

	Shenzhen NCT Testing Technology Co.,Ltd. 深圳诺测检测技术有限公司	File No. /文件编号	NCT-II-002
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Factory quality capability assurance requirements

工厂质量能力保证要求

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0. Introduction 引言

According to the requirements of the voluntary product certification management regulations, the manufacturer should control the consistency of the certified products, and its quality assurance ability should continue to meet the certification requirements. In order to standardize and guide the product manufacturers in the voluntary product certification catalogue to establish the quality assurance capacity to ensure that the products continue to meet the certification requirements, the factory quality assurance capacity requirements of the implementation rules are formulated.

按照自愿性产品认证管理规定的要求，生产企业应控制获证产品一致性，其质量保证能力应持续符合认证要求。为规范指导自愿性产品认证目录内产品生产企业建立确保产品持续符合认证要求的质量保证能力，制定本实施规则工厂质量保证能力要求。

In the specific implementation of the certification work, the factory shall ensure the consistency of the certified products and the type test samples as the goal, according to the requirements of the implementation rules, according to the product characteristics and production and processing characteristics, establish the quality assurance capacity in line with the requirements of the implementation rules.

在认证工作具体实施中，工厂应以保证生产的认证产品与型式试验样品的一致性为目标，根据本实施规则的要求，针对产品特性和生产加工特点，建立符合本实施规则要求的质量保证能力。

Note: The factories in this implementation rules involve the certification clients, producers and production enterprises.

注：本实施规则中的工厂涉及认证委托人、生产者、生产企业。

1. Application Scope 适用范围

This implementation rule stipulates the basic requirements for the quality assurance capacity of factories, and is also one of the bases for the certification body to implement the factory inspection.

本实施规则规定了工厂质量保证能力的基本要求，同时也是认证机构实施工厂检查的依据之一。

2. Terms and definitions 术语和定义

2.1 Certified Technical Director 认证技术负责人

Belong to the producer and / or the internal personnel of the production enterprise, master the certification according

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to the standard requirements, according to the scope of responsibility stipulated in the product certification implementation rules, the certification product change is confirmed for approval and bear the corresponding responsibility.

属于生产者和/或生产企业内部人员，掌握认证依据标准要求，依据产品认证实施规则规定的职责范围，对认证产品变更进行确认批准并承担相应责任的人。

2.2 Certified product consistency (product consistency) 认证产品一致性（产品一致性）

The certified products produced are consistent with the type test samples, and the specific requirements for product consistency are stipulated by the product certification implementation rules.

生产的认证产品与型式试验样品保持一致，产品一致性的具体要求由产品认证实施规则规定。

2.3 Routine inspection 例行检验

In order to eliminate the unqualified products caused by the accidental factors in the production process, the 100% inspection of the certified products is usually conducted in the final stage of the production. Routine tests allow equivalent, rapid methods.

为剔除生产过程中偶然性因素造成的不合格品，通常在生产的最终阶段，对认证产品进行的100%检验。例行检验允许用经验证后确定的等效、快速的方法进行。

Note: For special products, routine sampling inspection may be carried out in accordance with the requirements of the product certification implementation rules.

注：对于特殊产品，例行检验可以按照产品认证实施规则的要求，实施抽样检验。

2.4 Functional check 功能检查

Check to determine whether the expected function of the test equipment meets the specified requirements.

为判断检验试验仪器设备的预期功能是否满足规定要求所进行的检查。

3. Plant quality assurance capability requirements 工厂质量保证能力要求

The factory is the main body responsible for the product quality, its quality assurance ability should continue to meet the certification requirements, the products produced should meet the standard requirements, and ensure that the certified products are consistent with the type test samples. The factory shall accept and cooperate with the certification body to conduct on-site inspection, market inspection and sampling testing in accordance with these

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implementation rules and relevant product certification implementation rules.

工厂是产品质量的责任主体，其质量保证能力应持续符合认证要求，生产的产品应符合标准要求，并保证认证产品与型式试验样品一致。工厂应接受并配合认证机构依据本实施规则及相关产品认证实施规则所实施的各类工厂现场检查、市场检查、抽样检测。

3.1 Responsibilities and resources 职责和资源

3.1.1 Responsibilities 职责

The Plant shall define the personnel responsibilities, authority and interrelationships related to the certification requirements and shall designate the Quality Management in the management of the organization, and to:

工厂应规定与认证要求有关的各类人员职责、权限及相互关系，并在本组织管理层中指定质量负责人，无论该成员在其它方面的职责如何，应使其具有以下方面的职责和权限：

(a) Ensure that the requirements of this document are effectively established, implemented and maintained at the plant;

(a) 确保本文件的要求在工厂得到有效地建立、实施和保持；

(b) Ensure product consistency and conformity with products and standards;

(b) 确保产品一致性以及产品与标准的符合性；

(c) Correct use of certification certificates and marks to ensure that the certificate status of the added certification mark products remains valid.

(c) 正确使用认证证书和标志，确保加施认证标志产品的证书状态持续有效。

The person in charge of quality shall have full ability to be competent for their own work, and the person in charge of quality may serve as the certified technical person in charge at the same time.

质量负责人应具有充分的能力胜任本职工作，质量负责人可同时担任认证技术负责人。

3.1.2 Resource 资源

The factory shall be equipped with necessary production equipment and inspection and test equipment to meet the needs of stable production of products meeting the requirements of certification standards; corresponding human resources to ensure that the staff affecting the quality of product certification have the necessary capabilities; the necessary environment and facilities for product production, inspection, test and storage shall be established and

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maintained.

工厂应配备必须的生产设备、检验试验仪器设备以满足稳定生产符合认证依据标准要求产品的需要；应配备相应的人力资源，确保从事对产品认证质量有影响的工作人员具备必要的的能力；应建立并保持适宜的产品生产、检验试验、储存等必备的环境和设施。

For external resources to be leased, the factory shall ensure continuous availability and correct use of external resources; the plant shall keep records related to external resources, such as contract agreement, use records, etc.

对于需以租赁方式使用的外部资源，工厂应确保外部资源的持续可获得性和正确使用；工厂应保存与外部资源相关的记录，如合同协议、使用记录等。

3.2 Documents and records 文件和记录

3.2.1 The plant shall establish and maintain documented procedures to ensure effective control of the documents and records required for this document. The product design standard or specification shall not be less than the requirements of the certification basis standard of the product. For the main contents that may affect the product consistency, the factory shall have the necessary drawings, samples, key parts list, process documents, work instructions and other design documents, and ensure the continuous validity of the documents.

工厂应建立并保持文件化的程序，确保对本文件要求的文件、必要的外来文件和记录进行有效控制。产品设计标准或规范应不低于该产品的认证依据标准要求。对可能影响产品一致性的主要内容，工厂应有必要的图纸、样板、关键件清单、工艺文件、作业指导书等设计文件，并确保文件的持续有效性。

3.2.2 The factory shall ensure the adequacy, suitability of the documents and the valid version of the documents for use.

工厂应确保文件的充分性、适宜性及使用文件的有效版本。

3.2.3 The factory shall ensure that the records are clear, complete and traceable as evidence that the product complies with the specified requirements. The retention period of quality-related records shall meet the requirements of laws and regulations to ensure that the records after the previous inspection can be obtained during this inspection and for no less than 24 months.

工厂应确保记录的清晰、完整、可追溯，以作为产品符合规定要求的证据。与质量相关的记录保存期应满足法律法规的要求，确保在本次检查中能够获得前次检查后的记录，且至少不低于24个月。

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

工厂应识别并保存与产品认证相关的重要文件和质量信息，如型式试验报告、工厂检查结果、认证证书状态信息（有效、暂停、撤销、注销等）、认证变更批准信息、监督抽样检测报告、产品质量投诉及处理结果等。

3.3 Procurement and critical parts control 采购与关键件控制

3.3.1 Control of purchases 采购控制

For the key parts purchased, the factory shall identify and specify its technical requirements in the procurement documents, which shall also ensure that the final product meets the certification requirements.

对于采购的关键件，工厂应识别并在采购文件中明确其技术要求，该技术要求还应确保最终产品满足认证要求。

The factory shall establish and maintain the list of qualified producers / production enterprises of key parts and purchase the key parts. The factory shall keep the records of the purchase and use of key parts, such as purchase order, entry and exit list, ledger, etc.

工厂应建立、保持关键件合格生产者/生产企业名录并从中采购关键件，工厂应保存关键件采购、使用等记录，如进货单、出入库单、台帐等。

3.3.2 Quality control of the critical parts 关键件的质量控制

3.3.2.1 The plant shall establish and maintain documented procedures to complete verification and / or inspection of technical requirements for purchasing key parts and keep relevant records upon purchase (entry).

工厂应建立并保持文件化的程序，在进货（入厂）时完成对采购关键件的技术要求进行验证和/或检验并保存相关记录。

3.3.2.2 For the quality characteristics of the purchased key parts, the factory shall select the appropriate control mode to ensure that the technical requirements of the key parts and the final product meets the certification requirements and keep relevant records. Appropriate control methods may include:

对于采购关键件的质量特性，工厂应选择适当的控制方式以确保持续满足关键件的技术要求，以及最终产品满足认证要求，并保存相关记录。适当的控制方式可包括：

(a)The result of voluntary product certification or may be mandatory for the final product certification shall ensure the

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validity of the certificate status.

(a)获得认证证书或可为最终产品强制性认证承认的自愿性产品认证结果，工厂应确保其证书状态的有效。

(b)The factory shall formulate the control plan by itself, and the control effect shall not be less than the requirements of 3.3.2.2 (a) .

(b)工厂自身制定控制方案，其控制效果不低于3.3.2.2(a)的要求。

3.3.2.3 When purchasing key parts from distributors and traders, the factory shall take appropriate measures to ensure the consistency of purchasing key parts and continuously meet its technical requirements.

当从经销商、贸易商采购关键件时，工厂应采取适当措施以确保采购关键件的一致性并持续满足其技术要求。

For the key components, components, sub-assemblies, assemblies and semi-finished products produced by the entrusted subcontractor, the factory shall control them according to the procurement of key parts to ensure that the subcontracted products continue to meet the specified requirements.

对于委托分包方生产的关键部件、组件、分总成、总成、半成品等，工厂应按采购关键件进行控制，以确保所分包的产品持续满足规定要求。

For self-produced key parts, control according to 3.4.

对于自产的关键件，按3.4进行控制。

3.4 Industrial control 生产过程控制

3.4.1 The factory shall identify the processes affecting the quality of the certified products (the key processes), and the identified key processes shall meet the specified requirements. The operator of the key process shall have the corresponding ability; the control of the key process shall ensure the conformity between the certified products and the standards and the product consistency; if the quality of the certified products cannot be guaranteed without the documents of the key process, the corresponding operation instructions shall be formulated to control the production process.

工厂应对影响认证产品质量的工序（简称关键工序）进行识别，所识别的关键工序应符合规定要求。关键工序操作人员应具备相应的能力；关键工序的控制应确保认证产品与标准的符合性、产品一致性；如果关键工序没有文件规定就不能保证认证产品质量时，则应制定相应的作业指导书，使生产过程受控。

3.4.2 If the product production process has requirements for environmental conditions, the factory shall ensure that

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the working environment meets the specified requirements.

产品生产过程如对环境条件有要求,工厂应保证工作环境满足规定要求。

3.4.3 When necessary, the plant shall monitor and measure the appropriate process parameters.

必要时，工厂应对适宜的过程参数进行监视、测量。

3.4.4 The plant shall establish and maintain a maintenance system for the production equipment to ensure that the capacity of the equipment continues to meet the production requirements.

工厂应建立并保持对生产设备的维护保养制度，以确保设备的能力持续满足生产要求。

3.4.5 When necessary, the factory shall check, monitor and measure the products and their characteristics at the appropriate stage of production as required by the regulations to ensure the compliance between the products and the standards and the product consistency.

必要时，工厂应按规定要求在生产的适当阶段对产品及其特性进行检查、监视、测量，以确保产品与标准的符合性及产品一致性。

3.5 Routine inspection 例行检验

The factory shall establish and maintain documented procedures to control the routine inspection of the final product; the inspection procedures shall meet the specified requirements and the procedures shall include inspection frequency, item, content, method, determination, etc. The factory shall implement and maintain the relevant inspection records.


工厂应建立并保持文件化的程序，对最终产品的例行检验进行控制；检验程序应符合规定要求，程序的内容应包括检验频次、项目、内容、方法、判定等。工厂应实施并保存相关检验记录。

For inspections entrusted to external institutions, the factory shall ensure that the capacity of the external institutions meets the inspection requirements and save the evaluation results of relevant capabilities, such as laboratory accreditation certificate.

对于委托外部机构进行的检验，工厂应确保外部机构的能力满足检验要求，并保存相关能力的评价结果，如实验室认可证明等。

3.6 Test the instruments and equipment 检验试验仪器设备

3.6.1 Basic Requirements 基本要求

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

工厂应配备足够的检验试验仪器设备，确保在采购、生产制造、最终检验试验等环节中使用的仪器设备能力满足认证产品批量生产时的检验试验要求。

Inspection and test personnel should be able to use the instruments and equipment correctly, master the inspection and test requirements and implement them effectively.

检验试验人员应能正确使用仪器设备，掌握检验试验要求并有效实施。

3.6.2 Calibration and verification 校准、检定

The instruments and equipment used to determine the certified products meet the specified requirements shall be calibrated or verified in the specified cycle, and the calibration or verification cycle shall be set according to the use frequency of the equipment and the previous calibration; for internal calibration, the factory shall stipulate the calibration method, acceptance criteria and calibration cycle; the calibration or verification shall be traced to the national or international benchmark. The calibration or verification status of the instrument and equipment shall be easily identified by the use and management personnel. The factory shall keep the calibration or verification records of the instruments and equipment.

用于确定所生产的认证产品符合规定要求的检验试验仪器设备应按规定的周期进行校准或检定，校准或检定周期可按仪器设备的使用频率、前次校准情况等设定；对内部校准的，工厂应规定校准方法、验收准则和校准周期等；校准或检定应溯源至国家或国际基准。仪器设备的校准或检定状态应能被使用及管理人员方便识别。工厂应保存仪器设备的校准或检定记录。

For the calibration or verification activities entrusted to the external institutions, the factory shall ensure that the capacity of the external institutions meets the calibration or verification requirements and keep the relevant capability evaluation results.

对于委托外部机构进行的校准或检定活动，工厂应确保外部机构的能力满足校准或检定要求，并保存相关能力评价结果。

Note: For key monitoring and measuring devices in production process control, the factory shall manage them according to the requirements of product certification implementation rules.

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注：对于生产过程控制中的关键监视测量装置，工厂应根据产品认证实施规则的要求进行管理。

3.6.3 Functional check 功能检查

If necessary, the factory shall conduct functional inspection on the routine inspection equipment according to the prescribed requirements. When the functional inspection results are found not to meet the requirements, it shall be traceable to the tested products; these products shall be retested if necessary. The factory shall specify the measures to take when the operator finds the functional failure of the instrument and equipment.

必要时，工厂应按规定要求对例行检验设备实施功能检查。当发现功能检查结果不能满足要求时，应能追溯至已检测过的产品；必要时，应对这些产品重新检测。工厂应规定操作人员在发现仪器设备功能失效时需采取的措施。

The factory shall keep the results of functional inspection and measures taken during functional failure of instruments and equipment.

工厂应保存功能检查结果及仪器设备功能失效时所采取措施的记录。

3.7 Control of the nonconforming products 不合格品的控制

3.7.1 For the unqualified products found in the procurement, manufacturing, inspection and other links, the factory shall take measures such as identification, isolation and disposal to avoid the unexpected use or delivery of the unqualified products. The reworked or repaired products shall be re-inspected.

对于采购、生产制造、检验等环节中发现的不合格品，工厂应采取标识、隔离、处置等措施，避免不合格品的非预期使用或交付。返工或返修后的产品应重新检验。

3.7.2 For national and provincial supervision and spot inspection, product recall, customer complaints and complaints, the factory shall analyze the causes of unqualified and take appropriate corrective measures. The factory shall keep the records of the unqualified information, cause analysis, disposal and corrective measures of the certified products.

对于国家级和省级监督抽查、产品召回、顾客投诉及抱怨等来自外部的认证产品不合格信息，工厂应分析不合格产生的原因，并采取适当的纠正措施。工厂应保存认证产品的不合格信息、原因分析、处置及纠正措施等记录。

3.7.3 The factory learned that its certification products have major quality problems (such as national and provincial supervision and spot inspection unqualified, etc.), should timely notify the certification body.

工厂获知其认证产品存在重大质量问题时（如国家级和省级监督抽查不合格等），应及时通知认证机构。

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3.8 Internal quality audit 内部质量审核

The plant shall establish documented internal quality audit procedures to ensure continuous compliance with plant quality assurance capabilities, product consistency and product and standards. For the problems found in the audit, the factory shall take appropriate corrective measures and preventive measures. The factory shall preserve the internal quality audit results.

工厂应建立文件化的内部质量审核程序，确保工厂质量保证能力的持续符合性、产品一致性以及产品与标准的符合性。对审核中发现的问题，工厂应采取适当的纠正措施、预防措施。工厂应保存内部质量审核结果。

3.9 Change and consistency control of certified products 认证产品的变更及一致性控制

The factory shall establish and maintain documented procedures to control the changes (such as process, production conditions, key parts and product structure, etc.) that may affect product consistency and product and standard conformity, and the procedures shall comply with the specified requirements. The change shall be implemented after the approval of the certification body or the certification technical director, and the factory shall keep relevant records.

工厂应建立并保持文件化的程序，对可能影响产品一致性及产品与标准的符合性的变更（如工艺、生产条件、关键件和产品结构等）进行控制，程序应符合规定要求。变更应得到认证机构或认证技术负责人批准后方可实施，工厂应保存相关记录。

The factory shall control the product consistency from the applicable quality links, such as product design (design change), process and resources, procurement, manufacturing, inspection, product protection and delivery, to ensure that the products continue to meet the requirements of the certification basis standards.

工厂应从产品设计（设计变更）、工艺和资源、采购、生产制造、检验、产品防护与交付等适用的质量环节，对产品一致性进行控制，以确保产品持续符合认证依据标准要求。

3.10 Product protection and delivery 产品防护与交付

Product protection, such as identification, handling, packaging, storage and protection, shall meet the specified requirements. If necessary, the factory shall control the delivery process of the products as required.

工厂在采购、生产制造、检验等环节所进行的产品防护，如标识、搬运、包装、贮存、保护等应符合规定要求。必要时，工厂应按规定要求对产品的交付过程进行控制。

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3.11 The use of certification marks and certificates 认证标志和证书的使用

The management and use of certificates and marks by the factory should comply with the relevant regulations of Saso and NCT for voluntary certification. For uniformly printed marks or those added by printing or molding methods, the factory should keep usage records. For the following products, marks shall not be added or they shall not be released:

工厂对证书和标志的管理及使用应符合Saso以及NCT自愿性认证相关规定。对于统一印制的标志或采用印刷、模压等方式加施的标志,工厂应保存使用记录。对于下列产品,不得加施标志或放行:

(a) Unapproved products未获认证产品;

(b) After obtaining the certification, any changes must be confirmed by the certification body. However, products that have not been confirmed are not allowed.获证后的变更需经认证机构确认,但未经确认的产品;

(c) Products that have exceeded the validity period of certification超过认证有效期的产品;

(d) Products listed on certificates that have been suspended, revoked or cancelled已暂停、撤销、注销的证书所列产品;

(e) Non-conforming products不合格产品。

3.12 Certificate recovery 证书恢复

1) Confirm whether the reason for the suspension of the certificate has been eliminated确认证书暂停原因是否已消除?

2) Was the certificate product not produced or used with the certification mark during the suspension period?暂停证书产品未在暂停期间生产或使用认证标志?

3) If the certificate is suspended due to quality issues, have the non-compliant products been properly disposed of?如因质量原因暂停证书, 不合格产品是否已妥善处理?

3.13 The verification results of the rectification of the previous non-compliance issues 对的上次不符合项的整改验证情况

1) Have the non-conformities identified during the last inspection of the factory been rectified?工厂上次检查的不符合项是否已经纠正?

2) Have the relevant measures been effectively implemented?相关的措施是否得到有效实施?