body (institution), corporation, or group (hereafter referred as independent provider) pursuant to the provisions of Paragraph 2 of Article 78

of the Medical Devices Act shall process assignment through an open selection process.

Article 20 The independent provider shall meet the following requirements:

1. Possession of the experiences required for the accreditation of testing institutions and the necessary documents supporting said eligibility.
2. Employment of personnel meeting the following qualifications:
   (1) Graduates from the undergraduate or graduate program of a local college or university, or a foreign college or university and the academic records of which are recognized in accordance with the Regulations Governing the Assessment and Recognition of Foreign Academic Records by Institutions of Higher Education, with a major in food science, nutrition, biomedical engineering, medicine, chemistry, biology, life science, or other related disciplines, and with verified capabilities and experience performing inspection functions of inspection bodies;
   (2) Having completed studies of at least 15 academic credits of legal subjects involving civil law, criminal law, and administrative laws and regulations in a domestic university, with a transcript of records reflecting said credits.
3. Fulfillment of all other requirements announced by the central competent authority.

Chapter 5 Management of Independent Providers

Article 21 An independent provider shall have an established management system and the related operating procedures established in coordination with its accreditation procedures and produce an information manual; the information manual shall contain at least the following information:

1. organization chart;
2. document control;
3. records;
4. nonconformities and corrective actions;
5. preventive actions;
6. internal audit;
7. management review;

8. complaints.

The independent provider shall periodically review the aforementioned manual to ensure its appropriateness, and update or make amendments from time to time to suit actual operating conditions.

The independent provider shall implement the matters in Subparagraphs 6 and 7 of Paragraph 1 at least once a year.

Article 22 An independent provider shall ensure that the personnel implementing the accreditation procedures possess the necessary medical devices testing related knowledge and proficiency; moreover, the independent provider shall keep a record of the initial and regular assessments conducted on said personnel.

The personnel stated in the preceding paragraph shall attend at least 12 hours of continued education and training course conducted by an institution (body) or civilian institution or group recognized by the central competent authority every year. Education or training curriculum shall include audit techniques, testing knowledge and skills, and related laws.

Article 23 Any information acquired by an independent provider in the course of the accreditation process or any accreditation related information provided by the testing institution shall be retained on file for at least 15 years; whereas records of accreditation work related documents and information shall be permanently retained on file.

Upon the conclusion of the independent provider's outsourcing service, the aforementioned documents and information retained on file shall be turned over to the central competent authority.

Article 24 An independent provider shall be obliged to maintain the confidentiality of all information acquired in the course of implementing accreditation work, and shall refrain from disclosing said information.

Article 25 An independent provider implementing an on-site assessment pursuant to Paragraph 1 of Article 6 shall submit the prepared assessment schedule to the central competent authority a week before the assessment date; on the other hand, the central competent authority may appoint a representative to attend the assessment. The independent provider shall not evade, obstruct, or refuse such attendance.

Article 26 An independent provider shall inform the central competent authority of the accreditation results of every case processed; moreover, related documents and information shall be attached.

Article 27 The central competent authority may notify the independent provider of its requirement to submit operation-related documents and information and may conduct irregular audit procedures on the venue of operations of the independent provider.

The independent provider shall not evade, obstruct, or refuse the foregoing notice, requirement or audit.

Article 28 All documents and information provided to the central competent authority by the independent provider pursuant to the provisions of the Regulations shall be true and accurate.

Article 29 An independent provider and its personnel entrusted with the processing of accreditation work shall observe the "conflict of interest" regulations as dictated in the Administrative Procedure Law.

An independent provider processing the work in the preceding paragraph shall not be engaged in behaviors in violation of the criminal law. Upon any suspicion of violation, the central competent authority shall bring the case to the related law enforcement organizations.

Article 30 The central competent authority shall sign a work consignment contract with the independent provider. Contract shall clearly define matters and other details, related rights and obligations, breach of contract penalty and reasons, dispute processing, and factors for the revocation or temporary suspension of the consigned work and other information covered in the contract.

Article 31 In any of the following circumstances of the independent provider, the central competent authority may suspend or revoke the outsourcing eligibility of the independent provider. An independent provider shall not be qualified to accept any outsourcing appointment within one year if the outsourcing eligibility is revoked due to severe circumstances:

1. Violation of the provisions of Article 24.

2. Violation of the provisions of Article 25, by failing to notify the central competent authority within the time limit, or by evading, obstructing, or refusing the attendance in assessment by the central competent authority.
3. Violation of Paragraph 2 of Article 27.
4. Violation of the provisions of Article 28.
5. Violation of the provisions of Paragraph 1 of Article 29 on the "conflict of interest" regulations.
6. Any violation of the criminal law as provided in Paragraph 2 of Article 29.

Chapter 6 Supplementary Provisions

Article 32 These regulations shall be effective on May 1, 2021.