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Title : Directions for Recognition of Quality Management Systems Certification Bodies **Ch**

Date : 2019.07.03

Legislative :

1. Adopted by the Bureau of Standards, Metrology and Inspection on 27 September 2000.
2. Title and 11 clauses amended and adopted by the Bureau of Standards, Metrology and Inspection on 14 November 2002.
3. Amended and promulgated by the Bureau of Standards, Metrology and Inspection on 18 September 2006.
4. Amended and promulgated by the Bureau of Standards, Metrology and Inspection on 6 December 2012.
5. Amended and promulgated by the Bureau of Standards, Metrology and Inspection on 23 May 2016.
6. Amended and promulgated by the Bureau of Standards, Metrology and Inspection on 15 August 2017.
7. Amended and promulgated by the Bureau of Standards, Metrology and Inspection on 3 July 2019.

Content :

1. These Directions are established to recognize quality management systems certification bodies under the Registration of Product Certification (RPC) scheme, the Voluntary Product Certification (VPC) scheme and the approval of measuring instrument enterprises to conduct self-verification.

2. A quality management system certification body (hereinafter referred to as CB) that applies for recognition (hereinafter referred to as the applicant) shall meet one of the following requirements:

- (1) Being accredited by the Taiwan Accreditation Foundation, Republic of China; or
- (2) Being accredited by an accreditation body (hereinafter referred to as AB) that is located in the same country as the applicant and is a member of the Multilateral Recognition Arrangements (MLA) of the International Accreditation Forum, Inc. (IAF) or the Asia Pacific Accreditation Cooperation (APAC).

If there is no AB in the applicant's country or if the AB located in the applicant's country has not become a member of the IAF MLA or APAC MLA, the accreditation can be obtained from IAF MLA or APAC MLA member ABs located in other countries. When the AB located in the applicant's country becomes a member of the IAF MLA or APAC MLA, the applicant is required to obtain the accreditation from that AB within one year in order to retain recognition by the Bureau of Standards, Metrology and Inspection (BSMI).

3. The scope of application for recognition shall be limited to that covered by the RPC scheme, the VPC scheme or the approval of measuring instruments enterprises to conduct self-verification, and that accredited by the accreditation body mentioned in Clause 2.

4. The applicant shall apply for recognition to the BSMI by submitting documents as follows:

- (1)the application form;
- (2)a copy each of the accreditation certificate in English and the original language; however, in case that the accreditation information was provided by an AB by ways other than an accreditation certificate or there is no expiry date in the accreditation certificate, the applicant shall provide documents which could sufficiently identify the accreditation body, accredited organization, accredited scope, accreditation criteria, and expiry date of accreditation (or the latest issue date of accreditation certificate with accreditation cycle), etc. (hereinafter referred to as supporting documents)
- (3)samples of ISO 9001 Quality Management System certificate (in both English and the original language) issued by the applicant;
- (4)relevant certification operating procedures and organization location map of the applicant.

The application form mentioned in Clause 4(1) shall be filled out in Chinese or English. The supporting documents and relevant certification operating procedures shall be in Chinese or English.

A foreign applicant shall authorize an agent who has a domicile or business place within the territory of the Republic of China to submit the application. In such cases, a letter of authorization from the applicant shall also be provided.

5. The BSMI will issue the recognition certificate to the applicant after the review and approval of the application. The expiry date of the recognition certificate will be the same as that of the accreditation certificate or be determined based on the supporting documents provided by the applicant.

An applicant may apply for extension of the term of validity by providing the documents mentioned in Clause 4 within the period of three months prior to the expiry date of the recognition. The expiry date of each extended term of recognition will be given by following the principles mentioned in the previous paragraph.

The application will be rejected if it is found not complying with the requirements after the review.

6. The BSMI may request an applicant to provide related documents and may dispatch its staff to conduct on-site checks if necessary.

The BSMI may conduct regular or irregular on-site checks to its recognized CB annually.

The CB shall not deny, impede or evade checks mentioned in the preceding two paragraphs without justifiable reasons.

7. When the name or address of a recognized CB changes or its accredited scope is reduced and affects the recognition scope, it shall apply to the BSMI for changes to the recognition certificate by submitting the application form and a copy of the new accreditation certificate or supporting documents within one month upon receipt of the decision from the accreditation body.

Clauses 4-6 shall apply to the expansion of recognition scope, the application review process and the expiry date.

8. When a recognized CB is informed by the BSMI (or its commissioned commodity certification body) that an ISO 9001 certificate issued by it is used for BSMI's RPC or VPC scheme, it shall conduct inspection to the production premises at least once per

year. When undertaking the inspection, the recognized CB shall check the followings:

- (1) Do the production premises remain in operation or are they noted as closed by the competent authority?
- (2) Does the production premises' quality management system continuously conform to the requirements of ISO 9001?
- (3) Is the content of ISO 9001 certificate changed?
- (4) What is followed during the manufacturing processes to ensure that the products comply with the regulations and inspection standards applicable to RPC or VPC scheme?
- (5) How do the production premises manage the manufacturing processes to ensure that products subsequently manufactured are in compliance with the types registered in the RPC or VPC scheme?

The BSMI may carry out witness inspection of the activities mentioned in the previous paragraph, where necessary. The CB shall not evade, impede or deny without justifiable reasons.

A recognized CB shall fill out the "Checklist for Quality Management System of Production Premises Registered by BSMI" when conducting the inspection mentioned in the first paragraph and submit the completed Checklist to the BSMI (or its commissioned commodity certification bodies) within three months.

9. The certification personnel of a recognized CB are required to participate in training courses delivered by the BSMI or the BSMI designated institutes at least once per year in order to enhance their familiarity with relevant regulations, such as the Commodity Inspection Act, the subordinate regulations, the RPC scheme, VPC scheme and regulations governing self-verification conducted by measuring instrument enterprises, etc.

The audit of ISO 9001 quality management certification of intended applications for or registered organizations under the RPC, VPC scheme or self-verification of measuring instruments shall only be performed by personnel who have completed the training courses of the year or of the preceding year.

10. Where changes (including reduction of scope, cancellation and rescission of certificates, and issuance of certificates after re-assessment) are made to the content of ISO 9001 certificates, which were issued by the recognized CB and used for registering production premises under the RPC or VPC scheme by the BSMI (or its commissioned certification bodies), or for obtaining the approval from the BSMI to conduct self-verification of measuring instruments, the recognized CB shall also inform the BSMI (or its commissioned commodity certification bodies) when the new certificates are issued.

11. The BSMI shall revoke or rescind all or part of the recognition granted to a CB under any of the following circumstances:

- (1) If the accreditation certificate of a CB has been cancelled, withdrawn or terminated;
- (2) If the accredited scope of a CB is reduced;
- (3) If a CB fails to meet the requirements mentioned in Clauses 6, 8 and 10; or
- (4) If any fraudulent action related to the certificates and relevant documents has been made.

Where the recognition of a CB is revoked or rescinded by the BSMI, the CB shall

offer necessary assistance to the affected production premises and submit the implementation progress to the BSMI for references.

12. If the recognition has been rescinded or revoked by the BSMI, a CB may not re-apply for recognition until six months after the date of rescission or revocation.

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Data Source : Ministry of Economic Affairs R.O.C.(Taiwan) Laws and Regulations Retrieving System