Content

Title：	Directions for Recognition of Quality Management Systems Certification Bodies Ch
Date：	2017.08.15
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.
Content：	1. These Directions are established to recognize quality management systems certification bodies under the Registration of Product Certification (RPC) Scheme and the Voluntary Product Certification (VPC) Scheme. 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 Pacific Accreditation Cooperation (PAC). If there is no AB in an applicant's country, or if the AB located in the applicant's country has not yet become a member of the IAF MLA or PAC MLA, the accreditation can be obtained from other IAF MLA or PAC MLA member ABs located in other countries.When the AB located in an applicant's country becomes a member of the IAF MLA or PAC MLA, the applicant is required to obtain accreditation from this 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 in the RPC or the VPC Scheme and accredited by the AB specified as above. 4. An applicant shall apply for recognition to the BSMI by submitting the application form, a copy of an accreditation certificate and a sample of ISO 9001 certificate (in English and original language) issued by the applicant as well as relevant certification operating procedures and organization location map of the applicant. If an accreditation certificate and/or application form is presented in a language other than Chinese, the BSMI shall request the applicant to provide the Chinese translation version at the same time. A foreign applicant shall authorize an agent who has a domicile or business place within the

territory of Taiwan, 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 grant its recognition and issued the certificate to an applicant after application has been reviewed and approved. The recognition will be valid until the expiration date of accreditation. An applicant may apply for extension of the term of validity by providing the appropriate application form within a period of three months prior to the expiration date of the recognition. The extended recognition shall be valid until the expiration date of accreditation each time.
The application will be rejected if it is found not complying with the requirements after the review.

6. The BSMI may request an applicant for applying to be a CB recognized by the BSMI to provide related documents and may dispatch its staff to conduct on-site inspections, where necessary.
The BSMI may conduct a regular or random inspection to its recognized CB annually.
The CB shall not deny, impede or evade verification mentioned in the preceding two paragraphs without justifiable reasons.

7. A CB recognized by the BSMI shall apply to the BSMI for changes to the scope of recognition within three months if the scope of accreditation has been reduced and the scope of recognition is affected. The same shall also apply to situations where changes are made to the content specified in the recognition certificate.

8. A CB recognized by the BSMI will be informed when one of its registered organizations has been registered under the RPC or the VPC Scheme by BSMI or by the commodity certification body who
has been commissioned to conduct product certification by the BSMI in accordance with Article 4 of the Commodity Inspection Act. When performing surveillance visits to such organizations, a recognized CB shall audit the quality management systems of the organization to ensure:
(1) The quality management system of the organization continues to comply with the requirements of ISO 9001;
(2) The organization has the applicable versions of regulations and inspection standards pertaining to their registered products;
(3) The organization establishes adequate inspection plans for the registered products in accordance with the inspection standards to be implemented and devotes adequate resources to be certain of continuous compliance of its quality management system with the requirements; and
(4) The organization has maintained the original type-test reports and technical documents of their registered products, based on which adequate manufacturing plans are established and implemented accordingly.
In the event of a surveillance visit, the BSMI may carry out an on-site inspection, where necessary. The CB shall not evade, impede or deny without justifiable reasons.
A CB recognized by the BSMI shall conduct surveillance visits in accordance with the "Checklist for Assessment/Surveillance of Production Premises" (Forms SA-01-1 and SA-01-2) and send the completed checklist to the BSMI or its commissioned commodity certification bodies within three months after the surveillance visit.

9. The staff members of a CB recognized by the BSMI are required to participate in training courses delivered by the BSMI or designated institutes at least once per year in order to enhance their familiarity with the regulations and relevant technical parts, such as the Commodity Inspection Act, the subordinate regulations, the Registration of Product Certification (RPC) Scheme and the

Voluntary Product Certification (VPC) Scheme.
The assessments or surveillance visits of new applications for or registered organizations of ISO 9001 quality management certification under the RPC or VPC Scheme shall only be performed by staff members who have completed the training courses of the year or of the preceding year.

10. A CB recognized by the BSMI shall inform the BSMI or its commissioned commodity certification bodies of changes to the ISO 9001 certificates of RPC or VPC registered production premises, including an increase or reduction in the scope of certification.

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 described in Clauses 6, 8 and 10; or
(4) If any fraudulent actions related to certificates and relevant documents has been discovered.

12. A CB may re-apply for recognition after six months from the date of rescission or revocation if the recognition has been rescinded or revoked by the BSMI.

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