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Content

Title: Operational Procedures for Factory Inspection Ch Date: 2021.03.02 Legislative: 1.Adopted and promulgated by Bureau Order on 18 September 2002. 2.8 Clauses amended and promulgated in full by Bureau Order on 30 December 3.Clauses 2, 5 and 6 amended and promulgated by Bureau Order on 18 August 2003, and enforced on 1 September 2003. 4.8 Clauses amended and promulgated in full by Bureau Order on 21 June 2005, and enforced on the same date. 5. Annex CH-03 under Clause 5 and Annex CE-03 under Clause 6 amended by Bureau Order on 24 February 2010, and enforced on the same date. 6.8 Clauses amended and promulgated in full by Bureau Order on 22 February 2013, and enforced on 1 September 2013. 7.9 Clauses amended and promulgated in full by Bureau Order on 2 March 2021, and enforced on the same date.

Content: 1. Factory inspections under the conformity assessment procedures for product certification shall be conducted in accordance with these Procedures.

2. Application Acceptance and review

The Bureau of Standards, Metrology and Inspection, Ministry of Economic Affairs (hereinafter referred to as the BSMI), its branches or the factory inspection bodies recognized by the BSMI (hereinafter referred to as the Inspection Authority) shall register the application for factory inspection, after acceptance, in the factory inspection operating system, and shall assign appropriate personnel to check whether the application documents are appropriate and conform to the requirements for inspection. If the application documents are not clear or are incomplete, the applicant shall give explanations or corrections and may be required via correspondence to give explanations or corrections within the given time limit. Failure to do so will lead to the rejection of the application.

After confirming that the application documents are complete, the Inspection Authority shall assign a factory code and an application no. and charge an assessment fee. The coding principles for the factory code (first nine digits), the application no., and the report number (factory code, followed by year and serial number) are described in the Annex.

3. Appointment for inspection

(1) The Inspection Authority shall, according to the kind of products to be certified, the division of work, and the nature of expertise, appoint the appropriate personnel of the BSMI or its branches or those approved and registered by the BSMI to conduct factory inspections. Inspectors shall have

expertise in the kind of products to be certified, be familiar with relevant inspection standards, and have engaged in relevant inspections. Inspectors in follow-up factory inspections shall be appointed in the same process as the initial factory inspections.

(2) External inspectors shall be appointed by the unit in charge from the academia, industry, or related associations.

4. Factory inspection

Factory inspections shall be conducted in accordance with the following procedures:

- (1) Before conducting factory inspections, inspector shall prepare materials in relation to the products to be certified and contact the applicant for related inspection matters. Inspectors may visit the factories whenever necessary, and shall draw up a factory inspection plan for the applicant's confirmation before conducting the inspections. The plan shall cover the scope of factory inspection, basic factory information (including the number of employees), confidentiality statement, safety protection, and grievance channels. An initial factory inspection shall be carried out after the type test report prepared in conformity with the inspection standards is obtained.
- (2) In the course of factory inspection, inspectors shall ask the applicant about the safety rules

during the on-site inspection and ask them to abide by the safety rules at the beginning of the meeting. If any injury or safety concern occurs, inspectors shall seek assistance from the factory immediately.

- (3) Inspectors shall perform factory inspections in accordance with Articles 5 and 6 of the Directions Governing Factory Inspection (hereinafter referred to as the Directions), and shall determine the major, minor unsatisfactory findings in accordance with Article 8 of the Directions and fill out the Factory Inspection Record.
- (4) After a factory inspection is completed, the unit in charge shall appoint appropriate personnel to review the inspection records within 14 days following the date of completion of the factory inspection, and the inspectors shall not participate in the review; in case of corrective plan review or sampling or carry-back for inspection, the inspectors shall check and approve the corrective plan or inspection report within 7 days following the date of receipt of the corrective plan or inspection report. The period of review shall start from the day following the check and approval of the corrective plan.

If the re-inspection is conducted remotely, the Inspection Authority shall report to the BSMI for reference.

- 5. The Inspection Authority shall notify the BSMI of the inspection results after review. If major unsatisfactory findings are found during the follow-up factory inspections but are corrected in conformity with the after re-inspection, or an application for re-inspection is not made, or major unsatisfactory findings remain non-conforming after re-inspection, the Inspection Authority shall notify the product certification authority separately.
- 6. A factory inspection report issued by the Inspection Authority shall at least contain the following:
- (1) Report number: generated from the BSMI's information system;
- (2) Applicable product certification scheme;
- (3) Inspection mode: initial factory inspection or follow-up factory inspection;
- (4) Name of factory;
- (5) Address of factory;
- (6) Kind of product in Chinese or English;
- (7) Seal of the Inspection Authority or signature of the signatory of the factory inspection report;
- (8) Date of issuance: date of issuance of the current factory inspection report;
- (9) Date of original issuance: date of issuance of the initial factory inspection report for the factory;
- (10) Inspection/review date: date of factory inspection or date of review of a replacement of the factory inspection report;
- (11) Accreditation mark issued by the Taiwan Accreditation Foundation (applicable to factory inspection bodies accredited by the Taiwan Accreditation Foundation and recognized by the BSMI);

and

- (12) Embossing seal (applicable to the BSMI and its branches).
- 7. In case of the relocation of a factory or a change in the Inspection Authority, which leads to a change in the application no., the first factory inspection after the change shall be conducted by the responsible Inspection Authority to obtain a new application no. from the BSMI's information system first and to review the application form and relevant documents submitted by the factory so as to conduct follow-up factory inspection.

In case of the relocation of a factory or a change in the Inspection Authority, which does not lead to a change in the application no., the original Inspection Authority shall conduct the follow-up factory inspection after reviewing the application form and relevant documents submitted by the factory.

- 8. If the follow-up factory inspection is not conducted due to the shutdown, closure, relocation of the factory or is not conducted at least once every year in accordance with Article 10 of the Directions, the Inspection Authority shall notify the product certification authority.
- 9. Materials in relation to factory inspections shall be kept by the unit in charge for five years after the issuance of the factory inspection report.

Attachments: Annex Coding Principles for Application No. and Report Number.pdf