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**TECHNICAL**  
**SPECIFICATION**

**ISO/TS**  
**16949**

Third edition

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**质量管理体系—**  
**汽车生产件及相关服务件组织应用**  
**ISO9001:2008的特殊要求**

**Quality management systems —**

**Particular requirements for the application  
of ISO 9001:2008 for automotive production  
and relevant service part organizations**

*Systèmes de management de la qualité---*

*Exigences particulières pour l'application de l'ISO 9001:2008 pour la  
production de série et de pièces de rechange dans l'industrie automobile*



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## 前言 Foreword

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ISO/TS 16949 是由国际汽车工业特别行动小组 (IATF), 在 ISO/TC176 质量管理和质量保证技术委员会支持下制定的。

ISO/TS 16949 was prepared by the International Automotive Task Force (IATF) with support from ISO/TC 176, Quality management and quality assurance.

通过根据 ISO9001 :2008 所作的技术修订,第三版的 ISO/TS16949 取消并替代了第二版(ISO/TS 16949:2002)

This third edition of ISO/TS 16949 cancels and replaces the second edition (ISO/TS 16949:2002), which has been



technically amended according to ISO 9001:2008.

方框内的文本是 **ISO 9001: 2008** 的原文内容，方框外是行业特殊补充的要求。

Boxed text is original ISO 9001:2008 text. The sector-specific supplemental requirements are outside the boxes.

在本技术规范中，“应”（shall）表示要求，“应当”（should）表示建议。标示有“注”（NOTE）的段落是对理解或澄清相关要求的指南。

In this Technical Specification, the word “shall” indicates a requirement. The word “should” indicates a recommendation. Paragraphs marked “NOTE” are for guidance in understanding or clarifying the associated requirement.

所有用“例如”引出的建议都只具有指导性作用。

Where the term “such as” is used, any suggestions given are for guidance only.

附录 A 是本技术规范的引用文件，构成技术规范的一部分。

Annex A forms a normative part of this Technical Specification.

## 有关认证的说明

按照 IATF 的认证方案（见《IATF 认可规则》）所获取的本技术规范的认证，包括任何的顾客特殊要求（如果有），将获得 IATF 的顾客成员的认可。

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The certification to this Technical Specification, including customer-specific requirements if any, is recognized by the customer members of IATF when achieved according to the IATF certification scheme (see the “Rules for achieving IATF recognition”).

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## 引言 Introduction

### 0.1 总则 General

#### ISO9001:2008 质量管理体系要求

#### ISO 9001:2008, Quality management systems — Requirements

## 引言 Introduction

### 0.1 总则 General

采纳质量管理体系是组织的一项战略性决策。一个组织的质量管理体系的设计和实施受下列因素的影响：

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by

- a) 组织的环境、该环境的变化或与该环境有关的风险；
  - b) 组织不断变化的需求；
  - c) 组织的具体目标；
  - d) 组织所提供的产品；
  - e) 组织所采用的过程；
  - f) 组织的规模和组织结构；
- a) its organizational environment, changes in that environment, and the risks associated with that environment
  - b) its varying needs
  - c) its particular objectives
  - d) the products it provides
  - e) the processes it employs
  - f) its size and organizational structure

统一质量管理体系的结构或文件不是本标准的目的。

It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

本标准规定的质量管理体系要求是对产品要求的补充。“注”是理解和说明有关要求的指南。

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked «NOTE» is for guidance in understanding or clarifying the associated requirement.

本标准能用于内部和外部（包括认证机构）评价组织满足顾客、适用于产品的法律法规要求和组织自身要求的能力。

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.

本标准的制定已经考虑了 ISO 19000 和 ISO19004 中所阐明的质量管理原则。

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

## 0.2 过程方法 Process approach

### ISO9001:2008 质量管理体系体系一要求

### ISO 9001:2008, Quality management systems — Requirements

## 0.2 过程方法 Process approach

本标准鼓励在建立、实施质量管理体系以及在改进其有效性时采用过程方法，通过满足顾客要求，增强顾客满意度。

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

为了使组织有效运行，应确定和管理许多相互联系的活动。通过使用资源和管理，将输入转换为输出的一项或一组活动，可视为一个过程，通常，一个过程的输出直接形成下一个过程的输入。

For an organization to function effectively, it has to determine and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

为了产生期望的结果，由过程组成的系统在组织内的应用，连同这些过程的识别和相互作用，以及对这些过程的管理，可称之为“过程方法”

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the “process approach”

过程方法的一个优点是对过程系统中单个过程之间的联系以及过程的组合和相互作用进行连续的控制。An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

在质量管理体系应用过程方法时，强调以下方面的重要性：

- a) 理解和满足要求；
- b) 需要从增值的角度考虑过程；
- c) 获得过程绩效和有效性的结果；
- d) 在客观测量的基础上，持续改进过程。

When used within a quality management system, such an approach emphasizes the importance of

- a) understanding and fulfilling requirements,
- b) the need to consider processes in terms of added value,
- c) obtaining results of process performance and effectiveness, and
- d) continual improvement of processes based on objective measurement.

图 1 所反映的以过程为基础的质量管理体系模式展示了第 4 章至第 8 章中所提出的过程联系。该图反映了在规定输入要求时，顾客起着重要的作用。对顾客满意的监视，要求对顾客有关组织是否已满足其要求的感受信息进行评价。该模式虽覆盖了本标准的所有要求，但却未详细地反映各过程。

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

注：此外，称之为“PDCA”的方法可适用于所有过程。PDCA 模式可简述如下：

P—策划：根据顾客的要求和组织的方针，为提供结果建立必要的目标和过程；

D—实施：实施过程；

C—检查：根据方针、目标和产品要求，对过程和产品进行监视和测量，并报告结果；

A—处置：采取措施，以持续改进过程业绩。

NOTE In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

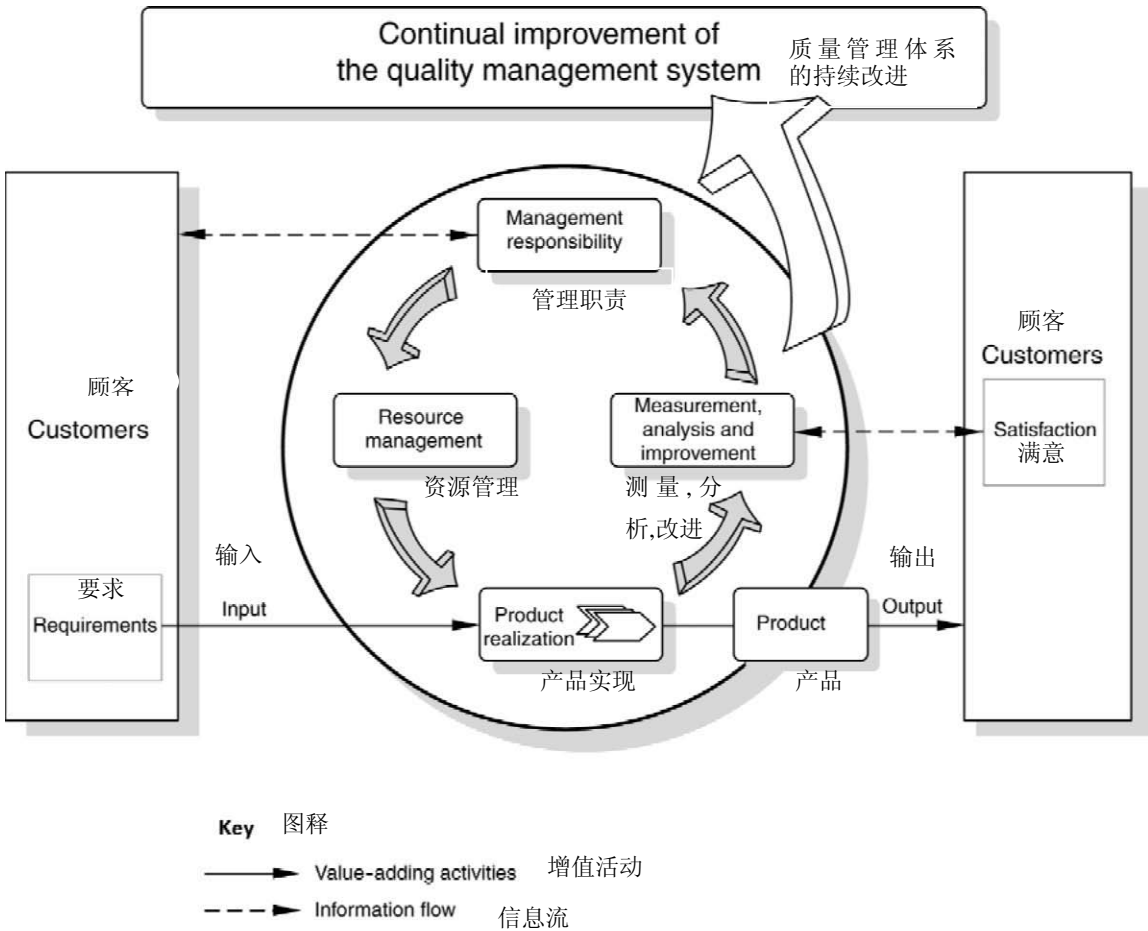


Figure 1 — Model of a process-based quality management system

图 1 以过程为基础的质量管理体系模式

### 0.3 与 ISO9004 的关系 Relationship with ISO 9004

#### ISO9001:2008,质量管理体系体系—要求

#### ISO 9001:2008, Quality management systems — Requirements

### 0.3 与 ISO9004 的关系 Relationship with ISO 9004

ISO9001 和 ISO9004 都是质量管理体系标准，这两项标准相互补充，但也可单独使用。

ISO9001 and ISO9004 are quality management system standards which have been designed to complement each other, but can also be used independently.

ISO9001 规定了质量管理体系要求，可供组织内部使用，也可用于认证或合同目的。ISO9001 所关注的是质量管理体系在满足顾客要求方面的有效性。

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

在本标准发布时，ISO9004 处于修订中。修订后的 ISO9004 将为组织在复杂、要求更高和不断变化的环境中获得持续成功提供管理指南。与 ISO9001 相比，ISO9004 关注质量管理的更宽范围；通过系统和持续改进组织的绩效，满足所有相关方的需求和期望。然而 ISO9004 不拟于用于认证、法律法规和合同的目的。

At the time of publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.

注：应当由最高管理者在组织内宣传和贯彻 ISO9000：2005 和 ISO9004 中涉及的八项质量管理原则的知识及其应用。

Note :The knowledge and use of the eight quality management principles referred to in the ISO 9000:2005 and ISO 9004 should be demonstrated and cascaded through the organization by top management.

## 0.4 与其它管理体系的相容性 Compatibility with other management systems

### ISO9001:2008 质量管理体制体系—要求

ISO 9001:2008, Quality management systems — Requirements

#### 0.4 与其它管理体系的相容性

为方便使用者，本标准在起草过程中适当的考虑了 ISO14001-2004 标准的内容，以增强两类标准的相容性。附录 A 表明了 ISO9001-2008 与 ISO14001-2004 之间的对应关系

During the development of this international standard, due consideration was given to the provision of ISO14001:2004 to enhance the compatibility of the two standards for benefit of the user community. Annex a shows the correspondence between ISO14001:2004.

本国际标准不包括其它管理体系所规定的要求，例如环境管理，职业健康和安全管理，财务管理或风险管理。然而本国际标准能够使组织的质量管理体系与有关的管理体系要求相互结合或一体化。组织为了建立符合本国际标准要求的质量管理体系，有可能会改变其现有的管理体系。

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

## **0.5 ISO/TS16949 的目的** Goal of this Technical Specification

本技术规范的目标是在供应链中建立持续改进，强调缺陷预防，减少变差和浪费的质量管理体系。

The goal of this Technical Specification is the development of a quality management system that provides for continual improvement, emphasizing defect prevention and the reduction of variation and waste in the supply chain.

本技术规范与适当的顾客特殊要求相结合，规定了签署本文件顾客的基本质量管理体系要求。

This Technical Specification, coupled with applicable customer-specific requirements, defines the fundamental quality management system requirements for those subscribing to this Technical Specification.

本技术规范旨在避免多重认证审核，并为汽车生产件及服务件的组织建立质量管理体系提供了一个通用的方法。

This Technical Specification is intended to avoid multiple certification audits and provide a common approach to a quality management system for automotive production, and relevant service part organizations.



# 质量管理体系 ——

## 汽车生产件及相关服务件组织应用 ISO9001:2008 的特殊要求

Quality management systems – Particular requirements for the application of ISO 9001:2008 for automotive production, and relevant service part organizations

### 1 范围 Scope

#### 1.1 总则 General

#### ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems — Requirements

### 1 范围 Scope

#### 1.1 总则 General

本标准有下列需求的组织规定了质量管理体系要求；

- a) 需要证实它具有稳定地提供满足顾客和适用的法律法规要求的产品的能力；
- b) 通过体系的有效应用，包括体系持续改进的过程的有效应用，以及保证符合顾客与适用的法律法规要求，旨在增进顾客满意。

This International Standard specifies requirements for a quality management system where an organization

- a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

注 1：在本标准中，术语“产品”仅适用于：

- a) 预期提供给顾客的或顾客所要求的产品；；
- b) 产品实现过程所产生的任何预期输出；

注 2：法律法规要求可称作法定要求。

NOTE1: In this International Standard, the term “product”only applies to:

- a) product intended for, or required by, a customer.
- b) And intended output resulting from the product realization processes.

Note2: Statutory and regulatory requirements can be expressed as legal requirements.

本技术规范与 ISO9001:2008 相结合，规定了质量管理体系要求，用于汽车相关产品的设计和开发、生产，相关时，也适用于安装和服务。

This Technical Specification, in conjunction with ISO 9001:2008, defines the quality management system requirements for the design and development, production and, when relevant, installation and service of automotive-related products.

本技术规范适用于组织进行顾客指定产品和/或服务零件的制造现场。

This Technical Specification is applicable to sites of the organization where customer-specified parts, for production and/or service, are manufactured.

“支持功能”，无论其在现场或外部场所（如设计中心、公司总部及分销中心），由于它们对现场其支持性作用而构成现场审核的一部分。但是，但不能获得本技术规范的认证。

Supporting functions whether on-site or remote (such as design centres, corporate headquarters and distribution centres), form part of the site audit as they support the site, but cannot obtain stand-alone certification to this Technical

Specification.

本技术规范可适用于整个汽车供应链。

This Technical Specification can be applied throughout the automotive supply chain.

## 1.2 应用 Application

### ISO9001:2008 质量管理体系体系—要求

### ISO 9001:2008, Quality management systems — Requirements

## 1.2 应用 Application

本标准规定的所有要求是通用的，旨在适用于各种类型、不同规模和提供不同产品的组织。

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

当本标准的任何要求因组织及其产品的特点不适用时，可以考虑对其进行删减。

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

如果进行删减，应仅限于本标准第 7 章的要求，并且这样的删减不影响组织提供满足顾客要求和适用法律法规要求的产品的能力或责任，否则不能声称符合本标准。

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

本技术规范仅允许在组织在没有产品设计和开发责任的情况下删减与 7.3 有关的内容。

不允许删减制造过程设计。

The only permitted exclusions for this Technical Specification relate to 7.3 where the organization is not responsible for product design and development.

Permitted exclusions do not include manufacturing process design.

## 2 引用标准 Normative reference

### ISO9001:2008 质量管理体系体系—要求

### ISO 9001:2008, Quality management systems — Requirements

### ISO9001:2008 质量管理体系体系—要求

下列文件的条款通过本标准的引用而成为本标准的条款。凡是注日期的引用文件，其随后所有的修改单（不包括勘误的内容）或修订版均不适用于本标准，然而，鼓励根据本标准达成协议的各方研究是否可使用这些文件的最新版本。凡是不注日期的引用文件，其最新版本适用于本标准。

ISO9000-2005 质量管理体系 基础和术语。

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2005, Quality management systems — Fundamentals and vocabulary.

### 3 术语和定义 Terms and definitions

#### **ISO9000:2008 质量管理体系—要求**

#### **ISO 9001:2008, Quality management systems — Requirements**

本标准采用 ISO9000 中所确立的术语和定义

For the purposes of this document the terms and definitions given in ISO 9000 apply.

本标准中所有出现的术语“产品”之处，也可指“服务”。

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

#### **3.1 汽车行业术语和定义 Terms and definitions for the automotive industry**

本文件应用了 ISO9001:2005 以及下列内容中所确立的术语和定义。

For the purposes of this document, the terms and definitions given in ISO 9000 : 2005 and the following apply.

##### **3.1.1. 控制计划 control plan**

对控制产品所要求的系统和过程的形成文件的描述。

注：见附录 A

documented description of the systems and processes required for controlling product .

Note: see annex A

##### **3.1.2. 具有设计责任的组织 design responsible organization**

有权制定一个新的或更改现有的产品规范的组织。

organization with authority to establish a new, or change an existing product specification .

注：该职责包括在顾客指定的应用范围内。试验并验证设计性能。

NOTE This responsibility includes testing and verification of design performance within the customer's specified application.

##### **3.1.3 防错 error proofing**

为防止制造不合格产品而进行的产品和制造过程的设计和开发。

product and manufacturing process design and development to prevent manufacture of non-conforming products.

##### **3.1.4 实验室 laboratory**

进行检验、试验和校准的设施，其范围包括但不限于化学、冶金、尺寸、物理、电性能或可靠性试验。

facility for inspection, test or calibration that may include, but is not limited to, chemical, metallurgical, dimensional, physical, electrical or reliability testing.

##### **3.1.5 实验室范围 laboratory scope**

受控文件包括：

- 实验室有资格进行的特定试验，评价和校准，
- 用来进行上述活动的设备清单，以及
- 用来进行上述活动的方法和标准的清单。

controlled document containing :

- specific tests, evaluations and calibrations that a laboratory is qualified to perform,
- a list of the equipment which it uses to perform the above, and
- a list of methods and standards to which it performs the above.

### 3.1.6 制造 manufacturing

以下制作或加工的过程:

- 生产材料;
- 生产或服务件;
- 装配, 或
- 热处理、焊接、喷漆、电镀或其他表面处理。

process of making or fabricating :

- o production materials,
- o production or service parts,
- o assemblies, or
- o heat treating, welding, painting, plating or other finishing services.

### 3.1.7 预测性维护 predictive maintenance

基于针对通过预测可能的失效模式的过程数据而避免维护问题的活动。

activities based on process data aimed at the avoidance of maintenance problems by prediction of likely failure modes.

### 3.1.8 预防性维护 preventive maintenance

为消除设备失效和生产的计划外中断的原因而策划的措施, 它是制造过程设计的一项输出。

planned action to eliminate causes of equipment failure and unscheduled interruptions to production, as an output of the manufacturing process design.

### 3.1.9 额外运费 premium freight

在合同约定的交付之外发生的超出成本或费用。

注: 可因方法、数量、未按计划或延迟交付等原因引起。

extra costs or charges incurred additional to contracted delivery.

NOTE this can be caused by method, quantity, unscheduled or late deliveries, etc.

### 3.1.10 外部地点 remote location

支持现场, 且不存在生产过程的场所。

location that supports sites and at which non-production processes occur .

### 3.1.11 现场 site

发生增值的制造过程的场所

location at which value-added manufacturing processes occur.

### 3.1.12 特殊特性 special characteristic

产品特性或制造过程参数, 可能影响产品的安全性或法规的符合性、配合、功能、性能或其后续过程的产品特性或制造过程参数。

product characteristic or manufacturing process parameter which may affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.

## 4 质量管理体系 Quality management system

### 4.1 总要求 General requirements

#### ISO9001:2008 质量管理体系—要求

#### ISO 9001:2008 Quality management systems – Requirements

## 4 质量管理体系 Quality management system

### 4.1 总要求 General requirements

组织应按本标准的要求建立质量管理体系，形成文件，加以实施和保持，并持续改进其有效性。

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

组织应：

- a) 确定质量管理体系所需要的过程及其在整个组织中的应用（见 1.2）
- b) 确定这些过程的顺序和相互作用；
- c) 确定所需的准则和方法，以确保这些过程的运作和控制有效；
- d) 确保可以获得必要的资源和信息，以支持这些过程的有效运行和监视；
- e) 监视、测量（适用时）和分析这些过程。
- f) 实施必要的措施，以实现对这些过程所策划的结果和对这些过程的持续改进。

The organization shall

- a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2),
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure where applicable and analyse these processes, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

组织应按本标准的要求管理这些过程。

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

组织如果选择将影响产品符合要求的任何过程外包，应确保对这些过程的控制。对此类外包过程的控制类型和程度应在质量管理体系中加以规定。

注 1：上述质量管理体系所需的过程应当包括与管理活动、资源提供、产品实现和测量、分析和改进有关的过程。

注 2：“外包过程”是为了质量管理体系的需要，由组织选择，并由外部方实施的过程

注 3：组织确保对外包过程的控制，并不免除其满足所有顾客要求和法律法规要求的责任。对外包过程控制的类型和程度可受诸如下列因素的影响

- a) 外包过程对组织提供满足要求的产品的能力的潜在影响。
- b) 对外包过程控制的分担程度。
- c) 通过应用 7.4 条款实现所需控制的能力

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

NOTE1: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement, analysis and improvement.

NOTE 2 An "outsourced process" is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

- a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,
- b) the degree to which the control for the process is shared,
- c) the capability of achieving the necessary control through the application of 7.4.

#### **4.1.1 General requirements — Supplemental**

##### **4.1.1 总要求—补充**

确保外包过程的控制不能免除组织对符合所有顾客要求的职责。

注：另见 7.4.1 和 7.4.1.3

Ensuring control over outsourced processes shall not absolve the organization of the responsibility of conformity to all customer requirements.

NOTE See also 7.4.1 and 7.4.1.3.

#### **4.2 文件要求 Documentation requirements**

##### **4.2.1 总则 General**

#### **ISO9001:2008 质量管理体系—要求**

#### **ISO 9001:2008, Quality management systems – Requirements**

#### **4.2 文件要求 Documentation requirements**

##### **4.2.1 总则 General**

质量管理体系文件应包括：

- a) 形成文件的质量方针和质量目标
- b) 质量手册
- c) 本国际标准所要求的程序文件和记录；
- d) 组织为确保其过程有效策划、运行和得到控制所需要的文件,包括记录；

The quality management system documentation shall include

- a) documented statements of a quality policy and quality objectives,
- b) a quality manual,
- c) documented procedures required by this International Standard,,and
- d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

注 1：本标准出现“形成文件的程序”之处，即要求建立程序，形成文件，并加以实施和保持；一个文件可包括对一个或多个程序的要求。一个形成文件的程序的要求可以被包含在多个文件中。

NOTE 1 Where the term «documented procedure» appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

注 2: 不同组织的质量管理体系文件的多少与详略程度可以不同, 取决于:

- a) 组织的规模和活动类型;
- b) 过程及其相互作用的复杂程度;
- c) 人员的能力

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

- a) the size of organization and type of activities,
- b) the complexity of processes and their interactions, and
- c) the competence of personnel.

注 3: 文件可采用任何形式或类型的媒体

NOTE 3 The documentation can be in any form or type of medium.

#### 4.2.2 质量手册 Quality manual

##### ISO9001:2008 质量管理体系—要求

##### ISO 9001:2008, Quality management systems – Requirements

#### 4.2.2 质量手册 Quality manual

组织应编制和保持质量手册, 质量手册包括:

- a) 质量管理体系的范围, 包括任何删减的细节和正当的理由 (见 1.2);
- b) 为质量管理体系而建立的形成文件的程序或对其引用;
- c) 质量管理体系过程之间相互作用的描述。

The organization shall establish and maintain a quality manual that includes

- a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),
- b) the documented procedures established for the quality management system, or reference to them, and
- c) a description of the interaction between the processes of the quality management system

#### 4.2.3 文件控制 Control of documents

##### ISO9001:2008 质量管理体系—要求

##### ISO 9001:2008, Quality management systems – Requirements

#### 4.2.3 文件控制 Control of documents

质量管理体系所要求的文件应予以控制。记录是一种特殊类型的文件, 应根据 4.2.4 的要求进行控制。

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

应编制形成文件的程序, 以规定以下方面所需的控制:

- a) 为使文件是充分与适宜的, 文件发布前得到批准。
- b) 必要时对文件进行评审与更新, 并再次批准;

- c) 确保文件的更改和现行修订状态得到识别;
- d) 确保在使用处可获得适用文件的有关版本;
- e) 确保文件保持清晰、易于识别;
- f) 确保组织所规定的策划和运行质量管理体系所需的外来文件得到识别;并控制其分发;
- g) 防止作废文件的非预期使用,若因任何原因而保留作废文件时,对这些文件进行适当的标识。

A documented procedure shall be established to define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin are determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

#### 4.2.3.1 工程规范 Engineering specifications

组织应有一个过程,以保证按顾客要求的时间安排及时评审、发放和实施所有顾客工程标准/规范及其更改。及时评审应当尽快进行,不应超过两个工作周。

组织应保存每项更改在生产中实施日期的记录。实施应包括对文件的更新。

The organization shall have a process to assure the timely review, distribution and implementation of all customer engineering standards/specifications and changes based on customer required schedule. Timely review should be as soon as possible. and shall not exceed two working weeks.

The organization shall maintain a record of the date on which each change is implemented in production. Implementation shall include updated documents.

注:当设计记录引用了这些规范或这些规范影响生产件批准过程的文件,例如:控制计划,FMEAs等时,这些标准/规范的更改要求对顾客的生产件批准记录进行更新。

NOTE A change in these standards/specifications requires an updated record of customer production part approval when these specifications are referenced on the design record or if they affect documents of production part approval process, such as control plan, FMEAs, etc.

#### 4.2.4 记录的控制 Control of records

##### ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems – Requirements

#### 4.2.4 记录的控制 Control of records

为提供符合要求和质量管理体系有效运行的证据而建立的记录,应得到控制。

组织应编制形成文件的程序,以规定记录的标识、贮存、保护、检索、保存期限和处置所需的控制。

记录应保持清晰、易于识别和检索。

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.



The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

注 1: 以上“处置”包括废弃。

注 2: “记录”还包括顾客指定的记录。

NOTE 1 "Disposition" above includes disposal.

NOTE 2 "Records" also include customer-specified records.

#### 4.2.4.1 记录保存 Records retention

记录控制应满足满足法规和顾客的要求。

The control of records shall satisfy regulatory and customer requirements.

## 5 管理职责 Management responsibility

### 5.1 管理承诺 Management commitment

#### ISO9001:2008 质量管理体系—要求

#### ISO 9001:2008, Quality management systems – Requirements

## 5 管理职责 Management responsibility

### 5.1 管理承诺 Management commitment

最高管理者应通过以下活动，对其建立、实施质量管理体系并持续改进其有效性的承诺提供证据：

- a) 向组织传达满足顾客和法律、法规要求的重要性；
- b) 制定质量方针；
- c) 确保质量目标的制定；
- d) 进行管理评审；
- e) 确保资源的获得。

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- b) establishing the quality policy,
- c) ensuring that quality objectives are established,
- d) conducting management reviews, and
- e) ensuring the availability of resources.

#### 5.1.1 过程绩效 Process efficiency

最高管理应评审产品实现过程和支持过程，以确保它们的有效性和效率。

Top management shall review the product realization processes and the support processes to assure their effectiveness and efficiency.

### 5.2 以顾客为关注焦点 Customer focus

#### ISO9001:2008 质量管理体系—要求

#### ISO 9001:2008, Quality management systems – Requirement

## 5.2 以顾客为关注焦点 Customer focus

最高管理者应以增进顾客满意为目的，确保顾客的要求得到确定并予以满足。见 7.2.1 和 8.2.1)

Top management shall ensure that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

## 5.3 质量方针 Quality policy

### ISO9001:2008 质量管理体系—要求

### ISO 9001:2008, Quality management systems – Requirements

## 5.3 质量方针 Quality policy

最高管理者应确保质量方针：

- a) 与组织的宗旨相适应；
- b) 包括对满足要求和持续改进质量管理体系有效性的承诺；
- c) 提供制定和评审质量目标的框架；
- d) 在组织内得到沟通和理解；
- e) 在持续适宜性方面得到评审。

Top management shall ensure that the quality policy

- a) is appropriate to the purpose of the organization,
- b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
- c) provides a framework for establishing and reviewing quality objectives,
- d) is communicated and understood within the organization, and
- e) is reviewed for continuing suitability.

## 5.4 策划 Planning

### 5.4.1 质量目标 Quality objectives

### ISO9001:2008 质量管理体系—要求

### ISO 9001:2008, Quality management systems – Requirements

## 5.4 策划 Planning

### 5.4.1 质量目标 Quality objectives

最高管理者应确保在组织的相关职能和层次上建立质量目标，质量目标包括满足产品要求所需的内容（见 7.1 a)）。质量目标应是可测量的，并与质量方针保持一致。

Top management shall ensure that quality objectives, including those needed to meet requirements for product (see 7.1a) are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy

#### 5.4.1.1 质量目标—补充 Quality objectives – Supplemental

最高管理者应确定质量目标及测量要求，并应包含在经营计划中，用于质量方针的展开。

注：质量目标应体现顾客期望并在规定的时间内是可以实现的。

Top management shall define quality objectives and measurements that shall be included in the business plan and used to

deploy the quality policy.

NOTE Quality objectives should address customer expectations and be achievable within a defined time period.

#### 5.4.2 质量管理体系策划 Quality management system planning

##### ISO9001:2008 质量管理体系—要求

##### ISO 9001:2008 Quality management systems — Requirements

#### 5.4.2 质量管理体系策划 Quality management system planning

最高管理者应确保：

- a) 对质量管理体系进行策划，以满足质量目标以及 4.1 的要求；
- b) 在对质量管理体系的变更进行策划和实施时，保持质量管理体系的完整性；

Top management shall ensure that

- a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
- b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

#### 5.5 职责、权限和沟通 Responsibility, authority and communication

##### 5.5.1 职责与权限 Responsibility and authority

##### ISO9001:2008 质量管理体系—要求

##### ISO 9001:2008, Quality management systems — Requirements

#### 5.5 职责、权限和沟通 Responsibility, authority and communication

##### 5.5.1 职责与权限 Responsibility and authority

最高管理者应确保组织内的职责、权限得到规定和沟通。

Top management shall ensure that the responsibilities and authorities are defined and communicated within the organization.

##### 5.5.1.1 质量职责 Responsibility for quality

不符合要求的产品或过程应立即通知给负有纠正措施职责和权限的管理者。

负责产品要求符合性的人员，应有权停止生产，以纠正质量问题。

所有班次的生产作业，应安排有负责确保产品要求符合性的人员，或指定其代理人员。

Managers with responsibility and authority for corrective action shall be promptly informed of products or processes which do not conform to requirements.

Personnel responsible for conformity to product requirement shall have the authority to stop production to correct quality problems.

Production operations across all shifts shall be staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements.

## 5.5.2 管理代表 Management representative

### ISO9001:2008 质量管理体系—要求

#### ISO 9001:2008, Quality management systems — Requirements

## 5.5.2 管理代表 Management representative

最高管理者应在本组织管理层中指定一名管理者，无论该成员在其他方面的职责如何，应具有以下方面的职责和权限：

- a) 确保质量管理体系所需的过程得到建立、实施和保持；
- b) 向最高管理者报告质量管理体系的业绩和任何改进的需求；
- c) 确保在整个组织内提高满足顾客要求的意识。

注：管理者代表的职责可包括与质量管理体系有关事宜的外部联络。

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes

- a) ensuring that processes needed for the quality management system are established, implemented and maintained,
- b) reporting to top management on the performance of the quality management system and any need for improvement, and
- c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

### 5.5.2.1 顾客代表 Customer representative

最高管理者应指定人员，赋予其职责和权限，以确保顾客要求得到体现，包括特殊特性的选择、制定质量目标和相关的培训、纠正和预防措施、产品设计和开发。

Top management shall designate personnel with responsibility and authority to ensure the customer requirements are addressed This includes selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development.

## 5.5.3 内部沟通 Internal communication

### ISO9001:2008 质量管理体系—要求

#### ISO 9001:2008, Quality management systems — Requirements

## 5.5.3 内部沟通 Internal communication

最高管理者应确保在组织内建立适当的沟通过程，并确保对质量管理体系的有效性进行沟通。

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

## 5.6 管理评审 Management review

### 5.6.1 总则 General

### ISO9001:2008 质量管理体系—要求

#### ISO 9001:2008, Quality management systems — Requirements

## **5.6 管理评审 Management review**

### **5.6.1 总则 General**

最高管理者应按策划的时间间隔评审质量管理体系，以确保其持续的适宜性、充分性和有效性。评审应包括评价质量管理体系的改进机会和变更的需要，包括质量方针和质量目标。

应保持管理评审的记录（见 4.2.4）。

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives

Records from management reviews shall be maintained (see 4.2.4)

#### **5.6.1.1 质量管理体系绩效 Quality management system performance**

作为持续改进过程的必不可少的部分。这些评审应包括对质量管理体系的所有要求及其绩效趋势的评审。

对质量目标进行监视及对不良质量成本的定期报告和评价应是管理评审的一部分内容（见 8.4.1 和 8.5.1）。

这些结果应予以记录，至少能为以下方面的成绩提供证据：

- a) 经营计划中规定的质量目标；
- b) 顾客对提供产品的满意度。

These reviews shall include all requirements of the quality management system and its performance trends as an essential part of the continual improvement process.

Part of the management review shall be the monitoring of quality objectives, and the regular reporting and evaluation of the cost of poor quality (see 8.4.1 and 8.5.1).

These results shall be recorded to provide, as a minimum, evidence of the achievement of

- a) the quality objectives specified in the business plan, and
- b) customer satisfaction with product supplied.

### **5.6.2 评审输入 Review input**

#### **ISO9001:2008 质量管理体系—要求**

ISO 9001:2008, Quality management systems — Requirements

#### **5.6.2 评审输入 Review input**

管理评审的输入应包括以下方面的信息：

- a) 审核结果；
- b) 顾客反馈；
- c) 过程表现和产品符合性；
- d) 预防和纠正措施的状况；
- e) 以往管理评审的跟踪措施；
- f) 可能影响质量管理体系的变更；
- g) 改进建议。

The input to management review shall include information on

- a) results of audits,

- b) customer feedback,
- c) process performance and product conformity,
- d) status of preventive and corrective actions,
- e) follow-up actions from previous management reviews,
- f) changes that could affect the quality management system, and
- g) recommendations for improvement.

#### **5.6.2.1 评审输入---补充 Review input – Supplemental**

管理评审的输入应包括实际的和潜在的外部失效以及他们对质量、安全或环境的影响分析。

Input to management review shall include an analysis of actual and potential field-failures and their impact on quality, safety, or the environment.

#### **5.6.3 评审输出 Review output**

##### **ISO9001:2008 质量管理体系—要求**

ISO 9001:2008, Quality management systems — Requirements

#### **5.6.3 评审输出 Review output**

管理评审的输出应包括与以下方面有关的任何决定和措施：

- a) 质量管理体系有效性及其过程有效性的改进；
- b) 与顾客要求有关的产品改进
- c) 资源需求

The output from the management review shall include any decisions and actions related to

- a) improvement of the effectiveness of the quality management system and its processes,
- b) improvement of product related to customer requirements, and
- c) resource needs

### **6. 资源管理 Resource management**

#### **6.1 资源的提供 Provision of resources**

##### **ISO9001:2008 质量管理体系—要求**

ISO 9001:2008, Quality management systems — Requirements

### **6 资源管理 Resource management**

#### **6.1 资源的提供 Provision of resources**

组织应确定并提供以下方面所需资源，以：

- a) 实施、保持质量管理体系并持续改进其有效性；
- b) 通过满足顾客要求，增强顾客满意。

The organization shall determine and provide the resources needed

- a) to implement and maintain the quality management system and continually improve its effectiveness, and
- b) to enhance customer satisfaction by meeting customer requirements.

#### **6.2 人力资源 Human resources**

## 6.2.1 总则 General

### ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems — Requirements

## 6.2 人力资源 Human resources

### 6.2.1 总则 General

基于适当的教育、培训、技能和经验，从事影响产品要求符合性工作的人员应是能够胜任的。

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience

NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

注：在质量管理体系中承担任何任务的人员都可能直接或间接地影响产品要求符合性。

## 6.2.2 能力、培训和意识 Competence, training and awareness

### ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems — Requirements

### 6.2.2 能力、培训和意识 Competence, training and awareness

组织应：

- a) 确定从事影响产品要求符合性的工作的人员的必要的能力；
- b) 适用时，提供培训或采取其他措施以满足这些需求；
- c) 评价采取措施的有效性；
- d) 确保员工意识到所从事活动的相关性和重要性，以及如何为实现质量目标做出贡献；
- e) 保持教育、培训、技能和经验的适当记录。

The organization shall

- a) determine the necessary competence for personnel performing work affecting conformity to product requirements.
- b) where applicable, provide training or take other actions achieve the necessary competence.
- c) evaluate the effectiveness of the actions taken,
- d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) maintain appropriate records of education, training, skills and experience (see 4.2.4)

#### 6.2.2.1 产品设计技能 Product design skills

组织应确保具有产品设计责任人员有达到设计要求的能力，并熟练地掌握适用的工具和技术。

组织应识别适用工具和技术。

The organization shall ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in applicable tools and techniques.

Applicable tools and techniques shall be identified by the organization.

### 6.2.2.2 培训 Training

组织应建立并保持形成文件的程序，识别培训需求并使所有从事对产品要求符合性有影响的人员具备能力。承担特定任务的人员应按要求进行资格认可，在满足顾客要求方面给予特别的关注。

注 1：本要求适用于组织各层次内所有影响质量的员工。

注 2：顾客特殊要求的范例之一是使用数字化的数学数据。

The organization shall establish and maintain documented procedures for identifying training needs and achieving competence of all personnel performing activities affecting conformity to product requirement. Personnel performing specific assigned tasks shall be qualified, as required with particular attention to the satisfaction of customer requirements.

NOTE 1 This applies to all employees having an effect on quality at all levels of the organization.

NOTE 2 An example of the customer specific requirements is the application of digitized mathematically based data.

### 6.2.2.3 岗位培训 Training on the job

对影响产品要求符合性的岗位，组织应对新的或调整工作岗位的人员提供岗位培训。包括合同工和代理工作人员。应将不符合要求给顾客带来的后果告知对质量有影响的人员。

The organization shall provide on-the-job training for personnel in any new or modified job affecting conformity to product requirements, including contract or agency personnel. Personnel whose work can affect quality shall be informed about the consequences to the customer of nonconformity to quality requirements

### 6.2.2.4 员工的鼓励 Employee motivation and empowerment

组织应建立一个激励员工实现质量目标、进行持续改进和建立促进创新的环境的过程。该过程应促进提高整个组织对质量和技术的认知。

组织应有一个过程，以测量员工对于所从事活动的相关性和重要性，以及如何为实现质量目标作出贡献（见 6.2.2.d）的认知程度。

The organization shall have a process to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment to promote innovation. The process shall include the promotion of quality and technological awareness throughout the whole organization.

The organization shall have a process to measure the extent to which its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives (see 6.2.2 d).

## 6.3 基础设施 Infrastructure

### ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems — Requirements

### 6.3 基础设施 Infrastructure

组织应确定、提供并维护为达到产品符合要求所需的基础设施。适用时，基础设施包括：

- a) 建筑物、工作场所和相应的设施；
- b) 过程设备（硬件和软件）；
- c) 支持性服务（如运输和通讯或信息系统）。

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

- a) buildings, workspace and associated utilities,



- b) process equipment,( both hardware and software ), and
- c) supporting services ( such as transport or communication or information systems ).

### 6.3.1 工厂、设施和设备策划 Plant, facility and equipment planning

组织应采用多方论证的方法(见 7.3.1.1) 来开发工厂、设施和设备的计划。工厂的布局应最大限度地减少材料地交转和搬运, 以及最大限度地增值使用场地空间, 便于材料的同步流动。应开发并实施对现有操作有效性进行评价和监视方法。

注: 这些要求应着重于精益制造原则, 并与质量管理体系的有效性相关联。

The organization shall use a multidisciplinary approach (see 7.3.1.1) for developing plant, facility and equipment plans. Plant layouts shall optimize material travel, handling and value-added use of floor space, and shall facilitate synchronous material flow. Methods shall be developed and implemented to evaluate and monitor the effectiveness of existing operations.

NOTE These requirements should focus on lean manufacturing principles and the link to the effectiveness of the quality management system.

### 6.3.2 应急计划 Contingency plans

组织应准备应急计划, 以在紧急事件下满足顾客的要求, 例如: 公用事业供应中断、劳动力短缺, 关键设备故障和外部退货等。

The organization shall prepare contingency plans to satisfy customer requirements in the event of an emergency such as utility interruptions, labour shortages, key equipment failure and field returns .

## 6.4 工作环境 Work environment

### ISO9001:2008 质量管理体系—要求

### ISO 9001:2008, Quality management systems — Requirements

### 6.4 工作环境 Work environment

组织应确定和管理为达到产品符合要求所需的工作环境。

注:术语工作环境是指工作时所处的条件, 包括物理的、环境的和其他因素, 如噪声、温度、湿度、照明或天气等。

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

NOTE The term “work environment” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).

### 6.4.1 为达到产品要求符合性的人员安全 Personnel safety to achieve conformity to product requirement

组织应落实产品安全性和方法以使员工潜在风险降至最低, 特别是在设计和开发以及制造过程活动中。

Product safety and means to minimize potential risks to employees shall be addressed by the organization, especially in the design and development process and in manufacturing process activities.

### 6.4.2 生产现场的清洁 Cleanliness of premises

组织应保持生产现场处于与产品和制造过程的需求相协调的有序、清洁和维护状态。

The organization shall maintain its premises in a state of order, cleanliness and repair consistent with the product and manufacturing process needs.

## 7 产品实现 Product realization

### 7.1 产品实现的策划 Planning of product realization

#### ISO9001:2008 质量管理体系—要求

#### ISO 9001:2008, Quality management systems — Requirements

## 7 产品实现 Product realization

### 7.1 产品实现的策划 Planning of product realization

组织应策划和建立产品实现所需的过程，产品实现的策划应与质量管理体系其他过程的要求相一致。（见 4.1）

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

在策划产品实现的过程中，组织应确定以下方面的适用内容：

- a) 产品的质量目标和要求；
- b) 针对产品确定过程、文件和资源的需求；
- c) 产品所要求的验证、确认、监视、检验和试验活动，以及产品接收准则；
- d) 为实现过程及其产品满足要求提供证据所需的记录（见 4.2.4）。

In planning product realization, the organization shall determine the following, as appropriate:

- a) quality objectives and requirements for the product;
- b) the need to establish processes, documents, and provide resources specific to the product;
- c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

策划的输出形式应适于组织的运作方式。

The output of this planning shall be in a form suitable for the organization's method of operations.

注 1：对应用于特定产品、项目或合同的质量管理体系的过程（包括产品实现过程）和资源作出规定的文件可称之为质量计划。

注 2：组织也可将 7.3 的要求应用于产品实现过程的开发。

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

注：有些顾客把项目管理或产品质量策划作为一种产品实现的方法。产品质量先期策划包括防错和持续改进的概念，与错误探测不同，并且基于多方论证的方法。

NOTE Some customers refer to project management or advanced product quality planning as a means to achieve product realization. Advanced product quality planning embodies the concepts of error prevention and continual improvement as contrasted with error detection and is based on a multidisciplinary approach.

### 7.1.1 产品实现的策划——补充 Planning of product realization – Supplemental

作为质量计划的一部分，产品实现的策划应包括顾客要求和对其技术规范的引用。

Customer requirements and references to its technical specifications shall be included in the planning of product realization as a component of the quality plan.

### 7.1.2 接收准则 Acceptance criteria

接收准则应由组织定义，要求时，应由顾客批准。

对于计数型数据抽样，接收水平应是零缺陷（见 8.2.3.1）。

Acceptance criteria shall be defined by the organization and, where required, approved by the customer.

For attribute data sampling, acceptance level shall be zero defects (see 8.2.3.1).

### 7.1.3 保密 Confidentiality

组织应确保顾客合同产品、正在开发的项目和有关产品信息的保密。

The organization shall ensure the confidentiality of customer-contracted products and projects under development, and related product information.

### 7.1.4 变更控制 Change control

组织应建立一个过程，对影响产品实现的更改进行控制和反应。任何更改的影响，包括由任何供方引起的更改，都应进行评估，并且验证和确认活动应得以规定，以确保和顾客要求相一致。变更在实施前应予以作确认。

具有专利权的设计，影响外形、配合和功能（包括性能，和/或耐久性）的更改，应与顾客一同评审，以便所有的影响都能得到适当的评价。

注 1：任何影响顾客要求的产品实现的更改都要通知顾客，并征得顾客同意。

注 2：以上要求适用于产品和制造过程更改。

The organization shall have a process to control and react to changes that impact product realization. The effects of any change, including those changes caused by any supplier, shall be assessed, and verification and validation activities shall be defined, to ensure compliance with customer requirements. Changes shall be validated before implementation.

For proprietary designs, impact on form, fit and function (including performance, and/or durability) shall be reviewed with the customer so that all effects can be properly evaluated.

When required by the customer, additional verification/identification requirements, such as those required for new product introduction, shall be met.

NOTE 1 Any product realization change affecting customer requirements requires notification to, and agreement from, the customer.

NOTE 2 The above requirement applies to product and manufacturing process changes.

## 7.2 与顾客有关的过程 Customer-related processes

### 7.2.1 与产品相关要求的确定 Determination of requirements related to the product

#### ISO9001:2008 质量管理体系—要求

#### ISO 9001:2008, Quality management systems — Requirements

## 7.2 与顾客有关的过程 Customer-related processes

### 7.2.1 与产品相关要求的确定 Determination of requirements related to the product

组织应确定：

- a) 顾客规定的要求，包括对交付和交付后活动的要求；
- b) 顾客虽然没有明示，但规定的用途或已知的预期用途所必需的要求；
- c) 与产品有关的法律法规要求；
- d) 组织确定的任何附加要求。

The organization shall determine

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- b) requirements not stated by the customer but necessary for specified or intended use, where known,
- c) statutory and regulatory requirements related to the product, and
- d) any additional requirements determined by the organization.

NOTE Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as, maintenance services, and supplementary services such as recycling or final disposal.

注：交付后活动包括诸如担保条款规定的措施、合同义务（例如，维护服务）、附件服务（例如，回收和最终处理）等。

注 1：交付后的活动包括作为顾客合同和采购订单一部分的任何售后产品服务。

注 2：本要求包括回收再利用、对环境的影响，以及根据组织对产品和制造过程的知识识别的特性（见 7.3.2.3）

注 3：条款 c) 的符合性包括所有适用的政府、安全和环境法规，适用于材料的获得、贮存、搬运、再利用、销毁或废弃。

NOTE 1 Post-delivery activities include any after-sales product service provided as part of the customer contract or purchase order.

NOTE 2 This requirement includes recycling, environmental impact and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes ( see 7.3.2.3).

NOTE 3 Compliance to item c) includes all applicable government, safety and environmental regulations, applied to acquisition, storage, handling, recycling, elimination or disposal of materials.

#### 7.2.1.1 顾客指定的特殊特性 Customer-designated special characteristics

组织应证实在特殊特性的指定、形成文件和控制方面符合顾客的要求。

The organization shall demonstrate conformity to customer requirements for designation, documentation and control of special characteristics.

#### 7.2.2 与产品相关要求的评审 Review of requirements related to the product

##### ISO9001:2008 质量管理体系—要求

##### ISO 9001:2008, Quality management systems — Requirements

#### 7.2.2 与产品有关要求的评审 Review of requirements related to the product

组织应评审与产品有关的要求。评审应在组织向顾客作出提供产品的承诺（如：在投标、接受合同或订单，接受合同或订单的变更）之前进行，并确保：

- a) 产品要求已得到规定；
- b) 与以前表述不一致的合同或订单的要求已得到解决；
- c) 组织有能力满足规定的要求。

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

- a) product requirements are defined,
- b) contract or order requirements differing from those previously expressed are resolved, and
- c) the organization has the ability to meet the defined requirements.

评审结果及评审所引起的措施的记录应予以保持（见 4.2.4）。

若顾客提供的要求没有形成文件，组织在接收顾客要求前应对顾客要求进行确认；

若产品要求发生变更，组织应确保相关文件得到修改，并确保相关人员知道已变更的要求。

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

注：在某些情况中，如网上销售，对每一个订单进行正式的评审可能是不实际的。而代之对有关的产品信息，如产品目录、产品广告内容等进行评审。

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertizing material.

#### **7.2.2.1 与产品有关的要求的评审——补充** Review of requirements related to the product - Supplemental 对 7.2.2 中所说明的正式评审（参见注）要求的弃权，应要求顾客授权。

Waiving the requirement stated in 7.2.2 for a formal review (see note) shall require customer authorization

#### **7.2.2.2 组织制造可行性** Organization manufacturing feasibility

组织应在合同评审过程中，对所涉及产品的制造可行性进行研究、确认并形成文件，包括进行风险分析。

The organization shall investigate, confirm and document the manufacturing feasibility of the proposed products in the contract review process, including risk analysis.

#### **7.2.3 顾客沟通** Customer communication

##### **ISO9001:2008 质量管理体系—要求**

ISO 9001:2008, Quality management systems — Requirements

#### **7.2.3 顾客沟通** Customer communication

组织应对以下有关方面确定并实施与顾客沟通的有效安排：

- a) 产品信息
- b) 问询、合同或订单的处理，包括对其的修改；
- c) 顾客反馈，包括顾客抱怨。

The organization shall determine and implement effective arrangements for communicating with customers in relation to

- a) product information,
- b) enquiries, contracts or order handling, including amendments, and
- c) customer feedback, including customer complaints.

### 7.2.3.1 顾客沟通——补充 Customer communication - Supplemental

组织应有能力按顾客规定的语言和方式来沟通必要的信息，包括数据（例如：计算机辅助设计数据、电子数据交换等）。

The organization shall have the ability to communicate necessary information, including data, in a customer-specified language and format (e.g. computer-aided design data, electronic data exchange).

## 7.3 设计和开发 Design and development

注：7.3 的要求包括产品和制造过程的设计与开发，并注重防错，而不是探测。

NOTE The requirements of clause 7.3 include product and manufacturing process design and development, and focus on error prevention rather than detection.

### 7.3.1 设计和开发策划 Design and development planning

#### ISO9001:2008 质量管理体系—要求

#### ISO 9001:2008, Quality management systems — Requirements

## 7.3 设计和开发 Design and development

### 7.3.1 设计和开发策划 Design and development planning

组织应对产品的设计和开发进行策划和控制。

在进行设计和开发的策划时，组织应确定：

- a) 设计和开发的阶段；
- b) 适于每个设计和开发阶段的评审、验证和确认活动；
- c) 设计和开发的职责和权限。

组织应对参与设计和开发的不同小组之间的接口实施管理，以确保有效的沟通，并明确职责分工。

随设计和开发的进展，在适当时，策划的输出应予以更新。

注：设计和开发的评审、验证和确认具有不同的目的，根据产品和组织的具体情况，可单独或以任意组合的方式进行并记录。

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

- a) the design and development stages
- b) the review, verification and validation that are appropriate to each design and development stage, and
- c) the responsibilities and authorities for design and development

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

### 7.3.1.1 多方论证的方法 Multidisciplinary approach

组织应采用多方论证的方法进行产品实现的准备工作，包括：

- 特殊特性的开发/最终确定和监视；
- 潜在失效模式及后果分析（FMEAs）的开发和评审，包括采取降低潜在风险的措施。
- 控制计划的开发和评审。

注：多方论证方法通常包括组织的设计、制造、工程、质量、生产和其他适当的人员。

The organization shall use a multidisciplinary approach to prepare for product realization, including

- development/ finalization and monitoring of special characteristics,
- development and review of FMEAs including actions to reduce potential risks, and
- development and review of control plans.

NOTE A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality, production and other appropriate personnel.

### 7.3.2 设计和开发的输入 Design and development inputs

#### ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems — Requirements

### 7.3.2 设计和开发的输入 Design and development inputs

应确定与产品要求有关的输入，并保持记录（4.2.4）。

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4).

这些输入应包括：

- a) 功能和性能要求；
- b) 适用的法律和法规要求；
- c) 适当时，以前类似设计提供的信息；
- d) 设计和开发所必需的其他要求。

These inputs shall include

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar designs, and
- d) other requirements essential for design and development.

应对这些输入的充分性与适宜性进行评审。要求应完整、清楚，并且不能自相矛盾。

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

注：特殊特性（见 7.2.1.1）包括在这此要求中。

NOTE Special characteristics (see 7.2.1.1) are included in this requirement.

#### 7.3.2.1 产品设计输入 Product design input

组织应识别产品设计输入要求，形成文件并进行评审，包括：

- 顾客要求（合同评审），如：特殊特性（见 7.3.2.3）、标识、可追溯性和包装；
- 信息的使用：组织应有一个过程，将从以往设计项目、竞争对手分析、供方反馈、内部输入、外部数据及其它相关来源获得的信息推广应用于当前或未来有相似性质的项目。
- 产品质量、寿命、可靠性、耐久性、可维修性、时间性和成本的目标。

The organization shall identify, document and review the product design inputs requirements including the following

- customer requirements (contract review) such as special characteristics (see 7.3.2.3), identification, traceability and packaging;
- use of information; the organization shall have a process to deploy information gained from previous design projects, competitor analysis, supplier feedback, internal input, field data, and other relevant sources, for current and future projects of a similar nature;
- targets for product quality, life, reliability, durability, maintainability, timing and cost.

### 7.3.2.2 制造过程设计输入 Manufacturing process design input

组织应识别制造过程设计输入的要求，形成文件并进行评审，包括：

- 产品设计输出数据；
- 生产率、过程能力和成本的目标；
- 顾客要求，如果有，和：
- 以往的开发经验。

制造过程设计包括采用放错方法，其程度与问题的重要性和所存在风险的程度相适应。

The organization shall identify, document and review the manufacturing process design input requirements, including

- product design output data,
- targets for productivity, process capability and cost,
- customers requirements, if any, and
- experience from previous developments.

NOTE The manufacturing process design includes the use of error-proofing methods to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.

### 7.3.2.3 特殊特性 Special characteristics

组织应识别特殊特性（见 7.3.3d），并且

- 在控制计划中包含所有特殊特性；
- 与顾客规定的定义和符号相一致，和
- 识别过程控制文件，包括图样、FMEAs、控制计划及作业指导书，它们都应标明顾客的特殊特性符号或组织的等效符号或记号，以包括对特殊特性有影响的过程步骤。

注：特殊特性可包括产品特性和过程参数。

The organization shall identify special characteristics (see 7.3.3 d) and

- include all special characteristics in the control plan,
- comply with customer specified definitions and symbols, and
- identify process control documents including drawings, FMEAs, control plans, and operator instructions with the customer's special characteristic symbol or the organization's equivalent symbol or notation to include those process steps that affect special characteristics.

NOTE Special characteristics can include product characteristics and process parameters.

## 7.3.3 设计和开发输出 Design and development outputs

**ISO9001:2008 质量管理体系—要求**

**ISO 9001:2008, Quality management systems — Requirements**

## 7.3.3 设计和开发输出 Design and development outputs



设计和开发的输出应以能够针对设计和开发的输入进行验证的方式提出，并应在放行前得到批准。

设计和开发输出应：

- a) 满足设计和开发输入的要求；
- b) 给出采购、生产和服务提供的适当信息；
- c) 包含或引用产品接收准则；
- d) 规定对产品的安全和正常使用所必需的产品特性。

注：生产和服务提供的信息可能包括产品防护的细节。

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

- a) meet the input requirements for design and development
- b) provide appropriate information for purchasing, production and for service provision
- c) contain or reference product acceptance criteria, and
- d) specify the characteristics of the product that are essential for its safe and proper use

NOTE Information for production and service provision can include details for the preservation of product

#### **7.3.3.1 产品设计输出—补充** Product design outputs - Supplemental

产品设计输出应以能根据产品设计输入的要求，进行验证和确认的方式来表示。产品设计输出应包括：

- 设计 FMEA、可靠性结果
- 产品特殊特性和规范
- 适当的产品防错
- 产品定义，包括图纸和数学数据；
- 产品设计评审结果，以及
- 在适用时的诊断指南。

The product design output shall be expressed in terms that can be verified and validated against product design input requirements. The product design output shall include

- design FMEA, reliability results,
- product special characteristics, specifications,
- product error-proofing, as appropriate,
- product definition including drawings or mathematically based data,
- product design reviews results, and
- diagnostic guidelines, where applicable.

#### **7.3.3.2 制造过程设计输出** Manufacturing process design output

制造过程设计输出应以能够对照制造过程设计输入的要求进行验证和确认的方式来表示。制造过程设计输出应包括：

- 规范和图样
- 制造过程流程图/制造过程平面布置图

- 制造过程 FMEAs
- 控制计划
- 作业指导书（见 7.5.1.1）
- 过程批准接受准则
- 有关质量、可靠性、可维修性和可量测性的数据
- 适当时，防错活动的结果，和
- 产品/制造过程不合格的快速探测和反馈方法。

The manufacturing process design output shall be expressed in terms that can be verified against manufacturing process design input requirements and validated. The manufacturing process design output shall include

- specifications and drawings,
- manufacturing process flow chart / layout,
- manufacturing process FMEAs,
- control plan ( see 7.5.1.1.),
- work instructions,
- process approval acceptance criteria,
- data for quality, reliability, maintainability and measurability,
- results of error-proofing activities, as appropriate, and
- methods of rapid detection and feedback of product/manufacturing process nonconformities.

#### 7.3.4 设计和开发评审 Design and development review

### ISO9001:2008 质量管理体系—要求

### ISO 9001:2008, Quality management systems — Requirements

#### 7.3.4 设计和开发评审 Design and development review

应依据所策划的安排（见 7.3.1）在适宜的阶段对设计和开发进行系统的评审,以便：

- a) 评价设计和开发的结果满足要求的能力；
- b) 识别任何问题并提出必要的措施。

评审的参加者应包括与所评审的设计和开发阶段有关的职能的代表。评审结果及任何必要措施的记录应予保持（见 4.2.4）

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1 )

- a) to evaluate the ability of the results of design and development to fulfil requirements, and
- b) to identify any problems and propose necessary actions

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

注：这些评审通常与设计阶段相协调，包括制造过程设计和开发。

NOTE These reviews are normally coordinated with the design phases and include manufacturing process design and development.

##### 7.3.4.1 监视 Monitoring

应对设计和开发特定阶段的测量加以规定、分析，并对汇总结果进行报告，作为管理评审的输入。

注：在适当的情况下，这些测量包括质量风险、成本、提前期、关键路径和其它事项。

Measurements at specified stages of design and development shall be defined, analysed and reported with summary results as an input to management review.

NOTE These measurements include quality risks, costs, lead-times, critical paths and others, as appropriate.

### 7.3.5 设计和开发的验证 Design and development verification

ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems — Requirements

#### 7.3.5 设计和开发的验证 Design and development verification

为确保设计和开发输出满足输入的要求，应依据所策划的安排（见 7.3.1）对设计和开发进行验证。验证结果及任何必要措施的记录应予以保持（见 4.2.4）。

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4)

### 7.3.6 设计和开发确认 Design and development validation

ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems — Requirements

#### 7.3.6 设计和开发确认 Design and development validation

为确保产品能够满足规定的使用要求或已知的预期用途的要求，应依据所策划的安排（见 7.3.1）对设计和开发进行确认。只要可行，确认应在产品交付或实施之前完成。确认结果及任何必要措施的记录应予以保持（见 4.2.4）。

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

注 1：确认过程通常包括类似产品外部报告的分析。

注 2：上述要求 7.3.5 和 7.3.6 的要求适用于产品和制造过程。

NOTE 1 The validation process normally includes an analysis of field reports for similar products.

NOTE 2 The requirements of 7.3.5 and 7.3.6 above apply to both product and manufacturing processes.

#### 7.3.6.1 设计和开发确认—补充 Design and development validation – Supplemental

设计和开发确认应与顾客要求一致，包括项目时间。

Design and development validation shall be performed in accordance with customer requirements including programme timing.

#### 7.3.6.2 样件计划 Prototype programme

当顾客要求时，组织应制定样件计划和控制计划。只要可能，组织就应使用与正式生产相同的供方、

工装和制造过程。

应监视所有的性能试验活动，以便及时完成并符合要求。

当这些服务被外包时，组织应对外包服务负责，包括提供技术指导。

When required by the customer, the organization shall have a prototype programme and control plan. The organization shall use, wherever possible, the same suppliers, tooling and manufacturing processes as will be used in production.

All performance-testing activities shall be monitored for timely completion and conformity to requirements.

While services may be outsourced, the organization shall be responsible for the outsourced services, including technical leadership.

### 7.3.6.3 产品批准过程 Product approval process

组织应符合顾客认可的产品和制造过程的批准程序。

注：产品批准应当在制造过程验证之后进行。

该产品和制造过程批准程序也应适用于供方。

The organization shall conform to a product and process approval procedure recognized by the customer.

NOTE Product approval should be subsequent to the verification of the manufacturing process.

This product and manufacturing process approval procedure shall also be applied to suppliers.

### 7.3.7 设计和开发变更的控制 Control of design and development changes

#### ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems — Requirements

### 7.3.7 设计和开发变更的控制 Control of design and development changes

应识别设计和开发的更改，并保持记录。在适当时，应对设计和开发的更改进行评审、验证和确认，并在实施前得到批准。设计和开发更改的评审应包括评价更改对产品组成部分和已交付产品的影响。

更改评审结果及任何必要措施的记录应予以保持（见 4.2.4）。

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and already delivered product.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

注：设计和开发的更改包括产品项目生命周期内的所有更改（见 7.1.4）。

NOTE Design and development changes include all changes during the product programme life (see 7.1.4)

## 7.4 采购 Purchasing

### 7.4.1 采购过程 Purchasing process

#### ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems — Requirements

## 7.4 采购 Purchasing

### 7.4.1 采购过程 Purchasing process

组织应确保采购的产品符合规定的采购要求。对供方及采购的产品控制的类型和程度应取决于采购的产品对随后的产品实现或最终产品的影响。

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

组织应根据供方按组织的要求提供产品的能力评价和选择供方。应制定选择、评价和重新评价的准则。评价结果及评价所引起的任何必要措施的记录应予以保持（见 4.2.4）

The organization shall evaluate and select suppliers based on their ability to supply products in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4)

注 1：上述采购产品包括所有影响顾客要求的产品和服务，例如：分装、排序、分选、返工和校准服务。

注 2：当发生与供方相关的兼并、收购或从属关系时，组织应当验证供方质量管理体系的延续性和有效性。

NOTE 1 Purchased products above include all products and services that affect customer requirements such as sub-assembly, sequencing, sorting, rework and calibration services.

NOTE 2 When there are mergers, acquisitions or affiliations associated with suppliers, the organization should verify the continuity of the supplier's quality management system and its effectiveness.

#### **7.4.1.1 法规的符合性 Regulatory conformity**

用于产品而采购的所有产品或材料应符合适用的法规要求。

All purchased products or materials used in product shall conform to applicable regulatory requirements.

#### **7.4.1.2 供方质量管理体系的开发 Supplier quality management system development**

组织应以供方符合本技术规范为目的，进行供方质量管理体系的开发。符合 ISO9001:2008 是达到这一目的的第一步。

The organization shall perform supplier quality management system development with the goal of supplier conformity with this Technical Specification. Conformity with ISO 9001 : 2008 is the first step of achieving this goal.

注：供方开发的优先顺序由供方的质量绩效和所供应产品的重要性决定。

除非顾客另有规定，否则组织的供方应通过经认可的第三方认证机构的 ISO9001:2008 第三方认证。

NOTE The prioritization of suppliers for development depends upon, for example, the supplier's quality performance and the importance of the product supplied.

Unless otherwise specified by the customer, suppliers to the organization shall be third party registered to ISO 9001 : 2008 by an accredited third party certification body.

#### **7.4.1.3 顾客批准的供方 Customer-approved sources**

若合同（如顾客工程图纸、规范）中有规定，组织应从经顾客批准的供方处采购产品、材料和服务。

Where specified by the contract (e.g. customer engineering drawing, specification), the organization shall purchase products, materials or services from approved sources.

采用顾客指定的供方（包括工装和量具供方）并不免除组织确保采购的零件、材料和服务质量的责任。

The use of customer-designated sources, including tool/gauge suppliers, does not relieve the organization of the responsibility for ensuring the quality of purchased products.

#### 7.4.2 采购信息 Purchasing information

##### ISO9001:2008 质量管理体系—要求

##### ISO 9001:2008, Quality management systems — Requirements

#### 7.4.2 采购信息 Purchasing information

采购信息应描述拟采购的产品，适当时包括：

- a) 产品、程序、过程和设备批准要求；
- b) 人员资格的要求；
- c) 质量管理体系的要求。

在与供方沟通前，组织应确保规定的采购要求是充分与适宜的。

Purchasing information shall describe the product to be purchased, including where appropriate

- a) requirements for approval of product, procedures, processes and equipment
- b) requirements for qualification of personnel, and
- c) quality management system requirements

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

#### 7.4.3 采购产品的验证 Verification of purchased product

##### ISO9001:2008 质量管理体系—要求

##### ISO 9001:2008, Quality management systems — Requirements

#### 7.4.3 采购产品的验证 Verification of purchased product

组织应确定并实施检验或其他必要的活动，以确保采购的产品满足规定的采购要求。

当组织或其顾客拟在供方的现场实施验证时，组织应在采购信息中对拟验证的安排和产品放行的方法作出规定。

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

##### 7.4.3.1 进货产品对要求的符合性 Incoming product conformity to requirement

组织应有一过程来保证采购产品的质量（见 7.4.3），可以采用下面一种或多种方法：

- 组织收集统计数据，并对其进行评价；
- 接收检验和/或试验，如基于绩效的抽样；
- 结合已交付产品对要求的符合性的可接受的记录，由第二方或第三方机构对供方现场进行评估或审核；
- 由指定的实验室进行的零件评价；
- 顾客同意的其他方法。

The organization shall have a process to assure the quality of purchased product (see 7.4.3) utilizing one or more of the following methods:

- receipt of, and evaluation of, statistical data by the organization;
- receiving inspection and/or testing such as sampling based on performance;
- second or third party assessments or audits of supplier sites, when coupled with records of acceptable delivered product conformity the requirememnt.
- part evaluation by a designated laboratory;
- another method agreed with the customer.

#### 7.4.3.2 对供方监视 Supplier monitoring

应通过以下指标，对供方绩效进行监视：

- 已交付产品对要求的符合性；
- 对顾客造成的干扰，包括外部退货；
- 按计划交付的绩效（包括发生的超额运费）；
- 与质量或交付有关的特殊状态顾客通知。

组织应促进供方对其制造过程绩效的监视。

Supplier performance shall be monitored through the following indicators :

- delivered product conformity the requirememnt,
- customer disruptions including field returns,
- delivery schedule performance (including incidents of premium freight),
- special status customer notifications related to quality or delivery issues.

The organization shall promote supplier monitoring of the performance of their manufacturing processes.

## 7.5 生产和服务提供 Production and service provision

### 7.5.1 生产和服务提供的控制 Control of production and service provision

#### ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems — Requirements

## 7.5 生产和服务提供 Production and service provision

### 7.5.1 生产和服务提供的控制 Control of production and service provision

组织应策划并在受控条件下进行生产和服务提供。适用时，受控条件应包括：

- a) 获得表述产品特性的信息；
- b) 必要时，获得作业指导书；
- c) 使用适宜的设备；
- d) 获得和使用监视和测量装置；
- e) 实施监视和测量；
- f) 放行、交付和交付后活动的实施。

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

- a) the availability of information that describes the characteristics of the product,
- b) the availability of work instructions, as necessary,
- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring devices,
- e) the implementation of monitoring and measurement, and
- f) the implementation of release, delivery and post-delivery activities.

#### 7.5.1.2 控制计划 Control plan

组织应：

—针对所提供的产品在系统、子系统、部件和/或材料各层次上开发控制计划（见附录 A），包括散装材料及零件的生产过程，

—考虑了设计 FEMA 和制造过程 FEMA 输出的试生产和生产控制计划；

控制计划应：

—列出用于制造过程控制的控制方法。

—包括对由顾客和组织共同定义的特殊性控制（见 7.3.2.3）监视的方法；

—若有，包括任何顾客要求的信息，以及

—当过程变得不稳定或统计能力不足时，启动规定的反应计划（见 8.2.3.1）。

The organization shall

- develop control plans (see Annex A) at the system, subsystem, component and/or material level, for the product supplied, including those for processes producing bulk materials as well as parts, and
- have a control plan for pre-launch and production that takes into account the design FMEA and manufacturing process FMEA outputs,

The control plan shall

- list the controls used for the manufacturing process control ,
- include methods for monitoring of control exercised over special characteristics (see 7.3.2.3) defined by both the customer and the organization,
- include the customer required information, if any, and
- initiate the specified reaction plan (see 8.2.3.1) when the process becomes unstable or not statistically capable.

当任何影响产品、制造过程、测量、物流、供应货源或 FEMA（见 7.1.4）的更改发生时，应评审并更新控制计划。

Control plans shall be reviewed and updated when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources or FMEA (see 7.1.4).

注：评审或更新后的控制计划可能要有顾客批准。

NOTE Customer approval may be required after review or update of the control plan.

#### 7.5.1.2 作业指导书 Work instructions

组织应为所有负责影响产品要求符合性的过程操作的人员提供文件化的作业指导书。这些指导书应在工作岗位易于得到。

这些指导书应来源于适当的文件，如质量计划、控制计划和产品实现过程。

The organization shall prepare documented work instructions for all employees having responsibilities for the operation of processes that impact product conformity to requirement. These instructions shall be accessible for use at the work station.

These instructions shall be derived from sources such as the quality plan, the control plan and the product realization process.

#### 7.5.1.3 作业准备的验证 Verification of job set-ups

无论何时进行作业准备，如作业的初次运行、材料的更换、作业更改，均应进行作业准备的验证。作业准备人员应能得到作业指导书。适用时，组织应使用统计方法进行验证。



注：推荐采用末件比较的方法。

Job set-ups shall be verified whenever performed, such as an initial run of a job, material changeover, job change. Work instructions shall be available for set-up personnel. The organization shall use statistical methods of verification where applicable.

NOTE Last-off-part comparisons are recommended.

#### **7.5.1.4 预防性和预见性维护** Preventive and predictive maintenance

组织应标识关键过程设备，为机器/设备的维护提供资源，并建立有效的、有计划的全面预防性维护系统。这个系统至少应包括：

- 有计划地维护活动
- 设备、工装和量具的包装和防护；
- 关键生产设备备件的可获得性；
- 将维护目标形成文件并予以评价和改进

组织应使用预见性维护方法，以持续改进生产设备的有效性和效率。

The organization shall identify key process equipment and provide resources for machine/equipment maintenance and develop an effective planned total preventive maintenance system . As a minimum, this system shall include the following :

- planned maintenance activities,
- packaging and preservation of equipment, tooling and gauging,
- availability of replacement parts for key manufacturing equipment,
- documenting, evaluating and improving maintenance objectives.

The organization shall utilize predictive maintenance methods to continually improve the effectiveness and the efficiency of production equipment.

#### **7.5.1.5 生产工装的管理** Management of production tooling

组织应为工装和量具的设计、制造和验证活动提供资源。

组织应建立并实施生产工装的管理系统，包括：

- 维护和修理的设施与人员；
- 贮存和修复；
- 工装准备；
- 易损工具的更换计划；
- 工装设计的修改的文件，包括工程更改等级；
- 工装的修改和文件的修订；
- 工装标识，明确其状态，如在用、修理或废弃。

如果其中任何一项工作被外包，组织应实施监视这些活动的系统。

注：该要求也适用于车辆服务零件的工装。

The organization shall provide resources for tool and gauge design, fabrication and verification activities.

The organization shall establish and implement a system for production tooling management including :

- maintenance and repair facilities and personnel,
- storage and recovery,
- set-up,
- tool-change programmes for perishable tools,

- tool design modification documentation, including engineering change level,
- tool modification and revision to documentation,
- tool identification, defining the status, such as production, repair or disposal.

The organization shall implement a system to monitor these activities if any work is outsourced.

NOTE This requirement also applies to the availability of tools for vehicle service parts.

#### 7.5.1.6 生产计划 Production scheduling

应有满足顾客要求的生产计划，如由信息系统支持的“准时”计划，该信息系统允许在过程的关键阶段获得生产信息并且是订单驱动的。

Production shall be scheduled in order to meet customer requirements, such as just-in-time supported by an information system that permits access to production information at key stages of the process and is order drive

#### 7.5.1.7 服务信息反馈 Feedback of information from service

应建立并保持与制造、工程和设计部门沟通服务问题的过程。

注：将“服务问题”增加到本条款，其目的是为了保证组织了解其外部发生的不合格。

A process for communication of information on service concerns to manufacturing, engineering and design activities shall be established and maintained.

NOTE The intent of the addition of "service concerns" to this clause is to ensure that the organization is aware of nonconformities that occur external to its organization.

#### 7.5.1.8 与顾客的服务协议 Service agreement with customer

当与顾客达成服务协议时，组织应验证下列项目的有效性：

- 组织的任何一个服务中心
- 任何专用工具或测量设备，和
- 服务人员的培训

When there is a service agreement with the customer, the organization shall verify the effectiveness of

- any organization service centres,
- any special purpose tools or measurement equipment, and
- the training of service personnel.

### 7.5.2 生产和服务提供过程的确认 Validation of processes for production and service provision

#### ISO9001:2008 质量管理体系—要求

#### ISO 9001:2008, Quality management systems — Requirements

#### 7.5.2 生产和服务提供过程的确认 Validation of processes for production and service provision

当生产和服务提供过程的输出不能由后续的监视或测量加以验证时，组织应对任何这样的过程实施确认。这包括仅在产品使用或服务已交付之后问题才显现的过程。

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

确认应证实这些过程实现所策划的结果的能力。

Validation shall demonstrate the ability of these processes to achieve planned results.

组织应规定确认这些过程的安排，适用时包括：

- a) 为过程的评审和批准所规定的准则；
- b) 设备的认可和人员资格的鉴定；
- c) 使用特定的方法和程序；
- d) 记录的要求（见 4.2.4）；
- e) 再确认。

The organization shall establish arrangements for these processes including, as applicable.

- a) defined criteria for review and approval of the processes,
- b) approval of equipment and qualification of personnel,
- c) use of specific methods and procedures,
- d) requirements for records (see 4.2.4), and
- e) revalidation.

### 7.5.2.1 生产和服务提供过程的确认——补充

Validation of processes for production and service provision – Supplemental

7.5.2 的要求应适用于所有生产和服务提供过程。

The requirements of 7.5.2 shall apply to all processes for production and service provision.

### 7.5.3 标识和可追溯性 Identification and traceability

#### ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems — Requirements

### 7.5.3 标识和可追溯性 Identification and traceability

适当时，组织应在产品实现的全过程中使用适宜的方法识别产品。

组织应针对监视和测量要求识别产品的状态。

在有可追溯性要求时，组织应控制和记录产品的唯一标识，并保持纪录（见 4.2.4）

注：在某些行业，技术状态管理是保持标识和可追溯性的一种方法。

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

注：在生产流程中产品所处的位置并不能表明其检验、试验状态，除非产品本身状态明显，如：自动化生产流程过程中的材料。如果状态能清楚的识别、形成了文件且达到了预定的目标，也可以采用替代的方法。

NOTE Inspection and test status is not indicated by the location of product in the production flow unless inherently obvious, such as material in an automated production transfer process. Alternatives are permitted, if the status is clearly identified, documented, and achieves the designated purpose.

### 7.5.3.1 标识和可追溯性——补充 Identification and traceability - Supplemental

以上 7.5.3 中的“适当时”不适用。

The words "Where appropriate" in 7.5.3 above, shall not apply.

#### 7.5.4 顾客财产 Customer property

##### ISO9001:2008 质量管理体系—要求

##### ISO 9001:2008, Quality management systems — Requirements

组织应爱护在组织控制下或组织使用的顾客财产。组织应识别、验证、保护和维持供其使用或构成产品一部分的顾客财产。若顾客财产发生丢失、损坏或发现不适用的情况时，应报告顾客，并保持记录（见4.2.4）。

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

注：顾客财产可包括知识产权和个人信息。

NOTE Customer property can include intellectual property and personal data..

注：这个条款包括顾客所有的可重复使用的包装。

NOTE Customer-owned returnable packaging is included in this subclause.

##### 7.5.4.1 顾客所有的生产工装 Customer-owned production tooling

顾客所有的工具以及制造、试验、检验的工装和设备应予以永久性标识，以使每一工装设备的权属关系清晰可见并可以确定。

Customer-owned tools, manufacturing, test, inspection tooling and equipment shall be permanently marked so that the ownership of each item is visible, and can be determined.

#### 7.5.5 产品防护 Preservation of product

##### ISO9001:2008 质量管理体系—要求

##### ISO 9001:2008, Quality management systems — Requirements

在内部处理和交付到预定的地点期间，组织应针对产品的符合性提供防护，这种防护应包括标识、搬运、包装、贮存和保护。防护也应适用于产品的组成部分。

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

##### 7.5.5.1 贮存和库存 Storage and inventory

应按策划的适宜的时间间隔检查库存品状况，以便及时发现变质情况。

组织应使用一种库存管理系统，以优化库存周转期，确保货物周转，如“先进先出（FIFO）”。应以对待不合格品的类似方法控制过期产品。

In order to detect deterioration, the condition of product in stock shall be assessed at appropriate planned intervals.

The organization shall use an inventory management system to optimize inventory turns over time and assure stock rotation, such as "first-in-first-out" (FIFO). Obsolete product shall be controlled in a similar manner to nonconforming product.

## 7.6 监控和测量设备的控制 Control of monitoring and measuring equipment

### ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems — Requirements

## 7.6 监控和测量设备的控制 Control of monitoring and measuring equipment

组织应确定需实施的监视和测量以及所需的监视和测量装置，为产品符合确定的要求（见 7.2.1）提供证据。

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

组织应建立过程，以确保监视和测量活动可行并以与监视和测量的要求相一致的方式实施。

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

当有必要确保结果有效的场合时，测量设备应：

a) 对照能溯源到国际或国家标准的测量标准，按照规定的时间间隔或使用前进行校准或检定。当不存在上述标准时，应记录校准或检定的依据；

b) 必要时进行调整或再调整；

c) 得到识别，以确定其校准状态；

d) 防止可能使测量结果失效的调整；

e) 在搬运、维护和贮存期间防止损坏或失效。

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded(see 4.2.4);;

b) be adjusted or re-adjusted as necessary;

c) have identification on order to determine its calibration status.

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

此外，当发现设备不符合要求时，组织应对以往测量结果的有效性进行评价和记录。组织应对该设备和任何受影响的产品采取适当的措施。校准和验证结果的记录应予保持（见 4.2.4）。

当计算机软件用于规定要求的监视和测量时，应确认其满足预期用途的能力。确认应在初次使用前进行，并在必要时予以重新确认。

注：确认计算机软件满足预期用途能力的典型方法包括验证和保持其适用性的配置管理。

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.

Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

注：可追溯到设备校准记录的编号或其他标识满足本要求 c) 的意图。

NOTE A number or other identifier traceable to the device calibration record meets the intent of requirement c) above.

### 7.6.1 测量系统分析 Measurement system analysis

为分析各种测量和试验设备系统得出的结果中出现的变差，应进行统计研究。此要求应适用于控制计划中提及的测量系统。所用的分析方法及接受准则应符合顾客关于测量系统分析的参考手册的要求。如果得到顾客的批准，也可使用其他分析方法和接受准则。

Statistical studies shall be conducted to analyse the variation present in the results of each type of measuring and test equipment system. This requirement shall apply to measurement systems referenced in the control plan. The analytical methods and acceptance criteria used shall conform to those in customer reference manuals on measurement systems analysis. Other analytical methods and acceptance criteria may be used if approved by the customer.

### 7.6.2 校准/验证记录 Calibration/verification records

对所有量具、测量和试验设备，包括员工和顾客所有的设备，都应提供校准/验证活动记录，用以提供符合确定的产品要求的证据。记录应包括：

- 设备标识，包括校准设备所依据的测量标准；
- 由工程更改所引发的修订；
- 在校准/验证时获得的任何超出规范的读数；
- 超出规范条件下影响的评估；
- 在校准/验证后，有关符合规范的说明；
- 在可疑产品或材料已发运的情况下，给顾客的通知。

Records of the calibration/verification activity for all gauges, measuring and test equipment, needed to provide evidence of conformity of product to determined requirements, including employee- and customer-owned equipment, shall include

- equipment identification, including the measurement standard against which the equipment is calibrated,
- revisions following engineering changes,
- any out-of-specification readings as received for calibration/verification,
- an assessment of the impact of out-of-specification condition,
- statements of conformance to specification after calibration/verification, and
- notification to the customer if suspect product or material has been shipped.

### 7.6.3 试验室要求 Laboratory requirements

#### 7.6.3.1 内部实验室 Internal laboratory

组织的内部实验室设施应有一个确定的范围，包括进行要求的检验、试验或校准服务的能力。实验室范围应包括在质量管理体系文件中。实验室至少应规定并实施以下方面的技术要求：

- 实验室程序的充分性
- 实验室人员的能力
- 产品试验
- 正确的进行这些服务，可追溯到相关的过程标准（如 ASTM，EN 等）的能力，以及
- 对相关记录的评审。

注：通过 ISO/IEC 17025 资格认可可以证明组织内部实验室符合这一要求，但不是强制的。

An organization's internal laboratory facility shall have a defined scope that includes its capability to perform the required inspection, test or calibration services. This laboratory scope shall be included in the quality management system documentation. The laboratory shall specify and implement , as a minimum, technical requirements for

- adequacy of the laboratory procedures,
- competency of the laboratory personnel,
- testing of the product ,
- capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN,etc.), and
- review of the related records.

NOTE Accreditation to ISO/IEC 17025 may be used to demonstrate supplier in-house laboratory conformity to this requirement but is not mandatory.

**7.6.3.2 外部实验室 External laboratory**

组织用于检验、试验或校准服务的外部/商业/独立的实验室设施应有一个确定的范围，包括进行要求的检验、试验或校准服务的能力，并且：

- 应有证据表明外部实验室对顾客是可接受的，或
- 实验室应通过 ISO/IEC17025 或同等的国家标准的认可

External/commercial/independent laboratory facilities used for inspection, test or calibration services by the organization shall have a defined laboratory scope that includes the capability to perform the required inspection, test or calibration, and either

- there shall be evidence that the external laboratory is acceptable to the customer, or
- the laboratory shall be accredited to ISO/IEC 17025 or national equivalent.

注 1：顾客的评定或顾客批准的第三方评定等方式可作为证明实验室满足 ISO/IEC17025 标准或相应国家标准意图的证据。

注 2：对于某一设备，当没有具有资格的实验室时，校准服务可以由原设备制造厂家进行。这种情况下，组织应当确保上述 7.6.3.1 要求已得到满足。

NOTE 1 Such evidence may be demonstrated by customer assessment, for example, or by customer -approved secondparty assessment that the laboratory meets the intent of ISO/IEC 17025 or national equivalent.

NOTE 2 When a qualified laboratory is not available for a given piece of equipment, calibration services may be performed by the equipment manufacturer. In such cases, the organization should ensure that the requirements listed in 7.6.3.1 have been met.

**8 测量、分析和改进 Measurement, analysis and improvement**

**8.1 总则 General**

**ISO9001:2008 质量管理体系—要求**  
**ISO 9001:2008, Quality management systems — Requirements**  
**8. 测量、分析和改进 Measurement, analysis and improvement**  
**8.1 总则 General**

组织应策划并实施以下方面所需的监视、测量、分析和改进过程：

- a) 证实产品的符合性;
- b) 确保质量管理体系的符合性;
- c) 持续改进质量管理体系的有效性。

这应包括对统计技术在内的适用方法及其应用程度的确定。

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

- a) to demonstrate conformity of the product requirements,
- b) to ensure conformity of the quality management system, and
- c) to continually improve the effectiveness of the quality management system

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

#### 8.1.1 统计工具的确定 Identification of statistical tools

在质量先期策划中应确定每一过程适用的统计工具，并应包括在控制计划中。

Appropriate statistical tools for each process shall be determined during advance quality planning and included in the control plan.

#### 8.1.2 基础统计概念知识 Knowledge of basic statistical concepts

整个组织应了解和使用基本的统计概念，如变差、控制（稳定性）、过程能力和过度调整。

Basic statistical concepts, such as variation, control (stability), process capability and over-adjustment shall be understood and utilized throughout the organization.

### 8.2 监视和测量 Monitoring and measurement

#### 8.2.1 顾客满意 Customer satisfaction

#### ISO9001:2008 质量管理体系—要求

#### ISO 9001:2008, Quality management systems — Requirements

### 8.2 监视和测量 Monitoring and measurement

#### 8.2.1 顾客满意 Customer satisfaction

作为对质量管理体系业绩的一种测量，组织应监视顾客关于组织是否满足其要求的感受的相关信息，并确定获取和利用这种信息的方法。

注：监视顾客感受可以包括从诸如顾客满意度调查、来自顾客关于已交付产品质量方面数据、用户意见调查、流失业务分析、顾客赞扬、索赔和经销商报告之类的来源活的输入。

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.

注：对内部和外部顾客均应当加以考虑。

NOTE Consideration should be given to both internal and external customers.

#### 8.2.1.1 顾客满意—补充 Customer satisfaction - Supplemental

顾客对组织的满意应通过对（产品）实现过程绩效的持续评价进行监视。绩效指标应基于客观数据，



包括但不限于：

- 交付零件的质量绩效；
- 对顾客造成的干扰，包括外部退货；
- 按计划交付的绩效（包括超额运费的情况）；以及
- 与质量或交付问题有关的顾客通知。

组织应监视制造过程的绩效以证明符合顾客对产品质量和过程效率的要求。

Customer satisfaction with the organization shall be monitored through continual evaluation of performance of the realization processes. Performance indicators shall be based on objective data and include, but not be limited to :

- delivered part quality performance,
- customer disruptions including field returns,
- delivery schedule performance (including incidents of premium freight),and
- customer notifications related to quality or delivery issues.

The organization shall monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and efficiency of the process.

## 8.2.2 内部审核 Internal audit

### ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems — Requirements

## 8.2.2 内部审核 Internal audit

组织应按策划的时间间隔进行内部审核，以确定质量管理体系是否：

- a) 符合策划的安排（见 7.1）、本标准的要求以及组织所确定的质量管理体系的要求；
- b) 得到有效实施与保持。

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

- a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and
- b) is effectively implemented and maintained.

组织应策划审核方案，策划时应考虑拟审核的过程和区域的状况和重要性以及以往审核的结果，应规定审核的准则、范围、频次和方法。审核员的选择和审核的实施应确保审核过程的客观性和公正性。审核员不应审核自己的工作。

An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

策划和实施审核以及报告结果和保持记录（见 4.2.4）的职责和要求应在形成文件的程序中作出规定。

负责受审区域的管理者应确保及时采取必要的纠正和纠正措施，以消除所发现的不合格及其原因。跟踪活动应包括对所采取措施的验证和验证结果的报告（见 8.5.2）

注：作为指南，参见 ISO19011

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results shall be maintained (see 4.2.4).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 19011 for guidance.

#### **8.2.2.1 质量管理体系审核 Quality management system audit**

组织应审核质量管理体系，以验证与本技术规范 and 任何附加的质量管理体系要求的符合性。

The organization shall audit its quality management system to verify compliance with this Technical Specification and any additional quality management system requirements.

#### **8.2.2.2 制造过程审核 Manufacturing process audit**

组织应对每一个制造过程进行审核以确定其有效性。

The organization shall audit each manufacturing process to determine its effectiveness.

#### **8.2.2.3 产品审核 Product audit**

组织应以确定的频次，在生产和交付的适当阶段对产品进行审核，以验证符合所有规定的要求，如产品的尺寸、功能、包装和标签等。

The organization shall audit products at appropriate stages of production and delivery to verify conformance to all specified requirements, such as product dimensions, functionality, packaging, labelling, at a defined frequency.

#### **8.2.2.4 内部审核计划 Internal audit plans**

内部审核应覆盖所有与质量管理有关的过程、活动和班次，且应按年度计划进行日程安排。  
当内部/外部不符合或顾客抱怨发生时，应适当增加审核频次。

注：每类审核应该使用规定的检查表。

Internal audits shall cover all quality management related processes, activities and shifts, and shall be scheduled according to an annual plan.

When internal/external nonconformities or customer complaints occur, the audit frequency shall be appropriately increased.

NOTE Specific checklists should be used for each audit.

#### **8.2.2.5 内部审核员资格 Internal auditor qualification**

组织应具有有资格审核本技术规范要求的内部审核员（见 6.2.2.2）。

The organization shall have internal auditors who are qualified to audit the requirements of this Technical Specification( see 6.2.2.2).

### **8.2.3 过程的监视和测量 Monitoring and measurement of processes**

#### **ISO9001:2008 质量管理体系—要求**

ISO 9001:2008, Quality management systems — Requirements

组织应采用适宜的方法对质量管理体系过程进行监视，并在适用时进行测量。这些方法应证实过程实现所策划的结果的能力。当未能达到所策划的结果时，应采取适当的纠正和纠正措施，以确保产品的符合性。

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

#### **8.2.3.1 制造过程的监视和测量 Monitoring and measurement of manufacturing processes**

组织应对所有新的制造过程（包括装配和定序）进行过程研究，以验证其过程能力并为过程控制提供附加的输入。过程研究的结果应形成文件，适用时，包括生产、测量和试验方法的规范及维护指导书等。这些文件应包括制造过程能力、可靠性、可维修性和可用性的目标及其接受准则。

The organization shall perform process studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control. The results of process studies shall be documented with specifications, where applicable, for means of production, measurement and test, and maintenance instructions. These documents shall include objectives for manufacturing process capability, reliability, maintainability and availability, as well as acceptance criteria.

组织应保持顾客生产件批准要求中规定的制造过程能力或性能。组织应确保实施控制计划和过程流程图，包括符合规定的：

- 测量技术
- 抽样计划
- 接收标准，和
- 当未满足接收准则时的反应计划

The organization shall maintain manufacturing process capability or performance as specified by the customer part approval process requirements. The organization shall ensure that the control plan and process flow diagram are implemented, including adherence to the specified

- measurement techniques,
- sampling plans,
- acceptance criteria, and
- reaction plans when acceptance criteria are not met.

应记录重要的过程事件，如更换工装或修理机器等。

组织应对统计能力不足或不稳定的特性启动控制计划中的反应计划。适当时，反应计划应包括对产品的遏制和 100% 检验。为保证过程变得稳定和有能力，组织随后应完成明确进度和责任要求的纠正措施计划。要求时，此计划应与顾客共同评审并经顾客批准。

组织应保存过程更改生效日期的记录。

Significant process events, such as tool change or machine repair, shall be recorded.

The organization shall initiate a reaction plan from the control plan for characteristics that are either not statistically capable or are unstable. These reaction plans shall include containment of product and 100% inspection as appropriate. A corrective action plan shall then be completed by the organization, indicating specific timing and assigned responsibilities to assure that the process becomes stable and capable. The plans shall be reviewed with and approved by the customer when so required.

The organization shall maintain records of effective dates of process changes.

**8.2.4 产品的监视和测量 Monitoring and measurement of product**

**ISO9001:2008 质量管理体系—要求**

ISO 9001:2008, Quality management systems — Requirements

**8.2.4 产品的监视和测量 Monitoring and measurement of product**

组织应对产品的特性进行监视和测量，以验证产品要求已得到满足。这种监视和测量应依据所策划的安排（见 7.1），在产品实现过程的适当阶段进行。

应保持符合接收准则的证据。记录应指明有权放行产品的人员（见 4.2.4）

除非得到有关授权人员的批准，适用时得到顾客的批准，否则在策划的安排（见 7.1）已圆满完成之前，不能放行产品和交付服务。

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

The release of Product and delivery of service shall not proceed until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

注：当选择产品参数以监视与规定的内部和外部要求的符合性时，组织确定产品特性的类型，并得出：

—测量的类型；

—适当地测量方法，和

—要求的能力和技术。

NOTE When selecting product parameters to monitor compliance to specified internal and external requirements, the organization determines the types of product characteristics, leading to

- the types of measurement,
- suitable measurement means, and
- the capability and skills required.

**8.2.4.1 全尺寸检验和功能试验 Layout inspection and functional testing**

应根据适用的顾客工程材料及性能标准，按控制计划的规定，对每一种产品进行全尺寸检验和功能验证。其结果应可供顾客评审。

注：全尺寸检验是对设计记录上显示的所有产品尺寸进行完整的测量。

A layout inspection and a functional verification to applicable customer engineering material and performance standards shall be performed for each product as specified in the control plans. Results shall be available for customer review.

NOTE Layout inspection is a complete measurement of all product dimensions shown on the design records.

#### 8.2.4.2 外观项目 Appearance items

若组织生产的零件被顾客指定为“外观项目”，则组织应提供：

- 适当的资源，包括评价用的照明；
- 适当时，颜色、纹理、光泽、金属亮度、结构、鲜映度（DOI）的标准样品；
- 外观标准样品及评价设备的维护和控制；
- 对从事外观评价人员的能力和资格的验证。

For organizations manufacturing parts designated by the customer as "appearance items", the organization shall provide

- appropriate resources including lighting for evaluation,
- masters for colour, grain, gloss, metallic brilliance, texture, distinctness of image (DOI) as appropriate,
- maintenance and control of appearance masters and evaluation equipment, and
- verification that personnel making appearance evaluations are competent and qualified to do so.

### 8.3 不合格产品的控制 Control of nonconforming product

#### ISO9001:2008 质量管理体系—要求

#### ISO 9001:2008, Quality management systems — Requirements

#### 8.3 不合格产品的控制 Control of nonconforming product

组织应确保不符合产品要求的产品得到识别和控制，以防止其非预期的使用或交付。不合格品控制以及不合格品处置的有关职责和权限应在形成文件的程序中作出规定。

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product

Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:

组织应通过下列一种或几种途径，处置不合格品：

- a) 采取措施，消除发现的不合格；
- b) 经有关授权人员批准，适用时经顾客批准，让步使用、放行或接收不合格品；
- c) 采取措施，防止其原预期的使用或应用。
- d) 当在交付或开始使用后发现产品不合格时，组织应采取与不合格的影响或潜在影响的程度相适应的措施。

The organization shall deal with nonconforming product by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c) by taking action to preclude its original intended use or application.
- d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to therequirements.

应保持不合格的性质以及随后所采取的任何措施的记录，包括所批准的让步的记录（见 4.2.4）。

应对纠正后的产品再次进行验证，以证实符合要求。

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

### 8.3.1 不合格品的控制——补充 Control of nonconforming product – Supplemental

状态未经标识或可疑的产品，应归类为不合格品（见 7.5.3）。

Product with unidentified or suspect status shall be classified as nonconforming product (see 7.5.3).

### 8.3.2 返工产品的控制 Control of reworked product

返工指导书，包括重新检验要求，应易于被适当的人员得到并使用。

Instructions for rework, including re-inspection requirements, shall be accessible to and utilized by the appropriate personnel.

### 8.3.3 顾客通知 Customer information

一旦发生不合格品被发运，应立即通知顾客。

Customers shall be informed promptly in the event that nonconforming product has been shipped.

### 8.3.4 顾客特许 Customer waiver

无论何时，只要产品或制造过程与当前的批准不同，在继续生产之前，组织应获得顾客的让步或偏离许可。

组织应保持授权的有效期限或数量方面的记录。当授权期满时，组织还应确保符合原有的或替代的规范和要求。被授权的材料装运时，应在每一集装箱上作适当的标识。

此规定同样适用于采购产品。在提交给顾客前，组织应与供方就其提出的任何要求达成一致。

The organization shall obtain customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved.

The organization shall maintain a record of the expiration date or quantity authorized. The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped on an authorization shall be properly identified on each shipping container.

This applies equally to purchased product. The organization shall agree with any requests from suppliers before submission to the customer.

## 8.4 数据分析 Analysis of data

### ISO9001:2008 质量管理体系—要求

ISO 9001:2008, Quality management systems — Requirements

### 8.4 数据分析 Analysis of data

组织应确定、收集和分析适当的数据，以证实质量管理体系的适宜性和有效性，并评价在何处可以持续改进质量管理体系的有效性。这应包括来自监视和测量的结果以及其他有关来源的数据。

数据分析应提供有关以下方面的信息：

- a) 顾客满意（见 8.2.1）；
- b) 与产品要求的符合性（见 7.2.1）；
- c) 过程和产品的特性及趋势，包括采取预防措施的机会；
- d) 供方。

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

- a) customer satisfaction (see 8.2.1)
- b) conformity to product requirements (see 8.2.4)
- c) characteristics and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4), and
- d) suppliers. (see 7.4).

#### 8.4.1 数据的分析和使用 Analysis and use of data

质量和运行绩效的趋势应与实现目标的进展进行比较，并形成措施以支持：

- a) 确定迅速解决与顾客相关问题的优先顺序；
- b) 确定与顾客相关的关键趋势和相互关系以支持状况评审、决策和长期策划；
- c) 及时报告产品使用信息的信息系统；

注：应当将数据与竞争对手和/或适用的基准加以比较。

Trends in quality and operational performance shall be compared with progress toward objectives and lead to action to support the following :

- development of priorities for prompt solutions to customer-related problems,
- determination of key customer-related trends and correlation for status review, decision making and longer term planning,
- an information system for the timely reporting of product information arising from usage.

NOTE Data should be compared with those of competitors and/or appropriate benchmarks.

### 8.5 改进 Improvement

#### 8.5.1 持续改进 Continual improvement

##### ISO9001:2008 质量管理体系—要求

##### ISO 9001:2008, Quality management systems — Requirements

#### 8.5 改进 Improvement

##### 8.5.1 持续改进 Continual improvement

组织应利用质量方针、质量目标、审核结果、数据分析、纠正和预防措施以及管理评审，持续改进质量管理体系的有效性。

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

##### 8.5.1.1 组织的持续改进 Continual improvement of the organization

组织应确定一个持续改进的过程

The organization shall define a process for continual improvement .

##### 8.5.1.2 制造过程的改进 Manufacturing process improvement

制造过程改进应持续地关注于产品特性及制造过程参数变差的控制和减少。

注 1：在控制计划中将受控特性形成文件。

注 2：持续改进是当制造过程有能力且稳定或当产品特性可预测并满足顾客要求时实施的。

Manufacturing process improvement shall continually focus upon control and reduction of variation in products characteristics and manufacturing process parameters.

NOTE 1 Controlled characteristics are documented in the control plan.

NOTE 2 Continual improvement is implemented once manufacturing processes are capable and stable or product characteristics are predictable and meet customer requirements.

## 8.5.2 纠正措施 Corrective action

### ISO9001:2008 质量管理体系—要求

### ISO 9001:2008, Quality management systems — Requirements

#### 8.5.2 纠正措施 Corrective action

组织应采取措施，以消除不合格的原因，防止不合格的再发生。纠正措施应与所遇到不合格的影响程度相适应。

应编制形成文件的程序，以规定以下方面的要求：

- a) 评审不合格（包括顾客抱怨）；
- b) 确定不合格的原因；
- c) 评价确保不合格不再发生的措施的需求；
- d) 确定和实施所需的措施；
- e) 记录所采取措施的结果（见 4.2.4）；
- f) 评审所采取的纠正措施的有效性。

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

- a) reviewing nonconformities (including customer complaints),
- b) determining the causes of nonconformities ,
- c) evaluating the need for action to ensure that nonconformities do not recur,
- d) determining and implementing action needed,
- e) records of the results of action taken (see 4.2.4), and
- f) reviewing the effectiveness of corrective action taken.

#### 8.5.2.1 解决问题的方法 Problem solving

组织应有一个确定的过程用于解决问题，使根本原因得到识别并消除。

若顾客有规定解决问题的方式，则组织应采用此方式。

The organization shall have a defined process for problem solving leading to root cause identification and elimination.

If a customer-prescribed problem solving format exists, the organization shall use the prescribed format.

#### 8.5.2.2 防错 Error-proofing

组织应在纠正措施的过程中采用防错方法。

The organization shall use error-proofing methods in their corrective action process.

#### 8.5.2.3 纠正措施影响 Corrective action impact

组织应将纠正措施和实施的控制应用于其它类似的过程和产品，以消除不合格原因。

The organization shall apply to other similar processes and products the corrective action, and controls implemented, to eliminate the cause of a nonconformity.

#### 8.5.2.4 拒收产品的试验/分析 Rejected product test/analysis

组织应对顾客的制造厂、工程部门及经销商退回的产品进行分析，组织应尽可能缩短该过程的短周期。应保存分析的记录，而且在要求时，可以提供。组织应进行分析，并采取纠正措施，以防止再发生。



注：有关退回产品的分析周期，应当与确定根本原因、纠正措施和实施有效性监视相一致。

The organization shall analyse parts rejected by the customer's manufacturing plants, engineering facilities and dealerships. The organization shall minimize the cycle time of this process. Records of these analyses shall be kept and made available upon request. The organization shall perform analysis and, initiate corrective action to prevent recurrence.

NOTE Cycle time related to rejected product analysis should be consistent with determination of root cause, corrective action and monitoring the effectiveness of implementation.

**8.5.3 预防措施 Preventive action**

**ISO9001:2008 质量管理体系—要求**  
**ISO 9001:2008, Quality management systems — Requirements**

**8.5.3 预防措施 Preventive action**

组织应确定措施，以消除潜在不合格的原因，防止不合格的发生。预防措施应与潜在问题的影响程度相适应。

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

应编制形成文件的程序，以规定以下方面的要求：

- a) 确定潜在不合格及其原因；
- b) 评价防止不合格发生的措施的需求；
- c) 确定并实施所需的措施；
- d) 记录所采取措施的结果（见 4.2.4）；
- e) 评审所采取的预防措施的有效性。

A documented procedure shall be established to define requirements for

- a) determining potential nonconformities and their causes
- b) evaluating the need for action to prevent occurrence of nonconformities,
- c) determining and implementing action needed
- d) records of results of action taken (see 4.2.4), and
- e) reviewing the effectiveness of preventive action taken.

**附录 A Annex A**  
**(规范性附录)(normative)**  
**控制计划Control plan**

**A.1 控制计划的阶段**

适当时,控制计划应覆盖三个不同的阶段:

- a) 样件: 对样件制造中将进行的尺寸测量、材料和性能试验的描述。如果顾客要求,组织应有样件控制计划。
- b) 试生产: 对样件制造后,全面生产前将进行的尺寸测量、材料和性能试验的描述。试生产被定义为在产品实现过程中样件制造后可能要求的一个生产阶段。
- c) 生产: 在批量生产中,对产品/过程特性、过程控制、试验和测量系统的形成文件的描述。每个零件应有一个控制计划,但是在很多情况下,系列控制计划可以覆盖采用能通用过程生产的多个相似零件。控制计划是质量策划的一项输出。

**A.1 Phases of the control plan**

The control plan shall cover three distinct phases as appropriate.

- a) Prototype: a description of the dimensional measurements, material and performance tests that will occur during building of the prototype. The organization shall have a prototype control plan if required by the customer.
- b) Pre-launch: a description of the dimensional measurements, material and performance tests that occur after prototype and before full production. Pre-launch is defined as a production phase in the process of product realization which may be required after prototype build.
- c) Production: documentation of product/process characteristics, process controls, tests and measurement systems that occur during mass production.

Each part shall have a control plan but, in many cases, family control plans may cover a number of similar parts produced using a common process. Control plans are an output of the quality plan.

**A.2 控制计划的要素**

组织应制定至少包括以下内容的控制计划;

**A.2 Elements of the control plan**

The organization shall develop a control plan that includes, as a minimum, the following contents.

**a) 基本数据**

- 控制计划编号;
- 发布日期和修订日期(若存在);
- 顾客信息(见顾客要求);
- 组织名称/指定的现场;
- 零件编号;
- 零件名称/描述;
- 工程更改等级;
- 覆盖的阶段(样件、试生产、生产);
- 主要联系人;
- 零件/过程步骤编号;
- 过程名称/作业描述。

**a) General data**

- control plan number,
- issue date, and revision date, if any,

- customer information (see customer requirements),
- organization's name/site designation,
- part number(s),
- part name/description,
- engineering change level,
- phase covered (prototype, pre-launch, production),
- key contact,
- part/process step number,
- process name/operation description.

#### **b) 产品控制**

- 与产品有关的特殊特性；
- 其它要控制的特性（编号、产品或过程）；
- 规范/公差

#### **b) Product control**

- product-related special characteristics,
- other characteristics for control (number, product or process),
- specification/tolerance.

#### **c) 过程控制**

- 过程参数；
- 与过程有关的特殊特性；
- 制造用机器、卡具、夹具、工具。

#### **c) Process control**

- process parameters,
- process-related special characteristics,
- machines, jigs, fixtures, tools for manufacturing.

#### **d) 方法**

- 评价测量技术；
- 防错；
- 样本容量和频次；
- 控制方法；

#### **d) Methods**

- evaluation measurement technique,
- error-proofing,
- sample size and frequency,
- control method.

#### **e) 反应计划和纠正措施**

- 反应计划（包括或引用）；
- 纠正措施。

#### **e) Reaction plan and corrective actions**

- reaction plan (include or reference),
- corrective action.

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