

Content

|               |  |
|---------------|--|
| Title :       |  Regulations Governing Implementation of Management System Certification<br>   |
| Date :        | 2021.02.01   |
| Legislative : | 1.Full text of 18 articles published by order of the Ministry of Economic Affairs Jing-Biao-Zhi No. 09004628880 on 9 January 2002<br>2.Amendments to Articles 2, 9, 13, 16 and 17 and the addition of Article 10-1 published by order of the Ministry of Economic Affairs Jing-Biao-Zhi No. 09304610120 on 13 January 2005<br>3.Amendments to Articles 3, 13 and 16 published by order of the Ministry of Economic Affairs Jing-Biao-Zhi No. 10304600520 on 6 February 2014<br>4.Amendments to the full text of 19 articles published by order of the Ministry of Economic Affairs Jing-Biao-Zhi No. 10404602190 on 18 May 2015<br>5.Abolished on Feb 1, 2021.   |
| Content :     | <p><b>Article 1</b><br/>These Regulations are established in accordance with Paragraph 2, Article 14 of the Commodity Inspection Act.</p> <p><b>Article 2</b><br/>The inspection authority (institution) referred to in these Regulations shall mean the Bureau of Standards, Metrology and Inspection of the Ministry of Economic Affairs (hereinafter the "BSMI"), its branches or other commissioned government agencies, legal entities or organizations.</p> <p><b>Article 3</b><br/>The management system certification set forth in these Regulations shall refer to the BSMI conducting an impartial and independent assessment of the quality, environmental, safety or health management system established by organizations and certifying that such management systems comply with the established standards.<br/>The standards for quality, environmental, safety or health management system certification shall be prescribed by the BSMI in accordance with national standards, international standards or other internationally recognized standards. BSMI may also determine the scope and period of implementation for the different types of system certification.<br/>The organizations referred to in these Regulations shall be a company, partnership, sole proprietorship, legal entity, group, school or government agency.</p> <p><b>Article 4</b><br/>Organizations applying for management system certification shall possess legal documentation of their establishment in relation to the application scopes.</p> <p><b>Article 5</b><br/>Organizations applying for management system certification shall apply to the inspection authority (institution) by submitting their Declaration of Rights and Obligations and a completed application form with the relevant documents attached.<br/>If the applicant organization mentioned in the preceding paragraph is a foreign organization, an agent that has an address or business location within the Republic of China (Taiwan) shall be appointed to make the application.<br/>The documents to be submitted and the regulations related to the certification procedures under the first paragraph shall be prescribed by the BSMI according to the type of management system certification being applied for.</p> <p><b>Article 6</b><br/>If the Declaration of Rights and Obligations is amended at any time, the registered organization shall re-sign it within the prescribed period.</p> <p><b>Article 7</b></p> |

Once an organization submits an application, the inspection authority (institution) shall review the documents and assign auditors to conduct an assessment.

#### Article 8

The inspection authority (institution) may reject an application even before conducting an assessment if the applicant organization has any of the following situations:

1. The application documents do not comply with the requirements mentioned in Article 5, or if the scope of application does not comply with Article 3-2 as set forth by the BSMI.
2. The applicant organization is unable to arrange for the assessment to be conducted within six months after its application is accepted.
3. If a previous application did not comply with the standard of certification, the period of the current application is within six months of receiving the non-conformity notice of the previous application.
4. If BSMI revoked or rescinded the application due to a violation of Article 16, 17-10 or 11, the period of the current application is within three years of the rescission or cancelation of the previous application.
5. If BSMI rescinded the application based on any other reason not mentioned in this Article, the period of the current application is within six months of such rescission.

#### Article 9

The BSMI shall approve certification registration and the use of the certification mark based on the certification type or scope of products, services or activities specified in the application documents of the organizations that are assessed to be in compliance with certification requirements and then shall issue a certificate.

The certificate in the preceding paragraph shall be valid for three years, which may be amended by BSMI when necessary. However, if BSMI designated the implementation period for a type of certification in accordance with Article 3-2, the validity period for certification in the preceding paragraph shall be shorter than the implementation period.

The format of the certificate and the certification mark mentioned in the previous paragraph will be prescribed by the BSMI.

#### Article 10

Registered organizations shall use the certificate and certification mark in a manner that observes the following requirements:

1. Use the name, address, and scopes of registration specified in the certificate within the period of validity.
2. Use the certification mark together with the first seven digits of the certificate number identified below the mark.
3. Identify the appropriate scopes when using the certification mark, if the scope of registration covers only a part of the organization's products, services or activities.
4. Affix the certification mark, certificate number, texts and inscriptions in a visible and easily legible form.
5. Do not affix the certification mark on the outside packaging of the product.
6. Do not interpret the certification mark in such a way that associates it with the usage of the product.
7. Do not promote the certification mark in a manner that could potentially mislead another party into believing that the product is certified.

#### Article 11

Registered organizations that intend to make changes to the items specified in a certificate, thus requiring a revised certificate, shall apply to the BSMI by providing relevant documents to seek such changes and the subsequent re-issuance of the certificate.

The inspection authority (institution) may conduct surveillance of the organization's management system regarding the changes under the previous paragraph if necessary. If the management system continues to comply with certification standards, the inspection authority shall approve the changes and issue a revised certificate.

#### Article 12

Where the management system certification standards or scope of registered organizations are revised by the BSMI in accordance with Paragraph 2, Article 3, the registered organizations shall comply with the new certification standards before the end of the transitional period designated by the BSMI.

#### Article 13

Registered organizations may apply to the BSMI for a replacement of the original certificate if the original certificate is lost or damaged.

#### Article 14

Registered organizations shall be subject to regular surveillance visits by the inspection authority (institution) at least once a year and random surveillance visits from time to time. The quantity of samples for the surveillance may be increased when necessary.

Organizations shall use raw materials that comply with the relevant regulations and shall keep a record of raw materials and their suppliers, which may also be inspected by the inspection authority (institution) as it deems fit.

Upon occurrence of any significant event related to the compliance of the management system that may lead to any concern that a registered organization may have breached certification standards, the BSMI may conduct an on-site audit of the organization and may prescribe a period for the organization to take corrective action depending on the status of the aforementioned non-compliance.

#### Article 15

Registered organizations that suspend production or business for more than one month shall report to the inspection authority (institution) within one month of the suspension. However, registered organizations who were ordered to suspend production or business shall report to the inspection authority (institution) within five days of said order.

The suspension of production or business by the registered organization's own decision in the preceding paragraph may not exceed six months.

If the suspension of production or business by the registered organization's decision or order does not exceed six months, the registered organization shall report to the inspection authority (institution) one month before termination of the suspension for inspection.

#### Article 16

The BSMI shall revoke registration that was acquired through fraudulent means.

#### Article 17

Registration shall be rescinded by the BSMI if a registered organization has any of the following situations:

1. Significant event related to the compliance of the certification standard found after second surveillance, on-site audit or failure to rectify within the designated period in accordance with Article 14-3.
2. If a registered organization fails to comply with new certification standards before the end of the given transitional period in accordance with Article 12.
3. If a registered organization fails to make payments for regular and random surveillance or any other payments in accordance with related requirements after receiving notice to make overdue payments.
4. If a registered organization fails to report to the inspection authority (institution) regarding its suspension of production or business or has received orders to suspend production or business for a period exceeding six months.
5. If a registered organization fails to apply for inspection within one month before termination of suspension of production or business or fails to resume production or business by the end of the suspension period.
6. If related licenses or certificates of the registered organization have been revoked, cancelled or rescinded by the relevant authorities
7. If a registered organization applies for cancellation of registration
8. If a registered organization fails to make proper arrangements to allow the inspection authority (institution) to conduct regular surveillance, random surveillance, on-site auditing, sampling or raw material and supplier record inspection.
9. If a registered organization fails to use the certificate and certification mark in the manner prescribed in Article 10 and fails to take corrective actions after receiving a notice from the inspection authority (institution)
10. The violation of the management system is detrimental to public social interests and the BSMI deems that the situation is significant.
11. Violation of any provision under the management system Declaration of Rights and Obligations or concealment of any fact or provision of any false information during regular surveillance, random surveillance, on-site auditing or raw material and supplier record inspection.

12. If a registered organizations fails to re-sign within the designated period in accordance with Article 6 in case of any amendments to the Declaration of Rights and Obligations.
13. If a registered organization fails to apply for amendment in case of amendments to certifications and fails to take corrective actions after receiving a notice.
14. If a registered organization fails to use raw materials in accordance with Article 14-2, or if raw material and supplier records are found to be incorrect after inspection.

#### Article 18

If the registration of an organization has been revoked or rescinded, it must stop using the certificate and certification mark and shall return the certificate within a given time limit. The BSMI shall automatically cancel the registration should the certificate not be returned by the deadline

#### Article 19

These Regulations shall take effect from the date of promulgation.

---

Data Source : Ministry of Economic Affairs R.O.C.(Taiwan) Laws and Regulations Retrieving System