Content

Title：	Directions for Recognition of Quality Management System Certification Bodies Ch
Date：	2022.11.08
Legislative：	1.Adopted by the Bureau of Standards, Metrology and Inspection on 27 September 2000. 2.Amended and promulgated 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. 8.Amended and promulgated by the Bureau of Standards, Metrology and Inspection on 8 November 2022.
Content：	1.These Directions are established in order to implement the recognition of quality management system certification bodies for product certifications. 2.The terms used by these Directions are defined as follows: (1)Product certification: It shall mean all kinds of product certification that the Bureau of Standards, Metrology and Inspection (BSMI) announces to accept applications, including the Registration of Product Certification (RPC) scheme, the Voluntary Product Certification (VPC) scheme, CNS Mark Certification System, the Approval of Measuring Instrument Enterprises to Conduct Self-verification, the Management-system-based Monitoring Inspection scheme, etc. (2)The recognized quality management system certification body (hereinafter referred to as recognized CB): It shall mean the certification body that has been recognized by the BSMI in accordance with these Directions and therefore the ISO 9001 Quality Management System certificate (hereinafter referred to as ISO 9001 certificate) issued by the recognized CB could be used as a supporting document for applying for product certification. 3.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 (hereinafter referred to as TAF); 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 Mutual Recognition Arrangement (MRA) of 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 is not a member of the IAF MLA or APAC MRA, the accreditation can be obtained from IAF MLA or APAC MRA member AB located in other countries. When the AB located in the applicant’s country becomes a member of the IAF MLA or APAC MRA, the applicant is required to obtain the accreditation from that AB within one year in order to retain recognition by the BSMI. 4.The scope of application for recognition shall be limited to that covered by product certifications and that accredited by the AB mentioned in Clause 3. 5.The applicant having the qualifications set forth under Clause 3 may apply to the BSMI for

recognition by submitting an application form and the following documents:
(1)Copies of the accreditation certificate in English and the original language demonstrating the qualifications set forth under Clause 3; 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 AB, accredited organization, accredited scope, accreditation standard, and expiry date of accreditation (or the latest issue date of accreditation certificate with accreditation period), etc. (hereinafter referred to as supporting documents)
(2)Samples of ISO 9001 certificate (in both English and the original language) issued by the applicant;
(3)Relevant certification operating procedures and organization location map of the applicant;
(4)Other documents designated by the BSMI.
The application form mentioned in the previous paragraph shall be filled out in Chinese or English. The supporting documents, relevant certification operating procedures and other documents designated by the BSMI 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 (hereinafter referred to as the agent) to submit the application. In such cases, a letter of authorization from the applicant shall also be provided.

6.The BSMI will issue the recognition certificate in accordance with the scope specified in the application form 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.
For the review mentioned in the previous paragraph, the BSMI may request the applicant to provide
related documents and may dispatch its staff to conduct an on-site assessment or visit the agent of the foreign applicant if necessary.
If the application documents are not clear or are incomplete, the BSMI may require the applicant to give explanations or corrections within the given time limit. Failure to take these actions will lead to the rejection of the application. However, if there are other special circumstances approved by the BSMI, the time limit can be extended for one time.
The application will be rejected if it is found not complying with the requirements after the review.

7.A recognized CB may apply for extension of the recognition by submitting the documents mentioned in Clause 5 within the period of three months prior to the expiry date of the recognition. The review process and the expiry date of each extended term of recognition will be given by following the principles mentioned in the previous clause.

8.The recognized CB shall accept surveillance conducted by the BSMI at least once a year, and the agent of the foreign recognized CB may also be checked if necessary.
If a recognized CB has any of the following circumstances, the BSMI may increase the frequency of surveillance mentioned in the preceding Paragraph:
(1)Having violated the provision of Clause 9, Clause 10, Paragraph 2 or 3 of Clause 11, Clause 12 or Clause 13;
(2)Other circumstances that are deemed by the BSMI as having unfavorable impact on the validity of product certifications.
The recognized CB and the agent of the foreign recognized CB shall not evade, impede or deny the surveillance mentioned in the preceding two Paragraphs without justifiable reasons.

9.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 AB.
When a foreign recognized CB changes it's agent, it shall apply to the BSMI for changes by submitting the application form and letter of authorization within one month.
If the circumstance mentioned in the first Paragraph affects the registered production premises under the product certification schemes (hereinafter referred to as clients), the recognized CB shall offer necessary assistance to the affected clients and submit the list of affected clients to the BSMI while applying for change.
When making any changes in the ISO 9001 certificate format (such as name, address, signature, etc.), the recognized CB shall inform the BSMI and provide the latest version for reference.
Clauses 5 and 6 shall apply to the application, review process and expiry date for the expansion of recognition scope.

10.The recognized CB shall establish management mechanism for the following subparagraphs, and the foreign ones shall authorize the agent to assist with related matters.
(1)Maintaining a proper and complete list of clients, and the domestic recognized CBs shall maintain information of validated clients on the TAF website;
(2)Assisting the BSMI or its commissioned product certification bodies in confirming the validity of the ISO 9001 certificate of clients;
(3)Providing the scheduled time table for annual audit of clients on the BSMI's "Quality Management Certification Institution System" (hereinafter referred to as BSMI's System) before March 1 of each year;
(4)Conducting surveillance or inspection to clients at least once a year;
(5)Notifying the changes regarding clients to the BSMI (including those changed or became invalid in the ISO 9001 certificates of clients);
(6)Notifying the irregular conditions of clients;
(7)Taking appropriate actions in increasing or strengthening surveillance or inspection to clients after receiving the notice from the BSMI.

11.The BSMI may carry out witness inspection of the activities mentioned in the Clause 10 (4), where necessary. The recognized CB shall not evade, impede or deny without justifiable reasons. When it is impossible to conduct surveillance or inspection at the production premise due to a special event, conducting remotely is acceptable after reporting to the BSMI.
When conducting surveillance or inspection mentioned in the first Paragraph to production premises registered under the RPC or VPC scheme, a recognized CB shall inspect the items listed in the Annex by filling out the "Checklist for Quality Management System of Production Premises Registered by BSMI". Within three months after the surveillance or inspection, a recognized CB shall upload the completed Checklist to the BSMI's System, and a foreign recognized CB may seek assistance from the agent.

12.The auditors of a recognized CB are required to participate in training courses delivered by the BSMI designated institutes at least once per year or complete training courses at the designated website in accordance with the BSMI's annual training plan, and shall obtain relevant certificates or documents, in order to enhance their understanding of relevant regulations of product certifications. The surveillance or inspection set forth under the Clause 10 (4) shall only be conducted by personnel who have completed the training courses of the year or of the preceding year set forth under preceding Paragraph.

13.Where changes (including reduction of scope, cancellation or rescission of certificates, and issuance of certificates after re-assessment) are made to the content of ISO 9001 certificates of clients, the recognized CB shall notify the changes at the BSMI's system or inform the BSMI directly at the same time of notifying to the clients.

14.The BSMI shall revoke all or part of the recognition granted to a recognized CB under any of the
following circumstances:
(1)Where the accreditation of a recognized CB has been revoked;
(2)Where the recognition of a recognized CB was acquired through fraudulent means.
If the recognition has been revoked by the BSMI, a CB may not re-apply for recognition for the same scope until six months after the date of revocation.

15.The BSMI shall rescind all or part of the recognition granted to a recognized CB under any of the
following circumstances:
(1)Where an application to cancel the recognition has been initiated by a recognized CB;
(2)Where all or part of the accreditation scope of a recognized CB has been suspended, rescinded or
reduced by the AB mentioned in Clause 3 and has an impact on the recognition scope;
(3)Where a recognized CB has failed to submit documents within the notified time limit without any justifiable reasons;
(4)Having violated the condition stated in Paragraph 2, Clause 3;
(5)Having violated the provisions of Paragraph 3 of Clause 8 or Paragraph 1 of Clause 11;
(6)Where the issued ISO 9001 certificate has been found to contain false information or be made fraudulently;
(7)Where the required fees were not paid, and payment is not made within the given time limit

	notified by BSMI; (8)Other violations that are deemed as serious events by the BSMI. When the situation stated in Paragraph 1 of Clause 14 or Clause 15 (2) to (7) happend or is likely to happen, the BSMI may reject the application stated in Clause 15 (1). If the recognition has been rescinded by the BSMI, a CB may not re-apply for recognition for the same scope until six months after the date of rescission, except for the condition of Clause 15 (1) or a special circumstance that has been approved by the BSMI. 16.Where all or part of the recognition scope of a recognized CB is rescinded or revoked by the BSMI in accordance with the circumstances mentioned in Clause 14 or Clause15, the recognized CB shall offer necessary assistance to the affected clients and submit the implementation progress to the BSMI.
Attachments：	Annex List of Inspection Items.pdf

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