

Regulations Governing Implementation of Management System Certification

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Article 1 These Regulations are established in accordance with Paragraph 2, Article 14 of the Commodity Inspection Act.

Article 2 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.

Article 3 The management system certification set forth under 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.

The standards and the applicable scopes 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.

The organizations referred to under these Regulations shall mean a company, partnership, sole proprietorship, legal entity, group, school or government agency.

Article 4 Organizations applying for management system certification shall possess legal documentation of their establishment in relation to the application scopes.

Article 5 Organizations applying for management system certification shall apply to the inspection authority (institution) by submitting a completed application form with the relevant documents attached.

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.

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.

Article 6 Once an organization submits an application, the inspection authority (institution) shall review the documents and assign auditors to conduct an assessment.

Article 7 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.

2. The applicant organization is unable to arrange for the assessment to be conducted within six months after its application is accepted. However, if a reasonable explanation is provided, the organization may apply to the BSMI for a single extension of no longer than six months.

Article 8 The BSMI shall approve certification registration and the use of the certification mark based on the certification type or scopes of products, services or activities specified in the application documents of the organizations that are assessed to be in compliance with certification requirements and issue a certificate. Said certificate is valid for three years.

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

Article 9 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 registration scopes cover only a part of the 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 10 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. If not, the case shall be handled according to Paragraph 2, Article 13.

Article 10-1 Where the certification standards 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 11 Registered organizations may apply to the BSMI for a replacement of the original certificate if the original certificate is lost or damaged.

Article 12 Applicant organizations that are assessed and found not to be in compliance with the certification standards may apply for a second assessment within two months after the original assessment results. Applicant organizations shall arrange for the second assessment to be conducted within six months of the application.

Applicant organizations that are unable to complete a second assessment within the prescribed period shall be considered as having terminated the application for a second assessment. However, if a reasonable explanation is provided, the organization may apply to the BSMI for a single extension of no longer than six months.

Article 13 Registered organizations shall be subject to surveillance visits by the inspection authority (institution) at least once a year.

If the management system of a registered organization does not comply with certification standards during the surveillance visits, the organization shall implement corrective actions within one month after receiving the results of the surveillance. The inspection authority (institution) shall then conduct a second surveillance.

If a registered organization is found to be not in compliance with Article 10-1 during the surveillance visits, the inspection authority (institution) shall conduct a second surveillance three months before the transitional period expires.

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 on the organization.

Article 14 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.

A period of suspension shall not exceed one year, unless a reasonable explanation is provided as to why production or operation is unable to resume within the reported period. A registered organization may apply in advance for a single extension of the suspension period for a period of no longer than six months.

Article 15 The BSMI shall revoke registration that was acquired through fraudulent means.

Article 16 Registration shall be rescinded by the BSMI if a registered organization has any of the following situations:

1. If the management system of a registered organization fails to comply with certification standards after a second surveillance is conducted in accordance with Paragraph 2, Article 13.

2. If a registered organization fails to comply with new certification standards before the end of the given transitional period in accordance with Article 10-1.

3. If a registered organization fails to make payments in accordance with related requirements after receiving a 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, and fails to report or resume production or business within 15 days after receiving notice from the inspection authority (institution).

5. If related licenses or certificates of the registered organization have been revoked, cancelled, or rescinded by the relevant authorities.

6. If a registered organization applies for cancellation of registration.

7. If a registered organization fails to make proper arrangements for surveillance, second surveillance or on-site audit to be conducted by the inspection authority (institution).

8. If a registered organization fails to use the certificate and certification mark in the manner prescribed in Article 9 and fails to take corrective actions after receiving a notice from the inspection authority (institution).

9. The violation of the management system is detrimental to public social interest and the BSMI deems that the situation is significant.

10. Violation of any provision under the Declaration of Rights and Obligations or concealment of any fact or provision of any false information during surveillance, second surveillance or on-site audit.

Article 17 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.

Organizations may apply for certification of their management systems again four months after the revocation or rescission.

Article 18 These Regulations shall take effect from the date of promulgation.