


## Content

Title :	Regulations Governing Monitoring Inspection of Products from Premises with Registered Management Systems 
Date :	2010.05.14
Legislative :	1. Adopted and promulgated by Ministerial Order on 9 January 2002. 2. Articles 4, 7, and 10 amended and promulgated by Ministerial Order on 11 December 2007. 3. Amended and promulgated by Ministerial Order on 14 May 2010.
Content :	<p><b>Article 1</b></p> <p>These Regulations are established in accordance with Paragraph 2 of Article 33 of the Commodity Inspection Act (the Act).</p> <p><b>Article 2</b></p> <p>The production premise of a commodity subject to monitoring inspection, while its quality management systems have been registered with the Bureau of Standards, Metrology and Inspection (the BSMI) of the Ministry of Economic Affairs or with certification bodies recognized by the BSMI, may apply for becoming a premise governed by these Regulations (management-system-based monitoring inspection) within the registered scope if it has obtained a monitoring inspection registration certificate and has equipped with basic inspection facilities. The basic inspection facilities mentioned in the preceding paragraph shall be prescribed by the BSMI. When revised, the BSMI may inform the production premises registered under these Regulations to be equipped with the revised facilities within a given time limit.</p> <p><b>Article 3</b></p> <p>An applicant shall apply to the BSMI or its branches with jurisdiction over the applicant (the inspection authority) for management-system-based monitoring inspection by submitting the application form, the quality management system certificates and a list of basic inspection facilities. Whenever necessary, the inspection authority may send its representative to conduct an on-site examination, or request samples to be provided by the applicant for performing necessary testing or witness testing on specific features of the commodity. Registration is granted under these Regulations if compliance is found after the review. If the applicant is a foreign-based premise, the application shall be made by an agent who has its domicile or business place in the Republic of China.</p>

#### Article 4

Premises that are registered under these Regulations in accordance with the preceding Article may conduct monitoring

inspection by following the provisions described below:

1. A production premise shall perform the inspection to its commodities in accordance with these Regulations and

issue, by countersigning, the monitoring inspection certificate if compliance is demonstrated after the inspection.

2. For the production premises of commodity concerned located outside the territory of the Republic of China, the

obligatory inspection applicant shall submit the inspection records to the inspection authority for approval before

issuing the monitoring inspection certificates.

Premises mentioned in subparagraph 1 of the preceding paragraph shall make written request for blank certificate

forms stamped with the steel seal by the inspection authority in advance and fill out a registry of countersigning

monitoring inspection certificates. The premises shall submit the registry and a copy of monitoring inspection

certificates that they countersigned to the inspection authority before the 10th day of each month, and pay the

inspection fees based on the ex-factory price of listed commodities on the registry.

The applicant mentioned in subparagraph 2 of the first paragraph when making the application inspection shall

also submit the original inspection records and a copy of registration certificates for the production premises

under management-system-based monitoring inspection.

#### Article 5

For production premises that are registered under the management-system-based monitoring inspection, the signatory

of monitoring inspection certificate and inspection personnel shall be subject to the supervision by the inspection

authority.

#### Article 6

The inspection authority may send its personnel to the production premises, storage places at harbors, importers,

distributors or any other related places to conduct sampling inspection or witness inspection for products that

are subject to monitoring inspection under these Regulations. The manufacturers or related personnel of the

places shall not refuse such activities.

#### Article 7

For production premises that are registered under the management-system-based monitoring inspection, the inspection

records, the monitoring inspection certificates, registry mentioned in paragraph 2 of Article 4, and

other relevant

inspection documents shall be maintained for at least 3 years.

#### Article 8

If the production premises registered under these Regulations stop production of commodities subject to monitoring

inspection for more than 30 days, they shall report to the inspection authority within 15 days starting from the

date of stopping production. They shall also report to the inspection authority when the production of such

commodities is resumed.

The period mentioned in the previous paragraph of stopping production of commodities shall not exceed 6 months. An

application for extension shall be made before expiry of the reported period if production cannot be resumed. The

extension is limited to one time and shall not exceed 6 months.

#### Article 9

Production premises registered under these Regulations shall apply to, by presenting relevant documentation, the

inspection authority for changes to their registration information, such as names, addresses, responsible persons

or other items, within 30 days of such changes.

#### Article 10

Under any of the following circumstances, the production premises registered under these Regulations shall not be

allowed to conduct monitoring inspection mentioned in paragraph 1 of Article 4 for a period of one to six months

and their products shall be subject to batch-by-batch inspection.

1. Where the production premises did not countersign monitoring inspection certificates in accordance with

provisions of these Regulations;

2. Where a trade dispute arises due to inferior quality of the products that the production premises manufactured

and verified by the inspection authority or inspected by organizations of the importing countries;

3. Where the inspection standards have changed and the products of the production premises did not comply with

the new standards after a designated date prescribed by the BSMI;

4. Where fraudulent actions are found to have mixed their products with products not under the management-system-based

monitoring inspection, products of other brands or non-compliance products;

5. Where violation is found against Articles 5, 7 or 9 of these Regulations;

6. Where markings are not affixed in accordance with Articles 11 or 12 of these Regulations; or

7. Where the sample(s), taken or purchased, are inspected to be not in conformity with related inspection standards.

If non-compliance products are found during the suspended period mentioned in the previous paragraph, the production

premises shall not be allowed to conduct monitoring inspection mentioned in paragraph 1 of Article 4 for an additional one-month period.

#### Article 11

Where the registration under these Regulations was acquired through fraudulent means, the inspection authority shall revoke the registration.

#### Article 12

Under any of the following circumstances, the registration of production premises registered under these Regulations shall be rescinded:

1. Where the production premises apply for cancellation of their registration under these Regulations on their own initiative;
2. Where the products are announced to be no longer subject to management-system-based monitoring inspection;
3. Where the registration of quality management system was revoked or rescinded;
4. Where the registration scope of quality management system is changed and thus does not cover the products subject to management-system-based monitoring inspection;
5. Where violation is found against Article 6 or 8 of these Regulations;
6. Where a defect of the product subject to management-system-based monitoring inspection causes substantial damage to the consumers or endangers the public; or
7. Where the basic inspection facilities are revised, the production premises registered under these Regulations have not been equipped with the revised facilities within a given time limit in accordance with paragraph 2 of Article 2 of these Regulations.
8. Other serious violations of regulatory provisions or acts of making false and incorrect statements.

#### Article 12-1

Where the registration of production premises registered under these Regulations is revoked or rescinded in accordance with the preceding 2 paragraphs, the production premises shall not re-apply for management-system-based monitoring inspection within 4 months starting from the date of revocation or rescission.

#### Article 13

These Regulations shall take effect upon the date of promulgation.