[Attachment 1]

Serial No.: CNCA-00C-005

CNCA-00C-005

China Compulsory Certification Implementation Rules - Factory quality assurance capacity requirements

强制性产品认证实施规则

工厂质量保证能力要求

Issued on: February 02, 2014 **Implemented on: September 01, 2014**

Issued by: Certification and Accreditation Administration of the People's Republic of China

Table of Contents

0 Introduction

According to the requirements of the “China Compulsory Certification Management Method”, the manufacturing enterprise shall control the consistency of the certified products, and its quality assurance capacity shall sustain the compliance with the certification requirements. This Implementation Rules is formulated for the purpose of normatively guiding the manufacturing enterprise of the products in the China Compulsory Certification (CCC certification) catalog to establish quality assurance capacity to ensure that the products sustain the compliance with the CCC certification requirements.

In the specific implementation of the certification work, the factory shall establish quality assurance capacity that meet the requirements of this Implementation Rules, aimed at ensuring the consistency of the certified products and the type test samples, according to the implementation rules and the requirements of the corresponding certification implementation rules/detailed-rules, and for product characteristics and manufacture processing characteristics.

NOTE: The factory in this Implementation Rules involves certification client, manufacturer and manufacturing enterprise.

1 Application scope

This Implementation Rules specifies the basic requirements for the quality assurance capacity of the factory and is also one of the bases for the certification body to implement the factory inspection.

2 Terms and definitions

2.1 Certification technical personnel in charge

An insider of the manufacturer and/or the manufacturing enterprise, who masters the requirements of certification standards, and confirms the approval of the change of certified products and assumes the corresponding responsibility according to the scope of duties specified in the certification implementation rules/detailed-rules.

2.2 Certified product consistency (product consistency)

The certified products manufactured are consistent with the type test samples. The specific requirements for product consistency are specified in the certification implementation rules/detailed-rules.

2.3 Routine inspection

In order to eliminate nonconforming products caused by accidental factors in the manufacturing process, 100 % inspection of certified products is usually carried out at the final stage of manufacture. Routine inspection is allowed to be carried out by an equivalent, fast method that is determined after verification.

NOTE: For special products, routine inspection may be sampling inspection according to the requirements of the certification implementation rules/detailed-rules.

2.4 Confirmation inspection

A sampling inspection carried out to verify whether the certified products are capable of sustaining the compliance with the certification standards.

2.5 Regular confirmation inspection of critical components

A regular sampling inspection carried out to verify whether the quality characteristics of critical components are capable of sustaining the compliance with certification standards and/or technical requirements.

NOTE: The critical component is a general term for components, parts, raw materials, etc. that play a critical role in meeting the certification requirements.

2.6 Function check

A check carried out to determine whether the intended function of the test equipment meets the specified requirements.

3 Factory quality assurance capacity requirements

Factory is the responsible body of product quality, and its quality assurance capacity shall be capable of sustaining the compliance with the certification requirements; the products manufactured shall meet the requirements of the standard and it shall ensure that the certified products are consistent with the type test samples. Factory shall accept and cooperate with various factory on-site inspection, market inspection and sampling test implemented by the certification body in accordance with this Implementation Rules and relevant certification implementation rules/detailed-rules.

3.1 Responsibilities and resources

3.1.1 Responsibilities

The factory shall specify the duties, authorities and mutual relations of various personnel related to the certification requirements, and designate the person in charge of quality in the management of the organization. Regardless of other duties of

3.2.4 The factory shall identify and keep important documents and quality information related to product certification, such as type test reports, factory inspection results, CCC certificate status information (valid, suspension, withdrawal, cancellation, etc.), certification change approval information, supervision sampling test report, product quality complaints and processing results.

3.3 Purchasing and critical component control

3.3.1 Purchasing control

For the purchased critical components, the factory shall identify and clarify their technical requirements in the purchasing documentation. The technical requirements shall also ensure that the final product meets the certification requirements.

The factory shall establish and keep a catalogue of qualified manufacturers/ manufacturing enterprises of critical components and purchase critical components from them. The factory shall keep records of the purchasing and use of critical components, such as purchasing orders, inbound and outbound orders, and accounts.

3.3.2 Quality control of critical components

3.2.2.1 The factory shall establish and maintain a documented procedure, and verify and/or inspect the technical requirements for the purchasing of critical components and keep relevant records upon receipt (incoming).

3.3.2.2 For the quality characteristics of the purchased critical components, the factory shall select the appropriate control method to ensure that the critical components sustain the compliance with the technical requirements, and that the final products meet the certification requirements; keep the relevant records. Appropriate control methods may include:

(a) Obtain a CCC certificate or a voluntary product certification result that can be recognized for compulsory certification of the final product. The factory shall ensure that the status of its certificate is valid.

(b) For the critical components of which the relevant certificate is not obtained, the regular confirmation inspection shall meet the requirements of the certification implementation rules/detailed-rules.

(c) The factory itself has a control plan with a control effect not lower than the requirements of 3.3.2.2(a) or (b).

3.3.2.3 When purchasing critical components from distributors and traders, the factory shall take appropriate measures to ensure the consistency of the purchased critical components and their sustaining the compliance with the technical requirements.

3.6 Inspection and test equipment

3.6.1 Basic requirements

The factory shall be equipped with sufficient inspection and test equipment and ensure that the capabilities of the equipment used in the purchasing, manufacturing, and final inspection tests meet the inspection and test requirements for the mass production of certified products.

The inspection and test personnel shall be able to use the equipment correctly, master the inspection and test requirements and implement them effectively.

3.6.2 Calibration and verification

The test equipment used to determine whether the certified products manufactured meet the specified requirements shall be calibrated or verified according to the specified period. The calibration or verification period may be set according to the use frequency and the previous calibration of the equipment. For internal calibration, the factory shall specify calibration methods, acceptance criteria and calibration periods. The calibration or verification shall be traceable to national or international standards. The calibration or verification status of the equipment shall be used and easily identified by the administrator. The factory shall keep the calibration or verification records of the equipment.

For calibration or verification activities commissioned by external organizations, the factory shall ensure that the capabilities of the external organization meet the calibration or verification requirements and keep relevant capability evaluation results.

NOTE: For critical monitoring and measuring devices in manufacture process control, the factory shall manage them in accordance with the requirements of the certification implementation rules/detailed-rules.

3.6.3 Function check

When necessary, the factory shall perform function checks on the equipment for routine inspection according to the specified requirements. When the function check results are found to be unsatisfactory, it shall be able to trace to the products that have been tested; when necessary, these products shall be re-tested. The factory shall specify the measures that the operator shall take when discovering function failure of the equipment.

The facility shall keep the record of the function check results and the actions taken when the equipment function fails.

3.7 Control of nonconforming products

3.7.1 For nonconforming products found in purchasing, manufacturing, inspection,

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