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| Title : | Directions Governing Recognition of Factory Inspection Bodies Ch |
| Date : | 2016.08.05 |
| Legislative : | <p>1.18 Clauses adopted and promulgated in full by Bureau Order on 26 November, 2003.</p> <p>2.19 Clauses amended and promulgated in full by Bureau Order on 2 August 2004.</p> <p>3.Clauses 1, 2, 9, 11 and 15 amended and promulgated by Bureau Order on 24 June 2005.</p> <p>4.19 Clauses amended and promulgated in full by Bureau Order on 1 July 2011.</p> <p>5.9 Clauses amended and promulgated in full by Bureau Order on 5 August 2016</p> |
| Content : | <p>1. These Directions are established in order to implement the recognition of factory inspection bodies.</p> <p>2. A recognized factory inspection body (hereinafter referred to as the “recognized body”) is the entity recognized by the Bureau of Standards, Metrology and Inspection (hereinafter referred to as BSMI) in accordance with this Directions to perform factory inspection that is promulgated as the conformity assessment procedures under the Registration of Product Certification and the Voluntary Product Certification Scheme.</p> <p>3. The inspection body applying for recognition (hereinafter referred to as the “applicant”) shall be an independent third-party organization and obtain recognition by the BSMI to act as a BSMI-designated testing laboratory for the relevant commodity inspection fields, or obtain qualification of competent technical body which is designated and promulgated to the public by the BSMI, as well as possess either of the following qualifications:</p> <p>(1) Having established a quality management system and factory inspection ability and been granted accreditation by the Taiwan Accreditation foundation (hereinafter referred to as TAF) in relevant categories; or</p> <p>(2) Other qualifications that have been announced by the BSMI to open up the application based on different geographic areas, inspection fields, inspection items, commodity categories or further requirements in reference to international practices. The applicant shall establish a quality management system and factory inspection ability and be granted accreditation by the MRA signatories of International Laboratory Accreditation Cooperation(ILAC) or International Accreditation Forum, Inc.(IAF) (hereinafter referred to as the “foreign accreditation body”) in relevant categories.</p> <p>4. The applicant shall meet the following requirements:</p> <p>(1) Possessing the required testing equipment, facilities, and personnel in the field of applicable product category; realizing thorough information and a full understanding of inspection standards as well as applicable laws and regulations in such applied factory inspection field; and</p> <p>(2) The personnel performing factory inspection shall possess on-hand technical experience of related product inspection activities for at least one year and shall be trained, qualified, and registered by the BSMI.</p> |

5. The applicant possessing the qualifications and fulfilling the requirements set forth under the preceding two Clauses may apply to the BSMI for recognition by submitting an application form and the following documents:

- (1) Relevant certificates or documents demonstrating the qualifications set forth under 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;
- (4) Organization chart and brief layout of the organization;
- (5) Brief map of the organization's location; and
- (6) Quality manual, system structure and a list for quality documents; and
- (7) Other documents designated by the BSMI.

6. The applicant that has passed a document review and an on-site assessment can be recognized on the scope of factory inspection that passes the review. The term of validity for the recognition shall be three years.

If the review and assessment result shows noncompliance, the applicant may apply for a re-assessment within 2 months after the noncompliance is confirmed. If the result of the re-assessment still shows noncompliance, the applicant shall not raise application for recognition again within 3 months after receiving the notice of above-mentioned noncompliance.

7. A recognized body may request for extension of recognition by submitting an extension application form and relevant documents required by Clause 5 within 3 months prior to the expiration of the recognition. A new application for recognition should be submitted if the extension request is made after the required time period.

If the preceding extension request is found to be in compliance with relevant requirements after review, the extended term of validity for the recognition shall be limited to 3 years each time.

8. The BSMI shall perform the regular or irregular surveillance for the recognized body.

The preceding surveillance shall be at least once a year. However, the frequency of surveillance may be increased if special circumstances arise.

Without justification, the recognized body shall not evade, obstruct or refuse the surveillance specified in Paragraph 1 of this Clause.

When the recognized body is also the BSMI-commissioned commodity certification body, the surveillance specified in Paragraph 1 of this Clause may be carried out together with the surveillance for commissioned commodity certification body.

9. The recognized body shall arrange to perform follow-up factory inspection after receiving the notice from the BSMI that the factory inspected by it has been granted RPC or VPC.

The recognized body performing factory inspection activities shall provide the application documents of factory inspection, inspection records and reports of the previous month in electronic format to the BSMI's online system for reference before the 10th day of each month.

10. If the results of the pre-view or re-view for the factory inspection record completed by a recognized body indicates noncompliance with the requirements, the record shall be sent to the Sixth Division or the branch of the BSMI that has jurisdiction over the applicant factory for final decision.

11. If there are any doubts on the results of factory inspection conducted by a recognized body, the BSMI may perform additional assessment or factory inspection and make a new decision on the results of factory inspection.

12. If any items listed in a factory inspection report has been changed (including increment, reduction or cancellation of the recognized scope), the recognized body issuing the said report shall provide such changes made in the previous month in electronic format to the BSMI's online system for reference before the 10th day of each month.

13. (Deleted)

14. If the accredited scope has been reduced for the recognized body that is accredited by the TAF or

the foreign accreditation body and such reduction of the accredited scope has affected the scope of recognition, the recognized body shall, within three months, apply to the BSMI for the reduction of the recognized scope by submitting an application form.

When the accredited scope of the recognized body has been reduced by TAF or the foreign accreditation body, the recognized body shall immediately stop receiving the application for factory inspection or follow-up factory inspection business that is involved in the reduction of the accredited scope.

If a recognized inspection body has relocated to a new address, has raised increment for the recognized scope, or has made any changes to the content of recognition, the recognized body shall apply for the approval to the BSMI by submitting an application form and relevant documents. The BSMI may assign its personnel to conduct an on-site assessment for the recognized body where necessary.

15. If the inspection body applying for recognition has been granted an accreditation by the TAF or the foreign accreditation body in relevant categories that demonstrates its factory inspection ability, the application for recognition and management procedures may be simplified as follows:

- (1) Exemption from application for extension stipulated in Clause 7; and
- (2) Exemption from regular surveillance for that year stipulated in Clause 8, when the annual surveillance-audit reports completed by TAF or the foreign accreditation body has been raised to BSMI.

Where the recognition is granted in accordance with the preceding Paragraph, the recognition shall remain valid during the term of validity of the accreditation mentioned in the first Paragraph.

16. Where the recognition of a recognized body was acquired through fraudulent means, the BSMI shall revoke such recognition.

If recognition has been revoked, the recognized body shall not be permitted to apply to become a recognized body again within three years after the revocation date.

17. The BSMI may rescind recognition of a recognized body under any of the following circumstances:

- (1) The accreditation of the factory inspection body performed by the TAF or the foreign accreditation body has been revoked or rescinded;
- (2) The factory inspection records or relevant documents have been discovered false;
- (3) The factory inspection body has lost its ability to perform inspection business or it can not conduct inspection activities impartially and effectively;

- (4) The factory inspection body has violated the requirements stated in Paragraph 2 of Clause 8;
- (5) The factory inspection body still conducts factory inspection in the name of a recognized body in areas beyond the recognized scope, or when it violates the condition stipulated in either Paragraph 2 of Clause 14 or Clause 18;
- (6) The factory inspection body fails to complete the process of taking corrective action and gaining approval from the BSMI within the specified time limit set out in Clause 18; or
- (7) Where it is proved serious that employees of the inspection 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.
- (8) Other violations of these Directions that are deemed as serious events by the BSMI.

If recognition has been rescinded, the recognized body shall not be permitted to apply again within three years after the rescission date, except for the situation that have been agreed by the BSMI.

18. The BSMI may temporarily suspend the right of a recognized body to conduct factory inspection in relevant inspection fields in the name of a recognized body under any of the following circumstances. The BSMI shall permit the recognized body to resume conducting factory inspection after it has completed the corrective actions within a required period, and be examined and approved by the BSMI.

- (1) The accreditation of the recognized body by the TAF has been temporarily suspended;
- (2) The recognized body fails to submit documents within the notified time limit without any justifiable reasons; or
- (3) The recognized body fails to take appropriate actions and cooperate with the BSMI in performing assessment, or handling appeals, complaints and disputes, and it still would not like to do so after receiving the notice from the BSMI.
- (4) The recognized body fails to submit the factory inspection records, reports or information for changes in accordance with Clauses 9, 10 and 12.

19. An inspection body that has been recognized by the BSMI through an international cooperation or a mutual recognition agreement/arrangement shall be deemed as a recognized body.