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Title: ODirections for Recognition of CNS Mark Quality Management System Certification Bodies Ch

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Legislative: 1. Adopted and promulgated by the Bureau of Standards, Metrology and Inspection on 27 January 2004.

> 2. Adopted and promulgated by the Bureau of Standards, Metrology and Inspection on 29 June 2005.

> 3.Adopted and promulgated by the Bureau of Standards, Metrology and Inspection on 01 July 2015

4.Adopted and promulgated by the Bureau of Standards, Metrology and Inspection on 28 September 2017, except Article 3, Subparagraph 3 of Article 5 and Paragraph 2 of Article 8 are adopted on 01 January, 2018. 5. Abolished on 2 December 2022.

Content: 1. These Directions are established for the recognition of domestic and foreign quality management system certification bodies (hereinafter referred to as "applicant") as CNS Mark quality management system certification bodies, to conduct assessment and surveillance activities required by the CNS Mark.

- 2. The application procedure for recognition is described below:
- (1)Quality management system certification bodies that apply for recognition in accordance with Article 32 of the Regulations Governing of CNS Mark (hereinafter referred to as "the Regulations") shall meet one of the following requirements:
- (i)Being accredited by the Taiwan Accreditation Foundation (TAF); or
- (ii)Being accredited by an accreditation body that is located in the Republic of China or the same country as the applicant and is a member of the Multilateral Recognition Arrangement (MLA) of the International Accreditation Forum, Inc. (IAF) or the Pacific Accreditation Cooperation (PAC). (2) In the case of the second item in the preceding subparagraph, if there is no accreditation body in the applicant's country, or if the accreditation body 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

MLA or PAC MLA member accreditation bodies located in other countries. When the accreditation

body located in the applicant's country becomes a member of the IAF MLA or PAC MLA, the applicant is required to obtain accreditation from this accreditation body within one year in order to maintain its recognition by the BSMI.

- (3) The scope for the application of recognition shall be limited to those covered in the CNS Mark product items as announced by the Bureau of Standards, Metrology and Inspection (BSMI) in accordance with Article 33 of the Regulations; and to those covered in the scope accredited by accreditation bodies mentioned in 2(1).
- (4) The applicant shall apply for recognition with the BSMI by completing the application form and attaching the following accreditation-related documents:
- (i) A copy of the accreditation certificate;
- (ii) Sample copy of ISO 9001 certificate issued in the original and English languages.
- (iii) Relevant certification operating procedures and organization location map of the applicant.
- (iv) A foreign applicant shall authorize an agent who has its domicile or business place in the Republic of China to submit the application. In such case, a letter of authorization shall also be provided.
- (v) If the application form and the accreditation certificate are presented in foreign languages, the applicant shall provide Chinese translations.
- (5) Where the applicant has become a recognized quality management system certification body under the BSMI Registration of Product Certification Scheme, the documents mentioned in previous items are not required.
- 3. The procedure for the application of review and approval of recognition is as follows:

When an applicant submits an application and copies of the accreditation certificates to the BSMI, the BSMI shall grant its recognition and issue the certificate to an applicant after application has been reviewed and approved.

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

- 4. Verification of the applicant's identity and the contents of the accreditation certificate may be performed in the following ways:
- (1) To inquire via information from the websites of the applicant and its accreditation body;
- (2)To inquire with the accreditation body of the applicant;
- (3) To inquire with TAF requesting for assistance;
- (4)To request the applicant to provide relevant information and send personnel to conduct on-site inspection when necessary, the applicant shall not deny, evade or impede such requests without legitimate reasons.
- 5. Procedures concerning the term of validity, extension and alteration of the recognition are as follows:
- (1) In accordance with the provision of paragraph 2 of Article 35 of the Regulations, the term of validity of the recognition is the same as the term of validity shown in the applicant's accreditation certificate.
- (2)Recognized quality management system certification bodies may apply for extension of the term of validity by providing the application form within a period of three months prior to the expiration of the recognition. The BSMI shall review the application and grant the extension if it complies with the requirements. Every extension for the term of validity of recognition also applies to the term of validity of the applicant's accreditation certificate. Upon review, the application shall be denied if it does not comply with the regulations.
- (3)When the scope of accreditation is reduced and the scope of recognition is affected, then the recognized quality management system certification bodies shall apply with the BSMI for changes to the scope of recognition within three months after the scope has been reduced. Such aforesaid regulation also applies to the situation where changes are made to the contents specified in the recognition certificate.
- 6. The BSMI may request recognized quality management system certification bodies to provide related documents for the purpose of management. The BSMI may dispatch its staff to conduct the regular or random on-site inspection annually when necessary and certification bodies shall not deny,

evade or impede such requests without legitimate reasons.

- 7. The management and inspections of recognized quality management system certification bodies for the manufacturers:
- (1) After the recognized quality management system certification bodies have been informed by the BSMI or third-party certification agencies that the products of their registered manufacturers are granted with the CNS Mark, the recognized quality management system certification bodies performing surveillance visits to these manufacturers shall audit the quality management systems every year; and ensure that the manufacturers comply with the following:
- (i) The requirement of continuous compliance with the designated quality management systems;
- (ii) The use of the most up-to-date versions of applicable laws, regulations and national standards concerning the CNS Mark; and
- (iii) The establishment of appropriate inspection plans for the CNS Mark products in accordance with national standards; and provide adequate resources to enable the continuous effective operation
- of quality management systems.
- (2)Recognized quality management system certification bodies shall conduct surveillance visits in accordance with Paragraph 1 of Article 38 of the Regulations and complete the "Checklist for Assessment/Surveillance of CNS Mark Certified Organizations" in accordance with Paragraph 2 of Article 38 of the Regulations. The completed checklist shall be sent to the BSMI (6th Division), the BSMI branch with jurisdiction or third-party certification agencies within three months after the surveillance visits
- (3)In the event of the surveillance visit, the BSMI or third-party certification agencies may assign personnel to conduct on-site inspection when necessary. The certification bodies shall not deny, evade or impede such requests without legitimate reasons.
- (4)Recognized quality management system certification bodies shall perform quality control surveillance visits in accordance with the requirements of the Regulations, the Directions Governing

the Application for the CNS Mark, and these Directions. A notice shall be sent by the BSMI to the recognized certification bodies for correction of any violations.

(5)The recognized quality management system certification bodies upon approval by the BSMI or third-party certification agencies allowing the recognized manufacturers to use the CNS Mark shall inform the BSMI or third-party certification agencies of changes or invalidations to the quality management system certificates issued by the CNS Mark certified manufacturers.

8. The staff members of certification bodies recognized by the BSMI shall participate in the training courses delivered by the BSMI or the designated institutions at least once per year in order to enhance their familiarity with the Regulations Governing of CNS Mark and other related legal regulations.

The assessments or surveillance visits of manufacturers applying for the use of CNS Mark or CNS Mark registered manufacturers of factories quality management certification shall only be performed by staff members who have completed the training courses of the year or of the preceding year.

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