


Content

Title :	Directions Governing Factory Inspection 
Date :	2017.02.09
Legislative :	<p>1.10 Clauses adopted and promulgated in full by Bureau Order on 19 April 2002, and enforced on 1 May 2002.</p> <p>2.10 Clauses amended and promulgated in full by Bureau Order on 12 August 2003, and enforced on 1 September 2003.</p> <p>3.10 Clauses amended and promulgated in full by Bureau Order on 24 June 2005, and enforced on the same date.</p> <p>4.Clauses 8, 9 and 10 amended, and Clause 11 added and promulgated by Bureau Order on 14 September 2009, and enforced on 1 January 2010.</p> <p>5.Clauses 3, 5, 6, 7 and 10 amended and promulgated by Bureau Order on 16 July 2011, and enforced on the same date.</p> <p>6.Clauses 3 and 5 amended and promulgated by Bureau Order on 3 August 2012, and enforced on the same date.</p> <p>7.Clauses 5 amended and promulgated by Bureau Order on 9 February 2017, and enforced on the same date.</p>
Content :	<p>1. These Directions are established in order to implement factory inspection specified as Module VII of the conformity assessment procedures under the Registration of Product Certification (hereinafter referred to as RPC) and the Voluntary Product Certification (hereinafter referred to as VPC) Scheme.</p> <p>2. The applicant for factory inspection shall be the manufacturer of commodities. If a manufacturer is located outside the territory of Taiwan, the applicant shall appoint a representative that has its domicile or business location in Taiwan to approach the application.</p> <p>3. The application form for factory inspection, basic information of the manufacturer and other relevant information, as described below, must be submitted to the Bureau of Standards, Metrology and Inspection (hereinafter referred to as the BSMI), its branches or the factory inspection bodies recognized by the BSMI (hereinafter referred to as the inspection authority or body):</p> <p>(1) A copy of the registration document of the applicant's factory, company or business. When the above-mentioned registration document is not available, the applicant shall provide the latest tax payment instead as proof;</p> <p>(2) Basic individual information of the mandatory inspection applicant of the regulated commodities or the applicant of VPC certificates. The basic information includes company name, address, contact person and contact information, etc. If the applicant has been granted the RPC or VPC certificate, a copy of the RPC or VPC certificate may be presented in place of the basic individual information for the applicant;</p> <p>(3) A route map of the factory location and the diagrams showing the layout of the factory;</p> <p>(4) A flow chart of the production processes;</p> <p>(5) A brief description of the inspection and / testing methods;</p> <p>(6) The type-test reports of the described commodities and technical documents demonstrating that the application for type-test is filed;</p> <p>(7) A letter of authorization and legal identification of the appointed representative in case the production premises are not based in Taiwan; and</p>

(8) Other relevant documents appointed by the BSMI.

If the submitted documents described previously are in a language other than Chinese, the inspection authority may request the applicant to provide Chinese translations of the documents.

4. Upon received the application for factory inspection from an inspection authority or body, inspectors shall be designated to conduct the initial factory inspection after reviewing the application documents.

Technical experts may be engaged to participate in the factory inspection.

5. Factory inspection will be carried out in accordance with the type-test reports and the relevant technical documents of the described commodities and the following inspecting items shall be covered:

- (1) Whether manufacturing equipment fulfills the requirements for the manufacturing process;
- (2) Whether main components and materials that are purchased comply with the specifications for the described commodities;
- (3) Whether production processes satisfy the necessary requirements;
- (4) Whether the inspection and testing equipment that meets the requirements for producing the described commodities, or the inspection and testing equipment that has the same functions is equipped;
- (5) Whether professional training for the inspection and testing personnel that satisfies the requirements for producing the described commodities are implemented;
- (6) Whether inspection and testing equipment necessary for producing the described commodities is equipped and the calibration traceable to the National standard is performed;
- (7) Whether the inspection and testing records that satisfy the requirements for the described commodities are maintained;
- (8) Whether the consumer services and treatment of customer complaints associated with the requirements for producing the described commodities are properly performed;
- (9) The consistency status of and subsequent modifications made to the certified products under the RPC Scheme; and
- (10) Other particular criteria prescribed by the BSMI for a specified product category.

The inspector shall fill out the Factory Inspection Record in duplicate which shall be confirmed and signed by both the inspector and the representative of the production premises. A copy of the record will be provided to the representative of the production premises.

If some special commodities that are not applicable to the requirements of items 1 to 10 in Paragraph 1 of this Clause, the inspection items will be designated and made known to the public by the BSMI separate public notice.

6. If the production premises have established quality management systems in accordance with the CNS 12681/ISO 9001 series of standards and have obtained registration certificates issued or recognized by the BSMI, the requirements set out in subparagraphs (5) to (8), Paragraph 1 of the preceding Clause may not be required.

7. If major defects are found during the factory inspection, the applicant shall apply for re-inspection within a given time limit. If any major defect remains after re-inspection or the re-inspection does not applied within the given time limit, the inspection shall be considered as failing to comply with the requirements. The applications for the re-inspection of the initial factory inspection or the follow-up factory inspection shall be submitted respectively within sixty days or thirty days after completion of the inspection.

If minor defects are found but the production premises still can operate effectively, the applicant shall submit a corrective action plan (including the specific corrective measures and time schedule) within ten days after completion of the inspection. The inspection authority or body may conduct inspections to verify the performance of the corrective action plan, where necessary. If no submission is made within the required time or the corrective action plan is reviewed as failing to correct the defects effectively, the result shall be judged as non-compliance with the requirements. Major and minor defects shall be judged by the following principles:

- (1) Major defects: defects that could lead to a failure in the manufacturing operation or substantially reducing the effects because a management system has not yet been established or has been established but the operation procedures are not followed;
- (2) Minor defects: defects that would not lead to a failure in the manufacturing operation or that occur occasionally when a management system has been established and the operation procedures have been followed.

8. When the result of an initial factory inspection has been reviewed and approved to comply with the requirements, the initial factory inspection report will be issued. The validity for the initial factory inspection report will be expired in one year.

9. The BSMI shall perform follow-up factory inspections to the production premises that are granted RPC or VPC based on factory inspection reports. When the result of follow-up factory inspection has been reviewed and approved to comply with the requirements, the follow-up factory inspection report will be issued.

The follow-up factory inspection mentioned in the preceding paragraph shall be conducted at least once per year; however, the frequency of the inspection may be increased if necessary.

10. When the inspection authority or body conducts the follow-up factory inspection, sample(s) shall be taken to verify conformity and consistency with the type as tested in type-testing procedure of the RPC or VPC Scheme and the testing shall be conducted when it's necessary. It shall be deemed as a major defect and shall be dealt with according to related commodity inspection regulations if the result of verification or testing does not comply with the requirements of testing, the type-testing reports or the related technical documentation.

11. If the commodity categories or any item listed in a factory inspection report has been changed or updated, the manufacturer shall apply to the inspection authority for a replacement of the factory inspection report.