Print Time：115.11.04 11:39

Content

Title：	Directions Governing Recognition of Factory Inspection Bodies Ch
Date：	2022.10.18
Legislative：	1.18 Clauses adopted and promulgated by BSMI Order No. 09230007180 on 26 November 2003. 2.19 Clauses amended and promulgated by BSMI Order No. 09330005720 on 2 August 2004. 3.Clauses 1, 2, 9, 11 and 15 amended and promulgated by BSMI Order No. 09430004880 on 24 June 2005. 4.19 Clauses amended and promulgated by BSMI Order No. 10030005100 on 1 July 2011. 5.9 Clauses amended and promulgated by BSMI Order No. 10530002580 on 5 August 2016. 6.17 Clauses amended and promulgated by BSMI Order No. 11150019460 on 18 October 2022.
Content：	1.These Directions are established to implement the recognition of factory inspection bodies under the conformity assessment procedures of product certification. 2.The terms used in these Directions are defined as below: (1)Product certification: product certification programs opening for application as announced by the Bureau of Standards, Metrology and Inspection (BSMI), including Registration of Product Certification Program, Voluntary Product Certification Program, CNS Mark Certification Program, Self-Verification Program of Weights and Measuring Instruments, etc. (2)Recognized factory inspection body (hereinafter referred to as the “inspection body”): the entity recognized by the BSMI in accordance with these Directions, of which the factory inspection report may be used as the conformity assessment documents required by the product certification programs. 3.The inspection body applying for recognition (hereinafter referred to as the “applicant”) shall be an independent third-party organization and meet the following qualifications: (1)recognized by the BSMI to act as a BSMI-designated testing laboratory for the relevant commodity inspection fields, or having obtained qualifications as BSMI designated technical bodies, except where the applicant is not able to be recognized by the BSMI due to special reasons and the BSMI approves with conditions; and (2)being accredited to show the competence of performing factory inspection by meeting any of the following conditions: i.The applicant shall establish a quality management system that is accredited by Taiwan’s accreditation body (hereinafter referred to as Taiwan’s AB) that is a signatory to the Mutual Recognition Arrangement of International Laboratory Accreditation Cooperation (ILAC) or the Multilateral Recognition Arrangement of the International Accreditation Forum (IAF) to demonstrate its ability of performing factory inspection in the relevant sectors. ii.Where the BSMI, by taking international approaches into consideration, announces to accept applications based on different geographic areas, inspection sectors, inspection items, commodity categories or other needs, the applicant shall establish a quality management system that is accredited by a signatory to ILAC MRA or IAF MLA (hereinafter referred to as foreign AB) to demonstrate its ability of performing factory inspection in the relevant sectors. 4.The applicant shall comply with the following requirements: (1)Be equipped with the testing equipment, facilities and personnel required by the scope of sectors; fully understand and possess sufficient information on the inspection standards as well as applicable laws and regulations regarding the applicable scope of sectors; (2)The personnel performing factory inspection shall possess on-hand technical experience of related product inspection activities for at least one year and shall pass initial training courses delivered by the BSMI or BSMI-designated training bodies at least once within three years by presenting the certificate of completion; and

(3)The personnel performing factory inspection shall be assessed by Taiwan's accreditation body or foreign accreditation body as competent in carrying out factory inspection required by the BSMI.

5.The applicant complying with the requirements mentioned in the preceding two Clauses may apply to the BSMI for recognition by submitting an application form and the following documents:
(1)Recognition Certificates issued by the BSMI for being designated testing laboratories or documents demonstrating fulfillment of qualification for designated technical bodies, and accreditation certificates covering the scope of factory inspection, as mentioned in Clause 3;
(2)A list of factory inspection personnel and relevant certificates or documents demonstrating compliance with the conditions set forth under subparagraph 2 of the preceding Clause;
(3)A list of testing equipment, organization chart, brief layout of the organization and a brief map of the organization's location;
(4)Operation procedures to perform factory inspection required by the BSMI;
(5)Where the proviso of Subparagraph 1, Paragraph 1, Clause 3 is applicable in terms of recognition
not granted by the BSMI due to special reasons, the relevant implementation plan and alternative measures shall be provided for evaluation by the BSMI; and
(6)Other documents designated by the BSMI.
The application documents, supporting and designated documents shall be in Chinese or English.

6.The applicant will be granted certificate of recognition for scopes that pass review. The certificate will be valid until the same date as that of the accreditation certificate or the supporting document.
The BSMI may request for additional documents and perform on-site assessment to facilitate the review mentioned in the preceding paragraph, where it is deemed necessary.
The BSMI may ask the applicant to submit the required documents within a specified time limit if there are deficiencies in the application documents received. The application will be rejected if the applicant fails to submit the documents within the specified time limit or deficiencies still exists in the submitted documents. An application for extending the time limit can be made under special circumstances approved by the BSMI, which is limited to one time only.
Recognition will not be granted if the results show non-compliant after the review.

7.An inspection body may apply to the BSMI for extension of recognition within 3 months prior to the expiration of the recognition. The application processes, documents to be submitted, review processes and validity period of the recognition shall follow those stated in Clauses 5 and 6. A new application for recognition should be submitted if the extension application is not made after the required time period.

8.An inspection body shall be subject to surveillance checks performed by the BSMI at the frequency of at least one time per year. The BSMI may increase the frequency under any of the following circumstances:
(1)Where the results of surveillance checks show non-compliance with Clauses 9-12;
(2)Where the inspection body fails to provide the requested documents within the specified time limit notified by the BSMI without justified reasons;
(3)Where the inspection body does not make relevant arrangements for the BSMI to process the checks, appeals, complaints or disputes, and fail to cooperate upon receipt of notice from the BSMI;
or
(4)Where other situations occur that the BSMI deems to affect the quality of factory inspection or validity of product certification.
The inspection body shall not evade, impede or refuse the surveillance checks mentioned in Paragraph 1 of this Clause without justified reasons.
The surveillance checks may be carried out together with the surveillance checks of product certification bodies if the inspection body is also the BSMI-commissioned product certification body,

9.An inspection body shall apply to the BSMI for changes to the name, address or other recognition items; or when the recognition scope mentioned in Clause 6 is affected due to reduced scope of accreditation or reduced scope of recognition of its testing laboratory. The application shall be made within one month upon receipt of notice from the accreditation body or the BSMI.
Where the recognition scope mentioned in Clause 6 is affected as mentioned in the preceding paragraph, the inspection body shall stop accepting applications or performing factory inspection for the scope that is reduced and provide the affected production premises with necessary assistance.
The inspection body shall submit a list of affected production premises and description of the

provided assistance to the BSMI when making the application for changes.
For applications made by the inspection body in accordance with Paragraph 1, the application processes, required documents, review processes and validity of recognition shall follow those stated in Clauses 5 and 6.

10.The inspection body shall ensure adequate management of the followings:
(1)To maintain a complete and accurate list of production premises;
(2)To assist product certification bodies to verify the validity of factory inspection reports;
(3)To draw up factory inspection operation guidelines in accordance with the Directions Governing Factory Inspection and Operation Procedures of Factory Inspection, and carry out factory inspection
accordingly;
(4)To create and maintain information about its factory inspection activities in BSMI's information system in a timely manner and upload documents or records within one month after completion of each factory inspection case;
(5)To cooperate with the BSMI for expanding or strengthening surveillance factory inspection activities upon receipt notice from the BSMI; and
(6)To inform product certification bodies of changes or irregularities of factory inspection cases or production premises.
The BSMI may dispatch its personnel to participate in the factory inspection activities mentioned in subparagraphs (3) or (5) when it is deemed necessary. The inspection body shall not evade, impede or refuse.

11.The changes or irregularities mentioned in Subparagraph (6) of the preceding Clause shall include, but not limited to, the followings:
(1)Major non-conformities found during factory inspection, including those corrected or not corrected after re-inspection and those of which an application for re-inspection is not made;
(2)Changes made to information listed in the factory reports, including reduction of scope or cancelation of reports); and
(3)Cases where the production premise stops operating, shuts down, is relocated, does not complete
follow-up inspection in accordance with Directions Governing Factory Inspection at the frequency of at least once per year or other irregularities.

12.The inspectors of inspection bodies shall pass training courses delivered by the BSMI or BSMI-designated training bodies at least once per year or complete on-line training courses at websites designated by the BSMI in its annual training programs. Certificates of Completion must be presented as supporting documents.
Inspection bodies shall arrange for their inspectors to receive assessments of competence from an accreditation body in Taiwan or in other countries during the recognition period. They shall also maintain that their inspectors are qualified to perform factory inspection according to BSMI requirements, by the assessment performed by an accreditation body in Taiwan or foreign countries.
Inspectors are allowed to perform factory inspection if they have completed the training courses mentioned in the first paragraph and the qualification assessment mentioned in the second paragraph of that year or previous year.

13.Where the recognition of an inspection body was acquired through fraudulent means, the BSMI shall revoke its recognition.
The inspection body shall not be permitted to apply for recognition again within one year after its recognition is revoked.

14.The BSMI may temporarily suspend the right of an inspection body to conduct factory inspection
required under its programs if the recognition of its testing laboratories by the BSMI mentioned in Subparagraph 1, Paragraph 1, Clause 3 is suspended by the BSMI or the accredited scope of the inspection body mentioned in Subparagraph 2, Paragraph 1, Clause 3 in relevant sectors is suspended by an accreditation body in Taiwan or in other countries. The BSMI shall permit the inspection body to resume conducting factory inspection after it has completed the corrective actions within a required time period and approved by the BSMI after review.

15.The BSMI may rescind recognition of an inspection body in full or in part under any of the following circumstances:
(1)Where the inspection body applies for rescission;

(2)Where the accreditation of the inspection body is revoked or rescinded, or the accredited scope is
reduced by the accreditation body in Taiwan or other countries;
(3)Where the inspection body does not comply with the proviso approved by the BSMI with conditions as stated in Subparagraph 1, Paragraph 1, Clause 3;
(4)Where the inspection records or relevant documents are found to be false;
(5)Where the inspection body fails to take corrective actions within the time limit notified by the BSMI as a result of surveillance checks mentioned in Paragraph 1, Clause 8, or non-compliance re-occurs after corrective actions are taken;
(6)Where the inspection body evades, impedes or refuses surveillance checks or participation by BSMI personnel in factory inspection activities, violating the requirements stated in Paragraph 2, Clause 8 or Paragraph 2, Clause 10;
(7)Where the inspection body accepts application or perform factory inspection in scopes that are not recognized, violates Paragraph 2 of Clause 9 when the recognition scope is affected due to reduction of its acccreded scope, or violates Clause 14 when its right of carrying out factory inspection is temporarily suspended under BSMI's programs;
(8)Where the factory inspection body fails to complete corrective actions within the specified time limit and gaining approval from the BSMI as set out in Clause 14;
(9)Where the inspection body does not pay fees and fails to make the payment within the time limit notified by the BSMI; or
(10)Other violations determined by the BSMI as significant.
The BSMI shall not accept application for rescission mentioned in subparagraph (1) of the preceding paragraph if the inspection body has violated or may violate requirements stated in Paragraph 1, Clause 13 or Subparagraphs (2)-(10) of the preceding paragraph.
The BSMI shall not accept application for recognition from an inspection body, of which its recognition is rescinded by the BSMI, within one year after the date of rescission, except where the rescission is made in accordance with Subparagraph (1) of the preceding paragraph or under special
circumstances approved by the BSMI.

16.Where the recognition of an inspection body is revoked, the right of that inspection body to perform factory inspection is temporarily suspended, or the scope of recognition is rescinded in full or in part by the BSMI in accordance with Paragraph 1 of Clause 13, Clause 14 or Paragraph 1 of Clause 15, the inspection body shall provide the affected production premises with the required assistance and report it to the BSMI for records.

17.An inspection body that has been recognized by the BSMI through an international cooperation or a mutual recognition agreement/arrangement shall be deemed as the inspection body defined in these Directions.
Where an inspection body is recognized by the BSMI by way of the preceding paragraph, it shall be
managed in accordance with the text of the agreement/arrangement. These Directions shall apply if there is no relevant text in the agreement/arrangement.

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