

Regulations Governing Commission of Commodity Inspection Operations

[Chronicle of Promulgation and Amendments]

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

25 Articles amended and promulgated in full by Ministerial Order on June 24, 2005.

Article 6 amended and promulgated by Ministerial Order on July 28, 2006.

Article 20-1 newly added, Article 4 deleted and Articles 1, 2, 3, 6, 9 and 23 amended and promulgated by Ministerial Order on December 17, 2007.

Articles 6, 7, 8, 9, 22 and 23 amended and promulgated by Ministerial Order on September 1, 2008.

Articles 23 amended and promulgated by Ministerial Order on July August 16, 2010.

Articles 2, 6 and 13 amended and promulgated by Ministerial Order on September 2, 2011.

Articles 8, 9, 11, 22 and 23 amended and promulgated by Ministerial Order on February 3, 2012.

Article 7 amended and promulgated by Ministerial Order on June 7, 2013.

33 Articles adopted and promulgated in full by Ministerial Order on January 4, 2018.

Chapter I General Principles

Article 1

These Regulations are established in accordance with Paragraph 4, Article 4 of the Commodity Inspection Act (hereinafter referred to as the “Act”).

Article 2

The commissioned commodity inspection operations shall mean the conformity assessment, issuance of certificates (new or replacement), surveillance for the certified commodities, sampling, sealing and examining with commodity inspection and relevant management activities for commodity certification.

Article 3

The other government agency, juristic person or organization commissioned to perform commodity inspection activities shall perform these activities according to the relevant regulations and requirements of the Act.

Article 4

The term “commodity certification body” (hereinafter referred to as the “certification body”) as used in these Regulations shall mean the bodies commissioned to perform commodity certification activities.

The categories and items of commissioned commodity certification activities shall be designated and made known to the public by the Bureau of Standards, Metrology and

Inspection of the Ministry of Economic Affairs (hereinafter referred to as the BSMI) per public notice.

The term “commodity inspection body” (hereinafter referred to as the “inspection body”) as used in these Regulations shall mean the bodies commissioned to perform sampling, sealing and examining with commodity inspection.

The commodity categories, period and work content of commissioned sampling, sealing and examining with commodity inspection shall be designated and made known to the public by the BSMI per public notice.

Chapter II Commission of Commodity Certification Activities

Article 5

The applicant applying for the certification body (hereinafter referred to as the “certification body applicant”) shall possess the following qualifications:

1. Administrative bodies or institutions, public or private college or university, or non-profit juristic persons of the Republic of China;
2. Having set up the product certification system compliant with the international standards and been granted an accreditation by the Taiwan Accreditation Foundation (hereinafter referred to as the “TAF”) for the relevant commodity fields;
3. Having obtained recognition by the BSMI as a designated testing laboratory for the relevant commodity inspection fields, or qualification for technical body which is designated and made known to the public by the BSMI per public notice. If above-mentioned application includes the module for the factory inspection business, the certification body applicant shall have obtained recognition by the BSMI as a designated factory inspection body for the relevant commodity fields; and
4. Other qualifications designated and made known to the public by the BSMI per public notice.

In case of the application for the certification category of Voluntary Product Certification, the qualification required in the first Subparagraph of the preceding Paragraph may be exempted.

The qualification required in Subparagraph 3 of Paragraph 1 may be exempted, provided that this has been made known to the public by the BSMI per public notice under special circumstances.

Article 6

The certification body applicant shall fulfill the following conditions:

1. One or more than one full-time professional certification personnel shall be established in each item of commissioned commodity certification activities. The certification personnel shall possess a college or university degree or higher in related field from domestic or foreign public or private colleges or universities recognized by the Ministry of Education, have the professional knowledge and capability of relevant commodity certification activities, understand the relevant government regulations and inspection requirements, and be trained by the BSMI or the BSMI's registered training body, and be qualified and registered by the BSMI; and
2. Possessing the necessary equipment, facilities, personnel and management system for the specific field of commissioned commodity certification activities; and possessing sufficient information and understanding of the certification standards and relevant regulations for such commissioned commodity certification field.

The condition of educational degree required in Subparagraph 1 of the preceding Paragraph may be exempted, provided that the certification personnel of the certification body applicant have working experience for testing, design or manufacturing of the relevant commodity, and the submitted documents of the working experience are approved by the BSMI.

The matters governing the registration conditions and application procedures of the training bodies, and the qualification and registration procedures of the certification personnel required in Subparagraph 1 of the first paragraph, these relevant administrative matters shall be prescribed by the BSMI.

The registered training bodies required in Subparagraph 1 of the first paragraph, these bodies shall be registered and made known to the public by the BSMI per public notice.

Article 7

The certification body applicant possessing the qualifications and fulfilling the conditions set forth under the preceding two Articles may apply to the BSMI by submitting the following documents:

1. The applicable items of commissioned commodity certification activities that the certification body applicant intends to carry out;
2. Certificates and relevant documents complying with the qualifications set forth under Article 5;
3. List of the registered certification personnel and applicable items of commissioned

commodity certification activities;

4. Organization charts and function statements;
5. Layout plan and location guide map for the applying body;
6. Quality manual, system structure and overview list for quality documents; and
7. Other documents designated by the BSMI.

If the documents submitted according to the preceding Paragraph are found incomplete, the certification body applicant shall submit supplement documents within one month from the next day of receipt of the notice. If the certification body applicant fails to supplement the documents as required, the application shall be rejected.

Article 8

An on-site assessment will be conducted by the BSMI for the certification body applicant mentioned in the preceding Article whose application has passed the document review.

If the document review and on-site assessment of the certification body applicants are completed and found in compliance with the requirements set forth in Article 5 and Article 6, the BSMI should issue the notification that shows the compliance to the requirements set forth in Article 5 and Article 6, and requires the certification body applicant discuss the commission contract for commodity certification activities with the BSMI before the specified date. The BSMI may select the distinguished ones to negotiate the price and enter into the commission contract for commodity certification activities.

Article 9

For the certification body applicant who fails the review process as prescribed in the preceding Article, the certification body applicant may apply for a second review process within two months from the next day of receipt of the notice. If the certification body applicant still fails the second review process, the certification body applicant shall not re-apply within three months from the next day of receipt of the notice.

Article 10

The certification body shall conduct commodity certification activities under his own name.

The certification body shall not reject any application for commodity certification activities or treat the applications differently unless reasonable cause is shown.

Article 11

The certification body shall perform surveillance for the commodities that have been certified by him.

Article 12

The certification body shall maintain sufficient resources and capability to efficiently conduct the commissioned works, and shall not subcontract with others to conduct the commissioned works.

The certification body may subcontract a part of the certification activities to other organizations provided that it is not the main part of the commissioned works and only with an approval by the BSMI.

Article 13

In special circumstances, the certification body may perform witness testing or on-site testing.

The certification body shall set up the operational procedures for witness testing and on-site testing set forth in the preceding Paragraph and submit them to the BSMI for approval.

Article 14

The certification body shall maintain the relevant documents appropriately. The minimum period of retention of documents for each type of document shall be prescribed by the BSMI depending on the character of the commissioned activities.

The expired documents may only be disposed after having reported to and obtained approval from the BSMI. The certification body shall keep the record for all disposed documents.

The certification body shall handover the relevant documents in full for all certification applications to the BSMI within seven days after the termination of the commission contract.

Article 15

For the application to expand the certification categories and items or to modify other matters related to certification activities, the certification body shall apply to the BSMI by submitting an application form and relevant documents.

If the scope of accreditation of the certification body has been reduced by the TAF, the certification body shall immediately stop performing the commodity certification activities relating to the affected area and apply to the BSMI within three months for modification of the scope of commissioned activities.

For the modification set forth in the preceding two Paragraphs, the BSMI shall conduct on-site assessment. However, document-review may be performed instead depending on the circumstances.

If the modifications in Paragraph 1 and Paragraph 2 are related to the content of the commission contract for commodity certification activities, the contract shall be amended accordingly.

Article 16

Any change of the certification personnel shall be reported by the certification body to the BSMI with the information of the new certification personnel within fifteen days after such change.

Article 17

If the certification body moves to a new location, he shall apply to the BSMI by submitting relevant documents. In such case, the certification body shall not perform the commissioned activities unless the document review and on-site assessment process have been completed and found in compliance with the relevant requirements by the BSMI,

Article 18

The BSMI shall conduct routine surveillance assessment for the certification body at least once per year. The BSMI may also conduct non-routine surveillance assessment.

The certification body shall not evade, impede or reject the assessment set out in the preceding Paragraph unless good cause is shown.

Article 19

When the certification body has been accredited by the TAF and demonstrated

compliance with the qualification requirements set forth in Subparagraph 2, Paragraph 1 of Article 5 continuously, the BSMI may exempt the certification body from routine surveillance assessment set out in the preceding Article.

Article 20

If the routine surveillance assessments conducted by the BSMI toward the certification body according to Paragraph 1 of Article 18 have shown the conformity with the requirements of this Regulations, the BSMI may continuously negotiate the price and enter into the commission contract for commodity certification activities with the certification body two months prior to the expiration date of the contract.

Article 21

If the commission contract for commodity certification activities is not renewed, the certification body may not accept any certification applications within one month prior to the expiry of the contract. All pending certification applications that have been accepted by the certification body shall be completed prior to the expiry of the contract.

Article 22

If a certification body has any of the following circumstances, the BSMI may temporarily suspend, pursuant to the commission contract, the right of the certification body to perform commissioned certification activities within a certain period of time. The BSMI shall resume the right after the certification body has completed the corrective action and been examined and approved by the BSM:

1. Where the certification body does not fill in a vacant position of the certification personnel and violates the requirements set out in Subparagraph 1, Paragraph 1 of Article 6;
2. Where the accreditation by the TAF has been suspended;
3. Where the recognition of the designated testing laboratory or designated factory inspection body that belongs to the certification body has been temporarily suspended by the BSMI, or the qualification for technical body which is designated by the BSMI per public notice according to Subparagraph 3, Paragraph 1 of Article 5 has been lost;
4. Having violated the provision set forth in Article 11;
5. Where the certification body has failed to submit documents within the given time limit after receiving a notice to submit by a given time limit unless reasonable cause is shown; or
6. Having failed to take appropriate actions and cooperate with the BSMI when notified by the BSMI to cooperate with in the BSMI's action for conducting

assessment or handling appeal, complain, or disputing case.

Article 23

If any of the following circumstances occurs, the BSMI may terminate the commission contract, in part or in whole, pursuant to the commission contract for commodity certification activities:

1. Where an application to terminate the commission contract for commodity certification activities has been initiated by the certification body;
2. Where the certification body's accreditation by the TAF have been withdrawn or revoked, or recognitions of designated testing laboratory or designated factory inspection body by the BSMI have been revoked or rescinded, or the qualification for technical body which is designated by the BSMI per public notice according to Subparagraph 3, Paragraph 1 of Article 5 has been lost;
3. Where the certification body losses his ability to perform certification activities or is unable to perform certification activities impartially and effectively;
4. Where the certification body has failed to avoid conflict of interests or violated his obligation of confidentiality;
5. Where the certification body performs certification activities beyond the scope authorized by the commission contract for commodity certification activities or is lazy to perform certification activities;
6. Where the certification body violates the requirements set forth in Paragraph 2 of Article 10 by rejecting certification applications or giving different treatment;
7. Where the certification body fails to comply with the requirements set forth in Article 14 regarding retention and disposal of documents;
8. Where the certification body fails to report or apply for the modifications as required under Article 15 or Article 16;
9. Where the certification body fails to comply with the application requirements or performs commissioned activities before obtaining the required approval as set out in Article 17;
10. Where the certification body violates the requirements set forth in Paragraph 2 of Article 18 by evading, impeding or rejecting the assessment conducted by the BSMI;
11. Where the certification body fails to complete corrective actions and been examined and approved by the BSMI within the prescribed timeframe as required under Article 22;
12. Where the certificate issued by the certification body is found to contain false or incorrect information;
13. Where the procedural fees due were not paid, and have further been not paid within the given time limit;

14. Where it is proved serious that employees of the certification body accept gifts, bribery, banquet invitations or requests from interested parties, or seek interests for himself or for any third parties by manipulating his power, methods or opportunities under his duty; or

15. Other violation of relevant regulations that are deemed as substantial and material events by the BSMI.

Article 24

If the commission contract for commodity certification activities is terminated pursuant to the preceding Article, the certification body shall return his certificate.

In the event of the preceding Paragraph, the certification body shall handover the pending certification applications to the BSMI or other certification body designated by the BSMI.

Within 3 years after the termination of the commission contract for commodity certification activities, the terminated certification body shall not be permitted to re-apply for the qualified certification body, except that the certification body terminates the commission contract for commodity certification activities voluntarily.

Chapter III Commission of Sampling, Sealing and Examining with Commodity Inspection

Article 25

The applicant applying for the inspection body (hereinafter referred to as the “inspection body applicant”) shall possess the following qualifications:

1. Administrative bodies or institutions, public or private college or university, or non-profit juristic persons of the Republic of China;
2. Having obtained recognition by the BSMI as a designated testing laboratory for the relevant commodity inspection fields; and
3. Other qualifications designated and made known to the public by the BSMI per public notice.

Article 26

The inspection body applicant possessing the qualifications set forth under the preceding Article may apply to the BSMI by submitting the following documents:

1. Certificates and relevant documents complying with the qualifications set forth under the preceding Article; and
2. The plan including to explain origin, goal, capability, sites, equipment, human

analysis, works schedule planning, the manner of management and execution, expected benefits, demand of budget and estimate of cost.

If the documents submitted according to the preceding Paragraph are found incomplete, the inspection body applicant shall submit supplement documents within fifteen days from the next day of receipt of the notice. If the inspection body applicant fails to supplement the documents as required, the application shall be rejected.

Article 27

The BSMI carry out document review about the application of preceding Article. An on-site assessment will be conducted by the BSMI, if necessary.

If the review of the inspection body applicants are completed and found in compliance with the requirements set forth in Article 25 and Article 26, the BSMI should issue the notification that shows the compliance to the requirements set forth in Article 25 and Article 26, and requires the inspection body applicant discuss the commission contract for sampling, sealing and examining with commodity inspection with the BSMI before the specified date. The BSMI may select the distinguished ones to negotiate the price and enter into the commission contract for sampling, sealing and examining with commodity inspection.

Article 28

The provisions set out in Article 10, Article 12, Article 14, Article 18 and Article 20 of this Regulation shall apply mutates mutandis to the commission of sampling, sealing and examining with commodity inspection.

Article 29

The inspection body shall submit monthly works statistics sheets of the commissioned operations to the BSMI before the 10th of next month.

The inspection body shall submit summary report including goal analysis, implementation results, analysis of outlays and achievement evaluation to the BSMI within one month after the end of the year. Briefing of summary report or on-site assessment will be required by the BSMI, if necessary.

Article 30

If an inspection body has any of the following circumstances, the BSMI may temporarily suspend, pursuant to the commission contract, the right of the inspection

body to perform the commissioned operations within a certain period of time. The BSMI shall resume the right after the inspection body has been examined and approved by the BSM:

1. The qualification according to Article 25 has been lost;
2. Where the inspection body fails to maintain sufficient resources and capability or subcontract with others to conduct the commissioned works as required under Paragraph 1 of Article 12, mentioned in Article 28;
3. Where the inspection body violates the requirements set forth in Paragraph 2 of Article 12, mentioned in Article 28 by subcontracting a part of the commissioned operations to other organizations provided that it is not the main part of the commissioned works and without an approval by the BSMI; or
4. Where the inspection body fails to submit monthly works statistics sheets as required under Paragraph 1 of Article 29 more than twice within the expiry of the same commission contract for sampling, sealing and examining with commodity inspection.

Article 31

If any of the following circumstances occurs, the BSMI may terminate the commission contract, in part or in whole, pursuant to the commission contract for sampling, sealing and examining with commodity inspection:

1. Where an application to terminate the commission contract for sampling, sealing and examining with commodity inspection has been initiated by the inspection body;
2. Where the recognitions of designated testing laboratory by the BSMI have been revoked or rescinded;
3. Where the inspection body has failed to avoid conflict of interests or violated his obligation of confidentiality;
4. Where the inspection body performs the commissioned operations beyond the scope authorized by the commission contract for sampling, sealing and examining with commodity inspection mentioned in Paragraph 2 of Article 27 or is lazy to perform the commissioned operations;
5. Where the inspection body violates the requirements set forth in Paragraph 2 of Article 10, mentioned in Article 28 by rejecting inspection applications or giving different treatment;
6. Where the inspection body fails to comply with the requirements set forth in Article 14, mentioned in Article 28 regarding retention and disposal of documents;
7. Where the inspection body violates the requirements set forth in Paragraph 2 of Article 18, mentioned in Article 28 by evading, impeding or rejecting the assessment conducted by the BSMI;

8. Where the inspection report or monthly works statistics sheets issued or submitted by the inspection body is found to contain false or incorrect information; or
9. Other violation of relevant regulations that are deemed as substantial and material events by the BSMI.

Article 32

If the commission contract for sampling, sealing and examining with commodity inspection is terminated pursuant to the preceding Article, the inspection body shall handover the pending inspection applications to the BSMI or other inspection body designated by the BSMI.

Within 3 years after the termination of the commission contract for sampling, sealing and examining with commodity inspection, the terminated inspection body shall not be permitted to re-apply for the qualified inspection body, except that the inspection body terminates the commission contract for sampling, sealing and examining with commodity inspection voluntarily.

Article 33

These Regulations shall take effect upon the date of promulgation.