Article Content

Title： Regulations Governing Border Inspection and Examination of Imported Medical Devices CH

Amended Date： 2025-03-31

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

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Chapter I General Provisions

Article 1 The Regulations are stipulated in accordance with Paragraph 2, Article 52 of the Medical Devices Act (hereinafter referred to as "the Act").

Article 2 Terms used in the Regulations shall have the following meanings:
1. Inspection: This refers to batch-by-batch verification or examination or random-selected batch verification or examination of imported medical device before permitting the importation.
2. Verification: This refers to examination or verification of items, packaging, appearance, labels or other items of products carried out by inspectors in accordance with the law.
3. Examination: This refers to conducting sensory, chemical, biological, or physical examination or tests in a laboratory.
4. Inspection authorities: This refers to the central competent authority in charge of inspection of imported medical device or refers to the organization(s) appointed or commissioned by the central competent authority.
5. Obligatory inspection applicants: This refers to importers of medical devices.

Chapter II Application for Inspection of Imported Medical Device

Article 3 Provisions governing medical device items requiring border inspection by the central competent authority are listed in Attachment 1.
Attachment 1 .pdf
Attachment 1 .doc

Article 4 In accordance with the provisions of Paragraph 1 of Article 52 of this Act, obligatory inspection applicants who apply to import medical devices referred in the preceding article shall file the completed application form for inspection and submit the following documents and information to the inspection authority at the port where the medical devices are to be imported, 15 days prior to the date of inspection:
1. A photocopy of the medical device license or listing, or approval document to import the medical devices as a special case.
2. A photocopy of application for import declaration.
3. Other documents and information designated by the central competent authority.
If the application is to be filed by a representative, an identification document for the representative and a letter of power of attorney shall be provided unless the obligatory inspection applicant can provide a copy of the long-term entrustment agreement and has notified the inspection authority of the entrustment.
The central competent authority may require the obligatory inspection applicant to submit the application of the preceding paragraph electronically.
In the event that the inspection authority discovers that the application documents and information are not complete but corrections can be made, the inspection authority shall notify the obligatory inspection applicant who shall make corrections within 20 days. In the event that the applicant fails to make corrections before the designated deadline, the application shall be rejected.

Article 5 Imported medical devices conforming to one of the following situations can be exempted from inspection referred to the preceding article:
1. Imported medical devices are for exclusive use as samples or for personal use only in accordance with the provisions of Subparagraph 4, Paragraph 1 of Article 35 of the Act.
2. Imported medical devices are originally manufactured domestically and exported, and they are shipped back to Taiwan with the approval of the central competent authority.
3. Imported medical devices are issued with a certificate of examination by the government of the country of origin who has signed an examination waiver reciprocity agreement with the government of the Republic of China.
4. The import has been approved by the central competent authority for national emergency situation or to improve the public welfare.

Chapter III Inspection Procedures

Article 6 The inspection authority may proceed inspection with one or more of the following measures:
1. Batch-by-batch inspection: Inspect each submitted batch of imported medical devices.
2. Randomly selected batch examination: Randomly select each submitted batch of imported medical devices by following inspection rate, and inspect the chosen medical devices:
(1) Regular randomly-selected batch inspection: The inspection is performed based on a 2-10% inspection rate.
(2) Reinforced randomly-selected batch inspection: The inspection is performed based on a 20-50% inspection rate.
3. On-site inspection: Verify the products at the storage site of medical devices.
Inspection items, test items and testing methods of imported medical devices as prescribed in Attachment 2.
Attachment 2： Verification items, test items and testing methods of imported medical devices.pdf
Attachment 2： Verification items, test items and testing methods of imported medical devices..doc

Article 7 Imported medical device applied for inspection that belong to one of the following situations shall be inspected on a batch-by-batch basis:

1. The first three batches of imported medical devices with the same item name, same trademark (brand name) and same origin imported by the obligatory inspection applicant.
2. Reinforced random-selected batch was performed on the previous batch of imported medical devices of the same item name, same trademark (brand name) and same origin imported by the obligatory inspection applicant and the inspection result does not conform to regulations.
3. The inspection authority determines that it is necessary to carry out the inspection on a batch-by-batch basis.

Prior to the completion of the batch-by-batch inspection, the same obligatory inspection applicant applied for inspection of products shall be subject to inspection on a batch-by-batch basis.

Article 8 Imported medical device applied for inspection that belong to one of the following situations shall be inspected on a reinforced random-selected batch basis:

1. Regular randomly-selected batch inspection is performed on the previous batch of imported medical devices of the same item name, same trademark (brand name) and same origin imported by the obligatory inspection applicant and the inspection result does not conform to the Regulations.
2. The inspection authority determines that it is necessary to carry out reinforced batch-by-batch inspection.

Article 9 Imported medical device applied for inspection that belong to one of the following situations shall be inspected on a regular random-selected batch basis:

1. The result of batch-by-batch inspection performed in accordance with Subparagraph 1, Paragraph 1 of Article 7 of the Regulations is in conformity with the provisions.

2. The inspection results of the previous five batches in a row in accordance with Subparagraph 2, Paragraph 1 of Article 7 or preceding Article of the Regulations are in conformity with the provisions and the quantity of the five conforming batches are three times of the quantity of non-conforming products.

Article 10 The samples required for inspection by the inspection authority shall be taken free-of-charge. The number (amount) of sampling shall be limited to requirements for examination.
After collecting the samples, the inspection authority shall issue a receipt for sampling to the obligatory inspection applicant.

Article 11 Sampling for inspection shall be conducted at the storage site of medical devices.
If the products were shipped in full container load, sampling shall be conducted in the centralized inspection area of port designated by the customs or designated area recognized by the inspection authority; but if it takes too long for sampling or has other difficult situations, the inspection authority may ask to open container for warehouse delivery.
During the inspection in the preceding paragraph, the obligatory inspection applicant shall cooperate accordingly and cannot appoint any specific sample.

Article 12 Examination of imported medical device shall be conducted in the order of sampling. However, the examination laboratory shall prioritize inspection on products applying for re-examination in accordance with Article 15 of the Regulations.

Article 13 For inspection of medical devices that are difficult to sample in a container yard, require five or more days for examination, perishable, or lack stability on safety efficacy, the inspection authority shall issue a Notice of Prior for Import for custom clearance after the obligatory inspection applicant declares to bear the responsibility for the safety and storage of

products imported by signing an Affidavit.
In the event that the pledged storage location of medical devices released for customs clearance with a Notice of Prior Release for Import in accordance with the preceding Paragraph does not conform to the actual storage location, or if the medical devices are put to use, are moved or sold before receiving the import permit, the inspection authority may temporarily suspend acceptance of an application for prior release of imports by the obligatory inspection applicant for a period of 1 year.

Article 14 In the event that imported medical device conforms to inspection, an import permit will be issued and the obligatory inspection applicant will be notified; the obligatory inspection applicant may apply for the inspection authority to issue a written import permit.
The obligatory inspection applicant can claim remaining samples by presenting the sampling receipt within 15 days after receipt of the notice of inspection results. However, if the sample is not collected within the time period or has short shelf life, the inspection authority may dispose of the samples directly.

Article 15 In the event that imported medical device fails to conform to inspection, the inspection authority shall issue a notification of noncompliance to the obligatory inspection applicant.
The obligatory inspection applicant can apply for re-examination to the original inspection authority within 15 days after receipt of the notification of results. However, applications for re-examination is limited to one time only.
The inspection authority can perform the re-examination using remaining samples; if the remaining samples are not adequate for re-examination, additional sampling may be required according to Article 11 of the Regulations.
For medical devices that do not conform to regulations upon inspection, as referred to in Paragraph 1, the remaining samples of products

shall be destroyed after the end of the period of application for re-examination, unless otherwise stated by law.

Article 16 Imported medical devices that do not conform to provisions of inspection, unless otherwise stated by law, shall be shipped back or destroyed by the obligatory inspection applicant.
If imported medical devices that have been released via a prior release notice do not conform to inspection, the inspection authority shall notify the obligatory inspection applicant to dispose the medical devices in accordance with the provisions of the preceding Paragraph and notify the municipality (county/city) competent authority.

Chapter IV Statutory Fees

Article 17 The obligatory inspection applicant shall pay the following administrative charge for inspection performed in accordance with the Regulations:
1. Review fees;
2. On-site inspection fees;
3. Notification fees;
4. Fees for updating information from on-line application;
5. Examination fees;
The inspection fees in the preceding Paragraph is described in Attachment 3.
Attachment 3.pdf
Attachment 3.doc

Chapter V Supplementary Provisions

Article 18 When conducting field inspections under the Regulations, inspectors shall carry and present certification documents related to the inspection operation or their credentials that show their identity.

Article 19 The Regulations shall be implemented on May 1st, 2021.
The amendments to the Regulations shall take effect on the date of promulgation.