

Directions Governing Factory Inspection

Adopted and promulgated by Bureau Order on 19 April 2002.

10 Clauses amended and promulgated in full by Bureau Order on 12 August 2003, and enforced on 1 September 2003.

10 Clauses amended and promulgated in full by Bureau Order on 24 June 2005, and enforced on the same date. (Original Name: Directions Governing Factory Inspection of Registration of Product Certification)

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.

Clauses 3, 5, 6, 7 and 10 amended and promulgated by Bureau Order on 16 July 2011, and enforced on the same date.

Clauses 3 and 5 amended and promulgated by Bureau Order on 3 August 2012, and enforced on the same date.

Clauses 5 amended and promulgated by Bureau Order on 9 February 2017, and enforced on the same date.

11 Clauses amended and promulgated in full by Bureau Order on 2 March 2021, and enforced on the same date.

1. These Directions are established by the Bureau of Standards, Metrology and Inspection, Ministry of Economic Affairs (hereinafter referred to as the BSMI) in order to implement factory inspection under the conformity assessment procedures for product certification.
2. The applicant for factory inspection shall be the factory of products. If a factory is located outside the territory of Taiwan, the applicant shall appoint an agent that has its domicile or business location in Taiwan to approach the application.
3. The application form for factory inspection and other relevant information, as described below, must be submitted to the BSMI, its branches, or the factory inspection bodies recognized by the BSMI (hereinafter referred to as the Inspection Authority):
 - (1) A copy of the registration document of the applicant's company or business and the registration document of the factory unless the applicant has filled in the application form with the company or business's unified business number and the factory registration number. When the above-mentioned registration document is not available for a foreign applicant, the applicant shall provide the latest tax payment certificate as proof;

- (2) A route map of the factory location and the diagrams showing the layout of the factory;
- (3) A flow chart of the production processes;
- (4) A brief description of the inspection and testing methods;
- (5) The product type test reports of the described products and technical documents demonstrating that the application for product type test is filed;
- (6) A letter of authorization and legal identification of the appointed agents in case the factories are not based in Taiwan; and
- (7) 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. After receiving and reviewing the application documents for factory inspection, the Inspection Authority shall designate inspectors to conduct the initial factory inspection.

If the application documents are not clear or are incomplete, and the applicant fails to give explanations or corrections as required by the Inspection Authority or within the given time limit, the application shall be rejected.

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

When it is impossible to conduct a factory inspection at the factory due to a special event, the factory inspection may be conducted remotely based on the inspection items and scope approved by the BSMI.

5. Factory inspection will be carried out in accordance with the product type test reports and the relevant technical documents of the described products, and the inspecting items listed in the Annex shall be covered.

The inspector shall fill out the Factory Inspection Record in duplicate which shall be confirmed and signed by both the inspector and the

Factory Representative. A copy of the record will be provided to the Factory Representative.

If some special products are not applicable to the requirements of the Annex, the inspection items will be designated and made known to the public by the BSMI separate public notice.

An initial factory inspection is exempted from the No. 8 inspection item listed in the Annex.

6. Factory inspection shall last half a man-day or more and may be extended after considering factors such as the kinds of product, the complexity of the production process, the scale or risk of the factories.

If the applicant holds a CNS 12681 (ISO 9001) certificate issued by a quality management certification body recognized by the BSMI, and the scope of registration of the certificate covers the factory within the scope of factory inspection, it may be exempt from the inspection items listed in the Annex and shall attach relevant materials or supporting documents as required by the Inspection Authority.

7. If major unsatisfactory findings are found during the factory inspection, the applicant shall apply for re-inspection within a given time limit. If any major unsatisfactory finding remains after re-inspection or an application for re-inspection is not made 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 unsatisfactory findings are found, 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 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 unsatisfactory findings

effectively, the result shall be judged as non-compliance with the requirements.

The re-inspection referred to in Paragraph 1 may be conducted remotely.

8. Major unsatisfactory findings in factory inspection shall be judged by the following principles:
 - (1) Finished products, semi-finished products, main components, sub-assemblies, or materials do not conform to product type test reports, technical documents, or relevant standards;
 - (2) The result of on-site sampling test or carry-back inspection does not meet the requirements for inspection;
 - (3) Changes in the certified products are not approved by the product certification authority;
 - (4) Relevant product certification marks for components, sub-assemblies, and materials are not obtained in accordance with the regulations;
 - (5) Relevant product certification marks for finished products are not used correctly in accordance with the regulations;
 - (6) The result of the inspection based on the specific regulation for applicable kinds of product as established by the BSMI does not conform;
 - (7) Minor unsatisfactory findings are found in the previous factory inspection and have not been improved; or
 - (8) Other unsatisfactory findings are found that could lead to a failure in the manufacturing operation or substantially reduce the effects because a management system has not yet been established or has been established but the operation procedures are not followed.

Minor unsatisfactory findings are 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 operating procedures have been followed.

9. 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; when an initial factory inspection fails

to meet the requirements, the Inspection Authority shall notify the applicant that a factory inspection report will not be issued. The validity for the initial factory inspection report will be expired in one year.

10. The Inspection Authority shall perform follow-up factory inspections at least once every year to the factories that are granted product certification by the BSMI based on factory inspection reports. When the Inspection Authority conducts a follow-up factory inspection, sample(s) shall be taken to verify conformity and consistency with the originally certified type, and tests shall be conducted whenever necessary. When the result of the follow-up factory inspection has been reviewed and approved to comply with the requirements, the follow-up factory inspection report will be issued.

In case of special circumstances, the frequency of the follow-up factory inspections mentioned in the preceding paragraph may be increased or the follow-up factory inspections may be combined with those in the following year upon approval of the BSMI.

11. If there is any change in kind of product or any item listed in a factory inspection report, the factory shall apply to the Inspection Authority for a replacement of the factory inspection report by providing the application form, the changed documents specified in Paragraph 1, Article 3, and other supporting documents. Follow-up factory inspections may be conducted whenever necessary.

If the change mentioned in the preceding paragraph is an addition of applicable kind of product and the manufacturing process is different from that of the originally approved product, a new application shall be made instead.

Annex

List of Factory Inspection Items

No.	Inspection Item	Priorities	Exempt according to Paragraph 2, Article 6
1	Whether the installation and management of main producing equipment meet the requirements for production	The installation, operation, and maintenance of main producing equipment at factories	√
2	Whether the management of main components, sub-assemblies, and materials complies with product type test reports or technical specifications	(1) Procurement standards and inspection/acceptance methods or procedures for components, sub-assemblies, and materials	
		(2) Relevant evidence provided by suppliers that are responsible for inspecting the components, sub-assemblies, and materials	
		(3) Relevant evidence of components, sub-assemblies, and materials that should contain certification marks in accordance with the regulations	
		(4) Conformity of components, sub-assemblies, and materials with product type test reports	
		(5) Identification and segregation of non-conforming components, sub-assemblies, and materials	

No.	Inspection Item	Priorities	Exempt according to Paragraph 2, Article 6
3	Whether the management of production processes meets the requirements for production	(1) Maintenance of technical materials and inspection standards	
		(2) Inspection procedures for the production processes	
		(3) Identification and segregation of non-conforming semi-finished products or finished products	
4	Whether the management of testing equipment and inspectors meets the requirements for production	(1) Installation and operation of testing equipment	
		(2) Correction of the malfunction of testing equipment	
		(3) Methods to ensure the product conformity with inspection standards where testing equipment is unavailable	
		(4) Competence of inspectors	√
5	Whether the calibration and inspection of testing equipment are traceable to standards for national and international measurement	(1) Calibration and verification of testing equipment	
		(2) Evidence of traceability to standards for national and international measurement	
		(3) Identification marks for calibration and verification	

No.	Inspection Item	Priorities	Exempt according to Paragraph 2, Article 6
6	Whether the handling and storage of conforming and non-conforming products comply with the principle of product traceability	(1) Handling and storage of conforming and non-conforming materials, components, sub-assemblies, semi-finished products, and finished products	
		(2) Correctness of the use of relevant product certification marks, such as Registration of Product Certification (RPC) or Voluntary Product Certification (VPC)	
7	Dealing of customer service and complaint	(1) Mechanisms and corrective measures for handling consumer service and complaint for manufactured products	√
		(2) Records of production and sales that should be established according to the regulations	
8	Consistency with the originally certified types in the product type test reports and subsequent changes	(1) Comparison or conformity of the on-site sampling test of main components, sub-assemblies, semi-finished products, and finished products with product type test reports	
		(2) Conformity of the on-site sampling test of finished products or carry-back finished products	

No.	Inspection Item	Priorities	Exempt according to Paragraph 2, Article 6
		(3) Approval of the product certification authority regarding changes in the main components, sub-assemblies of certified products	
9	The specific factory inspection regulation established by the BSMI for particular kind of product	Other items that should be inspected in accordance with specific regulation	