

Regulations Governing Type Approval of Commodities

[Chronicle of Promulgation and Amendments]

20 Articles adopted and promulgated in full by Ministerial Order on January 9, 2002.

Articles 5, 8, 13, 17 and 18 amended and promulgated by Ministerial Order on November 6, 2002.

Articles 5, 6, 7, 9, 13 and 16 amended and promulgated by Ministerial Order on December 31, 2003.

Articles 4, 5, 8, 9, 16 and 18 amended and promulgated by Ministerial Order on July 7, 2011.

Articles 5, 13, 16 and 19 amended and promulgated by Ministerial Order on March 19, 2018.

Article 1

These Regulations are established in accordance with Paragraph 3 of Article 28 of the Commodity Inspection Act (hereinafter referred to as the Act).

Article 2

These Regulations apply to commodities that have been designated as requiring type approval before the application for batch-by-batch inspection is made.

Article 3

The type mentioned in these Regulations shall mean the basic design of the commodity.

The serial commodities mentioned in these Regulations shall mean the commodities with the same basic design.

Article 4

An applicant for type approval of a commodity shall be either the manufacturer of the commodities or a person who entrusts others to manufacture the commodities (hereinafter referred to as the producer). When the producer is located outside the territory of the Republic of China (hereinafter referred to as the R.O.C.), the applicant shall be his sales agent or importer who has its domicile or business place in the R.O.C.

Article 5

Applicants shall fill out, for each type of commodity, the application form and submit the following documents for type approval of a commodity to the Bureau of Standards, Metrology and Inspection (hereinafter referred to as the BSMI) or its branches (all being referred to as the inspection authority hereinafter):

1. A copy of the registration document of the company, business, factory or other

equivalent establishment registration documents of the applicant except if identification documents have been previously submitted to the inspection authority for type approval of a commodity; and

2. A copy of the type-test report and relevant technical documents.

For applications under the preceding Paragraph that are made for special commodities or commodities of small quantities, the applicant shall file an application in advance to the BSMI for type approval of special commodities or commodities of small quantities by submitting an application form and relevant documents.

Article 6

Applicants shall obtain type test reports in accordance with the following requirements:

1. General type test: For type test of electromagnetic compatibility, applicants shall apply to a designated testing laboratory recognized by the BSMI with relevant technical documents and an adequate supply of samples required for testing purpose. For other type tests, applicants shall apply to the inspection authority or a designated testing laboratory recognized by the BSMI with relevant technical documents and an adequate supply of samples required for testing purpose. For commodities that are large in size or complex, the applicant may apply to the BSMI for the testing to be conducted at a specific testing facility.
2. Type test of special commodities or commodities of small quantities: Applicants may apply to a domestic or foreign testing laboratory accredited by a laboratory accreditation body or that of an accredited product certification body. The type test may be conducted by the original manufacturer upon approval by the BSMI.

If an applicant has been granted the use of other certification marks designated by the BSMI, the certificates of such marks may be presented in place of the type test report and relevant technical documents.

Article 7

A type approval certificate for a commodity shall be issued to the applicant after the said application has been reviewed and approved by the inspection authority. Upon the issuance of the certificate, the applicant shall be allowed to use the commodity inspection mark for type approval in accordance with the Regulations Governing the Use of Commodity Inspection Mark.

Article 8

The term of validity of the type approval certificate shall be determined by the BSMI in accordance with the types of commodity.

The certificate holder may apply for extension of the term of validity by providing relevant documents within a period of three months prior to the expiration of the certificate. A new certificate will be issued after the inspection authority has reviewed and approved the extension application. For applications that are made after the expiration of the certificate, a new application for type approval shall be required.

The extended term of validity of the type approval certificate shall be determined according to Paragraph 1 of this Article, beginning from the day following the expiry date of the original certificate.

Articles 5 to 7 shall apply to the application and review mentioned in Paragraph 2 of this Article, with the relevant changes having been made. For cases where the applicable inspection standards remain the same, a type test report and relevant technical documents need not be provided.

Article 9

If any changes are made to commodities that have been granted type approval, the following procedures shall apply:

1. Where the basic design has been changed, a new application shall be submitted;
2. Where the basic design remains the same but the inspection items of this serial commodity have been changed, an application shall be submitted for the type approval of serial commodity; or
3. Where the basic design remains the same and the changes mentioned in the previous subparagraph do not affect the registered items of certificate and commodity identification, an application shall be submitted to the inspection authority for permission.

Where the inspection standards of commodities granted type approval are revised, for purposes of safety, health, environmental protection, efficiency of resource utilization or other public interests, the BSMI may notify the certificate holder of the type approval to apply for renewing the certificate to conform to the revised standards within a given time limit.

Article 10

When an inspection authority reviews and approves an application for the type

approval of serial commodity, it shall request the applicant to return the original certificate and issue a replacement certificate by adding the serial commodity. The term of validity of the replacement certificate shall be the same as that of the original one.

Article 11

Where necessary, the inspection authority may ask an applicant to provide samples for conducting all or a part of the tests when reviewing the application for type approval.

Article 12

If the documents and information submitted by the applicant are incomplete or insufficient, the inspection authority shall notify the applicant to rectify within two months after receiving the rectification notice. If the applicant fails to rectify by the expiration of the preceding period, the inspection authority may reject its application.

Article 13

Once a commodity has been granted type approval, the applicant may apply for batch inspection of the commodity by completing an application form with a copy of the type approval certificate. However, copies of the type approval certificate need not be submitted if the certificate number of the type approval is provided. In case where the applicant is not the nominal holder of the type approval certificate, it shall provide additional documents providing evidence of the holder's authorization.

For commodities of which the type approval is granted based on the type test reports obtained in accordance with the requirements under Subparagraph 2, Paragraph 1 of Article 6, the inspection authority may limit the quantity of commodities to be filed for inspection application.

Article 14

For commodities that have been granted type approval, the inspection authority may simplify the inspection procedures, according to the following methods:

1. Document review: To issue a compliance certificate after a document review verifies conformity to type.
2. Batch examination: To issue a compliance certificate after each batch of commodities is checked by opening the containers and conformity to type is verified.
3. Random examination: To issue a compliance certificate after randomly selected batches of commodities are checked by opening the containers and conformity to

type is verified.

4. Sampling inspection: To select a sample of a commodity after verifying its conformity to type and forward it to testing units for inspection or testing against major testing criteria. A compliance certificate shall be issued after a commodity has passed inspection or testing.

Article 15

The inspection authority shall revoke type approval that has been obtained through fraudulent means and order a return of the type approval certificate within a given time limit. If the certificate is not returned within the required period, the inspection authority may make an announcement to cancel the certificate.

Article 16

If the commodity that has been granted type approval is found any of the following instances, its type approval shall be rescinded:

1. Where the commodity has failed to conform to the amended or revised inspection standards within a given time limit as required by the competent authority according to Paragraph 2 of Article 9;
2. Where the commodity is not recalled within a given time limit, as requested by the inspection authority;
3. Where the manufacturer of the commodity has failed to provide samples within a given time limit, without a reasonable explanation;
4. Where the commodity was not marked in the manner as required in Articles 11 and 12 of the Act, and the required rectification has not been made within a given time limit or where the commodity was marked falsely or incorrectly;
5. Where the type approval was used beyond the granted scope, and the required corrective action has not been finished within a given time limit after receipt of notice;
6. Where a defect of the commodity has caused severe injury to any person or is a hazard to public safety;
7. Where the nominal holder of the type approval certificate applies for cancellation of the type approval; or
8. Where the announcement of the commodity subject to type approval has been rescinded by a public notice.

Article 17

An application for a replacement of the original type approval certificate may be submitted to the inspection authority that issues the original certificate if the original

certificate is lost or damaged.

Article 18

(Deleted)

Article 19

(Deleted)

Article 20

These Regulations shall take effect from the date of promulgation.