Article Content

Title： Regulations Governing Commission of Medical Devices Management and Accreditation of Commissioned Institution CH

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Category： Ministry of Health and Welfare（衛生福利部）

Chapter I General Provisions

Article 1 The Regulations are enacted pursuant to Paragraph 2 of Article 79 of the Medical Devices Act (hereinafter referred to as the Act).

Article 2 Terms used in the Regulations shall have the following meanings:
1. Commissioned institution: It refers to an agency (or institution), a legal entity or an organization commissioned by the competent authority to carry out the tasks set forth in Paragraph 1 of Article 79 of the Act.
2. Accreditation: It refers to the procedure carried out by the competent authority to verify that a legal entity or an organization has the ability to carry out the tasks set forth in Paragraph 1 of Article 79 of the Act.

Article 3 When the central competent authority commissions another agency (or institution) to carry out education and training of technicians and inspection of medical device firms in accordance with the provisions of Paragraph 1 of Article 79 of the Act, the rights and duties of both parties shall be determined with administrative contracts.
When the central competent authority commissions a legal entity or an organization to carry out commissioned tasks referred to in the preceding Paragraph in accordance with the provisions of Paragraph 1 of Article 79 of the Act, the legal entity or organization shall apply for accreditation for each commissioned task in accordance with the provisions of the Regulations.

Chapter II Accreditation and Management for Education and Training of Medical Device Technicians

Article 4 Any legal entity or organization with the intent to accept a commission to carry out education and training of technicians shall submit an application to the central competent authority with the following documents and information to apply for accreditation:
1. Certificates showing that the legal entity or organization has been established or registered for three full years.
2. Documents and information proving that the legal entity or organization’s quality of training and performance have been evaluated with the Talent Quality-management System (TTQS) by the Workforce Development Agency, Ministry of Labor and has received “Pass” or above or “Qualified“.

In the event that the central competent authority discovers that the aforementioned application documents and information are not complete, but corrections can be made, the central competent authority shall notify the applicant who shall make corrections within a prescribed period of time. In the event that the applicant fails to make corrections before the designated deadline, the application shall be rejected.
For the application referred to in the first Paragraph, after the application has been reviewed and approved, the central competent authority will issue certificate letter of accreditation and commission contract.
The aforementioned certificate letter of accreditation shall state the following information:
1. The name and address of the legal entity or organization.
2. The scope of accreditation.
3. Effective period of the accreditation.

Article 5 When a commissioned institution is commissioned to carry out education and training of technicians, the training program shall follow the provisions of Articles 5 and 11 of Regulations for Management of Medical Devices Technicians.
Within 7 days after completing each education and training program, the commissioned institution shall upload trainees' names, national identification card numbers or numbers of the identification documents, the training program and number of training hours to the information system designated by the central competent authority.
Information and documents related to implementation of the above two commissioned tasks carried out by a commissioned institution shall be kept for three years; if any personal data is involved, the provisions of Personal Information Protection Act shall be followed.

Article 6 The central competent authority may conduct irregular audit to evaluate the commissioned institution regarding the content of the education and training and other relevant matters; the commissioned institution shall not evade, impede, or refuse such audit.
In the event that a commissioned institution is accredited through the use of false or inaccurate documents or information, or the employment of other illegitimate means, the central competent authority may revoke the accreditation and terminate the administrative contract for the commissioned education and training.
The central competent authority shall, under any of the following circumstances, notify the commissioned institution to make corrections within a prescribed period of time; In the event that the commissioned institution fails to make corrections before the designated deadline, its accreditation may be revoked and the administrative contract for the commissioned education and training may be terminated:
1. The training program provided by the commissioned institution violates the provisions of Paragraph 1 of the preceding Article.

2. The commissioned institution fails to follow the provisions of Paragraph 2 of the preceding Article to upload the required information before the designated date with the designated method, or the information provided are false or inaccurate.
3. The commissioned institution has violated the provisions of Paragraph 1 and has evaded, obstructed, or refused the audit conducted by the central competent authority.

Chapter III Accreditation and Management of Medical Device Firms Inspection

Article 7 The inspection of medical device firms, as stipulated in the Regulations, include the following scope:
1. Matters related to medical device quality management system as stipulated in Article 22 of the Act;
2. Matters related to good distribution practice system of medical devices as stipulated in Article 24 of the Act.

Article 8 When a legal entity or organization is commissioned to carry out inspection of medical device firms, the legal entity or organization shall meet the following criteria:
1. It has employed at least three full-time inspectors.
2. It has established procedures and requirements on inspection and inspector management.
3. Other matters designated by the central competent authority.

Article 9 Any legal entity or organization with the intent to apply for accreditation for inspection of medical device firms shall file an application the following documents and information to the central competent authority for accreditation:
1. Certificates of establishment or registration;
2. Certification documents and information manifesting the compliance with the requirements stipulated in the preceding Article;
3. Brief introduction of the organization, organization chart, person in charge, department heads, inspectors, business and services, inspection quality management capacity and operation procedures.
4. The list of trustees, supervisors, person in charge, chief executive officer or any person with the equivalent position and the person signing the inspection reports.
5. Other documents and information designated by the central competent authority.
In the event that the central competent authority discovers that the above-mentioned application documents and information are not complete, but corrections can be made, the central competent authority shall notify the applicant who shall make corrections within the prescribed period of time. In the event that the applicant fails to make corrections before the designated deadline, the application shall be rejected.

Article 10 Upon accepting the application referred to in the preceding Article, the central competent authority shall conduct on-site inspection; technical experts may be employed to participate in the inspection if necessary.

Records shall be prepared for the aforementioned inspection; if nonconformities are observed, the applicant shall be notified with the records of nonconformities and designated deadline for corrections.
The applicant shall submit the corrections report to the central competent authority before the aforementioned deadline. In the event that the applicant fails to make corrections before the designated deadline or fails to submit the corrections report in time, the application shall be rejected.

Article 11 The central competent authority will issue the certificate letter of accreditation and the commission contract to those who have passed the inspection referred to in the preceding Article.
The aforementioned certificate letter of accreditation shall state the following information:
1. The name and address of the legal entity or organization.
2. The name of the person in charge.
3. The scope of accreditation.
4. Accreditation number.
5. Validity period of the accreditation.
6. Other matters designated by the central competent authority.

Article 12 The effective period of the accreditation referred to in the preceding Article is three years. An application for extension, when necessary, shall be filed between six and twelve months preceding the date of expiration. The maximum period of an extension is three years. Provisions of Article 7 to the preceding Article shall be applied mutatis mutandis for the application and accreditation procedures for an extension.

Article 13 After a legal entity or organization has received the certificate letter of accreditation document and commission contract referred to in Paragraph 1 of Article 11, within one year, the legal entity or organization shall sign an administrative contract with the central competent authority and any commissioned task can only be carried out after the administrative contract has been signed.
If the applicant fails to follow the preceding Paragraph to sign an administrative contract, the central competent authority may revoke its accreditation.

Article 14 A legal entity or organization applying for change of particulars referred to in Subparagraph 1 or 2 of Paragraph 2 of Article 11 shall submit the application with relevant documents and information to the central competent authority.
A legal entity or organization applying for change of particulars referred to in Subparagraphs 2 to 4 of Paragraph 1 of Article 9 shall report relevant documents and information to the central competent authority for reference.
The application or report referred to in the preceding two Paragraphs shall be completed within 30 days from the date of occurrence of a change by the commissioned institution.

Article 15

The central competent authority may carry out routine or for cause inspection during the period when a legal entity or organization is carrying out commissioned tasks and the legal entity or organization shall not evade, obstruct, or refuse such inspection.
Records shall be prepared for the aforementioned inspection; if nonconformities are observed, the central competent authority shall notify the legal entity or organization with the records of nonconformities and designated deadline for corrections. The legal entity or organization shall submit the corrections report to the central competent authority before the designated deadline.

Article 16 When a commissioned institution carries out inspection of medical device firms, its inspectors and persons signing the inspection reports shall recuse themselves if the circumstances described in Articles 32 and 33 of Administrative Procedure Act apply or if any of the following circumstances applies:
1. The person is the designer, manufacturer, supplier, installer, buyer or renter, owner or repair manager of the medical device subject to inspection, or is an employee or agent of the one to be inspected, unless the medical device is for personal use, or if the purchase of the medical device is necessary for the operation or inspection of the commissioned institution.
2. The person has participated in the design, manufacture, assembly, market planning, installation and operation or repair of the medical device subject to inspection in the past five years.
3. The person is or was an employee of the medical device firm to be inspected.
4. The person is an employee of the consulting company providing advice to the medical device firm to be inspected.

Article 17 The commissioned institution shall notify the central competent authority when any of the following circumstances applies:
1. Inspectors and persons signing the inspection reports of the commissioned institution need to recuse themselves with the circumstances described in the preceding Article.
2. The independence or impartiality of the inspection has been or may be severely affected.
The central competent authority may change the commissioned institution with the above-mentioned notification.
When the commissioned institution is changed for reasons referred to in Paragraph 1, the original commissioned institution shall transfer documents and information, which it has acquired in the course of carrying out inspection of medical device firms, to the new commissioned institution.

Article 18 A commissioned institution shall establish and implement inspector training program and record the hours of training of each inspector as well as the review results.
The content of the above-mentioned training program shall state the following information based on the scope of accreditation:
1. The content of Medical Device Quality Management System Regulations and inspection practice.
2. The content of Medical Device Good Distribution Practice

Regulations and inspection practice.
When necessary, the central competent authority shall state the requirements for the commissioned institution to manage the ability of its inspectors and persons signing the inspection reports in the administrative contract.

Article 19

A commissioned institution shall be regulated as follows:
1. It shall maintain the confidentiality of all information acquired in the course of implementing its work, and shall not divulge such information without cause.
2. It shall not demand, agree to accept, or accept a bribe or other improper benefits;
3. It shall not forge or alter inspection results and records or make a false entry.
4. It shall not consign or transfer part or all of its inspection work to another legal entity, organization or institution.
5. It shall provide relevant documents, information, records and explanations to cooperate with the investigation of the central competent authority or when the central competent authority accepts inquiry, appeal or petition related to the inspection.
6. Documents, information and records provided by the medical device firm and generated by the commissioned institution shall be kept for at least six years.

Article 20

If any of the following situations apply to an accredited legal entity or organization, the central competent authority may cancel or revoke its accreditation issued in accordance with Article 11.
1. The accreditation is obtained through the use of false or inaccurate documents or information, or the employment of other illegitimate means.
2. The legal entity or organization has violated one of the provisions stated in Subparagraphs 1 to 5 of the preceding Article.
3. The legal entity or organization has violated the provisions of Paragraph 1 of Article 15 and has evaded, obstructed, or refused the inspection conducted by the central competent authority.
4. The legal entity or organization has violated the provisions of Paragraph 2 of Article 15 and has failed to make corrections before the designated deadline or failed to submit the corrections report to the central competent authority.
5. Inspectors and persons signing the inspection reports of the legal entity or organization have failed to follow the provisions of Article 16 to recuse themselves.
6. The legal entity or organization has violated the provisions of Paragraph 1 of Article 17 and failed to notify the central competent authority, or the legal entity or organization has violated the provisions of Paragraph 3 of the same Article and failed to transfer the documents and information.
7. The legal entity or organization has violated other provisions related to the commission, administrative contract or

laws, causing the central competent authority to deem the inspection may be influenced and such violations are considered significant.

Article 21 If any of the following situations apply to an accredited legal entity or organization and it has failed to make correction within the designated deadline after the central competent authority has notified it to make corrections, the central competent authority may stop part or all of its inspection. If the violations are considered significant, the central competent authority may revoke its accreditation.
1. The legal entity or organization has failed to follow the provisions of Article 8.
2. The legal entity or organization has failed to keep the documents, information or records in accordance with the provisions of Paragraph 6 of Article 19.
3. Poor quality of inspection or inefficient inspection.
4. The legal entity or organization has violated other provisions related to the commission, administrative contract or laws, causing the central competent authority to deem the inspection may be influenced.

Article 22 When the accreditation of a legal entity or organization is cancelled or revoked, the central competent authority shall order the legal entity or organization to stop carrying out any commissioned inspection and shall terminate the administrative contract for the inspection.
Under the aforementioned circumstances, the legal entity or organization shall return the documents, information and records of all completed and in-progress inspection to the central competent authority; the same applies for those who fail to extend its accreditation.

Chapter IV Supplementary Provisions

Article 23 The Regulations shall be implemented on May 1st, 2021.